

**WRITTEN COMMENTS RECEIVED DURING 45-DAY COMMENT PERIOD AND
TESTIMONY RECEIVED AT REGULATION HEARING JANUARY 20, 2010**

Pursuant to section 11346.9(a)(e), the board has prepared summary responses to comments those comments which are specifically directed at the proposed action [text] or to the procedures followed to promulgate these regulations.

General comments, not specifically directed at the proposed language are summarized as well. The board appreciates the comments and concerns expressed during the 45-day comment period, as well as at the regulation hearing held January 20, 2010, in response to its effort to establish a standardized, patient-centered prescription label for patients in California.

§1707.5(a)(1) – Font Size and percentage of label for specified elements

The NACDS, CPhA and CRA request that the board not mandate that certain items occupy 50% of the label.

The NACDS, CPhA and CRA state that the requirements for a specific type size, use of 50% of the label space, and the specified directions language are unreasonable due to limited label space. They state that a requirement to use 12 point sans serif for four specified items and to use 50% of the label space for these items is burdensome and unworkable in view of the other information that must be on the label and the limited label space. The NACDS, CPhA and CRA referred to Business and Professions Code §4076 – requirements for prescription labels, and assert that using only 50% of the label for all other items that need to be printed is not feasible.

Dr. Colenbrander states that the board may want to define what is “most important”; what is “important”; and what is “less important” and that such determinations should be based on a study of medication errors where misreading played a role.

At the regulation hearing conducted on January 20, 2010, Mr. Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy (NABP), testified that the board’s proposed regulations reflect the analysis prepared by the NABP’s Task Force on Uniform Prescription Labeling.

Proposed Response: In crafting the proposed language, the board determined that the clustering and display of the “patient-centered” elements contained in proposed 1707.5(a)(1) on to 50% of the label is necessary; this claim is supported by underlying data as provided in the Initial Statement of Reasons. Once dispensed, the label contains

important information needed by patients and their caregivers about how to administer their medications. Likewise, section 4001.1 of the Business and Professions Code states that protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions and that whenever the protection of the public is inconsistent with other interests sought, the protection of the public shall be paramount. The SCR 49 Medication Errors Panel, the National Association of Boards of Pharmacy, and health literacy data and research conclude that overwhelmingly patients have difficulty understanding and interpreting their prescription drug labels. The NABP identified, as reflected in this proposed regulation, that specified elements of a prescription drug label be distinguished from other elements in a label. The board believes that utilizing 50% of the prescription label to specify critical elements of a prescription in a designated font and typeface will best serve the needs of patients. As a result, some pharmacies may need to increase the size of the label(s) they currently use; other pharmacies currently use labels and containers that can comply with this requirement.

During board and committee meetings held throughout 2009, the board did determine what information is most important. These items include: patient name, drug name and strength, directions for use and purpose if it appears on the prescription document. Dr. Colenbrander's comment somewhat mirrors information provided to the board in October 2009. In an article in the September 2009 issue of Association News entitled "Updated Model Act Addresses Quality and Safety in Patient Care," a recommendation by the NABP Task Force on Uniform Prescription Labeling Requirements indicated that "critical information for patients" must be indicated in a minimum 12-point sans serif font and should include the patient name, directions for use, drug name and drug strength, and "use by" date. The board utilized a variety of medical literacy research and data (as specified in the Initial Statement of Reasons) and determined that the information in proposed 1707.5(a)(1) does indicate what is most important, and describes those elements in subparagraphs (A) through (D).

1707.5(a)(1) – Font size and type

The following persons provided comments or testified in support of the provision that labels must be printed in 12-point sans serif font or larger: Mr. Marty Martinez of California Pan-Ethnic Health Network, Ms. Goodfriend-Koven, Beth Abbott for Health Access California, Dr. Colenbrander, NHeLP, Stephen Rosati, RPh, Linda Okahars, Mrs. Im (via translator), Ms. Tina Diep of Asian Health Services and Ms. Angela Chen (via translator), Mr. Luis Miguel, Ms. Darlene March, Ms. Diana Madoshi a member of CARA and of a small senior group in Placer.

Dr. Michael Wolf, Northwestern University, and Director of the Center for Communication in Healthcare. Dr. Wolf stated that he has approximately three decades worth of research to support the use of 12-point font. He cautioned the use of a font size smaller than 12-point. Dr. Wolf spoke in support of various sans serif fonts. As a member of the U.S. Pharmacopeia Taskforce for drug labeling, he states that USP's recommendation follows the current proposal to utilized 12-point font. Dr. Wolf also testified as to comprehension, and that eye tracking studies clearly show that comprehension can be improved in 12-point font – which has been the standard that has been supported by multiple agencies within NIH. He suggests that there is a precedent for 12-point font that has been longstanding and available throughout health and human services. Dr. Wolf testified his disagreement with requiring only a 10-point font because requiring the critical pieces of information in a larger font makes the label patient-centered, and font size itself can be a cue to help people recognize that information is more important, and that it should stand out amongst other pieces of information, such as a pharmacy logo.

Dr. Colenbrander states that he supports the use of sans-serif font for labels. He adds that no matter what print size is used, there will be some people for which it is not large enough.

Dr. Colenbrander recommends that, rather than requiring a 12 pt font for all information, he recommends a standard that allows some variation, depending on the importance of the information – using the Target labels as an example.

Dr. Steve Gray, Kaiser Permanente, spoke in support of the concept of an alternative to a 12-point font requirement, but only one that would not reduce the font size below 10-point.

Mr. Bruce Wiswell and Mr. Don Gilbert, Rite Aid, testified in opposition of a 12-point font requirement and stated their support of a 10-point font requirement. They provided the board with sample vials wherein Rite Aid labels were printed in 12-point and in 10-point font, affixed to the sample vials, demonstrating that the 10-point font works best for them. The testified that they believe patients will not use a larger bottle that may be required to fit a label with 12-point font, and that patients will put their pills into a different container which would not have

the prescription label on it. Mr. Wiswell also testified that Rite Aid includes additional information on a prescription label for special services, things they define as patient-centric.

Ms. Angela Blanchard of Target Corporation testified that Target shares a commitment to ensure consumer friendly labels. She addressed font size on the label currently used at Target, indicating a variety of font sizes, from 9.5 for the guest name and up to size 14-point for the directions for use. She clarified that the patient's name is up to 10-point font; the maximum font utilized for the drug name is 14-point; and the maximum font size for directions is 13.5-point. She stated the 14-point font is the exception rather than the rule. Ms. Blanchard testified that 85% of dispensed drugs end up in a smaller bottle, and that should the instructions exceed five lines, the font is shrunk down accordingly. She stated that Target prioritizes instructions and the drug name. Ms. Blanchard testified as to her support of allowing some flexibility and that the board not be overly prescriptive on the font size.

Ms. Margie Metzler representing Gray Panthers and the Older Women's League, and as a member of CARA, testified in support of a 12-point font requirement, citing the needs of seniors and difficulties experienced when trying to read smaller fonts. She testified that the needs of patients need to come first.

Ms. Ria De Groot, a member of California Alliance for Retired Americans testified in support of a 12-point font requirement. She added that she needs to utilize reading aids for anything smaller than 12-point.

Ms. Nan Brasmer, California Alliance of Retired American, testified that on behalf of CARA's 850,000 members, support the use of a 12-point font.

Ms. Jan Howe, RN, testified that she is a member of CARA and the California Nurses Association. She testified that she concurred with the comments offered by Liz Abbott and Nan Brassmer, and that she is in support of the 12-point font requirement.

The NACDS, CPhA and CRA asked that the board require 10-point typeface for the patient name, prescription number and drug name and that the pharmacy use discretion in how the other items are placed on the label. If a patient needs a larger font, Ms. Staples stated that along with the prescription container, their pharmacies are able to provide patients with a separate sheet of paper in a larger font, if so requested. Ms. Lynn Rolston of the California Pharmacists Association testified that pharmacies generally do their best to make the font as large as possible, but that patients also complain about too large a vial size. She stated that the board should work more with a separate paper auxiliary label that is easy for patients to work with.

The NACDS, CPhA and CRA states concern about whether use of a standard font type is justified in light of the cost associated with that change.

Proposed response: While section 4076 of the Business and Professions Code specified required elements of a prescription drug label, the board is required to promulgate regulations that require a standardized, patient-centered prescription drug label on all prescription medicine dispensed to patients in California. In doing so, the board considered factors identified in section 4076.5(c) of the Business and Professions Code, Model Guidelines of the National Association of Boards of Pharmacy, research, studies, testimony and comments from health literacy experts and proponents, consumers, consumer groups and industry. Also, and as indicated in the Initial Statement of Reasons, the board information and testimony received at public forums, committee and board meetings, as well as information on medical literacy research.

The board considered comments and heard testimony from patients, advocates and health literacy experts testified in support of a minimum 12-point sans serif typeface; industry representatives commented and testified that they want 10-point sans serif typeface, citing unreasonable requirements, added cost and impact to the environment. Health literacy research and guidelines by the National Association of Boards of Pharmacy, and other research and data, support the board's proposed language in that 12-point sans serif typeface may improve readability, patient understanding and adherence to prescribed medication therapies.

The majority of data reflect that a minimum 12-point sans serif typeface is recommended or is more readable than a smaller font size. One source of background data stated that in one study 10-point font was easier to read than 8-point font. The board is not aware of any data that indicates a font size smaller than 12-point is optimal, nor was any data or research provided to support a claim that a smaller than 12-point font size is recommended. In crafting the proposed language, the board also considered its public protection mandate specified in section 4001.1 of the Business and Professions Code. One factor contained in section 4076.5(c) of the Business and Professions Code requires the board to consider the needs of senior citizens, among other things. To this end, the board determined that the needs of patients, and specifically seniors, would be best served by utilizing a minimum 12-point sans serif typeface, as supported by data, research, national guidelines and experts in health literacy.

The board also recognizes that, because standards do not currently exist, that pharmacies utilize a wide variety of fonts, font sizes, typefaces and bottle sizes in dispensing prescription drug medications. Some industry representatives have developed prescription drug labels based on health literacy and consumer needs – but

others dispense prescription drugs in containers with labels that are difficult to read and difficult to comprehend. With the establishment of section 4076.5 of the Business and Professions Code, and with the approval of regulations promulgated pursuant to that section, the board recognizes that some pharmacies will need to change their prescription drug labels; others may need to utilize different prescription drug bottles to accommodate a standardized “patient-centered” label; others may need to change both their label and bottle.

At the regulation hearing held January 20, 2010, industry members testified that 12-point typeface is “not reasonable” and would result in greater costs, yet no data was provided to support that assertion. One industry representative testified that the requirement to use a 12-point font typeface will not only limit the necessary information from being placed on the bottle, but it may prevent the patient’s full name from being placed on the bottle. Further, this representative asserted that in order to comply with the regulations as proposed, pharmacies would be required to use a 20 dram vial, citing increased costs and impact on the environment. Despite comments and testimony to indicate that a larger label or a larger size prescription drug bottle will result in added costs, the board received no data or research to support those claims during the 45-day comment period or at the regulation hearing held on January 20, 2010.

To those that claim added cost and impact on the environment as a result of using a larger prescription drug bottle, the board is not aware of any data to support claims that (for example) a 30 dram vial has a larger impact to the environment than a 20 dram vial, nor was any data offered to support those claims.

At the regulation hearing conducted January 20, 2010, the board also heard testimony from proponents of health literacy, health literacy experts, seniors, senior organization representatives and others that a 12-point font – at a minimum – is necessary. One independent pharmacist that testified prepared for the board’s observation sample prescription labels on 20 dram vials utilizing the proposed 12-point font and other proposed requirements and testified that the 12-point font requirement was reasonable, easy to accommodate, and that modifying their pharmacy’s label to accommodate the proposed regulation required little effort and could be done with minimal impact to pharmacy operations. This independent pharmacist indicated that after contacting his prescription bottle manufacturer, to comply with the proposed (initial) labeling requirements, he may incur a minimal increase in the cost of his prescription bottles, citing \$0.02 - \$0.03 per bottle. This pharmacist indicated the 2 cent to 3 cent increase is not reflective of discounts that he perceived larger chain pharmacies might receive

based on order sizes. The board also viewed a variety of current prescription bottles and labels that utilized a range of font sizes, from 6-point to 12-point.

The board considered comments received during the 45-day comment period, as well as testimony and public comment received at the regulation hearing, and voted to reduce the 12-point font requirement to that of 10-point font – contrary to the underlying research and data.

The board may wish to re-evaluate the minimum font size and typeface requirements contained in proposed 1707.5(a)(1), and in furtherance of its public protection mandate to utilize its regulatory functions for the protection of the public, in determining what size font and typeface best provides a “patient-centered” prescription drug label.

§1707.5(a)(1)(B)

The California Medical Association supports including the generic name of the drug on prescription labels as identified in §1707.5(a)(1)(B). They believe this requirement will facilitate patient’s understanding of their prescribed medication as well as increase compliance with the directions for use.

As proposed, the board specified in section (a)(1)(B) that a prescription drug label include the name of the drug and strength of the drug. The proposed regulation further specifies that “For the purposes of this section, “name of the drug” means either the manufacturer’s trade name, or the generic name and the name of the manufacturer.” The board believes that the proposed regulation, as noticed, allows for the “generic name of the drug” to be identified on the prescription label.

§1707.5(a)(1)(D) – Including Purpose or Condition on the Label, if requested by the patient

Ms. Veronica Ramirez of the California Medical Association states §1707.5(a)(1)(D) does not meet clarity and consistency standards outlined by the Administrative Procedures Act. Specifically §1707.5(a)(1)(D) states that the purpose or condition of the drug must be listed on the prescription label if “its inclusion on the label is desired by the patient.” (Emphasis added). CMA asserts it is impossible for a pharmacy or prescriber to know whether the inclusion of the purpose or condition is “desired” by the patient if this patient never requests such inclusion. CMA asserts the current language would subject individuals and entities to potential liability should it be found that such a desire existed, even if it was not explicitly requested.

Proposed Response: While the statute does not require the “purpose” of the medicine to be included on the label unless indicated on the prescription, it is in the best interest of the patient for this information to be included, when desired by the patient and known by the pharmacy. To accommodate this, the board voted to modify the text of proposed 1707.5(a)(1)(D) to reflect the “request” of the patient.

§1707.5(a)(2) and (a)(3) – emphasis and placement of other required items

The NACDS, CPhA and CRA request that the board allow pharmacists the flexibility to use different means to highlight information.

Proposed Response: The board wanted pharmacies to have some flexibility in designing labels that fits their needs and the technology they use. As such, the board only specified the patient centered elements, the portion of the label dedicated to these elements and the minimum font size. The pharmacy can choose additional methods to highlight information, e.g. using space or bolding.

§1707.5(a)(4) – Directions for Use – Proposed Phrases

Dr. Michael Wolf, Northwestern University, testified that the directions for use specified in the proposed regulation represent approximately 90% of all prescriptions. This percentage is built on evidence and is supported by a review of approximately 350,000 medications. The information was also backed up by data in talking with Kaiser as well as in a much, much larger data set. He testified that it is important to dissect and order the different elements in an instruction, and he offered to provide the board instructions based on their actual use assessment. Dr. Michael Wolf, Northwestern University, recommended that the term “pill” be used in lieu of the word “tablet” be used.

The California Medical Association comments that proposed 1707.5(a)(4) is unclear (directions for use) and clarity needs to be improved so that standards of patient care are not affected. CMA states “the proposed phrases for use in describing when a prescription medication should be consumed are too broad.” CMA states that rather than using a phrase such as “take 1 tablet in the morning, one tablet at noon, and one tabled in the evening (§1707.5(a)(4)(J)) – the directions for use should instead indicate the appropriate time increments between doses. CMA asserts that if suggested time increments between doses are included in the directions for use, patient safety would be protected.

Ms. Lynn Rolston, California Pharmacists Association, testified that there may be concern over the term “pill” as initially proposed. She stated pharmacists like to be more specific, i.e., “tablet” or “capsule”, etc.

The NACDS, CPhA and CRA request that the board not mandate the specific directions as they are unnecessarily lengthy and repetitive and allow pharmacists to use their professional judgment if such directions are needed.

Mr. Marty Martinez representing California Pan-Ethnic Health Network testified that the regulation doesn't fully meet the statutory requirement that the label itself address the needs of people who don't speak English. He states that as currently proposed, there is no requirement that a pharmacy put anything in writing that is in another language.

Mr. Rosati testified that the “form” of the drug should be in 12-point font. He said he thinks it is important for the consumer to realize whether they have a capsule or tablet and that, if it is not required, it could possibly disappear from the label. Mr. Rosati provided an additional seven phrases and recommended they be included in proposed 1707.5(a)(4).

Proposed Response: The board considered comments received during the 45-day comment period, as well as testimony received at the regulation hearing held January 20, 2010, and voted to modify the language found in proposed 1707.5(a)(4) to reflect the “appropriate dosage form” into the directions for use. The board did not vote to include the seven additional phrases recommended by Mr. Rosati. Likewise, the board modified the language to add a definition of “appropriate dosage form.”

The board believes that the directions for use specified in proposed 1707.5(a)(4) are clear. This subsection specifies that “when applicable” the directions for use shall be used. A prescriber’s order may contain a direction for use that is not provided in proposed 1707.5(a)(4). In that case, the pharmacist would place on the label the directions for use that is specified by the prescriber.

§1707.5(b) – Printed Translations

The California Medical Association (CMA) supports the requirement that the board publish on its Web site a translation of standard directions for use into at least five languages other than English. CMA suggests that proposed 1707.5(b) be expanded to require the Board to publish translations of these directions on its Web site into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California.

Mr. Bruce Wiswell and Mr. Don Gilbert of Rite Aid testified that they currently print translated languages on a separate sheet, along with a English translation so the pharmacist has a reasonable opportunity to do a legitimate quality assurance comparing the English to the other language. Mr. Wiswell testified that Rite Aid currently provides translations in 13 languages.

Dr. Michael Wolf, Northwestern University, testified that they are the principle investigator leading the California Endowment Study to translate the directions for use into five languages other than English. He testified that the proposed regulation does not limit the translations to five, rather it is saying at least five. He clarified that there is funding for five languages. With the support of the California Endowment, Dr. Wolf testified that the language translations will be provided to the board within the time specified in the proposed text. He provided additional testimony on the approach that would be utilized to develop the translations. He stated this effort is a very intensive process and, while they would love to do more languages, he supports the regulation to provide five to begin with.

Ms. Nan Brasmer, California Alliance of Retired American, testified that CARA supports keeping translations very broad so that as many people as possible can be protected by having proper instructions both orally and in writing.

APIAHF states the board can do better than translation of directions in five languages. APIAHF states that the cost for translating 17 simple directions is minimal and is a one-time cost. APIAHF states that translation costs range from .20-.80 per word. APIAHF states that Healthy Families translates its application into 10 languages; the California Department of Social Services has a bilingual unit that translates social services notices into over 16 languages; and the California Department of Health Care Services has translated a Language Services Notice in 12 languages. APIAHF asserts that the board can save on translation costs by providing a glossary of the terms already translated.

While the proposed regulation requires translation into at least five languages, APIAHF urges the board to raise the minimum number to at least 15 languages by October 2011, and at least five additional languages in each of the following years.

Ms. Tina Diep of Asian Health Services and Ms. Angela Chen (via translator) spoke in support of standard translation of common medication instructions. Ms. Chen stated she supports the regulation that pharmacies have instructions on the label translated into the patient's native language.

Mr. Marty Martinez, CPEHN, testified that prescription drug labels translated into the patient's language are vital for quality care and provided a list of what must be included in the board's final adopted regulations. These comments are mirrored by Mr. Luis Miguel and Ms. Darlene March.

Both CPEHN and Ms. Goodfriend-Koven recommend that the board place on its Web site standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited English speakers in California. Mr. Martinez asserts the cost for these translations is minimal with a large health payoff. Mr. Martinez provided census data indicating which languages are the top limited English Language. These comments are mirrored by Mr. Luis Miguel and Ms. Darlene March.

Ms. Elizabeth Abbott of Health Access California recommends that the board provide pharmacies with standard label language in at least the 14 threshold languages delineated for language assistance in California based on population size. She urged the board to include a requirement that a translation be placed on the label.

Ms. Ria De Groot, CARA, testified that written translations need to be provided, not just oral language translations. She stated that memory is a problem for seniors and that seniors need a written translation to reference should they need to reference the information after an oral language translation. She suggested that a patient could be provided with written instructions in English, and that the other side be provided in the translated language.

Ms. Doreena Wong, National Health Law Program, testified that the number of languages specified in the proposed regulations does not properly cover enough of the population, given the large population of limited English proficient patients in California. She states that the number of languages defined should follow the Medi-Cal managed care threshold requirements. Further, Ms. Wong further states that the proposed regulations do not *require* pharmacists to translate the items specified in proposed 1707.5(a)(1). She adds that without some kind of requirement for translation, it will be voluntary and may never be fully implemented. She referenced a New York settlement wherein seven of the largest chain pharmacies are required to translate drug container labels into six languages, adding that CVS, Rite Aid, WalMart, Target and Costco will be doing so nation wide. Ms. Wong recommends that the entire label be required to be translated, and that a phase-in period be utilized for implementation.

Ms. Linda Okahars, Asian Health Services, testified that the number of languages in which the standardized directions for use are available should follow the Medi-Cal managed care threshold requirements. She further indicated that she supports utilizing 12-point font, and that the patient's language be identified in the patient record.

Ms. Nisha Agarwal, Director, Health Justice Program, New York Lawyers for the Public Interest, Inc. (NYLPI) supports provisions that pharmacies be required to provide translated prescription labels. NYLPI is pleased that the proposed regulations require the board to publish on its Web site translations of the standardized directions for use into at least five languages.

Proposed response: In support of the board's efforts to establish standardized directions for use, the California Endowment has made a commitment to fund a project with Dr. Michael S. Wolf to translate and field-test the directions for use into the five predominant non-English languages in California. The board is grateful for the support of the California Endowment as the field study conducted for this purpose will fully vet these translations. The board believes that utilizing the resources of the California Endowment for this purpose is prudent and that such a study could easily expand to other languages in the future. If so desired, the board could access the services of translators to provide additional languages; however, any such additional languages would not be vetted through the California Endowment. However, other means to validate a translation could be used by the board without conducting a field study.

As specified in proposed section 1707.5(b) the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) to facilitate the use thereof by California pharmacies. The proposed regulation does not require that pharmacies or pharmacists utilize these translations; nor does the proposed regulation prohibit the board from providing more than what is specified in the proposed text. To ease the facilitation of translations, the board is providing a resource to assist pharmacies. To this end, the board believes the proposed regulation does consider the needs of patients with limited English proficiency and it balances the needs with those of pharmacists who may not be able to read a translation unless it is standardized against specific wording.

With respect to the establishment and maintenance of a multi-language glossary, the board does not believe that at this time, providing and maintaining such a document best utilizes the board's resources; however, the board would encourage industry partners and other interested parties to make additional resources available for various interest groups. For this reason, and at this time, the board does not anticipate modifying the proposed regulation to accommodate this recommendation.

The board is committed to the establishment of a standardized, patient-centered prescription label. To that end, and as specified in subdivision (e) of the proposed regulation, the board will re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5. This evaluation will include any amendment to or adopted of regulations that require translations pursuant to this section.

Mr. Marty Martinez, California Pan-Ethnic Health Enforcement Network, comments that final adopted regulations must provide for both a written translated label and an oral interpretation of the instructions for each patient who needs it.

Proposed Response: The board believes that the proposed regulation, as noticed, provides for oral interpretation of a prescription label – those which are considered “patient-centered” – as well as making a provision for the oral interpretation of those specified elements. The standardization of the elements specified in proposed §1707.5(a)(1)(A) through (D) is required so that a pharmacist checking a prescription label can be certain that the directions are appropriate and accurate if translated into a language not known by the pharmacist.

Ms. Goodfriend-Koven states that for non-standard labels and other languages, individual pharmacies could be responsible for providing translated labels. Ms. Goodfriend-Koven asserts that prescription drug labels translated into the patient’s language are vital for quality care. Mr. Luis Miguel and Ms. Darlene March mirror these comments.

APIAHF urges the board to add a provision in the regulation to require that pharmacies translate non-standardized labels in the most prevalent languages spoken in the service area.

Proposed Response: Although the enabling statute (section 4076.5 of the Business and Professions Code) speaks to a “standardized, patient-centered, prescription drug label” – the Board is standardizing labels only to the extent specified in 1707.5(a)(1)(A) through (D). Otherwise, the proposed regulation does not specify a definition of what is considered “standard.” Likewise, the term “non-standardized label” is not defined in the proposed regulation. The board does not anticipate modifying the proposed action to accommodate this recommendation because “non-standardized labels” are neither defined nor mandated.

The proposed regulation does not prohibit a pharmacy from providing translated prescription drug labels to all patients, and the proposed text does provide for the oral language interpretation of the prescription label elements found in proposed §1707.5(a)(1)(A) through (D) to accommodate persons with limited English proficiency.

Testimony provided by Rite Aid representatives during the hearing indicate that it provides medication information fact sheets in more than 10 languages to its patients.

As specified in subdivision (e) of the proposed regulation, the board will re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5. This evaluation will include any adopted regulations that require translations pursuant to this section.

NHeLP recommends that for patients who cannot read or understand English but can read in another language, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of the patient.

Proposed Response: As proposed, the board has committed to publish on its Web site translation of the “directions for use” (as specified in proposed 1707.5(a)(1)(A) through (D)). At this time, the board does not believe that it is reasonable to require translation of all elements of a prescription label as specified in subdivision (a) of proposed section 1707.5; however, the board will re-evaluate the oral language interpretation and translation components of the proposed regulation by 2013 as specified in proposed 1707.5(e) to determine if modifications are required for this purpose.

The NACDS, CPhA and CRA state that for written translation services pharmacies are limited by the technology available. They state that French and Spanish are the only languages available for drug information translation today, and that the ability to translate consumer medicine information and MedGuides into other languages is limited. They state that such services are generally not available, printers lack the capability, and written translations are not available on demand.

Proposed Response: The board is unclear if these statements are inconsistent. If accurate, it is unclear how pharmacies in New York City will be able to comply with the translation requirements for labels that the six pharmacy chains agreed to provide. Also, testimony provided by Rite Aid representatives during the hearing testified that it currently provides medication information fact sheets in more than 10 language.

§1707.5(d) – Oral Language Interpretive Services

APIAHF states that the proposed regulations only require an oral language translation of the prescription container upon request of the patient. APIAHF asserts that unless the patient is aware that this request can be made, the patient is unlikely to request it. APIAHF states that pharmacies must be required to provide a notice to patients that interpreter services are available at no cost to persons with limited English proficiency.

Mr. Lin Hokana, RPh, recommends modifying proposed 1707.5(d) to state “The pharmacist is encouraged to also furnish written directions for use in the patient’s native language that match the directions on the label.” He states that some pharmacies utilize software to generate the (prescription) label in a language other than English.

Ms. Elizabeth Abbott of Health Access California states that all patients with limited English proficiency should have the right to have their prescription drug instructions orally interpreted by a health professional working within his or her field of clinical expertise. She testified that patients are entitled to these services and that a notice of such services should be required.

Ms. Jan Howe, RN, a member of CARA and the California Nurses Association stated that as a practicing nurse, Kaiser made available oral interpretive services via phone. As an advice nurse and as a home care nurse for hospice, Ms. Howe testified that she could reach a translator anytime she needed to. She supports the board's regulation to change prescription labeling to increase safety for California patients.

Mr. Don Gilbert of Rite Aid testified that Rite Aid currently provides oral language translations via phone in approximately 150 languages.

Mr. Marty Martinez of California Pan-Ethnic Health Network states that all patients who do not speak English must have the right to have their prescription drug instructions orally interpreted, as currently proposed. Mr. Martinez states that final adopted regulations must provide for both a written translated label and an oral interpretation of the instructions for each patient who needs it. He stated that in a pharmacy's policies and procedures, the board could require how to identify the patient's language, how interpretive services will be provided, and how the sample labels provided by the board will be utilized where appropriate.

Ms. Goodfriend-Koven suggest that the board provide pharmacies with a listing of certified translators (by the American Translator's Association) and qualified interpreters (such as graduates of programs at the community colleges), so that those who do not speak English well can have their prescription drug instructions orally interpreted. She adds that pharmaceutical counseling is vital, and either telephonic or face-to-face interpreting needs to be part of the services offered to patients who cannot yet speak English.

NYLPI encourages the board to incorporate stronger, mandatory language into its proposed regulations regarding label translations. NYLPI is concerned that there is no requirement in the regulations for pharmacies to make these translated labels available to their customers. NYLPI provided background on a study conducted in New York which indicated that pharmacies overwhelmingly failed to provide their LEP customers with translated medication labels *despite having the capacity to do so*. In New York, that is now changing in response to a civil rights complaint NYLPI filed on behalf of community partners – which resulted in settlement agreements with all of the major chain pharmacies operating in NY. Under the settlements, CVS, Rite Aid, Costco, Target, Wal-Mart, A&P and Duane Reade pharmacies are required to make translated labels available in six languages and must add five more languages within six months of updating their computer systems to track language preference.

Ms. Doreena Wong testified that the proposed regulations do not require that a notice be provided to patients informing them of their right to have an oral language translation, if they so request. Ms. Wong States the board should have a standard notice that is posted in the pharmacy, similar to that of the Notice to Consumers, so that LEP patients know their rights.

Ms. Bush, California Grocers Association (CGA), states that while some pharmacies already provide an oral language translation of the prescription contents if requested by the patient, not all pharmacies are able to provide this service without economic impact. Ms. Bush states that the proposed regulation presents legal concerns for pharmacies that would be held liable if medication information was misinterpreted in translation; and that this service does not come without an economic impact.

Ms. Lynn Rolston of the California Pharmacists Association, testified and requested that in (a)(4)(D) can the language state “in the patient’s language if available”? [The board understands this comment to address proposed 1707.5(d).] She states that there are some dialects that translations services may not cover and, as proposed, it will be very difficult for pharmacies to find services to accommodate these languages. She requests modification to specify that such interpretive services be provided in a patient’s language if that language is available for such interpretation. Ms. Rolston also requested that if the board requires pharmacies to have policies and procedures in place, that the board specifies what is to be included.

Dr. Michael Wolf, Northwestern University, testified in support of a notice to consumers advising them of their right to request oral translations.

NHeLP supports the provision of an oral language translation of the instructions, but recommends the board adopt the following requirements:

- To publish the translation of the directions in section (a)(4) sooner than October 2011.
- When instructions for use specified by the prescriber do not conform to the items listed in subdivision (a)(4), the pharmacy shall secure its own translation.
- A pharmacy must offer oral interpretation of the label and/or provide an interpreter to any LEP patient and not rely on a specific request by the LEP patient.

Proposed Response: In consideration of comments received during the 45-day comment period and testimony received at the regulation hearing held January 20, 2010, the board modified proposed 1707.5(d) to specify that a pharmacy shall have policies and procedures in place to identify a patient’s language and to provide interpretive services of the “patient-centered” elements specified in proposed 1707.5(a).

The board believes that providing a notice to consumers advising them of the availability of oral language interpretive services and specified written translation services may be reasonable. At the board’s regulation hearing held January 20, 2010, the board asserted that it is reasonable that a future rulemaking to amend 16 CCR section 1707.2 “Notice to Consumers” to include such information, could be considered and initiated as a separate

rulemaking in 2010, and that the scope of the proposed regulation not be expanded for this purpose. It would be possible for the board to pursue a regulation change to the 1707.2 Notice to Consumers to include such information. Any such changes to the 1707.2 Notice to Consumers could take effect on January 1, 2011, consistent with the patient-centered label regulation effective date.

With respect to providing a listing of certified translators and qualified interpreters, the board believes that a modification of 16 CCR 1707.2 "Notice to Consumers" to advise consumers of their right to interpretive services and specified translations is sufficient. However, as specified in proposed 1707.5(e) the board will re-evaluate the regulation by December 2013 to ensure optimal conformance with section 4076.5 of the Business and Professions Code. It will also consider this request at the time the notice to consumers about language interpretative services is being developed.

Additionally, one vendor, RXTran, submitted written comments stating that it and other competitors could provide translated labels for as little as \$50.00/month.

GENERAL COMMENTS

Requests for Exemption

Dr. Steve Gray representing Kaiser Permanente testified that long-term care or residential facilities not be exempted from the proposed regulation. He added that he is more sympathetic if it is a skilled nursing facility where the Department of Public Health requires certain qualifications of individuals, but that residential care or assisted living – regulated by the Department of Social Services – require lower minimum qualifications. He added that Kaiser’s experience shows that pharmacists and physicians go out to these facilities frequently to resolve problems, in that care is often provided by minimally educated, sometimes limited English proficient personnel, including patient’s family members.

Mr. John Durham of PharMerica Inc. reiterated the comments of Mr. Greg Light and requested that residents in facilities licensed by the Department of Health Services and facilities licensed by the Department of Social Services be exempt from the proposed regulation. Likewise, Mr. Scott Huhn, PharmD, requests the proposed regulations be amended to exempt these facilities from the requirements therein.

Ms. Paige Tally, Director of the California Pharmacists Association’s Long-Term Care Management Counsel recommends the following amendment to exempt from the requirements of proposed 1707.5 prescription drug medications dispensed to patients in facilities licensed pursuant to section 1250 of the Health and Safety Code. Mr. Greg Light and Mr. Lee Myer, also representing CPhA’s Long-Term Care Management Counsel, testified in support of the letter submitted by CPhA during the 45-day comment period noting the requested exemption. Mr. Light testified as to the various dispensing methods utilized at skilled nursing and other facilities, emphasizing that the prescriptions dispensed for these patients are never in control of the resident, nor are they self-administered. He stated that, in these settings, the prescription drug medications are controlled and administered by nurses. He asserts that these facilities adhere to regulations and that the board’s proposed regulations would create inconsistency to nurses in these facilities. Mr. Myer also testified that he would not want progress in utilizing automated dispensing machines impeded by the requirements of the proposed regulations.

“Notwithstanding any other provision of law, it is not necessary to include the requirements of 1707.5 if a pharmacist dispenses a medication for a patient in a facility licensed pursuant to Section 1250 of the Health and Safety Code.”

Proposed Response: Board counsel suggests that the board lacks the statutory authority to provide an exemption or “opt-out” waiver of prescription drug labeling requirements as required by sections 4076 and 4076.5 of the Business and Professions Code.

With respect to medications dispensed via automated dispensing machines, the board's proposed regulations would not create inconsistency with those medications that are dispensed in dosage units.

If, in fact, a prescription drug order is being filled and it is patient-specific, such a prescription drug bottle would require drug labeling as currently specified in section 4076 of the Business and Professions Code

CPHA's Long Term Care Management Counsel recommends additional language as follows with respect to those patients being discharged from specified health care facilities:

"Upon discharge from a facility licensed pursuant to Section 1250 of the Health and Safety Code, a patient may choose not to have his or her medications pursuant to Title 16 Section 1707.5 by signing an opt-out waiver."

Mr. John Durham, PharMerica Inc., testified to request that facilities licensed by the Department of Health Services and facilities licensed by the Department of Social Services be exempt from this regulation, as they are caregiver focused.

Dr. Steve Gray representing Kaiser Permanente does not support an exemption from the labeling requirements for persons who are being discharged from skilled nursing or assisted living facilities. He testified that these patients essentially are given outpatient prescriptions and that when the patient goes home, they need all of the assistance in understanding and readability that would be provided to any outpatient. He stated such an exemption causes them concern because they see readmissions of patients following discharge from such facilities, because patients get confused.

Proposed Response: Board counsel suggests that the board lacks the statutory authority to provide an exemption or "opt-out" waiver of prescription drug labeling requirements as required by sections 4076 and 4076.5 of the Business and Professions Code.

The board believes the suggested modification provided by CPHA's Long Term Management Counsel is contrary to the intent of the proposed regulation. It is the view of the board that for the protection of the public, and especially for patients who are being discharged from a health care facility licensed pursuant to section 1250 of the Health and Safety Code, that patient requires the same standardized prescription labeling as provided to patients receiving prescription drug medications at any other pharmacy setting. Further, the proposed regulations reflect model guidelines developed by the National Association of Boards of Pharmacy which is representative of various practice settings.

The board recognizes that skilled nursing facilities, intermediate care facilities and other facilities utilize various methods in the administration of medications to patients. Statutory requirements to establish a standard prescription drug label do not specify any persons or groups to be excluded from the requirements of the regulation. In the event the patient and facility care givers have different languages, it would seem in the interest of patient care that some type of admissions document, signed by the patient, could indicate the patient's wishes as to what language a prescription drug label should reflect. To this end, the board believes that skilled nursing and other facilities licensed pursuant to section 1250 of the Health and Safety Code. For facilities licensed by other state agencies, such as the Department of Social services, where care givers may not be licensed health care providers, the medications dispensed to these containers should comply with the requirements of 1707.5. Where the language of the care giver and the patient is different, the dispensing pharmacy should take this in to account to assure the appropriate care of the patient.

As stated previously, the board does not have the authority to waive a statutory requirement. Individual care settings that are seeking an exemption should do so through the legislative process.

The requirements of section 4076.5 of the Business and Professions Code were fully vetted through the legislative process, resulting in the codification of Chapter 470, Statutes 2007. As the measure was considered by policy and fiscal committees, as well as the floors of each house, board staff could find no documented opposition to the measure from representatives of these health care settings or related state regulators in the various legislative analyses associated with the bill.

Mr. Greg Light testified that for patients in the community care licensed facilities, these facilities utilize multi-dose packaging systems. He states that it would be virtually impossible to comply with the board's proposed labeling requirements.

Proposed Response: This proposed regulation does not attempt to define the type of drug container or size of label utilized. This proposed regulation only specifies the format, content and placement of certain information (patient name, drug name and strength, directions for use and purpose if it appears on the prescription document) that is required to be provided with any prescription drug medication dispensed to a patient. The method currently employed to satisfy existing requirements in Business and Professions Code Section 4076 should continue.

Title VI of the Civil Rights Act of 1964

Ms. Deanna Jang of the Asian Pacific Islander American Health Forum (APIAHF) states that most pharmacies are recipients of Federal financial assistance and are required to comply with Title VI of the Civil Rights Act of 1964; implementing regulations of which require that recipients of Federal financial assistance must provide meaningful access to their programs, services and activities for LEP persons. She stated that the proposed regulation does not comply with Title VI of the Civil Rights Act of 1964.

Ms. Deanna Jang of the Asian Pacific Islander American Health Forum (APIAHF) also comments that the proposed regulations do not comply with Title VI of the Civil Rights Act of 1964.

Proposed Response: The board rejects this comment as outside of the scope of the proposed action. The initially noticed text did not address a requirement for posting notices or implementation of Title VI. Title VI of the Civil Rights Act of 1964 (42 U.S.C. Sections 2000d et seq.) prohibits discrimination on the basis of race, color and national origin in programs and activities receiving federal financial assistance. This action is directed at interpretation and implementation of Pharmacy Law at Section 4076.5 of the Business and Professions Code, and proposes to set requirements for standardized prescription drug container labels for all prescription medicine dispensed to all patients in California.

General Comments re: Oral Language Interpretations

Ms. Bush of the California Grocers Association comments that while some pharmacies already provide an oral language translation of the prescription contents if requested by the patient, not all pharmacies are able to provide this service without economic impact. Ms. Bush states that the proposed regulation presents legal concerns for pharmacies that would be held liable if medication information was misinterpreted in translation; and that this service does not come without an economic impact.

Ms. Doreena Wong, National Health Law Program (NHeLP) stated that they do not believe that the proposed regulation reflect the statutory requirement that the board take into consideration the needs of LEP patients. Ms. Wong adds that there are other federal and state requirements and guidelines to ensure linguistic access to LEP patients by pharmacists in various contexts, and provides references to various federal and state statutes, regulations and guidelines, including references to Board of Pharmacy regulations.

NHeLP states its support to expand the number of languages for the translation of standardized labels to match the Medi-Cal Managed Care threshold languages. NHeLP supports the

provision of an oral language translation of the instructions, but recommends the board adopt the following requirements:

- To publish the translation of the directions in section (a)(4) sooner than October 2011.
- When instructions for use specified by the prescriber do not conform to the items listed in subdivision (a)(4), the pharmacy shall secure its own translation.
- A pharmacy must offer oral interpretation of the label and/or provide an interpreter to any LEP patient and not rely on a specific request by the LEP patient.

Proposed Response: The board modified proposed 1707.5(d) to specify that a pharmacy shall have policies and procedures in place to identify a patient's language and to provide interpretive services of the "patient-centered" elements specified in proposed 1707.5(a). The proposed regulation requires oral interpretation of the prescription label at the time of dispensing. At this time, the board does not believe that it is reasonable to require translation of all elements of a prescription label as specified in subdivision (a) of proposed section 1707.5; however, the board will re-evaluate the oral language interpretation and translation components of the proposed regulation by 2013 as specified in proposed 1707.5(e) to determine if modifications are required for this purpose.

General Comments re: Label

The NACDS, CPhA and CRA requests that pharmacies be able to provide patients with prescription container information through other means, such as a separate sheet in a larger font.

The NACDS, CPhA and CRA state that chain pharmacies have estimated that many prescriptions currently dispensed in small vials will have to be dispensed in larger vials to accommodate the larger labels. They add that pharmacies will not be able to use the drug manufacturer unit of use containers that are helpful for patients and that patients will likely be dissatisfied with the vials that are several times larger than what they are used to. Further, the NACDS, CPhA and CRA assert that larger container vials will result in shipping, storage and handling problems, with increased costs to pharmacies.

Ms. Nan Brasmer, California Alliance of Retired American, testified that utilizing a larger bottle to accommodate a label that reflects 12-point font makes sense for many seniors who have difficulty opening small bottles. She testified that a larger label also allows for specific directions for use, which is more useful than utilizing a direction that states "take as directed." These comments were also reflected in the testimony of Ms. Jan Howe, also of CARA.

Stephen Rosati, RPh, testified that auxiliary and warning labels affixed to prescription drug containers be a minimum 6-point sans serif typeface, asserting that the patient needs to be able to read how to properly use the medication. He provided the board with sample vials with labels printed utilizing the 12-point sans serif typeface, as well as 6-point sans serif typeface for the warning or auxiliary labels, which the board viewed.

Proposed Response: Specifications for warning or auxiliary labels are regulated by the US Food and Drug Administration and are not within the scope of the proposed regulation. The board believes that modifying the language to address the auxiliary or warning labels would sufficiently expand the scope of the proposed regulation. At this time, and to make every effort to promulgate regulations in the time frame specified in section 4076.5 of the Business and Professions Code, the board is not modifying the text for this purpose. The board will, however, re-evaluate the requirements of the regulation before December 2013 to ensure optimal conformance with the provisions of section 4076.5 of the Business and Professions Code.

General Comments in Support

Mr. Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy spoke in support of the board's efforts to adopt or modify proposed 16 CCR §1707.5.

Mr. Catizone stated that NABP's support is founded in the findings of the NABP Task Force on Uniform Prescription Labeling Requirements. He stated that the results of the Task Force have only minor differences to the board's proposed regulation and agrees that the patient label is a critical piece of information – for which there are no alternatives to helping a patient understand and comply with their medication regimens. Mr. Catizone stated that the board's proposed regulation addresses the three critical issues as mandated by SB 472: that current wavering requirements in place in California and across the country do not address critical elements of the prescription label, such as what is necessary, what the font size should be, and what is understandable for the patient.

Mr. Catizone stated that he had reviewed the comments submitted during the 45-day comment period by those groups who oppose the board's efforts, and that he does not agree with those comments.

Mr. Catizone stated that the NABP's Task Force analysis confirmed the findings of the Board of Pharmacy that certain information needs to be mandated; certain information on the label needs to be at a different font size; and certain information needs to appear on the label but does not need to be highlighted.

Mr. Catizone stated that he does not agree with the contention that the proposed regulation would be overly burdensome for pharmacies to implement. In support of this, Mr. Catizone

stated that research conducted by NAPB and participants in the NAPB Task Force helped design the label based on current systems that are in place in pharmacies, some of which operate in various states throughout the country – the same label components that are proposed by the Board of Pharmacy.

Mr. Philip Swanger, California System of Health-System Pharmacists, spoke in support of the proposed regulation. He states that CSHP represents approximately 4,000 pharmacists, pharmacy technicians, and associates that practice in varied settings, including hospitals, ambulatory care, and long-term care. He stated that the proposed regulation was shared with CSHP's board and that they have received no opposition to the proposed rulemaking from their board. Mr. Swanger further testified that CSHP was a strong supporter of SB 472.

Dr. Steve Gray, Kaiser Permanente, spoke in strong support of a regulation that requires standardized, readable prescription patient-centered prescription label. He also testified in support of translations in at least five languages; in modifying the language "pill" to that of an appropriate dosage form, and alternative language for interpreter services especially if that requires pharmacies to establish policies and procedures.

Mr. David Grant, Director of Health Policy and Executive Director of Senior Action Network spoke in support of the proposed regulations. He testified he is speaking on behalf of consumers who originally helped pass the enacting legislation. He added that there are approximately 4.5 million seniors, taking an average of 8.5 prescriptions each. He testified that medication errors is one of the leading causes of readmission to acute care hospitals. He urged the board to adopt the regulations as proposed.

Ms. Diana Madishi, a member of CARA and of a small senior group in Placer, spoke in support of the proposed language. She testified to her support of a label, even if larger bottles are required. She also testified as to her support of the directions for use as it relates to the administration of pain medications.

Proposed Response: The board appreciates the comments of Mr. Catizone and others for providing the board with information regarding the efforts made on national level surrounding development of a patient-centered prescription label, and for stated support to develop a standardized, patient-centered prescription label.

Given this testimony, the board may want reconsider its decision to reduce the font size.

General Comments re: Auxiliary or Warning Labels; Advertising; Cost; Impact

Mr. Stephen Rosati testified that auxiliary or warning labels should be a minimum of 6-point sans serif typeface. He states that he believes the warning labels are part of the enabling

legislation. He states that auxiliary labels tell you how to utilize your medication and that if a patient can't read how to properly use the medication, that we're back to where we started. Mr. Rosati provided sample containers with mock-up labels utilizing 12-point, 8-point and 6-point typeface. He said the board has 'alternate' language that would require a pharmacy to provide at no less than 12-point font, a separate document with prescription drug information, but that there is no requirement that auxiliary or warning labels utilize a minimum font size. He states that if a separate document is being provided to a patient in a font no less than 12-points, that the same document provide the auxiliary or warning labels in no less than 12-point font typeface.

Mr. Rosati suggested that the board should require that "no form of advertising" should be allowed on the prescription label, prescription container or container top.

With respect to written translations, Mr. Rosati asserts that if a prescription label is translated, a pharmacist's screen should show the English directions on the same screen next to the translated label, so that there can be some hope of ensuring that the correct directions are being provided to the patient.

With respect to cost, Mr. Rosati stated he spoke with his container manufacturer and he understands that some manufacturers are making changes with the resins for plastics. With that, he states that the minimum bottle was going to jump up one size which may increase it approximately 3 cents per bottle. He states he believes that manufacturers are making shorter, wider bottles to compensate for increased width of a prescription label. Mr. Rosati stated that to comply with the proposed regulations he may incur a one-time cost of approximately \$40 for a new plate, and that if he has a custom plate made, he may incur a one-time cost of approximately \$400.

General Comments Not Related to Specific Text

Ms. Linda Okahars of Asian Health Services testified as to some of the challenges the Asian Health Services experience in terms of trying to overcome language barriers for their patients. She stated that Asian Health Services serves approximately 20,000 patients and that approximately 90 percent are limited English speakers. She stated that a patient's language is identified in their patients' records, and asks that the board consider the recording of a patient's language in the pharmacy's patient profile. Ms. Okahars stated she supports that prescription labels be translated, and that the standardized list of common translations be available in common threshold languages as identified by Medi-Cal Managed Care, as well as Health Families.

Ms. Missy Johnson of the California Retailers Association testified that national corporations operate on a very slim margin. She testified to the types of staff and services that are provided

in a retail setting. Ms. Johnson stated that the CRA supported the board's goal of reducing medication errors and developing a standardized patient label; however, she stated that she has significant concerns with the language as it is currently drafted. Ms. Johnson did not provide any recommendations related to specific section(s) of the proposed regulation.

Ms. Mary Staples of the National Association of Chain Drugstores (NACDS) stated that she would detail the joint letter authored by the California Retailers Association (CRA), the California Pharmacists Association (CPhA), and the National Association of Chain Drugstores (NACDS).

Ms. Staples stated that their pharmacies are willing and able to provide patients with a separate sheet of paper showing a large font size, upon the patient's request. She stated their stores currently provide this service which is appreciated by their patients.

In answer to a board member's question, Ms. Staples testified that the directions for use not be specified at all and that technology and innovation not be limited or specified.

Ms. Missy Johnson of the California Retailers Association stated that they have severe issues with the 12-point font requirement and they would prefer for it to be a 10-point font for the patient's name, the drug name and the prescription number. She stated they are not recommending that 12-point font be a mandate at all.

Ms. Lynn Rolston, California Pharmacists Association, testified generally in support of the regulation effort. She stated that the prescription label was only one of the recommendations provided by the original SCR 49 panel. She stated her concern that the board is being overly prescriptive in terms of mandating what the label looks like, and she said that pharmacies would like as much latitude as possible to serve their customers. Ms. Rolston stated pharmacies are sensitive to extra cost. She said many pharmacies may be required to purchase new label stock and have to discard old label stock. She referenced a comment regarding a \$400 strike plate for an independent pharmacist, noting there are 2,000 independents and a number of different systems. She supported prior testimony regarding a phase-in period for implementation. With respect to auxiliary and warning labels, she stated that the board – if they considered these items – would need to define what those items are for clarity.

Ms. Deanna Jang of the Asian Pacific Islander American Health Forum (APIAHF) states that ensuring that effective communication takes place between patients and pharmacists is critical to patient adherence to medication instructions and prevention of adverse events as a result of failure to adequately communicate or consult the patient.

Ms. Nisha Agarwal, Director, Health Justice Program, New York Lawyers for the Public Interest, Inc. (NYLPI) provided background that NYLPI is a nonprofit civil rights law firm, and is a national

leader in the effort to promote language access in pharmacies for people with limited English proficiency. NYLPI offers comments to strengthen the proposed regulations, based on experiences in New York.

NYLPI states that implementing SB 472 with strong regulations will send a forceful message to consumers and providers across the country that the civil rights of LEP individuals are to be protected and honored. NYLPI states that California is viewed as a leader in advancing the rights of LEP consumers, and that other states are looking to California to learn from the board's efforts to standardize and translate prescription drug labels.

NYLPI states that without translated medication labels, millions of individuals are denied meaningful care which jeopardizes their health and denies them their civil rights. NYLPI urges the board to adopt regulations that include a requirement for pharmacies to translate medication labels.

Mr. Brian Kratt, Chief Executive Officer of RxTran provided information related to the availability of translated directions for use, adding that RxTran is one such service. He states that translation services can be as low as \$50 per month for the equivalent translation of hundreds of thousands of SIGs per month into 11 languages. Mr. Kratt states that if the board decides to implement the proposed regulation, RxTran would be happy to provide the board with the translation of the directions for use into any five languages the board chooses, free of charge.

General Comments re: Font and Typeface

Dr. August Colenbrander states that adequate legibility of pharmacy labels is important to avoid medication errors and states that no matter what print size is used, there will be some people for which it is not large enough. He adds that there is a practical limit large the print can be on a given label. He further states that with an appropriate magnifier, reading pharmacy labels is still possible for 98% of users whose vision is too poor to read a standard label.

Dr. Colenbrander provided an example of the Target pharmacy label and provided background on how it was developed. He provided data on the various font sizes and text characteristics utilized on the label. He added that the use of smaller print for some items frees up space for larger print for more important items.

General Comments: Language Access

Mr. Marty Martinez, MPP, Policy Director, California Pan-Ethnic Health Network, provided information on CPEHN and expressed concern with ensuring the board's regulations are

sufficient to improve the care and safety of the 40% of Californians who speak a language other than English at home.

CPEHN states there is work to be done to create stronger regulations for language access. In particular, Mr. Martinez states that the board backed away from requiring labels to be translated into every patient's primary language. He asserts this recommendation was submitted by staff to the board, and that this provision should be brought back.

Proposed Response: In an August 13, 2009 memo to the board's Executive Officer, and to document the top five non-English languages in California, staff summarized a variety of state departments' publications and services that are provided in languages other than English. The memo was not a recommendation to the board to translate prescription drug labels into every patient's primary language.

General Comments: Elements on a Label

Mr. Laverone states that mandating where items appear on an Rx label may cause pharmacies and software providers to expend large amounts of money. He makes a statement that the requirements for labels is becoming so cumbersome that a label the size of a 3 x 5 card will be needed to get all the information on it. He states that the proposed regulation does not include a route of administration.

Proposed Response: The board considered the factors as defined in section 4076.5 of the Business and Professions code in crafting the proposed regulation. While the board did not include a requirement that the "route of administration" be required on a prescription label under this section (nor is this required by section 4076 of the Business and Professions Code), the regulation does not preclude such information from being included, should the pharmacist – in his or her professional judgment – determine that information is needed for safe and effective administration of the prescribed drug.

As a California certified Administrative Hearing Interpreter and instructor, Ms. Goodfriend-Koven, City College of San Francisco Health Care Interpreter Certificate Program, states she is acutely aware of the difficulties that many patients have in understanding their prescription drug instructions.

Mr. Anthony Wright, Executive Director, Health Access California, is a statewide coalition representing consumers, seniors, people with disabilities, religious, labor, and multi-lingual/multi-cultural groups. Health Access California states that the proposed regulations represent a credible start to the implementation of SB 472, which requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-

centered prescription drug label on all prescription medication dispensed to patients in California.

Mr. Wright reflected on testimony he heard at the board's October 2009 public hearing – testimony indicating difficulty in implementing the draft regulatory language, and those that spoke in favor, further indicating that in large measure they were already adhering to key features of the draft regulation. Health Access California believes that standardized, readable, language-accessible prescription labels are a vital element in appropriate health care delivery, and they strongly believe the draft regulations should be adopted at the January 2010 Board Meeting.

Ms. Kara Bush of the California Grocers Association provided background on the CGA, as well as membership data. Ms. Bush states that many of its member grocery companies operate full service pharmacies. Ms. Bush states that the proposed regulations do not meet intended objectives. She adds that for CGA members to comply with the proposed regulations, the requirements must be cost effective, feasible and practical for pharmacy retailers.

Ms. Bush states that while pharmacies are aware of potential for improvements in prescription medication labeling and counseling to improve health literacy and patient safety, physicians, pharmacists, and patients also have responsibilities in ensuring appropriate medication use. Specifically, patients have the responsibility to request information from their physicians, and if they need additional information, from their pharmacists. Ms. Bush states that more evidence is needed on how to make labels more comprehensible yet manageable.

Ms. Bush states that although some research has been conducted on how to improve labels, more analysis is needed to determine what changes can be made to fulfill the statutory requirements without causing such a significant impact on the pharmacies. She states that there is no strong evidence to demonstrate that changing the label, as defined in the proposed regulations, will lead to better adherence, fewer adverse consequences, or better patient outcomes.

Ms. Bush asks that the board collaborate with the CGA in an effort to develop regulations that are cost effective, feasible and practical to implement, and that CGA would be happy to work with the board to develop alternatives to achieve the statutory mandate.

Ms. Doreena Wong of the National Health Law Program (NHeLP) provided background on the organization. She stated that NHeLP believes that the proposed regulations represent a retrenchment from the intent of SB 472 and the board's draft language shared with the public at its July and October 2009 meetings. NHeLP believes that testimony presented to the board provides critical evidence about the needs of limited-English proficient patients and clearly supported the need for translation of prescription drug labels.

The NACDS, CPhA and CRA state that chain and independent pharmacies have numerous concerns with the proposed regulations and state that there are reasonable alternatives that would be equally effective for patient centered labels and less burdensome for pharmacies. The NACDS, CPhA and CRA state that the proposed regulatory requirements may hinder the use of the innovative prescription labeling for which the Board has indicated a preference.

The NACDS, CPhA and CRA ask that the board take a less burdensome approach that would be as effective for a patient-centered label.

The NACDS, CPhA and CRA state that the research conducted by the board is inadequate to support the proposed label changes and that basing the proposed regulations on 606 consumer responses is unreasonable, given California's 30 million consumers. The NACDS, CPhA and CRA further state that the board should consider all research, including a study conducted by Western University, and the weight that research should be given in developing the regulation. The NACDS, CPhA and CRA also reflected on comments they attribute to Michael S. Wolfe, PHD, MPH.

Proposed Response: As stated in the Initial Statement of Reasons, the board utilized research, studies and other data in crafting the proposed language. The survey results to which the NACDS, CPhA and CRA reference was also considered by the board, but was not used as the exclusive resource for the proposed language.

The NACDS, CPhA and CRA state that the underlying legislation (SB 472) does not require many of the requirements in the proposed regulation. They state they do not believe that components in the proposed regulation will result in an improvement of patient understanding of their medications and their use and that the board should avoid "too much detail" in the regulation.

Proposed Response: The board's rulemaking effort is prescribed by section 4076.5 of the Business and Professions Code. That statute mandates factors which shall be considered by the board when developing proposed regulatory language, but does not mandate specific requirements that are to be included in any adopted regulation. Further, the board believes that the details included in the proposed text area necessary to provide clarity and consistency for the practical application of the regulation.

The NACDS, CPhA and CRA state that pharmacies will face burdensome costs to implement the requirements and that the board considers the large number of technology changes those pharmacies would face – asserting that pharmacies will need to make extensive changes to their software and hardware systems resulting in overwhelming costs for pharmacies. They state that to impose California specific requirements in pharmacies who utilize automated systems, central fill services, and who fill prescriptions for patients in other states will result in

pharmacies incurring extensive costs to comply with both California and other states' requirements.

Proposed Response: Though the NACDS, CPhA and CRA make a general statement as to "burdensome costs" – no information or data was provided to the board to support that claim. As a group representing considerable industry partners, the board would welcome from NACDS, CPhA and CRA factual data that would demonstrate the "burdensome costs" to which they refer.

The NACDS, CPhA and CRA state that subsection (b) of 4076.5 requires the board to hold public meetings to ensure maximum public comment, and that there is nothing in the statute that restricts that effort to a specific time period. The NACDS, CPhA and CRA believes that the board should make a commitment as part of the regulation to continued public outreach regarding prescription labels and to use that outreach to enhance public understanding of their medications. They further state that while pharmacies and pharmacists play a key role in improving consumer understand, there is a corresponding responsibility on consumers to ask questions and seek information when they do not understand how or why to use dangerous drugs. They assert that the board, as a consumer protection agency, should commit to an effort to improve patient literacy in this area.

Proposed Response: Section 4076.5 of the Business and Professions Code specifies factors to be considered in developing the proposed regulation, as well as dates for implementation and reporting requirements. This mandate does not require the board to specify a public outreach program to implement any such regulations. However, the board has established a Communication and Public Education Committee for the purpose of providing relevant information to consumers and licensees. The board believes that through its existing committee structure and Strategic Plan the board can direct the resources and efforts of the board to provide relevant information to consumers and licensees and that modifying the proposed regulation for this purpose is unnecessary.

The NACDS, CPhA and CRA believe that the board's primary focus of the regulatory effort should be to improve medication safety and medication use. To that end, the NACDS, CPhA and CRA state that the regulation should exclude violations of this section from its Citation and Fine program without first giving the pharmacy and involved pharmacists the opportunity to correct any violations.

Proposed Response: Section 4314 of the Business and Professions Code authorizes the board to issue citations and assess fines for violations of pharmacy law. The board does

not agree that a licensee should be exempt from such disciplinary measures for violations of the proposed regulation.

Ms. Doreena Wong states that the regulations should require that the primary oral and written language of the patient be recorded in the pharmacy's patient medication profile. She states that with this requirement, the pharmacist will know what kind of services the patient may need.

Ms. Linda Okahars, Asian Health Services, also testified that the patient's language should be identified in the patient's record.

Proposed Response: The board believes that it is reasonable that a patient's preferred language be identified. In light of the comments received, the board modified proposed 1707.5 to add subdivision (f) to require that a pharmacy have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) and that the policies and procedures, at a minimum, include the selected means to identify the patient's language and to provide interpretive services in the patient's language.



California Medical Association
Physicians dedicated to the health of Californians

January 4, 2010

Carolyn Klein
Department of Consumer Affairs
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Patient-Centered Prescription Labels

Dear Ms. Klein:

The California Medical Association (CMA) appreciates the opportunity to comment on the Board of Pharmacy's (Board) proposed regulations regarding patient-centered prescription labels. CMA is a professional organization that represents more than 35,000 California physicians. Dedicated to the health of Californians, CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients.

In 2007, CMA supported The California Patient Medication Safety Act enacted by SB 472 (Corbett) in order to reduce medication errors by increasing the effectiveness of communication through prescription labels. CMA continues to support the intent of these proposed regulations to improve health care literacy and to reduce errors associated with the delivery of prescription and over-the-counter medication to consumers.

More specifically, CMA supports including the generic name of the drug on prescription labels as identified in §1707.5(a)(1)(B) of the proposed text. CMA believes that this requirement will facilitate patients' understanding of their prescribed medication as well as increase compliance with the directions for use.

CMA also supports proposed §1707.5(b), which would require the Board to publish on its Web site a translation of the directions for use into at least five languages other than English. CMA is committed to linguistic sensitivity in the provision of medical care, and we believe that effective communication with patients is essential to maintaining quality care and assuring a patient's compliance with treatment plans. We would, however, suggest that this provision be expanded to require the Board to publish translations of these directions on its Web site into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. Providing clear directions for use would result in a large health benefit for limited-English speakers.

Although CMA supports the goal of these regulations, portions of the proposed text fail to meet the clarity and consistency standards outlined by the Administrative Procedures Act. *See Government Code §11349.1*. Specifically, §1707.5(a)(1)(D) states that the purpose or condition of the drug must be listed on the prescription label if “its inclusion on the label is desired by the patient.” (Emphasis added). However, it is impossible for a pharmacy or prescriber to know whether the inclusion of the purpose or condition is “desired” by the patient if this patient never informs the prescriber of this desire. California law only imposes this requirement if the patient requests such inclusion. *See Business and Professions Code §4040 and §4076*. Requiring such labeling upon a patient’s desire is inconsistent with California law and provides no clarity to either prescribers or dispensers as to when the law applies. The current proposed language would subject individuals and entities to potential liability should it be found that such a desire existed, even if it was not explicitly requested.

Further, proposed §1707.5(a)(4) detailing the directions of use is also unclear. The proposed phrases for use in describing when a prescription medication should be consumed are too broad. Rather than using phrases such as “Take 1 tablet in the morning, 1 tablet at noon, and 1 tablet in the evening,” as indicated in proposed §1707.5(a)(4)(J), the directions for use should instead indicate the appropriate time increments between doses. For instance, if a patient took one tablet in the late morning and another at noon - thus not allowing sufficient time to pass in between doses - the dangers of overdosing escalate. If suggested time increments between doses were also included in the directions for use, patient safety would be protected. The clarity of these directions needs to be improved so as not to affect standards of patient care.

Again, CMA applauds the efforts of the Board of Pharmacy in promulgating regulations to reduce medication errors by increasing the effectiveness of prescription labels. However, we have concerns over the clarity and consistency of the current proposed standards. For these reasons, we urge the Board of Pharmacy to amend the proposed regulations. Thank you for your consideration.

Respectfully submitted,



Veronica Ramirez
Research Associate, Center for Medical and Regulatory Policy
California Medical Association

January 4, 2010

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2009-10

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*National Advocates for
Asian American,
Native Hawaiian &
Pacific Islander Health*

Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834

RE: Comments on Title 16, Board of Pharmacy Proposed Language

Dear Ms. Klein:

Thank you for the opportunity to provide comments on the proposed language to add section 1707.5 of Division 17 of Title 16 of the California Code of Regulation implementing Business and Professions Code section 4076.5 (The California Patient Medication Safety Act). Ensuring that effective communication takes place between patients and pharmacists is critical to patient adherence to medication instructions and prevention of adverse events as a result of failure to communicate: the dosage form, dosage, route of administration and use by the patient; special directions and precautions for preparation, administration and use by the patient; common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; techniques for self-monitoring drug therapy; proper storage; prescription refill information; and action to be taken in the event of a missed dose.

We do not believe that the proposed regulations are sufficient to ensure that effective communication concerning the above critical elements takes place with respect to limited English proficient patients in California, nor do we believe that the regulations are sufficient to ensure compliance with Title VI of the Civil Rights Act of 1964 and its implementing regulations.

With respect to the translation of the standard directions for use, the California Board of Pharmacy can do better than translation of these directions in five languages by October 2011. The cost for translating these 17 simple directions listed in (a)(4) is minimal and is a one time cost. California is a leader in the nation, translating its Healthy Families application into 10 languages. The California Department of Social Services has a bilingual unit that translates social services notices into over 16 different languages.

<http://www.cdss.ca.gov/cdssweb/entres/pdf/DSSFormsList.pdf> While the language of the proposed regulations requires that the directions be translated into at least five languages, we urge you to raise the minimum number to at least 15 languages, and because the cost is one time, more languages should be added over time as well as more standardized directions for use. For example, the regulation could be changed to require the directions be translated into at least 15 languages by October 2011 and at least five additional languages in each of the following years. One way to save on translation costs is for the Board to provide a glossary of the terms already translated

to avoid retranslating. The State of Washington has glossaries for social services that are available in many languages. Washington also translates notice, forms and letters to recipients in about 90 different languages. In New York State, the Attorney General recently entered into agreements with seven major pharmacy chains to provide language assistance to limited English proficient patients. The agreements include providing translations of ALL directions for use on pharmacy labels for five languages and an additional five languages six months after the pharmacy's new computer system is in place. We urge you to add a provision in the regulation to require that pharmacies translate non-standardized labels in the most prevalent languages spoken in the service area.

Regarding section (d) and oral translation of the prescription container label's information, the pharmacies must be required to provide notice that interpreter services are available at no cost to persons with limited English proficiency. Most pharmacies are recipients of Federal financial assistance and are required to comply with Title VI of the Civil Rights Act of 1964. The Title VI implementing regulations require that recipients of Federal financial assistance must provide meaningful access to their programs, services and activities for LEP persons. See "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," U.S. Department of Health and Human Services, 68 Fed. Reg. 47311 (August 8, 2003). The proposed Board regulations only require an oral language translation of the prescription container *upon request of the patient*. Unless the patient is aware that this request can be made, the patient is unlikely to request it. Furthermore, pharmacies that are subject to Title VI should provide interpreter services to limited English proficient persons beyond just providing a sight translation of the prescription label. Interpreter services are needed to solicit information necessary to maintain a patient medication profile; to offer prescription drug counseling; to provide that counseling when requested; accepting in-person and telephonic prescription drug refill requests; and at other times to ensure the safe and effective use of prescription drugs. We urge you to require that pharmacies post notices informing limited English proficient persons of their rights under these regulations and under Title VI. The California Department of Health Care Services has translated a Language Services Notice in twelve languages. <http://www.dhcs.ca.gov/formsandpubs/forms/Forms/MC%204034.pdf> With translation costs ranging from .20 - .80 per word, translating such a notice into many more languages and posting it on the Board's webpage for pharmacies to reproduce and use would entail minimal costs.

Thank you again for the opportunity to provide comments to strengthen the Board's regulations to meet SB 472's goal of ensuring prescription labels are truly patient-centered. Please feel free to contact me at: 202-466-7772 or djang@apiahf.org, if you have any questions.

Sincerely,



Deana L. Jang, JD
Policy Director

December 30, 2009

Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834
Fax: (916) 574-8618
Email: Carolyn_Klein@dca.ca.gov

**Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered
Prescription Container Labels**

Dear Ms. Klein:

New York Lawyers for the Public Interest (“NYLPI”) is a nonprofit civil rights law firm in New York City that has been a national leader in the effort to promote language access in pharmacies for people with limited English proficiency (“LEP”).¹ We have been closely watching California’s own efforts to ensure that LEP individuals receive accessible health care and prescription medications. In particular, the passage of Senate Bill No. 472 in 2007, which requires the California State Board of Pharmacy to develop standardized medication labels that, among other things, take into account the needs of LEP consumers, is an important step toward the goal of ensuring safe and equitable access to prescription medication for all. We applaud your state’s achievements thus far and write now to offer comments to strengthen the regulations that have been proposed based on our experience in New York.

In particular, we were pleased that the proposed regulations require the State Board of Pharmacy to publish on its website translations of all of the standardized directions for medication use into at least five languages by October 2011. However, we are concerned that there is no requirement in the regulations for pharmacies to make these translated labels available to their customers. In New York, a study by the New York Academy of Medicine found that New York City pharmacies overwhelmingly failed to provide their LEP customers with translated medication

¹ For more information related to NYLPI’s efforts with regard to language access in pharmacies, please visit: <http://healthjustice.wordpress.com/resources/#Rx>.

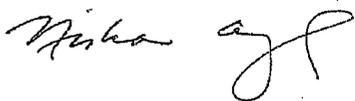
labels *despite having the capacity to do so in at least some languages.*² Pharmacies were not voluntarily offering the language assistance services necessary to ensure their patients' health and safety. This has now begun to change in response to a civil rights complaint our office filed on behalf of our community partners, which resulted in settlement agreements with all of the major chain pharmacies operating in New York. Under the settlements, CVS, Rite Aid, Costco, Target, Wal-Mart, A&P and Duane Reade pharmacies are required to make translated labels available in six languages and must add five more languages within six months of updating their computer systems to track language preference. In other words, chain pharmacies in New York will have the capacity to translate medication labels into at least 11 languages within the next year. We do not think this would have happened without a requirement for pharmacies to do so, and we therefore encourage the California State Board of Pharmacy to incorporate stronger, mandatory language into its proposed regulations regarding label translation. Many of the pharmacies that are subject to the settlement agreements in New York also operate in California and therefore have the capacity to provide the translations.

Implementing SB 472 with strong regulations that require patient-centered, translated, and standardized labels on all prescription medications will send a forceful message to consumers and providers across the country that the civil rights of LEP individuals are to be protected and honored. California is viewed as a leader in advancing the rights of LEP consumers to prescription medications. Advocates in other states are looking to California to learn from your efforts to standardize and translate prescription drug labels, making it all the more important for the Board to maintain and exemplify this commitment by immediately adopting these regulations.

Without translated medication labels, millions of individuals are denied meaningful care which jeopardizes their health and denies them their civil rights. We urge you to continue California's excellent work and adopt regulations that include a requirement for pharmacies to translate medication labels. If you have any questions or would like to contact us please do not hesitate to email me at nagarwal@nylpi.org or to call me at 212-453-5861. We will continue to follow California's efforts and your Board's progress on this matter.

Many thanks for your consideration.

With best wishes,



Nisha Agarwal
Director, Health Justice Program

² See: Linda Weiss, et. al., "Access to Multilingual Medication Instructions at New York City Pharmacies," Journal of Urban Health: Bulletin of the New York Academy of Medicine, vol. 84, no. 6 (2007), pp. 742-754.

August Colenbrander, MD

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December 19, 2009

Ramón Castellblanch
Associate Professor, Health Education
Member, California State Board of Pharmacy

Dear Ramon,

You asked my comments on the proposed rule that all pharmacy labels in California should be printed in 12 point sans-serif font.

I would like to offer the following comments.

How large is 12 pt?

Many people assume that the point size notation indicates the size of the print. This is not so. Printer's points refer to the size of the slug on which letters were mounted when type was still hand-set from individual letters. Since the ratio of the letter to the slug varies, so does the actual print size for different fonts. Here are some examples for the Arial font:

ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial Narrow 12 pt
ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial 12 pt
ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial 12 pt (bold)
ABCDEFGHIJKLMN OP abcdefghijklmnop	Verdana 12 pt
ABCDEFGHIJKLMN OP abcdefghijklmnop	Arial Black 12 pt

This shows that even for the variants of this common font actual print sizes vary.
Note: this letter is printed in Arial 11 pt.

Is 12 pt large enough?

Adequate legibility of pharmacy labels is important to avoid medication errors. This is an important issue, since the population is getting older, and since old age is often accompanied by poorer eye sight as well as by more medication use.

Obviously, the larger the print, the more people will be able to read it. However, no matter which print size is used, there will be some people for which it is not large enough. There also is a practical limit on how large the print can be on a given label. So any decision will be a compromise.

To calculate which percentage of patients will still have difficulty with 12 pt print one would need to know the incidence of reduced reading ability, which will be different for different age groups. Unfortunately, I do not know of any reliable quantitative data about this.

Even for users whose vision is too poor to read a standard label. With an appropriate magnifier reading pharmacy labels is still possible for 98% of them. Attached is a poster about a study the occupational therapist in our low vision rehabilitation service did some years ago. Obviously, the type and power of the magnifier and the reading training must be individualized, depending on the degree of vision loss.

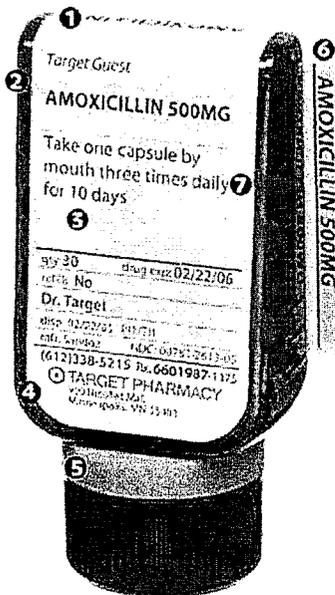
This finding, however, does not negate the fact that it is desirable to have labels that are readable without a magnifier for the majority of those with mild or moderate vision loss.

Is sans-serif a good choice?

The readability of various fonts depends on more than just the letter size. Line spacing and letter spacing also play an important role. Many people like fonts with serifs (such as Times Roman). It is thought that the serifs make it easier to follow along the line for continuous reading. This may be the reason why Times Roman is still used in most newspapers and magazines.

However, label reading is different from continuous text reading. For labels I support the sans-serif choice, if only because it avoids the much greater variability among fonts with serifs.

What is the best layout?



You may be familiar with the pill bottles used by the Target pharmacy. I have attached a description of how they were developed. A significant feature is that the bottle is not round, but has two flat surfaces, which makes reading easier. The flat surface also facilitates the use of magnifiers when needed.

I measured the font size on a Target bottle. The name of the medication is printed in bold 14 pt. The instructions are in 12 pt (non bold). Less important details (date, refills, physician name, etc.) are printed in 10 pt (some are bold).

The use of smaller print for some items frees up space for larger print for more important items. This arrangement also attracts most attention to the most important information.

For instance: it is desirable that the number of pills to take stands out from other numeric information on the label. For instance: one might consider bold facing the words "one capsule" on the bottle shown; alternatively, bold face the number of capsules if it is not one.

My recommendation

I am a strong proponent of readability standards for pharmacy labels. I support the choice of a sans-serif font.

Rather than requiring a 12 pt font for all information, I would recommend a standard that allows some variation, depending on the importance of the information. I would offer the Target labels as an example.

Your board may want to define what is most important (such as the name of the medication), what is important (such as the instructions) and what is less important (such as order number, refills, etc.). This determination should be based on a study of medication errors where misreading played a role. Such studies are probably available from the literature.

I hope that this information is helpful.

Sincerely,

August Colenbrander, MD

Attachments:

Curriculum Vitae

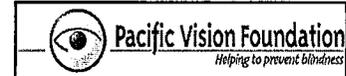
Print size samples

Pharmacy labels – Target

ARVO poster 2007



Ability to Read Medication Labels Improved by Participation in Low Vision Rehabilitation Program



C.K. Kent¹, S.N. Markowitz², R.A. Schuchard³, D.C. Fletcher¹

California Pacific Medical Center Dept of Ophthalmology and Smith-Kettlewell Eye Research Institute¹; Univ. of Toronto²; Atlanta VA Rehab R&D Center³

Purpose:

- To compare medication label reading performance pre and post- low vision rehabilitation.

Methods:

- 57 low vision patients referred for rehabilitation and currently taking medications were enrolled in a study to evaluate their ability to read medication bottle labels pre and post low vision rehabilitation.
- Medication bottles with standard labeling not being used by the patients were used for the evaluation.
- An occupational therapist evaluated the patients medicine bottle reading ability at initial evaluation and at the time of discharge from the program. Patients were allowed to use their own magnifiers for this evaluation. Thus, if a device was prescribed in their rehab program it was used at the time of discharge evaluation.
- Patients were rated as either
 - 0 = unable to access
 - 1 = able to access partially but not with confidence
 - 2 = able to accurately and reliably read the printed directions
- Low vision rehabilitation included visual function assessment, trial of vision enhancement equipment and adaptive training provided by and experienced OT.
- Non visual techniques for medication identification were not included in this study.

Population:

N = 57
 Age: 44 – 95 years Median: 80
 Gender: 39% male, 61% female
 Visual Acuity 20/40 – 20/635 Median: 20/105
 Diagnoses AMD..... 78%
 Glaucoma..... 9%
 Other..... 13%

Medications per patient
 Range: 1 – 14 Average: 4
 96% were on more than one medication

Results:

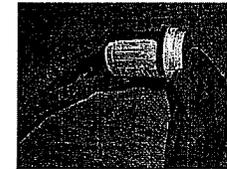
Medication Access	Pre Rehab	Post Rehab
•Unable:	0 = 33	0 = 1
•Partial:	1 = 23	1 = 2
•Accurate:	2 = 1	2 = 54

Cost

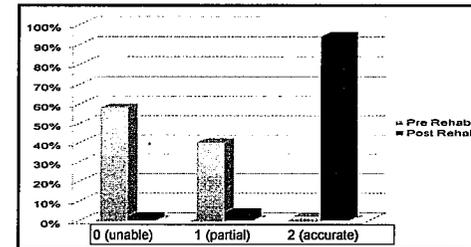
- To accomplish medicine bottle reading, 52/56 patients required optical devices for vision enhancement at an average cost to the patient of \$76.
- 4/56 patients required video magnifiers at an average cost of \$1075
- Patients received an average of 2 OT training sessions – Medicare covered expense of about \$250.

Associations

- The change in ratings is highly significant.
- The change in rating is not significantly related to age or visual acuity.



Medication Bottle Reading Performance



Medication Bottle Reading Performance (n = 57)

	0 = Unable to Access	1 = Partial Ability	2 = Accurate Access
Pre-Rehabilitation	58%	40%	2%
Post-Rehabilitation	2%	4%	94%

References:

- Kravitz R.L. & Melnikow J. (2004). Medical adherence research: Time for a change in direction? *Med Care*, 42: 197-199
- MacLaughlin E., Raehl C., Treadway A., Sterling T., Zoller, D., & Bond, C. (2005). Assessing medication adherence in the elderly. *Drugs & Aging*, 22(3):231-55
- Haynes, R.B. (2001). Determinants of compliance: the disease and the mechanisms of treatment. Haynes, R.B., Taylor, D.W., Sackett, D.L., Eds, *Compliance in Health care*. Baltimore, MD: Johns Hopkins University Press; 1979; 49-62.
- World Health Organization (2003). *The magnitude of the problem of poor adherence*.

Conclusions:

- The primary source of information available to a patient at the time of medication consumption is the prescription product label. Poor medication adherence has been associated with worsening of disease, death and increased healthcare costs.
- In this group of low vision patients, a significant improvement in ability to read medication labeling was observed with modest time and resource investment.
- For patients unable to visually read their labels other non-visual techniques can be utilized. These were not evaluated in this study.
- This appears to demonstrate an important outcome benefit to low vision rehabilitation.

Support: Pacific Vision Foundation

The Perfect Prescription

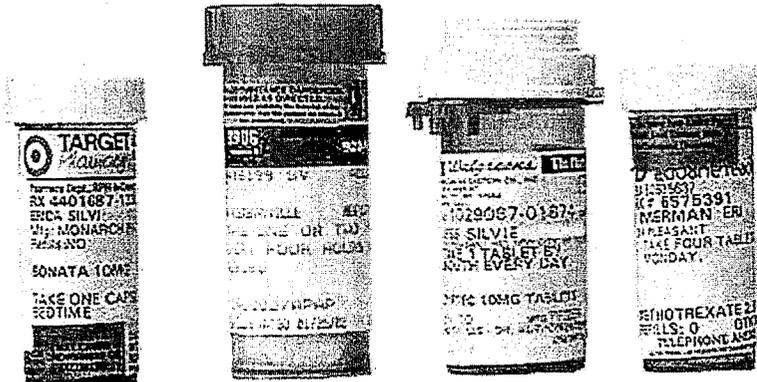
How the pill bottle was remade—sensibly and beautifully.

Published May 21, 2005

By the time an object, or an apartment, or a company hits the half-century mark, it's usually been through a redesign or two. Yet the standard-issue amber-cast pharmacy pill bottle has remained virtually unchanged since it was pressed into service after the second World War. (A child-safety cap was added in the seventies.) An overhaul is finally coming, courtesy of Deborah Adler, a 29-year-old graphic designer whose ClearRx prescription-packaging system debuts at Target pharmacies May 1.

Adler grew up in a family of doctors in Chappaqua, New York, but escaped medicine for an M.F.A. at the School of Visual Arts. She was inspired to return, at least tangentially, after her grandmother Helen accidentally swallowed pills meant for her husband, Herman. The drugstore prescription bottle, it occurred to Adler, is not just unattractive, it's actually dangerous. Statistics back her up: According to a recent poll conducted for Target, 60 percent of prescription-drug users have taken medication incorrectly.

For her SVA thesis project, called Safe Rx, Adler revamped the familiar canister, then approached the FDA—but one of Target's creative directors saw her work last summer, snapped up the patent, and rolled it out in record time. It's already approaching design-classic status: ClearRx will be included in a MoMA exhibit this October. Your medicine cabinet is next. Here's how Adler got from A to B.



(Photo credit: Davies + Starr)

Step 1

The Industry Standard

Inconsistent labeling.

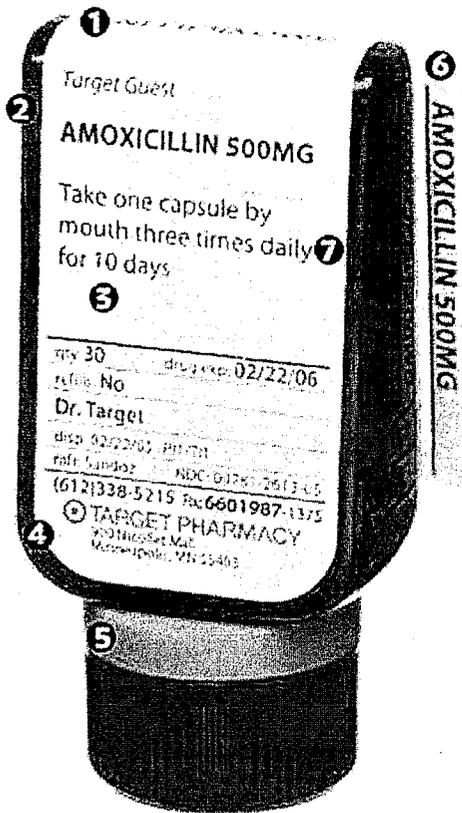
Every pharmacy's bottle has a different style and placement of information. At Duane Reade, the drug name appears at the bottom of the label, with the quantity below; at Metro Drugs, the quantity appears before the name of the medication, on the same line.

Branding trumps all.

The first and largest piece of type on a label is often the drugstore's logo and address—not the name of the drug and instructions on how to take it, which should be given priority.

Confusing numbers.

Numerals are often printed without explanation. The number 10 floating in empty space, for example, could be read as ten pills or "take ten times a day."



(Photo: Davies + Starr)

Step 3

The Solution

The ClearRx system Adler designed for Target includes bottles for pills and liquids and a measuring syringe. Here's the pill bottle that hits shelves in May.

(1) Easy I.D.

The name of the drug is printed on the top of the bottle, so it's visible if kept in a drawer.

(2) Code red.

The red color of the bottle is Target's signature— and a universal symbol for caution.

(3) Information hierarchy.

Adler divided the label into primary and secondary positions, separated by a horizontal line. The most important information (drug name, dosage, intake instructions) is placed above the line, and less important data (quantity, expiration date, doctor's name) is positioned below.

(4) Upside down to save paper.

Klaus Rosburg, a Brooklyn-based industrial designer hired by Target, came up with an upside-down version that stands on its cap, so that the label can be wrapped around the top. Every piece of paper in the package adds up to one eight-and-a-half-by-fourteen-inch perforated sheet, which eliminates waste and makes life easier for pharmacists.

(5) Green is for Grandma.

Adler and Rosburg developed a system of six colored rubber rings that attach to the neck of the bottle. Family members choose their own identifying shade, so medications in a shared bathroom will never get mixed up.

(6) An info card that's hard to lose.

A card with more detailed information on a drug (common uses, side effects) is now tucked behind the label. A separate, expanded patient-education sheet, designed by Adler, comes with three holes so it can be saved in a binder for reference.

(7) Take "daily."

Adler avoided using the word once on the label, since it means eleven in Spanish.

(8) Clear warnings.

Adler decided that many of the existing warning symbols stuck on pill bottles don't make much sense—the sign for "take on an empty stomach," for instance, looked like a gas tank to her—so together with graphic designer Milton Glaser, for whom she now works, she revamped the 25 most important.

ARIAL FONT at various font sizes

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VARIOUS 12 pt SANS SERIF FONTS

ABCDEFGH IJKLMNOP abcdefghijklmnop Cordia new 12 pt

ABCDEFGH IJKLMNOP abcdefghijklmnop Tunga 12 pt

ABCDEFGH IJKLMNOP abcdefghijklmnop Arial Narrow 12 pt ←

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ABCDEFGH IJKLMNOP abcdefghijklmnop Arial 12 pt ←

ABCDEFGH IJKLMNOP abcdefghijklmnop Lucida Sans 12 pt

ABCDEFGH IJKLMNOP abcdefghijklmnop Century Gothic 12 pt

ABCDEFGH IJKLMNOP abcdefghijklmnop Arial 12 pt (bold) ←

ABCDEFGH IJKLMNOP abcdefghijklmnop Verdana 12 pt ←

ABCDEFGH IJKLMNOP abcdefghijklmnop Lucida console 12 pt

ABCDEFGH IJKLMNOP abcdefghijklmnop Arial Black 12 pt ←

CURRICULUM VITAE

August Colenbrander, M.D.

SUMMARY SHEET

Dr. Colenbrander was born in Holland where he received his medical and ophthalmological training and served on the faculty of Leiden University Medical School until 1969.

In 1969 he was invited to the Department of Ophthalmology at the University of Iowa as a visiting professor. In 1971 he moved to San Francisco to become a member of the faculty of the Department of Ophthalmology at California Pacific Medical Center and an affiliate Scientist at the Smith-Kettlewell Eye Research Institute.

His principal clinical interest is in **Low Vision Rehabilitation**. Since 1974 to his clinical retirement in 1998, he was Director of the California Pacific Low Vision Services. His activities in the Low Vision field continue. He has promoted a multidisciplinary team approach for service delivery for the visually handicapped, conducted several studies of vision requirements in the work environment and served on national and international committees, including the Committee on Low Vision Rehabilitation of the American Academy of Ophthalmology. He was a founding Board member of the International Society for Low Vision Research and Rehabilitation (ISLRR) and represents the sub-specialty of Vision Rehabilitation on the Advisory Committee of the International Council of Ophthalmology (ICO).

Other professional interests include **Medical Information Systems, Classification and Coding**. His involvement started as a resident at the Royal Dutch Eye Infirmary in Utrecht, Netherlands (1960) and resulted in the worldwide implementation (1978) of a new Eye section in the 9th Revision of the International Classification of Diseases (ICD-9). For the ICO, he was involved with the development and promotion of an international Visual Acuity Measurement Standard (1984) and authored the 2002 Visual Standards report on Aspects and Ranges of Vision Loss, the 2006 report on Vision Requirements for Driving Safety and the 2008 report on Assessment of Functional Vision. He is co-chair of the Topic Advisory Group (TAG) for Ophthalmology to assist the WHO in the development of ICD-11.

Dr. Colenbrander has worked on the development of various **Instructional Materials** including a national curriculum in ophthalmology for medical students and a mannequin for direct ophthalmoscopy. He has been involved in WHO workshops on the prevention of blindness and has served as a WHO consultant to the South East Asia region.

Since 1977, until his clinical retirement in 1998, he established and maintained several successful **Matching Programs** for residency applicants for Ophthalmology, Ophthalmology Fellowships, Neurological Surgery, Otolaryngology, Neurology, and Plastic Surgery and for related Fellowships.

Dr. Colenbrander can be reached at: . gus@ski.org

Selected publications are available at: www.ski.org/Colenbrander

CURRICULUM VITAE

August Colenbrander, M.D.**EDUCATION:**

1943-1949 Gymnasium B, Delft, Netherlands
 1949-1959 Leiden University: Medical School, Internships and licensure (1959)
 1960-1964 Utrecht University: Residency in Ophthalmology
 1964 Qualified as Ophthalmologist, Netherlands Specialty Board
 1964 'Doctor's' degree (Ph.D.) at Utrecht University

APPOINTMENTS AND PROFESSIONAL EXPERIENCE:

1989-1991 Program Coordinator, Radiation Oncology Matching Program
 1986-1998 Program Coordinator, Plastic Surgery Matching Program
 1982-1998 Program Coordinator, Neurological Surgery Matching Program
 including Fellowships since 1993
 1982-1998 Program Coordinator, Otolaryngology Matching Program
 including Fellowships since 1993
 1980-1983 Program Coordinator, Dermatology Matching Program
 1980-1998 Program Coordinator, Neurology Matching Program
 1977-1998 Program Coordinator, Ophthalmology Matching Program
 including Fellowships since 1985
 1974-1998 Director, Low Vision Services,
 California Pacific Medical Center, San Francisco
 1971-present Full-time faculty, Dept. of Ophthalmology,
 California Pacific Medical Center, San Francisco
 1991-present Affiliate Senior Scientist, Smith-Kettlewell Eye Research Institute, San Francisco
 1982-1991 Affiliate Scientist, Smith-Kettlewell Eye Research Institute, San Francisco
 1979 World Health Organization, South East Asia Region,
 Consultant for Prevention of Blindness, Thailand
 1972-1973 Member planning team for 'A School of Health Professions',
 School of Medical Sciences, University of the Pacific,
 Pacific Presbyterian Medical Center
 1969-1971 Consultant on Strabismus Research Study, University of Iowa
 1969-1971 Consultant on Hospital Information System, University of Iowa
 1964-1969 Ophthalmological Consultant, Leiden University Hospital
 1969 Acting Head, Medical Records, Leiden University Hospital
 1966-1969 Designed, promoted and implemented a computerized central patient
 information system at Leiden University Hospital
 1960-1964 Royal Dutch Eye Infirmary, Utrecht University
 Chief Resident (1963-64), Resident (1960-63),
 1961-1963 Basic research on the response of the visual system to gravity forces

HONORS:

- 2000 "Outstanding Lifelong Contributions in Low Vision", Association for Education and Rehabilitation of the Blind and Visually Impaired (AER), Division 7.
- 1996 Honored Guest, Association of University Professors of Ophthalmology.
- 1985 Distinguished Service Award, American Academy of Ophthalmology.
- 1982 Honor Award, American Academy of Ophthalmology.

COMMITTEES:**International:**

- World Health Organization / International Council of Ophthalmology – Co-chair
Topic Advisory Group for Ophthalmology for ICD-11 (2008- present)
- Vision-2020 – Member of the Low Vision Working Group (2003- present)
- World Health Organization – Member, Expert Consultation Group on
Characterization of Vision Loss (Geneva, September, 2003)
- International Council of Ophthalmology – Advisory Committee, Consultant
(2000-2002), Representative for Vision Rehabilitation (2002- present)
- International Society for Low Vision Research and Rehabilitation, Founding
Board Member (1993-2002)
- International Council of Ophthalmology, Visual Functions Committee,
General Secretary (1982-1986)
- International Council of Ophthalmology, Committee on Information,
Secretary (1970-74), Chairman (1974-82)
- World Health Organization, Participant, WHO workshop to draft Guidelines for
Blindness Surveys (San Francisco, 1979)
- World Health Organization, Participant, WHO workshop to draft Guidelines for
Prevention of Blindness Programs (Asilomar, 1978)

National:

- American Medical Association, *Guides* Advisory Committee (2007- present)
Revision Committee, AMA Guides for Evaluation of Permanent Impairment
, 5th edition (1998-2000), 6th edition (2006, 2007).
- Expert Panel on Disability Determination for Special Senses, Social Security
Administration (1992)
- Low Vision Rehabilitation Committee, American Academy of Ophthalmology
Member (1978-1993), Chairman (1986-1989)
- Low Vision Advisory Committee, American Foundation for the Blind
(1976-1979)
- Ophthalmology Advisory Committee, National Association for Visually
Handicapped (1975-present)
- Advisory Board, Council of Citizens with Low Vision (1983-1995)
- Working Group #39 (Standards for Visual Acuity), Committee on Vision,
National Research Council (1976)
- Committee on Terminology, American Academy of Ophthalmology
(1971-1986)
- Commission on Clinical Nomenclatures Coding and Classifications, American
College of Surgeons, Director for American Academy of
Ophthalmology, member Steering Committee (1983-1985)
- Committee on Medical Informatics (E31-12), American Society for
Testing of Materials, Co-chairman (1985-1987)
- American National Metric Council, Biomedical Sector Committee, (1979)
- Committee on Medical Student Education, American Academy of
Ophthalmology and Association of University Professors of
Ophthalmology (1974-1985)
- American Medical Association, consultant for 'Current Procedural
Terminology,' 3rd edition (1972-73), 4th edition (1976-1986)

American Medical Association, Coordinating Committee on PSRO
Criteria Project (1979)
College of American Pathologists, member board of editors for
SNOMed (1973-1980)

State, Local:

Blind and Visually Impaired of Marin, Board member (2005 – present)
California Pacific Medical Center, Institutional Review Board, Alternate member
(1994 – 2005), Full member (2008 – present)
Advisory Committee, San Francisco VDT Ordinance (1991-1998)
Advisory Committee, Vision Requirements for California Driver's Licenses,
California DMV (1992-1993)
Advisory Committee on VDT terminals, California-OSHA (1987-1989)
California Medical Association, consultant for California
Relative Value Studies (1972-75)
Medical Records Committee, Presbyterian Hospital (1971-1982)
Library Committee, Pacific Presbyterian Medical Center (1975-1991)

MONOGRAPHS, INSTRUCTIONAL MATERIALS, TEXT BOOK CHAPTERS:

1. Eye and Otoliths. A study on the human centrifuge of the ocular response to otolith stimulation. Thesis for 'Doctor's' (Ph.D.) degree, Utrecht University, Utrecht, the Netherlands, 1965.
2. Coding System for Disorders of the Eye. J. Schappert-Kimmijser, A. Colenbrander, S. Franken. S. Karger, Basel (Switzerland) and New York, 1968.
3. Ophthalmoscopy: Basic Self-instruction for Medical Students. Gary M. Arsham, August Colenbrander, Bruce E. Spivey. Washington: National Audiovisual Center, 1973.
4. Glaucoma Screening - Tonometry: A Self-instructional Unit. Gary M. Arsham, August Colenbrander, Bruce E. Spivey. Washington: National Audiovisual Center, 1973.
5. General Ocular Examination: A Self-instructional Unit. August Colenbrander, Jane Creech, Gary M. Arsham. Washington: National Audiovisual Center, SIMO Project, 1976.
6. Basic Diagnostic and Treatment Procedures in Ophthalmology: A video-tape. Gary M. Arsham, Jane Creech, Robert L. Stamper, August Colenbrander. Washington: National Audiovisual Center, SIMO project, 1976.
7. Ophthalmologic Services, Procedural Terminology for Ophthalmology. American Academy of Ophthalmology and Otolaryngology, 1975 (principal coordinator).
8. Otolaryngologic Services, Procedural Terminology for Otolaryngology. American Academy of Ophthalmology and Otolaryngology, 1975 (principal coordinator).
9. Ophthalmology Study Guide for Students and Practitioners of Medicine. American Academy of Ophthalmology (and Otolaryngology), (special consultant),
1st edition 1975, 2nd edition 1976, 3rd edition 1978, 4th edition 1982.
10. Principles of Ophthalmoscopy, Vol. 1, chapter 63, in Clinical Ophthalmology, (T. Duane, ed.), Harper and Row, publishers, 1979, updated in 2003 edition.
11. Coding Manual for Medical Eye Services. California Association of Ophthalmology, 1980.
12. Low Vision Rehabilitation, Special issue of: Ophthalmology Clinics of North America, Colenbrander, Fletcher eds., 7, 2, 1994.
13. The Visual System. Chapter 12 in Guides to the Evaluation of Permanent Impairment, 5th edition (L. Cocchiarella, G.B.J. Anderson, eds.), AMA Press, Chicago, 2001.

14. The Visual System. Chapter 12 in Master the AMA Guides (L. Cocchiarella, S.J. Lord, eds.), AMA Press, Chicago, 2001.
15. Measuring Vision and Vision Loss, Vol. 5, chapter 51, in Duane's Clinical Ophthalmology, 2001 edition.
16. The Visual System. Chapter 36 in Disability Evaluation, 2nd edition (S.L. Demeter, G.B.J. Anderson, eds.), Mosby (Elsevier Science), St. Louis MO 63146, 2003.
17. The Visual System. Chapter 12 in Guides to the Evaluation of Permanent Impairment, 6th edition (Rondinelli RD, Genovese E et al. eds.), AMA Press, Chicago, 2007.
18. Measuring Vision and Vision Loss – chapter for *Duanes Ophthalmology* (expected April 2010).
19. Classification of Vision-related Functioning – A Framework – Chapter for book on *Visual Impairment in Children Due to Damage to the Brain* (in process).
20. Vision Rehabilitation – Chapter for Lange, *Clinical Ophthalmology* (in process).

REPORTS, SPECIAL STUDIES:

1. Classification of Disorders of the Eye - redesign of the Eye section of ICD-9, with national and international input. Field trial, 1975. Incorporated in:
International Classification of Diseases and 9th revision (ICD-9), WHO, Geneva, 1977.
ICD-9-CM (Clinical Modification for the U.S.), Committee on Professional and Hospital Activities, Ann Arbor, 1978.
2. Classification of Visual Performance, Field trial, 1976. Incorporated in:
International Classification of Impairments, Disabilities, and Handicaps, WHO, Geneva, 1980.
3. International Visual Acuity Standard - with input from Visual Functions Committee,
Approved by the International Council of Ophthalmology, 1984.
4. Vision Requirements Survey for Highway Maintenance Personnel, A study for the California State Personnel Board, with Brian Brown, OD, PhD, 1982.
5. Color Vision Requirements for 51 State Job Classes, A study for the California State Personnel Board, with Anthony J. Adams, OD, PhD, 1982.
6. Vision Requirements Survey for Correctional Officers, A study for the California Department of Corrections, with Leslie V. Woods, OD, 1985.
7. Guide for the Evaluation of Visual Impairment, prepared for the International Society for Low Vision Research and Rehabilitation (ISLRR), for the VISION-99 International Conference on Vision Rehabilitation (coordinator, with international advisory group). Pacific Vision Foundation, San Francisco, 1999.
8. Visual Standards, Aspects and Ranges of Vision Loss with Emphasis on Population Surveys. International Council of Ophthalmology, 2002. Available at: www.icoph/standards.
9. Visual Standards, Vision Requirements for Driving Safety, with Emphasis on Individual Assessment. International Council of Ophthalmology, 2006. Available at: www.icoph/standards.
10. (Visual Standards) Assessment of Functional Vision and its Rehabilitation. International Council of Ophthalmology and International Society for Low Vision Research and Rehabilitation, 2008. Available in: *Acta Ophthalmologica* (March 2010)

PAPERS, etc.:

1. The Influence of G Forces on the Counter-rolling of the Eye. A. Colenbrander, Ophthalmologica 146:309-313, 1963.

2. Quantitative Analysis of the Relations between Gravity, Head Position and the Subjective Plumb-Line. A. Colenbrander, Ophthalmologica 151:646-651, 1966.
3. Eye and Otoliths. A. Colenbrander, Aeromedica Acta 45-91, 1965.
4. Pediatric Ophthalmology. Bruce E. Spivey, August Colenbrander and R. R. Flickinger, Jr., Hospital Medicine 7:37-53, 1971.
5. University of Iowa Hospitals and Clinics Convert to the Metric System. A. Colenbrander, Journal of Iowa Medical Society 61:219-224, 1971.
6. Basic Instruction in Ophthalmology for Medical Students: A Systems Approach. G. M. Arsham, A. Colenbrander, B. E. Spivey, Proceedings of the 5th Rochester Conference on Self-Instruction in Medical Education, Rochester Clearinghouse, University of Rochester, Rochester, New York, 1972.
7. Comparison of Selected Ophthalmologic and Orthoptic Measurements in Families. David Smith, Peter Grutzner, August Colenbrander, J. P. Hegmann, Bruce E. Spivey, Arch. Ophth. 87:278-282, 1972.
8. Uniform Terminology. B. E. Spivey, A. Colenbrander, Editorial, Trans. AAOO 76:14-16, 1972.
9. A Simulation Device for Ophthalmoscopy. A. Colenbrander, Am. J. Ophth. 74:738-740, 1972.
10. International Expectation for Medical Student Performance in Ophthalmology. A. Colenbrander, Proc. 10th Annual Conf. on Research in Med. Ed., AAMC, 1971.
11. Instruction for Mastery in Medical Education. G. Arsham, A. Colenbrander, B. E. Spivey, Proc. 10th Annual Conf. on Research in Med. Ed. (abstract), AAMC, 1971.
12. A Prototype for Curriculum Development in Medical Education. Gary M. Arsham, August Colenbrander, Bruce E. Spivey, Journal of Medical Education 48:78-84, 1973.
13. Information Systems in Ophthalmology. A. Colenbrander, Current Concepts in Ophthalmology, Frederick Blodi, ed. C.V. Mosby Company, St. Louis, 1972.
14. Classification of Visual Performance. B. E. Spivey, A. Colenbrander, Arch. Ophth., 94:1227, 1976.
15. Classification and Coding in Ophthalmology and Otolaryngology. A. Colenbrander, Journal of Clinical Computing V, 2:83, 1976.
16. Low Vision, Definition and Classification. A. Colenbrander, in Clinical Low Vision, Eleanor Faye, ed. Little, Brown and Company, Boston, 1976.
17. A Clear Perspective on Low Vision, A. Colenbrander, Blindness, AAWB Annual, 1977-78, pp. 94-106.
18. How blind is blind? A. Colenbrander, Proceedings 2nd National Conference on Aging and Blindness, American Foundation for the Blind, 1978, pp. 15-24.
19. Aging and Visual Loss, invited testimony, A. Colenbrander, Record of the Senate Committee on Aging, August, 1978.
20. Low Vision Care, Epitome of Progress, Western Journal of Medicine (1979).
21. Dimensions of Visual Performance, A. Colenbrander, Low Vision Symposium, American Academy of Ophthalmology, Transactions AAOO, 83:332-337, 1977.
22. Classification and Coding in Ophthalmology, August Colenbrander, Computers in Ophthalmology, pp. 79-85, IEEE Computer Society, 1979.
23. Clinicians and Coding Systems. Can They Mix? August Colenbrander, Computers in Medicine, pp. 390-396, IEEE Computer Society, 1979.
24. Intraocular Lens Data. Robert L. Stamper, August Colenbrander. Ophthalmology, Instrument and Book Supplement, 1982:125-179.
25. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1983:120-135.

26. Intraocular Lens Data. Robert L. Stamper, August Colenbrander, Jan-Petter Haugen. Ophthalmology, Instrument and Book Supplement 1984:164-180.
27. Effect of luminance, contrast, and eccentricity on visual acuity in senile macular degeneration. Brown B, Zadnik K, Bailey IL, Colenbrander A. Am J Optom & Phys Optics. 61(4):265-70, 1984.
28. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1985:1-19.
29. International Visual Acuity Standard, Poster Exhibit, American Academy of Ophthalmology, 1985.
30. Lenses Mightier than Lasers, Invited speaker, Symposium on Aging, American Academy of Ophthalmology, 1986.
31. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1986:37-46.
32. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1987:1-13.
33. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1988:38-46
34. Visual Acuity Measurement Standard. August Colenbrander, MD, Visual Functions Committee, Consilium Ophthalmologicum Universale. Italian J. Ophth. II/I 1988:1-15.
35. Intraocular Lens Data. August Colenbrander, Leslie V. Woods, Robert L. Stamper. Ophthalmology, Instrument and Book Supplement, 1989:20-27.
36. Visual Acuity Measurements in Low Vision Patients. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Vision Rehabilitation, 4(1):1-9 (1990).
37. Low Vision Rehabilitation: Basic Concept and Terms. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(1):5-9 (1992)
38. Low Vision Rehabilitation: Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(2):62-69 (1992)
39. Low Vision Rehabilitation: Vision Requirements for Driving. August Colenbrander, MD, Donald C. Fletcher, MD. Journal of Ophthalmic Nursing and Technology, 11(3), 111-115 (1992)
40. How to Stabilize Gaze during Vision Tests in patients with Maculopathies. Manfred Mackeben, PHD, August Colenbrander, MD. Invest. Ophthal. Vis. Sc. 34/4 (Suppl.), # 3615, March 1992.
41. Mapping the Topography of Residual Vision in Patients with Maculopathies. August Colenbrander, MD, Manfred Mackeben, PHD. Invest. Ophthal. Vis. Sc. 34/4 (Suppl.), # 3622, March 1992.
42. Preliminary implementation of the Functional Vision Score system on the Humphrey Field Analyzer. August Colenbrander, MD, Marc F. Lieberman, MD, Daniel C. Schainholz, MD. Perimetry Update 1992/93, (Proceedings of the International Perimetric Society, Kyoto, October 1992), Kugler publications, 1993, pp 487-496.
43. The Operation was Successful, but the Patient Cannot See any Better - Where Do We Go from Here? Donald C. Fletcher, MD, August Colenbrander, MD. In: Management and Care of the Cataract Patient, editor: Frank J. Weinstock, MD, Blackwell Scientific Publications, Boston, 1992.
44. The Assesment of Residual Vision in Patients with Maculopathies. Mackeben M, Colenbrander A. Non-invasive Assesment of the Visual System, Technical Digest, Vol. 3 NMB3, 1993

45. The Functional Vision Score. A Coordinated Scoring System for Visual Impairments, Disabilities and Handicaps. August Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 552-561.
46. Visual Acuity Measurement for Low Vision. August Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 542-551.
47. Comparison of Three Ways to Assess Residual Vision in Patients with Macular Vision Loss. M. Mackeben, PhD, A. Colenbrander, MD, D. Schainholz, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 51-58.
48. Mapping the Topography of Residual Vision after Macular Vision Loss. M. Mackeben, PhD, A. Colenbrander, MD. In: Low Vision - Research and New Developments in Rehabilitation, Kooiman et al. eds., Studies in Health Technology and Informatics, IOS Press, Amsterdam, 1994, pp. 59-67.
49. Low Vision Rehabilitation. August Colenbrander, MD. In: Office Management of Refractive Error, Ophthalmology Clinics of North America, 1993, 6,4:591-597.
50. Low Vision and Vision Rehabilitation. August Colenbrander, MD, Donald C. Fletcher, editors. June 1994 Issue of: Ophthalmology Clinics of North America, June 1994, 7, 2.
51. Low Vision and Quality of Life - Aspects of Vision Loss. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation, Colenbrander, Fletcher eds., Ophthalmology Clinics of North America, 1994, 7,2:127-130.
52. Quantifying Low Vision - Ranges of Vision Loss. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation, Colenbrander, Fletcher eds., Ophthalmology Clinics of North America, 1994, 7,2:131-136.
53. The Basic Low Vision Examination. August Colenbrander, MD. In: Low Vision and Vision Rehabilitation, Colenbrander, Fletcher eds., Ophth. Clinics of North America (1994), 7-2: 151-162.
54. Basic Concepts and Terms for Low Vision Rehabilitation, August Colenbrander, MD, Donald C. Fletcher, MD. Am. J. Occupational Therapy, 49-9: 865-869 (Oct. 1995)
55. What's in a Name: More People are Blinded by Definition than by any other Cause, August Colenbrander, MD, J. of Videology, 1:1: 13-20.
56. Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD. Invest. Ophthal. Vis. Sc. 37/3, # 3306, Feb. 1996.
57. Visual Acuity Measurement in the Low Vision Range. August Colenbrander, MD. Proceedings, VISION-96, International Low Vision Conference, Madrid, 1996.
58. Quick assessment of the topography of macular vision loss using a new PC-based field analyzer. Mackeben, M. and Colenbrander, A. Proc. of the Int'l Low Vision Conference, O.N.C.E., Madrid, 1996
59. Preface in 'Foundations of Low Vision', Clinical and Functional Perspectives (AL Corn, AJ Koenig Eds.), AFB Press, New York, 1996.
60. Analysis of Match Algorithms. August Colenbrander, MD. Academic Medicine - 71:10 (10/96 Suppl.) S94-96
61. PC-based mapping of remaining letter recognition after foveal vision loss. Mackeben, M., Colenbrander, A. and Gofen, A. Invest. Ophthal. & Vis. Sci. 39, No.4 (Suppl.), 1998
62. Use your PC to quickly map remaining vision after foveal vision loss. Mackeben, M., Colenbrander, A. and Gofen, A. Perimetry Update (M. Wall & J.M. Wild, eds.), pp 307-316, Kugler Publications. (Proceedings of the XIIIth International Perimetric Society Meeting, Gardone Riviera, Italy, 1998)

63. Introducing Rehabilitation. Donald C. Fletcher, August Colenbrander, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
64. Evaluating Visual Function. August Colenbrander, Ronald A. Schuchard, Donald C. Fletcher, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
65. Enhancing Impaired Vision. August Colenbrander, Jeffrey T. Liegner, Donald C. Fletcher, in Low Vision Rehabilitation, Caring for the Whole Person, Monograph #12, American Academy of Ophthalmology, San Francisco, 1999.
66. Topographic measurements of low contrast letter recognition for diagnosis and rehabilitation. Mackeben, M., Colenbrander, A. IOVS 40/4 (Suppl), # 2261, 1999
67. Topographic Measurements of Low Contrast Letter Recognition as a Tool for Diagnosis and Vision Rehabilitation. Manfred Mackeben, August Colenbrander, in Vision Rehabilitation (Papers from Vision-99, International Low Vision Conference, New York, 1999). Swets & Zeitlinger, Netherlands, 2000.
68. How Blind is "Blind"? – Survey of Definitions of Blindness – Poster presentation at the Third International Symposium on Ophthalmology in the Developing World. San Francisco, 2001.
69. Visual Acuity Measurement – A Historical Perspective. August Colenbrander. Proceedings, Cogan Ophthalmic History Society, March 2001, 177 – 185.
70. How Blind is Blind? Colenbrander A. Poster presentation for the Third International Symposium on Ophthalmology in the Developing World, American Academy of Ophthalmology, San Francisco, (March 2001).
71. Preservation of Vision or Prevention of Blindness? Colenbrander A. Editorial, Am. J Ophth. 133:263-265, (2002).
72. Aspects and Ranges of Vision Loss. Basic and Clinical Science Course, Section 13, Chapter III (pp 37-53). American Academy of Ophthalmology, San Francisco, 2002.
73. Aspects of Vision Loss – Visual Functions and Functional Vision. Colenbrander A. Visual Impairment Research, 5(3): 115-136 (Dec., 2003).
74. Evaluation of a New Mixed Contrast Reading Card. ARVO-2004, poster # 4352.
75. The Mixed Contrast Reading Card Shows Aspect of Contrast Processing that Is Independent of Detail Processing, August Colenbrander, Donald C. Fletcher ARVO 2005, poster # 4587.
76. A Simple Screening Test for Contrast Sensitivity – The Colenbrander Mixed Contrast Reading Card. AAO 2005, poster # 387
77. Contrast Sensitivity and ADL Performance. A Colenbrander, DC Fletcher. ARVO 2006, poster # 5834.
78. The mixed contrast reading card, a new screening test for contrast sensitivity. Colenbrander A, Fletcher DC. International Congress Series, 1282:492-497 (Proceedings of Vision-2005 conference, London, 2005).
79. Reading Acuity – An important parameter of Reading Performance. August Colenbrander. International Congress Series, 1282:487-491 (Proceedings of Vision-2005 conference, London, 2005).
80. Visual Functions and Functional Vision. Colenbrander A International Congress Series, 1282:482-486 (Proceedings of Vision-2005 conference, London, 2005).
81. "How Blind is Blind?" – Flash presentation, available at: <http://www.mdsupport.org/presentation-howblind1/index.html>.
82. The Historical Evolution of Visual Acuity Measurement. August Colenbrander. Visual Impairment Research 10(2,3):57-66.

83. The Functional Classification of Brain damage-related Vision Loss. August Colenbrander. *Journal of Visual Impairment and Blindness* 103(2):118-123.
84. Assessment of Functional Vision and its Rehabilitation. August Colenbrander. 2008 report for ICO and ISLRR. *Acta Ophthalmologica* (expected April 2010).
85. Measuring Vision and Vision Loss – chapter for *Duanes Ophthalmology* (expected April 2010).
86. Classification of Vision-related Functioning – A Framework – Chapter for book on *Visual Impairment in Children Due to Damage to the Brain* (in process).
87. Vision Rehabilitation – Chapter for Lange, *Clinical Ophthalmology* (in process).

Some of the documents are available on the website: www.ski.org/Colenbrander



California Pan-Ethnic Health Network

January 4, 2010

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1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

James Allen Crouch, MPH
Executive Director
California Rural
Indian Health Board

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Vaka Folefale, MS
Wraparound/System of Care
Liaison SPA 4
Los Angeles County Department
of Children and Family Services/
Multi-Agency Services Division

Dear Dr. Schell and Members of the California Board of Pharmacy:

Calvin Freeman
President, Board of Directors
California Black Health Network

Robert Garcia, JD
Executive Director and Counselor
The City Project

On behalf of the California Pan-Ethnic Health Network (CPEHN) we submit the following comments to proposed regulations related to patient-centered prescription drug labeling. In particular we are concerned with ensuring the Board's regulations are sufficient to improve the care and safety of the 40% of Californians who speak a language other than English at home.

Al Hernandez-Santana, JD, MCP
Executive Director
Latino Coalition for a
Healthy California

Miya Iwazaki
Director, Office of Diversity Programs
Los Angeles County
Department of Health Services

CPEHN's mission is to improve access to health care and eliminate health disparities by advocating for public policies and sufficient resources to address the health needs of communities of color. CPEHN works to ensure that all Californians have access to health care and can live healthy lives.

Donzella Lee, MPH, CHES
Director of Operations
The Saban Free Clinic

Dong Suh, MPP
Associate Director
Asian Health Services

Ho Luong Tran, MD
Chief Executive Officer
Asian & Pacific Islander
American Health Forum

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medication dispensed to patients in California.

Kevin Williams, JD, MPH
Director of Development & Policy;
In-House Counsel
Berkeley Youth Alternatives

Antonette Yancy, MD, MPH
Professor
Department of Health Services
UCLA School of Public Health

While we are pleased the Board advanced the process at its October 2009 meeting, there is still work to be done to create stronger regulations for language access. In particular, the Board backed away from requiring labels to be translated into every patient's primary language. This provision was in the recommendations submitted by staff to the Board. We believe this provision should be brought back.

Prescription drug labels translated into the patient's language are vital for quality care. At the public hearing in October, you and the Board heard dramatic testimony from members of our communities on their desperate need for labels translated into their

STAFF

Ellen Wu, MPH
Executive Director

Ruben Cantu
Program Director

Pam Flood
Director of Operations

Rachel Larson, MPH
Communications Coordinator

Marin Martinez, MPP
Policy Director

Cary Sanders, MPP
Director of the Having Our Say Coalition
and Senior Policy Analyst

languages. You also heard from pharmacies who currently do translation of labels. You heard from them that it is doable and in some cases already required under public programs.

The final regulations approved by the Board must include the following provisions:

- We strongly support the provision that labels must be printed in 12-point font or larger. This is essential for seniors and those with limited vision.
- The Board should help pharmacies comply with providing translated labels to their patients. The Board should place on its website standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. The cost for these translations is minimal with a large health payoff. Attached to this letter is the census data indicating which languages are the top limited English languages.
- For non-standardized labels and other languages, individual pharmacies must be responsible for providing translated labels.
- All patients who do not speak English well must have the right to have their prescription drug instructions orally interpreted. This provision is in the current draft of the regulations. It is a necessary component of quality care but is not a substitute for a translated label. The final regulations must have provisions for both a written translated label and an oral interpretation of instructions for each patient who needs it.

Thank you for receiving these comments. We look forward to working with you on the continued effort to revise these regulations and improve care for our communities.

Sincerely,


Marty Martinez, MPP
Policy Director

COMBINED Don't speak English well & Don't speak English in CA	
1. SPANISH	2,841,237
2. CHINESE	265,269
3. VIETNAMESE	150,330
4. KOREAN	114,097
5. TAGALOG	55,894
6. ARMENIAN	44,245
7. RUSSIAN	37,798
8. JAPANESE	33,319
9. PERSIAN	24,807
10. PANJABI	24,431
11. MON-KHMER CAMBODIAN	22,472
12. ARABIC	17,037
13. HMONG	16,132
14. LAOTIAN	13,547
15. PORTUGUESE	9,493
16. FORMOSAN	9,113
17. THAI	8,539
18. HINDI	5,436
19. URDU	5,020
20. GUGARATHI	4,108

Source: 2005 American Community Survey

Link to source document:

http://www.mla.org/man_data_results&SRVY_YEAR_2005&geo=state&state_id_6&county_id=&mode=geographic&lang_id=&zip=&place_id=&city_id=®ion_id=&division_id=&ll=&a=&order=&carry=1



californiapharmacistsassociation

January 4, 2010

Ms. Virginia Herold,
Executive Officer
California State Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834

RE: Proposed Regulation Title 16 Section 1707.5

Dear Ms. Herold:

The California Pharmacist Association's Long Term Care Management Council would like to take this opportunity to provide the California State Board of Pharmacy with additional language for the proposed regulation listed above. Residents of licensed health care facilities do not physically possess, control, nor do they administer, their prescribed medications. This is accomplished by the facility licensed staff. All medications are contained in secured locations and accessed only by authorized facility staff. Moreover, the Title 22 regulations do not allow patients to keep or administer their own medications.

Further, when a facility patient/resident is discharged, we propose that they be given the choice to have new discharge prescriptions dispensed to take home or the pharmacy can provide patient drug information as is currently the practice. They could also sign an opt-out letter, similar to the opt-out letters for those patients who decline child-proof vials.

The Long Term Care Management Council proposes that the following language be amended into the proposed regulation of Title 16 Section 1707.5:

"Notwithstanding any other provision of law, it is not necessary to include the requirements of 1707.5 if a pharmacist dispenses a medication for a patient in a facility licensed pursuant to Section 1250 of the Health and Safety Code."

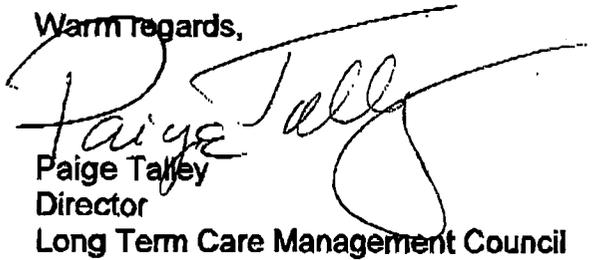
Additional language might read that "Upon discharge from a facility licensed pursuant to Section 1250 of the Health and Safety Code, a patient may choose not to have his or her medications pursuant to Title 16 Section 1707.5 by signing an opt-out waiver."

Herold 01.04.09 Page 2 of 2

The members of the Long Term Care Management Council would welcome the opportunity to discuss these amendments with you in more detail and look forward to attending the January 20 Board meeting.

Please call me if you require further information.

Warm regards,



Paige Talley
Director
Long Term Care Management Council

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BOARD OF PHARMACY



Omnicare

2009 DEC 28 PM 4:48

Scott R. Huhn PharmD
Omnicare
879 Second Street
Santa Rosa, CA 95404
707-486-7801
scott.huhn@omnicare.com

Virginia Herold, Executive Director
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

December 23, 2009

Dear Ms. Herold,

**Request to Amend for Exemption
California Board of Pharmacy
Proposed Language Section 1707.5 of Division 17 of Title 16 of the California Code of
Regulations**

The various dispensing systems involved with our patients in long term care include punchcards, Automated strip packs, and Opus cassettes. The medications are administered by licensed nurses and caregivers at various health care facilities; skilled nursing, intermediate care, psychiatric, assisted living and board/care.

The systems our pharmacies provide for medication administration are time pass oriented, involving a method of documentation via medication administration records (MAR) and centrally stored medication records (CSMR). Patients do not typically administer their own medications, unless requested and their healthcare provider determines the patient's cognitive abilities to allow for self-administration.

Please consider an exemption to this regulation for pharmacies servicing the above mentioned health care facilities because it does not involve direct to consumer prescription dispensing.

For additional information, I may be reached at 707-486-7801 or via email at scott.huhn@omnicare.com. Thank you in advance for your time and consideration.

Sincerely,

Scott R. Huhn PharmD



"Laverone, Stephen"
<Stephen.Laverone@cdcr.ca.gov>

11/23/2009 02:19 PM

To <Carolyn_Klein@dca.ca.gov>

cc

bcc

Subject RE: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

Thank you, I already looked at the web site. Mandating **where items appear** on the Rx label may cause pharmacies and software providers to expend large amounts of money which is not a welcome proposition in these recessionary times.

Steve Laverone, RPh
Pharmacist II
Northern California Youth Correctional Center
7650 S. Newcastle Road
Stockton, CA 95215
Stephen.Laverone@cdcr.ca.gov
Pharmacy (209) 463-9085
Pharmacy Office (209) 944-6365 Ext. 6725
Pharmacy FAX (209) 465-8627

From: Carolyn_Klein@dca.ca.gov [mailto:Carolyn_Klein@dca.ca.gov]

Sent: Monday, November 23, 2009 2:14 PM

To: Laverone, Stephen

Subject: Fw: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

Mr. Laverone,

I'm sorry the text of my email transmitted was small (my view appears at least 12 pt).

The email sent was to let you know that the proposed regulations can be found on the Board of Pharmacy's Web site:

http://www.pharmacy.ca.gov/laws_regs/regulations.shtml

If you have any difficulty pulling the documents off the board's Web site, please let me know.

Regards,
Carolyn Klein
California State Board of Pharmacy
(916) 574-7913

----- Forwarded by Carolyn Klein/Pharmacy/DCANotes on 11/23/2009 02:10 PM -----

"Laverone, Stephen" <Stephen.Laverone@cdcr.ca.gov>

11/23/2009 02:09 PM

To<Carolyn_Klein@dca.ca.gov>

cc

Subject: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

Your email is too small to read. What is seen below is at least twice the size. The requirements for labels is becoming so cumbersome that we will have to use a label the size of a 3 x 5 card to get all the information on it. The proposal example does not include a route of administration.

**Steve Laverone, RPh
Pharmacist II
Northern California Youth Correctional Center
7650 S. Newcastle Road
Stockton, CA 95215
Stephen.Laverone@cdcr.ca.gov
Pharmacy (209) 463-9085
Pharmacy Office (209) 944-6365 Ext. 6725
Pharmacy FAX (209) 465-8627**

From: Carolyn_Klein@dca.ca.gov [mailto:Carolyn_Klein@dca.ca.gov]
Sent: Thursday, November 19, 2009 10:03 AM
To: Carolyn_Klein@dca.ca.gov
Subject: Proposed Regulations: 1707.5 Patient-Centered Prescription Label

The Board of Pharmacy today released a Notice of proposed changes to 16 California Code of Regulations beginning with section 1707.5 related to standardized, patient-centered prescription labels. This notice and proposed text will be published in the Office of Administrative Law's Notice Register on Friday, November 20.

The Board of Pharmacy will accept comments to the proposed text until 5:00 p.m. on Monday, January 4, 2010.

Additionally, the board has scheduled a hearing on the proposed regulation for Wednesday, January 20, 2010, in Sacramento, at which time the board will accept oral or written testimony or comments to the proposed text. The hearing will be at the Department of Consumer Affairs, 1625 N. Market Blvd., First Floor, Sacramento, CA 95834.

Please click on the link below to view all documents associated with this



CALIFORNIA

RECEIVED BY CALIF. BOARD OF PHARMACY 2009 DEC 28 PM 2:41

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Asian & Pacific Islander
American Health Forum

JOHN TRASVINA
Mexican American
Legal Defense & Education Fund

HORACE WILLIAMS
CA Black Health Network

December 23, 2009
Kenneth H. Schell, PharmD, President
California Board of Pharmacy
Attn: Carolyn Klein
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Re: California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

Dear Dr. Schell and Members of the California Board of Pharmacy:

I am writing to you on behalf of the members of Health Access California, a statewide coalition representing consumers, seniors, people with disabilities, religious, labor, and multi-lingual/multi-cultural groups. We urge the Board of Pharmacy to adopt draft regulations implementing SB 472, California Patient Medication Safety Act (Corbett, D-San Leandro).

SB 472, signed by Governor Schwarzenegger, requires the Board to promulgate regulations that require, on or before January 1, 2011, a **standardized, patient-centered, prescription drug label** on all prescription medication dispensed to patients in California. This landmark legislation requires that the regulation outline requirements for drug labeling that take into account consumers' needs, particularly those of seniors and people with little medical literacy and/or limited English proficiency.

Over the last year we believe the staff of the Board of Pharmacy has done an excellent job researching the issues at hand, holding public hearings, conducting surveys, and incorporating research results into the draft regulation. We note that SB 472 underwent four revisions in the Senate and two in the Assembly before being signed into law. These revisions were largely to accommodate objections raised by the industry.

We believe the most recent draft regulations on the Board's website represent a credible start to the implementation of this statute. We are particularly supportive of the following:

- Labels should be printed in 12-point font or larger.
- The Board should provide pharmacies with standard label language in at least the 14 threshold languages delineated for language assistance in California based on population size.

ANTHONY WRIGHT
Executive Director

ORGANIZATION LISTED
FOR IDENTIFICATION PURPOSES

- All patients with limited English proficiency should have the right to have their prescription drug instructions orally interpreted by a health professional working within his or her field of clinical expertise.

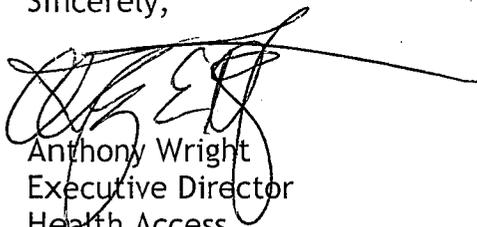
A few industry representatives testified at the Board's October public hearing regarding difficulties in implementing the proposed draft regulatory language. However, many pharmacists spoke in favor of the regulation and said that they were in large measure already adhering to key features of the law. We also listened to many consumers who offered compelling testimony regarding the necessity for swift implementation of this consumer protection law based on their inability to read the small print on the label or because of their low level English proficiency. Pharmacy board staff noted the Board's efforts to utilize external funding to support expanded translations of some of the most common phrasing used in prescription labeling. Therefore, we strongly believe that beginning the formal rule-making process is the appropriate venue to address any remaining concerns of the industry.

Consequently, we urge the Board to undertake the public review process as soon as possible. The prevalence of medical prescription errors and the lack of public comprehension of prescription labels provide a compelling and urgent rationale for this regulation. We urge strong action to implement what California's policymakers have determined is needed "to increase consumer protection and improve the health, safety, and well-being of consumers."

We believe that standardized, readable, language-accessible, prescription labels are a vital element in appropriate health care delivery. Without them we all risk injury, inappropriate care, or even death. We strongly believe these draft regulations should be adopted at the next Board meeting in January to begin this formal rulemaking process.

If you have any questions or need more information, please contact Elizabeth Abbott, Project Director at Health Access, at (916) 497-0923, ext. 201 or at eabbott@health-access.org.

Sincerely,



Anthony Wright
Executive Director
Health Access
1127 11th Street, Suite 234
Sacramento, CA 95814

cc: Senator Ellen Corbett, author
Senator Elaine Alquist (D-Santa Clara), Chair, Senate Health
Senator Denise Ducheny (D-San Diego), Chair, Senate Budget
Senator Negrete-McLeod (D-Chino), Chair, Senate Business, Professions, &
Economic Development
Assemblymember David Jones (D-Sacramento), Chair, Assembly Health
Assemblymember Noreen Evans (D-Santa Rosa), Chair, Assembly Budget
Assemblymember Mary Hayashi (D-Hayward), Chair, Assembly Business &
Professions
Fred Aguiar, Secretary, State and Consumer Services Agency



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January 4, 2010

RECEIVED BY CALIF. BOARD OF PHARMACY
2010 JAN -7 AM 11:41

Ms. Carolyn Klein
Manager, Legislation and Regulations
California State Board of Pharmacy
1625 N. Market Blvd., N219
Sacramento, CA 95834
Via email Carolyn_Klein@dca.ca.gov

RE: Patient-Centered Prescription Labels (16 Cal.Code Reg. §1707.5)

Dear Ms. Klein:

On behalf of the California Grocers Association (CGA), I write to provide comments in response to proposed regulations 16 Cal. Code Reg. §1707.5. These regulations are intended to specify how prescription drug information is to be placed on the prescription drug container label and clarify what interpretive services are required to be provided by pharmacies in compliance with Section 4076.6 of the Business and Professions Code.

CGA is a non-profit, statewide trade association representing the retail food industry since 1898. CGA represents approximately 500 retail members operating over 6,000 food stores in California and Nevada, and approximately 300 grocery supplier companies. Retail membership includes chain and independent supermarkets, convenience stores and mass merchandisers. Many of our member grocery companies operate full service pharmacies inside some or all of their stores.

While patient protection is the top priority of pharmacies, for our member companies to comply with these new regulations the requirements must be cost effective, feasible and practical for all pharmacy retailers. If requirements become too costly or unworkable, no patient benefit will be achieved. Unfortunately, the current regulatory draft does not meet intended objectives.

While pharmacies are aware of the potential for improvements in prescription medication labeling and counseling to improve health literacy and patient safety, physicians, pharmacists, and patients also have responsibilities in ensuring appropriate medication use. Specifically, patients have the responsibility to request information from their physicians, and if they need additional information, from their pharmacists. Although simplifying drug labels sounds like an easy task, more evidence is needed on how to make labels more comprehensible yet manageable.

The proposed regulations provide a list of items which must be clustered into one area of the label that comprises at least 50 percent of the label and requires each item be printed in at LEAST 12-point, Sans Serif typeface. The standard Rx label

is 2 inches tall and 3 1/8 inch long. This accommodates a 13 dram vial with 2 warning labels (may cause drowsiness, do not drive, etc.)

The 12-point font requirement limits the amount of space needed on a prescription bottle to effectively list all the directions or inclusions of the drug indication (purpose or condition). For example, increasing the font size will not only limit the necessary information from being placed on the bottle, it may prevent the patient's full name from being displayed. In order to comply, pharmacies would be required, as a minimum vial size to use a 20 dram vial. This means added cost and more plastic in the environment.

In addition to the labeling requirement, the proposed regulations state that a pharmacy shall provide an oral language translation of the prescription contents if requested by the patient. Although some pharmacies already provide this service to patients with limited English proficiency, not all are able to provide this service without economic impact. In addition, this regulation presents legal concerns for pharmacies that would be held liable if medication information was misinterpreted in translation----once again this service does not come without an economic impact to the pharmacies.

Although there has been some research conducted on how to improve labels, more analysis is needed to determine what changes can be made to fulfill the statutory requirements without causing such a significant impact on the pharmacies. Furthermore, there is no strong evidence to demonstrate that changing the label, as defined in the proposed regulations, will lead to better adherence, fewer adverse consequences, or better patient outcomes.

While we recognize solutions to this issue are not easily constructed, we would like to stress the need for additional collaboration with our Association in an effort to develop regulations that are cost effective, feasible and practical to implement. We would be happy to work with you to develop alternatives to achieve the mandates required by the statute.

If we can provide you with any additional information, please contact Kara Bush, Manager, Government Relations at 916.448.3545. Thank you.

Sincerely,



Kara Bush
Manager, Government Relations

January 4, 2010

**Board of
Directors**

Donn Ginoza, Chair
California Public
Employment
Relations Board

Carolyn Klein
California Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834
Via Fax (916) 574-8618

Byron Gross,
Vice-Chair
Hooper, Lundy &
Bookman

Re: 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Drug Labels

Lola FitzPatrick,
Treasurer
Consumer
Representative

Dear Ms. Klein:

Elisabeth Benjamin
Community Service
Society of New York

On behalf the National Health Law Program (NHeLP), we are submitting initial comments to the proposed regulations issued on November 20, 2009 and will be providing additional written comments and oral testimony at the Board of Pharmacy (Board) hearing scheduled for January 20, 2010. NHeLP is a national public interest legal organization seeking to improve health care for America's low-income population, including people of color, women, children, the elderly and people with special needs, including immigrants and limited-English proficient (LEP) individuals

Daniel Cody
Reed Smith, LLP

Jean Hemphill
Ballard Spahr
Andrews & Ingersoll

We are disappointed that the proposed regulations represent a retrenchment from the intent of SB 472 and the Board's initial proposed regulations shared with the public at the Board's July and October meetings. We have submitted comments, attended meetings, and presented testimony at several Board hearings during the last two years. We have also tried to assist the Board and have monitored the discussions and progress of the Board's research and findings. We believe that there has been ample testimony presented at the hearings that provided critical evidence about the needs of limited-English proficient (LEP) patients and clearly supported the need for translation of prescription drug labels.

Marilyn Holle
Protection &
Advocacy Inc.

Lucinda Horne
Consumer
Representative

Ninez Ponce
UCLA School of
Public Health

Janet Varon
Northwest Health
Law Advocates

As has been noted in prior comments, SB 472 requires the Board to take into account the needs of LEP patients. The current proposed regulation does not reflect this statutory requirement. As we have noted in prior comments and testimony, there are other federal and state requirements and guidelines to ensure linguistic access to LEP patients by pharmacists in various contexts. These include the following: 1) Title VI of the 1964 Civil Rights Act (see attached NHeLP Fact Sheet), 2) U.S. Department of Health and Human Services, Office for Civil Rights, *Guidance to Federal Financial Assistance*

Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (Aug. 8, 2000); 3) Executive Order 13166, 65 Fed. Reg. 50121 (Aug. 16, 2000); Office of Minority Health's *National Standards on Culturally and Linguistically Appropriate Services in Health Care*, 65 Fed. Reg. 80865 (Dec. 22, 2000), reprinted at: <http://www.omhrc.gov/clas>; 4) Cal. Govt. Code Section 11135 et al. and its implementing regulations, 22 Cal. Code Regs. Sections 98000 – 98413; 4) Cal. Govt. Code Section 7291 et al. (Dymally-Alatorre Act); 5) Cal Health & Safety Code Sections 1367, 1367.04 and 1367.07 and its implementing regulations, 28 Cal Code Regs. Sections 1300.67.04 & 1300.67.8; 6) Cal. Ins. Code Sections 10133.8 & 10133.9 and its implementing regulations, 10 Cal Code Regs. Sections 2538.1-2538.8; and 7) Medi-Cal and Healthy Families-related contract requirements. There are also specific regulations that require language access services: 1) for refills, the patient must be provided with written information, either on the prescription label or with the prescription container, which describes which pharmacy to contact if the patient has any questions about the prescription or medication (16 Cal. Code Regs. Section 1707.4(3)); and 2) if the patient is not in the pharmacy (including drugs shipped by mail), a pharmacy must ensure that the patient receives written notice of her right to request consultation, and a telephone number from which the patient may speak to a pharmacist (16 Cal. Code Regs. Section 1707.2(a)(2)). In order for an LEP patient to communicate with the pharmacist, he or she must have access to an interpreter or translated information.

In past comments, we have provided recommendations to strengthen access for LEP patients and seniors. We reiterate our support to expand the number of languages for the translation of standardized labels to match the Medi-Cal Managed Care threshold languages. While we continue to support section (a), including the requirement that the label be printed in 12-point, sans serif typeface, and (d), the provision of an oral language translation of the instructions, we advise the Board to adopt the following requirements, several of which were included in its originally proposed regulations: 1) to publish the translation of the directions in section (a)(4) sooner than October 2011, 2) when instructions for use specified by the prescriber do not conform to one of the items listed in subdivision (a)(4) the pharmacy shall secure its own translation, 3) for patients who cannot read or understand English but can read in another language, the pharmacy shall provide a prescription container labeled with the components specified in subdivision (a) in the language of patient, and 4) the pharmacy must offer oral interpretation of the label and/or provide an interpreter to any LEP patient and not rely on a specific request by the LEP patient.

We are also attaching some additional information regarding the need for language assistance services and some articles illustrating the existence of technology capable of performing translations into many languages, which is currently being done at many pharmacies across the country: 1) Rite Aid Now Offers Prescription Bottle Labels In 11 Different Languages (2005), http://www.riteaid.com/company/news/news_details.jsf?itemNumber=728; 2) Language problems at the pharmacy, Chattanooga Times Free Press, <http://www.timesfreepress.com/news/2009/apr/27/language-problems-pharmacy/>; 3) Giant Food Introduces Spanish Language Prescription Labels and Directions. (2007), <http://www.allbusiness.com/retail/retailers-food-beverage-stores-grocery-supermarkets/5330171-1.html>; 4) National Health Museum: Medical Misunderstandings, <http://www.accessexcellence.org/HHQ/qow/qow06/qow061204.php>, and 5) Language Barriers

Plague Almost Half of U.S. Drug Stores,
<http://health.usnews.com/usnews/health/healthday/070806/language-barriers-plague-almost-half-of-us-drug-stores.htm>. We hope that the Board finds the information useful.

We hope that the Board understands its key role in increasing access to pharmacy services for LEP patients and that the state continues to be a leader and model for other states to ensure that LEP residents have access to language assistance services, including translated labels on prescription drug containers. If you have any questions, please do not hesitate to contact Doreena Wong at wong@healthlaw.org or call (310) 204-6010, ext. 107.

Sincerely,

Doreena Wong
National Health Law Program

LANGUAGE SERVICES IN PHARMACIES: WHAT IS REQUIRED?¹

A 10-month old girl was taken to a pediatrician's office by her parents, who spoke no English. The infant was diagnosed with iron-deficiency anemia and prescribed an iron supplement. The parents took the prescription to a local pharmacy that did not provide language services, and the prescription label on the bottle was provided in English. The pharmacist attempted to demonstrate the proper dosing and administration. The prescribed dose was 15 mg per 0.6 ml (1.2 ml) daily. Fifteen minutes after the parents administered the medication to the infant, she appeared ill and vomited twice. She was taken to the emergency room where it was discovered that the parents had administered 15 ml (a 12.5-fold overdose).²

As this example illustrates, it is critical that pharmacists and limited English proficient (LEP) patients be able to communicate effectively. As complicated as it may be for English-speakers to understand medication instructions, the difficulties are exacerbated for LEP individuals. In a recent study, over one-quarter of LEP patients who needed, but did not get, an interpreter reported that they did not understand their medication instructions, compared with only two percent of those who either needed and received an interpreter or did not need an interpreter.³

Given that more than 4 billion prescriptions are written yearly and that 8.7% of Americans are LEP,⁴ millions of prescriptions are likely for LEP patients. This issue brief provides an overview of existing federal laws addressing the provision of language services in the pharmacy setting.

FEDERAL REQUIREMENTS

1. Is there a federal requirement for communication assistance (also called language services) to individuals who do not speak English well?

Yes. In 1964, Congress passed Title VI of the Civil Rights Act. This law prohibits discrimination and ensures that federal money is not used to support health care providers – including pharmacies and pharmacists – who discriminate on the basis of national origin.⁵ Title VI says:

No person in the United States shall, on ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.⁶

The U.S. Department of Health and Human Services (HHS) and the courts have applied Title VI to protect national origin minorities who do not speak English well. Thus, recipients of federal

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financial assistance (hereafter “federal funding”) must take reasonable steps to ensure that LEP individuals have meaningful access to their programs and services.⁷

2. Does Title VI cover pharmacies and pharmacists?

Yes. The obligations under Title VI (and HHS’ regulations and guidance implementing Title VI, see Q. 4-5, and 12 below) apply broadly to any “program or activity” that receives federal funding, either directly or indirectly (through a contract or subcontract, for example), and without regard to the amount of funds received.⁸ For independent and chain pharmacies and pharmacists, federal funding includes federal payments for prescription drugs (including dispensing fees or any other related payments) provided to Medicare, Medicaid and State Children’s Health Insurance Program (SCHIP) enrollees. It also applies to pharmacies providing prescription drugs to enrollees of federally-funded managed care plans (such as Medicaid managed care and Medicare Advantage plans) or Medicare Part D prescription drug plans.

Further, the Title VI protections extend to all of the operations of the organization or individual, not just that part that receives the federal funds.⁹ So once federal funds are accepted, language services must be provided to all pharmacy patients, not just those patients participating in federally funded programs. And if a pharmacy does not take federal funds but is located in a facility that does (such as a hospital or long term care facility), Title VI still applies.

3. Who is “limited English proficient?”

HHS defines individuals as “limited English proficient” if they do not speak English as their primary language and have a limited or no ability to read, write, speak, or understand English.

In determining language ability, the Census Bureau asks how well a person speaks English – the options are “very well,” “well,” “not well” or “not at all.” Due to the complex nature of health care interactions, it is generally accepted that a person who speaks English less than “very well” is likely LEP and will need language services. Nationally, over 24 million individuals speak English less than “very well.”¹⁰

4. How does a pharmacist know how to provide language services?

The federal Departments of Justice and Health and Human Services (HHS) have adopted four factors for assessing how to assist LEP persons. These factors call upon the federally funded pharmacy to determine:¹¹

- The number or proportion of LEP individuals served or encountered.¹²
- The frequency of contact with the program. If LEP individuals access the pharmacy on a daily or weekly basis, a recipient has greater duties than if contact is infrequent.
- The nature and importance of the program to beneficiaries. More steps must be taken if a denial or delay of services may have critical implications for daily life (e.g. medication errors that can result from a misunderstanding of prescription drug instructions).

- The resources available and cost considerations. If the number of LEP persons is limited, a small recipient with few resources may not have to take the same steps as a larger recipient. Costs are a legitimate consideration in identifying the reasonableness of particular language assistance measures.¹³

In balancing these factors, pharmacies and pharmacists should consider the appropriate mix of written and oral language assistance, considering which documents must be translated, when oral interpretation is needed, and whether such services should be immediately available.¹⁴

The HHS Office for Civil Rights (OCR) will apply these factors when determining whether an entity is compliance with Title VI. OCR recognizes that one size does not fit all and will determine compliance on a case-by-case basis.

5. Are there specific guidelines that explain how to provide language services?

Yes. On August 8, 2003, HHS' OCR issued guidance for federal fund recipients, including pharmacies and pharmacists participating in HHS-funded programs.¹⁵ The guidance is available at <http://www.hhs.gov/ocr/lep/>. This guidance does not impose any new requirements but merely brings together all of OCR's policies for overseeing Title VI since 1965.

6. How should a pharmacy offer oral language services?

The HHS Guidance describes various options to provide oral language assistance, including the use of bilingual staff, staff interpreters, contracting for interpreters, using telephone interpreter lines,¹⁶ and using community volunteers. It stresses that interpreters need to be competent, though not necessarily formally certified. A combination of oral language assistance may work best. For example, bilingual pharmacists could provide services directly in some non-English languages while other bilingual staff (including pharmacy or non-pharmacy in-store staff) may be competent to interpret between pharmacists and patients. A telephone language line can offer coverage when existing staff are unavailable. In general, all interpreters – whether staff or contract – must abide by the HIPAA (Health Insurance Portability and Accountability Act) privacy rules (see Q. 7 below).¹⁷

The HHS Guidance allows the use of a person's family members and friends to interpret but clearly states that an LEP person may not be *required* to use a family member or friend and that "extra caution" should be taken if an LEP person chooses to use a minor to interpret. Similarly, an LEP person may not be required to use unrelated individuals, such as other customers, to interpret. These untrained interpreters are often called "ad hoc" interpreters. Pharmacists should verify and monitor their competence and appropriateness of ad hoc interpreters, including the person's language and comprehension skills and awareness of confidentiality and HIPAA issues.

The HHS Guidance notes that particular care must be paid in situations involving health, safety or access to important benefits, or when credibility and accuracy are important to protect the individual – all directly relevant to pharmacy interactions. Moreover, OCR says recipients should make the LEP person aware that he or she has the "option" of having the pharmacy provide an interpreter without charge.

Patient counseling, which may be required under state pharmacy laws, is an area where

National Health Law Program, 2008.

the Guidance's emphasis on health and safety is highly relevant. Without being able to communicate with LEP patients, a pharmacist may be unable to provide information about correct dosing, drug interactions, and potential side effects. In addition to potential liability under state law, a pharmacy or pharmacist may be liable for malpractice or negligence if a patient suffers adverse harm because required information is not provided in a manner the patient understands.

The HHS Guidance's concern with access to important benefits is also implicated. For example, if a prescription coverage request is denied because the insurer refuses to cover it, the pharmacist should be able to explain the rejection codes or translate information provided about the denial. If the patient does not understand the basis for the denial, he may not understand his ability to appeal and thus is denied access to important benefits.

7. How does HIPAA impact pharmacies use of interpreters?

HIPAA protects individuals from the release of their private (or protected) health information. Generally, those working in a pharmacy setting may not disclose a patient's protected health information except in limited circumstances and to certain entities, as defined by law. If the pharmacy discloses the information to outside sources (for example, if it uses a language agency to provide interpreters), it should have a "business associate" agreement to ensure that the outside organization also protects the patient's health information.

The HIPAA privacy rule allows others to have access to a patient's health information *with the patient's consent*. To these persons approved by the patient, the pharmacy may disclose protected health information directly relevant to the patient's care or payment if the pharmacy:

- obtains the individual's agreement; *or*
- provides the individual with the opportunity to object to the disclosure and the individual does not express an objection; *or*
- reasonably infers from the circumstances, based on the exercise of professional judgment that the individual does not object to the disclosure. (For example, when a person comes to a pharmacy to pick up a prescription on behalf of an individual he identifies by name, a pharmacist, based on professional judgment and experience with common practice, the pharmacist may allow the person to do so.¹⁸)

Under any of these circumstances, if a patient consents, a family member or friend brought by the patient to the pharmacy would be allowed to interpret and have access to a patient's protected health information. This could also include, *but only if the patient consents*, an *ad hoc* interpreter such as another patient or pharmacy customer. Because in this situation the patient has consented *and* the interpreter is neither a member of the covered entity's workforce nor a business associate, the interpreter is not bound by the privacy rule.

Before a pharmacy relies on an *ad hoc* interpreter, the pharmacy should ensure that the patient is informed of the need to provide consent; without informed consent, the pharmacy may be liable for a HIPAA violation.¹⁹ The patient may ask the covered entity to provide an interpreter who would be subject to the protections of the HIPAA privacy rule.

WRITTEN TRANSLATED MATERIALS

8. When should a pharmacist translate written materials?

It depends on the relevant circumstances of each pharmacy based on the four factors listed above (see Q. 4). After these have been assessed, pharmacies and pharmacists should decide what reasonable steps to take to ensure meaningful access. At a minimum, the pharmacist should translate dosage instructions and warning labels to ensure that a patient fully understands the instructions for usage. Many pharmacy software programs have translation capacity built in; pharmacies and pharmacists should check with their vendors about availability.

Nothing in federal or state law prohibits the translation of prescription drug labels, instructions or inserts. While federal law requires certain information to be on the label in English,²⁰ it takes a permissive approach and allows, but does not require, the inclusion of other languages on the prescription drug label.²¹ Posted information or handouts about patients' rights, such as the right to seek a written explanation or to appeal a denial in Medicaid or the Medicare Part D program, are also items where the importance of translated materials should be considered.

As noted, OCR will evaluate a provider's efforts on a case-by-case basis. For the translation of written materials, the HHS Guidance designates "safe harbors" that, if met, will provide strong evidence of compliance.²²

STATE REQUIREMENTS

9. In addition to federal law, do state laws require pharmacies to provide oral language services?

It depends on the state. All states have enacted laws that address the provision of language services in healthcare settings and some of these apply to pharmacies.²³ In the coming months, the National Health Law Program will be conducting a 50-state survey of pharmacy laws related to language access and will provide results when available. As one example, New York pharmacy regulations include a counseling requirement when pharmacists dispense prescriptions to new pharmacy patients or dispense new medications to current patients.²⁴ The regulations do not include an exemption for LEP patients. Thus, a pharmacist will be unable to comply with the counseling requirement if language services are not provided. The pharmacist should ensure that effective communication occurs, either by using an interpreter or translating drug information handouts (however, it is unlikely that providing translated documents alone would satisfy the counseling requirement because it implies oral communication).

10. What about pharmacies located in hospitals, nursing homes, or other health care settings?

For co-located pharmacies, Title VI may independently apply to both the pharmacy and host facility since both are likely recipients of federal funds. Even if the host facility does not receive federal funds, the pharmacy would still be subject to Title VI if it does. Further, additional state laws may require language access in the host facility.²⁵ For example, Massachusetts, Rhode Island and New York require hospitals to provide language services. A pharmacy located in a hospital would be subject to these laws.

The pharmacy should obtain information about the facility's policies and whether pharmacy staff can access the facility's interpreters and translated materials.²⁶

ADDITIONAL INFORMATION

11. Is a pharmacy liable if it does not provide language services to LEP patients?

Yes, it is potentially liable under both federal and state law. Under federal law, OCR investigates complaints against pharmacies and first has an obligation to seek compliance from those who fail to abide by Title VI. OCR is also available to provide ongoing technical assistance. If compliance is not obtained voluntarily, OCR may refer the issue to the Department of Justice for formal compliance proceedings that could result in suspension or termination of federal assistance.²⁷

If a patient suffers medical harm caused by the pharmacist, the patient could initiate a malpractice or negligence claim against the pharmacy or pharmacist. And if the HIPAA privacy rules are violated, a pharmacy may be liable for fines of \$100 per violation, up to \$25,000 per year.

Depending on state law, additional liability may apply. For example, under New York law, the failure to abide by the requirements for labeling and counseling could result in a pharmacist facing misdemeanor charges with fines and possible jail time for multiple violations.²⁸

12. What if a pharmacist unintentionally discriminates against individuals?

HHS' regulations prohibit federal fund recipients from:

- Using criteria or methods of administration that have the *effect* of discriminating against LEP patients;
- Restricting access to advantages or privileges for LEP patients that non-LEP patients receive from the same program;
- Providing services or benefits to LEP patients that are different, or provided in a different way, from those provided to non-LEP patients (NOTE: a translated document should not be considered "different" since the content is the same as the English document while being presented in a non-English language);
- Treating LEP patients differently from non-LEP patients in determining admission, enrollment, eligibility, or other requirements to receive services.²⁹

13. How can pharmacies document their language services?

Pharmacies and pharmacists can develop a written implementation plan as a means of documenting compliance with Title VI. The Office for Civil Rights suggests five elements when designing a plan:

- Identify LEP individuals who need language assistance, using for example, language identification cards or recording patient language needs in the pharmacy's computer system.
- Describe language assistance measures, such as the types of language services available, how staff can obtain these services and respond to LEP persons, and how competency of language services can be ensured.
- Train staff, including pharmacists, pharmacy interns, and cashiers, to understand LEP policies and procedures and how to work effectively with LEP patients and interpreters (both in-person and telephonic).
- Provide notice of language services by, for example, posting signs in intake areas and other entry points, providing information in outreach brochures, working with community groups, using a telephone voice mail menu, providing notices in local non-English media sources, and making presentations in community settings.
- Monitor and update the LEP plan, considering changes in demographics, types of services, and other factors.³⁰

14. How can pharmacies pay for language services?

HHS' Centers for Medicare & Medicaid Services (CMS) recognizes that federal Medicaid and SCHIP funds can be used for language activities and services.³¹ States can thus submit the costs of language services needed by Medicaid and SCHIP enrollees to the federal government for partial reimbursement.

Currently, twelve states plus the District of Columbia directly pay for language services in Medicaid and SCHIP. Some states have limited the reimbursement to "fee-for-service" providers so providers participating in managed care plans might not be eligible. Other states report that they currently set their reimbursement rates for all providers to include the costs of language services as part of the entity's overhead or administrative costs.³²

15. Where can pharmacies and pharmacists get more information?

The federal government has launched a website called "Let Everyone Participate," <http://www.lep.gov>. In addition to tracking federal activities, the website offers direct assistance to federal fund recipients and advocates. For example, fund recipients can download "I Speak" cards that allow LEP persons to identify their primary language. The presidential "Executive Order" (EO) entitled *Improving Access to Services for Persons with Limited English Proficiency*,³³ and OCR Guidance are also available on this website.

The "CLAS Standards" (Standards for Culturally and Linguistically Appropriate Services in health care) from the HHS Office of Minority Health, offer additional information and resources.³⁴

¹ This issue brief was made possible with the generous support of the California Endowment, the New York Academy of Medicine and the Altman Foundation.
National Health Law Program, 2008.

² Agency for Healthcare Research and Quality, *Language Barrier: The Case, Pediatrics* (2006), at <http://www.webmm.ahrq.gov/>.

³ D. Andrulis, N. Goodman, C. Pryor, *What a difference an Interpreter Can Make* (April 2002), at <http://www.accessproject.org>.

⁴ LEP is defined as individuals who are unable to speak English "very well". See U.S. Census Bureau, "Language Spoken at Home" (Table S1601), 2006 American Community Survey, at www.factfinder.census.gov.

⁵ 100 Cong. Rec. 1658 (1964). The United States Supreme Court has treated discrimination based on language as national origin discrimination. See *Lau v. Nichols*, 414 U.S. 563 (1974). "National origin" is not defined in federal law but generally refers to the country where one is born. The U.S. Supreme Court and federal agencies have determined that language can be a proxy for national origin.

⁶ 42 U.S.C. § 2000d. See also 45 C.F.R. § 80 app. A (listing examples of federal financial assistance, including Medicare, Medicaid, Maternal and Child Health grants).

⁷ While some states or localities have declared English as their official language, federal fund recipients must continue to follow federal laws regarding non-discrimination. See, e.g., 42 C.F.R. §§ 438.6(f), 438.100(d).

⁸ See 42 U.S.C. § 2000d-4a (defining "program or activity").

⁹ *Id.*

¹⁰ 2006 American Community Survey, (Tables S1601, B16001), at <http://www.factfinder.census.gov>.

¹¹ See 65 Fed. Reg. 50123 (Aug. 16, 2000). In addition to Executive Order 13166, this Guidance is authorized by 28 C.F.R. § 42.404(a), directing agencies to "publish title VI guidelines for each type of program to which they extend financial assistance, where such guidelines would be appropriate to provide detailed information on the requirements of Title VI." According to the Department of Justice, the Guidance does not create new obligations beyond those already mandated by law.

¹² See 67 Fed. Reg. 41459 (June 18, 2002). "But even recipients that serve LEP persons on an unpredictable or infrequent basis should use this balancing analysis to determine what to do if an LEP individual seeks services under the program in question." *Id.* at 41460.

¹³ *Id.* at 50124-25. See also, e.g., 67 Fed. Reg. 41455, 41457 (June 18, 2002).

¹⁴ See 67 Fed. Reg. 41460 (June 18, 2002).

¹⁵ 68 Fed. Reg. 47311 (Aug. 8, 2003). For previous versions of this guidance, see 65 Fed. Reg. 52762 (Aug. 30, 2000).

¹⁶ Previous guidance cautioned the fund recipient that telephone interpreter lines should not be the sole language assistance option, unless other options were unavailable. See 67 Fed. Reg. at 4975.

¹⁷ For more information on the use of interpreters and HIPAA, see *HIPAA and Language Services in Health Care*, National Health Law Program, at <http://www.healthlaw.org>.

¹⁸ HIPAA Frequently Asked Questions, Notice and Other Individual Rights, *Does the HIPAA Privacy Rule permit a doctor to discuss a patient's health status, treatment, or payment arrangements with the patient's family and friends?* at <http://www.hhs.gov/hipaafaq/notice/488.html>.

¹⁹ See footnote 17.

²⁰ This information includes the date of filling; pharmacy name and address; serial number of the prescription; name of the patient; name of the prescribing practitioner; and directions for use and cautionary statements, if any contained in such prescription or required by law. 21 C.F.R. § 1306.14(a) and § 1306.24.

²¹ 21 C.F.R. § 201.15.

²² The safe harbors designate that the recipient provides written translations of "vital" documents (e.g. intake forms with the potential for important consequences, consent and complaint forms, eligibility and service notices) for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally. Or, if there are fewer than 50 persons in a language group that reaches the five percent trigger, above, the recipient provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of vital written materials, free of cost. 68 Fed. Reg. at 47319.

²³ See J. Perkins and M. Youdelman, "Summary of State Law Requirements Addressing Language Needs in Health Care," National Health Law Program (March 2007), at http://www.healthlaw.org/library/item.174993-Summary_of_State_Law_Requirements_Address_Language_Needs_in_Health_Care.

²⁴ N.Y. Comp. Codes R. & Regs tit. 8, § 63.6(b)(8). Counseling can include, but is not limited to: (1) the name and description of the medication and known indications; (2) dosage form, dosage, route of administration and duration

of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose.

Counseling requirements are also required, but adapted to the specific situations of in-pharmacy delivery to the patient, dispensing to a person authorized to act on behalf of a patient, and mail delivery of prescription drugs.

²⁵ For more information on state laws related to language access and health care, see J. Perkins and M. Youdelman, "Summary of State Law Requirements Addressing Language Needs in Health Care," National Health Law Program (March 2007), at <http://www.healthlaw.org/library/item.174993->

[Summary of State Law Requirements Addressing Language Needs in Health Care](http://www.healthlaw.org/library/item.174993-Summary_of_State_Law_Requirements_Addressing_Language_Needs_in_Health_Care) .

²⁶ N.Y. Comp. Codes R. & Regs. tit. 10, § 405.7(a)(7).

²⁷ 45 C.F.R. § 80.8.

²⁸ NY CLS Educ § 6816 (1)(a). A second conviction for violation of § 6816 ("untrue labels" violation) can result in the pharmacist being fined a maximum of \$1,000 fine and/or a maximum of one year in prison. A third conviction can result in the above fines and/or jail time in addition to the individual pharmacist's license revocation.

²⁹ 45 C.F.R. § 80.3(b).

³⁰ 68 Fed. Reg. at 47319-21. Previous guidance called on recipients to develop and implement a language assistance program that addressed: (1) assessment of language needs; (2) development of a comprehensive policy on language access; (3) training of staff; and (4) vigilant monitoring. See 67 Fed. Reg. at 4971.

³¹ See CMS, *Dear State Medicaid Director* (Aug. 31, 2000), available at <http://www.cms.hhs.gov/states/letters/smd83100.asp>.

³² Of the 13 states currently using Medicaid/SCHIP funds to pay for language services, none are doing so in the pharmacy setting. However, there is no prohibition on this. For more information on this issue, see M. Youdelman, *Medicaid and SCHIP Reimbursement Models for Language Services, 2007 Update*, at <http://www.healthlaw.org>.

³³ See 65 Fed. Reg. 50121 (Aug. 16, 2000); see also 67 Fed. Reg. 41455 (June 18, 2002).

³⁴ See 65 Fed. Reg. 80865 (Dec. 22, 2000), at <http://www.omhrc.gov/clas>.



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES



californiapharmacistsassociation

January 4, 2010

Via email Carolyn_Klein@dca.ca.gov

Carolyn Klein
1625 N Market Blvd, N219
Sacramento, CA 95834

RE: Proposed Title 16 CCR Section 1707.5 Delivery of Prescriptions

Dear Ms. Klein:

On behalf of its members operating retail pharmacies in the State of California, the National Association of Chain Drug Stores (NACDS), the California Pharmacists Association, (CPhA), and the California Retailers Association (CRA) are writing to provide comments regarding proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations, Patient Centered-Labels on Medication containers. We thank the Board of Pharmacy ("Board") for the opportunity to submit comments on the proposed rule. We also appreciate the work of the Board in holding meetings during the development of this proposed rule. Chain and independent retail community pharmacies have worked very hard and spent significant resources to ensure that prescription labels clearly provide patients with information necessary to ensure the safe and proper use of prescription medications. We believe that we have made great strides in this area. Nonetheless, we look forward to continuing to work with the Board to find a reasonable approach for patient-centered labels for prescription medication containers.

However, as currently written, chain and independent pharmacies have numerous concerns with the proposed rule. There are other reasonable alternatives that would be equally effective for patient centered labels and less burdensome for pharmacies than this proposal. Indeed, we are concerned that the proposed regulatory requirements may hinder the use of the innovative prescription labeling for which the Board has indicated a preference.

The notice requires that the Board "must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to it's attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected private persons than the proposal described in the Notice." Furthermore, the Board is only required to "consider" specified changes to prescription labels. The Board is not required to adopt all of the label changes currently outlined in the proposed regulation. Accordingly, we ask that the Board consider the information provided in these comments and that the Board take a less burdensome approach that would be as effective for a patient centered label. Specifically, we ask that the Board:

- Only require size 10 typeface for the patient name, prescription number, and drug name.
- Not mandate the specific directions as they are unnecessarily lengthy and repetitive and allow pharmacists to use their professional judgment if such directions are needed.
- Not mandate that certain items occupy 50% of the label

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Carolyn Klein

Sacramento, CA 95834

January 4, 2010

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- Allow pharmacies the flexibility to use different means to highlight information
- Allow pharmacies to provide patients with prescription container information through other means such as a separate sheet in a larger font.

The research conducted by the Board is inadequate to support the proposed label changes

The Board conducted significant outreach during 2008 in hopes of obtaining significant public input into the revisions of pharmacy labels. During that time period the Board received only 606 public responses. With over 30 million consumers in the State of California, dictating these label changes based on the responses of 606 consumers seems to us to be unreasonable. This conclusion is reinforced by the preliminary results of an ongoing consumer survey conducted by Western University (which has been provided to the Board) which indicates that over 75% of consumers are able to understand current prescription labels. NACDS, CPhA and CRA agree that some revision of pharmacy labels may improve patient care, but we urge the Board to consider all the research – and the weight that research should be given – in developing this regulation.

Finally, the Board should carefully consider the comments of one of the experts it consulted in this effort. In the minutes of a meeting held in Los Angeles on November 20, 2008, Michael S Wolfe, PHD, MPH is credited with stating:

“ . . . that he hopes the board does not get “bogged down” with details. He reiterated the fact that the rest of the country is watching California and looking to our state for direction. He pointed out that decisions will need to be made that best represent the majority of the public, and that it is not feasible to accommodate all requests given. He noted that too much detail can also create distraction, which causes more harm than good.”

The underlying legislation does not require many of the requirements in the proposed regulation

SB472 added CA B&P Code section 4076.5, which requires regulations to require a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Subsection (c) of the statute details several factors the board “shall consider” in developing the regulatory requirements. The statute does not *require* that those factors be addressed in the regulation, only that they be *considered*. In fact, two of the factors, “directions for use” and “font types and sizes,” both of which are key components of the proposed regulation, include specific language in the statute that they “improve” current practices. As noted below, we have serious concerns about the use of the standardized directions for use proposed in the regulation. We likewise have concerns about whether use of a standard font type is justified in light of the cost associated with that change. Further, as noted below, we do not believe that other components in the proposed regulation will result in an improvement of patient understanding of their medications and their use.

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January 4, 2010

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While the Board is required to consider many factors in developing this regulation, you are not required to incorporate any or all of them. What factors are included in the final regulation, and what weight each should be given, should be a function of what will truly improve prescription labels and patient understanding of their medications. In addition, the regulation should avoid the "too much detail" identified by Dr. Wolf in order to avoid more harm than good.

Pharmacies face burdensome costs to implement the requirements

The requirements in the proposed rule will be extremely burdensome for pharmacies to implement. In accord with the implementing statute, we ask that the Board consider the large number of technology changes that pharmacies would face. Pharmacies will need to make extensive changes to their software and hardware systems resulting in overwhelming costs for pharmacies. Pharmacy costs are expected to be in the millions of dollars due to the need for computer changes, new printers, new larger labels, and switching all prescriptions to much larger prescription vials to accommodate the larger labels. The result will be large prescription container labels that must be placed on large vials which consumers will find unworkable. Many if not most pharmacies now use automated systems for prescription dispensing, use centralized filling services, and also fill prescriptions for patients in other states with their own different labeling requirements. Imposing California's specific requirements in such a diverse environment will result in pharmacies incurring extensive costs to comply with both California and the other states' requirements. Pharmacies cannot easily switch their systems and prescription labeling back and forth from one state to another, nor can they afford the costs of implementing a California labeling system and another for other states.

Chain pharmacies have estimated that many prescriptions currently dispensed in much smaller vials will have to be dispensed in much larger vials - possibly up to 40 dram vials - to accommodate the larger labels and that they will not be able to use the drug manufacturer unit of use containers that are helpful for patients. Moreover, patients will likely be dissatisfied with the vials that are several times larger than what they are used to. Patients may easily decide to take their medications out of the larger vials and put them in smaller vials that are unlabeled to avoid the larger vials.

In addition, the increased size of prescription container vials that would be required due to the use of much larger labels will result in shipping, storage, and handling problems. More shipments will be needed to ship the much larger vials, with increased costs for pharmacies from the increased number of shipments and trucking miles and resulting increased carbon emissions.

The requirements for a specific type size, use of 50% of the label space, and the specified directions language are unreasonable due to limited label space.

The requirement for pharmacies to use 12 point sans serif for the specified four items and to use 50% of the label for these items is burdensome and unworkable in view of the other information that must be on the label and the limited label space. Business & Professions Code § 4076 also requires that the label include the prescriber's name, date, name and address of the pharmacy, prescription number, quantity, expiration date of the drug's effectiveness, and the physical description of the medication including its color, shape, and any identification code. In addition,

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January 4, 2010

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the purpose for the prescription must be placed on the prescription if requested on the prescription. Pharmacies also put other information that patients want on the label such as the number of refills remaining and the deadline date for using the remaining refills. All of this information must be on the label. Accordingly, mandating that only 50% of the remaining label be set aside for all of these other items is not feasible and would likely make the information too small creating other problems and patient complaints. Patients are unlikely to want the huge vials which would be necessary to accommodate the label that would result from this regulation.

There are other reasonable alternatives for these mandates that would be equally effective and less burdensome for pharmacies. Size 10 typeface could be used for the patient name, prescription number, and drug name. Pharmacies could provide patients with a separate sheet in a larger font with the prescription information along with the labeled prescription container.

The text for the specific directions should not be mandated as they are unnecessarily lengthy and repetitive. Pharmacists should be permitted to use their professional judgment to determine if such directions are needed for the patient. In addition, there should not be a mandate that certain items occupy 50% of the label. Pharmacists should have the professional flexibility to use different means to highlight the information such as bolding or highlighting with a different color.

Language Translations

For limited English proficiency patients, pharmacies can provide translation services through language assistance services. This will assist patients who need such services.

For written translation services, pharmacies are limited by the technology available. As discussed above, we ask that the Board take into consideration the technological issues. Pharmacies have the ability to translate into some other languages. However, the only languages available for drug information translation today are French and Spanish. The ability to translate consumer medicine information and MedGuides into other languages is limited. Such services are generally not available, printers lack the capability, and written translations are not available on demand.

Other recommendations

We have several suggestions for additional content the Board should consider in order to achieve its goal of improving consumer understanding of their medications:

- Subsection (b) of 4076.5 requires the Board to hold public meetings to “ensure maximum public comment.” There is nothing in the statute that restricts that effort to a specific time period. We believe the Board should make a commitment as part of this regulation to continued public outreach regarding prescription labels and to use that outreach to enhance public understanding of their medications. A prescription label with improved design and appearance is of little use to a consumer who doesn’t understand his or her medication. While pharmacies and pharmacists play a key role in improving consumer understanding, there is a corresponding responsibility on consumers to ask questions and seek information when they do not understand how or why to use dangerous drugs. The Board, as a consumer

Via email Carolyn_Klein@dca.ca.gov

Carolyn Klein

Sacramento, CA 95834

January 4, 2010

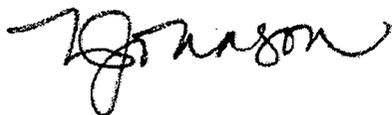
Page 5 of 5

protection agency, should commit to an effort to improve patient literacy in this area. This regulation is a perfect vehicle for such a commitment by the Board.

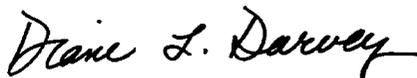
- For several years now the organizations represented here and the Board have been pursued efforts to improve medication safety and medication use. That goal should be seen as the primary focus of this regulatory effort. To enhance that effort, the Board should include language in the regulation that excludes violations of this section from its Citation and Fine program without first giving the pharmacy and involved pharmacists the opportunity to correct any violations. By doing so, the Board will emphasize its focus on meeting the needs of consumers rather than enforcing technical violations of the law and it will avoid any perception by those it regulates that any new label requirements are merely another unfunded mandate intended to victimize licensees who have difficulty meeting the new requirements.

Chain and independent pharmacies wish to continue to work to improve patient safety and patient compliance when taking their prescription medications. However, we wish to accomplish this objective in a manner that does not create new problems and is not unreasonably burdensome. In view of the huge cost impact on pharmacies and reasonable alternatives, we ask that the proposed regulation be amended and look forward to continued work with the Board. We thank you for consideration of our comments. Please do not hesitate to contact us with any questions.

Sincerely,



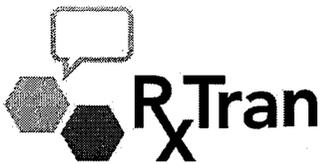
Missy Johnson
CRA



Diane L. Darvey, Pharm.D., JD
NACDS



Lynn Rolston
CPhA



A RIC International Company

Carolyn Klein
California State Board of Pharmacy
Carolyn_Klein@dca.ca.gov

January 4, 2010

Dear Ms. Klein,

These comments are submitted to the California State Board of Pharmacy pursuant to the Board's invitation to comment on the proposed Patient-Centered Prescription Label Regulations (proposed Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations) and in connection with the hearing on said matter to take place on January 20, 2010. In particular, these comments pertain to paragraph 1705.5.b of the proposed regulations concerning the translation of Directions for Use (SIGs) into several languages other than English.

1. There are several private companies in the U.S. that directly (over 1,800 U.S. translation agencies indirectly) offer the service of providing on-demand translated Directions for Use (SIGs) in over a dozen languages. RxTran (see www.rxtran.com/translation-of-patient-instructions.html) is one of them, and, in the interest of fairness, Polyglot Systems (see www.pgsl.com/Products/Meducation.aspx) is another.

RxTran's prices are quite affordable even for small independent pharmacies: they can be as low as \$50 per month for the equivalent translation of hundreds of thousands of SIGs per month via our online catalog into any 11 languages. This cost is less than that of a typical cell phone or cable bill for a pharmacy. Therefore we are not certain why the Board feels it needs to provide some of these translations for free on its website as opposed to involving private sector vendors. Our concern is that the published translations will be available not only to California pharmacies but to all our potential customers across the world.

At the very least, we would hope that if the Board goes ahead with providing some translations for free to the California pharmacies, it would publish along with the translations the list of private sector vendors who offer to provide on-demand catalog translations of hundreds of thousands of SIGs into a wide variety of languages at reasonable cost.

2. Regardless of point 1 above, if the Board decides to implement the proposed Rule as published, we will be happy to provide the Board with the translation of the Instructions for Use listed in 1705.5.a.4 into any 5 languages the Board chooses free of charge as a public service.

I invite any interested Board member to contact me for more information.

Sincerely yours,

Brian Kratt
Chief Executive Officer
www.RxTran.com (a division of RIC International)
617-621-0940 x. 130
bkratt@ricintl.com

Pharmacy Language Solutions



Darlene March
<darlenemarch@ymail.com>
12/09/2009 10:18 AM

To carolyn_klein@dca.ca.gov
cc
bcc
Subject Fw: Support Translated Prescription Drug Labels

Ms. Klein, please help in support of the below subject.

Respectfully,
Darlene March

Subject: Support Translated Prescription Drug Labels

- Prescription drug labels translated into the patient's language are vital for quality care.
- The Board should provide pharmacies with standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. The cost for these translations is minimal with a large health payoff.
- For non-standardized labels and other languages, individual pharmacies must be responsible for providing translated labels.
- All patients who do not speak English well must have the right to have their prescription drug instructions orally interpreted.
- We strongly support the provision that labels must be printed in 12-point font or larger.

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94612

Phone: (510) 832-1160 / Fax: (510) 832-1175 / info@cpehn.org



Luis Miguel
<luis@avantpage.com>
12/08/2009 09:05 PM

To <Carolyn_Klein@dca.ca.gov>
cc
bcc
Subject | Support Translated Prescription Drug Labels

Dear Carolyn

Prescription drug labels translated into the patient's language are vital for quality care.

The Board should provide pharmacies with standard labels translated into at least the 14 languages spoken by groups of 10,000 or more limited-English speakers in California. The cost for these translations is minimal with a large health payoff.

For non-standardized labels and other languages, individual pharmacies must be responsible for providing translated labels.

All patients who do not speak English well must have the right to have their prescription drug instructions orally interpreted.

We strongly support the provision that labels must be printed in 12-point font or larger.

Sincerely,
/luis

--

Luis Miguel, PhD | CEO | luis@avantpage.com
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American Foundation for the Blind

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Access to Drug Labels Survey Report

Summary: The Access to Drug Labels Survey explored the personal stories of people who had trouble reading prescription or over-the-counter medication information. Approximately 100 individuals completed the online survey and, in nearly every instance, respondents explained serious negative consequences of unreadable drug labeling information including illness, emergency room visits, hospitalization, additional expense, and increased anxiety.

Introduction

According to the 2006 National Health Interview Survey (NHIS)¹, approximately 21.2 million Americans reported that they have difficulty seeing, even when wearing eyeglasses or contact lenses, or that they are blind or unable to see at all. For many of these more than 20 million Americans with vision loss, reading drug container labels, such as those on prescription medications, and package inserts about the medication is difficult, or even impossible. Given that the incidence of vision loss is expected to continue to dramatically increase, this poses a significant public health challenge.

The American Foundation for the Blind (AFB) has launched Rx Label Enable, a campaign to improve access to drug labeling information for people with vision loss. The campaign aims to ensure that people with vision loss have access to the vital information available to all consumers via prescription labeling and related documentation, enabling them to take medications safely, effectively, and independently. To achieve this goal, AFB is reaching out to consumers experiencing vision loss, policymakers, federal regulators, doctors, the pharmaceutical industry, retailers, assistive technology providers, and public and private insurers to promote solutions, build consensus and take action. The Access to Drug Labels Survey was one component of the Rx Label Enable campaign.

Methodology

The Access to Drug Labels Survey explored the personal stories of people who had trouble reading prescription or over-the-counter medication information. Respondents voluntarily completed the online questionnaire. This informal online questionnaire consisted of four open ended questions that asked about the extent of vision loss, descriptions of why drug labeling information was unreadable, negative consequences of the unreadable drug information, and strategies or techniques that were used to properly identify and take medications.

Results

Approximately 100 individuals completed the Access to Drug Labels Survey. Respondents included people of all ages with vision loss, people with all degrees of vision loss, people who have vision loss and may have additional disabilities, and family members of people with vision loss as well as professionals with substantial experience and expertise in this area of vision rehabilitation. Data indicated that the inability to access necessary instructions supplied with prescription and over-the-counter medications often resulted in people with vision loss not taking a proper dose of necessary medication.

People with vision loss frequently reported that they have mistakenly taken expired medications or incorrect doses of medication because they were unable to see the expiration dates or dosage information. People with vision loss also reported that they have taken incorrect medication because they were unable to visually tell the difference between medicine containers. In some instances, people with vision loss explained that they were victims of pharmacy errors due to the fact that they could not read the prescription numbers to verify they were given the correct medicine. In other instances, people with vision loss were unable to read the refill instructions. They did not know it was necessary to refill their prescriptions nor did they know the drug number necessary to refill. Nearly every one of the approximately 100 respondents explained that they were dependent either on trusted sighted companions or complete strangers to convey necessary drug information.

Respondents consistently reported serious negative consequences of the unreadable drug labeling information including illness, emergency room or hospital visits, additional expense, and increased anxiety. Many of the personal stories respondents shared are provided to further emphasize the critical situation.

- **Inability to detect pharmacy errors involving an infant**
A husband and wife who are both legally blind shared their story. They are parents of an infant. They are unable to read drug labeling information because it is not available in braille. They must manage several prescriptions. They have been given the wrong medication by a pharmacy and told the medication was the prescription they had intended. The only reason they figured this out was because they had the medication on a previous occasion and the packaging was so different that they asked a sighted neighbor who happened to be visiting. The mistake made by the pharmacy could have been lethal. Because they could not read the label, they had no way to ensure they were provided the correct medication.
- **Dependence on complete strangers to convey necessary drug information for two young children**
A mother of two young children explained her story. This woman is totally blind. Reading prescription labels has always been a problem. There are no braille instructions. Doctors often forget to mention necessary drug information that is provided in the drug labels. She is unable to double check that the pharmacist gave her the correct bottle of medication. There are no after hours number that she can telephone for verbal instructions. To properly identify medications, she has been forced to seek out sighted assistance. She tries to memorize instructions verbally explained by sighted people. Sometimes she has had to ask strangers for sighted assistance. She does not know if she can always trust complete strangers with medicine information. This makes her feel like her family's privacy is being invaded.
- **Total lack of access**
A respondent who has very little functional sight explained that he is on several prescriptions due to other medical conditions. He is the only person in his household. He is unable to read print. The pharmacy does not provide braille. He can call the pharmacy to ask for directions, but that only works if he knows exactly which bottle he is holding. He relies on the size, shape, and texture of the pills or bottles to properly identify and take medications. At times he has taken the wrong medication. Other times he has taken the incorrect dosage.

- Taking the incorrect medicine**

A respondent who has low vision regularly takes prescriptions with labels that have very small print. She often confuses blood pressure medicine with stomach medication or antidepressant medication. She uses different rubber bands on each of her pill bottles in an effort to avoid further confusion.
- Hospitalization**

A respondent who has low vision explained that he cannot read the prescriptions on his medicine bottles and he cannot tell the difference between insulin bottles. He has given himself the wrong insulin and ended up in the hospital.
- Emergency room visit**

A respondent explained he has received the wrong dosage of insulin due to not being able to read the label. The prescription was for 50 unit insulin syringes and the pharmacy filled it with 100 unit syringes. He passed out from hypoglycemia and ended up in the hospital.
- Inability to detect pharmacy errors and other serious difficulties**

A respondent who is legally blind indicated that the regular print drug information is too small for him to read. The prescription number is also only available in regular print. The warnings on the sides of the vial or box are even smaller print that he is unable to read as well. One of the negative consequences he faces is that sometimes he misses taking one of his medications. He has also been the victim of pharmacy errors due to the fact that he cannot read the prescription numbers. He explained the strategies and techniques he uses to properly identify and take medications. He keeps his medications organized in a box with the eye drops on the bottom half of the box and the pills vials on the top end of the box, using rote memory to determine what he has to take. To tell how full or empty his prescription medicine containers are, he shakes the medicine containers.
- Expired medication and illness**

A respondent who was diagnosed with multiple sclerosis had to start taking several prescriptions. Shortly after her diagnosis with multiple sclerosis she experienced vision loss and had to manage several more prescriptions. At one point, she had a daily medication in prefilled syringes that expired. Not being able to verify that the medicine had expired, she continued to take the expired medicine and it resulted in a relapse of multiple sclerosis. The medication was unable to do what it is prescribed to do because it was expired. She was hospitalized for three weeks and then spent two weeks in rehabilitation followed by an additional three months before she was well enough to return to work.
- Refill problems and additional expenses**

A respondent who is a totally blind braille reader explained that labeling information such as the prescription number, pharmacy phone number to order refills, number of refills that remain, dosage, and side effects are not available in braille. One of her prescriptions has a fill by date. Unable to access the refill information, she forgot what that date was and was not able to refill the prescription on time. This resulted in an unnecessary delay and her having to pay for another doctor visit to obtain the necessary refill.
- Anxiety**

A respondent who is totally blind explained that she cannot read medicine bottles or medicine package print. She further explained that medication errors are constantly possible and something that is quite anxiety provoking. She makes her own braille labels for the containers but still requires sighted assistance to obtain the information for the braille labels. Braille labels only provide the name, of the medication, not the dosage, frequency or warnings.
- Inability to maintain confidentiality and dependence on others**

A respondent who has low vision shared her story. All the labels on her prescription bottles are too small for her to read. She has had to put her drugs in special places in a cardboard box so that she knows which medicine she is taking. She has managed to find a friend who tells her what she gets

when she has prescriptions refilled. The pharmacists refuse to print the medication in larger print for her. She is left with no choice but to have her friend help her manage the situation. She further explained how embarrassing and degrading it is for her to be dependent on sighted assistance.

- **Dependence on sighted assistance**

A respondent with recent vision loss explained that the printed drug labeling information is too small for his vision. He has experienced errors when attempting to organize and take his medication. If he could access the printed drug information, he would be capable of managing the situation. Due to the inaccessible drug labels, someone must assist him in organizing and taking his medication.

In summary, data indicated that the inability to read medication labels and instructions has resulted in serious negative consequences for people with vision loss. The most commonly reported negative consequences of unreadable drug labeling information included:

- taking the wrong medication
- taking an incorrect dosage of medication
- taking expired medications
- inability to access the necessary information to refill medications on time
- illness due to taking the wrong medication or incorrect dosage of medication
- emergency room visits or hospitalization
- additional expenses
- increased anxiety
- inability to maintain confidentiality
- inability to detect pharmacy errors
- dependence on either trusted sighted companions or complete strangers to convey necessary drug information

The fourth and final item on the survey asked respondents to share strategies or techniques used by people with vision loss to properly identify and take medications. The suggestions included strategies such as tactually labeling medicine bottles, differentiating between medicines by their smell, size, texture, or shape as well as asking for sighted assistance. The obvious shortcoming of identifying medication by pill texture, shape, or size clues, for example, was a great matter of concern discussed by many of the participants.

Assistive technology devices that use smart-label and speech synthesis technologies to verbalize prescription information can enable people with vision loss to more effectively identify and take medications. There were only a few respondents who addressed the use of these assistive technology devices. The use of this sort of assistive technology can allow those who cannot read their prescription labels, a better way to manage their own medication. Nearly all those who addressed the use of such assistive technology devices explained that these devices were not affordable.

Another trend in the response to this fourth and final item was that people who experienced the challenge of vision loss also often experienced the challenge of other disabilities in addition to their vision loss. The presence of additional disabilities can further limit the ability of people with vision loss to effectively manage their medications while also increasing the need for more types of medication. This complicated their ability to devise effective strategies or techniques for properly identifying and taking medications.

Discussion

Overall results from this informal online questionnaire demonstrated that people with vision loss find themselves unable to take prescription and over-the-counter medicines safely, effectively, and independently due to inaccessible printed drug labeling information. Open ended questions gave respondents the opportunity to share their personal stories. Data indicated that the inability to access necessary instructions supplied with prescription and over-the-counter medicines often resulted in people with vision loss not taking a proper dose of necessary medication. In nearly every instance, respondents explained the serious negative consequences of unreadable drug labeling information and that they were dependent either on trusted sighted companions or complete strangers to convey necessary drug information.

There were only a few personal stories that addressed the use of assistive technology devices that can allow those who cannot read their prescription labels, a better way to manage their own medication. The few respondents who did address the use of such assistive technology devices explained that these devices were not affordable. The findings of this survey indicated that the lack of awareness and affordability were two substantial barriers people with vision loss experienced in accessing these high-tech devices.

No single currently available assistive technology or modality can meet the needs of all of the growing population of people with vision loss. This population of people with vision loss is not homogenous and, therefore, multiple means of communicating drug information are necessary. Increasing age, additional disabilities, socioeconomic status, severity of vision loss, and skill in the use of computer and/or assistive technologies should be taken into consideration when researching or developing assistive technologies or modalities for use by people with vision loss to access prescription drug information.

Thus, assistive technology devices that use smart-label and speech synthesis technologies to verbalize prescription information seem to have not yet reached their full potential. To be most effective, an assistive technology or modality that allows those with vision loss a better way to manage their own medication should have certain features. The assistive technology device should:

- provide essential drug information that is understandable and readily comprehensible to consumers, as well as the most current labeling information, as it becomes available;
- have the ability to reach the majority of individuals with vision loss;
- be easy to use; and
- be affordable.

Policy Implications

Even though people of all ages with all degrees of vision loss are affected by the negative consequences of inaccessible drug labeling information, there are essentially no federal guidelines for pharmacists to follow in making prescription labels accessible.

The Food and Drug Administration (FDA) implements laws and regulations that govern prescription drug information. However, the FDA has never issued specific regulations or guidelines to guarantee that prescription drug information intended for patients is accessible for people with vision loss. In general, states are the primary regulators of the content and format provided directly on a prescription bottle and/or pharmacy-provided packaging. Nearly all of the states in the union have statutory requirements pertaining to prescription labeling. However, no state law ensures that prescription labeling is accessible to persons with vision loss. Even the state of Massachusetts, which attempts to establish such requirements, merely provides: "upon the request of-a person visually impaired [sic], directions on the label affixed by the pharmacist to a container of a prescription drug shall be typed in a print size allowing no more than ten characters per inch (Mass. Gen. Laws Ch. 94C, §21)." Few states have ever

considered adopting a clear accessibility requirement-the California legislature is currently considering such a proposal, AB 1399, which provides: "upon the request of a customer who is blind or visually impaired, a pharmacist shall provide a prescription drug label that is readable by an assistive technology device for the blind or visually impaired".

Some pharmacies are beginning to experiment with different ways to offer their customers alternate means of identifying prescription medications. However, while such efforts are well-intentioned, they do not amount to a national trend and are not based on any reliable standards or evidence of their effectiveness. Nationally, few pharmacies are voluntarily providing their customers with meaningful access to the labeling and other information related to prescription medications they dispense. Moreover, those pharmacies that have begun to try to provide their customers with vision loss with prescription information they can use are doing so in a vacuum without standards that ensure complete and consistent presentation of information.

Recent Actions

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress called upon the FDA to investigate solutions addressing the problem of inaccessible prescription drug labeling. Unfortunately, the report issued to Congress in May 2005 failed to describe specific processes, regulatory changes, or other solutions ensuring access. Nevertheless, the report does affirm that "all Americans, whether visually impaired or not, should have equal access to essential prescription drug information". In essence the FDA missed an opportunity to offer meaningful answers to the challenge of inaccessible labeling and related information. Since the study's release in May 2005, some effort has been made to convene expert panels to begin to formulate questions for future research and the development/communication of stopgap solutions. Even though the Secretary of Health and Human Services, Mike Leavitt, in announcing the introduction of FDA's new packaging insert format requirements, recognized that "clear and concise information about prescriptions will help ensure safe and optimal use of drugs", this language is limited only to package inserts and fails to consider accessibility for people with disabilities.

Action Needed Now

Congress should grant the FDA clear authority to regulate this area and develop standards to ensure that prescription labeling is accessible to individuals with vision loss. A number of existing solutions demonstrate the feasibility of providing access to prescription drug labeling and pharmacies should be prepared to provide prescription labeling in multiple modalities.

¹ Data source: National Center for Health Statistics, National Health Interview Survey, 2006, www.cdc.gov/nchs/nhis.htm . For further information, see "Pleis J.R., Lethbridge-Çejku M. (2007). Summary health statistics for U.S. adults: National Health Interview Survey, 2006. National Center for Health Statistics. Vital Health Stat 10 (235)."

Prepared December 2008

For further information, contact Stacy Kelly, Policy Research Associate



Lin
Hokana/Pharmacy/DCANotes
11/19/2009 11:46 AM

To Carolyn Klein/Pharmacy/DCANotes@DCANotes
cc
bcc
Subject Re: Proposed Regulations: 1707.5 Patient-Centered
Prescription Label

History: This message has been replied to.

Are comments sent to you?

If so, I propose 1707.5 subdivision (d) add to the last sentence, "The pharmacist is encouraged to also furnish written directions for use in the patient's native language that match the directions on the label." Some pharmacies (illegally) use computer software to generate the label in a language other than English so the patient can understand the instructions. This is a good for the patient but not legal and should somehow be encouraged with a supplemental label or instruction sheet or by another means.

Thank you.

Lin Hokana, R.Ph.
Inspector, CA Board of Pharmacy
1625 N Market Blvd, N219
Sacramento, CA 95834 (916) 574-7900
Office: (209) 245-3207
Fax: (209) 245-5263

What Would It Take to Move Toward Prescription Use Instruction Standardization?

ROGER WILLIAMS, M.D.

United States Pharmacopeia

The United States Pharmacopeia (USP) is a standard-setting body. There are about 500 standard-setting bodies in the United States. Three hundred or so are accredited by the American National Standard Institute (ANSI), which is a professional association that watches over all the U.S. standard-setting bodies. At the global level there is the International Standards Organization (ISO) in Geneva, Switzerland.

Standards can be either documentary or physical. The USP sells physical reference materials, as does the National Institute of Standards in Technology (NIST). Documentary standards include such things as best practices, guidelines, guidance, regulations, and laws. From this perspective, the patient package insert is a standard.

Standards can be voluntary or mandatory. Additionally, there are different kinds of standard-setting bodies. For example, there are voluntary consensus standard-setting bodies where individuals affected by the standards participate in developing them. Government is a very strong standard-setting body, but that is a different model.

The USP is a convention of about 450 associations, and it is a practitioner-based body. There are about 40 pharmacopeias worldwide, but the only one of them that is nongovernmental is the USP. The USP was started in 1820 by practitioners who desired good standards and good names for the medicines they used.

Improving Prescription Drug Labeling

Michael S. Wolf, PhD, MPH; Stacy Cooper Bailey, MPH

According to a 2006 report by the Institute of Medicine of the National Academies, *Preventing Medication Error*, approximately 1.5 million preventable adverse drug events occur each year.¹ Attention to the root causes of medication errors leading to adverse events has most often been attributed to the provider's or health care system's contributing role in errors during the prescribing, ordering, dispensing or administering of a medicine.^{2,3} The reason attention was focused on those causes may be that most studies investigating medication error have been conducted in inpatient hospitals or nursing homes.⁴ However, more than one-third of adverse drug events take place in outpatient settings at a cost approaching \$1 billion annually.¹ It has been estimated that a large proportion of outpatient medication errors occur as a result of patients themselves not administering a medicine as intended.³ For ambulatory care, the patient, rather than the provider, is ultimately responsible for correctly administering a medicine as prescribed. Therefore, the processes of quality control and monitoring of medication error shift from provider to patient.

The current body of evidence detailing the incidence and causes of outpatient medication error is limited. Yet problems are likely to intensify as patients increasingly self-manage greater numbers of prescription and over-the-counter medications. Chronically ill patients and the elderly are at greatest risk for experiencing medication errors because as they take more

prescription drugs annually than younger and healthier patients, and visual/cognitive impairments by age may limit reading ease and comprehension.⁵⁻⁹ The risk for miscommunication and error may be further compounded since the average older adult sees several different health care providers annually.¹⁰

Health Literacy as a Medication Safety Concern

Limited health literacy is another significant risk factor that could account for outpatient medication errors that are the result of improper dosing administration. Numerous studies have found low health literacy to be significantly associated with a poorer understanding of medication names, indications, and instructions.¹¹⁻¹⁴ More recently, health literacy skills have been linked to requisite knowledge for adherence to treatment regimens.¹⁵ This current and well-publicized body of research has focused on the ability of patients to read, understand, and demonstrate instructions on drug container labels. The line of inquiry has been supported by parallel work in human factors research.^{5,6} Davis and colleagues conducted a multisite study among adults receiving primary care at community health centers and found a high prevalence of patients, especially those with limited literacy, misunderstanding seemingly simple dose instructions provided on the primary label of medication containers.¹¹ In this study, 46% of adults misunderstood at least one prescription container label they encountered. The problem extends to the auxiliary sticker labels that provide accompanying warnings and instructions for use of the medicine. Another study demonstrated over half (53%) of patients, especially those with limited literacy, had difficulty interpreting text and icons commonly used on these auxiliary warning instructions.¹²

Beyond the container, drug labeling also includes accompanying medication information materials that provide indications for use and

“...the manner in which the current health care system delivers necessary medication information to patients is clearly inadequate.”

Michael S. Wolf, PhD, MPH, is assistant professor of medicine and director of the Health Literacy and Learning Program at the Institute for Healthcare Studies in the Division of General Internal Medicine, Feinberg School of Medicine, Northwestern University. He can be reached at mswolf@northwestern.edu or 676 N St. Clair Street, Suite 200, Chicago, IL 60611.

Stacy Cooper Bailey, MPH, is program manager of the Health Literacy and Learning Program in the Institute for Healthcare Studies at Northwestern University.

further detailed precautions that can not fit on the container due to space constraints. Studies have found that these materials, as with the container label, are not useful for a majority of patients, particularly those with limited health literacy.¹⁶ This includes consumer Medication Guides (aka Med Guides) that are required by the Food and Drug Administration to be dispensed along with certain prescribed medicines that have been identified as having serious public health concerns. Patients with limited health literacy were significantly less likely to attend to these materials. These findings are supported by earlier research studies that suggest consumer medication materials are too difficult for most patients to read.¹⁷ As a result, the patient information leaflets and Med Guides that accompany many prescription medications may be ignored.

A System Failure

The 2004 Institute of Medicine of the National Academies report on health literacy, *A Prescription to End Confusion*, aptly identified the problem of health literacy as encompassing more than limitations in individual abilities.¹³ Rather, the complexity of demands placed upon the individual by the health care system must clearly be addressed. While patients must have adequate cognitive capacity and proficiency to read, understand, and act on medication label instructions to ensure proper and safe use, the manner in which the current health care system delivers necessary medication information to patients is clearly inadequate. Physicians, who are legally responsible for delivering important drug information directly to patients, frequently miss opportunities to adequately counsel their patients on how to self-administer their medicines.¹⁹ Pharmacists, next in line to counsel patients, also frequently fail to verbally communicate detailed information to patients at the point of dispensing medicines.²⁰

In light of these failures, patients must depend more on the print drug labeling materials (ie, the container label, consumer medication information, Med Guides, patient information leaflets) that are challenging for patients across all health literacy levels.^{17,18} With the exception of Med Guides and a very limited set of similar patient package inserts that are available for only a select number of drugs, no national standards or regulations exist for the development and oversight of consumer medication information or container drug labels. Informational leaflets are industry-generated, and state laws minimally govern content and format on prescription container vials. This all leads to what can best be described as a fragmented system of patient information.

Taking Action

Improving the readability and understanding of instructions and supplementary information for prescription drugs is warranted as it may ultimately stimulate appropriate and safe medication use among patients. Evidence is available now supporting the design of better drug labeling.²¹ This includes considerations for both the container label and accompanying materials. Based on recent health literacy studies and work by

the American College of Physicians Foundation (ACPF) on prescription drug labeling, certain general recommendations can be issued that espouse the importance of promoting health literacy as a medication safety issue.²²

First, seemingly simple dosage instructions printed on the container label should be written in the most clear and concise manner. Previous research has found that patients have more difficulty understanding vague medication directions as compared to more explicit ones.^{23,24} The less a patient is required to make inferences, the more easily medication schedules can be comprehended (ie, "take every 6 hours" vs "take at 8am, 2pm and 8pm"). This is especially important for more complex dosing schedules, where patients may become easily confused or more prone to errors if instructions are read in haste.

Second, Shrank and colleagues examined the variability in content and format on prescription drug container labels.²⁵ They found that pharmacies consistently emphasized provider-directed content versus information most pertinent to the patient. The use of bolding, highlighting, and larger font should be directed solely to label content that is most salient to the patient. Information such as prescription number or the pharmacy logo should be de-emphasized and segregated from dosage instructions, warnings, or indications so as to not detract from the most important label content detailing its appropriate use. Every effort should be made to organize the container label in the most patient-friendly manner. It likely will be the most tangible source of drug information repeatedly used by patients.

Third, accompanying materials should abide by core principles upheld by adult literacy practitioners.^{17,26} Consumer medication information should keep to simple language and avoid medical jargon. The scope of information should be limited and summaries more frequently used to highlight actionable messages. Shrank and colleagues further describe the type of content that is desired by patients to support appropriate use.²¹ Surveys have shown that patients want to know, in addition to dosage instructions, the indications for use of a prescribed medicine, any precautions, and the duration of treatment. Information on the benefits and side effects of drugs is also sought after by patients, and providing this information has been found to improve adherence.²⁰

Finally, steps should be taken to ensure that these separate elements of drug labeling, the container label and accompanying materials, are developed together as an integrated and complimentary set of information sources. Patients should be included in this process so materials are appropriately organized, and they accurately reflect the common schemas imposed by patients of all literacy levels when seeking to understand how to use prescribed medicines.

Conclusion

System change is urgently needed to promote health literacy for greater medication safety. Patients must be able to easily understand how to use prescription drugs correctly. Standardizing and integrating drug labeling must be a central goal to ensure that best practices are implemented because



Improving Prescription Drug Container Labeling in the United States

A Health Literacy and Medication Safety Initiative



A White Paper Commissioned by the American College of Physicians Foundation

Presented to the Institute of Medicine Roundtable on Health Literacy

October 12, 2007

THE
PHARMACOPOEIA

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Report Presented on Behalf of the ACPF Medication Labeling Technical Advisory Board

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EXECUTIVE SUMMARY

According to the Institute of Medicine (IOM) 2006 report, Preventing Medication Errors, more than half a million adverse drug events (ADEs) occur in the United States each year in outpatient settings. Problems with prescription drug (Rx) labeling were cited as the cause of a large proportion of outpatient medication errors and ADEs, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. Recent health literacy research has highlighted the alarmingly high prevalence of patients misunderstanding seemingly simple instructions and warnings placed on Rx container labels. The elderly, those with limited literacy skills, and individuals managing multiple medication regimens were found to be at greater risk for making errors in interpreting container label instructions.

The ability to understand Rx container label instructions is critical, both as *health literacy* and *medication safety* concerns. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines. Other supplementary sources, such as patient information leaflets and Medication Guides dispensed with the prescribed medicine are too complex and written at a reading level unsuitable for the majority of patients to comprehend. As a result, these materials are often ignored. While all of these sources are best viewed as a *system* of patient information, the Rx container label is particularly important as it is often the sole source of specific instructions received and repeatedly used by patients on how to self-administer medicines.

Despite its potential value, there are clear problems with Rx container labels. Minimal standards and regulations exist regarding their content and format, and Rx labels can vary by dispensing pharmacy. Specific dosage instructions on the container label are dependent on what the prescribing physician writes, as well as how the pharmacist interprets these instructions. While the format and content of Rx container labels may differ between and within local and national pharmacies, all share the common attribute of being unnecessarily complex

and not offering a patient-friendly interface. Instead, the greatest emphasis is placed on provider-directed content.

This report reviews in detail the problem with Rx container labels in the United States. The 'best practices' in drug container labeling are summarized. Recommendations are offered to guide medical and pharmacy practice, and related state and federal policy. The overall objective of this paper is to move forward a set of evidence-based, Rx container label standards that will minimize patient confusion and promote patient awareness of how to use a prescribed medicine safely and effectively, thereby reducing risk of medication error.

Table 1. Primary Findings

Finding 1	<i>Inadequate patient understanding of prescription medication instructions and warnings is prevalent and a significant safety concern.</i>
Finding 2	<i>Lack of universal standards and regulations for medication labeling is a 'root cause' for misunderstanding and medication error.</i>
Finding 3	<i>An evidence-based set of practices should guide all label content and format.</i>
Finding 4	<i>Instructions for use on the container label are especially important for patients and should be clear and concise. Language should be standardized to improve patient understanding for safe and effective use.</i>
Finding 5	<i>Drug labeling should be viewed as part of an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.</i>
Finding 6	<i>Health care providers are not adequately communicating to patients, either orally or in print, about prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.</i>
Finding 7	<i>Support is necessary for research on drug labeling and to identify 'best practices' for patient medication information.</i>

PROLOGUE

Since 2002, the American College of Physicians Foundation (ACPF) has sought to address the problem of limited health literacy by developing initiatives to mitigate the impact of this highly prevalent problem on health outcomes. The issue of inconsistent and confusing medication information and labeling soon became a primary target of the ACPF health literacy agenda. A few projects were commissioned by the ACPF, and informal activities were spearheaded to engage experts and stakeholders from academia, industry, and government. In September 2006, a meeting was held in Washington D.C. to discuss the ACPF's medication labeling initiatives and to suggest next steps for ACPF. The overall objective of the meeting was to consolidate an understanding of the broad problem of inadequate patient understanding of medication labels, and to identify a specific course of action to improve drug labeling in the United States. The meeting served as a timely response to Institute of Medicine (IOM) reports, released in July and September 2006, which targeted medication error and drug safety, respectively. Participants at this meeting included national experts in health literacy, patient safety, pharmacology, and pharmacy policy and practice. The Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM), and the Food and Drug Administration (FDA) were represented.

Participants reviewed the nature and extent of the problems surrounding medication labeling, particularly for prescription drugs. Summaries were provided from the July 2006 IOM report, Preventing Medication Errors, the FDA over-the-counter (OTC) consumer education initiatives, an ACPF-commissioned medication labeling systematic literature review, and recent health literacy research studies. Herein, this white paper presents the ACPF perspective on the current prescription medication *container* labeling system, with a focus on improving the format, content, and dosage and use instructions on the container label.

Medication Safety

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review

William Shrank, Jerry Avorn, Cony Rolon, and Paul Shekelle

With the passage of the Medicare Modernization Act, the US federal government has a dramatically expanded role in the provision of prescription drugs to Americans.^{1,2} This investment has led to even greater attention to the appropriate and safe use of prescription medications, and substantial concerns exist. Patients are typically adherent to only about 50% of their medication doses,³ even for essential chronic drug therapy,⁴⁻⁶ with dramatic consequences in terms of health outcomes and associated healthcare costs.⁷⁻⁹ In addition, substantial shortfalls in the quality of medication therapy exist¹⁰⁻¹⁴; medication errors and adverse drug reactions occur frequently, with an estimated annual cost of \$50 billion.¹⁵⁻¹⁹ Efforts to improve medication adherence and safety in the Medicare prescription drug benefit are warranted and may improve the effectiveness of the federal investment in prescription drug care.

Some of these quality deficits may be due to poor comprehension by patients about their medications.²⁰⁻²³ Several recent studies have demonstrated that patients frequently have difficulty reading and understanding medication labels.²⁴⁻²⁷ The recent Institute of Medicine report, "Preventing Medication Errors," cited poor labeling as a central cause for medication errors in the US.²⁸ Although patients should receive medication counseling from their physicians and pharmacists, numerous

OBJECTIVE: To evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use.

DATA SOURCES: We performed a systematic review of randomized controlled trials, observational studies, and systematic reviews from MEDLINE and the Cochrane Database (1990–June 2005), supplemented by reference mining and reference lists from a technical expert panel.

STUDY SELECTION: We selected studies that focused on the content of physician–patient communication about medications and the content and format of prescription drug labels.

DATA EXTRACTION: Two reviewers extracted and synthesized information about study design, populations, and outcomes.

DATA SYNTHESIS: Of 2009 articles screened, 36 that addressed the content of physician–patient communication about medications and 69 that were related to the content or format of medication labels met review criteria. Findings showed that patients request information about a drug's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. Little evidence linked label design or content to measurable health outcomes, adherence, or safety.

CONCLUSIONS: Evidence suggests that specific content and format of prescription drug labels facilitate communication with and comprehension by patients. Efforts to improve the labels should be guided by such evidence, although additional study assessing the influence of label design on medication-taking behavior and health outcomes is needed. Several policy options exist to require minimal standards to optimize medical therapy, particularly in light of the new Medicare prescription drug benefit.

KEY WORDS: patient information, prescription drug label.

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studies have shown that discussions about drugs are often limited,²⁹⁻³¹ and patients frequently do not remember those conversations,³² forcing many to rely on drug labels for information.

We sought to evaluate the evidence pertaining to the optimum content and format of patient-oriented prescription

Author information provided at the end of the text.

labels. We evaluated evidence pertaining to both container labels and auxiliary medication information leaflets that, when used together, might improve readability, understanding, and medication-taking behavior. To assess the optimum content of prescription drug labels, we reviewed the literature pertaining to patient preferences for the content of communication about prescription drugs. We then reviewed the literature to assess the evidence evaluating the effect of the content and format of prescription drug labels on readability, understanding, and health outcomes. Our goal was to evaluate the evidence to inform the improvement of prescription drug labels so that future efforts at redesign can be evidence-based.

Literature Search and Selection

A systematic search of the medical literature was performed to identify studies addressing prescription drug labels and patient-provider communication about prescription drugs. The initial searches were limited to articles written in English and published between January 1990 and June 2005. Sources of our search included MEDLINE and the Cochrane Database. We also reference-mined articles included from our initial search and sought input from members of a technical expert panel, drawn from diverse fields and assembled for this project. We included systematic literature reviews, observational studies, and controlled trials. All case reports and expert perspectives were excluded. Articles published before 1990 that were identified from expert recommendations or reference mining were included in this review.

Two searches were performed. Articles were included in the patient-provider communication search if they addressed patient preferences about specific content for discussions that may enhance medication-taking behavior. Articles were searched on MEDLINE, using the following search criteria: (communication or misunderstanding or miscommunication) and (patient or professional-patient relations or physician-patient relations or patient education) and (medicine or drug information services or prescriptions or drug therapy) or (risk or adverse event or adverse effect or risk factors or risk assessment). Articles from the patient-provider communication component of the search were included only if the results could be used to inform potential content of prescription drug labels. Considering that labels communicate medication information to patients, we believe that patient preferences for the communication content about medications may be assessed and used to inform optimal prescription label creation.

In the prescription drug labeling search, articles were included if they addressed either the format or content of any type of patient-oriented labels or drug information. Several MEDLINE searches were performed and included the following criteria: drug labeling/standards or (patient educa-

tion or health education) or (label or leaflet). Patient-oriented labeling has several components, all of which were included in this review. One component is the label that is directly affixed to the container. It must identify information about the medication, prescriber, and patient³³ and typically includes auxiliary stickers imprinted with directions and warnings. Package inserts are created by manufacturers, approved by the Food and Drug Administration (FDA), required for some drugs, and voluntary for others.³⁴ They are created primarily to educate physicians,³⁵ although recent improvements aim to provide summary information for patients, as well.³⁶

Consumer medication information (CMI) consists of leaflets created by the private sector (pharmacies and drug information publishers).^{37,38} These leaflets accompany most prescriptions dispensed at pharmacies.³⁹ Medication Guides, established by the FDA in 1996,⁴⁰ are standardized leaflets prepared by manufacturers for medications thought to pose a "serious and significant public health concern," and are disseminated at the pharmacy.⁴¹ Patient-oriented information is also prepared by manufacturers for direct-to-consumer advertising (DTCA). We included all patient-oriented medication information as part of the "label" so that evidence about any type of prescription drug information may aid in future labeling developments.

Extraction of Study-Level Variables

Two reviewers (WS, PS) extracted data from the same articles, with one reviewer (WS) extracting data and the other (PS) checking the information for accuracy. Disagreements were resolved by consensus. Variables assessed included patient population (ie, age, education, location, presence of chronic conditions) and study design (ie, experimental or hypothesis testing, descriptive, or review). We assessed the relationship between the outcomes reported in the study and health outcomes in patients, ranging from patient preferences (lowest level), label readability and comprehension, medication adherence, and actual health outcomes such as blood pressure control or adverse drug events (highest level). Studies evaluating prescription label preferences, readability, and comprehension rely on an assumed relationship between readability, comprehension, and the capacity to take medications appropriately.

Data Synthesis

Articles were grouped by topics under 2 headings: patient-physician communication content about medications and medication labeling format and content. Articles addressing patient-provider communication about prescription drugs were categorized under the following topics: patient preferences for content in general, content aimed to improve adherence, administration directions, and risk

communication. Topics associated with previous research on the content and format of medication labels included label organization, print, language, use of icons, and container design. Evidence tables were created for each category, and a narrative synthesis was performed.

Search Results

A total of 1944 articles were identified in our literature search. Additionally, expert advisors suggested articles, many from nonmedical sources, including psychology, business, marketing, and ergonomics literature; 65 of those articles were considered relevant. From all sources, 187 articles were identified as potentially relevant by a physician reviewer (WS) and confirmed by another physician reviewer (PS). Of those, 69 articles were excluded because they were either case reports or perspectives. In total, 36 articles addressing the preferred content of patient-provider communication about medications^{32,42-76} and 69 articles related to the content or format of prescription drug labels^{39,68,77-143} were included in our evaluation. Details of the search and yield of articles are presented in Figure 1.

Patient-Requested Information

A description of information that patients request about medications is shown in Table 1.^{32,42-76}

One survey of elderly patients found that only 46% recalled the drugs listed in their medical records,⁶³ and a second survey indicated that only 58% of elderly patients were familiar with their dosing instructions immediately after a physician visit.³² To guide communication efforts, researchers have descriptively assessed the specific information that patients request about medication administration. In a convenience sample, 67 patients in a health maintenance organization were surveyed about medication information they request; 67% asked for information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment.⁵⁶ Another survey of 100 patients recruited at a pharmacy found that the information most commonly considered important was dosing frequency (87%), adverse effects (85%), and indication (84%).⁷⁵ This survey was also a convenience sample, with a poor response rate (11%), raising questions about the generalizability of these findings.

A survey of a convenience sample of 66 white, hypertensive patients explored the com-

munication content that they believed would improve their adherence; 90% of those surveyed wanted to know about all possible adverse effects and 96% wanted to know about benefits of the medication.⁵⁷ In addition, 82% of patients requested more information about their disease, and concerns about duration of therapy and life-style effects were frequent. Although physicians and pharmacists express concern that discussion of adverse drug effects may adversely affect patient adherence,^{52,58} 3 descriptive studies found that patients desire complete information about potential adverse effects and prefer to participate in the decision-making process.^{43,54,58} All studies identified found similar results; however, none was performed in a population-based representative sample, raising concerns about generalizability.

Few studies have linked specific communication content to medication-taking behavior. One descriptive survey of 137 physicians who wrote prescriptions for antidepressant medication for 401 patients indicated that patients who were specifically advised to continue therapy for longer than 6 months were significantly more likely to adhere to

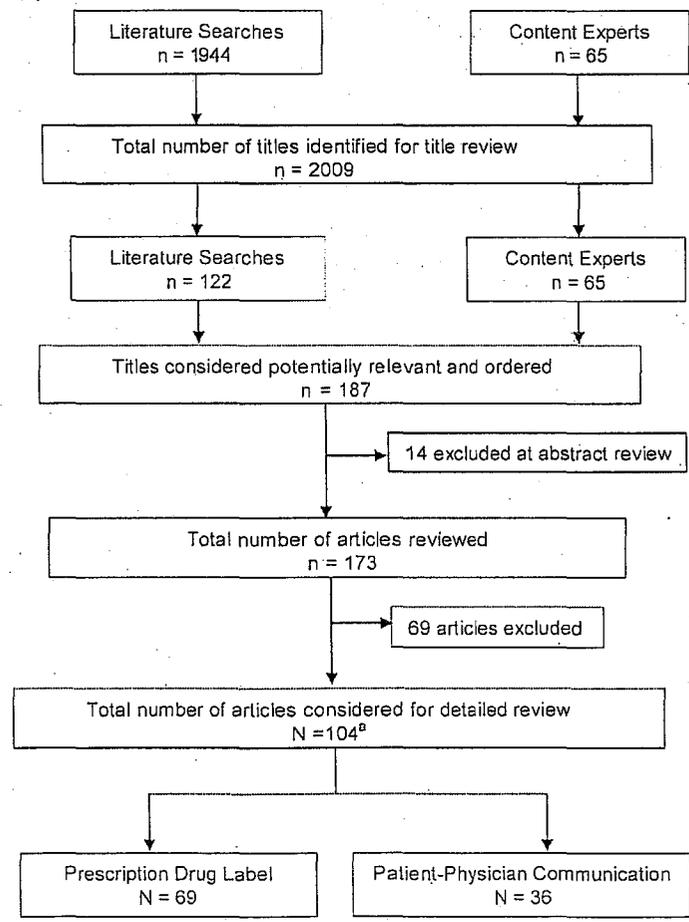


Figure 1. Article flow.

^aOne article was used in both evidence tables.

Table 1. Evidence about Physician–Patient Communication about Drugs

Reference	Type of Article/ Design	Research Question	Population	Findings
Technical aspects^a				
Jackson (2005) ⁶¹	RCT; pt. report of adherence	Does communication about implementation intention improve adherence?	220 pts.	Implementation intentions specify exactly when and where pts. will perform a behavior (eg, take medications). An intervention using this technique did not significantly impact adherence to short-term antibiotics.
Bikowski (2001) ⁴⁷	descriptive; physician questionnaires and pt. observation	Do physicians and elderly pts. agree about medication doses and frequency?	50 physician–pt. pairs	In 74% of pairs, either the physician was unaware that the pt. was taking a medication or thought the pt. was taking a drug that they were not taking; 12% of pairs had dose or frequency discrepancies.
Bull (2002) ⁴⁶	descriptive; matched physician–pt. interviews	Does communication about duration of therapy and ADRs impact adherence to antidepressants?	401 pts. and 137 prescribing physicians	Discussion of therapy duration (>6 mo) led to 3 times greater odds of continuation after 6 mo. vs pts. told to take the drug for <6 mo. Discussion of ADRs was associated with 2 times greater odds of adherence.
Fletcher (1979) ³²	descriptive; pt. interview	Do pts. understand information about their prescribed medication?	143 pts.	While 90% of pts. identified drugs prescribed during the visit, only 58% knew the dosing schedules of all medications immediately after leaving their physician's office.
Gardner (1988) ⁵⁶	descriptive; pt. questionnaire	What information do pts. request about medications?	67 previsit pt. questionnaires, 70 postvisit	67% of pts. requested information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment. One of 3 pts. was not given basic information.
Lyons (1996) ⁷⁵	descriptive; pt. questionnaire	What information do pts. desire about their medications, and how often are they provided with that information?	100 pts. responding out of 873 surveys distributed	Although >60% of pts. believed the information was important, <50% received information about storage, drug interactions, missed doses, and avoidance of ADRs; >75% received information about a drug's name, indication, dosing frequency, and duration of therapy.
Makoul (1995) ⁶⁶	descriptive; videotaped encounters, pt. interviews, written questionnaires, medical record reviews, and physician questionnaire	Do physicians and pts. in England communicate about prescription drugs in primary care, and do they agree about levels of communication?	271 pts. had full survey and videotaped data	Physicians frequently discussed product name (78%) and instructions for use (87%); pts. were passive, rarely offering their opinion or initiating discussions about medical treatment. Both groups overestimate the frequency of communication about medications.
Morris (1997) ⁵⁵	descriptive; pt. telephone survey	What are the trends over time concerning what pts. and physicians discuss about prescription drugs?	≥1000 pts. in 4 surveys conducted in 1982, 1984, 1992, and 1994	About two-thirds of physicians discuss the prescription during the encounter. About 60% discuss administration and only one-third discuss ADRs. In 1992, physicians and pts. discussed drugs more frequently than in the 1980s.
Rost (1987) ⁶³	descriptive; pt. interview and audiotaped pt.–physician encounters, medical record review	What predicts recall of medication regimens?	83 elderly pts.	On average, elderly pts. recalled 46% of the drugs in their medical records and 41% of the drugs mentioned in the clinical encounter. When physicians asked more closed-ended questions and provided more information about the medication, the pt. better recalled the medication after the visit.
Scherwitz (1985) ⁵⁹	descriptive; qualitative evaluation of tape-recorded encounters	What do physicians and pts. discuss about medications?	11 physicians making 267 physician–pt. encounters	There was little communication about drugs after the initial prescription. At the initial prescription, instructions were discussed 77% of the time, directions 31%, and indications 21%.
Sleath (1999) ⁵³	descriptive; qualitative analysis of taped physician–pt. communication	What do physicians and pts. talk about concerning prescription drugs?	467 physician–pt. encounters	On average, physician–pt. communication about drugs accounted for about 4 min per encounter. About half of the pts. recorded asked no questions about their prescription drugs; they most commonly asked about quantity (16%), drug identification (15%), dosage (9%), and indication (9%). Physicians asked pts. about identification (80%), effect on medical condition (56%), quantity (51%), dosing (41%), and barriers or ADRs (27%).

ADRs = adverse drug reactions; RCT = randomized controlled trial.

^aIndication, dose, administration, directions, and duration of therapy.

(continued on page 787)

Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Adherence Peveler (1999) ⁶⁷	factorial; RCT testing counseling and educational leaflets; measurement by pt. interviews and MEMS caps	Do antidepressant drug counseling and information leaflets improve adherence to treatment in primary care?	250 pts.	63% of pts. continued with therapy in the counseled group vs 39% who did not receive counseling (OR = 2.7; 95% CI 1.6 to 4.8). Counseling focused on daily routine and lifestyle, understanding the disease, and treatment of ADRs and their management. Treatment leaflets had no significant effect overall.
Tuldra (2000) ⁶⁹	RCT; self-reported adherence and lab testing	Does a psychoeducative intervention to educate pts. about medications and adherence improve adherence to HAART?	116 pts.	Intervention included consultation with a psychologist who provided better education about the medication and communication follow-up about adherence. Pts. who received the intervention had >6 times the odds of adequate adherence and better viral load control than those without ($p = 0.008$ and $p = 0.026$, respectively).
Raynor (2000) ⁷³	intervention; pre–post design; pt. interviews	Does a pharmacist intervention to improve communication about prescription drugs improve adherence?	143 pts. in England	Intervention that allowed pts. to communicate with pharmacists about drugs led to a 24% decrease in nonadherence (from 38% to 14%; $p < 0.001$) and a 36% improvement in pts.' reporting of medical problems.
Bailey (1997) ⁶⁷	descriptive; pt. questionnaires	What information do hypertensive pts. prefer to receive about medications to improve adherence?	66 pts.	90% of pts. wanted to know about all possible ADRs, 96% wanted to know about benefits of the medication, and 82% wanted more information about their disease. Concerns about duration of therapy and lifestyle effects were frequent.
Britten (2000) ⁵¹	descriptive; qualitative evaluation of recorded consultation and pt. interviews	What are physician–pt. misunderstandings about prescribing?	20 physicians and 35 pts. in England	14 categories of misunderstandings were identified between physicians and pts., including physician misunderstandings about pt. beliefs and vice versa. Disagreement existed about attribution of ADRs; all misunderstandings were associated with potential or actual ADRs such as nonadherence.
Hulka (1976) ⁷⁰	descriptive; pt. interview and medical record review	Does communication influence adherence and error rates for chronic medications?	46 physicians and 357 pts. with CHF or diabetes	4 types of errors were identified: omission, commission, scheduling misconceptions, and nonadherence. Greater number of drugs and greater regimen complexity were associated with more errors. Better communication of instructions was associated with fewer errors in pts. with CHF.
Ogedegbe (2004) ⁴⁴	descriptive; pt. interview	What are barriers to adherence in hypertensive African Americans?	106 pts.	Forgetfulness and poor understanding about disease are important barriers. Reminders, knowledge of disease, better communication with physicians, having a routine for medication administration, and social support networks facilitate adherence.
Schneider (2004) ⁴²	descriptive; pt. questionnaires	What aspects of physician–pt. relationship lead to better adherence to HAART?	554 pts. at 22 HIV practices	Adherence dialogue, general communication, disease-specific information, trust in physician, and physician satisfaction are all related to self-reported adherence.
Schillinger (2003) ⁶⁸	descriptive; observed physician–pt. interactions and evaluated pt. lab outcomes	Do physician communication techniques in which the physician assesses recall and comprehension impact health?	38 physicians and 74 diabetic pts. with low functional health	Physicians assessed recall and comprehension only 20% of the time. Assessment of recall and comprehension was associated with improved glycemic control, even after controlling for health literacy.
Hall (1988) ⁶⁵	systematic review and meta-analysis	Is physician–pt. communication about prescription drugs associated with greater adherence?	41 studies	There was a statistically significant relationship between information-giving about medication and adherence to medical regimens ($p < 0.0005$). Giving more information was also associated with greater understanding and recall about medications.

ADRs = adverse drug reactions; CHF = congestive heart failure; HAART = highly active antiretroviral therapy; MEMS = Medication Event Monitoring System; RCT = randomized controlled trial.

(continued on page 788)

Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Adherence Haynes (2002) ⁵⁵	systematic review	What interventions improve adherence?		A number of interventions have been shown to improve adherence, typically using a complex, multifaceted approach. More convenient care, information, counseling, reminders, and other interventions have been shown to be helpful.
Stevenson (2004) ⁴⁵	systematic review	What is the relationship between communication about drugs and adherence?	134 articles considered relevant, of which 116 were descriptive	There has been little research concerning whether exchange of views takes place between physicians and pts. (concordance). Physicians tend to dominate discussions. Some interventions to improve communication rates have been successful, but little guidance exists about the specific content associated with improving adherence.
Risk/benefit ADRs Dyck (2005) ⁶⁰	descriptive; qualitative evaluation of tape-recorded encounters	What do pharmacists discuss with pts. about drugs?	10 pharmacists, each encountering 2 pts.	Pharmacists discussed ADRs in all encounters, but discussed frequency of ADRs using vague terms and did not focus on potential benefits of the drugs. Using a leaflet did not substitute for communication about risk.
Gramling (2004) ⁴⁸	descriptive; physician survey	Do physicians believe it is more important to communicate quantitative or qualitative information about risk?	300 physician members of the Massachusetts Academy of Family Practice	When asked whether it is more important to communicate qualitative vs quantitative information about risk to pts., 63% of physicians felt they were of equal importance. Of the remainder of respondents, 94% rated qualitative as more important than quantitative information.
Hassell (1998) ⁵²	descriptive; qualitative evaluation of physician–pt. encounters and pt. questionnaires	What information do consumers hope pharmacists will provide and what do they actually provide?	2379 observed encounters and 1000 pt. interviews in England	Consumers are more interested in learning about the effectiveness of their medications, and pharmacists focus their guidance on ADRs and safety.
Lisper (1997) ⁷⁶	descriptive; qualitative evaluation of pt. interviews	From whom do pts. prefer to receive their information and what information do they need about medications?	21 Swedish pts. with hypertension	Pts. prefer to receive drug information from physicians rather than pharmacists. They prefer information at the onset of therapy and especially request information concerning possible ADRs.
McGrath (1999) ⁵²	descriptive; qualitative evaluation of physician interviews	What are physicians' perceptions about communicating prescription drug information?	20 physicians	Physicians think communication about drugs should be 2-way and participatory. Physicians express concern that too much information about ADRs may impair adherence.
Morrow (1996) ⁶⁴	descriptive; pt. interviews	Do pts. have a schema for understanding drug information?	study 1 and 2: 42 older and 42 younger adults in each study	Pts. prefer to "lump" information into packages that are easier to understand. They tend to package directions and indications together. Another group includes ADRs and emergency information.
Nair (2002) ⁵⁸	descriptive; pt., physician, and pharmacist focus groups in Canada	What do pts., physicians, and pharmacists want to discuss about medications?	88 pts., 27 physicians, 35 pharmacists, all in Canada	Physicians and pharmacists believe that pts. want less information about ADRs than they actually do and are concerned that information may impede adherence. Pts. desire both general and specific information.
Peters (2006) ⁷⁴	4 descriptive studies	How are risk frequencies best communicated when communicating risk?	1–100 students, 2–46 students, 3–46 students, 4–171 students	Framing effects were more influential in less numerate pts. More numerate pts. drew more precise affective meaning from numerical information.
Schwartz (2005) ⁷¹	descriptive; pt. questionnaire	How well do pts. interpret health-related data?	178 pts.	There is a wide range in pts.' ability to interpret health information. Those with high numeracy scored better than those with low numeracy (71% vs 36%), high vs low quantitative literacy (65% vs 28%), and high vs low education (69% vs 42%).
Walter (2004) ⁴³	descriptive; focus groups	How can risk about hormone replacement be best discussed?	40 women in England	Pts. prefer open communication of risks and benefits so that they can participate in the decision-making process. Pts. also want individualized risk and benefit information.

ADRs = adverse drug reactions.

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those instructions (OR 3.12; 95% CI 1.21 to 8.07).⁴⁶ In addition, patients who discussed adverse effects with their physicians were less likely to discontinue therapy than were patients who did not discuss them (OR 0.49; 95% CI 0.25 to 0.95). Two systematic reviews generally found a relationship between communication about medications and adherence, but did not specify communication content that is effective.^{54,65}

Drug Labeling

Findings on the content and format of prescription drug labeling are presented in Table 2.^{39,68,77-143}

Organization

Three descriptive studies indicate that patients prefer that information be organized in a schematic, logical way, with information about the drug, directions for use, and its benefits followed by warnings and adverse effects.^{116,132,135} A survey of 140 participants recruited from a university, a flea market, and a retirement community found that patients of all ages prefer information about indications and benefits of medications prior to information about adverse effects and warnings.¹³⁵

In presenting risk and benefit information, patients prefer drug information to be organized into a simplified schema. Researchers in a laboratory setting asked 42 young adults and 42 elderly adults to sort medication items (eg, indication, instructions, adverse effects) to create a preferred instruction set. Young and elderly adults shared a similar schema for medication taking, preferring to read the drug's name and indication, followed by directions (schedule and duration), followed by warnings and adverse

effects.⁶⁴ In addition, patients exhibited better recall of medication information compatible with this schema. The samples for the descriptive studies were either not in the US¹¹⁶ or were small,¹³⁵ and the experimental design included a sample of only 84 patients in a laboratory setting,⁶⁴ raising some concerns about the generalizability of these findings.

Three studies used experimental designs to demonstrate that list formats on medication labels improve patient understanding and recall.^{101,106,136} One study presented 27 elderly patients with labels in different formats.¹³⁶ The subjects preferred labels in categorized lists (lists with headers) over simple lists and simple lists over paragraph format. Elderly patients found categorized lists to be easier to read, with improved recall, answer time, and accuracy. In another experiment, older and younger patients were presented with labels of different formats; list formats were again found to be easier to read and recall than were paragraph formats, and list formats reduced age differences in both answer time and accuracy.¹⁰¹ Three studies with experimental designs have demonstrated that patients prefer leaflets that use headers to organize material^{96,101,106} and white space to separate related concepts.¹⁰⁶ Another study with 101 elderly adults and 109 young adults indicated that patients, especially the elderly, could more easily read labels that judiciously used white space by separating related sections and grouping related material together.⁸⁷ These experiments were performed in a laboratory setting and should be evaluated in the real world setting.

Print

Font size influences readability and comprehension in both CMI and container labels. In one randomized controlled trial (RCT), 101 elderly adults and 109 young

Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Provider/venue/language choice				
Savas (2001) ⁵⁰	RCT; pt. questionnaire	Does verbal or written information improve understanding about medications in an undereducated population?	38 received written alone, 30 received verbal alone, 40 received both written and verbal information	78% read the written material. Pts. who received both verbal and written material had the best understanding about their drugs as measured by a series of 8 questions about administration and ADRs. Written information was more effective than verbal information.
Smith (1994) ⁷²	descriptive; pt. questionnaire	What are pts.' perceptions of the most valuable source of information about drugs and the optimal content of discussions about drugs?	110 pts. taking OTC medications, 218 pts. taking prescription drugs	Pts. prefer to discuss prescription drugs with their physicians and would like to hear about indications, directions, ADRs, and duration of therapy. Pts. believe that they have to bring up the topic of drugs with their physicians.
Schaafsma (2003) ⁴⁸	review; MEDLINE literature review	How do pts. whose first language is not English access drug information?		There has been little research in this area. Foreign languages and cultural differences provide barriers to accessing drug information; interpreting services can help.
ADRs = adverse drug reactions; OTC = over-the-counter; RCT = randomized controlled trial.				

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels

Reference	Type of Article/ Design	Type of Label	Research Question	Population	Findings
Leaflets Bower (2003) ⁷⁷	experiment; pt. questionnaire	CMI	What language characteristics affect intention to adhere?	260 students	Adherence intention is greater when instructions are set in a negative frame and the language is simple, understandable, and avoids medical jargon.
Dickinson (2001) ⁹⁶	RCT; pt. questionnaire	CMI	comparison of 2 CMI formats and an assessment of the proposed EU standardized format	2 groups of 20 pts.	On average, pts. correctly answered only 3 of 15 questions after reading the EU CMI and 8 of 15 from the best practice CMI. Headers and clearer language improved understanding.
Knapp (2005) ¹²¹	RCT; pt. questionnaire	CMI	Can pts. comprehend the messages from icons? Does icon size or the frequency of presentation influence comprehension?	part 1: 160 adults part 2: 67 elderly adults in the UK	There was great variability in pts.' interpretations of icons. In the 10 icons evaluated, pts. correctly interpreted 7.5–90%; only 3 were understood by >85%. Older and less educated pts. were less likely to understand icons. Icons were better understood when larger ($p = 0.04$) and when presented to pts. more than once ($p < .001$).
Miselli (1990) ¹⁰⁵	prospective observational study; pts. exposed to 2 different leaflets and pt. questionnaire	CMI	Do different labels impact information accessibility and understandability?	6692 pts. in Italy	Experimental labels were more effective. Pts. judged an experimental label with simple language and checklists superior to a conventional label.
Morrow (1995) ¹³⁶	experimental; 3 trials evaluating pt. perceptions of label formats and impact on recall and understanding	CMI	Do list vs paragraph formats improve older pts.' understanding and recall of drug instructions?	trial 1: 27 older adults trial 2: 36 older adults trial 3: 27 older adults	List formats improved pts.' understanding, recall, and speed of accessing information vs paragraph format.
Morrow (1998) ¹⁰⁰	experiment with 2 trials of labels with and without icons	CMI	Does the use of icons to communicate dosing schedules improve older and younger pts.' understanding?	trial 1: 36 older and 36 younger adults trial 2: 45 older and 36 younger adults	In older and younger adults, questions about dose and time information were answered more quickly and accurately when a timeline icon was used. An icon that was less integrated to the text was ineffective.
Morrow (1998) ¹⁰¹	RCT; trials using pt. questionnaires to evaluate understanding and recall of different label formats	CMI	Does the use of list format and category headers on CMI impact understanding of medication instructions?	trial 1: 44 elderly and 44 young adults trial 2: 48 elderly and 32 young adults	Lists improved pts.' ability to infer information from labels. Pts. prefer lists and headers. Lists improved understanding and recall and reduced age differences in answer time as well as accuracy. The benefit of lists was greater in older vs younger adults. Evidence of the effect of headers was inconclusive.
Ngho (1997) ¹²⁴	RCT; pt. interview and pill count	CMI	Does CMI with icons produced by local artists and with educational organizers lead to better adherence and understanding in nonliterate pts.?	78 nonliterate pts. in Cameroon who were started on antibiotics	Both visual aids (CMI with icons) and educational organizers led to improved comprehension about drugs and adherence to antibiotic regimens.
Peveler (1999) ⁵⁷	RCT; intervention with measurement by pt. interviews and MEMS caps	CMI	Do antidepressant drug counseling and information leaflets improve adherence in primary care?	250 pts.	63% of pts. continued with therapy in the counseled group vs 39% who did not receive counseling. Treatment information leaflets had no significant effect overall.
Vuorma (2003) ⁷⁸	RCT	CMI	Does provision of a booklet with treatment information options impact treatment choices for menorrhagia?	393 pts.	Written information significantly impacted pt. behavior. Pts. who received the information chose more medical treatment, but surgical procedure rates did not change and fewer "new" procedures were performed.
Whalley (2002) ¹⁴³	RCT	CMI	Does the use of icons or graphs to depict risk and benefit information influence intention to take the medication?	196 pts. in Canada	Pts. randomized to the traditional, text-only CMI were less likely to consider taking the drug than were pts. randomized to receive CMI with either icons or graphs to depict risk and benefit information ($p < 0.001$).
Basara (1994) ¹¹⁹	descriptive; content evaluation of 63 CMIs	CMI	Are PPIs/CMI readable?	63 CMI	Inserts written at a 9th grade reading level with small font are not very readable.

CMI = consumer medication information; EU = European Union; MEMS = Medication Event Monitoring System; PPI = patient package inserts; RCT = randomized controlled trial.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
Leaflets					
Bernardini (2000) ⁹⁷	descriptive; pt. questionnaire	CMI	Can pts. understand CMI, and do they prefer the use of symbols or icons?	1004 pts. in Italy	83.5% of Italian pts. read the leaflet; 53.5% found the leaflet hard to read, 63% of those >50 y old. 47% had difficulty finding the information they sought. Although 74% of pts. preferred the use of icons, there was little agreement about which versions were most effective.
Bernardini (2001) ¹¹⁶	descriptive; pt. questionnaire	CMI	How do color, print size, and layout influence readability of labels?	1004 pts. in Italy	Pts. reported that font size must be at least 10 point to be readable, preferably larger. Pts. requested more detail, but in a schematic organization; they also noted that certain color print is more appropriate for certain sections (eg, warnings/ADRs should be red).
Berry (2003) ⁷⁹	descriptive; pt. interview	CMI	Do the standardized European Community guidelines for communicating risk lead pts. to understand risk?	4 studies in the UK: 1-268 students 2-112 adults 3-120 adults 4-360 adults	Using language to communicate risk led pts. to significantly overestimate the risk of ADRs vs a numerical presentation, which was much closer to the actual risk.
Estrada (2000) ⁹⁸	descriptive; SMOG evaluation of leaflets	CMI	Is warfarin CMI or handout information readable?	50 leaflets	Written at an average level of 10.7th grade, which is beyond the comprehension of most pts.
Gibbs (1990) ¹³¹	descriptive; pt. mail survey	CMI	Do leaflets improve understanding about medications and their ADRs? Are pts. satisfied with leaflets?	3410 pts.	Pts. had better understanding of their indications for the medication, administration directions, and what to do in case of an ADR. Pts. were satisfied, overall, with leaflets and did not experience more ADRs than did those who did not receive CMI.
Gustafsson (2005) ¹¹⁰	descriptive; expert evaluation of the leaflets and pt. questionnaires	CMI	Are leaflets readable and well understood by pts.?	1060 pts. who received CMI for 30 drugs in Sweden	Leaflets contained about half of the important topics desired and were deemed readable. Pts. had difficulty understanding interactions and contraindications of the drugs.
Hameen-Anttila (2004) ⁸⁵	descriptive; pt. interview	CMI	Do children understand icons in medication leaflets?	90 children in Finland	Correct interpretations of pictograms ranged from 30% to 99%, but were generally well understood. However, even well understood icons did not influence children's understanding of the leaflets.
Khurana (2003) ⁸⁸	descriptive; SMOG and other tests to measure readability	CMI	Can pts. read ocular medication inserts?	10 drug inserts	CMI for ocular medications are often too complex, average of 12th or 13th grade reading level.
Krass (2002) ⁹¹	descriptive; leaflet evaluation	CMI	Does CMI meet the 1996 FDA Action Plan? Do consumers comprehend existing CMI and model CMI?	24 pts., 36 CMI, and 3 model CMI	Both the language and format recommendations of the Action Plan have not been widely met by the CMI evaluated. Pts. strongly preferred the model CMI to the existing ones and could understand it better.
Morris (1984) ¹³⁸	descriptive; mailed survey	CMI	Do patients who take hypertension, tranquilizer, or arthritis drugs read CMI or keep it?	1650 pts.	95% of those surveyed read the CMI, 76% keep it, and 56% discuss it with another person; 42% said that the leaflet made them feel better about taking the medication.
Morrow (1991) ¹⁴⁰	descriptive; 2 trials requiring pt. to sort and answer questions about labels	CMI	How do elderly pts. organize medication information for best understanding? Do instructions that follow this schema increase understanding?	trial 1: 33 elderly pts. trial 2: 27 elderly pts.	Elderly patients have a schema that they use to understand drug information, and they prefer information to follow in that order: (1) medication and purpose, (2) how to take (dose, schedule, duration, warnings), (3) outcomes (ADRs, emergency information). Instructions in this order were easier to remember.
Svarsted (2003) ⁹⁹	descriptive; evaluated the CMI received by trained shoppers after filling prescriptions	CMI	How frequently do pts. receive CMI, and what is the quality of the CMI?	918 prescriptions filled at 306 randomly selected pharmacies	Shoppers received leaflets 87% of the time, but leaflet length and quality varied greatly. Only 49% of leaflets had acceptable administration directions, 28% had acceptable information about precautions, 19% had acceptable information about contraindications and what to do about them; 26% of pts. did not receive leaflets that were adequately readable or comprehensible.

ADRs = adverse drug reactions; CMI = consumer medication information; FDA = Food and Drug Administration; RCT = randomized controlled trial; SMOG = Simplified Measure of Gobbledygook.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
Leaflets					
Swanson (1990) ¹⁰⁸	descriptive; evaluated PIs and CMI	CMI/PIs	How readable are leaflets for oral contraceptives?	93 leaflets	A great deal of variability was seen among leaflet readability levels, ranging from grade 5.5 to 13.6.
Vander Stichele (1991) ¹⁰⁵	descriptive; pt. survey	CMI	How do people feel about CMI?	398 respondents in Belgium	89% of respondents read the CMI and find it useful to learn about ADRs, dosage, indications, contraindications, and shelf life. Respondents were generally pleased with CMI.
Buck (1998) ¹¹⁷	systematic review	CMI	Are pts. receiving high-quality CMI? Are they receiving CMI at all?	NA	Leaflets are commonly dispensed. However, content is not standardized, materials are written at a high grade level, and there are poor resources for non-English-speaking pts.
Kroner (1994) ¹¹⁸	review	container labels and CMI	challenges with reading labels	NA	Describes the importance of better physician-pt. communication about medications. Also demonstrates that labels are not very readable, but large font and particular language improve readability.
Morrow (1988) ¹³²	review	CMI	describes prescription drug nonadherence	NA	Medication instructions should be complete, organized in a logical way, and in list format. Precise instructions improve adherence by 10-20%.
Container labels					
Kalsher (1996) ¹³³	experimental; 2 pt. surveys after reading various labels	container labels	Do fold-out or tag labels improve readability? Do icons improve readability?	trial 1: 84 undergraduates trial 2: 58 older adults	Tag or fold-out labels were rated as easier to read, and pts. were more likely to read warnings, recommend label use, and prefer labels. Icons were helpful across the same domains.
Luscombe (1992) ¹²⁰	experiment; pt. survey	container labels	Do pts. have preferences for container label typology?	55 pharmacy clients in Great Britain	Pts. strongly preferred laser-printed labels compared with those printed on a dot matrix printer. In general, glossy labels were preferred over matte-finish labels.
Mansoor (2003) ⁸⁶	experiment; pt. interview	container labels and CMI	How do pictograms affect readability of pt. information materials?	60 low-literate pts. from South Africa	The presence of pictograms significantly improved acquisition and comprehension of drug information; 73% vs 53% had >80% understanding when reading CMI with icons vs no icons.
Morrell (1990) ¹⁰⁷	RCT; pt. interview	container labels	Do icons improve younger and older adults' understanding of prescription labels?	32 older adults and 32 young adults	Younger pts. understood the labels better and more quickly. Use of icons improved younger adults' understanding but interfered with older adults' understanding of the medication directions.
Smither (1994) ¹³⁴	experiment; evaluated pts.' ability to read and comprehend labels with different formats	container labels	Do font size and font selection impact understanding and ease of reading labels?	trial 1: 19 young adults and 20 seniors trial 2: 18 young adults and 16 seniors	Larger font and certain font types are associated with ease of reading and better understanding of the labels. More errors were seen with 9 point vs 12 or 14 point font and with Courier rather than Helvetica or Century Schoolbook font.
Wogalter (2003) ⁸⁷	experimental evaluation of hypothetical container labels that varied in print size, spacing, and design	container labels	What is the effect of label format on knowledge acquisition and perceived readability of labels?	101 elderly subjects, 109 young adults	Older pts. benefit substantially from larger print. While previous studies have supported the use of extended (fold-out) labels, this study was inconclusive on that issue. Use of white space or chunking of information was helpful, especially in the elderly.
Wogalter (1999) ⁸¹	experimental evaluation of hypothetical container labels that included cap labels	container labels	Can information acquisition in older adults be enhanced by using the container surface area in new ways?	trial 1: 60 subjects trial 2: 75 subjects	Trial 1: pts. preferred labels that included a large identification label attached to the cap. Trial 2: cap labels also improved pt. knowledge about the drug. Cap labels in colors different from the container also improved pt. satisfaction and knowledge.
Container labels					
Benson (2002) ⁹²	descriptive; pt. interview	container labels	Can affluent seniors read container labels (as well as other health information)?	93 seniors	30% of seniors could not comprehend basic health information in prescription labels. Older seniors and those with less education performed worse.

ADRs = adverse drug reactions; CMI = consumer medication information; NA = not applicable; PIs = package inserts; RCT = randomized controlled trial.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/ Design	Type of Label	Research Question	Population	Findings
Container labels					
Dowse (2005) ¹²²	descriptive; pt. interview	container labels	Do labels with pictograms improve understanding and adherence in low-literacy pts.?	87 Xhosa pts. from South Africa	Labels were constructed in culturally appropriate ways by local artists. Patients with pictogram labels experienced 25% greater understanding about medications and 18% improvement in adherence.
Dowse (2001) ¹²³	descriptive; pt. interview	container labels	Are locally created, culturally targeted pictograms more effective than accepted pictograms for communicating with low-literate pts.?	46 Xhosa pts. from South Africa shown 23 local CMI and 23 USP CMI	Pts. exposed to locally produced, culturally appropriate icons were more likely to understand the information than were pts. exposed to USP pictograms. Almost 2 times as many pts. who received local labels understood them at ≥85% level.
Filik (2004) ¹³⁰	descriptive; pt. eye-tracking when evaluating an array of labels	container labels	Does the use of capitalized "tall man" font improve pts.' likelihood of selecting appropriate medications?	20 students and staff (non-healthcare professionals)	Pts. were almost half as likely to incorrectly identify a target drug presented in an array of drugs when using "tall man" letters, suggesting that capitalizing sections of potentially confusing drug names improves identification.
Hallworth (1984) ¹³⁸	descriptive; pt. survey	container labels	Do geriatric pts. understand the contents of container labels?	92 elderly pts.	Geriatric pts. frequently misinterpreted medication directions, and there was substantial variability in their understanding. Confusion frequently stemmed from timing of dosing and the relationship to meals.
Holt (1992) ¹⁴²	descriptive; pt. questionnaire	container labels	Can pts. correctly interpret dosage directions from container labels, and what characteristics of instructions improve interpretation?	321 pts.	While labels more frequently used language that vaguely instructed pts. about dosing directions (ie, "Take three times daily"), dosage instructions that specified the number of hours between doses were better understood (ie, "Take every 8 hours").
Lohiya (2004) ¹¹²	descriptive; evaluation of container labels	container labels	Is there variability in the presentation of expiration dates on prescription drug labels?	84 drug labels	Substantial variability was seen in location, font, and legibility of expiration dates
Mazzullo (1974) ¹²⁷	descriptive; pt. interviews	container labels	How well do pts. understand prescription label instructions?	67 pts.	Pts. had substantial difficulty with instructions that were vague. Even when responding to clear instructions, the frequency of interpretive errors ranged from 8% to 64%.
Moisan (2002) ⁹³	descriptive; pt. interviews	container labels	Do pts. who have difficulty reading labels adhere less to their drugs?	325 seniors	No clear relationship was identified between understanding labels and adherence. However, 95% CIs are very wide and an important effect cannot be excluded.
Morrell (1989) ¹⁴¹	descriptive; pt. questionnaires	container labels	Do age, memory load, and study time affect drug label memory and comprehension? 3 experiments varied study time, memory load, and label quality.	experiment 1: 36 elderly and 48 young adults experiments 2 and 3: 36 elderly and young adults	Older pts. had poorer recall than did younger subjects, regardless of who determined the study time. Both older and younger subjects recalled less information as more was presented. Both young and older pts. had difficulty understanding information from a community pharmacy but had better understanding when presented with a standard, high-quality label.
Zuccollo (1985) ¹²⁶	descriptive; pt. interviews and assessment of labels	container labels	How well do elderly pts. read and understand container labels?	60 British pts. and 163 medication labels	Only 40% of pts. had no difficulty reading instructions on the label. Scriptwriter typeface was least easy to read. About half of the labels were judged to have directions that were unclear.
OTC labels/DTCA					
Berry (2004) ⁹³	experiment; pt. questionnaire	OTC	Is risk communicated better numerically or verbally on OTC labels?	188 adults	Pts. overestimate risk in all cases, but overestimated it to a much greater extent when risk was presented verbally vs numerically.
Discenza (1992) ⁸⁰	RCT comparing 3 levels of warnings	OTC	How does the strength of warnings on labels affect intention to use medication?	252 volunteers attending business school	As warnings were more forceful and threatening, study participants reported they would be less likely to use the medication.

CMI = consumer medication information; DTCA = direct-to-consumer advertising; OTC = over-the-counter; RCT = randomized controlled trial; USP = United States Pharmacopoeia.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
OTC labels/DTCA					
Friedman (1997) ¹⁰³	controlled trial comparing 3 prototype labels	OTC	Are cholestyramine OTC labels comprehensible?	2225 randomly selected subjects from across the US	99% of subjects understood the key message that they should call the physician before using the drug and should read the full insert. They were able to follow directions 67–92% of the time. There were no statistically significant differences among labels with text, graphics, or symbols except that high school nongraduates had significantly lower comprehension with symbols.
Sansgiry (2001) ⁹⁴	experiment assessing degree of involvement	OTC	How does consumer involvement or hypothetical symptoms impact label understanding?	256 college students	Pts. more involved in purchase of OTC drugs (those with symptoms) understood the labels better than did those who were not involved. There was no difference between hypothetical symptoms of a cold or headache.
Sansgiry (1997) ¹⁰⁴	experiment assessing 4 label designs: pictures only, verbal only, congruent picture-verbal, and noncongruent picture-verbal	OTC	Does congruence between icons and text improve understanding and intention to buy medications?	48 elderly adults and 48 young adults	Congruence between the icons and verbal information on labels leads pts. to best understand the medication directions and increases the intention to purchase the drug.
Woloshin (2004) ¹³⁷	experiment; before and after comparison	DTCA information	Do pts. prefer to have access to a "benefit box" of quantitative risks and benefits for prescription drugs that are advertised?	203 subjects in New England communities	The benefit box was widely rated as useful and readable. When added to DTCA for rofecoxib, clopidogrel, and pravachol, pts. had a lower perception of efficacy after reading the benefit box.
Brass (2004) ¹²⁸	descriptive; pt. interview and lab tests	OTC	How well did pts. follow instructions on OTC label for cholesterol-lowering medication (the CUSTOM trial)	3316 pts. who self-selected to enroll	Only 44% of all pts. who self-selected the drug met LDL-C criteria; 24% had >20% 10 y coronary risks. Only 42% of pts. talked with their physicians before use.
Ciociola (2001) ⁹⁵	descriptive; recordings of drug use in a diary, tablet counts, and pt. interview	OTC	Do pts. understand OTC ranitidine labels?	1405 pts.	More than 84% of pts. understood contraindication of use, dose, and duration of another drug for PUD. 90% followed maximum daily dose instructions.
Kaphingst (2004) ¹¹¹	descriptive; expert evaluation of DTCA supplements	DTCA television ads and related Web sites	Is the information associated with DTCA readable?	23 supplements to television DTCA	Using SMOG assessments, text DTCA supplements were written at the high school level for the body sections and college level for the summary, with specific shortfalls in layout, typology, and graphics use.
Melin (2004) ¹²⁹	descriptive; pt. questionnaires and lab tests	OTC	Do pts. understand OTC label for Mevacor?	3316 pts. who self-selected to enroll	Pts. understood labels and LDL-C improved, but 23% of pts. demonstrated behavior that created the potential for suboptimal safety.
Nabors (2004) ⁹⁴	descriptive; pt. questionnaire	OTC	Do adolescents and young adults read or understand CMI?	876 high school and college students	75% of subjects read the labels. Those with "immediate health concerns" were most likely to read them. Students were interested in dosage, ADRs, and symptoms treated. (Note: pain was not statistically significant in multivariate models.)
Patel (2002) ⁸⁹	descriptive; pt. interview	OTC	How well do pts. interpret directions that require calculations?	oral rehydration therapy: 13 subjects OTC drops: 48 subjects OTC tabs: 31 subjects; subjects selected to have broad cultural and educational diversity	77% of subjects were unable to correctly administer oral rehydration therapy, and performance was weakly related to cultural background and education; 56% were unable to calculate appropriate doses for their children's cough syrup. Pts. had no difficulty in understanding the appropriate dose of the tablets, but 68% planned therapy schedules that led to incorrect doses.

ADRs = adverse drug reactions; CMI = consumer medication information; CUSTOM = Consumer Use Study of OTC Mevacor; DTCA = direct-to-consumer advertising; LDL-C = low-density lipoprotein cholesterol; OTC = over-the-counter; PUD = peptic ulcer disease; SMOG = Simplified Measure of Gobbledygook.

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adults were presented with 12 otherwise identical over-the-counter (OTC) drug bottles with varied container labels along 3 dimensions, one of which was font size (7 vs 10 point).⁸⁷ While younger participants performed equally well in the small and large font size label groups, elderly patients had significantly reduced recall and understanding after reading the small-font labels. Both young and elderly participants preferred the larger font labels. In another experiment with 19 young and 20 elderly patients, patients of all ages preferred labels written in larger font and reported that 14 point font was easier to read than 12 point, which was easier to read than 9 point.¹³⁴ This survey also found

that patients read labels with larger font more rapidly and accurately than labels with smaller font. Bernardini et al.¹¹⁶ surveyed 1004 Italian patients concerning CMI; 63% of the respondents requested larger font size than is currently seen in European leaflets, and almost 80% preferred that font size be 10 point or larger. Although this survey took place in Italy, it is likely that concern about font size is less sensitive to cultural norms and that the findings are likely representative of sentiments in the US.

One experiment evaluated patients' preferences for 3 font styles for medication labels (Century Schoolbook, Helvetica, and Courier) and found that patients preferred

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
OTC labels/DTCA					
Raymond (2002) ⁹⁰	descriptive; pt. survey	OTC	Do pts. understand an OTC label for the emergency contraceptive?	663 women	A prototype label was created; >85% of women understood 7 of 11 objectives. Worse comprehension was seen on an important safety-related topic (don't take if vaginal bleeding is present).
Sansgiry (1997) ¹⁰²	descriptive; assessed labels on criteria from guidelines	OTC	Did OTC label contents meet label readability guidelines (prior to the Drug Facts)?	100 labels, 103 subjects	Poor guideline adherence: use of small font (≤ 6 points on warnings and indications), all uppercase letters and use of hyphenation, lack of paragraph breaks or boldface; >40% contained advertising claims.
Thomas (1998) ⁹⁹	descriptive; evaluated using SMOG techniques	PEMs	Can pts. understand education materials about hormone replacement therapy?	27 PEMs	Pt. education materials were often hard to read and understand, ranging from grade 8 to grade 14 reading level (mean 10.8). Professional associations created the most readable PEMs.
Vigilante (1997) ¹³⁵	descriptive; pt. survey	OTC	Do pts. prefer medication information on labels to be presented in a particular order?	140 pts.; 3 stratified convenient samples that varied in age and educational status	Pts. have preferred order for items on the label: (1) indications, (2) hazards/warnings, (3) active ingredients.
PIs					
Brinker (2002) ¹¹⁴	descriptive; evaluation of pharmacy claims data	PIs	Do physicians prescribe in compliance with PIs when prescribing moxifloxacin?	793 700 pts.	Physicians prescribed moxifloxacin concomitantly with a contraindicated medication (amiodarone; 0.11%). This study shows that even physicians are frequently unaware of PIs when prescribing.
Smalley (2000) ¹²⁵	descriptive; evaluation of pharmacy claims data	PIs	Do pts. respond to black box warnings on cisapride by taking the drug more appropriately?	24 840 pts.	In the year subsequent to FDA action requiring a black box warning for cisapride, there was only a 2% reduction in inappropriate cisapride use in each of 3 sites, with rates of inappropriate use ranging from 24% to 58%.
Stearman Ross (2004) ¹¹³	descriptive; pt. and provider surveys	PIs	Are PIs for oral contraceptives readable?	94 pts. and 18 providers 34 expert reviews	Oral contraceptive PIs were frequently written at 10th to 12th grade levels and included substantial medical jargon. A new PI was created at the 6th grade level with simpler language.
Steinmetz (2005) ¹⁰⁹	descriptive; evaluation of PIs	PIs	What information about geriatric pts. is present on PIs?	50 PIs from the most prescribed oral medications at 1 university medical center	Approximately 50% of PIs contained precautionary statements for the elderly. Only 56% had dosing information and only 16% provided specific milligram amounts. More information is necessary about elderly dosing information on labels.
Willy (2004) ⁹²	descriptive; evaluation of PIs	PIs	How much variability is there in the PIs of drugs known to be hepatotoxic?	95 PIs	12% of PIs had hepatotoxic warnings in a black box, 54% in the warnings section, and 34% in the ADRs section. Mean informativeness score was 35%.
Marroum (2002) ¹¹⁵	review	PIs	How is pharmacokinetic and pharmacodynamic information reported?	NA	PIs present outdated and poor-quality information about pharmacokinetic and pharmacodynamic information to physicians. Proposed a new FDA rule to improve PIs.
ADRs = adverse drug reactions; FDA = Food and Drug Administration; NA = not applicable; OTC = over-the-counter; PEMs = patient education materials; PIs = package inserts; SMOG = Simplified Measure of Gobbledygook.					

Century Schoolbook.¹³⁴ In a descriptive survey of 60 elderly patients exposed to labels written with 5 different fonts, Scriptwriter font was considered the most difficult to read, and fonts that appeared larger were considered easier to read.¹²⁶ The survey by Bernardini et al.¹¹⁶ of patient preferences concerning CMI in Italy evaluated whether the color of print affects label readability. The investigators found that approximately 66% of respondents reported that, in general, they prefer labels to be printed in black and white. Yet the same patients noted that if colors were used, certain colors are more appropriate for certain sections of the patient leaflet; warnings and adverse effects were easier to identify when printed in red type. These findings did not suggest an overall preference for the use of color and did not address concerns about color-blindness.

Language

Two descriptive studies and one RCT have found that patients have more difficulty understanding vague versus precise medication directions.^{48,110,127} In a survey of medication leaflet comprehensibility for 30 commonly prescribed medications in 1060 Swedish patients, leaflets using more complex messages to communicate drug warnings and interactions were less comprehensible.¹¹⁰ In one RCT, researchers presented 260 students with medication labels that varied in the use of medical jargon and risk presentation.⁷⁷ The authors found that adherence intention was greater when the instructions were set in a negative frame (ie, the risks of nonadherence rather than the benefits of adherence) and when the language was simple and understandable, without medical terminology (ie, replacing "gastrointestinal problems" with "heartburn" on a label). The samples studied (Swedish and younger adults in the US) limit our ability to generalize the findings to a broader population.

Researchers in England performed a series of descriptive surveys to compare 2 risk communication approaches.⁷⁹ In 1998, the European Commission Pharmaceutical Guidelines required that every medicine be accompanied by a comprehensive leaflet, that a list of all known adverse effects be listed on those leaflets, and that the adverse effects be categorized into 5 verbal descriptors ranging from "very rare" to "very common." Researchers performed 4 patient surveys with a total of almost 850 participants to assess whether verbal versus numerical presentation of risk influences risk perception. In each of the surveys, patients substantially overestimated medication risks when they were presented in prose; estimation of risks was more accurate when they were presented numerically. While these studies evaluated the specific nomenclature adopted in Europe, concerns about the use of prose to communicate risk may be generalizable to other settings.

When presented with risk information, patients also request accurate benefit information. In a study of 203 pa-

tients presented with DTCA for common medications, patients were asked about their perceptions of the benefits of the medication.¹³⁷ Patients were then randomly assigned to receive the same DTCA with and without a "benefit box" that presented specific data concerning the expected benefits and risks of the drugs. Although patients had a lower perception of efficacy after reading the benefit box, approximately 93% reported that they preferred labels to include this risk and benefit information.

We found no evidence to assist with the problem of label production for patients who do not speak the languages used in the product information.

Use of Icons

Results concerning the use of icons have been mixed. One study found that a timeline icon improves patients' understanding of medication administration; however, it was helpful only when the icon was closely integrated with the text of the leaflet.¹⁰⁰ In children, icons were not found to improve understanding about medications.⁸⁵ In an RCT of 87 low-literacy patients in South Africa, patients given a leaflet with locally created, culturally sensitive icons were found to better understand (25% increase) and adhere to (18% increase) their medications compared with controls who received leaflets with no icons.¹²² Another study in the same population found that not all icons are equally effective, and patients understood locally created icons much better than typical icons from the US.¹²³

While one experimental study of 60 low-literate patients from South Africa found that the presence of icons significantly improved acquisition and comprehension of drug information,⁸⁶ another experiment with young and elderly adults in the US found that older patients have more difficulty understanding icons and icons did not improve readability in an elderly sample.¹⁰⁷ A more recent RCT found great variability in patients' interpretations of icons. A survey of 160 patients asked to interpret 10 icons found that patients interpreted between 7.5% and 90% correctly and that only 3 icons were understood by more than 85% of the participants.¹²¹ As a result, findings about icons are inconclusive, and further research is needed to explore the specific icons that most effectively communicate information to patients.

Containers

Three RCTs have evaluated the efficacy of methods to increase container label surface area. In one trial with young and elderly adults, container labels designed as tags or fold-out labels with greater surface area were easier to read and were preferred by patients.¹³³ When 60 older patients were exposed to a variety of OTC drug container designs, they preferred a design with a cap having an additional label that identified the drug and listed key informa-

tion.⁸¹ However, another trial evaluating the efficacy of fold-out labels found that they did not improve patient understanding about the medication.⁸⁷ The lack of consistent findings in these small studies with nonrepresentative samples makes it difficult to draw conclusions about the effect of newer container designs.

Discussion

This review of the literature points to several key components of both the content and format of prescription drug labels. When optimizing content, patients prefer information about the indication for the medication, expected benefits, duration of therapy, and a thorough list of potential adverse effects, in addition to typical information identifying the drug's name, directions for use, and warnings. When optimizing label format, lists, headers, and white space enhance readability, and content should be organized to follow the schema that patients use to understand medication information. The print should be the largest size possible of fonts that are easiest to read, and language should be simple, precise, and devoid of formal medical terminology. The evidence concerning the use of icons is mixed; only well-tested, culturally appropriate icons should be used and they should be carefully tested in elderly patients. New approaches to enhance container label surface area seem promising, but more study is needed. Table 3 summarizes label features for which we judged the evidence to strongly suggest benefit.

Although numerous studies have evaluated patients' perceptions about readability of medication labels and comprehension, there is limited evidence linking label design to patient outcomes such as adherence or safety. Our review is limited by our assumption of a significant relationship between readability, comprehension, and appropriate medication-taking behavior. While it seems reasonable to assume that if patients cannot read and comprehend medication labels they are less likely to be adherent, the nature of this relationship has not been well tested. Further studies evaluating the effects of label content and format should focus on their effects on medication-taking behavior (ie, adherence and error rates) and health outcomes. Additionally, many of the studies cited here were performed in a non-clinical setting; although many were randomized, they may not capture the true complexity of medication-taking in a real world setting in which patients may be taking multiple medications and have numerous competing demands. Future studies should be focused on the effects of label design in clinical settings.

Efforts to improve prescription drug labels are needed. A growing body of research has found that patients frequently misinterpret prescription drug labels. Challenges in reading and understanding labels may represent one cause for the high rates of medication errors and poor adherence. The extent to which deficits in labeling contribute to poor adherence or unsafe use of medications is unknown, but it is worth striving for improvements in these domains.

These findings come at an important time in the evolution of prescription drug labels. With the passage of the Medicare prescription drug benefit, the federal government plays an even greater role in purchasing prescription drugs. Federal payers will likely be increasingly interested in maximizing the safe and appropriate use of medications. To the extent that labeling practices can improve adherence and safety, efforts to improve prescription drug labels may have more traction. In addition, in 2007 the FDA will reevaluate whether quality and distribution guidelines for CMI are being met⁸⁸; evidence of poor outcomes could strengthen an argument for improving CMI. Future efforts to improve prescription drug labels should focus on the need for creative design but also should be grounded in the evidence about optimal label content and format.

These findings also raise important policy issues. Previous FDA policy has relied on private industry to self-regulate CMI and state laws to regulate container labels. Our findings suggest that certain content and format compo-

Table 3. Summary of Findings about Content and Format of Prescription Drug Labels

Items	Study Design	Outcomes Measured
Content to be included		
clinical indication for drug	3 observational studies	pt. preferences
administration instructions	3 observational studies	pt. preferences
thorough information about potential adverse effects	3 observational studies	pt. preferences
importance of adherence	2 systematic reviews	medication adherence
duration of therapy	1 observational study	medication continuation
language describing directions should be precise	2 observational studies and 1 RCT	pt. comprehension
information about benefits of medication	1 RCT	pt. preferences
numerical information about risk	4 observational studies	pt. comprehension
Format to be used		
lists	3 RCTs	label comprehension and recall
headers	3 RCTs	label comprehension, recall, and preferences
white space	1 RCT	pt. preferences
uniform schema that orders drug information	4 observational studies	medication recall
larger font size	2 RCTs and 1 observational study	label comprehension and recall
particular font styles	1 RCT and 1 observational study	label comprehension and recall

RCT = randomized controlled trial.

nents should be included on all labels, and minimum standards could be generated to enhance readability and comprehension of prescription drug information. The lack of any centralized oversight of CMI or container labels impedes the implementation of labeling improvements. Policymakers should consider developing clear standards for both the format and content of prescription drug labels to simplify patients' access to risk, benefit, and administration information about medications. Such strategies may improve the likelihood that patients will understand, safely administer, and adhere to their drug therapy.

Summary

We performed a systematic review of the published literature to evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. The evidence suggests that patients request information about a medication's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. There was little evidence to link label design or contents to measurable health outcomes, adherence, or safety.

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EXTRACTO

INTRODUCCIÓN: Los pacientes, especialmente los ancianos, tienen con frecuencia dificultades para leer y entender los prospectos, que pueden originar problemas con la adherencia a los tratamientos y con la seguridad de los mismos.

OBJETIVO: Intentamos evaluar las evidencias disponibles sobre el contenido y formato más adecuados de los prospectos para mejorar su legibilidad y comprensión y el uso de la medicación.

FUENTES DE DATOS: Se llevó a cabo una revisión sistemática de ensayos controlados aleatorios y revisiones sistemáticas de MEDLINE y la base de datos Cochrane (1990-junio 2005), también se revisaron las referencias bibliográficas de los artículos seleccionados y las referencias aportadas por un panel de expertos.

SELECCIÓN DE ESTUDIOS: Seleccionamos los estudios enfocados al contenido de la comunicación médico-paciente sobre medicamentos y al contenido y formato de los prospectos.

EXTRACCIÓN DE DATOS: Dos revisores extrajeron y sintetizaron los datos sobre diseño de los estudios, población, y resultados.

RESULTADOS: De 2009 artículos revisados, 36 de los orientados al contenido de la comunicación médico-paciente sobre los medicamentos y 69 relacionados con el contenido y formato de los prospectos cumplían los criterios de la revisión. Los pacientes solicitaron información sobre las indicaciones, los beneficios esperables, la duración del tratamiento, y los efectos adversos potenciales. Las evidencias disponibles sobre el formato del prospecto apoyan que el uso de letras de tamaño grande, listados con encabezado, espacios en blanco para separar los puntos relacionados, y la utilización de un lenguaje sencillo y una organización lógica de la información mejoran la legibilidad y la comprensión. No hay evidencias suficientes para apoyar el uso de pictogramas. Hay pocas evidencias que relacionen el diseño del prospecto a su contenido con resultados medibles en salud, adherencia a la medicación o seguridad de los tratamientos.

CONCLUSIONES: Existen evidencias que indican que un determinado formato y contenido de los prospectos facilita la comunicación y la comprensión de los pacientes. Los esfuerzos para mejorar los prospectos deben ser guiados por estos datos, aunque se necesitan estudios adicionales para valorar la influencia del diseño de los prospectos en la forma de tomar los medicamentos y en los resultados de salud. Existen distintas opciones para establecer normativas que exijan unos criterios mínimos para optimizar la terapéutica medicamentosa, particularmente teniendo en cuenta la nueva cobertura de medicamentos recetados de Medicare.

Juan del Arco

RÉSUMÉ

OBJECTIF: Les patients, plus particulièrement les personnes âgées, ont souvent de la difficulté à lire et à comprendre l'étiquetage des médicaments, ce qui pourrait causer des problèmes reliés à leur utilisation. Nous avons évalué les caractéristiques du contenu et de format optimaux des étiquettes de médicaments qui pourraient augmenter la lisibilité, la compréhension, et l'utilisation des médicaments.

SOURCE DES DONNÉES: Revue systématique des essais contrôlés à répartition aléatoire, d'études observationnelles et de recherches systématiques dans MEDLINE et dans la Cochrane Database (1990-juin 2005), jumelées aux références croisées et à des listes de références fournies par des experts.

SÉLECTION DES ÉTUDES ET EXTRACTION DES DONNÉES: Les études portant sur la communication entre les patients et le médecin concernant les médicaments et le contenu et format des étiquettes. Deux réviseurs ont extrait et synthétiser les données relatives aux plans des études, populations, et résultats.

SYNTHÈSE DES DONNÉES: De 2009 articles ont été évalués; 36 articles retenus portaient sur la communication sur les médicaments, et 69 autres sur le format et le contenu des étiquettes. Il a été démontré que les patients demandent de l'information sur les indications des médicaments, les bienfaits attendus, la durée de la thérapie et sur les effets indésirables. Les données sur le format des étiquettes suggèrent que l'utilisation de caractères plus gros, de listes, d'en-têtes, et davantage d'espaces vides en utilisant un langage clair, et une organisation logique pourraient augmenter la lisibilité et la compréhension. Par contre, les données n'étaient pas suffisantes pour suggérer l'utilisation d'icônes et de pictogrammes. Peu de données ont mis un lien en cause entre le format des étiquettes et un impact sur la santé, les résultats de la thérapie, l'observance ou la sûreté des médicaments.

CONCLUSIONS: Les données suggèrent sur le contenu et format de l'étiquetage des médicaments facilitent la communication et la compréhension de la part des patients. Des efforts devraient donc être faits en ce sens, même si d'autres études sont nécessaires pour évaluer l'impact sur l'utilisation et sur les résultats de santé. Plusieurs législations existent pour définir les standards minimaux visant à optimiser la thérapie médicamenteuse, particulièrement dans le contexte du nouveau programme de médicaments Medicare.

Nicolas Paquette-Lamontagne

Executive Summary

Understanding is a two-way street. —*Eleanor Roosevelt*

ABSTRACT

I have a very good doctor. He takes the time to explain things and break it down to me. Sometimes, though, I do get stuff that can be hard—like when I first came home from the hospital and I had all these forms and things I had to read. Some words I come across I just can't quite understand (National Center for the Study of Adult Learning and Literacy, 2003).¹

Nearly half of all American adults—90 million people—have difficulty understanding and acting upon health information. The examples below were selected from the many pieces of complex consumer health information used in America.

- *From a research consent form: "A comparison of the effectiveness of educational media in combination with a counseling method on smoking habits is being examined." (Doak et al., 1996)*

¹All vignettes in shaded text in this report represent actual stories or materials. Names were omitted in most cases to protect the privacy of the author, and stories may have been edited for brevity and clarity. If not otherwise attributed, vignettes were drawn from the experiences of members of the committee.

- From a consumer privacy notice: "Examples of such mandatory disclosures include notifying state or local health authorities regarding particular communicable diseases."
- From a patient information sheet: "Therefore, patients should be monitored for extraocular CMV infections and retinitis in the opposite eye, if only one infected eye is being treated."

Forty million Americans cannot read complex texts like these at all, and 90 million have difficulty understanding complex texts. Yet a great deal of health information, from insurance forms to advertising, contains complex text. Even people with strong literacy skills may have trouble obtaining, understanding, and using health information: a surgeon may have trouble helping a family member with Medicare forms, a science teacher may not understand information sent by a doctor about a brain function test, and an accountant may not know when to get a mammogram.

This report defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Ratzen and Parker, 2000). However, health literacy goes beyond the individual obtaining information. Health literacy emerges when the expectations, preferences, and skills of individuals seeking health information and services meet the expectations, preferences, and skills of those providing information and services. Health literacy arises from a convergence of education, health services, and social and cultural factors. Although causal relationships between limited health literacy and health outcomes are not yet established, cumulative and consistent findings suggest such a causal connection.

Approaches to health literacy bring together research and practice from diverse fields. This report examines the body of knowledge in this emerging field, and recommends actions to promote a health-literate society. Increasing knowledge, awareness, and responsiveness to health literacy among health services providers as well as in the community would reduce problems of limited health literacy. This report identifies key roles for the Department of Health and Human Services as well as other public and private sector organizations to foster research, guide policy development, and stimulate the development of health literacy knowledge, measures, and approaches. These organizations have a unique and critical opportunity to ensure that health literacy is recognized as an essential component of high-quality health services and health communication.

INTRODUCTION

A two-year-old is diagnosed with an inner ear infection and prescribed an antibiotic. Her mother understands that her daughter should take the prescribed medication twice a day. After carefully studying the label on the bottle and deciding that it doesn't tell how to take the medicine, she fills a teaspoon and pours the antibiotic into her daughter's painful ear. (Parker et al., 2003).

Modern health systems make complex demands on the health consumer. As self-management of health care increases, individuals are asked to assume new roles in seeking information, understanding rights and responsibilities, and making health decisions for themselves and others. Underlying these demands are assumptions about people's knowledge and skills.

National and international assessments of adults' ability to use written information suggest that these assumptions may be faulty. Current evidence reveals a mismatch between people's skills and the demands of health systems (Rudd et al., 2000a). Many people who deal effectively with other aspects of their lives may find health information difficult to obtain, understand, or use. While farmers may be able to use fertilizers effectively, they may not understand the safety information provided with the fertilizer. Chefs may create excellent dishes, but may not know how to create a healthy diet. Indeed, health literacy can be a hidden problem—because it is often not recognized by policy makers and health care providers, and because people with low literacy skills or who are confused about health care may be ashamed to speak up about problems they encounter with the increasingly complex health system (Baker et al., 1996; Parikh et al., 1996). Without improvements in health literacy, the promise of scientific advances for improving health outcomes will be diminished.

The Institute of Medicine (IOM) convened the Committee on Health Literacy, composed of experts from a wide range of academic disciplines and backgrounds, to assess the problem of limited health literacy and to consider the next steps in this field. The committee addressed the following charge:

1. Define the scope of the problem of health literacy. The intent is to clarify the root problems that underlie health illiteracy. This would include identifying the affected populations and estimating the costs for society. Develop a set of basic indicators of health literacy to allow assessment of the extent of the problem at the individual, community, and national levels.

2. Identify the obstacles to creating a health-literate public. These are likely to include the complexity of the health care system, the many and often contradictory health messages, rapidly advancing technologies, limits within public education to promote literacy of adults as well as children, etc.

3. Assess the approaches that have been attempted to increase health literacy both in the United States and abroad. Identify the gaps in research and programs that need to be addressed. The focus should be on public health interventions attempting to increase health literacy of the public rather than on improving health provider/primary care interactions.

4. Identify goals for health literacy efforts and suggest approaches to overcome the obstacles to health literacy in order to reach these goals. These might include research or policy initiatives, interventions, or collaborations that would promote health literacy.

WHAT IS HEALTH LITERACY?

In this report, the committee accepted the definition of health literacy presented by the National Library of Medicine (Selden et al., 2000) and used in *Healthy People 2010* (HHS, 2000):

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Ratzen and Parker, 2000).

Health literacy is a shared function of social and individual factors. Individuals' health literacy skills and capacities are mediated by their education, culture, and language. Equally important are the communication and assessment skills of the people with whom individuals interact regarding health, as well as the ability of the media, the marketplace, and government agencies to provide health information in a manner appropriate to the audience.

The committee developed a framework for health literacy which identifies three major areas of potential intervention and forms the organizational principle of this report (see Figure ES-1). This framework illustrates the potential influence on health literacy as individuals interact with educational systems, health systems, and cultural and social factors, and suggests that these factors may ultimately contribute to health outcomes and costs. The proposed framework is a model, because available research supports only limited conclusions about causality. However, the cumulative effect of a body of consistent evidence suggests that causal relationships may exist between health literacy and health outcomes. Research is needed to establish the nature of the causal relationships between and among the various factors portrayed in the framework.

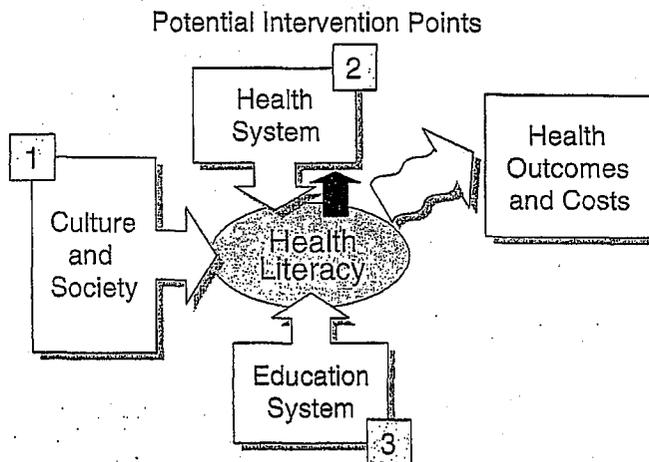


FIGURE ES-1 Potential points for intervention in the health literacy framework.

The committee reviewed the strengths and limitations of currently available measures of literacy and health literacy. Health literacy involves a range of social and individual factors, and includes cultural and conceptual knowledge, listening, speaking, arithmetical, writing, and reading skills. However, most of the tools currently available to measure health literacy primarily measure reading skills, and do not include other critical skills. Furthermore, adults' reading abilities are often estimated with a "grade level" measure, an estimate that is imprecise at best. Advancement of the field of health literacy requires the development of new measures which can be used to establish baseline levels and monitor change over time.

Finding 2-1 Literature from a variety of disciplines is consistent in finding that there is strong support for the committee's conclusion that health literacy, as defined in this report, is based on the interaction of individuals' skills with health contexts, the health-care system, the education system, and broad social and cultural factors at home, at work, and in the community. The committee concurs that responsibility for health literacy improvement must be shared by these various sectors. The committee notes that the health system does carry significant but not sole opportunity and responsibility to improve health literacy.

Finding 2-2 The links between education and health outcomes are strongly established. The committee concludes that health literacy may be

one pathway explaining the well-established link between education and health, and warrants further exploration.

Finding 2-3 Health literacy, as defined in this report, includes a variety of components beyond reading and writing, including numeracy, listening, speaking, and relies on cultural and conceptual knowledge.

Finding 2-4 While health literacy measures in current use have spurred research initiatives and yield valuable insights, they are indicators of reading skills (word recognition or reading comprehension and numeracy), rather than measures of the full range of skills needed for health literacy (cultural and conceptual knowledge, listening, speaking, numeracy, writing, and reading). Current assessment tools and research findings cannot differentiate among (a) reading ability, (b) lack of background knowledge in health-related domains, such as biology, (c) lack of familiarity with language and types of materials, or (d) cultural differences in approaches to health and health care. In addition, no current measures of health literacy include oral communication skills or writing skills and none measure the health literacy demands on individuals within different health contexts.

THE EXTENT AND ASSOCIATIONS OF LIMITED HEALTH LITERACY

Studies of health literacy or of literacy in health contexts suggest that limited health literacy skills, as measured by current assessment tools, are common, with significant variations in prevalence depending on the population sampled (see Chapter 3). People of all literacy levels may be able to manage texts that they frequently encounter and use for everyday activities, but will often face problems with difficult and confusing types of text (Kirsch et al., 1993).

Findings from the National Adult Literacy Survey (NALS) and International Adult Literacy Surveys (IALS) indicate that a large percentage of adults lack the literacy skills needed to meet the demands of twenty-first century society. More than 47 percent, or 90 million, of U.S. adults have difficulty locating, matching, and integrating information in written texts with accuracy and consistency. Of the 90 million with limited literacy skills, about 40 million can perform simple and routine tasks using uncomplicated materials. An additional 50 million adults can locate information in moderately complicated texts, make inferences using print materials, and integrate easily identifiable pieces of information. However, they find it difficult to perform these tasks when complicated by distracting information and complex texts (Kirsch, 2001; Kirsch et al., 1993).

These findings have serious implications for the health sector. Over 300

studies, conducted over three decades and assessing various health-related materials, such as informed consent forms and medication package inserts, have found that a mismatch exists between the reading levels of the materials and the reading skills of the intended audience. In fact, most of the assessed materials exceed the reading skills of the average high school graduate (Rudd et al., 2000a).

Studies suggest that while individuals with limited health literacy come from many walks of life, the problem of limited health literacy is often greater among older adults, people with limited education, and those with limited English proficiency (e.g., Beers et al., 2003; Gazmararian et al., 1999; Williams et al., 1995). For individuals whose native language is not English, issues of health literacy are compounded by issues of basic communication and the specialized vocabulary used to convey health information.

Associations with Health Knowledge, Behavior, and Outcomes

Research linking limited health literacy as it is currently measured to health knowledge, health behaviors, and health outcomes is accumulating. Patients with limited health literacy and chronic illness have less knowledge of illness management than those with higher health literacy (Kalichman et al., 2000; Schillinger et al., 2002; Williams et al., 1998a, b). Compared to those with adequate health literacy, patients with limited health literacy have decreased ability to share in decision-making about prostate cancer treatment (Kim et al., 2001), lower adherence to anticoagulation therapy (Lasater, 2003; Win and Schillinger, 2003), higher likelihood of poor glyce-mic control (Schillinger et al., 2002), and lower self-reported health status (Arnold et al., 2001; Baker et al., 2002; Kalichman and Rompa, 2000; Kalichman et al., 2000; Williams et al., 1998a, b).

Financial Associations of Limited Health Literacy

The limited amount of data available suggests that there is an association between health literacy, health-care utilization, and health-care costs. Baker and others (2002) found that public hospital patients with limited health literacy had higher rates of hospitalization than those with adequate health literacy. This increased hospitalization rate may be associated with greater resource use. Another analysis (Friedland, 1998) concluded that the additional health expenditure attributable to inadequate reading skills (as identified by the NALS) in 1996 was \$29 billion. This estimate would increase to \$69 billion if as few as half the individuals with marginal reading skills were also not health literate. Weiss and Palmer (2004) reported on a direct measure of cost in a small sample of Medicaid patients in

Arizona. Patients with reading levels at or below third grade had mean Medicaid charges \$7,500 higher than those who read above the third grade level.

For this report, David Howard examined the expenditure data collected in association with the Baker and colleagues (2002) utilization study (see Appendix B). He found that predicted inpatient spending for a patient with inadequate health literacy was \$993 higher than that of a patient with adequate reading skills. A difference of \$450 remained after controlling for health status, although the causality of the associations between health status and health-care cost could not be determined. In both analyses, higher emergency care costs were incurred by individuals with limited health literacy compared to those with marginal or adequate health literacy as measured by the Test of Functional Health Literacy in Adults (TOFHLA), while pharmacy expenses were similar and outpatient expenditures lower.

Although a robust estimate for the effect of limited health literacy on health expenditures is lacking, the magnitudes suggested by the few studies that are available underscore the importance of addressing limited health literacy from a financial perspective.

Finding 3-1 About 90 million adults, an estimate based on the 1992 NALS, have literacy skills that test below high school level (NALS Level 1 and 2). Of these, about 40–44 million (NALS Level 1) have difficulty finding information in unfamiliar or complex texts such as newspaper articles, editorials, medicine labels, forms, or charts. Because the medical and public health literature indicates that health materials are complex and often far above high school level, the committee notes that approximately 90 million adults may lack the needed literacy skills to effectively use the U.S. health system. The majority of these adults are native-born English speakers. Literacy levels are lower among the elderly, those who have lower educational levels, those who are poor, minority populations, and groups with limited English proficiency such as recent immigrants.

Finding 3-2 On the basis of limited studies, public testimony, and committee members' experience, the committee concludes that the shame and stigma associated with limited literacy skills are major barriers to improving health literacy.

Finding 3-3 Adults with limited health literacy, as measured by reading and numeracy skills, have less knowledge of disease management and of health-promoting behaviors, report poorer health status, and are less likely to use preventive services.

Finding 3-4 Two recent studies demonstrate a higher rate of hospitalization and use of emergency services among patients with limited literacy. This higher utilization has been associated with higher health-care costs.

THE CONTEXTS OF HEALTH LITERACY AND OPPORTUNITIES FOR INTERVENTION

Culture and Society

The hi'ola said Mom should confess to me and before God Jehovah. She did. She asked me to forgive her and I did. I wasn't angry. . . . And later Mom's sickness left her. Of course, she still had diabetes, but the rest—being so confused and miserable—all that left her (Shook, 1985: 109).

Culture is the shared ideas, meanings, and values that are acquired by individuals as members of a society. Culture is socially learned, continually evolves, and often influences us unconsciously. We learn culture through interactions with others, as well as through the tangible products of culture such as books and television (IOM, 2002). Culture gives significance to health information and messages, and can shape perceptions and definitions of health and illness, preferences, language and cultural barriers, care process barriers, and stereotypes. These culturally influenced perceptions, definitions, and barriers can affect how people interact with the health care system and help to determine the adequacy of health literacy skills in different settings.

The fluid nature of culture means that health-care encounters are rich with differences that are continuously evolving. Differing cultural and educational backgrounds between patients and providers, as well as between those who create health information and those who use it, may contribute to problems in health literacy. Culture, cultural processes, and cross-cultural interventions have been discussed in depth in several recent IOM reports and represent possible nexuses of culture and health literacy (IOM, 2002, 2003a).

It is important to understand how people obtain and use health information in order to understand the potential impact of health literacy. Information about health is produced by many sources, including the government and the food and drug industries, and is distributed by the popular media. Commercial and social marketing of health information, products, and services is a multibillion dollar industry. People are frequently and repeatedly exposed to quick, often contradictory bits of information. This

inundation with information has increased as the Internet has become an increasingly important source of health information. Socioeconomic status, education level, and primary language all affect whether consumers will seek out health information, where they will look for the information, what type of information they prefer, and how they will interpret that information. Limited health literacy decreases the likelihood that health-related information will be accessible to all (Houston and Allison, 2002).

Finding 4-1 Culture gives meaning to health communication. Health literacy must be understood and addressed in the context of culture and language.

Finding 4-2 More than 300 studies indicate that health-related materials far exceed the average reading ability of U.S. adults.

Finding 4-3 Competing sources of health information (including the national media, the Internet, product marketing, health education, and consumer protection) intensify the need for improved health literacy.

Finding 4-4 Health literacy efforts have not yet fully benefited from research findings in social and commercial marketing.

The Educational System

Adult education is an important resource for individuals with limited literacy or limited English proficiency. A major source of support for American adult education programs in literacy is the U.S. adult basic education and literacy (ABEL) system. ABEL programs provide classes in topics that support health literacy including basic literacy and math skills, English language, and high school equivalence, and predominantly serve students with literacy and math skills in NALS Levels 1, 2, or the low end of NALS Level 3. Sadly, these programs serve far fewer than the millions of Americans who could benefit.

Both childhood literacy education and childhood health education can provide a basis for health literacy in adulthood. Although most elementary, middle, and high schools require students to take health education, the sequence of coursework is not coordinated. The percentage of schools that require health education increases from 33 percent in kindergarten to 44 percent in grade 5, but then falls to 10 percent in grade 9, and 2 percent in grade 12. The absence of a coordinated health education program across grade levels may impede student learning of needed health literacy skills. Furthermore, only 9.6 percent of health education classes have a teacher

who majored in health education or in combined health and physical education (Kann et al., 2001).

In 1995, the Joint Committee on National Health Standards published the *National Health Education Standards* with the subtitle *Achieving Health Literacy*. These standards describe the knowledge and skills essential for health literacy, and detail what students should know and be able to do in health education by the end of grades 4, 8, and 11. They provide a framework for curricula development and student assessment. Unfortunately, these standards have not been widely met.

Finding 5-1 Significant obstacles and barriers to successful health literacy education exist in K-12 education programs.

Finding 5-2 Opportunities for measuring literacy skill levels required for health knowledge and skills, and for the implementation of programs to increase learner's skill levels, currently exist in adult education programs and provide promising models for expanding programs. Studies indicate a desire on the part of adult learners and adult education programs to form partnerships with health communities.

Finding 5-3 Health professionals and staff have limited education, training, continuing education, and practice opportunities to develop skills for improving health literacy.

Health Systems

Health systems in the United States are complex and often confusing. Their complexity derives from the nature of health care and public health itself, the mix of public and private financing, and the variations across states and between types of delivery settings. An adult's ability to navigate these systems may reflect this systemic complexity in addition to individual skill levels. Even highly skilled individuals may find the systems too complicated to understand, especially when these individuals are made more vulnerable by poor health. Directions, signs, and official documents, including informed consent forms, social services forms, public health information, medical instructions, and health education materials, often use jargon and technical language that make them unnecessarily difficult to use (Rudd et al., 2000b). In addition, cultural differences may affect perceptions of health, illness, prevention, and health care. Lack of mutual understanding of health, illness and treatments, and risks and benefits has implications for behavior for both providers and consumers, and legal implications for providers and health systems. Imagine having to face this complexity if you

are one of the 90 million American adults who lack the functional literacy skills in English to use the U.S. health care system.²

Health literacy permeates all areas of the provider–consumer information exchange, and provides a common pathway for the successful transfer of information. A number of emerging areas are likely to increase the burden of limited health literacy on those entering and using the health-care system. These include demands inherent in chronic disease management, increased use of new technologies, decreased time for patient/provider discussions, and legal and regulatory requirements.

Many different interventions and approaches that may hold promise for addressing limited health literacy are being attempted across health-care systems, professional organizations, federal and state agencies, educational institutions, and community and advocacy groups across the United States and in other countries. Those profiled in the report are indicators of the creativity and promise for future improvements in countering the effects of limited health literacy. However, few of these approaches have been formally evaluated, and most are fragmented single approaches rather than part of a systematic approach to health literacy. In order for progress to be made, many more systematic demonstrations must be funded and rigorously evaluated.

Finding 6-1 Demands for reading, writing, and numeracy skills are intensified due to health-care systems' complexities, advancements in scientific discoveries, and new technologies. These demands exceed the health-literacy skills of most adults in the United States.

Finding 6-2 Health literacy is fundamental to quality care, and relates to three of the six aims of quality improvement described in the IOM Quality Chasm Report: safety, patient-centered care, and equitable treatment. Self-management and health literacy have been identified by IOM as cross-cutting priorities for health-care quality and disease prevention.

Finding 6-3 The readability levels of informed consent documents (for research and clinical practice) exceed the documented average reading levels of the majority of adults in the United States. This has important ethical and legal implications that have not been fully explored.

VISION FOR A HEALTH-LITERATE AMERICA

The evidence and judgment presented in this report indicate that health literacy is important to improving the health of individuals and popula-

²See Finding 3-1.

tions. This is supported by the conclusions and statements of others. Health literacy was one of two cross-cutting factors that affect health care identified by the IOM in its recent report *Priority Areas for National Action in Quality Improvement* (IOM, 2003b). The Surgeon General recently stated that "health literacy can save lives, save money, and improve the health and well being of millions of Americans . . . health literacy is the currency of success for everything I am doing as Surgeon General" (Carmona, 2003).

More needs to be known about the causal pathways between education and health, the role of literacy, and the discrete contribution of health literacy to health. With this knowledge we will be able to understand which interventions and approaches are the most appropriate and effective. This Committee believes that a health-literate America is an achievable goal. We envision a society within which people have the skills they need to obtain, interpret, and use health information appropriately and in meaningful ways. We envision a society in which a variety of health systems structures and institutions take responsibility for providing clear communication and adequate support to facilitate health-promoting actions based on understanding. We believe a health-literate America would be a society in which:

- Everyone has the opportunity to improve their health literacy.
- Everyone has the opportunity to use reliable, understandable information that could make a difference in their overall well-being, including everyday behaviors such as how they eat, whether they exercise, and whether they get checkups.
 - Health and science content would be basic parts of K-12 curricula.
 - People are able to accurately assess the credibility of health information presented by health advocate, commercial, and new media sources.
 - There is monitoring and accountability for health literacy policies and practices.
 - Public health alerts, vital to the health of the nation, are presented in everyday terms so that people can take needed action.
 - The cultural contexts of diverse peoples, including those from various cultural groups and non-English-speaking peoples, are integrated in to all health information.
 - Health practitioners communicate clearly during all interactions with their patients, using everyday vocabulary.
 - There is ample time for discussions between patients and health-care providers.
 - Patients feel free and comfortable to ask questions as part of the healing relationship.
 - Rights and responsibilities in relation to health and health care are presented or written in clear, everyday terms so that people can take needed action.

- Informed consent documents used in health care are developed so that all people can give or withhold consent based on information they need and understand.

While achieving this vision is a profound challenge, we believe that significant progress can and must be made over the coming years, so that the potential for optimal health can benefit all individuals and populations in our society.

Recommendation 2-1 The Department of Health and Human Services and other government and private funders should support research leading to the development of causal models explaining the relationships among health literacy, the education system, the health system, and relevant social and cultural systems.

Recommendation 2-2 The Department of Health and Human Services and public and private funders should support the development, testing, and use of culturally appropriate new measures of health literacy. Such measures should be developed for large ongoing population surveys; such as the National Assessment of Adult Literacy Survey, Medical Expenditure Panel Survey, and Behavioral Risk Factor Surveillance System, and the Medicare Beneficiaries Survey, as well as for institutional accreditation and quality assessment activities such as those carried out by the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance. Initially, the National Institutes of Health should convene a national consensus conference to initiate the development of operational measures of health literacy which would include contextual measures.

Recommendation 3-1 Given the compelling evidence noted above, funding for health literacy research is urgently needed. The Department of Health and Human Services, especially the National Institutes of Health, Agency for Healthcare Research and Quality, Health Resources and Services Administration, the Centers for Disease Control and Prevention, Department of Defense, Veterans Administration, and other public and private funding agencies should support multidisciplinary research on the extent, associations, and consequences of limited health literacy, including studies on health service utilization and expenditures.

Recommendation 4-1 Federal agencies responsible for addressing disparities should support the development of conceptual frameworks on the intersection of culture and health literacy to direct in-depth theoretical explorations and formulate the conceptual underpinnings that can guide interventions.

4-1.a The National Institutes of Health should convene a consensus conference, including stakeholders, to develop methodology for the incorporation of health literacy improvement into approaches to health disparities.

4-1.b The Office of Minority Health and Agency for Healthcare Research and Quality should develop measures of the relationships between culture, language, cultural competency, and health literacy to be used in studies of the relationship between health literacy and health outcomes.

Recommendation 4-2 The Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Indian Health Service, the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration should develop and test approaches to improve health communication that foster healing relationships across culturally diverse populations. This includes investigations that explore the effect of existing and innovative communication approaches on health behaviors, and studies that examine the impact of participatory action and empowerment research strategies for effective penetration of health information at the community level.

Recommendation 5-1 Accreditation requirements for all public and private educational institutions should require the implementation of the National Health Education Standards.

Recommendation 5-2 Educators should take advantage of the opportunity provided by existing reading, writing, reading, oral language skills, and mathematics curricula to incorporate health-related tasks, materials, and examples into existing lesson plans.

Recommendation 5-3 The Health Resources and Services Administration and the Centers for Disease Control and Prevention, in collaboration with the Department of Education, should fund demonstration projects in each state to attain the National Health Education Standards and to meet basic literacy requirements as they apply to health literacy.

Recommendation 5-4 The Department of Education in association with the Department of Health and Human Services should convene task forces comprised of appropriate education, health, and public policy experts to delineate specific, feasible, and effective actions relevant agencies could take to improve health literacy through the nation's K-12 schools, 2-year and 4-year colleges and universities, and adult and vocational education.

Recommendation 5-5 The National Science Foundation, the Department of Education, and the National Institute of Child Health and Human Development should fund research designed to assess the effectiveness of different models of combining health literacy with basic literacy and instruction. The Interagency Education Research Initiative, a federal partnership of these three agencies, should lead this effort to the fullest extent possible.

Recommendation 5-6 Professional schools and professional continuing education programs in health and related fields, including medicine, dentistry, pharmacy, social work, anthropology, nursing, public health, and journalism, should incorporate health literacy into their curricula and areas of competence.

Recommendation 6-1 Health care systems, including private systems, Medicare, Medicaid, the Department of Defense, and the Veterans Administration should develop and support demonstration programs to establish the most effective

Continued

tive approaches to reducing the negative effects of limited health literacy. To accomplish this, these organizations should:

- Engage consumers in the development of health communications and infuse insights gained from them into health messages.
- Explore creative approaches to communicate health information using printed and electronic materials and media in appropriate and clear language. Messages must be appropriately translated and interpreted for diverse audiences.
- Establish methods for creating health information content in appropriate and clear language using relevant translations of health information.
- Include cultural and linguistic competency as an essential measure of quality of care.

Recommendation 6-2 The Department of Health and Human Services should fund research to define the needed health literacy tasks and skills for each of the priority areas for improvement in health care quality. Funding priorities should include participatory research which engages the intended populations.

Recommendation 6-3 Health literacy assessment should be a part of health-care information systems and quality data collection. Public and private accreditation bodies, including Medicare, the National Committee for Quality Assurance, and the Joint Commission on Accreditation of Healthcare Organizations should clearly incorporate health literacy into their accreditation standards.

Recommendation 6-4 The Department of Health and Human Services should take the lead in developing uniform standards for addressing health literacy in research applications. This includes addressing the appropriateness of research design and methods and the match among the readability of instruments, the literacy level, and the cultural and linguistic needs of study participants. In order to achieve meaningful research outcomes in all fields:

- Investigators should involve patients (or subjects) in the research process to ensure that methods and instrumentation are valid and reliable and in a language easily understood.
- The National Institutes of Health should collaborate with appropriate federal agencies and institutional review boards to formulate the policies and criteria to ensure that appropriate consideration of literacy is an integral part of the approval of research involving human subjects.
- The National Institutes of Health should take literacy levels into account when considering informed consent in human subjects research. Institutional Review Boards should meet existing standards related to the readability of informed consent documents.

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Low Literacy Impairs Comprehension of Prescription Drug Warning Labels

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BACKGROUND: Adverse events resulting from medication error are a serious concern. Patients' literacy and their ability to understand medication information are increasingly seen as a safety issue.

OBJECTIVE: To examine whether adult patients receiving primary care services at a public hospital clinic were able to correctly interpret commonly used prescription medication warning labels.

DESIGN: In-person structured interviews with literacy assessment.

SETTING: Public hospital, primary care clinic.

PARTICIPANTS: A total of 251 adult patients waiting for an appointment at the Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) Primary Care Clinic.

MEASUREMENTS: Correct interpretation, as determined by expert panel review of patients' verbatim responses, for each of 8 commonly used prescription medication warning labels.

RESULTS: Approximately one-third of patients ($n=74$) were reading at or below the 6th-grade level (low literacy). Patient comprehension of warning labels was associated with one's literacy level. Multistep instructions proved difficult for patients across all literacy levels. After controlling for relevant potential confounding variables, patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly (95% confidence interval: 2.3 to 4.9).

CONCLUSIONS: Patients with low literacy had difficulty understanding prescription medication warning labels. Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple-step instructions. Warning labels should be developed with consumer participation, especially with lower literate populations, to ensure comprehension of short, concise messages created with familiar words and recognizable icons.

KEY WORDS: literacy, warning labels, prescription drug labels, medication error, patient comprehension, lexile.

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Adverse events resulting from improper medication administration are a serious concern.¹ Patients are increasingly managing multiple prescription and over-the-counter medications; therefore, patient understanding is essential for proper adherence.^{2,3} This issue is relevant to the majority of adults in the United States; two-thirds of all adults use prescription drugs, representing 16% (\$73 billion) of all health care expenditures.⁴ According to the Medical Expenditure Panel Survey (MEPS), the average adult in the United States

fills 9 prescriptions annually. This number is even higher among adults over 65 years of age, who fill an average of 20 prescriptions a year.⁴

Low literacy may be an overlooked contributing factor to patient misuse of prescription medications. The Institute of Medicine's recent report, *A Prescription to End Confusion*, indicates that 90 million adults in the United States have trouble understanding and acting on health care information.⁵ Shame may prevent individuals with limited literacy from telling providers they need help with medication instructions.⁶ The recently released National Assessment of Adult Literacy (NAAL), the most accurate measurement of literacy in America today, found that adults who are socioeconomically disadvantaged belong to racial/ethnic minority groups, and/or are elderly are disproportionately hindered by such literacy barriers.⁷ These individuals are also more likely to be in poorer health and may be taking multiple medications.

The purpose of this descriptive study was to identify factors associated with patient understanding of prescription drug warning labels (PWLs). We hypothesized that low literacy would be associated with incorrect interpretations of PWLs.

METHODS

Subjects

Study participants were patients aged 18 and older attending the Primary Care Clinic (PCC) at Louisiana State University Health Sciences Center—Shreveport (LSUHSC) during July 2003. Patients were ineligible if they had severe visual or hearing impairments, were too ill to participate, or were non-English speaking. The LSUHSC Institutional Review Board approved the study and all patients gave informed consent for participation. A total of 276 patients were approached before the medical encounter, and 273 consented to participation. Twenty-two patients were excluded based on self-reported impairments with hearing ($n=5$) or vision ($n=12$), English as a second language ($n=3$), or incomplete information ($n=2$). A total of 251 patients participated in the study.

Structured Interview and Literacy Assessment

Interviews with community pharmacists ($N=9$) and primary care physicians ($N=5$) were conducted to identify the most important PWLs for patients to understand. Through consensus, 8 PWLs were identified for study inclusion; all were developed by the most commonly used pharmaceutical labeling software package.⁸

A trained research assistant (RA) administered a structured interview that included self-report of sociodemographic

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information (age, gender, race/ethnicity, education, source of payment for medications). Color copies (actual size) of each of the 8 PWLs were then shown in the same order to all of the patients for review. To assess patient comprehension, the RA asked "what does this label mean to you?" for each PWL. The RA then documented the verbatim response on a separate form. A panel of physicians and pharmacists trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message. For quality assurance, an additional RA, blinded to patient information (including literacy) and following the same panel guidelines, independently reviewed all patient responses to the 8 labels ($N=2,008$). The RAs were unable to score 317 (15.8%) responses as either correct or incorrect. An expert panel that included 3 physicians, a clinical psychologist, and a pharmacist reviewed and graded the uncoded responses. Each member was blinded to subjects' literacy level, and decisions were made by majority rule.

After the patient had provided his or her interpretation on all of the PWLs, the RA administered the Rapid Estimate of Adult Literacy in Medicine (REALM), a health word recognition test that is the most common measure of adult literacy in medical settings.^{9,10} The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (TOFHLA).^{9,11}

Lexile Score

We used a measure of reading difficulty termed Lexile Framework to gauge reading level for the text on each PWL.¹²⁻¹⁵ Lexile scores are based on sentence length and word frequency in the popular literature, with higher values indicating higher levels of reading difficulty. The possible range of these scores is from below 0 (representing a beginning reading level) to 2000. A program available to registered users over the internet, called the Lexile Analyzer, calculated the Lexile score for each warning label text.¹² These values can be easily translated to corresponding reading grade levels. For instance, a Lexile value of 300 corresponds to a 2nd-grade level of reading difficulty, 400 to 3rd grade, and 1,300 to a 12th-grade level.

Analysis Plan

All statistical analyses were performed using STATA, version 8.0 (College Station, TX). Descriptive statistics were calculated for each variable. Chi-square or ANOVA tests were used to evaluate the association between literacy, sociodemographic characteristics, and correct interpretation of each of the 8 PWLs. In multivariate analyses, the 8 binary repeated responses per subject were modeled using a generalized linear model with logit link. A generalized estimating equation (GEE) approach was used to adjust model coefficients and standard errors for within-patient correlation.^{16,17} The final multivariate model included potential confounding variables age, gender, race/ethnicity, number of medications currently taken, and the additional risk factor of Lexile score. Patient literacy was classified either as low (6th grade and below), marginal (7th to 8th grade), or functional (9th grade and higher). Patient age was categorized by tertiles (<45, 45 to 64, ≥65), and Lexile score by quartiles (2 labels per category; ≤3rd grade, 4th to 5th grade, 6th to 7th grade, and ≥8th grade).

RESULTS

Among the 251 respondents, 70.9% were female and 66.1% African American. Patients ranged in age from 18 to 86, with a mean age of 47.2 years (S.D. =14.9). Patient literacy was limited; 29.5% were reading at or below a 6th-grade level (low literacy) and 31.1% were reading at the 7th to 8th grade level (marginal literacy). Forty-two percent of patients reported that they did not graduate from high school or receive a graduate equivalency diploma (GED).

Respondents were taking an average of 3 prescription medications, and nearly two-thirds (64.5%) lacked insurance for prescription medications. Low literacy was associated with male gender ($P<.05$), African-American race ($P<.001$), and less education ($P<.001$) (Table 1). No significant differences were reported between literacy level and age or source of payment for medications.

Lexile scores for each PWL were calculated and are listed in Table 2. Correct interpretation of the warning labels varied according to reading difficulty and complexity, with correct interpretation rates ranging from 83.7% for the simplest label (*Take with Food*, Lexile =beginning reading) to 7.6% for a label with multistep instructions (*Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*, Lexile =1,110). Patients with low literacy skills were less able to correctly interpret the meaning of 7 of the 8 warning labels, with the exception of the most basic single-step instruction, *Take with food* (Table 2). Patients who were 65 years of age and older were less able to correctly interpret the PWL, *Do not drink alcoholic beverages when taking this medication* ($P<.05$). No statistically significant differences in rates of correct interpretation of PWL were noted by number of prescription medications currently taken by patients. Verbatim examples of the most common incorrect interpretations for each of the PWLs by patients are detailed in Table 3.

Table 1. Patient Characteristics by Literacy Level

Characteristic	Literacy Level			P value
	≤6th grade (n=74)	7th to 8th grade (n=78)	≥9th grade (n=99)	
Age, mean (SD)	50.0 (15.5)	47.6 (15.0)	44.9 (14.2)	NS
Female, %	60.8	70.5	78.8	<.050
Race/ethnicity, %				<.001
African American	89.2	76.9	40.4	
White	9.5	20.5	56.6	
Other	1.3	2.6	4.0	
Education, %				<.001
Grades 1 to 8	21.6	6.4	4.0	
Grades 9 to 11	42.0	37.2	20.2	
Completed high school/GED	33.8	43.6	40.4	
>High school	2.7	12.8	35.4	
Payment source for medications, %				NS
Private insurance	5.4	6.4	12.1	
Medicaid	5.4	7.7	9.1	
Out of pocket	58.1	71.8	63.6	
Other	16.2	14.1	15.2	
Medications taken daily; mean (SD)	2.9 (0.62)	3.5 (0.40)	2.8 (0.21)	NS

NS, not significant ($P>.05$).

GED, graduate equivalency diploma.

Table 2. Percent of Respondents Correctly Interpreting Warning Labels by Literacy Level

Label (Lexile, Grade Level)	Literacy Level			P value
	≤ 6th grade (n=74)	7th to 8th grade (n=78)	≥ 9th grade (n=99)	
One-step instructions				
Take with food (<0, BR*)	78.4	85.9	85.9	NS
Do not chew or crush, swallow whole (600, 5th grade)	46.0	84.6	77.8	<.001
Medication should be taken with plenty of water (520, 4th grade)	36.5	73.1	65.7	<.001
Do not drink alcoholic beverages when taking this medication (870, 8th grade)	41.9	65.4	59.6	<.010
For external use only (100, <1st grade)	8.1	64.1	77.8	<.001
Multi-step instructions				
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication (1,300, 12th grade)	4.1	35.9	35.4	<.001
Refrigerate, shake well, discard after (date) (800, 7th grade)	8.1	18.0	22.2	<.050
Do not take dairy products, antacids, or iron preparations within 1 hour of this medication (1,110, 10th grade)	0.0	6.4	14.1	<.010

*BR, beginning reading; Text with a Lexile score of 0 or below.
NS, not significant ($P > .05$).

Multivariate analyses identified low literacy as a significant independent predictor of incorrect interpretation of warning labels (adjusted odds ratio [AOR] 3.4, 95% CI 2.3 to 4.9). Other factors associated with incorrect interpretation of PWLs included older age (65 and older), higher Lexile score (6th-grade reading difficulty and above), and male gender (Table 4). No interactions between literacy, Lexile

score, age, number of medications taken, and race were significant.

DISCUSSION

This is the first study to our knowledge to evaluate the relationship between patient literacy skills and correct

Table 3. Common Examples of Misinterpretations of Prescription Drug Warning Labels

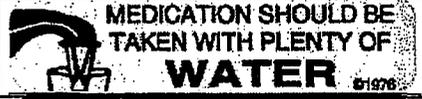
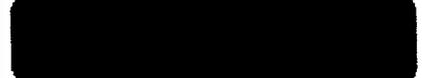
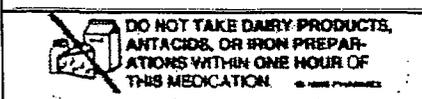
Labels	Misinterpretations
 TAKE WITH FOOD © 1990	Don't take food
	Chew pill and crush before swallowing Chew it up so it will dissolve, don't swallow whole or you might choke Just for your stomach
 MEDICATION SHOULD BE TAKEN WITH PLENTY OF WATER © 1976	Don't take when wet Don't drink hot water Don't need water
	Don't drink and drive Don't drink alcohol, it's poison and it'll kill you
	Use extreme caution in how you take it Medicine will make you feel dizzy Take only if you need it
 YOU SHOULD AVOID PROLONGED OR EXCESSIVE EXPOSURE TO DIRECT AND/OR ARTIFICIAL SUNLIGHT WHILE TAKING THIS MEDICATION. © 1986	Don't leave medicine in the sun Don't leave [medicine] in sunlight, but a cool place
 REFRIGERATE-SHAKE WELL DISCARD AFTER _____	Keep medicine chilled Mix it well, discard when done
 DO NOT TAKE DAIRY PRODUCTS, ANTACIDS, OR IRON PREPARATIONS WITHIN ONE HOUR OF THIS MEDICATION. © 1986 PHARMACEUTICALS	If allergic to dairy, don't take medicine Don't eat for one hour after taking medicine

Table 4. Generalized Estimating Equation (GEE) Model for Incorrect Interpretation of Warning Labels

Variable	OR	95% CI	AOR	95% CI
Literacy level				
≥ 9th grade (Functional)	1.0	Referent	1.0	Referent
7th to 8th grade (Marginal)	1.1	0.8, 1.4	0.9	0.7, 1.3
≤ 6th grade (Low)	3.2	2.4, 4.3	3.4	2.3, 4.9
Age, y				
< 45	1.0	Referent	1.0	Referent
45 to 64	1.0	0.8, 1.3	1.1	0.8, 1.4
≥ 65	1.6	1.0, 2.4	1.7	1.1, 2.8
Race				
White	1.0	Referent	1.0	Referent
African American	1.8	1.4, 2.3	1.3	0.9, 1.8
Gender				
Female	1.0	Referent	1.0	Referent
Male	1.4	1.0, 1.8	1.3	1.0, 1.8
Number of prescription medications currently taken				
≥ 3	1.0	Referent	1.0	Referent
1 to 2	0.9	0.7, 1.2	1.0	0.7, 1.3
None	1.1	0.8, 1.5	1.3	0.9, 1.9
Lexile score, reading level				
≤ 3rd grade	1.0	Referent	1.0	Referent
4th to 5th grade	1.1	0.9, 1.4	1.2	0.9, 1.5
6th to 7th grade	3.7	3.0, 4.7	4.3	3.3, 5.6
≥ 8th grade	10.4	8.0, 13.6	12.9	9.6, 17.5

OR, odds ratio; CI, confidence interval; AOR, adjusted odds ratio.

interpretation of warning labels routinely used with prescription medications. Low literacy was significantly associated with more than a 3 times greater likelihood of incorrect interpretation of PWLs. Our findings indicate that these warning labels are not likely to be useful to patients in their current form, especially those with low literacy skills, and could result in misuse of medications (e.g., the text message: *Do not chew or crush, swallow whole* vs the patient interpretation of *Chew pill and crush before swallowing*).

The Lexile score (reading difficulty) attributed to each PWL was also a significant independent predictor of patient comprehension. Labels with text written at the 6th- to 7th-grade level were 4.3 times more likely to be interpreted incorrectly, and PWLs that had text written at the 8th-grade level and above were 12.9 times more likely to be interpreted incorrectly compared with PWLs that had text written at the 3rd-grade level or below. These findings suggest that existing recommendations by health educators that patient information materials be written below an 8th-grade level should be revised.¹⁸⁻²⁰ Instead, a more appropriate goal for health information in print might be a Lexile score below a 6th-grade level.

Most patients in our study were able to understand simple, routine tasks using uncomplicated words, such as the label, *Take with food*. However, the single-step label, *For external use only*, was written at a 1st-grade level and yet proved difficult for many patients, especially those with low literacy skills. Possibly this was due to the fact that this PWL does not clearly state a specific action to be taken and uses unfamiliar wording or concepts. Over half of low literate patients could not properly interpret moderately complicated messages such as *Do not drink alcoholic beverages when taking this medication* (written at a 7th- to 8th-grade level), and people across all literacy levels found it challenging to fully comprehend unfamiliar and complex, multistep health instructions written at a high school level (e.g., *Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*).

The awareness of the impact of low literacy on health and health care has led to increased attention to "health literacy." Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.⁵ The IOM Patient Safety Report (2000), *To Err is Human*, stresses that health literacy is an essential aspect of addressing patient safety and is fundamental to quality care.¹ The 2004 IOM Report on Health Literacy and recent literature note a growing discordance among individual reading skills and the increasingly complex demands of the health care system, particularly the demands on patients and families in managing chronic diseases.^{5,21,22} Low literacy has been strongly linked to higher rates of hospitalization and use of emergency services,^{23,24} poorer understanding of one's medical condition,^{25,26} poorer adherence to medical instructions,^{27,28} and worse health outcomes.^{21,29} In our study, low literacy is related to limited understanding and misinterpretation of warning labels, and therefore may be a factor in unintentional nonadherence and therapeutic failure. Incomplete understanding of labels may be an unrecognized contributor to the estimated 2% to 11% of hospital admissions in the United States caused by misuse of prescription medications.³⁰

The elderly may be especially vulnerable to misunderstanding of prescription labels and instructions. Our finding that adults over 65 were less likely to interpret PWLs correctly is supported by previous studies that examined comprehension of medication instruction labels.³¹⁻³⁴ The elderly comprise an increasingly larger portion of the population and consume 2 to 3 times more medication than the general public. They are also more likely to have lower literacy skills.⁷

Study limitations should be noted. First, participation was limited to patients proficient in the English language. However, 2 of 3 prescription medication warning labels currently used by the majority of pharmacies in the United States are only available in English.⁸ Second, patients were sampled from a public hospital, which may limit the generalizability of findings. However, patients in the sample reflect a group disproportionately affected by poor health outcomes, and whose health and health care is targeted for improvement by Healthy People 2010.³⁵ Finally, sample size may have limited the ability to detect significant and clinically meaningful relationships in the multivariate analyses.

The Food and Drug Administration (FDA), the American Pharmaceutical Association (APA), the American Society of Health-System Pharmacists (ASHSP), and the National Association of Boards of Pharmacy (NABP) are increasingly directing attention to the quality of drug labels and accompanying patient educational handouts.³⁶⁻⁴² All of these organizations agree that for the information to be useful for the consumer, it must be read and understood before it can be acted upon. However, evidence-based evaluation of these goals is limited.⁴³⁻⁴⁵

Our findings suggest that there is a need for improving prescription drug warning labels. The U.S. Food and Drug Administration (FDA) has supported the development of useful consumer information and established standard guidelines for over-the-counter medication. Similar standards are needed for PWLs. The development process for warning labels needs to involve consumers, especially those with low literacy, and take advantage of tools such as the Lexile Framework and knowledge gained through patient education literature to produce warning labels that convey information that all patients can understand.

Misunderstanding of prescription drug warning labels among patients with low literacy

MICHAEL S. WOLF, TERRY C. DAVIS, HUGH H. TILSON, PAT F. BASS III, AND RUTH M. PARKER

Nearly half of the adult population in the United States lack the reading and numeracy skills required to process, understand, and act on health information.¹ Forty million U.S. adults are reading at the lowest levels of literacy proficiency and may have profound difficulty understanding health information for their own or a loved one's needs.^{2,3} Prior studies have linked low literacy to a poor understanding of one's medical condition and nonadherence to medical instructions.⁴⁻⁷

Individuals with low literacy skills may be at particular risk for misunderstanding information on pharmaceutical drug labels and package inserts, thus misusing these medications.^{8,9} Recent concern over patient safety has increased awareness of the poor quality of consumer information describing proper use of medications and associated risks.^{10,11} This has led to an expanded interest in the causes of medication-related errors, from a focus on physician or health care system failure to analysis of potential patient errors.⁸⁻¹² As health care delivery continues to shift from

Purpose. The common causes for misunderstanding prescription drug warning labels (PWLs) among adults with low literacy were studied.

Methods. A total of 74 patients reading at or below the sixth-grade level and receiving care at the primary care clinic at the Louisiana State University Health Sciences Center in Shreveport were recruited to participate in structured interviews. Patients were asked to interpret and comment on eight commonly used warning labels found on prescription medications. Correct interpretation was determined by expert panel review of patients' verbatim responses. Qualitative methods were employed to code responses and generate themes regarding the misunderstanding of these PWLs.

Results. Among this sample of patients with low literacy skills, rates of correct interpretation for the eight warning labels ranged from 0% to 78.7%. With the exception of the most basic label, less than half of all patients were able to provide adequate interpretations of the warning label mes-

sages. Five themes were derived to describe the common causes for misunderstanding the labels: single-step versus multiple-step instructions, reading difficulty of text, use of icons, use of color, and message clarity. Labels were at greater risk for being misunderstood if they included multiple instructions, had a greater reading difficulty, included unfamiliar terms, or used confusing icons that were discordant with text messages. Participants also frequently imposed an incorrect meaning on label colors, which led to further confusion.

Conclusion. Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

Index terms: Comprehension; Labeling; Patients; Prescriptions; Readability
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inpatient to outpatient settings, the burden of quality control over proper medication use will also shift from provider to patient.^{1,9,13,14} An alarm-

ing trend has already emerged as a result: between 1983 and 1993, there was a ninefold increase in deaths due to outpatient medication errors in

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the United States.¹⁵ A recent study reported that 28% of emergency department visits are drug related, with over two thirds of these visits deemed preventable and 24% resulting in hospital admission.¹⁶

The Food and Drug Administration (FDA), along with the American Pharmacists Association, the American Society of Health-System Pharmacists, and the National Association of Boards of Pharmacy (NABP), is directing greater attention to the quality of labels on prescription and nonprescription drugs and accompanying patient educational handouts and package inserts.¹⁷⁻²³ In 1997, the Keystone Dialogue, initiated by the Department of Health and Human Services and the abovementioned organizations, was charged with developing an action plan for improving medication information and labeling.²⁴ One of the many recommendations made was to directly involve consumers to ensure that information included on medication labels and package inserts could be properly understood by patients across all literacy levels.

Our research team previously investigated the quality of prescription drug warning labels (PWLs) that appear as stickers placed on the outside of medication bottles.⁸ These adhesive labels are widely used and provide important information regarding the safe administration of prescription medications. Failure to heed the warnings or special instructions on these labels could lead to a loss of drug potency or a change in the rate of absorption of the medication. As a consequence, patients may become ill or gain little or no treatment benefit from taking the prescribed drug.²⁵ For example, many long-acting antihypertensive agents should be swallowed whole, as chewing or crushing them would intensify the dose and could possibly cause acute hypotension.

Our findings revealed very low rates of comprehension of PWLs and

that low literacy was a significant independent predictor of an incorrect interpretation of their meaning. In the present study, the causes for misunderstanding text and icons found on eight commonly used PWLs among patients reading at or below the sixth-grade level (low literacy) were explored.

Methods

Subjects. Study participants were adult patients who attended the primary care clinic (PCC) at the Louisiana State University Health Sciences Center—Shreveport (LSUHSC) in July 2003. The PCC is a public hospital clinic that serves an indigent adult population. Seventy-five percent of PCC patients are African American, 50% are female, 25% receive Medicaid, and 5% have private insurance. Patients were ineligible for study inclusion if they were under 18 years of age; if a physician or a trained research assistant (RA), through the course of an interview, identified them as having hearing problems or a visual impairment not correctable with eyeglasses; if they were too ill to participate; or if they did not speak English.

The LSUHSC institutional review board approved this study, and oral informed consent was obtained from all participants. Patients were approached by one of five RAs immediately after seeing their physician for a routine, scheduled visit. Each RA had been specifically trained by one of three study investigators to administer a literacy assessment, conduct a structured research interview, and objectively rate patient interpretations of PWLs. The RA described the study to patients and sought their participation. If patients agreed, the RA orally reviewed informed-consent procedures and administered the survey instrument and literacy assessment.

Structured interview and literacy assessment. A structured interview was developed to assess correct in-

terpretation of eight common medication warning labels developed by Pharmex, the largest U.S. pharmacy supplier of adhesive warning labels. After patients orally consented to the study, an RA administered the structured interview that included self-report of sociodemographic information (age, sex, race, education, and source of payment for medications). Color copies (actual size) of each PWL were then shown to each patient in the same order. After the patients had provided their interpretation of all eight PWLs, the RA administered a brief literacy assessment, concluding the interview. The entire protocol took approximately 15 minutes per patient.

To assess patient comprehension for each PWL, the RA asked each patient what the label meant. The RA would follow by asking several probing questions about specific attributes of the label (i.e., what is the picture saying?, is the picture helpful?, what do you think about the color of the label?, do the different colors mean different things to you?). The RA then documented the verbatim responses on a separate form, and these responses were later transcribed for content analysis.

The RAs rated each response as either correct or incorrect, using stringent guidelines developed by a panel of pharmacists and physicians. The panel trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message and an incorrect score if the patient's response was inaccurate or contained only a partial meaning of the message. For quality assurance, an additional RA, blinded to patient information (including literacy) and following the same panel guidelines, independently reviewed all patient responses to the eight labels. If the two RAs produced discordant ratings, an expert panel consisting of a pharmacist, two general internal medicine physicians, and two behavioral scientists with expertise in

health literacy made a determination based on majority rule.

At the end of the structured interview, patients' literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test of 66 health-related words.²⁶ Reading recognition tests are useful predictors of general reading ability of English. Using the REALM, raw scores (0–66) can be converted into one of four reading grade levels: third grade or less (0–18), fourth to sixth grade (19–44), seventh to eighth grade (45–60), and ninth grade or above (61–66). The REALM, which can be administered and scored in less than three minutes, is the most commonly used test of patient literacy in medical settings.²⁷ The REALM is highly correlated with standardized reading tests, including the Wide Range Achievement Test—Revised (WRAT-R) ($r = 0.88$), the Slosson Oral Reading Test—Revised (SORT-R) ($r = 0.96$), and the Peabody Individual Achievement Test—Revised (PIAT-R) ($r = 0.97$).^{26,27} The REALM is also highly correlated with the Test of Functional Health Literacy in Adults (TOFHLA) ($r = 0.84$).²⁸

Lexile score. We used a Lexile framework to gauge the reading level for the text on each PWL.²⁹ Lexile scores are based on sentence length and word frequency in popular literature, with higher values indicating higher levels of reading difficulty. The possible range of scores is below 0 (representing a beginning reading level) to 2000. A program available to registered users over the Internet, called the Lexile Analyzer (Metra-Metrics, Inc., Durham, NC), was used to calculate the Lexile score for each label's text. These values can be easily translated to corresponding reading grade levels. For instance, a Lexile score of 300 might correspond to a second-grade reading level, 400 to a third-grade level, and 1300 to a 12th-grade level.

Data analysis. Statistical analyses were conducted using STATA, ver-

sion 8.0 (Stata Corp., College Station, TX). Descriptive statistics were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and correct interpretation (yes or no) of each of the eight PWLs. For qualitative analyses, a grounded theory approach was used to explore the basis for patients' incorrect interpretations of each of the eight PWLs using their documented verbatim responses. Grounded theory, according to Strauss and Corbin,³⁰ is a systematic method for generating theoretical statements from case studies. Based on our qualitative, cognitive interviews, grounded theory guides the inductive process of organizing content derived from patient responses. For this study, patients' misinterpretations were reviewed and classified using both predetermined and emergent coding schemes. The qualitative data were coded according to predetermined factors, including text difficulty, use of icons, and use of color. Responses were then examined for additional coding of emergent factors.

Results

Of the 1162 patients seen at the PCC in July 2003, 276 were asked to participate in the study. Of these, 3 refused participation, 17 were excluded based on self-reported impairments with hearing ($n = 5$) or vision ($n = 12$), 3 were excluded because English was their second language, and 2 were excluded due to incomplete information. A total of 251 patients were assessed for literacy. Of these 251, 74 were reading at the sixth-grade level or below and were included in our study.

The characteristics of study participants are detailed in Table 1. The mean \pm S.D. age for the participants was 50.0 ± 15.5 years (range, 19–81 years). Most patients were African American, older, and female, with the average REALM score corre-

sponding to approximately the fifth-grade reading level. Approximately one third of patients had completed high school or received a general equivalency diploma. The mean \pm S.D. number of prescription medications patients were taking was 2.9 ± 0.6 (range, 0–15).

Label comprehension. Rates of correct interpretation of the eight PWLs ranged from 0% to 78.7% (Table 2). With the exception of the label "Take with food," less than half of all patients were able to provide adequate interpretations of the warning labels' messages. None of the respondents were able to correctly interpret the label "Do not take dairy products, antacids, or iron preparations within one hour of this medication."

Compared with patients reading at the fourth- to sixth-grade level, those with very low literacy skills (reading at or below the third-grade level) were less able to correctly interpret six of the eight labels (Table 3). No significant differences in correct interpretation were noted by age, sex, number of years of education, race, payment method, number of medications currently taken, or the two literacy categories.

Causes of misunderstandings.

The types of misunderstanding of PWLs by patients with low literacy were first determined by preselecting a coding scheme for the likely cause leading to misunderstanding and then allowing additional causes to emerge within the qualitative review process. Predetermined causes included single-step versus multiple-step instructions, reading difficulty of text, use of icons, and use of label color. One emergent cause of misunderstanding PWLs was identified and referred to as message clarity.

Single-step versus multiple-step instructions. Three of the eight PWLs were considered by the expert panel as having multiple precautions or steps instructing proper use of the medication. These included "Refrigerate, shake well, discard after

(date),” “Do not take dairy products, antacids, or iron preparations within one hour of this medication,” and “You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this

medication.” Rates of comprehension among patients were the lowest for these PWLs (8.0%, 0%, and 5.3%, respectively). Respondents frequently became confused when interpreting the multiple-step instructions or did

not address all messages of the PWL in their response (Table 2).

Reading difficulty of text. Overall, comprehension was lowest for two PWLs that had higher Lexile scores: “You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication” (Lexile score = 1300) and “Do not take dairy products, antacids, or iron preparations within one hour of this medication” (Lexile score = 1110). Both labels were written at a high school level or higher. Comprehension was highest for the label “Take with Food,” which was written at below the first-grade level.

Use of icons. Many of the icons used on the PWLs appeared to confuse patients. This was especially true if the text was difficult to comprehend. On the label “For external use only,” the pictogram was often interpreted as “radioactive,” “chills or shaking,” or “take anywhere.” One patient’s interpretation clearly relied on the pictogram and not the text: “Medicine will make you feel dizzy.” For the label “Do not chew or crush, swallow whole,” interpretations of the icon itself included “someone

Table 1. Participant Characteristics (n = 74)

Characteristic	No. (%)
Female	45 (61)
Race	
African American	66 (89)
White	7 (10)
Other	1 (1)
Literacy level	
3rd grade or below	28 (38)
4th–6th grade	46 (62)
Highest grade completed	
Grades 1–8	16 (22)
Grades 9–11	34 (46)
High school or GED ^a	21 (29)
Secondary education	3 (4)
Payment source for medications	
Private insurance	16 (22)
Medicaid	5 (7)
Self-pay	45 (61)
Other	8 (11)
Sources of medication information ^b	
Physician	53 (72)
Pharmacist	33 (45)
Family	16 (22)

^aGED = general equivalency degree.

^bParticipants could list multiple sources.

Table 2. Prescription Drug Warning Labels and Respondent Interpretations (n = 74)

Label	Lexile Score/ Grade Level	No. (%) Participants With Correct Interpretations	Incorrect Interpretations
Take with food	BR ^a	58 (78)	Don't take food; bread with food
For external use only	100/1st grade	7 (9)	Use extreme caution in how you take it; medicine will make you feel dizzy; take only if you need it; for adults not kids
Medication should be taken with plenty of water	520/4th grade	28 (38)	Don't take when wet; don't drink hot water; don't need water
Do not chew or crush; swallow whole	600/5th grade	35 (47)	Chew it up so it will dissolve; don't swallow whole or you might choke; just for your stomach; have something on medicine before you take it
Refrigerate—shake well. Discard after _____	800/7th grade	6 (8)	Keep medicine chilled; mix it well, discard when done; put in refrigerator
Do not drink alcoholic beverages when taking this medication	870/8th grade	31 (42)	Don't drink and drive; don't drink alcohol, it's poison and it'll kill you
Do not take dairy products, antacids, or iron preparations within one hour of this medication	1110/10th grade	0	If allergic to dairy, don't take medicine; don't eat for one hour after taking medicine
You should avoid prolonged or excessive exposure to direct or artificial sunlight while taking this medication	1300/12th grade	4 (5)	Don't leave medicine in the sun; don't leave [medicine] in sunlight, but a cool place

^aBR = beginning reading, the term used in the Lexile Framework to convey a reading level below the first grade.

Table 3.
Literacy Level of Respondents Who Correctly Interpreted Prescription Drug Warning Labels

Label	No. (%) Participants		p
	Third Grade or Below (n = 28)	Fourth to Sixth Grade (n = 46)	
Take with food	17 (61)	41 (89)	0.003
For external use only	0	7 (15)	0.032
Medication should be taken with plenty of water	4 (14)	24 (52)	0.001
Do not chew or crush, swallow whole	5 (18)	30 (65)	<0.001
Refrigerate, shake well, discard after (date)	0	6 (13)	0.049
Do not drink alcoholic beverages when taking this medication	6 (21)	24 (54)	0.004
Do not take dairy products, antacids, or iron preparations within one hour of this medication	0	0	NS ^a
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	1 (4)	2 (4)	NS

^aNS = not significant.

swallowed a nickel,” “indigestion,” and “a bladder.” For PWLs that conveyed multiple steps for proper compliance, such as “Refrigerate, shake well, discard after (date),” icons were not able to convey all aspects of the text. The icon (a refrigerator) used on this label addressed only the first step of the instruction, and common incomplete responses to the PWL were subsequently limited: “keep medicine chilled” and “put in refrigerator.”

Use of label color. Many patients attributed the use of color to the severity of the label’s message. Patients reported that red meant danger; yellow translated to caution; and blue, white, and green labels were viewed as “recommendations” that were not as severe or important as the instructions on red labels. Thirty-one patients (41.9%) applied this cognitive valuation of color to the PWLs.

Message clarity. Text messages on certain PWLs, regardless of Lexile score, were not understood by most patients. For example, “For external use only” had a very low Lexile score (approximately first-grade level) but proved difficult for 90.7% of respon-

dents. For other labels, it was apparent that only a part of the message could be interpreted. For the PWL “Do not chew or crush, swallow whole,” some patients provided interpretations that suggested they had read some but not all of the words on the label (e.g., “do not swallow whole,” “chew it up so it will dissolve”). Often, patient interpretations of several PWLs were reliant on the pictogram, which led to discordance between the text and icon messages. For instance, many patients derived opposing meanings for the PWL “Do not chew or crush, swallow whole,” such as “Don’t swallow whole or you might choke.”

Discussion

Adhesive PWLs were originally developed to highlight important instructions for the safe use of a medication that were contained within the longer package insert and to be visible every time the patient picked up the medication bottle. These labels are important, considering that many consumers report not reading the longer and more complicated package insert.^{31,32} Among our sam-

ple of patients with low literacy skills, less than a third (28.7%) reported reading the package inserts that are routinely distributed with prescription medications.

Overall, the eight PWLs in this study were not helpful to patients with low literacy skills. The majority of patients misinterpreted all labels with the exception of “Take with food.” The causes for misunderstanding were attributed to one or a combination of problems associated with label text (word choice, message length, and number of steps for action), icons, and color. In fact, our findings indicated that some PWLs may inadvertently promote a misunderstanding of safety information that could potentially lead to hazardous administration of the drug and an adverse reaction. This scenario was most notable on the label “Do not chew or crush, swallow whole,” which was interpreted as “do not swallow whole” and “chew it up so it will dissolve.”

The example above also highlights a cognitive process that is common among individuals with low literacy skills. These patients may seek out and identify one or two words in print materials that they tentatively recognize and induce meaning from these words.³³ This often leads to an improper placement of the message context, as “swallow” or “chew” was recognized but the opposite action was interpreted. Similarly, adults with low literacy may misread a central word in the message, such as the word “external” in “For external use only.” Several patients interpreted the message as “use extreme caution.” In this scenario, these adults recognize the first few letters of the word and make an educated guess to decipher the whole word. These individuals lack the vocabulary and reading skills to further grasp the entire content of the message. Adults with low literacy skills may therefore rely more heavily on icons and colors to interpret the meaning of labels, but

these may also mislead or confuse patients.

Though all of the text on the PWLs was brief, some was unnecessarily complex (“You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication”) or vague (“medication should be taken with plenty of water”). Some terms reflect lay or professional jargon and may not be universally understood (“iron preparations,” “dairy products,” “antacids”). Consumers with low literacy need more concrete and specific instructions to respond accordingly.³³⁻³⁵ In addition, the font size and boldfacing of words varied widely, and often the words emphasized were not central to the action requested. This may cause patients with reading difficulties to take these messages out of context. Finally, all letters in these PWLs were capitalized, despite recommendations that uppercase and lowercase text be used to improve accessibility among beginning readers.³³⁻³⁵

Limitations. This study had several limitations. First, participation was limited to English-speaking patients. However, the majority of PWLs currently used in the United States are only available in English. Second, patients were sampled from one public hospital, which may limit the generalizability of findings. However, patients in the sample reflected a group disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010.³⁶ Finally, the sample size limited the ability to detect significant and clinically meaningful relationships within subgroups, such as differences across age groups. Previous studies found that older adults were less able to comprehend prescription labels compared with younger adults.^{37,38} Another study found that 67% of elderly persons did not fully understand the information on the drug labels.⁹ Less than 5% of patients in

our sample were 75 years of age or older.

Opportunities for improvement. Over the past decade, improvements have been sought to make the general prescription drug label and any patient information included in package inserts more accessible to all consumers.^{1,10,39} We offer the following steps as a road map to move from policy to practice, providing direction for the development of new messages, icons, and labels to better convey these important warnings and dosage instructions.

Develop standards, regulations, and guidelines. The Federal Food, Drug, and Cosmetic Act of 1938 provides FDA with regulatory oversight to mandate reform for the general drug label and package inserts.⁴⁰ However, these adhesive warning labels have not been viewed within the scope of this act, were not included in the Keystone Dialogue, and have largely been ignored by FDA, manufacturers, and other organizations. The development and use of PWLs should become an essential component of package labeling and should receive regulatory oversight to ensure that standards are in place for their continued development and use. Recognizing that such national regulation will take time, and realizing the urgency posed by the clear evidence of misunderstanding and the potential for harm, concerted voluntary action is needed. NABP and the Pharmaceutical Research and Manufacturers of America should develop consensus guidelines to ensure safe and consistent messages through PWLs.

Involve consumers. Consumers need to be actively involved in the development of new PWLs to ensure that the icon design, words, and formatting are useful to all individuals, including those with low literacy. Intensive cognitive testing of patients of all literacy levels should be conducted to confirm the appropriate meaning of text, icons, and color.

Feedback from pharmacists and physicians, who may counsel patients on the safe administration of prescription medications and eventually distribute and explain the revised labels, should also be sought.

Seek universal acceptance and consistent use of label icons. Several companies currently produce PWL stickers for U.S. pharmacies. As a result, different icons have been developed to convey similar messages regarding medication administration. Therefore, patients may be exposed to multiple PWLs and icons for the same medication if they fill prescriptions at more than one pharmacy or if their pharmacy changes label vendors. Icons should be consistent and universal acceptance of their meaning sought.

Train professionals in literacy issues and communication. Pharmacists, physicians, and other health care professionals should be oriented to this approach to supplemental labels to ensure that they, too, are communicating a consistent message. Specifically, the pharmacist may be the first to recognize problems with patient literacy and proper understanding of how to safely use prescription medications. However, pharmacists should be educated to the larger problem of health literacy and learn simple ways for both recognizing patients at risk and responding accordingly.⁴¹ Low literacy communications training modules currently exist that could provide pharmacists with useful skills, such as the “teach back” technique to confirm patients’ understanding of medication instructions, including those listed on warning labels.⁴²

Simplify text used on labels. Reading difficulty formulas, such as the Lexile Framework, should be used as a starting point to gauge the complexity of the print message on PWLs. However, these formulas should be used with more comprehensive assessments³³⁻³⁵ that focus on other contributing factors to reading

ease, such as organization, complexity, and clarity.³³

Minimize the action sought per label. Our findings suggest that multiple-step instructions on PWLs should be avoided when possible. For instance, the PWL "Do not take dairy products, antacids, or iron preparations within one hour of this medication" might be divided into three separate messages. For the label "Refrigerate, shake well, discard after (date)," it may be important to include multiple icons rather than one that only addresses the first action.

Give meaning to color and standardize its use. Consumers, like those in our study, may impose a "traffic light" color scheme to a label and its message. We recommend limiting the number of colors used and applying a consistent color scheme to different messages. For instance, messages conveying a warning or restriction might use red and yellow colors, and PWLs that provide instructions could be printed on white labels.

Aim for message concordance across languages. While some PWLs have translations in Spanish, many do not, and it is not clear how message concordance was achieved across languages for these labels. A systematic approach to the development and translation of PWLs across languages needs to be established. Existing resources are available to guide the translation process.⁴³ Cultural considerations should specifically be addressed, including semantic differences associated with both text and icons within a language.

Conclusion

Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

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Literacy and Misunderstanding Prescription Drug Labels

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Background: Health literacy has increasingly been viewed as a patient safety issue and may contribute to medication errors.

Objective: To examine patients' abilities to understand and demonstrate instructions found on container labels of common prescription medications.

Design: Cross-sectional study using in-person, structured interviews.

Setting: 3 primary care clinics serving mostly indigent populations in Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois.

Patients: 395 English-speaking adults waiting to see their providers.

Measurement: Correct understanding of instructions on 5 container labels; demonstration of 1 label's dosage instructions.

Results: Correct understanding of the 5 labels ranged from 67.1% to 91.1%. Patients reading at or below the sixth-grade level (low literacy) were less able to understand all 5 label instructions. Although 70.7% of patients with low literacy correctly stated the instructions, "Take two tablets by mouth twice daily," only 34.7%

could demonstrate the number of pills to be taken daily. After potential confounding variables were controlled for, low (adjusted relative risk, 2.32 [95% CI, 1.26 to 4.28]) and marginal (adjusted relative risk, 1.94 [CI, 1.14 to 3.27]) literacy were significantly associated with misunderstanding. Taking a greater number of prescription medications was also statistically significantly associated with misunderstanding (adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥ 5 medications).

Limitations: The study sample was at high risk for poor health literacy and outcomes. Most participants were women, and all spoke English. The authors did not examine the association between misunderstanding and medication error or evaluate patients' actual prescription drug-taking behaviors.

Conclusions: Lower literacy and a greater number of prescription medications were independently associated with misunderstanding the instructions on prescription medication labels.

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Reducing adverse events associated with medication errors in the ambulatory care setting remains an important patient safety objective for physicians and for the health care community at large (1-7). Although much attention has been directed to medication-related errors attributed to physician or system failure (1, 8-10), patient-initiated errors in medication use have received less recognition. As the focus on health care delivery continues to shift from inpatient to outpatient settings, the practice of quality control over medication use is becoming more the responsibility of the patient and less the responsibility of the provider. Yet, patients do not always take medications as prescribed, and as a result, outpatient adverse drug events are common (4-6).

Previous studies have found that many patients are not receiving oral or written instructions from their physicians and pharmacists on how to appropriately manage prescription medications (11, 12). As a result, instructions on the prescription container label assume greater importance. The Institute of Medicine (13) estimates that 90 million adults in the United States may have trouble understanding and acting on health information. Medication container labels, in particular, may be confusing and difficult to comprehend for many patients (14-18).

The incidence of patient medication errors is likely to increase, because Americans are taking more prescription medications annually (19). The physician and the pharmacist may assume that their patients can read, understand, and act on brief instructions found on prescription medication labels, but this may not be the case (11-13). The

purpose of this study was to examine whether adult primary care patients were able to read and correctly state how they would take various medicines after reviewing label instructions on actual pill bottles. We hypothesized that low literacy would be associated with higher rates of misunderstanding and incorrect demonstration.

METHODS

Participants

Study participants were adult patients who attended 1 of 3 outpatient primary care clinics that predominantly serve indigent community populations in 3 distinct cities and states (Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois). Participant recruitment took place in Shreveport, Louisiana, during July 2003 and at the remaining 2 sites during July 2004. In Shreveport, the primary care clinic was situated within a public hospital, whereas the clinics in Chicago and Jackson are both federally qualified health centers that provide care to medically underserved neighborhoods.

See also:

Print

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Conversion of tables into slides

Context

Low literacy contributes to medical and drug nonadherence.

Contribution

The authors tested patients in indigent communities to see how well they understood pill bottle labels. Patients with lower literacy levels and those taking a greater number of medications were less able to understand the meaning of the labels. Even among patients who understood the labels, only a minority could correctly demonstrate how to take the pills.

Cautions

Patients' actual drug-taking behaviors were not observed, so the authors could not demonstrate a link between misunderstanding and medication errors.

Implications

Lower literacy and a greater number of medications being taken were associated with patient misunderstanding of pill bottle labels.

—The Editors

Patients were considered eligible for the study if they were 18 years of age or older and were considered ineligible if the clinic nurse or study research assistant (during the course of the interview) identified a patient as having 1 or more of the following conditions: 1) severely impaired vision, 2) hearing problems, 3) illness too severe to participate, and 4) inability to speak English. The institutional review boards at all locations approved the study. All participants provided informed consent. A total of 458 patients were approached in the order they arrived at the clinics and before the medical encounter; 446 consented to participate in the study. Seventeen patients were excluded on the basis of self-reported impairments in hearing ($n = 5$) or vision ($n = 12$). Nine patients were excluded because they spoke English as a second language, and 25 additional patients were excluded on the basis of incomplete information. In all, 395 patients participated in the study. A response rate was determined following the American Association for Public Opinion Research standards (20), which estimated that 91.6% of approached eligible patients participated in the study.

Structured Interview and Literacy Assessment

A structured "cognitive" interview protocol was developed to assess patients' understanding the instructions of 5 common prescription medication container labels. Interviews were conducted with 6 primary care physicians and 1 hospital pharmacist to identify common medication prescriptions for acute and chronic health conditions. Through these interviews, a consensus was reached and 5 medications were identified for the study, including 2 anti-

biotics (amoxicillin [for pediatric use] and trimethoprim); an expectorant (guaifenesin); an antihypertensive, channel-blocking agent (felodipine); and a diuretic (furosemide).

After patients consented to participate in the study, a trained research assistant administered the structured interview that included self-report of sociodemographic information (age, sex, race and ethnicity, education, source of payment for medications, and number of prescription medications currently taken daily). Actual prescription pill bottle containers with labels were then shown in the same order to all of the patients for review. Once the patient provided his or her interpretation of all of the labels, the research assistant administered a brief literacy assessment, which concluded the interview.

Understanding Medication Container Label Instructions

To assess patient understanding of the instructions on each of the 5 prescription medication labels, the research assistant asked, "How would you take this medicine?" The patient's verbatim response was then documented on a separate form. All patient responses ($n = 1975$) to the instructions for each of the 5 medications were then independently rated as either correct or incorrect by 3 general internal medicine attending physicians from 3 academic medical centers. Each physician-rater was blinded to all patient information and was trained to follow stringent coding guidelines previously agreed on by the research team. Specifically, correct scores were to be given only if the patient's response included all aspects of the label's instruction, including dosage; "timing"; and if applicable, duration. Responses were given an incorrect score if they were inaccurate or if they did not contain all aspects of the instructions.

Interrater reliability was high among the 3 physicians who coded the patient responses ($\kappa = 0.85$). The 147 responses (7.4%) that received discordant ratings among the 3 reviewers were sent to an expert panel for further review. This panel included 3 primary care physicians and 2 behavioral scientists with expertise in health literacy. Each panel member, also blinded to patient information, independently reviewed and coded the responses as correct or incorrect. For 76.2% ($n = 112$) of the 147 responses, a consensus ruling was achieved among the 5-member panel for a final ruling on the coding of those responses. For the remaining 35 patient responses, a majority rule was imposed and the rating by a minimum of 3 panel members was used to determine the scores.

In a final review, responses that were coded as incorrect were qualitatively reviewed by 3 research assistants, who were trained by the expert panel members to code the responses according to the nature of the misunderstanding (incorrect dosage, incorrect frequency, incomplete response, navigation difficulty as defined by stating information on the container other than the primary label instruction, and no attempt because of self-reported reading

difficulties). Interrater agreement was high among the research assistants ($\kappa = 0.82$).

Attendance to Auxiliary Label Instructions

We also investigated the patient's attentiveness to the auxiliary or "secondary" warning labels on the pill bottles. These labels provide supplementary instructions, such as "Take with food" or "Do not chew or crush, swallow whole," which support the safe administration of the medications. Research assistants were instructed to document whether patients attempted to interpret the auxiliary label along with the primary label, or whether they physically turned the bottle to inspect the color stickers on which these warning messages are placed. Patient attendance to the auxiliary label was coded as "yes" if his or her response or behavior was noted by the reviewer and "no" if the label was disregarded. Our research team has previously investigated patients' understandings of these auxiliary labels (21).

Understanding versus Demonstration

A substudy was conducted among all patients to test whether those who could accurately read and state the instructions for guaifenesin ("Take two tablets by mouth twice daily") could correctly demonstrate how many pills were to be taken daily. After patients answered the first question, "How would you take this medicine?" they were asked, "Show me how many pills you would take [of this medicine] in one day". The medication container was filled with candy pills for patients to dispense and count out the correct amount. Responses were coded as correct if their answer was "4" and incorrect if any other response was provided.

Literacy Assessment

Patient literacy was assessed by using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test comprising 66 health-related words (22–24). This is the most commonly used test of patient literacy in medical settings (24). Raw scores can be converted into 1 of 3 reading levels: sixth grade or less (score, 0–46), seventh to eighth grade (score, 45–60), and ninth grade and above (score, 61–66). The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (14).

Statistical Analysis

All statistical analyses were performed by using SAS software, version 9.1 (SAS Institute, Inc., Cary, North Carolina). Descriptive statistics (percentage, mean, and SD) were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and patient understanding of primary label instructions of 5 prescription medications and attendance to the auxiliary labels. In multivariate analysis, the 5 binary repeated responses of understanding per patient were modeled by using a generalized linear model with a complementary log-log link function. A generalized estimating equation approach was used to adjust model coefficients

and standard errors for within-patient correlation by using PROC GENMOD (SAS Institute). Wald 95% CIs were calculated for adjusted relative risk ratios by using the robust estimate of the standard error as detailed by Liang and Zeger (25). The final multivariate model included the potential confounding variables: age, sex, race (white vs. African American), education, and number of medications currently taken daily. Although education is associated with literacy, it was examined separately but included in the final model to present conservative estimates of the effect of literacy on rates of understanding. This issue has previously been reviewed by Wolf and colleagues (26) and the same method was used in our study. Site was also entered into the model to adjust for any potential differences across study locations. In multivariate analyses, patient literacy was classified as low (sixth grade and below), marginal (seventh to eighth grade), or adequate (ninth grade and higher). For the substudy analyses, chi-square tests were used to evaluate the association between sociodemographic characteristics and correct demonstration of the specified medication instructions. A multiple logistic regression model was used to examine the relationship between literacy and comprehension of the medication labels while controlling for the previously mentioned confounding variables and study site. Model fit was assessed by using the *c*-statistic from the receiver-operating characteristic curves and the Hosmer–Lemeshow goodness-of-fit chi-square test.

Role of the Funding Sources

The study was internally funded by the Health Education and Literacy program at Louisiana State University Health Sciences Center and by a career development award from the Centers for Disease Control and Prevention.

RESULTS

The mean age for all respondents ($n = 395$) was 44.8 years (SD, 13.7; range, 19 to 85 years). Fifty-seven percent of patients were recruited from Shreveport, Louisiana; 25% from Jackson, Michigan; and 18% from Chicago, Illinois. Two thirds (67.8%) were women, approximately half were African American (47.4%) and half were white (48.4%), and 28.4% reported less than a high school level of education. Patient literacy was limited; 19.0% read at or below a sixth-grade level (low literacy), and 28.6% read at the seventh- to eighth-grade level (marginal literacy).

Patients were taking an average of 1.4 prescription medications, and 22.8% lacked insurance for these medications. Low literacy was associated with older age ($P < 0.001$), African-American race ($P < 0.001$), and less education ($P < 0.001$) (Table 1). No statistically significant differences were reported between literacy level, sex, source of payment for medications, or number of prescription medications taken daily.

Overall, the 395 patients gave a total of 1975 responses for the 5 medication labels. Of these responses,

Table 1. Sample Characteristics Stratified by Literacy Level*

Characteristic	Literacy Level			P Value
	Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Mean age (SD), y	42.6 (13.6)	44.9 (13.5)	50.8 (12.7)	<0.001
Female, %	60.0	68.1	70.5	0.25
Race, %				<0.001
African-American	29.0	63.7	73.3	
White	65.2	32.7	25.3	
Other	5.8	3.6	1.4	
Education, %				<0.001
Grades 1-8	1.9	2.7	14.7	
Grades 9-11	11.6	34.5	41.3	
Completed high school/GED degree	43.0	45.1	40.0	
>High school	43.5	17.7	4.0	
Payment source for medications, %				0.43
Private insurance	18.8	14.2	12.0	
Medicaid	46.4	55.8	58.7	
Out-of-pocket	24.6	19.5	22.7	
Other	10.2	10.5	6.6	
Mean medications taken daily (SD), n	1.4 (1.1)	1.5 (1.1)	1.4 (0.9)	0.37
Study site, %				<0.001
Shreveport, Louisiana	60.0	68.1	43.0	
Jackson, Michigan	14.0	19.5	20.3	
Chicago, Illinois	26.0	12.4	36.7	

* GED = general educational development.

374 (18.9%) were coded as incorrect. Almost half (46.3%) of patients misunderstood 1 or more of the prescription label instructions, and the prevalence among patients with adequate, marginal, and low literacy was 37.7%, 51.3%, and 62.7%, respectively ($P < 0.001$). The rates of understanding individual labels ranged from 67.1% for the instructions for trimethoprim ("Take one tablet by mouth twice daily for seven days") to 91.1% for the instructions on the label for felodipine ("Take one tablet by mouth once each day"). Patients with low literacy were less able to understand the meaning of all 5 medication labels than those with adequate literacy (Table 2). No statistically significant differences in rates of understanding the medication labels were noted by either age or number of prescription medications currently taken.

The majority (51.8%) of incorrect patient responses reflected an error in dosage (that is, tablespoon vs. teaspoon), and 28.2% stated the wrong dose frequency (that is, "one tablet each day for seven days" instead of "Take one tablet by mouth twice daily for seven days"). For the instruction, "Take one tablet by mouth twice daily for seven days", 11.1% of responses omitted the duration of use. In 5.8% of the incorrect responses, patients had difficulty finding the instructions on the prescription label, and in 3.2% of incorrect responses, the patient acknowledged to the interviewer that he or she was unable to read.

Multivariate analyses identified low and marginal lit-

eracy as statistically significant independent predictors of misunderstanding the primary medication label instructions (adjusted relative risk, 2.32 [CI, 1.26 to 4.28] for low literacy and adjusted relative risk, 1.94 [CI, 1.14 to 3.27] for marginal literacy) (Table 3). Patients who took more prescription medications were also independently found to be more likely to misunderstand the labels (adjusted relative risk, 2.29 [CI, 1.16 to 4.54] for 1 to 2 medications; adjusted relative risk, 3.22 [CI, 1.53 to 6.77] for 3 to 4 medications; and adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥ 5 medications) (Table 3). No statistically significant interactions were found between literacy, age, number of medications taken, sex, and race.

One-way sensitivity analyses were conducted to account for responses that were coded as incorrect because of incomplete information on duration of use ($n = 41$ [11.1% of incorrect responses]). When these responses were recoded as correct, no substantial differences were noted for the association between misunderstanding and low literacy (adjusted relative risk, 2.29 [CI, 1.29 to 3.34]) or marginal literacy (adjusted relative risk, 1.84 [CI, 1.11 to 4.26]).

Substudy Analyses

A substudy analysis compared the percentage of patients who accurately read and correctly stated the label instructions for guaifenesin ("Take two tablets by mouth

twice daily") compared with the percentage of patients who correctly demonstrated the number of pills to be taken. Patients at all literacy levels were more able to read label instructions than to demonstrate the correct number of pills to be taken. Among patients with adequate literacy, 89.4% were able to read the instructions, whereas 80.2% properly demonstrated the correct number of pills to be taken. Differences in the ability to read versus the ability to demonstrate use were larger among patients with marginal (84.1% vs. 62.8%) and low literacy (70.7% vs. 34.7%). In multivariate analysis, low literacy was the only statistically significant independent predictor of correct demonstration of the label instructions (adjusted relative risk, 3.02 [CI, 1.70 to 4.89]). The model was tested for interactions; none were found to be statistically significant.

DISCUSSION

Physicians may assume that patients can understand instructions on prescription medication containers, because their appearance suggests that they are simple and clear. However, in this multisite study of primary care patients, approximately half (46.3%) were unable to read and correctly state 1 or more of the label instructions on 5 common prescriptions. Rates of misunderstanding were higher among patients with marginal and low literacy, yet more than one third (37.7%) of patients with adequate literacy skills misunderstood at least 1 of the label instructions.

This is cause for concern, because patient misunderstanding could be a potential source of medication error.

The instructions on the 5 prescription labels were typical in that they were short and used seemingly simple words. Nonetheless, the information was not clear for many patients. Mistakes were more common when the instructions had several components with varying numerical information (for example, "Take one tablet by mouth twice daily for seven days" vs. "Take one tablet by mouth once each day"). Misunderstanding was less frequent for the label with the most explicit dosing instructions ("Take one tablet in the morning and one at 5 p.m."), and differences by literacy did not reach statistical significance. However, this is probably the result of a higher rate of comprehension among patients with marginal literacy, because the difference between patients with adequate and low literacy skills was still similar to that found for other labels with less explicit instructions. Beyond the clarity of the instructions, patients may misread labels as a result of haste or limited literacy. Twenty-two percent ($n = 23$) of the patients with incorrect responses to the instructions, "Take one teaspoonful by mouth three times daily," misinterpreted the dose as "tablespoon" rather than "teaspoon."

Among the patients correctly stating the instruction, "Take two tablets by mouth twice daily" ($n = 333$ [84.3%]), one third were unable to demonstrate the correct number of pills to take per day. This was most pronounced

Table 2. Percentage of Patients Understanding Primary Prescription Drug Label Instructions and Attending to Auxiliary Labels* by Literacy Level

Drug Name	Instruction	Literacy Level			P Value
		Adequate ($n = 207$)	Marginal ($n = 113$)	Low ($n = 75$)	
Amoxicillin					
Correctly interpreted primary label	Take one teaspoonful by mouth three times daily	82.6	65.5	58.7	<0.001
Attended to auxiliary labels		5.3	4.4	0.0	0.130
Trimethoprim					
Correctly interpreted primary label	Take one tablet by mouth twice daily for seven days	73.0	66.4	52.0	<0.001
Attended to auxiliary labels		7.8	7.1	1.3	0.144
Guaifenesin					
Correctly interpreted primary label	Take two tablets by mouth twice daily	89.4	84.1	70.7	<0.001
Attended to auxiliary labels		14.1	7.1	0.0	<0.001
Felodipine					
Correctly interpreted primary label	Take one tablet by mouth once each day	94.7	87.6	86.7	0.032
Attended to auxiliary labels		12.6	10.6	4.0	0.115
Furosemide					
Correctly interpreted primary label	Take one tablet in the morning and one at 5 p.m.	91.3	91.2	82.7	0.092
Attended to auxiliary labels		14.5	8.9	2.7	0.011

* The multicolored labels that provide auxiliary instructions, such as "Take with food" and "Do not chew or crush, swallow whole."

Table 3. Risk Factors for Misunderstanding Prescription Medication Label Instructions*

Variable	Relative Risk (95% CI)	P Value	Adjusted Relative Risk† (CI)	P Value
Literacy level				
Adequate	1.00		1.00	
Marginal	1.59 (1.12–2.26)	<0.001	1.94 (1.14–3.27)	0.014
Low	2.38 (1.64–3.45)	<0.001	2.32 (1.26–4.28)	<0.001
Age, y				
<40	1.00		1.00	
40–49	1.18 (0.81–1.74)	0.39	1.18 (0.70–2.03)	0.53
50–59	1.26 (0.84–1.89)	0.26	0.63 (0.33–1.19)	0.155
≥60	1.42 (0.89–2.27)	0.146	1.09 (0.58–2.08)	0.78
Sex				
Female	1.00		1.00	
Male	1.65 (1.21–2.23)	<0.005	1.43 (0.95–2.14)	0.083
Race				
White	1.00		1.00	
African-American	1.46 (1.08–1.98)	0.016	0.99 (0.63–1.55)	0.95
Education				
>High school	1.00		1.00	
Completed high school or GED degree	1.09 (0.76–1.58)	0.63	1.07 (0.64–1.80)	0.79
Grades 9–11	1.46 (0.97–2.19)	0.075	0.89 (0.48–1.65)	0.70
Grades 1–8	2.53 (1.31–4.87)	<0.001	1.83 (0.85–3.99)	0.121
Medications taken daily, n				
None	1.00		1.00	
1–2	1.60 (1.05–2.44)	0.032	2.29 (1.16–4.54)	0.022
3–4	1.77 (1.13–2.76)	0.012	3.22 (1.53–6.77)	<0.005
≥5	1.63 (1.01–2.62)	0.054	2.98 (1.40–6.34)	<0.001

* GED = general educational development.

† Multivariate adjusted relative risks derived from generalized estimating equation regression models, adjusting for site in addition to all variables shown.

among patients with low literacy—fewer than half—who correctly stated the instruction were then able to count the right number of pills. This may reflect more of a patient's numeracy skills than reading proficiency; however, numeracy is an aspect of functional literacy. According to the National Adult Literacy Act of 1991 (27), functional literacy is defined as "the ability to read, write, and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential." Our finding that patients may be able to read label instructions but not correctly demonstrate the number of pills to be taken suggests that numeracy may be a more difficult literacy task than decoding relatively simple words (28).

Currently recommended methods for confirming patient understanding include the "teach-back" technique in which patients are asked to repeat instructions to demonstrate their understanding (29). This may be inadequate for identifying potential errors in medication administration, because study results documented a gap between a patient's ability to correctly state instructions and his or her ability to correctly demonstrate the correct number of pills to be taken daily. A system approach in which someone (pharmacist, nurse, clinic assistant, or physician) verifies that patients can accurately demonstrate or articulate specific

correct medication taking behaviors is important to ensure quality care. A recent report from the Institute of Medicine (7) notes the importance of providers having enhanced discussions with patients as a means of improving medication safety. This study suggests that medication review needs to verify that patients, or their surrogates, can accurately describe and demonstrate how to take medications safely.

Most patients did not pay attention to the auxiliary (warning) labels, and those with low literacy were more likely to ignore them. Lack of attention to the warning labels has been recognized as a problem (21). In a previous study, patients reported that they rarely attended to warning labels. This may be attributed to a limited effort by physicians or pharmacists to counsel patients about the importance of these labels. Nonetheless, failure to heed the special instructions on these labels could potentially lead to a loss of drug potency; change in the rate of absorption of the medication; or in certain formulations, cause such adverse events as gastrointestinal bleeding (30).

In addition to limited literacy, the greater number of prescription medications taken by patients was a statistically significant, independent predictor of misunderstanding label instructions. It is possible that as patients take more prescription medications, the complexity and possible confusion of managing multiple instructions may be greater. It is also possible that the number of medications

taken is a proxy for a greater number of comorbid conditions. Previous studies have shown that poorer health status is not only associated with more prescription medications in one's regimen but also with low literacy skills (26). This is noteworthy in light of recently reported trends. According to the Medical Expenditures Panel Survey (19), the average number of prescription medications filled annually by adults in the United States increased from 7 to 10 prescriptions between 1996 and 2003. An earlier study reported parallel trends in the increase of hospitalizations and deaths associated with medication errors (31).

Few studies have assessed actual patient understanding of medication instructions, and those that have more often focused solely on the elderly, a population especially vulnerable to misunderstanding prescription labels and instructions (17, 18, 32, 33). Senior citizens consume 2 to 3 times more medicine than does the general public, are more likely to have lower literacy skills, and have repeatedly been found to have poorer comprehension and recall of information on medication labels (28, 33). Although these studies have identified problems among elderly patients, our findings show that patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs.

Our study has limitations. We investigated patient understanding only of the primary label on prescription medications. The association between misunderstanding of label instructions and medication error was not examined. We also did not study the patients' actual prescription drug-taking behaviors. Motivation, concentration, and comprehension might have been greater if the patients were reporting on their own medication given by their physician for conditions they or their children actually had. Because the study design did not include a chart review, we could not identify whether patients had actual experience with the study medications.

Patients in our study were socioeconomically disadvantaged persons from 3 primary care clinics in diverse areas of the United States. Recruitment solely at clinics mandated to serve indigent populations was intentional. Our sample addresses those persons who are disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010 (34). The generalizability of our findings is further limited because the participants in our study were predominantly women (an accurate depiction of the clinic patient populations) and participation was limited to those who were proficient only in English. This was due in part to criteria for using the REALM as our literacy assessment. Additional research is needed to examine the language barrier to understanding instructions on prescription drug labels.

Our estimated prevalence of misunderstanding 1 or more prescription container labels (46.3%) was very similar to the estimates published by the National Assessment of Adult Literacy of 2003 (28), which reported that 43%

of adults in the United States read at the lowest levels of reading proficiency. Previous studies suggest that misunderstanding instructions on prescription medication labels is more common among elderly persons (17, 18, 33). Only 12% of patients in our sample were older than 60 years, and it is possible that we underestimated this relationship.

The Institute of Medicine Patient Safety Report (1) and a more recent report (7) stress the importance of addressing patient safety as a critical first step in improving quality of care. Our study found hidden health literacy problems with seemingly simple prescription medication labels. Although the prescriptions we examined have a relatively wide therapeutic margin, errors in their use have clinical importance. Moreover, it is probable that the rates of misunderstanding would be similar among medications with a more narrow range for clinical efficacy and safety. These medications may have similar dosing instructions to those we studied but possess greater risks for serious treatment failure or adverse events if taken incorrectly.

In summary, patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs (35–37). The text and format of existing primary and auxiliary labels on prescription medication containers should be redesigned and standardized. Less complex and more explicit dosing instructions may improve patient understanding; however, more research is needed to properly evaluate different instructional formats.

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EDITORIAL

Misunderstanding Prescription Labels: The Genie Is Out of the Bottle

► Dean Schillinger, MD

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The U.S. health care system largely operates under the assumption that all patients have high English-language literacy skills (1). In fact, many patients do not. In this issue, Davis and coworkers (2) carefully show that a substantial proportion of users of the U.S. health care system don't understand the instructions on prescription bottle labels and are unable to correctly execute these instructions. For those interested in improving health care quality and safety for vulnerable populations, this multisite study has important implications for practice, research, and policy. It forces us to focus on developing better "operating instructions" for medication taking. We are left wondering whether we could improve current labeling practice to communicate instructions about taking medication. I know that we can. So, who should be accountable for implementing a better system?

Briefly, in a sample of ethnically diverse primary care patients from community health centers, the investigators demonstrated a high rate of misunderstanding instructions on prescription labels for 5 common medications. Although the highest rates of misunderstanding across each of the 5 bottle labels (13% to 48%) occurred among patients with the lowest literacy levels, misunderstanding was common even among those with the highest literacy levels (5% to 27%). In multivariate analyses, lower literacy and greater number of prescription medications taken were associated with misunderstanding. Even worse, among those who seemed to understand a standard prescription label—by correctly reading and restating the instructions—far fewer correctly demonstrated how they would take the medication at home. Specifically, participants were asked to show how many pills they would take in 1 day, using candy pills from the bottle. Lower literacy was also associated with failure to correctly execute pill-taking instructions.

Does the authors' evidence fully support their conclusion that poor reading skills were responsible for poor understanding? In fact, the evidence is incomplete because the authors did not account for patients' cognitive function or visual acuity—each of which can impair reading comprehension and could explain poor understanding of labels. However, although this oversight may undermine the strength of the association between low literacy and poor understanding, it does not weaken the conclusion that many patients do not comprehend prescription labels and cannot act on their instructions. Some may argue that it is not surprising that doing poorly on a formal literacy "test" is associated with doing poorly on another form of literacy test: reading a prescription label. They would claim that this study confirms that poor test-taking skills beget poor test-taking and that the results of this particular test may not adequately reflect patients' behaviors at home. Although the authors did not assess actual

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medication-taking behaviors, other research has found that misunderstanding one's own warfarin prescription label, as measured by a similar test, is associated with limited literacy and unsafe anticoagulant outcomes (3), providing support for Davis and colleagues' conclusion that low literacy can have clinical consequences.

Do the findings of Davis and coworkers apply to other populations? While study participants were recruited from sites that serve the economically disadvantaged, the prevalence of low literacy was similar to that documented in a recent national assessment of literacy. This study categorized 36% of the U.S. population as having basic or below-basic literacy skills as regards to health-related tasks (4). The nature of the study design by Davis and colleagues was somewhat artificial—the authors asked participants to read, interpret, and demonstrate how to follow instructions from hypothetical sample prescription bottles and labels for commonly prescribed medications. This approach was necessary to standardize the test of prescription label reading, but it may raise concerns that the results do not reflect a "true" understanding of a patient's own prescription bottle labels—labels that patients arguably have learned to read and interpret correctly despite poor reading skills. However, more than one third of patients who take warfarin cannot demonstrate how to follow label instructions on their own medications (5), which suggests that the results from the study by Davis and coworkers do apply to patients' own prescription medications. Finally, the patients in the study were atypical: They took few medications regularly (mean, 1.4 medications), were relatively young, and spoke fluent English (6). Rates of misunderstanding in a typical internal medicine practice are probably even higher, because greater medication burden, older age, and limited English-language proficiency are all associated with misunderstanding prescription labels (5).

Davis and colleagues move the health literacy field forward considerably by developing improved research methods. The investigators' rigorous method for determining agreement between patients' and clinical investigators' interpretations of the same instructions will be useful for future descriptive and intervention studies. In addition, the researchers were able to tease out the "understanding" component of task performance, as measured by having participants verbally interpret prescription label instructions, from the "demonstration" component, as measured by having participants actually show how many pills they would take of the medicine in 1 day.

The study has several important implications. First, for the practitioner, it confirms that detailed medication reconciliation—ensuring that the patient knows which medications have been prescribed and can demonstrate how to correctly use all of them—must be part of routine practice. Medication reconciliation is important for all patients, but may be especially so for patients taking several medications, those taking medications that require stringent adherence, or those taking medications that cause adverse events if taken incorrectly. The best way to efficiently assess comprehension and elicit correct demonstration as part of the reconciliation process is unclear (5). The methods will probably include interactive communication strategies (7, 8) and using information from multiple sources (patient verbal report, demonstration of correct medication taking, and pharmacy records). However, in the absence of significant changes in prescription labeling and/or development of a more robust and standardized prescription communication system, medication reconciliation will usurp a substantial portion of clinical visit time, thereby infringing on the practice of a more relationship-centered type of care.

Second, from the perspective of patient safety research, the study findings challenge the fields of health communication, human cognition, and ambulatory medication safety to do better. For example, 2 related methods for assessing comprehension used in this study provided divergent results (many patients who correctly stated the instructions could not correctly demonstrate how to take the medications). This study was not designed to show which types, design, or formatting of label instructions is particularly challenging or effective, which should now be an area for intense scientific inquiry. Although the study did not examine the relationship between misunderstanding prescription labels and adverse events, research from our group has clarified this causal link. We found that providing a visual aid that shows the weekly pill regimen seems to increase comprehension of prescription labels and reduce the risk for medication-related adverse events (9).

Finally, this study has profound implications for health policy. In the United States, transmission of information on written prescriptions occurs in 4 ways (William Shrank, MD, MSHS, personal communication; 16 October 2006). The first is the label affixed to the bottle, the focus of the current study. The U.S. Food and Drug Administration (FDA) and state boards of pharmacy jointly regulate the content—but not the format—of this label. Not

surprisingly, practices within and among states vary. Second, pharmacies voluntarily provide consumer medication information in the form of nonstandardized, privately developed information leaflets delivered with most filled prescriptions. Consumer medication information is entirely unregulated and is often of poor quality. Third, package inserts, which are heavily regulated by the FDA, are intended for the use of the prescribing physician, are rarely delivered with prescriptions, and offer little benefit to patients (10). It is the prescribing physician, in his or her capacity as a "learned intermediary" between the drug manufacturer and the patient, who ultimately is accountable for successfully transmitting information about prescription medications. However, physician communication of basic prescription information to patients is notoriously spotty, and physicians do not seem to make a greater effort to communicate with less educated patients (11). Finally, in the past decade, the FDA has required the development of patient-directed medication guides for particularly high-risk medications (often those with "black box warnings"). In a recent study of a representative sample of such guides, none met federal readability recommendations, and nearly all were unsuitable for the average user (12). Nonetheless, the FDA's action to require medication guides at least provides a regulatory template within which we can operate as we develop more effective strategies to ensure effective and consistent prescription communication.

Why don't we have a standardized system to transmit medication instructions that all patients can understand and act on? Perhaps it is because the field of health literacy is in its infancy and research findings have not yet been translated into policy changes. To date, we have invested too little in generating the scientific evidence to show that 1 labeling practice or communication system is superior to another (5, 9). Furthermore, because the framework for regulating the content of prescription labels and accompanying materials is inadequate, patients and clinicians are suffering. With this study, the genie is out of the bottle.

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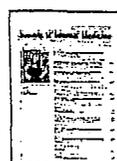
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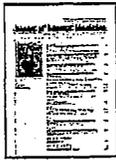
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To err is human: Patient misinterpretations of prescription drug label instructions

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Abstract

Objective: To examine the nature and cause of patients' misunderstanding common dosage instructions on prescription drug container labels.

Methods: In-person cognitive interviews including a literacy assessment were conducted among 395 patients at one of three primary care clinics in Shreveport, Louisiana, Jackson, Michigan and Chicago, Illinois. Patients were asked to read and demonstrate understanding of dosage instructions for five common prescription medications. Correct understanding was determined by a panel of blinded physician raters reviewing patient verbatim responses. Qualitative methods were employed to code incorrect responses and generate themes regarding causes for misunderstanding.

Results: Rates of misunderstanding for the five dosage instructions ranged from 8 to 33%. Patients with low literacy had higher rates of misunderstanding compared to those with marginal or adequate literacy (63% versus 51% versus 38%, $p < 0.001$). The 374 (19%) incorrect responses were qualitatively reviewed. Six themes were derived to describe the common causes for misunderstanding: label language, complexity of instructions, implicit versus explicit dosage intervals, presence of distractors, label familiarity, and attentiveness to label instructions.

Conclusion: Misunderstanding dosage instructions on prescription drug labels is common. While limited literacy is associated with misunderstanding, the instructions themselves are awkwardly phrased, vague, and unnecessarily difficult.

Practice implications: Prescription drug labels should use explicit dosing intervals, clear and simple language, within a patient-friendly label format. Health literacy and cognitive factors research should be consulted.

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Keywords: Prescription; Drug; Medication; Dosage; Instructions; Warnings; Misunderstanding; Health literacy

1. Introduction

According to the Institute of Medicine (IOM) 2006 report, *Preventing Medication Error*, more than one third of the 1.5 million adverse drug events that occur in the United States each year happen in outpatient settings [1]. Problems with

prescription drug labeling were specifically cited as a leading root cause of a large proportion of outpatient medication errors and adverse events, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. The prescription container label, in particular, is often the sole, tangible source of specific dosage/usage instructions given to and repeatedly used by the patient. Despite their potential value, problems are clearly evident with container labels [2–5]. Dosage instructions on the label can vary, as they are dependent on what the prescribing physician writes, as well as how the pharmacist interprets them [6,7]. With little guidance available to providers, instructions

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commonly found on prescription drug labels may not always be clearly stated. In prior studies, half of adults in outpatient primary care settings misunderstood one or more primary and auxiliary prescription instructions and warnings they encountered [2–4]. Patients with limited literacy skills and those managing multiple medication regimens made more errors.

Improving prescription drug container label instructions is both a matter of health literacy and *patient safety* [1,8,9]. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines [10–12]. Other supplementary sources, such as consumer medication information sheets and FDA-approved medication guides that may be dispensed with a prescribed medicine are too complex and written at a reading grade level too high for the majority of patients to comprehend [13]. As a result, these materials are not read [13–15]. Patients' ability to decipher the brief text instructions on the container label itself takes on greater importance to ensure proper use.

1.1. Sources of comprehension failure: a conceptual model

The ability to read and understand prescription label instructions may appear to be a simple task, yet van den Broek & Kremer describe various sources of failure in comprehension that are particularly applicable for the abbreviated text on container labels [16–18]. These include readers' cognitive characteristics, constraints on the reading situation, and the nature of the presented health information. The influence of the latter set of factors is particularly applicable to the truncated text on container labels, and may include text complexity, formatting and organizational issues. Failure may also occur if instructions are not explicit, or if purpose is not evident, such as providing an indication for use on the bottle label itself (i.e. "take for diabetes"), which is not part of routine practice for either physicians to add to the script or pharmacists to include on the dispensed container label. The presence of distracting information may limit comprehension of the pertinent dosage/usage instructions and auxiliary warnings that patients need to understand in order to safely use a medicine. This might include the more prominently displayed pharmacy logo, phone number, serial number and drug code, and other provider-directed content on the label.

1.2. Purpose of study

The purpose of this study was to investigate how patients approached and interpreted prescription drug label instructions, and to document the nature of misunderstanding that may contribute to the high prevalence of medication error. We took a health literacy perspective towards the problem of misunderstanding prescription medication instructions. From this view, it was hypothesized that misunderstanding would be the result of both patient literacy limitations and the ambiguity and inherent difficulty of label instructions themselves.

2. Methods

The methods and quantitative findings from this research study that detail the relationship between patient literacy and misunderstanding prescription label instructions have been reported upon previously [2].

2.1. Subjects

Subjects were adult patients who attended one of three outpatient primary care clinics serving low-income community populations in Shreveport, Louisiana, Jackson, Michigan and Chicago, Illinois. Recruitment took place over consecutive summers beginning July 2003. Patients were eligible if they were 18 or older, and ineligible if the clinic nurse or study research assistant identified a patient as having one or more of the following conditions: (1) blindness or severely impaired vision not correctable with eyeglasses; (2) deafness or hearing problems uncorrectable with a hearing aid; (3) too ill to participate; (4) non-English speaking. Institutional Review Boards at each location approved the study.

A total of 458 patients were approached in the order they arrived at the clinics and prior to the medical encounter. Twelve patients refused participation 26 were deemed ineligible, and 25 had incomplete information, leaving 395 patients participating in the study. A response rate was determined following American Association for Public Opinion Research (AAPOR) standards; 92% of approached eligible patients participated in the study [19].

2.2. Structured interview and literacy assessment

A structured, cognitive interview protocol was developed to assess understanding of different label dosage instructions placed on five common prescription medications. This process has been widely used by the research team, among others [2–4,20,21]. These included two antibiotics (amoxicillin (for pediatric use) and trimethoprim), an expectorant (guaifenesin), an anti-hypertensive, channel blocking agent (felodipine), and a diuretic (furosemide). A trained research assistant (RA) at each site administered the interview to consenting patients that included self-report of sociodemographic information (age, gender, race/ethnicity, education) source of payment for medications, and number of prescription medications currently taken daily. Actual prescription pill bottle containers with labels were then shown to patients, one at a time, for review. Once patients provided their interpretation on all of the labels, the RA administered a brief literacy assessment, ending the interview.

2.2.1. Understanding of medication primary container label instructions

To assess patient understanding of prescription medication instructions included on the container primary labels, the RA asked "how would you take this medicine?" This question was often followed by one to two short probes (i.e. "anything else?", "exactly how would you take the pills [medicine]?") to

initiate more detailed description of administration. The RA documented the verbatim response on a separate form. Responses to the instructions for the five medications ($N = 1,975$) were then independently rated correct or incorrect by three general internal medicine attending physicians from three different academic medical centers. Each physician rater was blinded to all patient information and was trained to follow stringent coding guidelines agreed upon previously by the research team. Correct scores were to be given only if patient responses included all aspects of the label's instruction, including dosage, timing, and if applicable, duration.

Inter-rater reliability was high ($\kappa = 0.85$). The 147 responses (7.4%) that received discordant ratings between the three reviewers were sent to an expert panel that included three primary care physicians and two health literacy experts for further review. Each panel member, also blinded to patient information, independently reviewed and coded responses as correct or incorrect. For 76.2% ($n = 112$) of the 147 responses, consensus was achieved among the five-member panel. A majority rule was imposed for the remaining responses ($n = 35$).

2.2.2. Attendance to auxiliary (secondary) warning label instructions

Attentiveness to the auxiliary or "secondary" warning label on the pill bottles by patients was also investigated. These labels provide supplementary instructions supporting the safe administration of the medications, such as "take with food" or "do not chew or crush, swallow whole." RAs were instructed during the interview to document (yes or no) whether patients either attempted to interpret the auxiliary label along with the primary label, or physically turned the bottle to inspect the color stickers on which these warning messages are placed.

2.2.3. Reading versus demonstrating instructions

Patients were further tested on their functional understanding of the primary label instruction for guaifenesin ("take two tablets by mouth twice daily"). They were asked to demonstrate how many pills were to be taken on a daily basis. After patients answered the first question, "how would you take this medicine?" they were asked, "show me how many pills you would take [of this medicine] in one day". The container was filled with candy pills for patients to dispense and count out the correct amount. Responses were coded as correct if their answer was "four", and incorrect if any other response was provided.

2.2.4. Literacy assessment

Patient literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test comprised of 66 health-related words [22]. The REALM is the most commonly used test of patient literacy in medical settings [23]. In healthcare studies where patients need only be categorized as low (scores 0–44), marginal (scores 45–60) or adequate (scores 61–66) readers, the information provided by the REALM is generally sufficient. The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (TOFHLA) [23,24].

2.3. Analysis plan

Mixed methods were used. Chi-square tests were calculated to examine bivariate associations between health literacy (adequate, marginal, low), sociodemographic variables (age, gender, race, education, number of medications currently taken), and understanding (yes or no) primary label instructions and attendance (yes or no) to the auxiliary warning instructions. Quantitative analyses were conducted using Stata 9.0 (College Station, TX).

For qualitative analyses, a grounded theory approach was used to explore the basis for patients' misunderstanding of each of the five dosage instructions using their documented verbatim responses [25]. Grounded theory is a systematic method for generating theoretical statements from case studies. Based on our qualitative, cognitive interviews, grounded theory guides the inductive process of organizing content derived from patient responses. Patient misunderstandings were first reviewed by investigators (MSW, TCD, RMP) and classified using both selective and *in vivo* coding schemes [26]. Data were then reduced by one of the lead investigators (MSW) through detailed a priori coding to classify the reason for error in understanding (label language, complexity, explicitness of instruction, presence of distracters, and label familiarity). These predetermined codes were based on previous studies and the conceptual model of sources of comprehension failure [16]. The reduced data was confirmed based on the a priori coding scheme, and *in vivo* codes were allowed to develop based on emergent themes in responses. Agreement among investigators was sought prior to classifying patient responses with any new themes. Open coding techniques were used [27]. Qualitative analyses were supported by NVivo 7 software (QSR International; Doncaster, Australia).

3. Results

3.1. Description of study sample

Table 1 describes the study sample in detail, stratified by literacy. The mean age was 45 years (S.D. = 14; range 19–85 years). Fifty-seven percent of patients were recruited from Shreveport, Louisiana, 25% from Jackson, Michigan, and 18% from Chicago, Illinois. Two-thirds (68%) were female, approximately half of patients were African American (47%) and half white (48%), and 28% reported less than a high school level of education attainment. Patient literacy was limited; 19% were reading at or below a sixth grade level (low literacy) and 29% were reading at the seventh to eighth grade level (marginal literacy).

Patients were taking an average of three prescription medications, and 23% lacked insurance to cover these prescribed drugs. The physician was the most likely source of medication information for patients (71%). Low literacy was associated with older age ($p < 0.001$), African American race ($p < 0.001$), and less education ($p < 0.001$); differences were also noted by site ($p < 0.002$). No significant differences

Table 1
Sample characteristics stratified by literacy level

Characteristic	Literacy level			p-Value
	Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Age, mean (S.D.)	43 (14)	45 (14)	51 (13)	<0.001
Female (%)	60	68	71	0.25
Race (%)				<0.001
African American	29	64	73	
White	65	33	25	
Other	6	4	1	
Education (%)				<0.001
Grades 1–8	2	3	15	
Grades 9–11	12	35	41	
Completed High School/GED	43	45	40	
>High School	44	18	4	
Payment source for medications (%)				0.43
Private insurance	19	14	12	
Medicaid	46	56	59	
Out of pocket	25	20	23	
Other	10	11	7	
Source of support for understanding prescription medication instructions (%)				
Physician	71	72	68	0.81
Nurse	10	12	19	0.12
Pharmacist	45	53	57	0.35
Family member	22	9	4	<0.001
Number of medications taken daily, mean (S.D.)	2 (1)	2 (1)	1 (1)	0.37
Misunderstanding 1 or more dosage instructions (%)	38	51	63	<0.001

were reported between literacy, gender, source of payment for medications, or number of prescription medications taken daily.

3.2. Prevalence and associations of misunderstanding dosage instructions

Overall, 46% of patients misunderstood one or more dosage instructions. The prevalence of misunderstanding among patients with adequate, marginal and low literacy was 38%, 51%, and 63%, respectively ($p < 0.001$). The rates of misunderstanding individual labels ranged from 8% for the instructions on the label for Felodipine (“Take one tablet by mouth once each day”) to 33% for the instructions for Trime-thoprim (“Take one tablet by mouth twice daily for 7 days”; Table 2). Patients with low literacy were less able to understand instructions compared to those with adequate literacy.

3.3. Reading versus demonstrating dosage instructions

The ability to read dosage instructions did not always preclude the ability to demonstrate a functional understanding of prescription drug use (Fig. 1). When asked how pills were to be taken in a given day for the instruction, “Take two tablets by mouth twice daily”, one third of patients were unable to correctly state “four pills”. Rather, the most common incorrect answer was “two pills”. Patients with low literacy were less able to state the correct number of pills taken daily compared to those with marginal and adequate literacy (35% versus 63%

versus 80%, $p < 0.001$). No statistically significant associations were noted by number of medications or age.

3.4. Nature of patient misunderstanding label dosage instructions

The 374 (18.9%) total responses that were coded as incorrect were qualitatively reviewed and coded using the pre-selected

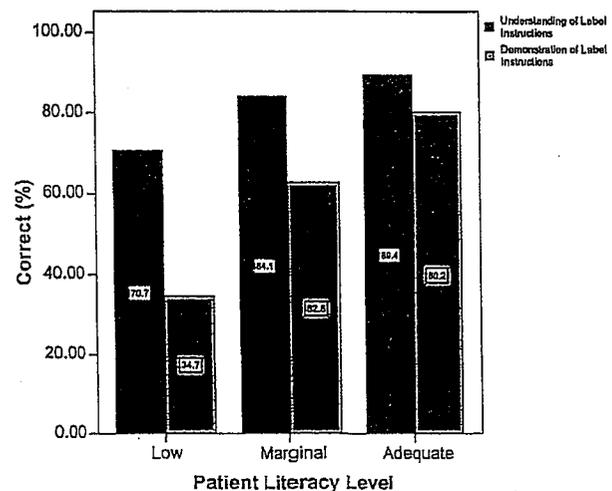


Fig. 1. Rates of correct understanding vs. Demonstration for the primary label instruction, “Take two tablets by mouth twice daily”.

Table 2
Rates of understanding primary label instructions and attendance to auxiliary warnings, stratified by literacy level

Generic drug name (dose)	Primary instructions and auxiliary warnings ^a	Literacy level			p-Value
		Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Amoxicillin					
Correctly interpreted primary label	Take one teaspoonful by mouth three times daily	86	66	59	<0.001
Attended to auxiliary label(s)	Refrigerate, shake well, discard after [date]	5	4	0	0.13
Trimethoprim					
Correctly interpreted primary label	Take one tablet by mouth twice daily for 7 days	73	66	52	<0.001
Attended to auxiliary label(s)	You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	8	7	1	0.14
Guaifenesin					
Correctly interpreted primary label	Take two tablets by mouth twice daily	89	84	70	<0.001
Demonstrated understanding		80	63	35	<0.001
Attended to auxiliary label(s)	Medication should be taken with plenty of water	14	7	0	<0.001
Felodipine					
Correctly interpreted primary label	Take one tablet by mouth once each day	95	88	87	0.03
Attended to auxiliary label(s)	Do not chew or crush, swallow whole	13	11	4	0.11
Furosemide					
Correctly interpreted primary label	Take one tablet in the morning and one at 5 p.m.	91	91	83	0.09
Attended to auxiliary label(s)	Do not take dairy products, antacids, or iron preparations within 1 h of this medication	15	9	3	0.01

^a Included behavioral demonstration for Guaifenesin only.

coding scheme of likely causes for error in interpretation (Table 3). One emergent cause, referred to as attentiveness to label instructions, was included in addition to the predetermined causes of label language, complexity of instructions, implicit versus explicit dosage, presence of distracters, and label familiarity.

3.4.1. Label language

Certain common phrases used on medicine labels seemed confusing and unfamiliar to patients within the context of the instruction itself. Errors that appeared to be the result of label language were most prevalent on the instruction, "Take two tablets by mouth twice daily". The repetitiveness between dosage ("two") and frequency ("twice") often led to the common interpretation "Take a pill twice a day", whereas dosage would go ignored. This was confirmed in the follow-up demonstration task, "How many pills would you take in one day" with the common incorrect response of "two" (72% of incorrect responses).

Many terms commonly used on prescription labels had exceptionally poor recognition rates by patients. Specifically, among patients reading at the 6th grade level and below

(n = 75), 79% of these patients could not recognize and pronounce "antibiotic", 73% "orally", 70% "teaspoonful", 48% "medication", 45% "prescription", and 35% the word "dose". Poor word recognition may have contributed to patients misreading words on labels, such as "tablespoon" instead of "teaspoon". This accounted for 9% of errors (n = 34).

Interestingly, feedback documented by RAs from patient interviews recommended the use of numeric symbols within the instruction rather than the written word equivalent (i.e. "2" versus "two") for further reading ease.

3.4.2. Complexity of instructions

Instructions ranged in complexity, both with regards to the calculation of the number of pills and times to be taken daily (i.e. "Take one pill by mouth once each day" versus, "Take two tablets by mouth twice daily") and in the amount of content to be retained (dosage, frequency, and/or duration, as in "Take one tablet by mouth twice daily for seven days"). Patients found simpler dosing regimens to be easier to understand, while more complex regimens had more errors in their interpretation (Table 2). Eleven percent (n = 41) of incorrect responses

Table 3
Examples of the most common misunderstandings, by dosage instruction

Dosage instruction	Misunderstanding
Take one teaspoonful by mouth three times daily	Take three teaspoons daily; take three tablespoons every day; you should drink it three times a day
Take one tablet by mouth twice daily for 7 days	Take two pills a day; take it for 7 days; take one every day for a week; I'd take a pill every day for 7 days
Take two tablets by mouth twice daily	Take it every 8 h; take it every day; take one every 12 h
Take one tablet by mouth once each day	Take it as directed
Take one tablet in the morning and one at 5 p.m.	I would take it every day at 5 o'clock; take it at 5 p.m.

omitted duration of use from the specified instruction. The inclusion of duration on the label instruction also led to a loss of other aspects of the instruction. For the label, “Take one tablet by mouth twice daily for seven days”, the second most common error made was an incorrect interpretation of dosing frequency ($n = 34$; i.e. “I’d take a pill every day for seven days”).

3.4.3. Implicit versus explicit dosage intervals

Patients were better able to interpret more explicit dose frequencies as in “Take one tablet in the morning and one at 5 p.m.” (90%), compared with the more vague “Take two tablets by mouth twice daily” (83%), and “Take one teaspoonful by mouth three times daily” (73%). For the latter two instructions, patients varied in their interpretation of “twice daily” and “three times daily”. For example, patients interpreted “twice daily” as both “every 8 h” and “every 12 h”, and “three times daily” ranged from “every 4 h” to “every 8 h”.

3.4.4. Presence of distracters

In 6% ($n = 21$) of the incorrect responses, patients had difficulty navigating the label content itself and identifying the instructional content. Rather than describing the dosage of the medicine, responses detailed provider-directed content that surrounded and may have obscured the dosage instructions (i.e. stated combinations for the name of the drug, physician’s name, refill and date). Patients turned the bottle to acknowledge auxiliary warnings, as they were also recited along with the provider-directed content instead of the dose and frequency for use (i.e. “Take it with Food”; “I would take them every day but not with dairy products, antacids, or iron preparations”; “I would stay out of the heat”).

3.4.5. Label familiarity

Auxiliary instructions are often placed as stickers surrounding or in back of the primary label. Very few patients were familiar with these instructions. Less than 10% of patients physically turned any of the bottles to examine these stickers (Table 2). Sixteen percent of patients attended to at least one auxiliary instruction, and 2% made the action part of the routine inspection of the prescription bottle for all five medicines.

3.4.6. Attentiveness to label instructions

Several patients provided detailed responses that verbally “implemented” the regimen (“It’s an antibiotic, and I would take one pill in the morning when I wake, and another pill after dinner—I would do that for a week”). Even though tasks were not timed, many patients appeared to have responded quickly, and by doing so made simple mistakes. When answers were provided in haste, patients often skipped or omitted dosage information (“Take two a day”; “I’d take three pills daily”).

Patients with adequate literacy were more likely than patients with low literacy to omit the duration of use for the instruction, “Take one tablet by mouth twice daily for seven days” ($n = 41$; 44% versus 18%, $p < 0.001$). They were equally likely to make errors wherein dose and interval were inverted for the same instruction and for “Take one teaspoonful by mouth three times daily” ($n = 60$; 39% versus 43%, $p = 0.65$).

Mistaking “teaspoon” for “tablespoon” was more common among patients with limited literacy, but one third of these errors were made by patients with adequate literacy ($n = 12$).

4. Discussion and conclusion

4.1. Discussion

Although there may be a finite number of ways a physician can prescribe a medicine, the same dose and frequency schedule may be written in several different ways (i.e. every 12 h, twice daily, in the morning and evening, 8 a.m. and 5 p.m., etc.). This becomes especially problematic as many patients may have more than one healthcare provider prescribing medicine [28]. The ability to follow instructions is crucial in ambulatory care, since the patient assumes the bulk of responsibility for medication safety. Our present research offers timely evidence classifying the nature and causes of patient misunderstanding of commonly-written dosage instructions that could potentially lead to errors and adverse events [1].

Our prior studies have repeatedly shown that limited literacy significantly impairs one’s ability to read and demonstrate an understanding of instructions and warnings found on commonly prescribed medicines [2–5]. While individual differences in reading ability may be related to a greater risk for misunderstanding, problems are clearly evident with the label itself, and the implicit nature and syntax of instructions. Improving the reading ease of dosage instructions is therefore warranted.

Many patients might presume the task of reviewing prescription drug labels to be overly simple. As a result, they may not allot adequate time to process and understand the information. This could explain why a majority of patients were able to read back the instruction, while far fewer could demonstrate a proper understanding when probed further. An earlier study by Morrell and colleagues found that older adults, who on average manage more medications than younger patients, spent less time processing dosage instructions and consequently made more errors in interpretation [29]. These mistakes could lead to compromised health outcomes, such as under-treatment (i.e. taking two rather than four pills a day) or possible harm (i.e. taking too much of a medicine or not attending to warnings).

The manner in which physicians write dosage instructions requires patients to make inferences as to when to specifically implement the prescribed regimen (i.e. Take two tablets by mouth twice daily; Take one teaspoon by mouth three times daily). Our findings suggest that patients’ interpretations may widely vary when dosing intervals are presented in vague terms as “twice daily” or “three times daily”, which may stray from the original intent of the prescribing physician. Park and colleagues suggest that making inferences is a complex cognitive process, and the elderly may have greater difficulty when faced with these types of tasks [30].

Some misunderstandings appeared to be the result of container label organization. The prescription labels were

typical of the order in which most pharmacies present drug information, often emphasizing (by yellow highlight, large font, bold text) content that is irrelevant to the patient. The inclusion of such distracting information may be particularly problematic for individuals with limited literacy, who face greater reading difficulty in less familiar and technical contexts [31].

4.2. Limitations

We investigated patient understanding of prescription drug label instructions, not whether a medication error occurred. Patients' actual prescription drug-taking behaviors were not examined. Patients' motivation, concentration and comprehension might have been greater if they reported on their own medicine. Similarly, we interviewed patients before their medical encounter. It is also possible that the reason for the medical visit altered patients' concentration, although patients were offered the opportunity to refuse and anyone too acutely ill was not interviewed. We also did not conduct a chart review, and thereby could not identify if patients had actual experience with any of the study medications. Only patients who were proficient in the English language were also included. This was due in part to criteria for using the Rapid Estimate of Adult Literacy in Medicine (REALM) as our literacy assessment. Further research should investigate the effect of cultural differences and language barriers on misunderstanding prescription drug label instructions.

4.3. Conclusion

Prescription drug labels often are the only print source of dosage instructions received by patients. Given the tangible nature of the prescription bottle, these label instructions may be the 'last line' of informational support detailing how and when a patient should administer a prescribed medicine. Yet many of the common phrases used to describe dosage instructions are inadequately written and contribute to misunderstanding. Patients with limited literacy may face greater difficulty when attempting to infer and interpret instructions. Research is needed to evaluate the use of enhanced strategies of communicating dosage information and warnings for improving comprehension among patients across all literacy levels. In the end, all patients would benefit from more clearly presented prescription drug information.

4.4. Practice implications

Unfortunately, there are only minimal standards and regulations set by state boards of pharmacy that dictate any recommendations for content and organization of prescription drug labels [32]. As such, rules vary by state. Our research study provides initial guidance for improving the dosage instructions on prescription bottles, and 'best practices' can be derived from our study. These are supported by health literacy principles and cognitive/human factors research [31–33].

4.4.1. Use explicit language when describing dose intervals.

Three previous studies also found more explicit instruction improved comprehension [34–36]. This might help pace patients and allow them to direct necessary attention for processing each component of dosage. For instance, the actual dose (number of pills to be taken at a time) could be separated from the interval (times per day), as in the example "Take 2 tablets in the morning, and take 2 tablets in the evening."

4.4.2. Organize label in a way to minimize distracters

The label should be re-organized, separating distracting elements that often comprise provider-directed content (pharmacy logo, drug serial number, pharmacy address and phone number) away from dosage instructions. Auxiliary instructions might also be placed in a set location (i.e. backside of label), instead of being stuck on in various locations, so patients can have routine expectations of their location.

4.4.3. Simplify language

Doak, Doak, and Root (1993) offer guidance as to how to make health information more suitable for patients with limited literacy, such as dosage instructions and warning messages on auxiliary labels. The use of numbers rather than the text equivalent should be promoted for reading ease, and unclarified medical jargon (i.e. antibiotic) or awkward terms (i.e. twice) avoided.

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Prescription for Improving Patient Safety: Addressing Medication Errors

An Executive Summary of the The Medication Errors Panel Report

Pursuant to California Senate Concurrent Resolution 49 (2005)

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the healthcare system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the Executive Summary of the Panel's report complete with its consensus recommendations.

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing¹, transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds \$177 billion per year.² Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.³ Extrapolating these figures to California suggests that on an annual basis, the problem costs our state \$17.7 billion and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

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Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual “wrong doers,” but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a “systems approach” for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/ processes and three key stakeholder groups which served as the focus of its recommendations.

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The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

- 1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).
- 2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.
- 3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.
- 4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

- 1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.
- 2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and provider licensing/oversight Boards.
- 3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements**, with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

- 1) *Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.*
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- 3) *Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.*
- 4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

- 5) *Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.*
- 6) *Establish an on-going public education campaign to prevent medication errors,*

targeting outpatients and persons in community settings.

- 7) *Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.*

C. **Pharmacy Standards and Incentives**, with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

- 8) *Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.*
- 9) *Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.*

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

- 10) *Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.*

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- 11) *Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.*

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

- 12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

Acknowledgements

This project has benefited from the generous contributions of many individuals and organizations. In particular the Panel would like to thank former Senator Jackie Speier who authored the resolution; Lynn Rolston of the California Pharmacists Association which sponsored SCR 49 (2005); Judith Babcock of the Pharmacy Foundation of California which managed funding for the Panel and arranged for administrative support; the Kaiser Family Foundation and California HealthCare Foundation which funded the Panel; Sandra Bauer, Michael Negrete and Ronald Spingarn who provided staff support for the Panel; and of course all of the Panel members listed on the following page with special thanks to Carey Cotterell for helping to write this report.

End Notes and References

¹While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

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*Prescription for
Improving Patient Safety:
Addressing Medication Errors*



A report from
The Medication Errors Panel
Pursuant to California Senate Concurrent Resolution 49 (2005)

March 2007

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EXECUTIVE SUMMARY

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- 12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

SECTION I: REPORT OF THE PANEL

Background & Overview

The Problem of Medication Errors

For the purpose of its work, the SCR 49 Panel defined a medication error as “any preventable event occurring in the medication-use process, including prescribing¹, transcribing, dispensing, using and monitoring, which results in inappropriate medication use or patient harm.”

Errors involving prescription and over-the-counter medications represent an enormous public health problem. When an error occurs, the best possible outcome is for a medication to simply not elicit an adverse result. Even under this best-case scenario, medication errors have a significant negative impact on the US healthcare system, contributing to increasing costs for consumers, employers and other persons who pay for health care. Even worse than the financial cost is the harm to consumers’ health and well-being caused by medication errors, which can range from mild to life-threatening and even death.

The scope and severity of medication errors and the related consequences have been documented by many health researchers. For the year 2000, experts estimated the overall cost of drug-related morbidity and mortality to be in excess of \$177.4 billion.² That amount greatly exceeds the \$120.8 billion spent on prescription drugs during that year.³ In terms of patient harm from medication errors, the Institute of Medicine (IOM) estimates that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.⁴ Extrapolating these figures to California suggests that on an annual basis, the problem costs our state \$17.7 billion dollars and causes harm to 150,000 Californians.

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Perhaps the most disturbing aspect of medication errors is that these tremendous human and financial costs are not the result of some serious disease, but rather well-intentioned efforts to treat or prevent illness.

The Importance of Addressing Errors in Community Settings

When imagining places where medication is dispensed and taken or “administered,” many people think of hospitals or other health care facilities. But, in fact, the vast majority of medications are taken by out-patients in “community settings,” including homes, schools, offices, independent living facilities, and children or adult day care centers. Last year, over 5,000 licensed “community” pharmacies in California filled about 400 million prescriptions for community dwelling individuals.

In community settings a person often has a prescription written by his or her health care provider, usually a doctor, and has it filled at a community pharmacy, often a neighborhood drug-store, supermarket or other retail outlet. After a consumer receives medication from a community pharmacy, they or their caregiver is largely left on their own to take/administer the medication and monitor for signs and symptoms of efficacy or toxicity.

Compounding the problem of medication errors in community settings are the increasing numbers of consumers that buy and use over-the-counter medicines, herbals or other alternative treatments. While many consumers believe the “all-natural” or non-prescription status of these therapies suggests inherent safety, these products do have the potential to cause adverse effects and interact with prescription medications or each other.

In spite of incredible potential for medication errors to occur in the community setting, much of the attention paid to the problem thus far has focused on hospital and other institutional settings. In fact, there are already many state and national efforts underway aimed at reducing errors in these settings. This, coupled with evidence regarding the magnitude of the problem outside of institutional settings, led the Panel to focus on making recommendations about medication errors that occur in the community.

U.S. and California Medication Error Data

There is no organization responsible for maintaining comprehensive data about medication errors in the United States or California. Several national organizations collect information related to medication errors, but their data is not comprehensive and has many limitations – it may focus on health care professionals, not consumers or on health care facilities, not community settings – or organizations may mix data about medication errors with other data – for example, data about “medical” errors or “adverse drug events.” Also, organizations often define “medication error” differently, creating challenges with combining or comparing data.

Finding medication error data specific to California is even more challenging. One could extrapolate from data at the State’s Board of Pharmacy and Medical Board, although neither body is charged with actively monitoring medication errors or collecting comprehensive error data. They simply document and respond, as appropriate, to complaints made by health care professionals or consumers about medication errors and other issues related to their areas of oversight.

California-specific research studies identified by the Panel did not include information about community-settings, only hospitals and residential care settings. National organizations, including the federal Food and Drug Administration (FDA) and the nonprofit Institute for Safe Medication Practices (ISMP), contacted by the Medication Errors Panel staff were unable to report medication error data specific to California.

Types of Medication Errors

In the community setting, there are three general types of medication errors that can occur: those related to the prescribing process; those that occur when the medication is dispensed at the pharmacy; and those related to the consumer’s use of the medication.

Prescribing Errors

The first step in obtaining a prescription medication occurs when a consumer visits a physician, or other health care professional with prescribing authority, and receives a prescription.

In order to avoid selecting a drug that could be inappropriate or harmful to a patient, it is important for

the prescriber to have access to the patient’s complete health information record at the time the patient is being seen. The patient information should include all medicines the patient is taking, lab test results, other physicians the patient has seen, and any past hospitalizations or drug allergies.

The Panel heard testimony that prescribers in California often do not have ready access to vital patient information at the time that a prescription is written. This is largely due to continued reliance on paper-based documentation systems which lend themselves to having important patient information be missing, inaccessible, illegible and inaccurate – all of which can contribute to prescribing errors.

While the Panel identified drug and dose selection as a place where errors can occur, it decided to focus its analysis and recommendations on areas of the medication-use system that occur *after* the point where such decisions are made. From a prescribing standpoint, this includes practices related to the transcription and transmission of prescription information which may contribute to patients not receiving the intended medication or dose. More information on these types of errors is included in the next section of this report.

Dispensing Errors

Dispensing errors occur when a patient is given a medication other than the one intended by the prescriber. These types of errors are often the result of sound/alike or look/alike drugs, according to testimony provided by Patricia Harris, Executive Officer of the California Board of Pharmacy. Ms. Harris noted that an increasingly reported mistake is the dispensing of the “right drug” to the “wrong person,” often the result of similar names shared by several members of a family, many of whom may speak limited English.

To help address errors such as these, the California Board of Pharmacy created a requirement in 2002 for every pharmacy to adopt a quality assurance program. Such programs require pharmacies to document and identify the cause of any errors that occur, and develop systems and workflow processes designed to prevent the same type of error from occurring in the future.

The Panel heard testimony regarding other types of dispensing errors from Michael Cohen, RPh, ScD, founder and director of the Institute for Safe Medication Practices (ISMP). His data is based on voluntary reports of errors received by the ISMP from health practitioners and consumers nationally over many years. A summary of all the major medication error causes identified by

ISMP is listed in Table 1. Causes of dispensing errors include confusing drug names, labels, and/or packaging (look/sound alike problems); environmental, staffing, or workflow issues (poor lighting, excessive noise, workload, interruptions); lack of quality control or independent verification systems; missing patient information (allergies, age, weight, pregnancy); and missing drug information (outdated references, inadequate computer screening).

In relation to the last two causes, it is pertinent to note a California regulation which requires pharmacies to maintain records on all patients who have prescriptions filled at their pharmacy for at least one year. These records must include "patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent".⁵ For the purposes of creating as complete a record as possible in one location, the Board of Pharmacy recommends that consumers use only one pharmacy when feasible.

By reviewing patient records, a dispensing pharmacist can determine whether a new medication the patient is being prescribed is appropriate and compatible (not contraindicated or in conflict with) with other medications the patient is already taking. Reviewing patient records in this way is called Drug Utilization Review (DUR) and is a very important safety feature.

Administration/Medication Use Errors

A key characteristic of the community setting that contributes to medication errors is that medications are administered by patients or other persons who are not health care professionals trained to do so. This is in sharp contrast to inpatient hospital settings where prescribers write orders for medications on patients' medical charts and drugs are subsequently administered by health care professionals. In hospitals, patients are often passive, and rely on others for their treatment. In community settings the opposite is true, and medication use is almost completely dependent upon consumer knowledge and motivation which can often be lacking. In fact, it has been estimated that people who are prescribed self-administered medications typically take less than half the prescribed doses.⁶

Many consumers simply do not understand what medications they are taking, their importance, their contraindications, or proper usage. In addition, consumers may not be asked by their health care professionals what non-prescription medications or supplements they are taking and may not know the importance of volunteering this information to avoid problems such as therapeutic duplications or interactions.

Because the majority of medication errors in community settings are made by consumers, it is clear that real progress will require significant efforts to improve consumers' knowledge, skills and motivation to use their medications correctly. Health care professionals and others involved with prescribing, dispensing, administering and monitoring medication use in community settings can all help achieve these goals.

TABLE 1: Institute of Safe Medication Practices' Major Causes of Medication Errors

- Critical patient information is missing (allergies, age, weight, pregnancy, etc.)
- Critical drug information is missing (outdated references, inadequate computer screening, etc.)
- Miscommunication of drug order (illegible, incomplete, misheard, etc.)
- Drug name, label, packaging problem (look/sound alike, faulty drug identification)
- Drug storage or delivery problem
- Drug delivery device problem (poor device design, IV administration of oral syringe contents, etc.)
- Environmental, staffing, workflow (lighting, noise, workload, interruptions, etc.)
- Lack of staff education
- Patient education problem (Lack on patient consultation, non-compliance)
- Lack of quality control or independent check systems in pharmacy
- Physician knowledge is lacking (when a drug comes to market that replaces an existing one or several ones, i.e., a combination drug may mean that a person takes it once a week instead of daily)

⁵ California Code of Regulations, Title 16, Section 1707.1

⁶ Haynes RB, Yao X, Degani A, Kripalani S, Garg AX, McDonald HP. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev* 2005;(4):CD000011.

Working Towards Patient Safety: A Systems Approach

Several experts who testified to the Panel cited multiple reports indicating that efforts to address errors are best targeted not at a particular group of individual “wrong doers,” but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. The Panel consequently agreed to take a “systems approach” for studying the problem and developing its recommendations.

As a result, the Panel spent considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component. The Panel determined the medication-use system to be quite complex involving a multitude of stakeholders. A detailed explanation of the entire system is beyond the scope of this report, but through its work, the Panel identified four key processes and three key stakeholder groups which served as the focus of its recommendations.

Key Medication Use Processes

Prescription, Transcription and Transmission Processes

Once a prescriber decides what medication and dose to prescribe, he or she must find a way to communicate that information to the pharmacy where the patient will have their prescription filled. It is through this communication where a significant proportion of prescription errors occur.

Often, prescribing information is communicated via handwritten prescriptions which employ the use of Latin abbreviations that can sometimes be confusing. These prescriptions can be illegibly written and may be submitted to pharmacies via fax which can further contribute to legibility problems. The most frequent problems of this sort are related to medication names (particularly for drugs that have “look-alike” names such as those in Table 2), and medication strengths.

Table 2: Look-alike/Sound-alike Drug Name Examples	
Seroquel 200mg	Serzone 200 mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg

Alternatively, the prescription can be communicated to a pharmacy verbally over the telephone but this mode of communication is not without its own challenges, such as the confusion of “sound alike” drugs (see examples in Table 2). These problems can be exacerbated through the use of non-professional medical office staff who may not be familiar with drug names and medical terminology. It should also be noted that whenever a person other than the prescriber is used to communicate prescription information over the telephone, they are almost always reading information that was written by another individual, which of course is subject to the same legibility issues as hard-copy prescriptions.

Electronic or “e-prescribing” is, most broadly, the transmission of prescription information from a prescriber to a pharmacy using computer technology. While recent efforts have been made by some prescribers and pharmacies to adopt e-prescribing, medical offices has been slow to do so, predominantly because of high-costs and a lack of incentives for providers to change their practices. Compounding the situation is the fact that state and federal e-prescribing standards have not been set or are inconsistent or conflicting.

Even when medical offices have the technology to facilitate e-prescribing, most do not fully employ it. Rather, they simply use their electronic record systems to send computer generated prescriptions via fax.

While some persons may consider the transmission of a prescription from a computer to a fax machine as “e-prescribing,” others believe that transmitting a static image, picture or facsimile is of limited value to helping ensure information accuracy, quality control or data analysis. The benefit is maximized from e-prescribing only when prescriptions are transmitted in a manner so that a recipient may use and analyze the information without having to manually copy or enter the data received.

The end goal with e-prescribing should be full system connectivity between pharmacies and medical offices to allow for *two-way* communication. Such connectivity could better leverage pharmacy data and has the potential to notify prescribers of possible medication-related problems before they occur.

Another problematic aspect of the prescribing process is that it frequently does not engage the consumer to an appropriate degree. All too often patients leave the prescriber's office without having the adequate medication-related information effectively communicated to them. Of particular concern are the consumers who present to the pharmacy without knowing the most basic information such as the name of the medication or what it is for. Without this minimal knowledge, there is very little consumers can do on their own to identify errors – even the most obvious ones such as receiving the wrong medication.

Consumer Education Processes

At the center of the medication-use process is the consumer. In the community setting, successful medication use is heavily dependent upon consumer knowledge and motivation which can often be lacking. When a person is not well-informed and motivated to manage their therapy, they cannot be expected to take their medication correctly or be an active partner in screening for signs and symptoms of medication efficacy or toxicity. There are a variety of complex reasons why many consumers allow themselves to be passive participants in the medication use process but the most significant is that consumers are largely unaware of, or do not accept the personal risks associated with medication use.

In addition to the consumer education challenges that pertain to the prescribing process, the Panel identified other aspects of the medication use process that could be modified to provide patients with better information and tools to reduce medication errors.

Pharmacist Consultation

While pharmacists are widely known for their dispensing activities, they can also play an important role educating consumers to ensure that the patient or their caregiver knows what the medicine is for, how to take it correctly, and what signs/symptoms should be monitored to assess for efficacy and toxicity.

State regulation requires pharmacists to provide a verbal medication consultation to the patient or the patient's agent each time a new medication is dispensed, or whenever an existing medication therapy is dispensed with a change in dosage form, strength or instructions for use.⁷ This consultation is to include "directions for use and storage and the importance of compliance with the

directions." Also included should be a "discussion of the precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered."

In spite of these requirements, the Panel received testimony suggesting considerable variability in the quality of these consultations as well as the consistency to which they are offered by pharmacy staff and utilized by consumers. The reasons for this are not well defined but there appear to be contributing factors from both the pharmacist end (lack of time and incentives) and the consumer end (lack of awareness regarding availability and perceived value).

While there is not a lot of data about the effectiveness of this dispensing-related counseling, it is reasonable to assume that the significant number of consumer-related medication errors could be positively influenced by greater efforts in this arena, particularly with at risk populations including seniors and minority patients.

Prescription Labels and Labeling

The information that consumers need to know about their medication is often complex and may include unfamiliar language or concepts. Expecting a consumer to retain all the pertinent knowledge from a brief verbal encounter may not be reasonable in many instances. For this reason, it is important that consumers also receive written information regarding their prescription.

Often-times however, even this information can be forgotten and lost, and in those instances, the consumer may be left with nothing more than the prescription packaging and label to guide them. Testimony provided to the Panel identified many limitations related to the prescription label as an effective communication tool. These included the limited size of a prescription label (approximately 2 x 3 inches) which, due to established pharmacy systems, processes, and drug container variability would be functionally and financially difficult for the pharmacy industry to change.

Further complicating matters is the fact that there is already a significant amount of information required by California law to be printed on the label.⁸ The most recent label requirement went into effect on January 1, 2006 and was created to help consumers identify erroneously filled prescriptions by mandating that pharmacies include the physical description of the dispensed medication, including its color, shape, and

⁷ California Code of Regulations, Title 16, Section 1707.2

⁸ California Business and Professions Code 4076

any identification code that appears on the tablets or capsules.

While this requirement is obviously directed at reducing errors, one might question the utility of some of the other label requirements which include the date of issue, the name of the pharmacy, the address of the pharmacy, the prescription number or other means of identifying the prescription, the name of the patient, the name of the prescriber, the name of the medication, the name of the medication's manufacturer, the strength of the drug, the quantity dispensed, the expiration date of the drug, and of course the directions for use. Given the limited space available, are all of these elements the most valuable pieces of information for the patient?

Regarding the directions of use, even when individuals are able to read and repeat back the directions, they may still not understand how to take the medication. This is particularly a problem for individuals with limited health literacy (the ability to read, understand and act on health information). A recent study by Davis, Wolf and others showed that even though 70.7% of patients with low literacy could correctly read and repeat the instructions, "Take two tablets by mouth twice daily," only 34.7% could accurately demonstrate the actual number of pills to be taken daily.⁹ In this study the researchers found that it was common for consumers to make mistakes when dosing medicine for themselves, their elderly parents, and their children.

Tailoring and Targeting Consumer Education Efforts

To maximize the impact of consumer education activities, efforts will need to be tailored and targeted to individuals who are likely to achieve the greatest benefit. While the Panel did not come to consensus on the most important subset of consumers that are at "high risk" for medication errors, it did acknowledge that there are a variety of factors which may increase an individual's risk for experiencing a medication error.

In addition to 1) low health literacy, these can include; 2) limited English proficiency; 3) cultural incongruence with healthcare providers; 4) physical, cognitive and/or other impairments that make understanding and/or complying with medication instructions difficult; 5) age at either end of the age spectrum (the variability of a medication's response, metabolism and dose increases in children and seniors); 6) multiple medications; 7) multiple prescribers;

⁹ Davis TC, Wolf MS, Bass PF 3rd, Thompson JA, Tilson HH, Neuberger M. et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006;146:887-94.

8) non-prescription medication use (including herbals, dietary supplements alcohol and tobacco); and 9) medication procurement from more than one pharmacy including mail-order. These factors must be taken into consideration in the development of any consumer education efforts.

Provider Payment/Incentive Processes

Incentives that directly or indirectly influence the behavior of prescribers and pharmacists are a key aspect of the medication use system. Testimony provided to the Panel indicated that prescriber incentives are frequently not aligned to promote spending time educating patients about medication use, or to closely follow patient compliance and medication monitoring parameters.

A fairly recent collaboration between healthcare purchasers, payers and medical groups provides incentives byway of "pay-for-performance" and shows promise for realigning prescriber incentives to reward behavior that results in positive outcomes. However, it is clear that there is still room for improvement in this area, particularly as it relates to safe and effective medication use.

Similarly, pharmacy incentives appear to do little to encourage pharmacist activity in areas related to patient education and the promotion of safe and effective medication use. Since pharmacies generally only receive compensation when a product is dispensed, financial pressures may, in fact, be driving pharmacy processes and personnel to minimize any activities not directly related to product distribution. Ironically, the structure of this financial model may possibly create disincentives for pharmacists to identify and prevent prescriptions with prescribing errors from leaving the pharmacy.

Fortunately, testimony provided to the Panel suggests that the healthcare system may be in the very early stages of what could be a paradigm shift. It appears that increasing numbers of healthcare purchasers and payers are beginning to understand that there is more to consider when it comes to medication than the simple cost of distribution, and the speed and convenience by which it can be put into the hands of consumers. There is a growing recognition that no matter how cheaply a drug can be purchased, the cost is too great if it does not elicit the desired effect, or worse, causes patient harm.

In response to this growing recognition, more and more healthcare purchasers and payers are developing

specialized initiatives focused around improving medication use, particularly in target populations where safe, appropriate and effective medication use is critical. These “medication therapy management programs” have been developed for people with particular conditions such as diabetes¹⁰, individuals who have multiple chronic conditions and/or take multiple medications, and those whose medication costs exceed a certain threshold.

Perhaps the most prominent example of this early trend is the requirement placed in the Medicare Modernization Act for sponsors of the Medicare Part D drug benefit to have in place a medication therapy management program designed to promote optimal therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

While medication therapy management programs may hold significant promise for reducing medication errors, many issues will need to be resolved before the full potential of such programs can be known and realized. As with any new healthcare initiative, there is uncertainty regarding how the quality and financial returns-on-investment can be maximized by adjusting program variables such as:

- The types of services that are provided (e.g. patient education, medication compliance packaging and comprehensive medication reviews);
- The patient populations that are targeted (e.g. those with a particular condition, medication, cost, or combination thereof);
- The types of providers who deliver various services (e.g. physicians, nurses and pharmacists);
- Service delivery models (e.g. face-to-face, telephone or mail); and
- Payment and documentation methodologies.

Until there is more information and standardization around issues such as these, the spread of medication therapy management programs will likely be slower than perhaps it should. Nonetheless, the fact that innovative purchasers and payers of healthcare are developing novel models to incentivize physicians, nurses, and/or pharmacists to pursue behaviors that will decrease medication errors is a positive step in the right direction.

Healthcare Provider Training and Licensure Processes

Obviously, simply aligning incentives to encourage safe medication practices among healthcare providers is not enough. Providers must also be cognizant of the seriousness of medication errors, know the behaviors to adopt that will reduce errors, and possess the knowledge and skills to effectively execute those behaviors.

Healthcare providers undergo extensive training to become licensed practitioners. Subsequent to licensure, providers must continue training to maintain their licenses. The vast majority of this training is clinical in nature. Most providers receive little education on subjects such as healthcare administration, error prevention, patient communication, and effective, systematic approaches to medication therapy management.

While testimony provided to the Panel indicates that some formal education on topics related to medication errors may be included in provider training programs, the very size of the medication errors problem suggests that the current amount may not be enough. More education in these areas would likely promote greater awareness among providers about what they can do to protect consumers. Informed providers can also be powerful advocates of change in a variety of healthcare settings.

Key Stakeholder Groups

In addition to the four key processes, the Panel identified three key stakeholder groups believed to play critical roles in the development and implementation of initiatives designed to address medication errors.

Consumer-Oriented Organizations

Since the consumer is at the center of the medication use process, it is imperative that all relevant consumer organizations be solicited to join the effort to prevent medication errors. These organizations can play critical roles in educating consumers about medication errors and advocating for healthcare policy and practice changes that have the potential to reduce errors. These groups may be government-related (e.g. the California Department of Consumer Affairs), private foundations, member-benefit organizations (e.g. AARP), or public-benefit organizations.

¹⁰ Information was presented to the Panel on APhA Foundation's Asheville Project. Details can be found at www.aphafoundation.org/programs/Asheville_Project

Healthcare Provider Groups and Related Entities

Healthcare providers such as physicians, nurses and pharmacists are on the front lines of healthcare. In many respects, the burden of reducing medication errors will fall largely on their shoulders. A problem of this scope and size, however, cannot be solved by any single group of individuals, or even by a single sector of the healthcare system acting alone.

Any appreciable reduction in medication errors will require that the entities which support, direct, or influence provider behavior also be actively engaged in addressing this problem. These entities include the academic institutions and professional societies that train providers; the associations that advocate for them; the individuals that manage them; the companies that employ them; and the oversight boards that license and regulate them.

Healthcare Purchasers, Payers and Related Entities

The group that has perhaps greatest opportunity to influence the healthcare system consists of the entities that actually purchase and administer healthcare benefits

– and to some extent, those which regulate and oversee the activities of these groups. Many of these entities have the power to decide which healthcare-related behaviors and outcomes are truly of value, and they can create payment structures, non-financial incentives and/or requirements to drive processes and behaviors that seek to deliver those results.

Stakeholders in this group include: the State of California which uses taxpayer monies to purchase, and through its Department of Health Services, administer healthcare benefits through programs such as Medi-Cal; private purchasers of health care such as employers which purchase healthcare for a majority of Californians under 65; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and, of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Conclusion

Based upon the information provided to the Panel, and the identification of these key processes and stakeholders, the Panel developed 12 consensus recommendations in the following subject areas:

- **Communication Improvements** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients;
- **Consumer Education** to increase consumer awareness regarding the proper use, and dangers of misuse, of prescription and over-the-counter medications;
- **Provider Standards and Incentives** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety;
- **Training and Education for Healthcare Providers** on various medication safety practices;

- **Research** with a focus on obtaining information about the incidence, nature and frequency of medication errors in the community setting.
- **Other Topics to be Addressed** which were determined to be beyond the scope of the Panel but which the Panel recognizes must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

The recommendations are provided in their entirety in the next section of the report.

SECTION II: RECOMMENDATIONS

A. Communication Improvements

Background:

Improving the quality of communication among prescribers, pharmacists and patients is critical to the success of any effort aimed at decreasing medication errors. The existing process for communication among health professionals and their patients leaves much room for improvement, according to testimony received by the Panel. Indeed, California health practitioners have been slow in their adoption of computer-based patient records and electronic prescribing.

Currently, pharmacist-patient consultation is often compromised by the pharmacist's lack of knowledge of the prescriber's treatment objectives, including such basic information as the condition being treated. Confirming prescriber intent with the patient at the time of dispensing is an additional means of confirming that the medication treatment is understood and properly implemented.

In addition, prescribers' lack of writing legibility has long compromised pharmacists in their efforts to correctly dispense the desired drug product and provide accurate instructions for use. Addressing these two problems of communication between prescribers and pharmacists has been shown to substantially decrease medication errors.

In regard to communication between consumers and their health care providers, an important step would be to adopt techniques that bridge the language and cultural diversity of the patient population in California. This would provide the prescriber and pharmacist with the means to confirm that the medication treatment is understood and will be properly implemented.

Another important improvement in communication between health care providers and their patients would result from improved readability of drug labels and user-friendly packaging.

Goal 1: Improve prescriber-pharmacist communication quality and accuracy regarding prescriptions.

Recommendation 1

Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies (allowing for some exceptions) to use electronic prescribing.

Methods

- 1.1 Require each prescription to be legibly hand written or printed, computer generated or typed, and by 2010 that all prescriptions be computer generated or typed.

The California Board of Pharmacy and the California Medical Board shall review and seek modification of statutory and regulatory requirements as needed to implement adoption of computerized prescriber order entry (CPOE) systems and secure 2-way electronic communication between prescribers and pharmacies, with consideration for identified exceptions to the requirement.

- 1.2 Require the California Medical Board to collect and disseminate information in order to educate and assist physicians about the benefits of and ways to adopt electronic prescribing systems and supporting CPOE and secure 2-way transmission to pharmacies. Coordinate these efforts with related activities undertaken by the State. For example, Executive Order S-12-06 was issued by Governor Schwarzenegger on July 24, 2006 regarding efforts planned to make reforms regarding healthcare, especially regarding health information technology.
- 1.3 Require the California Medical Board to adopt regulations by January 1, 2008 that require

prescribers using electronic prescription systems to provide patients with a written "receipt" of the information that has been transmitted electronically to a pharmacy. The document should include at least the patient's name, the dosage and drug prescribed and the name of the pharmacy where the electronic prescription was sent, and should indicate that the receipt cannot be used as a duplicate order for the same prescription.

Goal 2: Improve prescriber-pharmacist and pharmacist-consumer communications to enhance understanding of the intended use of prescribed medication.

Recommendation 2

Require that the intended use of the medication be included on all prescriptions and require that the intended use of medication be included on medication label/labeling unless disapproved by the prescriber or the patient.

Methods

- 2.1. Require the California Board of Pharmacy and the California Medical Board to pursue necessary statutory and/or regulatory changes to require that by January 1, 2008 these entities coordinate efforts to develop plans to require prescribers to include the diagnosis, medical condition, symptoms or other indicators of the intended use of the medication on each prescription written, allowing for some exemptions.
- 2.2. Require the California Board of Pharmacy to pursue necessary statutory and/or regulation changes to require that the intended use of any prescribed medication be included on the medication label, unless the prescriber or consumer disapproves, and consumer disapproval is documented by the pharmacist.

Recommendation 3

Improve access to and awareness of language translation services by

pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

Methods

- 3.1 The California Board of Pharmacy, Department of Health Services and/or the Department of Consumer Affairs should develop and implement methods, when possible in coordination with other state entities, that are designed to reduce barriers for pharmacists at community pharmacies to access and utilize language translation services. These entities should report their respective related activities planned and undertaken annually on their respective websites and to the Assembly and Senate health committees, beginning January 1, 2008. They should, but not be limited to distributing information to pharmacies about the pharmacies' obligations to provide language translation services and resources for pharmacies to do so via the telephone.

Messages related to this method and goal should be included in the public awareness campaign (Recommendation #6) to inform consumers about their right to use language translation services and availability of these services at community pharmacies and other health care providers.

Recommendation 4

Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain a medication consultation from a pharmacist.

Methods

- 4.1 Require the California Board of Pharmacy to examine the existing requirements for prescription container labels, prescription containers, and supplementary consumer information, and to consider revising these requirements to encompass required, supplemental consumer information and California Board of Pharmacy contact information.

Require these finding be issued by January 1, 2009 and distributed to the Senate and Assembly Health committees, posted on the California Board of Pharmacy's website and that public notice be made by issuance of a press release.

4.2 Encourage prescription drug plans, health care service plans, and health insurance companies to develop strategies to provide incentives for pharmacies and drug manufacturers to package medications in a manner that increases medication compliance, safety and efficacy.

4.3 Require the California Board of Pharmacy to adopt regulations mandating all pharmacies, including non-resident pharmacies, provide written materials with all dispensed prescriptions that inform consumers of their right to receive a medication consultation from a pharmacist with any new or changed prescriptions. These regulations should include enforcement provisions and the California Board of Pharmacy should make enforcement a priority.

B. Consumer Education

Background:

There is a great need to increase consumer awareness of the proper use, and dangers of misuse, of prescription and over-the counter-medications. Consumers often do not appreciate the potency and risks involved in the use of drugs that are widely advertised and promoted on television, radio and print media.

The California Board of Pharmacy is in an excellent position to spearhead an educational effort directed toward the public concerning drug safety issues. In recent years, the Board has been recognized nationally for its consumer protection efforts. A Board program that capitalizes on their proven expertise in consumer safety and which takes into account health literacy and culturally appropriate communication could be very effective in alerting consumers to potential medication errors, and in motivating them to adhere to their drug treatment instructions. A commitment by the State of California to capitalize on this proven expertise will go far to aid consumers in understanding their role in recognizing potential medication errors and preventing injury from those that do occur.

Goal 3: Improve consumer awareness and knowledge about the risks of medication errors and about steps they can take to reduce their risk of medication errors.

Recommendation 5

Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

Methods

- 5.1 Propose legislation allocating funds to and requiring the California Board of Pharmacy to:
- a) Identify effective methods for educating consumers about ways to prevent and report medication errors. Include methods that are culturally and linguistically appropriate, especially addressing the needs of persons at high-risk for medication errors.
 - b) Develop guidelines and/or related regulations to define ways for effectively educating consumers to prevent medication errors. Include both verbal and written education strategies.
 - c) Disseminate information about the methods and guidelines/standards to specific relevant public and private sector entities, including mail-order (non-residential pharmacies) and pharmacies that dispense prescriptions to outpatients.
 - d) Improve public access to California Board of Pharmacy services (e.g., telephone, mail, and internet).

Recommendation 6

Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

Methods

- 6.1 Pass legislation allocating funds to and requiring the Department of Consumer Affairs and/or the California Board of Pharmacy to oversee development and implementation of a public education campaign to reduce medication errors. Public and/or private funds may be pursued.

The campaign shall be based on principles of public health practice and shall use methods that have been shown effective in educating consumers. The methods shall be culturally and linguistically appropriate and shall be developed in collaboration with other state entities.

The campaign shall develop messages that educate consumers about their medication use, risks, rights and responsibilities and shall include a consumer's right to basic consultation from a pharmacist with each new or changed prescription.

- 6.2 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with appropriate state entities and stakeholder groups, including but not limited to health plans, retail pharmacists, and consumer advocates representing persons at high risk for medication errors to:
- a) Develop an evidence-based "safe medication use curriculum" that is designed to be used for educating consumers, and promote its availability to intermediaries, such as health care service plans, colleges, high schools, health insurers, Medi-Cal providers, and healthcare providers throughout the state who can educate consumers.
 - b) Post the curriculum on the websites of the relevant state departments and promote its

availability through issuance of a press release and other public notice activities;

- c) Develop and disseminate suggested strategies, possibly unique to each intermediary, to encourage consumers to attend presentations based on the curriculum.
 - d) Create a web-based interactive version of the curriculum that will be posted on websites of designated state entities and require those entities to promote the availability of the curriculum via no or low cost methods, such as press releases, faxes and email.
 - e) Coordinate this activity with the efforts to educate health care professionals about medication errors and prevention issues in Goal 5, Recommendation 10.
- 6.3 Recommend that the California Medical Board and the California Board of Pharmacy encourage physicians and other prescribers to post notice in their offices informing consumers of their right to know, and the benefits of understanding the name of any medication prescribed and the indication(s) and instructions for use, in addition to their right to consult with a pharmacist.

Recommendation 7

Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

Methods

- 7.1 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with a cross-section of public and private sector entities, including prescription drug plans, health care service plans, health insurers, and/or mail-order pharmacies, to support and/or undertake efforts to educate consumers about safe medication use. Use legislative and regulatory means to ensure a joint effort is made by all agencies that regulate these entities to collaborate in these efforts.

C. Provider Standards and Incentives

Background:

The drug consultation given by a pharmacist to their patient, or the patient's agent, can be a powerful means for educating consumers about drug safety. However, current law regarding pharmacists' consultation contains only the minimal requirements that were established in the early 1990s. In light of the substantial changes the State's health care system has undergone since that time, a re-examination of the pharmacist's consultation requirement is in order.

The Panel recommends that the Board of Pharmacy establish new pharmacist consultation standards that would provide greater benefit and protections to the public. Consistency should be a key component of the new standards, and they should take into account the economic and workforce conditions that impact the ability of pharmacists to provide this essential service.

Medication therapy management programs (MTM) provide another important tool in avoiding medication errors. The purpose of these programs is to evaluate whether prescribed medications are yielding desired results and, if not, to recommend or implement adjustments to therapies to maximize outcomes. To properly protect consumers, MTM programs should meet minimum standards for provider qualifications and program design.

Goal 4: Improve the quality and availability of pharmacist-patient medication consultation.

Recommendation 8

Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

Methods

- 8.1 Require the California Board of Pharmacy to review and, as needed, revise current regulations regarding patient consultation to

focus on what would actually be useful to patients to help maximize their therapeutic outcomes and take their medications safely and effectively.

The California Board of Pharmacy shall invite stakeholders, including consumer representatives, to collaborate to develop minimal standards for required consultation. These deliberations should consider factors that reflect the current conditions of the business and healthcare environments, various types of pharmacy practices and practice settings (e.g. community, mail-order, extended care), and the "learning environment" available in those settings for providing consultation. The standards should be applied equally to all providers or entities dispensing medications to California consumers, including non-resident pharmacies.

Nothing in consideration of these standards shall preclude pharmacists from being paid for services that exceed these minimal standards.

These standards should address, at a minimum:

- a) Encouraging or providing incentives to pharmacists for providing patient medication consultation with prescription renewals, when appropriate.
- b) Re-examining the circumstances involved with patients' refusal of consultation, and what type of documentation is required, if any, for patients who refuse consultation. The Panel strongly emphasized that the following factors be considered as part of the re-examination process: (1) prohibiting any pharmacy employee from asking a patient or patient's agent if he/she wants pharmacist prescription consultation (i.e. no "screening" questions) and (2) requiring that the patient communicate the refusal of consultation directly to a pharmacist.

Recommendation 9

Establish standards for medication therapy management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers

Methods

- 9.1 Require the California Board of Pharmacy to identify best practices and to develop evidence-based standards of care for MTM programs, and to disseminate these to known MTM providers, the Department of Health Services, Department of Managed Health Care, Department of Insurance, the Managed Risk Medical Insurance Board, CalPERS, California Medical Board, and to applicable professional and healthcare associations (e.g. California Medical Association, California Pharmacists Association, California Association of Health Plans).
- 9.2 Require the Department of Health Services, Department of Managed Health Care, Department of Insurance, Managed Risk Medical Insurance Board, California Medical Board, Board of Registered Nursing, Board of

Pharmacy, and appropriate private sector entities to develop and implement strategies to incentivize payers, pharmacists and other healthcare providers to implement and routinely use MTM standards of care. These public entities shall report their respective related activities to the Assembly and Senate Health Committees, and to notify the public by posting descriptions of their activities and/or any findings on their websites and notifying the public and media by issuing one or more press releases.

- 9.3 Consistent with the standards developed in this recommendation, require the Department of Managed Health Care, the Department of Health Services and the Department of Insurance to allow health plans, health insurers, and Pharmacy Benefit Managers flexibility in methods of implementing MTM programs, including via face-to-face interaction, call center advice lines, and secure e-mail communication.
- 9.4 Encourage state-funded programs (e.g., Medi-Cal and CalPERS) to establish financial and other incentives for healthcare providers and patients improving drug therapy compliance, including cases of over-use (including therapeutic duplication) and under-use of prescription medication.

D. Healthcare Provider Training and Education

Background:

Good communication skills are essential in the current health care environment, and are a key tool in reducing medication errors. Pharmacists and other health care professionals must take into account their patients' language skills and cultural characteristics in order to effectively convey essential information to them. There is therefore a need to educate prescribers and pharmacists concerning improved ways to help their patients understand the proper use of medications, the importance of complying with their treatment regimen, and the need to report any problems to their prescriber or pharmacist.

Considering the ever increasing numbers of patients who have conditions that can be managed with therapies that are frequently long-term and involve the use of multiple medications, healthcare providers are also likely to

benefit from more training and education around the intricacies of medication therapy management (MTM). While much of this information is already an integral component of pharmacist training, many of the skills needed to apply it are distinct from a pharmacist's traditional dispensing role. Consequently some pharmacists may have a need to obtain other types of training as well.

Goal 5: Improve education and training of pharmacists and other health care professionals about medication errors and prevention methods.

Recommendation 10

Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

Methods

- 10.1 Require that the licensing boards for relevant health care professionals (e.g., pharmacists, physicians, nurses, dentists and optometrists) establish specific requirements for training/education about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, and medication therapy management methods) as part of licensure, certification, and/or continuing education requirements. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.
- 10.2 Encourage the colleges, universities, and schools that provide degree programs for health care professionals (e.g., pharmacists, physicians, nurses, dentists, optometrists, pharmacy technicians) to establish and maintain specific curricular requirements about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).
- 10.3 Encourage employers of healthcare providers, as well as the healthcare professional associations (e.g., the California Medical Association, California Pharmacists Association, California Society of Health System Pharmacists, and California Nurses Association), to establish and maintain ongoing training and educational activities for their respective constituencies about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).
- 10.4 Require that the licensing boards of relevant healthcare professions (e.g. pharmacists, physicians, nurses, dentists and optometrists) evaluate the effectiveness of their respective licensing requirements (e.g. board examinations) in determining a licensee's ability to communicate medication-related information and instructions to consumers in a manner that reduces the risk of medication errors related to patient misunderstanding. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

E. Research about Prevalence & Occurrence of Medication Errors

Background:

Obtaining information about the incidence, nature and frequency of medication errors in the community setting is challenging. Most research on medication errors has been conducted in hospitals, even though the drugs administered in inpatient settings represent a very small proportion of medications dispensed. Indeed, there is comparatively little academic research available regarding medication errors occurring in the community setting. While it appears that this situation is beginning to improve, a greater emphasis on research related to medication errors in the community setting is definitely warranted.

Goal 6: Increase evidence-based information about the nature and prevalence of medication errors available to policy-makers, pharmacists, consumers, and other interested parties.

Recommendation 11

Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

Methods

- 11.1 Require by legislation, regulation, joint legislative resolution, and/or issuance of a Governor's Executive Order that the California Board of Pharmacy establish an agreement with a private sector organization, such as the Institute of Safe Medication Practices (ISMP), to establish a pilot project to collect and analyze data about the nature and prevalence of medication errors at California community-based pharmacies.

Require that the cost of this project to the State be negligible.

Require the California Board of Pharmacy to share data about medication errors reported to it with the entity responsible for implementing this recommendation and that the Board collaborate with the entity responsible for implementing this recommendation to promote the project to consumers, pharmacies and providers. The project should ensure that:

- a) Prescribers, pharmacists and consumers may voluntarily and confidentially report errors to the ISMP or other responsible entity.

- b) The entity responsible for implementing this recommendation report annually to the California Board of Pharmacy, the California Medical Board and the Senate and Assembly health committees, and that these reports indicate if an error occurred either under the auspices of a health care facility or in a community setting (i.e., retail pharmacy or private residence) and the severity of the error (i.e., if it resulted, contributed or may have been associated with death, hospitalization or serious injury).
- c) The information collected and reported by this project should not be used in any legal proceedings against prescribers and/or pharmacists.
- d) The project be designed to minimize conflict with existing systems that are used to collect data from pharmacies as part of their current California Board of Pharmacy Quality program.
- e) Efforts to inform consumers about this project include information handed out at pharmacies, on medication information sheets, and with related public education campaigns.
- f) The California Board of Pharmacy and the Medical Board post the reports produced by this project on their respective websites.
- g) Persons reporting errors to the entity responsible for implementing this recommendation be informed of their right to also report errors to the California Board of Pharmacy and the benefits of doing so.

F. Other Topics to be Addressed

Background:

The many obstacles that pharmacists face in providing drug consultation to their patients as required by law are exacerbated by the lack of a payment system that would compensate them for the time and expense associated with performing these mandated tasks. Before additional duties can be imposed on pharmacists practicing in the outpatient setting, changes to the health care financing/

reimbursement system must occur. This issue was beyond the charge of the Panel, but it was recognized to be an issue that must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

Goal 7: Develop strategies designed to increase incentives for pharmacists to offer and provide medication consulting and medication therapy management services to consumers.

Recommendation 12

Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

Methods

- 12.1 The Legislature should convene a panel of stakeholders representing California pharmacists, healthcare providers, consumer groups, payers, health plans and other perspectives to hold a series of public meetings and issue recommendations addressing the reimbursement of pharmacists for non-dispensing services.

Reimbursement for medication consultation should be based on standards of care (see recommendations and discussion under Goal 4). If such standards have not been adopted at the time that the panel is convened, then the panel should make recommendations to the California Board of Pharmacy about development of the standards.

In considering recommendations for reimbursing pharmacists for patient medication consultations, the panel should weigh factors based on patient-specific information, including, but not limited to time spent providing the consultation or complexity of the consultation (the number of medications taken by the consumer, the consumer's compliance challenges, language, literacy or translation needs, or patient diagnosis). Additionally, the panel should take into account the most current thinking on this subject from relevant regional or national entities such as the US Centers for Medicare and Medicaid Services, Quality Improvement Organizations, and pertinent payer and provider organizations.

SECTION III: APPENDICES

Appendix A: Panel Meeting Dates and Speakers

The Medication Errors Panel held 12 meetings in Sacramento, the first on May 5 and the last on November 16, 2006. Presentations were made to the panel by persons listed below on the dates indicated.

May 5

- Senator Jackie Speier, Panel Chair and Author of SCR 49
- Senator Sam Aanestad, Panel Member
- Lynn Rolston, CEO of CA Pharmacists Association
- Robert MacLaughlin, Aging and Long Term Care, Senate Health Subcommittee
- John Gilman, Assembly Health Committee
- Dawn Adler, Office of Assemblymember Betty Karnette
- Sang-ick Chang, M.D., San Mateo County Medical Center
- Michael J. Negrete, Pharm.D., Pharmacy Foundation of CA

May 19

- Eleanor M. Vogt, R.Ph., Ph.D., Health Sciences Clinical Professor and 2004 – 2005 Presidential Chair, UC San Francisco School of Pharmacy
- Patricia Harris, Executive Director, Board of Pharmacy
- John Gallapaga, SmartRx for Seniors
- Lisa Chan, Office of Assemblymember Wilma Chan

June 2

- Michael Cohen, R.Ph., MS, FASHP, founder of the Institute for Safe Medication Practices (ISMP)
- Patricia Harris, Executive Director, CA Board of Pharmacy
- Dave Thornton, Executive Director, CA Medical Board
- Dr. William Soller, PhD, Executive Director, Center for Consumer Self-Care, University of CA, San Francisco

June 16

- Bill G. Felkey, Professor, Pharmacy Care System, Auburn University, Alabama
- David Murphy, SureScripts
- Pam Bernadella, RPh, Manager, Pharmacy Professional Services, Target Corporation, Minnesota

June 30

- Victoria Bermudez, RN, CA Nurses Association
- Lori Hack, Interim CEO, CA Regional Health Information Organization
- Sharon Youmans, Pharm.D, MPH, Professor of Clinical Pharmacy, University of CA, San Francisco

August 11

- Dr. Robert E. Lee, Jr., Eli Lilly, and U.S. Food and Drug Administration Trademark Focus Group Member
- Tom Williams, CEO, Integrated Healthcare Association
- David Murphy, SureScripts and Get Connected CA
- Carmella Gutierrez, Lumetra
- Peter Boumenot, Lumetra, Electronic Health Records Implementation Consultant

August 25

- Paul Tang, MD, Vice President, Chief Medical Information Officer, Palo Alto Medical Foundation, Sutter Health

- Susan L. Ravnan, Pharm. D., Associate Professor, University of The Pacific Thomas J. Long School of Pharmacy and Health Sciences; CA Society of Health System Pharmacists representative

September 15

- Robert Friis, PhD, California State University Long Beach, Department of Health Sciences Chair, and American Public Health Association Southern California Chapter President
- Gurbinder Sadana, MD, FCCP - Director of Critical Care Services, Pomona Valley Hospital Medical Center; California Medical Association representative

September 29

- Panel committees begin work of drafting recommendations for final report

October 13

- J. Kevin Gorospe, Pharm. D., Chief, Medi-Cal Pharmacy Policy Unit
- Loriann De Martini, Pharm.D., Chief Pharmaceutical Consultant, Licensing and Certification Division, Department of Health Services

November 2

- Senator Jackie Speier, Panel Chair, met with the Panel to discuss major issues, and Panel's progress on developing final recommendations

November 16

- Final meeting of the Panel to discuss recommendations

Appendix B: Prior Legislative Efforts to Address Medication Safety

The following legislation relevant to the objectives of the Panel has been enacted:

- SB 1339 (Figueroa) became law in 2000 and requires pharmacies to establish quality assurance programs to reduce frequency of medication errors. Every pharmacy is required to have a system of tracking and assessing errors so that the proper steps can be taken to reduce the chance of a reoccurrence. It exempts any documents generated by the program from legal discovery proceedings.
- SB 1875 (Speier), 2000, requires hospitals and surgical centers to develop medication error reduction plans and submit the plans to the Department of Health Services. In order for a health facility or clinic to obtain a license it must complete a plan to eliminate or substantially reduce medication error by 2005.
- SB 292 (Speier) 2003, requires labels on pill bottles to include a written description of the drug that was prescribed, including its color, shape, and any identification code appearing on the tablets or capsules. (This bill initially sought to have a color image of the pill or tablet printed on the bottle label.)
- SB 151 (Burton), 2004, requires that tamper-resistant security forms be used for nearly all *written* prescriptions for controlled substances (Schedules II-V). This pre-printed and numbered form must contain at least ten security features and replaces the Schedule II triplicate prescription forms. Pharmacies must report Schedule III prescriptions to the CURES program.

There were six bills before the legislature during the 2005-2006 session that had objectives relevant to medication safety. They were the following:

- AB 71 (Chan) would have established the Office of the California Drug Safety Watch to administer a database of information about the safety and effectiveness of highly advertised prescription drugs. The database was to include reports of adverse drug reactions (ADRs) which would have been accessible to health professionals and the public. This bill is inactive.
- AB 657 (Karnette) would have required that the purpose or indication of a medication be listed on the prescription label if a prescriber had written it on the prescription. This bill is inactive.
- SB 1301 and SB 380 were both introduced by Senate Elaine Alquist in 2005. SB 1301 was chaptered September 29, 2006 and requires acute care facilities to report ADRs to the Department of Health Services within five days of the occurrence. SB 380 originally contained a mandatory reporting requirement to the federal Food and Drug Administration for all serious ADRs, but was amended to address a non-related issue.
- SB 329 (Cedillo) 2005, would have established the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency. The Commission would request assistance from a unit of the University of California and be a repository of information about prescription drug safety and effectiveness. In February 2006, this bill was returned to Secretary of Senate pursuant to Joint Rule 56.
- AB 72 (Frommer) 2005, would have established the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. On January 31, 2006, this bill died on the inactive file.

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**Testimony and Comments before the California State Board of Pharmacy
RE: 16 California Code of Regulations Section 1707.5 Relating to Patient-
Centered Prescription Drug Labels**

**Board of Pharmacy Hearing, Sacramento, CA
January 20, 2010
Doreena Wong, Senior Attorney, NHeLP**

On behalf of the National Health Law Program (NHeLP), I am submitting the following comments to the proposed regulations issued on November 20, 2009. NHeLP is a national public interest legal organization seeking to improve health care for America's low-income population, including people of color, women, children, the elderly and people with special needs, including immigrants and limited-English proficient (LEP) individuals

As expressed in our initial comments to the proposed regulations submitted on January 4, 2010, we believe that SB 472 requires the Board to issue stronger regulations in order to address the needs of LEP patients. The current proposed regulations do not reflect the intent or the statutory requirements of SB 472. We are submitting an attached document with recommended changes to the proposed regulations for your review and the comments below provide support for the proposed changes in the order presented by the proposed regulations, and not necessarily the order of importance.

Sections (a) & (c)

We strongly support subdivisions (a)-(c), with some slight exceptions as noted, especially the requirement that the four listed items in (a)(1) shall be printed in 12-point font, which is critical to ensure that seniors and older patients will be able to read the labels. This proposed requirement has been supported by strong testimony provided by seniors to the Board of Pharmacy (Board) and by many studies share with the Board.

With regard to subsection (a)(1)(D), we recommend that the phrase, "and its inclusion on the label is desired by the patient" be deleted. Since the patient is unlikely to have this information or to know to ask for the information, it does not seem reasonable to require the patient to ask for the "purpose or condition" to be included. As will be explained below to support the notice requirement for patients, if the patient does not know what rights she or he has, or what to ask for or to expect, he or she will not know to make specific requests such as this. The requirement that the patient "desires" the information is not required in the container and labeling requirements in Cal. Business & Professions Code Section 4076(a)(10).

Section (b) & Recommendation (d)

We also recommend that the number of languages for which the Board should translate the seventeen (17) directions listed in subdivision (a)(4) be expanded to match the twelve (12) non-English Medi-Cal Managed Care threshold languages. These languages have been identified by the Department of Health Care Services as the top languages of Medi-Cal LEP beneficiaries and can be a useful guide to identify the most common languages spoken by LEP patients. It would expedite the Board's identification of the languages for which the labels should be translated. There is precedent for the Board to defer to the Department of Health Care Services to designate the languages for the translation of information, such as the lists of drugs covered in the state's AIDS drug program, in which pharmacies may participate. *See* Cal. Health & Safety Code Section 120970(j). The Board has also translated Emergency Contraception Fact Sheets into ten (10) non-English languages.¹

Recommendations (d) & (e)

In order to ensure that LEP patients understand medication instructions, at a minimum, the seventeen (17) directions that the Board will translate and post on its website must be used by pharmacists/pharmacies. Title VI of the 1964 Civil Rights Act² prohibits discrimination on the basis of race, color, or national origin and provides the framework to support the provision of language assistance services, including the translation of vital documents, such as prescription drug labels. Any provider that receives federal funding, including pharmacists and pharmacies, must take reasonable steps to ensure that LEP individuals have meaningful access to their programs and services. Since most pharmacies receive some form of federal funding through their participation in the Medi-Cal, Healthy Families, Medicare, or any other federal program.

There is also an analogous state statute that prohibits any state-funded entity from discriminating on the basis of race, color, national origin, ethnic group identification, religion, age, sex, or disability.³ Since many pharmacies and pharmacists participate in state-funded health programs, including programs which are joint federal-state programs, such as Medi-Cal and Healthy Families, they must ensure full and equal access to their services to all patients and cannot subject LEP patients to any discriminatory activity.

According to the 2006 American Community Survey of the U.S. Census, over 42% of Californians speak a language other than English at home, which is significantly above the national figure of 19.7%. Of these, 47% report that they do not speak English "very well" and thus could be considered LEP (representing just over 20% of all Californians). Given the large LEP population in California, and after hearing repeatedly from LEP patients at these Board hearings about the serious consequences of misunderstanding medication instructions, there should not be

¹ *See* http://www.pharmacy.ca.gov/consumers/emergency_cont.shtml; Cal. Business and Professions Code Section 4052.3(e).

² 42 U.S.C. § 2000d. *See also* Executive Order 13166, 65 Fed. Reg. 50121 (August 11, 2000).

³ Cal. Govt. Code Section 11135 et al. Regulations implementing the statute address language-based discrimination and provide a clear list of general discriminatory practices, including specific types of discrimination based on ethnic group identification. 22 Cal. Code Reg. §§ 98101 & 98211. One provision states that it is a "discriminatory practice for a recipient to fail to take appropriate steps to ensure that alternative communication services are available to ultimate beneficiaries. 22 Cal. Code Reg. §98211(c). "Alternative communication services" means the method used or available for purposes of communicating with a person unable to read, speak, or write in the English language, including the provision of a multilingual employee or an interpreter, or written translated materials in a language other than English. 22 Cal. Code Reg. §98210(a).

any question of the critical need for translated labels. Numerous articles and studies have highlighted the language barriers faced by LEP patients.⁴ Guidance issued by the Office for Civil Rights, U.S. Department of the Health and Human Services, also provides strong support for the translation of “vital documents,” such as prescription drug labels, dosage instructions, and warning labels.⁵

As noted in prior comments, a complaint based upon Title VI and two state pharmacy provisions related to counseling and label misbranding was filed with the New York Attorney General’s office against chain pharmacists in New York. This resulted in a settlement that should guide the Board’s current deliberation. It required seven major pharmacy chains to provide free language assistance services and required pharmacies to: (1) identify whether a customer needs assistance in understanding their prescription medication, (2) provide oral counseling in a patient’s primary language regarding prescriptions, (3) translate prescription labels and directions regarding dosage and safety information, warning information, and other written important information in languages that are spoken by more than one per cent (1%) of the population in New York, which is currently Spanish, Chinese, Italian, Russian, French, and Polish, (4) train staff in language assistance policies, and (5) inform customers of their right to free language assistance services, including free oral interpretation and/or assistance in reading and understanding their prescription medication in multi-lingual signs. Written translation of other written important or vital information includes notices of privacy, written offers of counseling and any other materials that the pharmacy considers important to a customer’s safe and effective use of the prescription medication. Therefore, translation of the prescription drug label is only the initial step in addressing the translation needs of the LEP patients.

There is further support for the translation of prescription drug labels and other clinical information in the Office of Minority Health’s National Standards on Culturally and Linguistically Appropriate Services in Health Care.⁶ One of its mandates based on Title VI, Standard 7, states that health care organizations, including pharmacies, “must make available

⁴ See e.g., Institute of Medicine Report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health* (2002); Chattanooga Times Free Press, *Language problems at the pharmacy*, at: <http://www.timesfreepress.com/news/2009/apr/27/language-problems-pharmacy>; National Health Museum, *Medical Misunderstandings*, <http://www.accessexcellence.org/HHQ/qow/qow06/qow061204.php>; and *Language Barriers Plague Almost Half of U.S. Drug Stores*, <http://health.usnews.com/usnews/health/healthday/070806/language-barriers-plague-almost-half-of-us-drug-stores.htm>.

⁵ U.S. Department of Health and Human Services, Office for Civil Rights (OCR), Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (OCR LEP Guidance), 68 Fed. Reg. 47311 (Aug. 8, 2003). There is a four factor analysis to determine compliance with Title VI: 1) the number or proportion of LEP persons eligible or likely to be served, directly affected, or encountered by the program, 2) the frequency with which LEP persons have or should have contact with the service, 3) the nature and importance of the program or service to the people’s lives, and 4) the resources available to the federal fund recipient and costs. 68 Fed. Reg. 47314-15. OCR balances the four factors on a case-by-case basis. With regard to written translation, the guidance designates “safe harbors” that provides evidence of compliance if met (if the language groups constitutes 5% or 1000, whichever is less, of the population of persons to be served or likely to be served or encountered, or if fewer than 50, the recipient provides written notice in the primary language of the right to receive competent oral interpretation of vital materials, free of cost. *Id.* at 47319.

⁶ Office of Minority Health, *National Standards on Culturally and Linguistically Appropriate Services in Health Care (OMH CLAS Standards)*, 65 Fed. Reg. 80865 (Dec. 22, 2000), reprinted at: <http://www.omhrc.gov/clas>.

easily understood patient-related materials and post signage in the languages of the commonly encountered groups and/or groups represented in the service area.”⁷ Patient-related materials include “medical and treatment instructions” and “clinical information.”⁸ Therefore, usage of the 17 translated directions should not only be mandated by pharmacies and pharmacies, but translation of all of the items in the standardized label as described in subdivision (a)(1) must be required.

As noted in previous comments, there are also state pharmacy requirements that require written information, which should also be translated: 1) for refills, the patient must be provided with written information, either on the prescription label or with the prescription container, which describes which pharmacy to contact if the patient has any questions about the prescription or medication;⁹ and 2) if the patient is not in the pharmacy (including drugs shipped by mail), a pharmacy must ensure that the patient receives written notice of her right to request consultation, and a telephone number from which the patient may speak to a pharmacist.¹⁰ In order for an LEP patient to receive written information, it must also be translated for the LEP patient. So the requirement for translation of materials goes beyond the prescription drug labels.

Many of the major chains, which operate in California, including CVS, Rite Aid,¹¹ Costco, Target and Wal-Mart, are currently or will be translating prescription drug labels by May 2010 and can provide guidance to, and share promising practices with, smaller pharmacies. However, we understand that some of the independent pharmacies may take longer to develop procedures for providing bilingual staff and interpreters, and written language assistance, including translated prescription drug labels, for their LEP patients. Therefore, the Board may decide to phase-in the translation requirement if necessary. However, as many LEP patients have been experiencing serious harm and suffering over the years and have been waiting for translated labels for many years, we would urge a deadline, such as a phase-in period no more than a year from the effective date of the regulations.

Section (d)/Recommendation (f)

All stakeholders agree that LEP patients must be provided oral language assistance, and in fact, pharmacy representatives have testified that they are already providing interpreter services. Thus, it is recognized that oral language assistance must be provided to the LEP patients in order to ensure that they understand how to take their medications and can ask questions and receive

⁷ *Id.*, *Final Report* at 13 available at [t: http://minorityhealth.hhs.gov/assets/pdf/checked/finalreport.pdf](http://minorityhealth.hhs.gov/assets/pdf/checked/finalreport.pdf).

⁸ *Id.* “An effective language assistance program ensures that written materials routinely provided in English to applicants, patients/consumers, and the public are available in commonly encountered languages other than English. It is important to translate materials that are essential to patients/consumers accessing and making educated decisions about health care. Examples of relevant patient-related materials include applications, consent forms, and medical or treatment instructions.” *Final Report* at 77. *Clinical information*—“prevention and treatment instructions, including how to prevent transmission of a contagious disease, what to do before, during, and after a procedure or treatment (e.g., surgery, chemotherapy), how to take medications, and how to perform routine self-care or self-monitoring.” *Final Report* at 78, available at:

<http://www.minorityhealth.hhs.gov/templates/browse.aspx?|v|=2&|v|ID=15>.

⁹ Cal. Code Regs. tit 16 § 1707.4(a)(3).

¹⁰ Cal. Code Regs. tit. 16 § 1707.2(b)(2).

¹¹ See e.g., Rite Aid Now Offers Prescription Bottle Labels In 11 Different Languages (2005), http://www.riteaid.com/company/news/news_details.jsf?itemNumber=728.

responses from the pharmacists.¹² It is clear that the burden cannot be placed on the LEP patient and that the pharmacy or pharmacist is responsible for providing interpreters to ensure effective communication is provided to the LEP patient. This is not only required by previously discussed federal and state statutes and regulations but specifically with regard to counseling requirements in federal and state law.

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), which amended a section of the Medicaid Act, had a significant impact on standardizing pharmacy laws.¹³ In order to receive federal Medicaid matching funds, OBRA requires standards for dispensing prescriptions to assure the quality of use and distribution of prescription drugs. Each state must have a Prospective Drug Use Review (DUR) Program, which sets forth minimum standards in patient counseling and requirements for recording and maintaining a patient medication profile.¹⁴

With respect to counseling of Medi-Cal recipients, the DUR requires that a pharmacist offer to counsel each individual (or a caregiver) who presents a prescription. The counseling should be done in person whenever practicable, or through a telephone service, which must be toll-free for long-distance calls.¹⁵ When applying these standards to LEP patients, pharmacist should conduct in-person counseling when possible and not charge LEP patients any long-distance charges.

According to state regulations, pharmacists must provide oral consultation to patients in all care settings when the patient is present in the pharmacy for new prescriptions and when a prescription has not been dispensed to the patient in the same dosage, form, strength, or with the same directions.¹⁶ Further, a pharmacist must provide counseling in all care settings upon request or when the pharmacist deems it warranted in his or her professional judgment.¹⁷ When oral consultation is provided, it shall include directions for use and storage and the importance of compliance with directions and precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.¹⁸ In order to comply with these counseling requirements, the pharmacist must engage the use of bilingual staff and/or competent interpreters to communicate with the patient effectively, and must do so regardless if the patient requests such counseling.

Recommendation (g)

The issue of providing notice to LEP patients of their right to free interpreter and translation services needs to be addressed in the regulations. Title VI recommends notice to LEP persons

¹² Many of the same federal and state requirements for written language assistance services, such as translation of materials, also apply even more clearly to the provision of oral language assistance services, such as interpreter services. *See infra*, footnotes 2-6. *See also OMH CLAS Standards*, Standard 4: Health care organizations must offer and provide language assistance services, including bilingual staff and interpreter services, at no cost to each patient/consumer with limited English proficiency at all points of contact, in a timely manner during all hours of operation. **Standard 6:** Health care organizations must assure the competence of language assistance provided to limited English proficient patients/consumers by interpreters and bilingual staff. Family and friends should not be used to provide interpretation services (except on request by the patient/consumer).

¹³ 42 U.S.C. § 1396r-8(g).

¹⁴ *See id.*

¹⁵ *Id.*

¹⁶ Cal. Code Regs. Tit. 16, §1707.2(b).

¹⁷ *Id.* at § 1707.2(a).

¹⁸ *Id.* at §1707.2(c).

about available language assistance services through, for example, posting signs in intake areas and other entry points.¹⁹ One of the OMH CLAS Standards, Standard 5, states that health care organizations “must provide to patients/consumers in their preferred language both verbal offers and written notices informing them of their right to receive language assistance services.”²⁰

State pharmacy requirements also recognize the need for consumer notices. For example, pharmacies must have a prominent and conspicuous notice, readable by prescription drug consumers, that includes information about the availability of prescription drug prices, generic drugs, *services provided by pharmacies*, and a statement of patients’ rights (emphasis added).²¹ The notices also encourage patients to talk to their pharmacists with concerns or questions.

If an LEP patient is not provided notice of his or her rights to an interpreter or translated written materials, he or she will not ask for any language assistance services. Therefore, similar to the need for required consumer notices, notices informing LEP patients of the availability of language assistance services is necessary to ensure that such services will be provided when needed.

Recommendation (h)

Pharmacies must maintain medication profiles for all patients that contain demographic and medical information, as well as additional information the pharmacist deems appropriate in his or her professional judgment.²² As mentioned above, OBRA also requires the pharmacist to make a reasonable effort to obtain, record, and maintain certain information, including comments relevant to the individual’s drug therapy.²³ Pharmacists should record a patient’s language in the patient medication profile under a “comment relevant to drug therapy” or other appropriate field capturing individual demographic information and history. The pharmacist’s knowledge of the patient’s primary oral and written language is not only relevant, but critical to being able to communicate with the patient regarding her or his drug therapy to achieve optimum results. Having the information in the medication profiles would also help facilitate and expedite any necessary language assistance services the LEP patient may need.

Section(e)/Recommendation (i)

We believe that the proposed time period of nearly four years to re-evaluate the requirements in these regulations is too long. The pharmacies have been on notice since the passage of SB 472 in 2007 and the Board must submit another report to the Legislature by January 1, 2013 regarding the status of implementation of the requirements. It would be more useful if the Board evaluates the implementation of the regulations before it must submit its report to the Legislature in December 2012.

We appreciate the opportunity to provide the Board with our recommendations and hope that the Board finds the information helpful. If you have any questions, please do not hesitate to contact me at wong@healthlaw.org or call (310) 204-6010, ext. 107.

¹⁹ See *infra* footnote 5, OCR LEP Guidance, 68 Fed. Reg. at 47319-21

²⁰ See *infra* footnote 7, *Final Report* at 70.

²¹ Cal. Bus. & Prof. Code § 4122(a); see also Cal. Code Regs. tit. 16, § 1707.2(f).

²² Cal. Code Reg. tit. 16 §1707.1

²³ See *infra* footnote 13, §1396r-8(g).

Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss

A Collaborative Project of

**American Society of Consultant Pharmacists
Foundation**

and

American Foundation for the Blind

These Guidelines provide pharmacists and pharmacies with specific recommendations for making important medication information accessible for patients with vision loss. The Guidelines also serve as a resource for persons with vision loss and organizations serving this population.

Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss

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Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss

INTRODUCTION

The American Society of Consultant Pharmacists Foundation, in collaboration with the American Foundation for the Blind, developed Guidelines for Prescription Labeling and Consumer Medication Information for Persons with Vision Loss (“Guidelines”). The purpose of the Guidelines is to provide pharmacists and pharmacies with specific recommendations for making important medication information accessible for patients with vision loss. The Guidelines will also serve as a resource for persons with vision loss and organizations serving this population.

There are many medication safety issues associated with vision loss. Low vision and blindness affect the ability to read prescription labels and information sheets about medications; determine the color, shape, and markings distinguishing a medication; or see markings on measuring or testing devices. People who cannot read prescription labels or distinguish among different medications must rely on memory, use compensatory strategies or devices, or depend on someone else for help when managing medications.

Lack of access to prescription information due to vision loss is a problem that cannot be ignored by pharmacy. A concerted effort on the part of pharmacists and pharmacies is needed to address the problem, which will increase in magnitude as the population ages. The leading cause of vision impairment and blindness among older adults in the U.S. is age-related eye disease. These conditions—including age-related macular degeneration, cataracts, diabetic retinopathy, and glaucoma—affect more Americans than ever before. The number of persons at risk for age-related eye disease is increasing as the baby boomer generation ages, and the number of Americans with age-related eye disease and the vision impairment that results is expected to double within the next three decades. In addition to age-related eye disease, physiologic changes in vision that occur with age, such as loss of near focus (presbyopia), reduced contrast sensitivity, and visual field impairment contribute to a reduction in visual acuity.

Most older people who lose their vision due to age-related eye disease are not aware of services that can help them cope with vision loss or techniques and devices that can make their activities of daily living easier. In order to ensure access to prescription information, pharmacists and pharmacies must take steps to identify and accommodate their patients with vision loss. In addition, pharmacists and pharmacies have an important role to play in directing their patients with vision loss to rehabilitation services, assistive technology, and other resources.

The components of the Guidelines and specific recommendations were developed by an advisory board comprised of individuals from vision loss organizations, government, pharmacy, and pharmacy system vendors. The draft Guidelines were circulated to stakeholders in pharmacy, vision loss organizations, and other relevant organizations for comment. In addition to specific format recommendations for prescription labeling and consumer medication information (CMI), the Guidelines also provide suggestions for making information accessible to people for whom larger print is not useful and

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general information on assistive technology, resources, and services that pharmacists and pharmacies can share with their patients with vision loss (See appendices).

CONSIDERATIONS FOR MEETING NEEDS OF PERSONS WITH VISION LOSS

To best meet the needs of persons with vision loss, consider:

- Who will benefit from large-print prescription labels and large-print CMI.
- Who may require enhanced magnification.
- Who are braille readers (only a small percentage of people with vision loss).
- Who has access to Internet resources.
- Who has access to assistive technology, such as audible prescription label readers, recorders, or scanners.
- Who has other impairments in addition to vision loss, such as cognition, physical function, or hearing, which may affect the ability to access prescription information or manage medications.
- Who may require assistance of another person to manage medications.

GENERAL RECOMMENDATIONS FOR PRESCRIPTION LABELS

- Use the largest font size label will allow.
- Use sans serif, standard font (not narrow or condensed), such as Arial, Verdana, or APHont™. APHont™ was developed specifically for low vision readers and embodies characteristics that have been shown to enhance reading speed, comprehension, and comfort for large print users. Available free at www.aph.org/products/aphont.html.
- Use upper and lower case, not ALL CAPS.
- Use **bold typeface** for labels. Do not use *italic*, oblique, or condensed type.
- Use non-gloss paper and label stock. Do not cover label with tape.
- When affixing labels to a manufacturer-supplied bottle, do not cover medication name and strength on original label.
- Provide written description of medication and picture of medication, if possible. In the alternative, refer patient to Web sites that provide pictures of medications, such as <http://www.mypillbox.org/mypillbox.php>; www.healthline.com; www.webmd.com.
- If the pharmacy offers prescription label information in large print, this should be prominently posted at the prescription counter or communicated directly to each patient.

See Table 1 for specific format recommendations.

SPECIFIC RECOMMENDATIONS FOR LARGE-PRINT PRESCRIPTION AND AUXILIARY LABELS

In addition to the General Recommendations for Prescription Labels, the Advisory Board recommends that a minimum of 18-point type be used for people with vision loss. The Advisory Board recognizes that standard prescription label size will not accommodate the required labeling information in 18-point type. Therefore, the Advisory Board recommends that pharmacies:

- Provide “duplicate labels” (prescription and auxiliary) printed in a minimum of 18-point type on paper stock.
- If pictograms are used, these should also be provided in “large print” format and high contrast (saturated black on white background).
- The “duplicate labels” should be matched in some way to the prescription container, such as by using a large-print number or colored sticker on both the duplicate label and the corresponding medication container.

See Table 1 for specific format recommendations.

SPECIFIC RECOMMENDATIONS FOR CONSUMER MEDICATION INFORMATION

- All information required to take a medication correctly and safely should be provided verbally and in accessible format directly to every patient with vision loss, including precautions and information about medication preparation and/or storage.
- Print drug monographs in minimum 18-point type.
- Provide drug monographs in electronic format if patient has computer access.
- Refer patients to specific consumer medication information Web sites if patient has Internet access.
- Provide consumer medication information in braille or refer to service that provides braille “translation” for individuals who can read braille (See Appendix 7).

See Table 1 for specific format recommendations.

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for People with Vision Loss**

Table 1. Format Recommendations for Prescription Labels and CMI for People with Vision Loss

<p>Contrast Text should be printed with the highest possible contrast.</p>	<p>–Use black letters on white or pale yellow background. –Avoid the use of red, yellow, or blue type and backgrounds other than white or yellow.</p>
<p>Paper Finish Paper with a glossy finish can lessen legibility because of glare.</p>	<p>–Use uncoated paper/label stock. –Do not cover prescription label with reflective tape, which may cause glare.</p>
<p>Case</p>	<p>Use upper and lower case, rather than ALL CAPS.</p>
<p>Font Family Sans Serif fonts are fixed-stroke width fonts providing consistent letter contrast to aid reading acuity and efficiency.</p>	<p>Use sans serif font, such as Arial, Verdana, or APFont™. APFont™ was developed specifically for low vision readers and embodies characteristics that have been shown to enhance reading speed, comprehension, and comfort for large print users. Available free at www.aph.org/products/aphont.html.</p>
<p>Letter spacing</p>	<p>Use standard spaced fonts, not narrow or condensed.</p>
<p>Type Style</p>	<p>–Use bold typeface for the most important information on prescription labels and CMI. –Do not use <i>italic</i>, oblique, or condensed type.</p>
<p>Leading (spacing between lines of text)</p>	<p>Font size plus 30%; 24 pt leading for 18 pt font. Alternative: 1.5 lines between text.</p>
<p>Type size</p>	<p>Use minimum 18-point type. Note: There may be patients who require larger font size for readability, or for whom large print is not useful.</p>
<p>Format CMI</p>	<p>–Use single column, left justified text. –Minimum one inch margins. –Avoid bullet points; instead left justify text and use extra spacing between lines to differentiate between points and sections. –Make meaningful headings boldface in larger font. –Bold critical portions of narrative sections within text. –Provide a summary of most critical points for quick reference</p>

RECOMMENDATIONS FOR DISTINGUISHING AMONG PRESCRIPTION CONTAINERS

Persons with vision loss can use a variety of methods and tools to identify and distinguish among medication containers. A combination of labeling methods—visual, tactile, and audible—can be used with environmental modifications, such as organization of medications and use of adequate lighting. Techniques may be as simple as placing a large-print, bold letter on the container, to using an audible labeling system. A person with vision loss may require assistance to use these techniques and devices.

Pharmacists can assist patients with, or make recommendations for, visual, tactile, or audible labeling to differentiate medication containers. Some people may prefer a system with both visual and tactile cues; others may need audible prescription label technology. Once the patient has established a personalized system to identify medications, have the patient demonstrate its use to verify comprehension, memory, and accuracy.

When determining the best method to distinguish among medication containers, several factors should be taken into consideration (Sokol and Michels, 2006). The most critical is the level of vision loss, including visual acuity, visual field, contrast sensitivity, and color discrimination. Additional patient-related factors are cognitive skills, hearing ability, manual strength, range of motion, fine motor coordination, tactile sensation, the number and type of medications and their storage and preparation requirements, the complexity of the patient's medication regimen, and the availability and level of caregiver support. The availability and cost of labeling materials or devices and ease of use also should be considered.

Audible labeling, tactile labeling, and other identifier aids are available through many of the independent living products suppliers listed in Appendix 1 and the audible device suppliers listed in Appendix 2.

Visual Labels

Depending on the level of vision loss, visual labels may be adequate for some patients to distinguish among medication containers and to match large-print duplicate labels and CMI with the prescription container.

- **Letter Coded**—Letters can be handmade using permanent, pointed markers, or computer-generated. Self-adhesive large-print letters are commercially available.
- **Color Coded**—For people who have color vision, brightly colored stickers (available at office supply stores) may be used.

Visual-Tactile Labels

- **3-D “Ink” or Paint**—Visual or tactile labels can be made using color contrasting liquid fabric paint (available in craft and sewing stores) or specialty 3-D ink products (such as HI-MARK™ or Spot ‘n Line pens, which are designed for this purpose), to differentiate medication containers.

- **Rubber Bands**

- Different numbers, thicknesses, and even colors of rubber bands can be used to differentiate among medication containers.
- Different numbers of rubber bands can also be used to indicate dosage instructions (e.g., number of rubber bands indicates number of times per day the medication is taken).
- Rubber bands can and do break and may come off the container. If they are used, they should be new and the right size for the container. An alternative is the use of elastic hair bands, which can also be used to attach tactile identifiers.
- The use of rubber bands may not be appropriate to distinguish among more than three or four medications.

- **Touch-to-See Identifiers**

- Self-adhesive, bold, black letters and numbers, composed of sharply raised dots and the equivalent braille symbol located below, on a white background.

Tactile Labels

Note that tactile markings may only be useful for differentiating two or three items from one another, since elaborate memorization schemes would be required to deal with more items.

- **Bump Dots**—Raised dots in a variety of colors, shapes, and sizes, with peel-and-stick backs, can be used to differentiate medication containers or indicate dosage instructions (e.g., number of bump dots indicates number of times per day the medication is taken).
- **Tape**—Strips of tape can be affixed in different directions (vertical, horizontal, or zigzag). Some people may lack the sensation in the fingertips required to distinguish strips of tape.

Audible Labels

There are numerous audible prescription labeling devices available. See Appendix 2 for a list of devices and suppliers.

Medication Container and Organization

- Some medication containers may be distinguished by size and shape.
- The size and shape of a pill may help with identification. The individual may need to practice feeling the different shapes and sizes of the pills.
- Medication containers may be kept in a logical order, such as alphabetical or sorted by the time of day the medication is taken; or different medications can be stored in different locations (e.g., nightstand and kitchen).
- Suggest using a dark or light colored tray (depending on the color of the medication containers) when organizing medications. The tray can provide contrast with the

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medication containers to help with identifying them. Also, a tray with a raised edge can catch pills if they are dropped and prevent them from rolling onto the floor.

The American Foundation for the Blind provides helpful information on medication management at its website:

<http://www.afb.org/seniorsite.asp?SectionID=66&TopicID=305&DocumentID=3271>.

ASSISTIVE TECHNOLOGY[†]

There are a variety of medication use aids and other assistive technology designed for people with vision loss, including “talking” prescription labels, voiced scanning devices, and magnification systems, which should be recommended to individuals with low vision as an alternative to label modification. See Appendix 1 for independent living product suppliers, Appendix 2 for descriptions of audible devices and suppliers, Appendix 3 for insulin syringe filling aids, and Appendices 4 and 5 for assistive reading technology devices and suppliers.

[†] Assistive technology is used by individuals with disabilities in order to perform functions that might otherwise be difficult or impossible. Assistive technology can be anything homemade, purchased off the shelf, modified, or commercially available that is used to help an individual perform some task of daily living. The term assistive technology encompasses a broad range of devices from “low tech” (e.g., pencil grips, paper stabilizers) to “high tech” (e.g., computers, speech synthesizers, braille readers).

BACKGROUND

There are currently no requirements for the format of information on prescription labels, and existing formatting requirements for consumer medication information are inadequate for persons with vision loss. To address this problem, the American Society of Consultant Pharmacists Foundation, in collaboration with the American Foundation for the Blind, developed Guidelines for Prescription Labeling and Consumer Medication Information (CMI) for Persons with Vision Loss (“Guidelines”).

The purpose of the Guidelines is to provide pharmacists and pharmacies with recommendations for making important medication information accessible for patients with vision loss. The Guidelines will also serve as a resource for persons with vision loss and organizations serving this population.

Scope of the Problem

Although estimates vary, there are approximately 10 million blind and visually impaired people in the United States; of these, 1.3 million Americans are legally blind, and more than one half (6.5 million) are age 65 and older (American Foundation for the Blind). The prevalence of blindness and vision impairment increases rapidly in the later years, particularly after age 75 (Prevent Blindness America, 2002). People age 80 years and older currently make up 8% of the population but account for 69% of blindness (Eye Diseases Prevalence Research Group, 2004).

According to the Eye Diseases Prevalence Research Group, the leading cause of blindness among white Americans is age-related macular degeneration, accounting for 54% of all blindness; while among black persons, cataract and open-angle glaucoma account for more than 60% of blindness. Cataract is the most frequently reported condition in persons with low vision, responsible for approximately 50% of low vision cases among white, black, and Hispanic persons (Eye Diseases Prevalence Research Group, 2004). Uncorrected refractive error is perhaps the most prevalent form of correctable visual disability occurring in the United States among all segments of the population (Vitale et al, 2006).

The leading causes of vision impairment and blindness among older adults in the U.S. are age-related eye diseases (Prevent Blindness America, 2002). The number of Americans at risk for age-related eye diseases is increasing as the baby boomer generation ages. These conditions—including age-related macular degeneration, cataracts, diabetic retinopathy, and glaucoma—affect more Americans than ever before. The number of Americans with age-related eye disease and the vision impairment that results is expected to double within the next three decades (Prevent Blindness America, 2002). In addition to age-related eye diseases, physiologic changes in vision that occur with age, such as loss of near focus (presbyopia), reduced contrast sensitivity, and visual field impairment contribute to a reduction in near as well as distance visual acuity (Watanabe 1994).

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According to a 2007 study, the impact of vision loss on the U.S. economy is estimated at \$51.4 billion annually (Prevent Blindness America, 2007). The number of persons who are blind is projected to increase by 70% by 2020, with a similar rise projected for persons with low vision (Eye Diseases Prevalence Research Group, 2004).

Most older people who lose their vision due to age-related eye disease are not aware of services that can help them cope with vision loss or devices that can make their activities of daily living easier.

Medication Safety Issues

There are many medication safety issues associated with vision loss. Low vision and blindness affect the ability to read prescription labels and information sheets about medications; determine the color, shape, and markings distinguishing a medication; or see markings on measuring or testing devices. In a 2007 national poll conducted by the American Foundation for the Blind (AFB), 65% of those surveyed expressed concern about properly identifying medication (AFB, 2007).

The information provided on the prescription label is essential for the correct taking of medication. People who cannot read prescription labels or distinguish among different medications must rely on memory, use compensatory strategies or devices, or depend on someone else for help. As a result, many people with vision loss and older adults with reduced visual acuity are unable to “access” important instructions for use and safety information from prescription labels and consumer medication information.

Several studies have demonstrated the importance of label format—font type, point size, letter compression, line spacing—on readability, comprehensibility, and usefulness to consumers (Watanabe, 1994; Cramer, 1998; Cohen, 2000; Wogalter and Vigilante, 2003). One recent study noted significant improvements in comprehension and adherence among older adults when the prescription label was printed in 22 pt Arial font (Drummond et al, 2004), which is almost three times the point size usually used on prescription labels. The findings of many of the studies suggest that older consumers may be unable to acquire information—such as product identification, instructions for use, and safety information—from prescription or product labels and various sources of consumer medication information. It is essential to ensure that the size of the print is large enough to enable information transmission from the label to the receiver (Wogalter and Vigilante, 2003).

Current Regulations and Guidelines

Existing recommendations and practices for prescription labeling and consumer medication information (CMI) are inadequate to ensure access to important medication information for those who are blind or visually impaired or have decreased visual acuity. This presents a patient safety issue that may result in medication errors and medication nonadherence.

State Boards of Pharmacy

State boards of pharmacy specify the requirements for the content of prescription labels; however, there are no requirements for the format of the information. In general, the information required on a prescription label includes:

- Name and address of the dispenser or pharmacy
- Telephone number of the pharmacy
- Serial number of the prescription
- Current date of its filling or refilling
- Name of the prescriber
- Name of the patient
- Directions for use, including precautions, if any, as indicated on the prescription
- Drug name and strength and quantity; if generic, the name of the manufacturer
- The phrase "use by" followed by the product's use by date, if dispensed in any packaging other than the manufacturer's original packaging
- All auxiliary labeling as recommended by the manufacturer and/or as deemed appropriate in the professional judgment of the dispensing pharmacist
- Initials or name of the dispensing pharmacist

The state boards of pharmacy provide no guidance for prescription labeling for people with vision loss.

Food and Drug Administration

In 1995, the Food and Drug Administration (FDA) proposed a regulation entitled Prescription Drug Product Labeling: Medication Guide Requirements (60 FR 44182; August 24, 1995), designed to set specific distribution and quality goals and time frames for distributing written consumer medication information (CMI). In 1996, a steering committee—which included health care professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and others—developed a report entitled Action Plan for the Provision of Useful Prescription Medicine Information. The Action Plan delineated criteria for evaluating whether a particular piece of written medication information is useful to consumers (Steering Committee, 1996).

To provide clarification on how the Action Plan criteria should be interpreted and implemented, the FDA developed a guidance document on useful written consumer medication information, which is intended to assist individuals or organizations (e.g., pharmacies, private vendors, health care associations) in developing useful, written CMI (Food and Drug Administration, 2006). The FDA guidance recommends the following formatting for CMI:

- Use 10-point or larger type size.
- Do not use ornate typefaces and italics. Choose a bolder type over a thin version of the same style.

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- Use upper- and lower-case lettering, not all capitals.
- Use boldface type or a box to call attention to important information rather than highlighting or underlining.
- Provide adequate space between letters, lines, and paragraphs. Text should generally have no more than –3 *Kerning* (space between letters). With 10-point type, 12-point *leading* (space between lines) is recommended (at least 2.2 millimeters). Provide adequate space between paragraphs and space above and below headings.
- Do not use a line length that is too long. In 10-point or 12-point type, optimal line length is approximately 40 letters long.
- Select text color and paper that give a strong contrast. Black, dark blue, or brown ink on white or pale yellow uncoated paper provides the best contrast. Other combinations should be avoided.
- Use short paragraphs and bullets where possible.

The Guidelines Advisory Board believes that the FDA recommendation regarding minimum type size falls far short of meeting the needs of persons with vision loss or decreased visual acuity. Studies regarding print legibility for persons who are visually impaired indicate that type should be at least 16- to 18-point (Arditi, 2002). Furthermore, the FDA CMI guidance does not address the needs of individuals who cannot read print due to vision loss.

Medicare Prescription Drug, Improvement, and Modernization Act Provision

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that the Secretary of Health and Human Services undertake a study on how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually impaired individuals. The legislation required that the study “include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually impaired individuals.” This task was given to the Food and Drug Administration (FDA).

The 2004 FDA study—which included a review of the published literature, a call for comments from a 30-day public docket, and consultation with other federal agencies and technology manufacturers—found that a significant number of blind and visually impaired individuals were not using assistive technology to access prescription drug label and usage information because they were unaware of its availability or it was not effective or practical to meet their particular needs (Department of Health and Human Services, 2005). Among the study’s key findings:

- Two of the most critical barriers to the use of assistive technology are lack of awareness and cost of some assistive technologies.

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- No single currently available assistive technology can meet the needs of all or even the majority of people with vision loss; therefore, multiple means of communicating drug information are necessary.

The National Institute on Disability and Rehabilitation Research (NIDRR) was asked to convene a meeting of experts and key stakeholders in eye health, assistive technology, and pharmacology to address the issues raised in the FDA study; the meeting was held March 22, 2006. The work was continued on September 19, 2007, when NIDRR and the U.S. Department of Health and Human Services convened an expert panel to develop a federal research agenda that addresses the use of assistive technologies and modalities to make prescription drug information accessible to individuals who are blind or visually impaired.

SUMMARY

With no requirements for the format of information on prescription labels and inadequate formatting requirements for CMI, the collaborating organizations believe that guidelines are needed that enable pharmacists and pharmacies to make important medication use information accessible to their patients with vision loss.

COLLABORATING ORGANIZATIONS

The **American Foundation for the Blind** (AFB) is a national nonprofit organization that expands possibilities for people with vision loss. AFB's priorities include advocating on behalf of people with vision loss, broadening access to technology, elevating the quality of information and tools for the professionals who serve blind and visually impaired persons, and promoting independent and healthy living for individuals with vision loss by providing them and their families with relevant and timely resources. Visit AFB's Web site at www.afb.org, and its component for older consumers, www.afb.org/seniorsite.

AFB's principal product is knowledge. AFB fulfills its mission by publishing seminal textbooks, conducting crucial research, and presenting teacher training courses, professional conferences, and symposia. In addition, it shapes the public agenda by defining the important issues affecting blind and visually impaired persons and mobilizing support to bring about change in these areas.

AFB has embarked on the Rx Label Enable campaign to ensure that people with vision loss have ready access to the vital information available to all consumers via prescription labeling and consumer medication information, enabling them to take medications safely, effectively, and independently. AFB is reaching out to all stakeholders, including consumers experiencing vision loss, policymakers, federal regulators, doctors, the pharmaceutical industry, retailers, assistive technology providers, and public and private insurers to promote solutions, build consensus, and take action (www.afb.org/Section.asp?SectionID=3&TopicID=329).

The **ASCP Foundation** is the research and education affiliate of the American Society of Consultant Pharmacists (ASCP). The ASCP Foundation has a proven track record of

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developing practical interventions for improving medication use in the senior population. The mission of the ASCP Foundation is to foster appropriate, effective, and safe medication use in older persons. The unique focus of the ASCP Foundation is the development, integration, and application of knowledge regarding medication use in the senior population and the practice of senior care pharmacy to optimize health outcomes. The ASCP Foundation has a history of leadership, innovation, and expertise in medicines and aging and has collaborated with numerous organizations to address the information and education needs of consumers, families, caregivers, health care professionals, and the aging network regarding medication use. Visit the ASCP Foundation's Web site at www.ascpfoundation.org.

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APPENDIX 1. INDEPENDENT LIVING PRODUCTS SUPPLIERS

The following is a list of some of the suppliers of independent living products for people with vision loss, such as lamps; magnifiers; scales (talking and large print); measuring aids; timers, watches and clocks (talking, braille, and low vision); large print and braille playing cards; tactile labeling aids and item identifiers; and medication aids, including specialized syringes and syringe holders, syringe magnifiers, and label magnifiers. This list is not intended to be a complete listing of all organizations that sell such products, nor is it intended to be an endorsement of the actual products.

New products are continually marketed, and suppliers change; check these sites for new products and suppliers:

www.afb.org/prodMain.asp

www.nfb.org/nfb/Technology_Resource_List1.asp?SnID=1730878500

www.nyise.org/lowvision.htm

ActiveForever – Low vision products. www.activeforever.com/c-8-low-vision-aids.aspx

American Printing House for the Blind – Adapted educational and daily living products. www.aph.org

Ann Morris Enterprises – Wide variety of products for people with vision loss. www.annmorris.com

Carolyn's Low Vision Products – www.carolynscatalog.com

CAPTEK – Extensive array of items adapted for use by the vision impaired. www.captek.net/

Dynamic Living – Kitchen products, bathroom helpers, and unique daily living aids for independent living. www.dynamic-living.com

Enable Mart – Assistive technology, including vision products. www.enablemart.com

EnvisionEveryday – Adapted aids for people who are blind or have low vision. www.orderscenter.com/cart.asp?MerchantID=WCM00001

“Eye-Dea” Shop – Assistive aids for people with vision loss. clevelandsightcenter.org

Full Life Products – Big button phones, talking caller ID, talking calculators, and VoiceMate Organizer. www.superproducts.com

Hear-More – Products for people with vision and hearing loss. www.hearmore.com

Independent Living Aids, Inc. – Wide variety of products and aids for daily living designed for people with vision loss. www.independentliving.com

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LS&S Group – Products for people with vision and hearing loss. www.lssproducts.com

Maxi Aids – Products for independent living. www.maxiaids.com/store/default.asp

Medicool – Aids for daily living for diabetes patients.
www.medicool.com/diabetes/diabetes_injectaid.php

Mons International, Inc. – Low vision products and services. www.magnifiers.com

National Federation of the Blind – Blindness-related resources and products.
www.nfb.org

New York Institute for Special Education, Blindness Resource Center – List of vendors specializing in technology for the blind. www.nyise.org/vendors.htm

RehabMart.com – Medical equipment, including products for low vision.
www.rehabmart.com

See-More Vision Aiding Products, Inc. – Wide variety of products and aids for daily living designed for people with vision loss. www.seemorevision.com

ShopLowVision.com – Electronic low vision products and daily living aids.
www.shoplowvision.com

Speak To Me – A catalog of talking products. www.speaktomecatalog.com

APPENDIX 2. AUDIBLE DEVICES

The following is a list of some of the suppliers of audible devices for people with vision loss. This list is not intended to be a complete listing of all organizations that sell such products, nor is it intended to be an endorsement of the actual products. New products are continually marketed, and suppliers change; check these sites for new products and suppliers:

www.afb.org/prodMain.asp

www.nfb.org/nfb/Technology_Resource_List1.asp?SnID=1730878500

www.nyise.org/lowvision.htm

AUDIBLE PRESCRIPTION LABELING DEVICES

This list is not intended to be a complete listing of all products, nor is it intended to be an endorsement of the actual products.

Rex-The Talking Bottle – Disposable talking bottle that provides audible label information. A special bottle recorder microphone allows the user to record the medication use information directly into the bottle. To playback the recorded information, users simply press a button on the base of the bottle and listen to the message. Batteries will last approximately 300 message plays. Starter kit contains three disposable bottles, a recording unit, a microphone that makes the recording possible by simply pressing a button and speaking, power supply, and easy-to-follow instructions. www.rxtalks.com

ScripTalk™ Talking Prescription Reader – The ScripTalk System requires the pharmacy to have the software to print and program an auxiliary smart label using a dedicated, small-footprint printer. The smart label, which stores prescription information, is placed onto the prescription container by the pharmacist. In the home, the patient uses a hand-held ScripTalk Reader that speaks out the label information using speech synthesis technology. Supports Spanish or English. Runs on batteries. www.envisionamerica.com

Sherlock Talking Label Identifier Kit – A digital voice recorder with each recorded message keyed to an adhesive label or plastic disk tag. Holds up to two-and-a-half hours of recorded information and supports up to 2,000 labels. Available from American Printing House for the Blind. <http://sun1.aph.org/starweb/APHBLLouis/servlet.starweb>

Talking Rx® – Portable, re-usable digital memo recorder that attaches to common-sized prescription bottles and allows a physician, pharmacist, caregiver, family member, or patient to record up to sixty seconds of recorded information about the medication. Can only be used for one prescription at a time. www.talkingrx.com

Tel-Rx Prescription Recorder – Twenty second recording time allows user to record necessary information about the medication. Attached to prescription bottle with tie or

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band (included). Runs on batteries. Can only be used for one prescription at a time. Available through various outlets: www.learnmoreshop.com; www.maxiaids.com

VOXCOM III – A verbal marking system that records a 10-second message on a card, which is then attached to the item. To “read” the card, insert it into the VOXCOM to hear the recording. Several methods of attachment are included: rubber bands, plastic ties, magnets, and hook and loop attachments. Available through various outlets: www.maxiaids.com; www.hearmore.com

“VOICED” SCANNING DEVICES

This list is not intended to be a complete listing of all products, nor is it intended to be an endorsement of the actual products.

i.d. mate OMNI – Portable "all-in-one" talking bar code scanner. It allows an individual to identify items using the product's bar code or UPC. A database of more than a million North American UPCs and descriptions give the user a huge head start in identifying the product and getting the information needed about the item. The user can add additional voice recorded information to existing products or to items not found in the database. The user can also record, play, erase and organize messages in the memo mode. Used products are available for half-price through the manufacturer. www.envisionamerica.com/products.php

Kurzweil-National Federation of the Blind Reader – A portable, hand-held device that scans and reads printed material. Combining a digital camera with a personal data assistant housed in a case, the Kurzweil–National Federation of the Blind Reader puts character recognition software together with text-to-speech conversion technology. To use, hold the Reader's camera over print (e.g., a restaurant menu, directions, or a memo) and snap a picture. In seconds the contents of the printed document are read in clear synthetic speech. The Reader also has a headphone jack. www.knfbreader.com

“TALKING” BLOOD GLUCOSE MONITORS

This list is not intended to be a complete listing of all products, nor is it intended to be an endorsement of the actual products.

Advocate™ – English/Spanish talking blood glucose monitors. Advocate Duo includes a blood pressure meter. www.pharmasupply.com/

Digi-Voice Voice Module – Plugs into the data port of standard One Touch Basic or Sure Step blood glucose meters and announces what appears in the display, including prompts, error messages, and readings. www.captex.net

Prodigy® Voice – Totally audible blood glucose monitoring system specially designed for the blind. Does not require calibration; has tactually distinct buttons for different

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features; is fully accessible in all functions; and includes instructions in audio format.
www.prodigymeter.com/home.cfm

“TALKING” BLOOD PRESSURE MONITORS

This list is not intended to be a complete listing of all products, nor is it intended to be an endorsement of the actual products.

LifeSource[®] Talking Auto-Inflation Blood Pressure Monitor – Audio announcement of measurement results. www.lifesourceonline.com

Lumiscope[®] Talking Wrist Blood Pressure Monitor – Audio announcement of measurement results. www.lumiscope.net/index.shtml

Oregon Scientific Talking Wrist Blood Pressure Monitor – Audio announcement of measurement results. www2.oregonscientific.com

Reizen Bi-Lingual Talking Blood Pressure Monitor Kit – Available from www.maxiaids.com and other independent living aid suppliers.

APPENDIX 3. INSULIN SYRINGE FILLING AIDS

The following is a list of some of the suppliers of insulin syringe filling aids for people with vision loss. This list is not intended to be a complete listing of all organizations that sell such products, nor is it intended to be an endorsement of the actual products. New products are continually marketed, and suppliers change; check these sites for new products and suppliers:

www.afb.org/prodMain.asp

www.nfb.org/nfb/Technology_Resource_List1.asp?SnID=1730878500

www.nyise.org/lowvision.htm

BD Magni-Guide™ Scale Magnifier – Magnifies the scale on syringe 1.7 times for easier reading and helps to guide the insulin syringe needle into the vial.

www.bddiabetes.com/us; www.medicool.com/diabetes/index.php

Count-a-Dose – Syringe filling device for blind or partially-sighted people with diabetes. Uses only a ½ cc B-D syringe. Available from various suppliers.

www.medicool.com/diabetes/index.php; <http://eyedeashop.com>

Ezy-Dose Syringe Magnifier – Clips to insulin syringe for easier reading of calibrations; fits on 1 cc and ½ cc syringes. Available from various suppliers.

Inject Assist – Guides the syringe into the vial. Can be used to measure a single dose pre-set by a sighted person. www.apothecaryproducts.com

Insul-Eze – Syringe loading device with magnifier for those with visual or manual dexterity problems. Magnifies (2.5 times) syringe calibrations and automatically aligns the bottle seal with the needle. Manufactured by Palco Labs, www.palcolabs.com

Safe Shot Syringe Loader – Allows secure adjustment of intake of insulin or other injectables; can be preset for accurate volume. Available from various suppliers.

www.maxiaids.com; www.hearmore.com

Syringe Support – For use with U-100 insulin. Fills a BD 100 unit syringe using a calibrated screw that can be set by a blind user. Available from various suppliers.

www.maxiaids.com; <http://eyedeashop.com>

Tru-Hand Insulin Holder and Magnifier – Syringe needle guide and vial holder designed to magnify the syringe scale for individuals with low vision. The device holds the insulin bottle and has a magnifying window that enlarges the syringe's print two-fold. Manufactured by Whittier Medical. Available from various suppliers.

www.diabeticexpress.com; www.diabeticcareservices.com

Unit Calibration Aid – Incorporates two adjustable preset stoppers, allowing two different doses or insulin mixing. Secures the syringe in place leaving the plunger free to set an accurate dose with a pre-set dosage guide. Holds U-100, U-80, and U-40 syringes. Any adjustment of dose requires sighted aid. <http://eyedeashop.com>

APPENDIX 4. GLOSSARY OF ASSISTIVE “READING” TECHNOLOGY

Braille Display. Provides access to information on a computer screen in braille. These desk-top devices operate by electronically raising and lowering different combinations of pins to produce in braille what appears on a portion of the computer screen. The device displays up to 80 characters from the computer screen at one time and is refreshable; that is, it changes continuously as the user moves around the screen.

Braille Embosser. A printer that renders text as braille.

Braille Translation Software. Software used to convert a standard document from a word processor into braille for printing on a braille embosser.

Large-Print Printer. Any inkjet, dot matrix, or laser printer can produce large print if the font size is set larger before printing.

Optical Character Recognition (OCR) System. Software used to convert scanned text, from books or other documents, into electronic format. The blind or visually impaired user can access the scanned text by using adaptive technology devices that magnify the computer screen or provide speech or braille output.

Screen Magnification Software. Software designed to work like a magnifying glass moving over a page.

Screen Reading Software. Software used to convert text on the computer screen into spoken words. A synthetic speech system is composed of two parts: the synthesizer that does the speaking and the screen reader that tells the synthesizer what to say. The synthesizers used with PCs are text-to-speech systems.

Video Magnifier, or closed-circuit television (CCTV). Uses a stand-mounted or hand-held video camera to project a magnified image onto a video monitor, a television screen, or a computer monitor. It also can be used to magnify the print in books and newspapers, write letters and checks, and do different types of crafts, such as needlepoint.

APPENDIX 5. ASSISTIVE “READING” TECHNOLOGY SUPPLIERS

The following is a list of some of the suppliers of assistive technology for people with vision loss. This list is not intended to be a complete listing of all organizations that sell such products, nor is it intended to be an endorsement of the actual products. New products are continually marketed, and suppliers change; check these sites for new assistive technology and suppliers:

www.afb.org

www.nfb.org/nfb/Technology_Resource_List1.asp?SnID=1730878500

www.nyise.org/lowvision.htm

Access Ingenuity – Catalog with a wide variety of assistive technology for low vision and blindness. www.accessingenuity.com/products/vision

Adaptive Solutions, Inc. – Sells assistive technology products for persons who are blind or visually impaired. www.talksight.com

Ai Squared – Leading developer of screen magnification and screen reading software. www.aisquared.com

Vision Cue – Catalog with a wide variety of assistive technology for low vision and blindness. www.visioncue.com

BIGSHOT – Screen magnification. www.bigshotmagnifier.com

Clarity Solutions – Manufactures autofocus video magnifiers (CCTV) for near and distance viewing. www.clarityusa.com

Duxbury Systems – Braille Translation software for Windows, Macintosh, DOS, and UNIX. www.duxburysystems.com

Enabling Technologies – Braille embossers (braille printers) for the smallest home office to the largest commercial printing house. www.brailier.com

Enhanced Vision – Manufactures head mounted and stand type CCTVs. www.enhancedvision.com

Eschenbach Optik – Optical and other magnification products. www.eschenbach.com

Freedom Box – Voice-controlled Internet access device that combines an audio output interface with voice recognition. www.freedombox.info

Freedom Scientific – Screen reading and magnification software, Web access software, braille note takers, embossers and displays, scanning and reading software/hardware. www.freedomscientific.com

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GW Micro – Window-Eyes screen reading software and other adaptive technology for computer, PDA, palm-top, and CCTV devices. www.gwmicro.com

Innoventions, Inc. – Magni-Cam is an affordable electronic magnifier that turns your television set in to a CCTV. www.magnicam.com

Kurzweil Educational Systems – Software that converts the printed word into speech output. www.kurzweiledu.com

Mons International, Inc. – Sells low vision products, including CCTVs, telescopes, and binoculars. www.magnifiers.com

New York Institute for Special Education, Blindness Resource Center – List of vendors specializing in technology for the blind. www.nyise.org/vendors.htm

Net-Tamer – A shareware DOS PPP dial-up access program. www.nettamer.com

Optelec – CCTVs, high-quality magnifiers, and other products for people with low vision. www.optelec.com

OVAC Reading Systems for the Visually Impaired – Makers of affordable low vision reading systems (CCTVs). www.ovac.com

Pulse Data HumanWare – Refreshable braille displays, braille note takers, braille embossers, screen access software, and braille translation software. www.pulsedata.com

RJ Cooper & Associates – Adaptive software and hardware for persons with special needs. www.rjcooper.com

Telesensory – Video magnifiers (CCTVs), scanners (OCR), and screen magnification products. www.telesensory.com

APPENDIX 6. BLINDNESS/VISION LOSS ORGANIZATIONS AND RESOURCES

Many state, local, and national organizations/agencies provide information on services, resources, and vendors specializing in products for people with vision loss. The following is a list of some of these organizations. See the following links for current lists or locators:

- www.lowvision.com/services/national-resources/
- www.nyise.org/orgs.htm
- <http://afb.org/services.asp>

ABLEDATA. Provides objective information on assistive technology and rehabilitation equipment available from domestic and international sources to consumers, organizations, professionals, and caregivers within the United States. Serving the nation's disability, rehabilitation, and senior communities, ABLEDATA is sponsored by the [National Institute on Disability and Rehabilitation Research \(NIDRR\)](#), part of the [Office of Special Education and Rehabilitative Services \(OSERS\)](#) of the [U.S. Department of Education](#). www.abledata.com/

American Council of the Blind. Membership organization of blind and visually impaired people. Web site contains helpful resources for people who are blind or visually impaired. www.acb.org

American Foundation for the Blind (AFB). National nonprofit organization that advocates on behalf of people with vision loss and focuses on broadening access to technology, elevating the quality of information and tools for the professionals who serve blind and visually impaired persons, and promoting independent and healthy living for individuals with vision loss by providing them and their families with relevant and timely resources. www.afb.org

- **AFB AccessWorld®: Technology and People who are Blind or Visually Impaired.** A free, Web-based publication that provides technology news and product evaluations. www.afb.org/aw/main.asp
- **AFB Senior Site.** Site to encourage aging adults with eye diseases to live independently and productively. Includes locator to find senior services by state. www.afb.org/seniorsitehome.asp

American Macular Degeneration Foundation. Works for the prevention, treatment, and cure of macular degeneration through raising funds, educating the public, and supporting scientific research. Low vision resources, low vision centers, reading services, state agencies. www.macular.org

Lighthouse International. A leading non-profit organization dedicated to preserving vision and to providing critically needed vision and rehabilitation services to help people of all ages overcome the challenges of vision loss. www.lighthouse.org

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Macular Degeneration Partnership. Coalition of patients and families, researchers, clinicians, industry partners, and leaders in the fields of vision and aging collaborating to disseminate information about age-related macular degeneration, provide support to patients, and marshal resources for a cure. Web site contains links to resources for health, aging, and low vision information, along with tools and other related resources. www.amd.org

National Association for Visually Handicapped. Non-profit health agency providing assistance to those with limited vision. Web site contains NAVH locator and catalogue of vision aids. www.navh.org

National Eye Institute. Established by Congress in 1968 to protect and prolong the vision of the American people. As one of the Federal government's National Institutes of Health (NIH), the NEI conducts and supports research that helps prevent and treat eye diseases and other disorders of vision. www.nei.nih.gov

National Federation of the Blind. Membership organization of blind people in the United States. Web site provides information on vision loss, resources, products, and technology. www.nfb.org

New York Institute for Special Education, Blindness Resource Center. Low vision resources, blindness organizations, vendors specializing in technology for the blind. www.nyise.org/blind.htm

VisionAWARE. "Self help for vision loss" Web site. Web site provides information and self-help tips for people with vision loss on topics ranging from eye disorders and rehabilitation services to tips for independent living and advice on coping with vision loss. www.visionaware.org/

APPENDIX 7. BRAILLE TRANSCRIPTION SERVICES LINKS

Braille is a system of writing or printing, devised by Louis Braille in 1824, for use by people who are blind or visually impaired. The system uses raised dots that are read by touch. There are numerous commercial and volunteer organizations that provide braille transcription services. Some links are provided below.

- **New York Institute for Special Education, Blindness Resource Center:** www.nyise.org/braille.htm#transcription
- **Braille Plus:** www.brailleplus.com
- **Braille Plus, Inc.:** www.brailleplus.net
- **Valley Braille Service Inc:** www.valleybraille.com
- **National Federation of the Blind,** braille transcription resource list: www.nfb.org/nfb/Braille_transcription.asp
- **All-Braille:** www.allbraille.com
- **Quik-Scrybe:** www.quikscrybe.com
- **The Braille Bookstore:** www.braillebookstore.com/braille-transcription.htm
- **The Hadley School for the Blind:** www.hadley.edu/7_f_brailleTranscribing.asp

APPENDIX 8. VISION GLOSSARY

Cataract: A clouding of the lens in the eye that affects vision, causing cloudy or blurry vision, poor night vision, and problems with glare. Cataracts are very common in older people; by age 80, more than half of all Americans either have a cataract or have had cataract surgery.

Diabetic Retinopathy: A complication of diabetes and a leading cause of blindness. It occurs when diabetes damages the tiny blood vessels inside the retina in the back of the eye. Often there are no visual symptoms or pain in the early stages of the disease; therefore persons with diabetes should have a comprehensive dilated eye exam at least once a year.

Glaucoma: Glaucoma is a group of eye diseases that can damage the eye's optic nerve and result in vision loss and blindness. Optic nerve damage produces certain characteristic visual field defects in peripheral (side) as well as central vision. Once nerve damage and visual loss occur, it is permanent. Early detection and treatment are the keys to preventing optic nerve damage and vision loss from glaucoma.

Low Vision or Visual Impairment: Vision loss that may be severe enough to impede a person's ability to carry on everyday activities but still allows some functionally useful sight. Low vision may be caused by macular degeneration, cataracts, glaucoma, or other eye conditions or diseases. Low vision may range from moderate impairment to near-total blindness; it cannot be fully corrected by eyeglasses, contact lenses, or surgery. However, a person with low vision may benefit from any of a variety of available optical devices, such as magnifying lens or hand-held magnifiers, and task-directed lighting. Special software developed for computer users with low vision can display type in large size or read text aloud.

Macular Degeneration: A type of retinal degenerative disease that causes dysfunction of the macula, the area in the middle of the retina that makes possible the sharp central vision needed for such everyday activities as reading, driving, and recognizing faces and colors. There are two forms: "wet" and "dry." Age-related macular degeneration is the leading cause of severe vision loss in people over age 60. Macular degeneration causes blurred, distorted, or dim vision or a blind spot in the center of the visual field; peripheral vision is generally not affected. The condition is painless and may progress so gradually that the affected person at first notices little change.

Presbyopia: The eye's gradually decreasing ability to focus on nearby objects. Presbyopia is a normal part of aging and affects virtually everyone, usually becoming noticeable after age 40. People with presbyopia typically hold reading materials at arm's length in order to bring the words into focus. Presbyopia can be corrected with reading glasses, bifocal or variable focus lenses, or contact lenses. Using bright, direct light when reading is also helpful.

APPENDIX 9. VISION LOSS SIMULATION

<p>Age-related Macular Degeneration (AMD) causes blurred, distorted, or dim vision, or a blind spot in the center of the visual field, which can make it difficult to read, drive, recognize faces, or perform other activities requiring fine, detailed vision. Peripheral vision is generally not affected. AMD often causes difficulties with contrast or focusing, rivalry between the two eyes (ghost images), images jumping into the field of view (eccentric viewing), or the seeing of objects that do not exist (Charles Bonnett Syndrome).</p>	 <p style="text-align: right; font-size: small;">Age-related Macular Degeneration</p> <p>Source: National Eye Institute</p>
<p>Cataract is the clouding of the eye's lens, which can interfere with vision, causing images to appear blurred or fuzzy and colors to seem faded.</p>	 <p style="text-align: right; font-size: small;">Cataract</p> <p>Source: National Eye Institute</p>
<p>Glaucoma is the term for a diverse group of eye diseases, all of which involve progressive damage to the optic nerve. Glaucoma can result in mild peripheral (side) field loss with good central acuity; severe peripheral field loss, or tunnel vision, with good central acuity; or tunnel vision with very poor central acuity. The most important hallmark of the visual disability from glaucoma is the loss of contrast. Glaucoma sufferers need high contrast print with good glare-free lighting.</p>	 <p style="text-align: right; font-size: small;">Glaucoma</p> <p>Source: National Eye Institute</p>
<p>Diabetic retinopathy is a complication of diabetes that damages the eye's retina, which can lead to vision loss, including blindness. In the early stages, there may not be any noticeable change in vision; in its final stage, bleeding can occur. Symptoms may include "spiders," "cobwebs" or tiny specks floating in the visual field, dark streaks or a red film that blocks vision, vision loss or blurred vision, a dark or empty spot in the center of the visual field, poor night vision, and difficulty adjusting from bright light to dim light.</p>	 <p style="text-align: right; font-size: small;">Diabetic Retinopathy</p> <p>Source: National Eye Institute</p>

What Would It Take to Move Toward Prescription Use Instruction Standardization?

ROGER WILLIAMS, M.D.

United States Pharmacopeia

The United States Pharmacopeia (USP) is a standard-setting body. There are about 500 standard-setting bodies in the United States. Three hundred or so are accredited by the American National Standard Institute (ANSI), which is a professional association that watches over all the U.S. standard-setting bodies. At the global level there is the International Standards Organization (ISO) in Geneva, Switzerland.

Standards can be either documentary or physical. The USP sells physical reference materials, as does the National Institute of Standards in Technology (NIST). Documentary standards include such things as best practices, guidelines, guidance, regulations, and laws. From this perspective, the patient package insert is a standard.

Standards can be voluntary or mandatory. Additionally, there are different kinds of standard-setting bodies. For example, there are voluntary consensus standard-setting bodies where individuals affected by the standards participate in developing them. Government is a very strong standard-setting body, but that is a different model.

The USP is a convention of about 450 associations, and it is a practitioner-based body. There are about 40 pharmacopeias worldwide, but the only one of them that is nongovernmental is the USP. The USP was started in 1820 by practitioners who desired good standards and good names for the medicines they used.

Improving Prescription Drug Labeling

Michael S. Wolf, PhD, MPH; Stacy Cooper Bailey, MPH

According to a 2006 report by the Institute of Medicine of the National Academies, *Preventing Medication Error*, approximately 1.5 million preventable adverse drug events occur each year.¹ Attention to the root causes of medication errors leading to adverse events has most often been attributed to the provider's or health care system's contributing role in errors during the prescribing, ordering, dispensing or administering of a medicine.^{2,3} The reason attention was focused on those causes may be that most studies investigating medication error have been conducted in inpatient hospitals or nursing homes.⁴ However, more than one-third of adverse drug events take place in outpatient settings at a cost approaching \$1 billion annually.¹ It has been estimated that a large proportion of outpatient medication errors occur as a result of patients themselves not administering a medicine as intended.³ For ambulatory care, the patient, rather than the provider, is ultimately responsible for correctly administering a medicine as prescribed. Therefore, the processes of quality control and monitoring of medication error shift from provider to patient.

The current body of evidence detailing the incidence and causes of outpatient medication error is limited. Yet problems are likely to intensify as patients increasingly self-manage greater numbers of prescription and over-the-counter medications. Chronically ill patients and the elderly are at greatest risk for experiencing medication errors because as they take more

prescription drugs annually than younger and healthier patients, and visual/cognitive impairments by age may limit reading ease and comprehension.⁵⁻⁹ The risk for miscommunication and error may be further compounded since the average older adult sees several different health care providers annually.¹⁰

Health Literacy as a Medication Safety Concern

Limited health literacy is another significant risk factor that could account for outpatient medication errors that are the result of improper dosing administration. Numerous studies have found low health literacy to be significantly associated with a poorer understanding of medication names, indications, and instructions.¹¹⁻¹⁴ More recently, health literacy skills have been linked to requisite knowledge for adherence to treatment regimens.¹⁵ This current and well-publicized body of research has focused on the ability of patients to read, understand, and demonstrate instructions on drug container labels. The line of inquiry has been supported by parallel work in human factors research.^{5,6} Davis and colleagues conducted a multisite study among adults receiving primary care at community health centers and found a high prevalence of patients, especially those with limited literacy, misunderstanding seemingly simple dose instructions provided on the primary label of medication containers.¹¹ In this study, 46% of adults misunderstood at least one prescription container label they encountered. The problem extends to the auxiliary sticker labels that provide accompanying warnings and instructions for use of the medicine. Another study demonstrated over half (53%) of patients, especially those with limited literacy, had difficulty interpreting text and icons commonly used on these auxiliary warning instructions.¹²

Beyond the container, drug labeling also includes accompanying medication information materials that provide indications for use and

“...the manner in which the current health care system delivers necessary medication information to patients is clearly inadequate.”

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further detailed precautions that can not fit on the container due to space constraints. Studies have found that these materials, as with the container label, are not useful for a majority of patients, particularly those with limited health literacy.¹⁶ This includes consumer Medication Guides (aka Med Guides) that are required by the Food and Drug Administration to be dispensed along with certain prescribed medicines that have been identified as having serious public health concerns. Patients with limited health literacy were significantly less likely to attend to these materials. These findings are supported by earlier research studies that suggest consumer medication materials are too difficult for most patients to read.¹⁷ As a result, the patient information leaflets and Med Guides that accompany many prescription medications may be ignored.

A System Failure

The 2004 Institute of Medicine of the National Academies report on health literacy, *A Prescription to End Confusion*, aptly identified the problem of health literacy as encompassing more than limitations in individual abilities.¹³ Rather, the complexity of demands placed upon the individual by the health care system must clearly be addressed. While patients must have adequate cognitive capacity and proficiency to read, understand, and act on medication label instructions to ensure proper and safe use, the manner in which the current health care system delivers necessary medication information to patients is clearly inadequate. Physicians, who are legally responsible for delivering important drug information directly to patients, frequently miss opportunities to adequately counsel their patients on how to self-administer their medicines.¹⁹ Pharmacists, next in line to counsel patients, also frequently fail to verbally communicate detailed information to patients at the point of dispensing medicines.²⁰

In light of these failures, patients must depend more on the print drug labeling materials (ie, the container label, consumer medication information, Med Guides, patient information leaflets) that are challenging for patients across all health literacy levels.^{17,18} With the exception of Med Guides and a very limited set of similar patient package inserts that are available for only a select number of drugs, no national standards or regulations exist for the development and oversight of consumer medication information or container drug labels. Informational leaflets are industry-generated, and state laws minimally govern content and format on prescription container vials. This all leads to what can best be described as a fragmented system of patient information.

Taking Action

Improving the readability and understanding of instructions and supplementary information for prescription drugs is warranted as it may ultimately stimulate appropriate and safe medication use among patients. Evidence is available now supporting the design of better drug labeling.²¹ This includes considerations for both the container label and accompanying materials. Based on recent health literacy studies and work by

the American College of Physicians Foundation (ACPF) on prescription drug labeling, certain general recommendations can be issued that espouse the importance of promoting health literacy as a medication safety issue.²²

First, seemingly simple dosage instructions printed on the container label should be written in the most clear and concise manner. Previous research has found that patients have more difficulty understanding vague medication directions as compared to more explicit ones.^{23,24} The less a patient is required to make inferences, the more easily medication schedules can be comprehended (ie, "take every 6 hours" vs "take at 8am, 2pm and 8pm"). This is especially important for more complex dosing schedules, where patients may become easily confused or more prone to errors if instructions are read in haste.

Second, Shrank and colleagues examined the variability in content and format on prescription drug container labels.²⁵ They found that pharmacies consistently emphasized provider-directed content versus information most pertinent to the patient. The use of bolding, highlighting, and larger font should be directed solely to label content that is most salient to the patient. Information such as prescription number or the pharmacy logo should be de-emphasized and segregated from dosage instructions, warnings, or indications so as to not detract from the most important label content detailing its appropriate use. Every effort should be made to organize the container label in the most patient-friendly manner. It likely will be the most tangible source of drug information repeatedly used by patients.

Third, accompanying materials should abide by core principles upheld by adult literacy practitioners.^{17,26} Consumer medication information should keep to simple language and avoid medical jargon. The scope of information should be limited and summaries more frequently used to highlight actionable messages. Shrank and colleagues further describe the type of content that is desired by patients to support appropriate use.²¹ Surveys have shown that patients want to know, in addition to dosage instructions, the indications for use of a prescribed medicine, any precautions, and the duration of treatment. Information on the benefits and side effects of drugs is also sought after by patients, and providing this information has been found to improve adherence.²⁰

Finally, steps should be taken to ensure that these separate elements of drug labeling, the container label and accompanying materials, are developed together as an integrated and complimentary set of information sources. Patients should be included in this process so materials are appropriately organized, and they accurately reflect the common schemas imposed by patients of all literacy levels when seeking to understand how to use prescribed medicines.

Conclusion

System change is urgently needed to promote health literacy for greater medication safety. Patients must be able to easily understand how to use prescription drugs correctly. Standardizing and integrating drug labeling must be a central goal to ensure that best practices are implemented because



Improving Prescription Drug Container Labeling in the United States

A Health Literacy and Medication Safety Initiative



A White Paper Commissioned by the American College of Physicians Foundation

Presented to the Institute of Medicine Roundtable on Health Literacy

October 12, 2007

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EXECUTIVE SUMMARY

According to the Institute of Medicine (IOM) 2006 report, Preventing Medication Errors, more than half a million adverse drug events (ADEs) occur in the United States each year in outpatient settings. Problems with prescription drug (Rx) labeling were cited as the cause of a large proportion of outpatient medication errors and ADEs, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. Recent health literacy research has highlighted the alarmingly high prevalence of patients misunderstanding seemingly simple instructions and warnings placed on Rx container labels. The elderly, those with limited literacy skills, and individuals managing multiple medication regimens were found to be at greater risk for making errors in interpreting container label instructions.

The ability to understand Rx container label instructions is critical, both as *health literacy* and *medication safety* concerns. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines. Other supplementary sources, such as patient information leaflets and Medication Guides dispensed with the prescribed medicine are too complex and written at a reading level unsuitable for the majority of patients to comprehend. As a result, these materials are often ignored. While all of these sources are best viewed as a *system* of patient information, the Rx container label is particularly important as it is often the sole source of specific instructions received and repeatedly used by patients on how to self-administer medicines.

Despite its potential value, there are clear problems with Rx container labels. Minimal standards and regulations exist regarding their content and format, and Rx labels can vary by dispensing pharmacy. Specific dosage instructions on the container label are dependent on what the prescribing physician writes, as well as how the pharmacist interprets these instructions. While the format and content of Rx container labels may differ between and within local and national pharmacies, all share the common attribute of being unnecessarily complex

and not offering a patient-friendly interface. Instead, the greatest emphasis is placed on provider-directed content.

This report reviews in detail the problem with Rx container labels in the United States. The 'best practices' in drug container labeling are summarized. Recommendations are offered to guide medical and pharmacy practice, and related state and federal policy. The overall objective of this paper is to move forward a set of evidence-based, Rx container label standards that will minimize patient confusion and promote patient awareness of how to use a prescribed medicine safely and effectively, thereby reducing risk of medication error.

Table 1. Primary Findings

Finding 1	<i>Inadequate patient understanding of prescription medication instructions and warnings is prevalent and a significant safety concern.</i>
Finding 2	<i>Lack of universal standards and regulations for medication labeling is a 'root cause' for misunderstanding and medication error.</i>
Finding 3	<i>An evidence-based set of practices should guide all label content and format.</i>
Finding 4	<i>Instructions for use on the container label are especially important for patients and should be clear and concise. Language should be standardized to improve patient understanding for safe and effective use.</i>
Finding 5	<i>Drug labeling should be viewed as part of an integrated system of patient information. Improvements are needed beyond the container label, and other sources of consumer medication information should be targeted.</i>
Finding 6	<i>Health care providers are not adequately communicating to patients, either orally or in print, about prescribed medicines. More training is needed to promote best practices for writing prescriptions and counseling patients.</i>
Finding 7	<i>Support is necessary for research on drug labeling and to identify 'best practices' for patient medication information.</i>

PROLOGUE

Since 2002, the American College of Physicians Foundation (ACPF) has sought to address the problem of limited health literacy by developing initiatives to mitigate the impact of this highly prevalent problem on health outcomes. The issue of inconsistent and confusing medication information and labeling soon became a primary target of the ACPF health literacy agenda. A few projects were commissioned by the ACPF, and informal activities were spearheaded to engage experts and stakeholders from academia, industry, and government. In September 2006, a meeting was held in Washington D.C. to discuss the ACPF's medication labeling initiatives and to suggest next steps for ACPF. The overall objective of the meeting was to consolidate an understanding of the broad problem of inadequate patient understanding of medication labels, and to identify a specific course of action to improve drug labeling in the United States. The meeting served as a timely response to Institute of Medicine (IOM) reports, released in July and September 2006, which targeted medication error and drug safety, respectively. Participants at this meeting included national experts in health literacy, patient safety, pharmacology, and pharmacy policy and practice. The Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM), and the Food and Drug Administration (FDA) were represented.

Participants reviewed the nature and extent of the problems surrounding medication labeling, particularly for prescription drugs. Summaries were provided from the July 2006 IOM report, Preventing Medication Errors, the FDA over-the-counter (OTC) consumer education initiatives, an ACPF-commissioned medication labeling systematic literature review, and recent health literacy research studies. Herein, this white paper presents the ACPF perspective on the current prescription medication *container* labeling system, with a focus on improving the format, content, and dosage and use instructions on the container label.

Medication Safety

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review

William Shrank, Jerry Avorn, Cony Rolon, and Paul Shekelle

With the passage of the Medicare Modernization Act, the US federal government has a dramatically expanded role in the provision of prescription drugs to Americans.^{1,2} This investment has led to even greater attention to the appropriate and safe use of prescription medications, and substantial concerns exist. Patients are typically adherent to only about 50% of their medication doses,³ even for essential chronic drug therapy,⁴⁻⁶ with dramatic consequences in terms of health outcomes and associated healthcare costs.⁷⁻⁹ In addition, substantial shortfalls in the quality of medication therapy exist¹⁰⁻¹⁴; medication errors and adverse drug reactions occur frequently, with an estimated annual cost of \$50 billion.¹⁵⁻¹⁹ Efforts to improve medication adherence and safety in the Medicare prescription drug benefit are warranted and may improve the effectiveness of the federal investment in prescription drug care.

Some of these quality deficits may be due to poor comprehension by patients about their medications.²⁰⁻²³ Several recent studies have demonstrated that patients frequently have difficulty reading and understanding medication labels.²⁴⁻²⁷ The recent Institute of Medicine report, "Preventing Medication Errors," cited poor labeling as a central cause for medication errors in the US.²⁸ Although patients should receive medication counseling from their physicians and pharmacists, numerous

OBJECTIVE: To evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use.

DATA SOURCES: We performed a systematic review of randomized controlled trials, observational studies, and systematic reviews from MEDLINE and the Cochrane Database (1990–June 2005), supplemented by reference mining and reference lists from a technical expert panel.

STUDY SELECTION: We selected studies that focused on the content of physician–patient communication about medications and the content and format of prescription drug labels.

DATA EXTRACTION: Two reviewers extracted and synthesized information about study design, populations, and outcomes.

DATA SYNTHESIS: Of 2009 articles screened, 36 that addressed the content of physician–patient communication about medications and 69 that were related to the content or format of medication labels met review criteria. Findings showed that patients request information about a drug's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. Little evidence linked label design or content to measurable health outcomes, adherence, or safety.

CONCLUSIONS: Evidence suggests that specific content and format of prescription drug labels facilitate communication with and comprehension by patients. Efforts to improve the labels should be guided by such evidence, although additional study assessing the influence of label design on medication-taking behavior and health outcomes is needed. Several policy options exist to require minimal standards to optimize medical therapy, particularly in light of the new Medicare prescription drug benefit.

KEY WORDS: patient information, prescription drug label.

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studies have shown that discussions about drugs are often limited,²⁹⁻³¹ and patients frequently do not remember those conversations,³² forcing many to rely on drug labels for information.

We sought to evaluate the evidence pertaining to the optimum content and format of patient-oriented prescription

Author information provided at the end of the text.

labels. We evaluated evidence pertaining to both container labels and auxiliary medication information leaflets that, when used together, might improve readability, understanding, and medication-taking behavior. To assess the optimum content of prescription drug labels, we reviewed the literature pertaining to patient preferences for the content of communication about prescription drugs. We then reviewed the literature to assess the evidence evaluating the effect of the content and format of prescription drug labels on readability, understanding, and health outcomes. Our goal was to evaluate the evidence to inform the improvement of prescription drug labels so that future efforts at redesign can be evidence-based.

Literature Search and Selection

A systematic search of the medical literature was performed to identify studies addressing prescription drug labels and patient-provider communication about prescription drugs. The initial searches were limited to articles written in English and published between January 1990 and June 2005. Sources of our search included MEDLINE and the Cochrane Database. We also reference-mined articles included from our initial search and sought input from members of a technical expert panel, drawn from diverse fields and assembled for this project. We included systematic literature reviews, observational studies, and controlled trials. All case reports and expert perspectives were excluded. Articles published before 1990 that were identified from expert recommendations or reference mining were included in this review.

Two searches were performed. Articles were included in the patient-provider communication search if they addressed patient preferences about specific content for discussions that may enhance medication-taking behavior. Articles were searched on MEDLINE, using the following search criteria: (communication or misunderstanding or miscommunication) and (patient or professional-patient relations or physician-patient relations or patient education) and (medicine or drug information services or prescriptions or drug therapy) or (risk or adverse event or adverse effect or risk factors or risk assessment). Articles from the patient-provider communication component of the search were included only if the results could be used to inform potential content of prescription drug labels. Considering that labels communicate medication information to patients, we believe that patient preferences for the communication content about medications may be assessed and used to inform optimal prescription label creation.

In the prescription drug labeling search, articles were included if they addressed either the format or content of any type of patient-oriented labels or drug information. Several MEDLINE searches were performed and included the following criteria: drug labeling/standards or (patient educa-

tion or health education) or (label or leaflet). Patient-oriented labeling has several components, all of which were included in this review. One component is the label that is directly affixed to the container. It must identify information about the medication, prescriber, and patient³³ and typically includes auxiliary stickers imprinted with directions and warnings. Package inserts are created by manufacturers, approved by the Food and Drug Administration (FDA), required for some drugs, and voluntary for others.³⁴ They are created primarily to educate physicians,³⁵ although recent improvements aim to provide summary information for patients, as well.³⁶

Consumer medication information (CMI) consists of leaflets created by the private sector (pharmacies and drug information publishers).^{37,38} These leaflets accompany most prescriptions dispensed at pharmacies.³⁹ Medication Guides, established by the FDA in 1996,⁴⁰ are standardized leaflets prepared by manufacturers for medications thought to pose a "serious and significant public health concern," and are disseminated at the pharmacy.⁴¹ Patient-oriented information is also prepared by manufacturers for direct-to-consumer advertising (DTCA). We included all patient-oriented medication information as part of the "label" so that evidence about any type of prescription drug information may aid in future labeling developments.

Extraction of Study-Level Variables

Two reviewers (WS, PS) extracted data from the same articles, with one reviewer (WS) extracting data and the other (PS) checking the information for accuracy. Disagreements were resolved by consensus. Variables assessed included patient population (ie, age, education, location, presence of chronic conditions) and study design (ie, experimental or hypothesis testing, descriptive, or review). We assessed the relationship between the outcomes reported in the study and health outcomes in patients, ranging from patient preferences (lowest level), label readability and comprehension, medication adherence, and actual health outcomes such as blood pressure control or adverse drug events (highest level). Studies evaluating prescription label preferences, readability, and comprehension rely on an assumed relationship between readability, comprehension, and the capacity to take medications appropriately.

Data Synthesis

Articles were grouped by topics under 2 headings: patient-physician communication content about medications and medication labeling format and content. Articles addressing patient-provider communication about prescription drugs were categorized under the following topics: patient preferences for content in general, content aimed to improve adherence, administration directions, and risk

communication. Topics associated with previous research on the content and format of medication labels included label organization, print, language, use of icons, and container design. Evidence tables were created for each category, and a narrative synthesis was performed.

Search Results

A total of 1944 articles were identified in our literature search. Additionally, expert advisors suggested articles, many from nonmedical sources, including psychology, business, marketing, and ergonomics literature; 65 of those articles were considered relevant. From all sources, 187 articles were identified as potentially relevant by a physician reviewer (WS) and confirmed by another physician reviewer (PS). Of those, 69 articles were excluded because they were either case reports or perspectives. In total, 36 articles addressing the preferred content of patient-provider communication about medications^{32,42-76} and 69 articles related to the content or format of prescription drug labels^{39,68,77-143} were included in our evaluation. Details of the search and yield of articles are presented in Figure 1.

Patient-Requested Information

A description of information that patients request about medications is shown in Table 1.^{32,42-76}

One survey of elderly patients found that only 46% recalled the drugs listed in their medical records,⁶³ and a second survey indicated that only 58% of elderly patients were familiar with their dosing instructions immediately after a physician visit.³² To guide communication efforts, researchers have descriptively assessed the specific information that patients request about medication administration. In a convenience sample, 67 patients in a health maintenance organization were surveyed about medication information they request; 67% asked for information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment.⁵⁶ Another survey of 100 patients recruited at a pharmacy found that the information most commonly considered important was dosing frequency (87%), adverse effects (85%), and indication (84%).⁷⁵ This survey was also a convenience sample, with a poor response rate (11%), raising questions about the generalizability of these findings.

A survey of a convenience sample of 66 white, hypertensive patients explored the com-

munication content that they believed would improve their adherence; 90% of those surveyed wanted to know about all possible adverse effects and 96% wanted to know about benefits of the medication.⁵⁷ In addition, 82% of patients requested more information about their disease, and concerns about duration of therapy and life-style effects were frequent. Although physicians and pharmacists express concern that discussion of adverse drug effects may adversely affect patient adherence,^{52,58} 3 descriptive studies found that patients desire complete information about potential adverse effects and prefer to participate in the decision-making process.^{43,54,58} All studies identified found similar results; however, none was performed in a population-based representative sample, raising concerns about generalizability.

Few studies have linked specific communication content to medication-taking behavior. One descriptive survey of 137 physicians who wrote prescriptions for antidepressant medication for 401 patients indicated that patients who were specifically advised to continue therapy for longer than 6 months were significantly more likely to adhere to

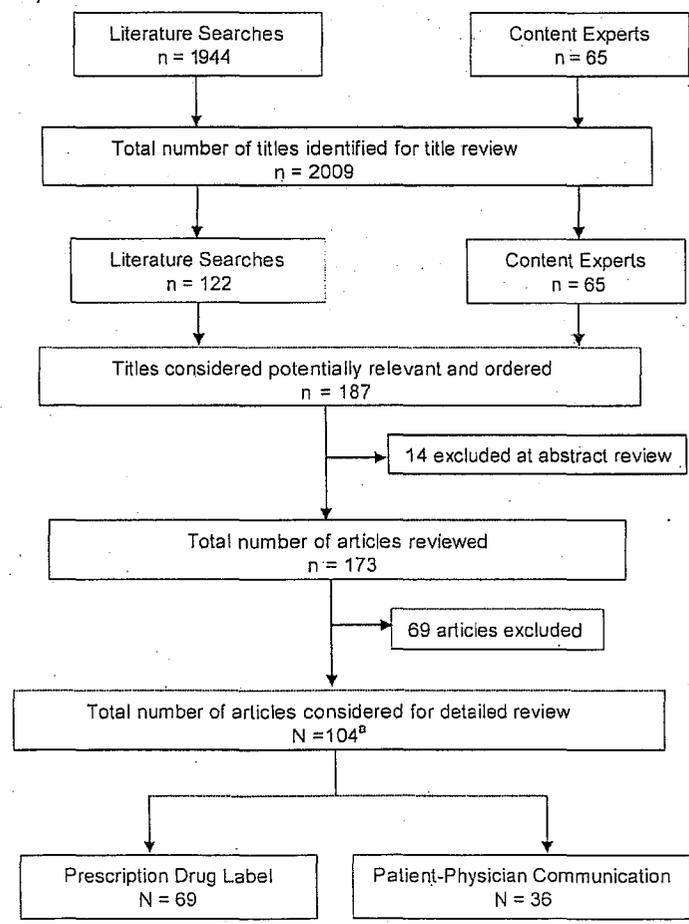


Figure 1. Article flow.

^aOne article was used in both evidence tables.

Table 1. Evidence about Physician–Patient Communication about Drugs

Reference	Type of Article/ Design	Research Question	Population	Findings
Technical aspects^a				
Jackson (2005) ⁶¹	RCT; pt. report of adherence	Does communication about implementation intention improve adherence?	220 pts.	Implementation intentions specify exactly when and where pts. will perform a behavior (eg, take medications). An intervention using this technique did not significantly impact adherence to short-term antibiotics.
Bikowski (2001) ⁴⁷	descriptive; physician questionnaires and pt. observation	Do physicians and elderly pts. agree about medication doses and frequency?	50 physician–pt. pairs	In 74% of pairs, either the physician was unaware that the pt. was taking a medication or thought the pt. was taking a drug that they were not taking; 12% of pairs had dose or frequency discrepancies.
Bull (2002) ⁴⁶	descriptive; matched physician–pt. interviews	Does communication about duration of therapy and ADRs impact adherence to antidepressants?	401 pts. and 137 prescribing physicians	Discussion of therapy duration (>6 mo) led to 3 times greater odds of continuation after 6 mo. vs pts. told to take the drug for <6 mo. Discussion of ADRs was associated with 2 times greater odds of adherence.
Fletcher (1979) ³²	descriptive; pt. interview	Do pts. understand information about their prescribed medication?	143 pts.	While 90% of pts. identified drugs prescribed during the visit, only 58% knew the dosing schedules of all medications immediately after leaving their physician's office.
Gardner (1988) ⁵⁶	descriptive; pt. questionnaire	What information do pts. request about medications?	67 previsit pt. questionnaires, 70 postvisit	67% of pts. requested information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment. One of 3 pts. was not given basic information.
Lyons (1996) ⁷⁵	descriptive; pt. questionnaire	What information do pts. desire about their medications, and how often are they provided with that information?	100 pts. responding out of 873 surveys distributed	Although >60% of pts. believed the information was important, <50% received information about storage, drug interactions, missed doses, and avoidance of ADRs; >75% received information about a drug's name, indication, dosing frequency, and duration of therapy.
Makoul (1995) ⁶⁶	descriptive; videotaped encounters, pt. interviews, written questionnaires, medical record reviews, and physician questionnaire	Do physicians and pts. in England communicate about prescription drugs in primary care, and do they agree about levels of communication?	271 pts. had full survey and videotaped data	Physicians frequently discussed product name (78%) and instructions for use (87%); pts. were passive, rarely offering their opinion or initiating discussions about medical treatment. Both groups overestimate the frequency of communication about medications.
Morris (1997) ⁵⁵	descriptive; pt. telephone survey	What are the trends over time concerning what pts. and physicians discuss about prescription drugs?	≥1000 pts. in 4 surveys conducted in 1982, 1984, 1992, and 1994	About two-thirds of physicians discuss the prescription during the encounter. About 60% discuss administration and only one-third discuss ADRs. In 1992, physicians and pts. discussed drugs more frequently than in the 1980s.
Rost (1987) ⁶³	descriptive; pt. interview and audiotaped pt.–physician encounters, medical record review	What predicts recall of medication regimens?	83 elderly pts.	On average, elderly pts. recalled 46% of the drugs in their medical records and 41% of the drugs mentioned in the clinical encounter. When physicians asked more closed-ended questions and provided more information about the medication, the pt. better recalled the medication after the visit.
Scherwitz (1985) ⁵⁹	descriptive; qualitative evaluation of tape-recorded encounters	What do physicians and pts. discuss about medications?	11 physicians making 267 physician–pt. encounters	There was little communication about drugs after the initial prescription. At the initial prescription, instructions were discussed 77% of the time, directions 31%, and indications 21%.
Sleath (1999) ⁵³	descriptive; qualitative analysis of taped physician–pt. communication	What do physicians and pts. talk about concerning prescription drugs?	467 physician–pt. encounters	On average, physician–pt. communication about drugs accounted for about 4 min per encounter. About half of the pts. recorded asked no questions about their prescription drugs; they most commonly asked about quantity (16%), drug identification (15%), dosage (9%), and indication (9%). Physicians asked pts. about identification (80%), effect on medical condition (56%), quantity (51%), dosing (41%), and barriers or ADRs (27%).

ADRs = adverse drug reactions; RCT = randomized controlled trial.

^aIndication, dose, administration, directions, and duration of therapy.

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Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Adherence Peveler (1999) ⁶⁷	factorial; RCT testing counseling and educational leaflets; measurement by pt. interviews and MEMS caps	Do antidepressant drug counseling and information leaflets improve adherence to treatment in primary care?	250 pts.	63% of pts. continued with therapy in the counseled group vs 39% who did not receive counseling (OR = 2.7; 95% CI 1.6 to 4.8). Counseling focused on daily routine and lifestyle, understanding the disease, and treatment of ADRs and their management. Treatment leaflets had no significant effect overall.
Tuldra (2000) ⁶⁹	RCT; self-reported adherence and lab testing	Does a psychoeducative intervention to educate pts. about medications and adherence improve adherence to HAART?	116 pts.	Intervention included consultation with a psychologist who provided better education about the medication and communication follow-up about adherence. Pts. who received the intervention had >6 times the odds of adequate adherence and better viral load control than those without ($p = 0.008$ and $p = 0.026$, respectively).
Raynor (2000) ⁷³	intervention; pre–post design; pt. interviews	Does a pharmacist intervention to improve communication about prescription drugs improve adherence?	143 pts. in England	Intervention that allowed pts. to communicate with pharmacists about drugs led to a 24% decrease in nonadherence (from 38% to 14%; $p < 0.001$) and a 36% improvement in pts.' reporting of medical problems.
Bailey (1997) ⁶⁷	descriptive; pt. questionnaires	What information do hypertensive pts. prefer to receive about medications to improve adherence?	66 pts.	90% of pts. wanted to know about all possible ADRs, 96% wanted to know about benefits of the medication, and 82% wanted more information about their disease. Concerns about duration of therapy and lifestyle effects were frequent.
Britten (2000) ⁵¹	descriptive; qualitative evaluation of recorded consultation and pt. interviews	What are physician–pt. misunderstandings about prescribing?	20 physicians and 35 pts. in England	14 categories of misunderstandings were identified between physicians and pts., including physician misunderstandings about pt. beliefs and vice versa. Disagreement existed about attribution of ADRs; all misunderstandings were associated with potential or actual ADRs such as nonadherence.
Hulka (1976) ⁷⁰	descriptive; pt. interview and medical record review	Does communication influence adherence and error rates for chronic medications?	46 physicians and 357 pts. with CHF or diabetes	4 types of errors were identified: omission, commission, scheduling misconceptions, and nonadherence. Greater number of drugs and greater regimen complexity were associated with more errors. Better communication of instructions was associated with fewer errors in pts. with CHF.
Ogedegbe (2004) ⁴⁴	descriptive; pt. interview	What are barriers to adherence in hypertensive African Americans?	106 pts.	Forgetfulness and poor understanding about disease are important barriers. Reminders, knowledge of disease, better communication with physicians, having a routine for medication administration, and social support networks facilitate adherence.
Schneider (2004) ⁴²	descriptive; pt. questionnaires	What aspects of physician–pt. relationship lead to better adherence to HAART?	554 pts. at 22 HIV practices	Adherence dialogue, general communication, disease-specific information, trust in physician, and physician satisfaction are all related to self-reported adherence.
Schillinger (2003) ⁶⁸	descriptive; observed physician–pt. interactions and evaluated pt. lab outcomes	Do physician communication techniques in which the physician assesses recall and comprehension impact health?	38 physicians and 74 diabetic pts. with low functional health	Physicians assessed recall and comprehension only 20% of the time. Assessment of recall and comprehension was associated with improved glycemic control, even after controlling for health literacy.
Hall (1988) ⁶⁵	systematic review and meta-analysis	Is physician–pt. communication about prescription drugs associated with greater adherence?	41 studies	There was a statistically significant relationship between information-giving about medication and adherence to medical regimens ($p < 0.0005$). Giving more information was also associated with greater understanding and recall about medications.

ADRs = adverse drug reactions; CHF = congestive heart failure; HAART = highly active antiretroviral therapy; MEMS = Medication Event Monitoring System; RCT = randomized controlled trial.

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Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Adherence Haynes (2002) ⁵⁵	systematic review	What interventions improve adherence?		A number of interventions have been shown to improve adherence, typically using a complex, multifaceted approach. More convenient care, information, counseling, reminders, and other interventions have been shown to be helpful.
Stevenson (2004) ⁴⁵	systematic review	What is the relationship between communication about drugs and adherence?	134 articles considered relevant, of which 116 were descriptive	There has been little research concerning whether exchange of views takes place between physicians and pts. (concordance). Physicians tend to dominate discussions. Some interventions to improve communication rates have been successful, but little guidance exists about the specific content associated with improving adherence.
Risk/benefit ADRs Dyck (2005) ⁶⁰	descriptive; qualitative evaluation of tape-recorded encounters	What do pharmacists discuss with pts. about drugs?	10 pharmacists, each encountering 2 pts.	Pharmacists discussed ADRs in all encounters, but discussed frequency of ADRs using vague terms and did not focus on potential benefits of the drugs. Using a leaflet did not substitute for communication about risk.
Gramling (2004) ⁴⁸	descriptive; physician survey	Do physicians believe it is more important to communicate quantitative or qualitative information about risk?	300 physician members of the Massachusetts Academy of Family Practice	When asked whether it is more important to communicate qualitative vs quantitative information about risk to pts., 63% of physicians felt they were of equal importance. Of the remainder of respondents, 94% rated qualitative as more important than quantitative information.
Hassell (1998) ⁵²	descriptive; qualitative evaluation of physician–pt. encounters and pt. questionnaires	What information do consumers hope pharmacists will provide and what do they actually provide?	2379 observed encounters and 1000 pt. interviews in England	Consumers are more interested in learning about the effectiveness of their medications, and pharmacists focus their guidance on ADRs and safety.
Lisper (1997) ⁷⁶	descriptive; qualitative evaluation of pt. interviews	From whom do pts. prefer to receive their information and what information do they need about medications?	21 Swedish pts. with hypertension	Pts. prefer to receive drug information from physicians rather than pharmacists. They prefer information at the onset of therapy and especially request information concerning possible ADRs.
McGrath (1999) ⁵²	descriptive; qualitative evaluation of physician interviews	What are physicians' perceptions about communicating prescription drug information?	20 physicians	Physicians think communication about drugs should be 2-way and participatory. Physicians express concern that too much information about ADRs may impair adherence.
Morrow (1996) ⁶⁴	descriptive; pt. interviews	Do pts. have a schema for understanding drug information?	study 1 and 2: 42 older and 42 younger adults in each study	Pts. prefer to "lump" information into packages that are easier to understand. They tend to package directions and indications together. Another group includes ADRs and emergency information.
Nair (2002) ⁵⁸	descriptive; pt., physician, and pharmacist focus groups in Canada	What do pts., physicians, and pharmacists want to discuss about medications?	88 pts., 27 physicians, 35 pharmacists, all in Canada	Physicians and pharmacists believe that pts. want less information about ADRs than they actually do and are concerned that information may impede adherence. Pts. desire both general and specific information.
Peters (2006) ⁷⁴	4 descriptive studies	How are risk frequencies best communicated when communicating risk?	1–100 students, 2–46 students, 3–46 students, 4–171 students	Framing effects were more influential in less numerate pts. More numerate pts. drew more precise affective meaning from numerical information.
Schwartz (2005) ⁷¹	descriptive; pt. questionnaire	How well do pts. interpret health-related data?	178 pts.	There is a wide range in pts.' ability to interpret health information. Those with high numeracy scored better than those with low numeracy (71% vs 36%), high vs low quantitative literacy (65% vs 28%), and high vs low education (69% vs 42%).
Walter (2004) ⁴³	descriptive; focus groups	How can risk about hormone replacement be best discussed?	40 women in England	Pts. prefer open communication of risks and benefits so that they can participate in the decision-making process. Pts. also want individualized risk and benefit information.

ADRs = adverse drug reactions.

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those instructions (OR 3.12; 95% CI 1.21 to 8.07).⁴⁶ In addition, patients who discussed adverse effects with their physicians were less likely to discontinue therapy than were patients who did not discuss them (OR 0.49; 95% CI 0.25 to 0.95). Two systematic reviews generally found a relationship between communication about medications and adherence, but did not specify communication content that is effective.^{54,65}

Drug Labeling

Findings on the content and format of prescription drug labeling are presented in Table 2.^{39,68,77-143}

Organization

Three descriptive studies indicate that patients prefer that information be organized in a schematic, logical way, with information about the drug, directions for use, and its benefits followed by warnings and adverse effects.^{116,132,135} A survey of 140 participants recruited from a university, a flea market, and a retirement community found that patients of all ages prefer information about indications and benefits of medications prior to information about adverse effects and warnings.¹³⁵

In presenting risk and benefit information, patients prefer drug information to be organized into a simplified schema. Researchers in a laboratory setting asked 42 young adults and 42 elderly adults to sort medication items (eg, indication, instructions, adverse effects) to create a preferred instruction set. Young and elderly adults shared a similar schema for medication taking, preferring to read the drug's name and indication, followed by directions (schedule and duration), followed by warnings and adverse

effects.⁶⁴ In addition, patients exhibited better recall of medication information compatible with this schema. The samples for the descriptive studies were either not in the US¹¹⁶ or were small,¹³⁵ and the experimental design included a sample of only 84 patients in a laboratory setting,⁶⁴ raising some concerns about the generalizability of these findings.

Three studies used experimental designs to demonstrate that list formats on medication labels improve patient understanding and recall.^{101,106,136} One study presented 27 elderly patients with labels in different formats.¹³⁶ The subjects preferred labels in categorized lists (lists with headers) over simple lists and simple lists over paragraph format. Elderly patients found categorized lists to be easier to read, with improved recall, answer time, and accuracy. In another experiment, older and younger patients were presented with labels of different formats; list formats were again found to be easier to read and recall than were paragraph formats, and list formats reduced age differences in both answer time and accuracy.¹⁰¹ Three studies with experimental designs have demonstrated that patients prefer leaflets that use headers to organize material^{96,101,106} and white space to separate related concepts.¹⁰⁶ Another study with 101 elderly adults and 109 young adults indicated that patients, especially the elderly, could more easily read labels that judiciously used white space by separating related sections and grouping related material together.⁸⁷ These experiments were performed in a laboratory setting and should be evaluated in the real world setting.

Print

Font size influences readability and comprehension in both CMI and container labels. In one randomized controlled trial (RCT), 101 elderly adults and 109 young

Table 1. Evidence about Physician–Patient Communication about Drugs (continued)

Reference	Type of Article/ Design	Research Question	Population	Findings
Provider/venue/language choice				
Savas (2001) ⁵⁰	RCT; pt. questionnaire	Does verbal or written information improve understanding about medications in an undereducated population?	38 received written alone, 30 received verbal alone, 40 received both written and verbal information	78% read the written material. Pts. who received both verbal and written material had the best understanding about their drugs as measured by a series of 8 questions about administration and ADRs. Written information was more effective than verbal information.
Smith (1994) ⁷²	descriptive; pt. questionnaire	What are pts.' perceptions of the most valuable source of information about drugs and the optimal content of discussions about drugs?	110 pts. taking OTC medications, 218 pts. taking prescription drugs	Pts. prefer to discuss prescription drugs with their physicians and would like to hear about indications, directions, ADRs, and duration of therapy. Pts. believe that they have to bring up the topic of drugs with their physicians.
Schaafsma (2003) ⁴⁸	review; MEDLINE literature review	How do pts. whose first language is not English access drug information?		There has been little research in this area. Foreign languages and cultural differences provide barriers to accessing drug information; interpreting services can help.
ADRs = adverse drug reactions; OTC = over-the-counter; RCT = randomized controlled trial.				

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels

Reference	Type of Article/ Design	Type of Label	Research Question	Population	Findings
Leaflets Bower (2003) ⁷⁷	experiment; pt. questionnaire	CMI	What language characteristics affect intention to adhere?	260 students	Adherence intention is greater when instructions are set in a negative frame and the language is simple, understandable, and avoids medical jargon.
Dickinson (2001) ⁹⁶	RCT; pt. questionnaire	CMI	comparison of 2 CMI formats and an assessment of the proposed EU standardized format	2 groups of 20 pts.	On average, pts. correctly answered only 3 of 15 questions after reading the EU CMI and 8 of 15 from the best practice CMI. Headers and clearer language improved understanding.
Knapp (2005) ¹²¹	RCT; pt. questionnaire	CMI	Can pts. comprehend the messages from icons? Does icon size or the frequency of presentation influence comprehension?	part 1: 160 adults part 2: 67 elderly adults in the UK	There was great variability in pts.' interpretations of icons. In the 10 icons evaluated, pts. correctly interpreted 7.5–90%; only 3 were understood by >85%. Older and less educated pts. were less likely to understand icons. Icons were better understood when larger ($p = 0.04$) and when presented to pts. more than once ($p < .001$).
Miselli (1990) ¹⁰⁵	prospective observational study; pts. exposed to 2 different leaflets and pt. questionnaire	CMI	Do different labels impact information accessibility and understandability?	6692 pts. in Italy	Experimental labels were more effective. Pts. judged an experimental label with simple language and checklists superior to a conventional label.
Morrow (1995) ¹³⁶	experimental; 3 trials evaluating pt. perceptions of label formats and impact on recall and understanding	CMI	Do list vs paragraph formats improve older pts.' understanding and recall of drug instructions?	trial 1: 27 older adults trial 2: 36 older adults trial 3: 27 older adults	List formats improved pts.' understanding, recall, and speed of accessing information vs paragraph format.
Morrow (1998) ¹⁰⁰	experiment with 2 trials of labels with and without icons	CMI	Does the use of icons to communicate dosing schedules improve older and younger pts.' understanding?	trial 1: 36 older and 36 younger adults trial 2: 45 older and 36 younger adults	In older and younger adults, questions about dose and time information were answered more quickly and accurately when a timeline icon was used. An icon that was less integrated to the text was ineffective.
Morrow (1998) ¹⁰¹	RCT; trials using pt. questionnaires to evaluate understanding and recall of different label formats	CMI	Does the use of list format and category headers on CMI impact understanding of medication instructions?	trial 1: 44 elderly and 44 young adults trial 2: 48 elderly and 32 young adults	Lists improved pts.' ability to infer information from labels. Pts. prefer lists and headers. Lists improved understanding and recall and reduced age differences in answer time as well as accuracy. The benefit of lists was greater in older vs younger adults. Evidence of the effect of headers was inconclusive.
Ngho (1997) ¹²⁴	RCT; pt. interview and pill count	CMI	Does CMI with icons produced by local artists and with educational organizers lead to better adherence and understanding in nonliterate pts.?	78 nonliterate pts. in Cameroon who were started on antibiotics	Both visual aids (CMI with icons) and educational organizers led to improved comprehension about drugs and adherence to antibiotic regimens.
Peveler (1999) ⁵⁷	RCT; intervention with measurement by pt. interviews and MEMS caps	CMI	Do antidepressant drug counseling and information leaflets improve adherence in primary care?	250 pts.	63% of pts. continued with therapy in the counseled group vs 39% who did not receive counseling. Treatment information leaflets had no significant effect overall.
Vuorma (2003) ⁷⁸	RCT	CMI	Does provision of a booklet with treatment information options impact treatment choices for menorrhagia?	393 pts.	Written information significantly impacted pt. behavior. Pts. who received the information chose more medical treatment, but surgical procedure rates did not change and fewer "new" procedures were performed.
Whalley (2002) ¹⁴³	RCT	CMI	Does the use of icons or graphs to depict risk and benefit information influence intention to take the medication?	196 pts. in Canada	Pts. randomized to the traditional, text-only CMI were less likely to consider taking the drug than were pts. randomized to receive CMI with either icons or graphs to depict risk and benefit information ($p < 0.001$).
Basara (1994) ¹¹⁹	descriptive; content evaluation of 63 CMIs	CMI	Are PPIs/CMI readable?	63 CMI	Inserts written at a 9th grade reading level with small font are not very readable.

CMI = consumer medication information; EU = European Union; MEMS = Medication Event Monitoring System; PPI = patient package inserts; RCT = randomized controlled trial.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
Leaflets					
Bernardini (2000) ⁹⁷	descriptive; pt. questionnaire	CMI	Can pts. understand CMI, and do they prefer the use of symbols or icons?	1004 pts. in Italy	83.5% of Italian pts. read the leaflet; 53.5% found the leaflet hard to read, 63% of those >50 y old. 47% had difficulty finding the information they sought. Although 74% of pts. preferred the use of icons, there was little agreement about which versions were most effective.
Bernardini (2001) ¹¹⁶	descriptive; pt. questionnaire	CMI	How do color, print size, and layout influence readability of labels?	1004 pts. in Italy	Pts. reported that font size must be at least 10 point to be readable, preferably larger. Pts. requested more detail, but in a schematic organization; they also noted that certain color print is more appropriate for certain sections (eg, warnings/ADRs should be red).
Berry (2003) ⁷⁹	descriptive; pt. interview	CMI	Do the standardized European Community guidelines for communicating risk lead pts. to understand risk?	4 studies in the UK: 1-268 students 2-112 adults 3-120 adults 4-360 adults	Using language to communicate risk led pts. to significantly overestimate the risk of ADRs vs a numerical presentation, which was much closer to the actual risk.
Estrada (2000) ⁹⁸	descriptive; SMOG evaluation of leaflets	CMI	Is warfarin CMI or handout information readable?	50 leaflets	Written at an average level of 10.7th grade, which is beyond the comprehension of most pts.
Gibbs (1990) ¹³¹	descriptive; pt. mail survey	CMI	Do leaflets improve understanding about medications and their ADRs? Are pts. satisfied with leaflets?	3410 pts.	Pts. had better understanding of their indications for the medication, administration directions, and what to do in case of an ADR. Pts. were satisfied, overall, with leaflets and did not experience more ADRs than did those who did not receive CMI.
Gustafsson (2005) ¹¹⁰	descriptive; expert evaluation of the leaflets and pt. questionnaires	CMI	Are leaflets readable and well understood by pts.?	1060 pts. who received CMI for 30 drugs in Sweden	Leaflets contained about half of the important topics desired and were deemed readable. Pts. had difficulty understanding interactions and contraindications of the drugs.
Hameen-Anttila (2004) ⁸⁵	descriptive; pt. interview	CMI	Do children understand icons in medication leaflets?	90 children in Finland	Correct interpretations of pictograms ranged from 30% to 99%, but were generally well understood. However, even well understood icons did not influence children's understanding of the leaflets.
Khurana (2003) ⁸⁸	descriptive; SMOG and other tests to measure readability	CMI	Can pts. read ocular medication inserts?	10 drug inserts	CMI for ocular medications are often too complex, average of 12th or 13th grade reading level.
Krass (2002) ⁹¹	descriptive; leaflet evaluation	CMI	Does CMI meet the 1996 FDA Action Plan? Do consumers comprehend existing CMI and model CMI?	24 pts., 36 CMI, and 3 model CMI	Both the language and format recommendations of the Action Plan have not been widely met by the CMI evaluated. Pts. strongly preferred the model CMI to the existing ones and could understand it better.
Morris (1984) ¹³⁸	descriptive; mailed survey	CMI	Do patients who take hypertension, tranquilizer, or arthritis drugs read CMI or keep it?	1650 pts.	95% of those surveyed read the CMI, 76% keep it, and 56% discuss it with another person; 42% said that the leaflet made them feel better about taking the medication.
Morrow (1991) ¹⁴⁰	descriptive; 2 trials requiring pt. to sort and answer questions about labels	CMI	How do elderly pts. organize medication information for best understanding? Do instructions that follow this schema increase understanding?	trial 1: 33 elderly pts. trial 2: 27 elderly pts.	Elderly patients have a schema that they use to understand drug information, and they prefer information to follow in that order: (1) medication and purpose, (2) how to take (dose, schedule, duration, warnings), (3) outcomes (ADRs, emergency information). Instructions in this order were easier to remember.
Svarsted (2003) ⁹⁹	descriptive; evaluated the CMI received by trained shoppers after filling prescriptions	CMI	How frequently do pts. receive CMI, and what is the quality of the CMI?	918 prescriptions filled at 306 randomly selected pharmacies	Shoppers received leaflets 87% of the time, but leaflet length and quality varied greatly. Only 49% of leaflets had acceptable administration directions, 28% had acceptable information about precautions, 19% had acceptable information about contraindications and what to do about them; 26% of pts. did not receive leaflets that were adequately readable or comprehensible.

ADRs = adverse drug reactions; CMI = consumer medication information; FDA = Food and Drug Administration; RCT = randomized controlled trial; SMOG = Simplified Measure of Gobbledygook.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
Leaflets					
Swanson (1990) ¹⁰⁸	descriptive; evaluated PIs and CMI	CMI/PIs	How readable are leaflets for oral contraceptives?	93 leaflets	A great deal of variability was seen among leaflet readability levels, ranging from grade 5.5 to 13.6.
Vander Stichele (1991) ¹⁰⁵	descriptive; pt. survey	CMI	How do people feel about CMI?	398 respondents in Belgium	89% of respondents read the CMI and find it useful to learn about ADRs, dosage, indications, contraindications, and shelf life. Respondents were generally pleased with CMI.
Buck (1998) ¹¹⁷	systematic review	CMI	Are pts. receiving high-quality CMI? Are they receiving CMI at all?	NA	Leaflets are commonly dispensed. However, content is not standardized, materials are written at a high grade level, and there are poor resources for non-English-speaking pts.
Kroner (1994) ¹¹⁸	review	container labels and CMI	challenges with reading labels	NA	Describes the importance of better physician-pt. communication about medications. Also demonstrates that labels are not very readable, but large font and particular language improve readability.
Morrow (1988) ¹³²	review	CMI	describes prescription drug nonadherence	NA	Medication instructions should be complete, organized in a logical way, and in list format. Precise instructions improve adherence by 10-20%.
Container labels					
Kalsher (1996) ¹³³	experimental; 2 pt. surveys after reading various labels	container labels	Do fold-out or tag labels improve readability? Do icons improve readability?	trial 1: 84 undergraduates trial 2: 58 older adults	Tag or fold-out labels were rated as easier to read, and pts. were more likely to read warnings, recommend label use, and prefer labels. Icons were helpful across the same domains.
Luscombe (1992) ¹²⁰	experiment; pt. survey	container labels	Do pts. have preferences for container label typology?	55 pharmacy clients in Great Britain	Pts. strongly preferred laser-printed labels compared with those printed on a dot matrix printer. In general, glossy labels were preferred over matte-finish labels.
Mansoor (2003) ⁸⁶	experiment; pt. interview	container labels and CMI	How do pictograms affect readability of pt. information materials?	60 low-literate pts. from South Africa	The presence of pictograms significantly improved acquisition and comprehension of drug information; 73% vs 53% had >80% understanding when reading CMI with icons vs no icons.
Morrell (1990) ¹⁰⁷	RCT; pt. interview	container labels	Do icons improve younger and older adults' understanding of prescription labels?	32 older adults and 32 young adults	Younger pts. understood the labels better and more quickly. Use of icons improved younger adults' understanding but interfered with older adults' understanding of the medication directions.
Smither (1994) ¹³⁴	experiment; evaluated pts.' ability to read and comprehend labels with different formats	container labels	Do font size and font selection impact understanding and ease of reading labels?	trial 1: 19 young adults and 20 seniors trial 2: 18 young adults and 16 seniors	Larger font and certain font types are associated with ease of reading and better understanding of the labels. More errors were seen with 9 point vs 12 or 14 point font and with Courier rather than Helvetica or Century Schoolbook font.
Wogalter (2003) ⁸⁷	experimental evaluation of hypothetical container labels that varied in print size, spacing, and design	container labels	What is the effect of label format on knowledge acquisition and perceived readability of labels?	101 elderly subjects, 109 young adults	Older pts. benefit substantially from larger print. While previous studies have supported the use of extended (fold-out) labels, this study was inconclusive on that issue. Use of white space or chunking of information was helpful, especially in the elderly.
Wogalter (1999) ⁸¹	experimental evaluation of hypothetical container labels that included cap labels	container labels	Can information acquisition in older adults be enhanced by using the container surface area in new ways?	trial 1: 60 subjects trial 2: 75 subjects	Trial 1: pts. preferred labels that included a large identification label attached to the cap. Trial 2: cap labels also improved pt. knowledge about the drug. Cap labels in colors different from the container also improved pt. satisfaction and knowledge.
Container labels					
Benson (2002) ⁹²	descriptive; pt. interview	container labels	Can affluent seniors read container labels (as well as other health information)?	93 seniors	30% of seniors could not comprehend basic health information in prescription labels. Older seniors and those with less education performed worse.

ADRs = adverse drug reactions; CMI = consumer medication information; NA = not applicable; PIs = package inserts; RCT = randomized controlled trial.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/ Design	Type of Label	Research Question	Population	Findings
Container labels					
Dowse (2005) ¹²²	descriptive; pt. interview	container labels	Do labels with pictograms improve understanding and adherence in low-literacy pts.?	87 Xhosa pts. from South Africa	Labels were constructed in culturally appropriate ways by local artists. Patients with pictogram labels experienced 25% greater understanding about medications and 18% improvement in adherence.
Dowse (2001) ¹²³	descriptive; pt. interview	container labels	Are locally created, culturally targeted pictograms more effective than accepted pictograms for communicating with low-literate pts.?	46 Xhosa pts. from South Africa shown 23 local CMI and 23 USP CMI	Pts. exposed to locally produced, culturally appropriate icons were more likely to understand the information than were pts. exposed to USP pictograms. Almost 2 times as many pts. who received local labels understood them at ≥85% level.
Filik (2004) ¹³⁰	descriptive; pt. eye-tracking when evaluating an array of labels	container labels	Does the use of capitalized "tall man" font improve pts.' likelihood of selecting appropriate medications?	20 students and staff (non-healthcare professionals)	Pts. were almost half as likely to incorrectly identify a target drug presented in an array of drugs when using "tall man" letters, suggesting that capitalizing sections of potentially confusing drug names improves identification.
Hallworth (1984) ¹³⁸	descriptive; pt. survey	container labels	Do geriatric pts. understand the contents of container labels?	92 elderly pts.	Geriatric pts. frequently misinterpreted medication directions, and there was substantial variability in their understanding. Confusion frequently stemmed from timing of dosing and the relationship to meals.
Holt (1992) ¹⁴²	descriptive; pt. questionnaire	container labels	Can pts. correctly interpret dosage directions from container labels, and what characteristics of instructions improve interpretation?	321 pts.	While labels more frequently used language that vaguely instructed pts. about dosing directions (ie, "Take three times daily"), dosage instructions that specified the number of hours between doses were better understood (ie, "Take every 8 hours").
Lohiya (2004) ¹¹²	descriptive; evaluation of container labels	container labels	Is there variability in the presentation of expiration dates on prescription drug labels?	84 drug labels	Substantial variability was seen in location, font, and legibility of expiration dates
Mazzullo (1974) ¹²⁷	descriptive; pt. interviews	container labels	How well do pts. understand prescription label instructions?	67 pts.	Pts. had substantial difficulty with instructions that were vague. Even when responding to clear instructions, the frequency of interpretive errors ranged from 8% to 64%.
Moisan (2002) ⁹³	descriptive; pt. interviews	container labels	Do pts. who have difficulty reading labels adhere less to their drugs?	325 seniors	No clear relationship was identified between understanding labels and adherence. However, 95% CIs are very wide and an important effect cannot be excluded.
Morrell (1989) ¹⁴¹	descriptive; pt. questionnaires	container labels	Do age, memory load, and study time affect drug label memory and comprehension? 3 experiments varied study time, memory load, and label quality.	experiment 1: 36 elderly and 48 young adults experiments 2 and 3: 36 elderly and young adults	Older pts. had poorer recall than did younger subjects, regardless of who determined the study time. Both older and younger subjects recalled less information as more was presented. Both young and older pts. had difficulty understanding information from a community pharmacy but had better understanding when presented with a standard, high-quality label.
Zuccollo (1985) ¹²⁶	descriptive; pt. interviews and assessment of labels	container labels	How well do elderly pts. read and understand container labels?	60 British pts. and 163 medication labels	Only 40% of pts. had no difficulty reading instructions on the label. Scriptwriter typeface was least easy to read. About half of the labels were judged to have directions that were unclear.
OTC labels/DTCA					
Berry (2004) ⁹³	experiment; pt. questionnaire	OTC	Is risk communicated better numerically or verbally on OTC labels?	188 adults	Pts. overestimate risk in all cases, but overestimated it to a much greater extent when risk was presented verbally vs numerically.
Discenza (1992) ⁸⁰	RCT comparing 3 levels of warnings	OTC	How does the strength of warnings on labels affect intention to use medication?	252 volunteers attending business school	As warnings were more forceful and threatening, study participants reported they would be less likely to use the medication.

CMI = consumer medication information; DTCA = direct-to-consumer advertising; OTC = over-the-counter; RCT = randomized controlled trial; USP = United States Pharmacopoeia.

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Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
OTC labels/DTCA					
Friedman (1997) ¹⁰³	controlled trial comparing 3 prototype labels	OTC	Are cholestyramine OTC labels comprehensible?	2225 randomly selected subjects from across the US	99% of subjects understood the key message that they should call the physician before using the drug and should read the full insert. They were able to follow directions 67–92% of the time. There were no statistically significant differences among labels with text, graphics, or symbols except that high school nongraduates had significantly lower comprehension with symbols.
Sansgiry (2001) ⁹⁴	experiment assessing degree of involvement	OTC	How does consumer involvement or hypothetical symptoms impact label understanding?	256 college students	Pts. more involved in purchase of OTC drugs (those with symptoms) understood the labels better than did those who were not involved. There was no difference between hypothetical symptoms of a cold or headache.
Sansgiry (1997) ¹⁰⁴	experiment assessing 4 label designs: pictures only, verbal only, congruent picture-verbal, and noncongruent picture-verbal	OTC	Does congruence between icons and text improve understanding and intention to buy medications?	48 elderly adults and 48 young adults	Congruence between the icons and verbal information on labels leads pts. to best understand the medication directions and increases the intention to purchase the drug.
Woloshin (2004) ¹³⁷	experiment; before and after comparison	DTCA information	Do pts. prefer to have access to a "benefit box" of quantitative risks and benefits for prescription drugs that are advertised?	203 subjects in New England communities	The benefit box was widely rated as useful and readable. When added to DTCA for rofecoxib, clopidogrel, and pravachol, pts. had a lower perception of efficacy after reading the benefit box.
Brass (2004) ¹²⁸	descriptive; pt. interview and lab tests	OTC	How well did pts. follow instructions on OTC label for cholesterol-lowering medication (the CUSTOM trial)	3316 pts. who self-selected to enroll	Only 44% of all pts. who self-selected the drug met LDL-C criteria; 24% had >20% 10 y coronary risks. Only 42% of pts. talked with their physicians before use.
Ciociola (2001) ⁹⁵	descriptive; recordings of drug use in a diary, tablet counts, and pt. interview	OTC	Do pts. understand OTC ranitidine labels?	1405 pts.	More than 84% of pts. understood contraindication of use, dose, and duration of another drug for PUD. 90% followed maximum daily dose instructions.
Kaphingst (2004) ¹¹¹	descriptive; expert evaluation of DTCA supplements	DTCA television ads and related Web sites	Is the information associated with DTCA readable?	23 supplements to television DTCA	Using SMOG assessments, text DTCA supplements were written at the high school level for the body sections and college level for the summary, with specific shortfalls in layout, typology, and graphics use.
Melin (2004) ¹²⁹	descriptive; pt. questionnaires and lab tests	OTC	Do pts. understand OTC label for Mevacor?	3316 pts. who self-selected to enroll	Pts. understood labels and LDL-C improved, but 23% of pts. demonstrated behavior that created the potential for suboptimal safety.
Nabors (2004) ⁹⁴	descriptive; pt. questionnaire	OTC	Do adolescents and young adults read or understand CMI?	876 high school and college students	75% of subjects read the labels. Those with "immediate health concerns" were most likely to read them. Students were interested in dosage, ADRs, and symptoms treated. (Note: pain was not statistically significant in multivariate models.)
Patel (2002) ⁸⁹	descriptive; pt. interview	OTC	How well do pts. interpret directions that require calculations?	oral rehydration therapy: 13 subjects OTC drops: 48 subjects OTC tabs: 31 subjects; subjects selected to have broad cultural and educational diversity	77% of subjects were unable to correctly administer oral rehydration therapy, and performance was weakly related to cultural background and education; 56% were unable to calculate appropriate doses for their children's cough syrup. Pts. had no difficulty in understanding the appropriate dose of the tablets, but 68% planned therapy schedules that led to incorrect doses.

ADRs = adverse drug reactions; CMI = consumer medication information; CUSTOM = Consumer Use Study of OTC Mevacor; DTCA = direct-to-consumer advertising; LDL-C = low-density lipoprotein cholesterol; OTC = over-the-counter; PUD = peptic ulcer disease; SMOG = Simplified Measure of Gobbledygook.

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adults were presented with 12 otherwise identical over-the-counter (OTC) drug bottles with varied container labels along 3 dimensions, one of which was font size (7 vs 10 point).⁸⁷ While younger participants performed equally well in the small and large font size label groups, elderly patients had significantly reduced recall and understanding after reading the small-font labels. Both young and elderly participants preferred the larger font labels. In another experiment with 19 young and 20 elderly patients, patients of all ages preferred labels written in larger font and reported that 14 point font was easier to read than 12 point, which was easier to read than 9 point.¹³⁴ This survey also found

that patients read labels with larger font more rapidly and accurately than labels with smaller font. Bernardini et al.¹¹⁶ surveyed 1004 Italian patients concerning CMI; 63% of the respondents requested larger font size than is currently seen in European leaflets, and almost 80% preferred that font size be 10 point or larger. Although this survey took place in Italy, it is likely that concern about font size is less sensitive to cultural norms and that the findings are likely representative of sentiments in the US.

One experiment evaluated patients' preferences for 3 font styles for medication labels (Century Schoolbook, Helvetica, and Courier) and found that patients preferred

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels (continued)

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
OTC labels/DTCA					
Raymond (2002) ⁹⁰	descriptive; pt. survey	OTC	Do pts. understand an OTC label for the emergency contraceptive?	663 women	A prototype label was created; >85% of women understood 7 of 11 objectives. Worse comprehension was seen on an important safety-related topic (don't take if vaginal bleeding is present).
Sansgiry (1997) ¹⁰²	descriptive; assessed labels on criteria from guidelines	OTC	Did OTC label contents meet label readability guidelines (prior to the Drug Facts)?	100 labels, 103 subjects	Poor guideline adherence: use of small font (≤ 6 points on warnings and indications), all uppercase letters and use of hyphenation, lack of paragraph breaks or boldface; >40% contained advertising claims.
Thomas (1998) ⁹⁹	descriptive; evaluated using SMOG techniques	PEMs	Can pts. understand education materials about hormone replacement therapy?	27 PEMs	Pt. education materials were often hard to read and understand, ranging from grade 8 to grade 14 reading level (mean 10.8). Professional associations created the most readable PEMs.
Vigilante (1997) ¹³⁵	descriptive; pt. survey	OTC	Do pts. prefer medication information on labels to be presented in a particular order?	140 pts.; 3 stratified convenient samples that varied in age and educational status	Pts. have preferred order for items on the label: (1) indications, (2) hazards/warnings, (3) active ingredients.
PIs					
Brinker (2002) ¹¹⁴	descriptive; evaluation of pharmacy claims data	PIs	Do physicians prescribe in compliance with PIs when prescribing moxifloxacin?	793 700 pts.	Physicians prescribed moxifloxacin concomitantly with a contraindicated medication (amiodarone; 0.11%). This study shows that even physicians are frequently unaware of PIs when prescribing.
Smalley (2000) ¹²⁵	descriptive; evaluation of pharmacy claims data	PIs	Do pts. respond to black box warnings on cisapride by taking the drug more appropriately?	24 840 pts.	In the year subsequent to FDA action requiring a black box warning for cisapride, there was only a 2% reduction in inappropriate cisapride use in each of 3 sites, with rates of inappropriate use ranging from 24% to 58%.
Stearman Ross (2004) ¹¹³	descriptive; pt. and provider surveys	PIs	Are PIs for oral contraceptives readable?	94 pts. and 18 providers 34 expert reviews	Oral contraceptive PIs were frequently written at 10th to 12th grade levels and included substantial medical jargon. A new PI was created at the 6th grade level with simpler language.
Steinmetz (2005) ¹⁰⁹	descriptive; evaluation of PIs	PIs	What information about geriatric pts. is present on PIs?	50 PIs from the most prescribed oral medications at 1 university medical center	Approximately 50% of PIs contained precautionary statements for the elderly. Only 56% had dosing information and only 16% provided specific milligram amounts. More information is necessary about elderly dosing information on labels.
Willy (2004) ⁹²	descriptive; evaluation of PIs	PIs	How much variability is there in the PIs of drugs known to be hepatotoxic?	95 PIs	12% of PIs had hepatotoxic warnings in a black box, 54% in the warnings section, and 34% in the ADRs section. Mean informativeness score was 35%.
Marroum (2002) ¹¹⁵	review	PIs	How is pharmacokinetic and pharmacodynamic information reported?	NA	PIs present outdated and poor-quality information about pharmacokinetic and pharmacodynamic information to physicians. Proposed a new FDA rule to improve PIs.
ADRs = adverse drug reactions; FDA = Food and Drug Administration; NA = not applicable; OTC = over-the-counter; PEMs = patient education materials; PIs = package inserts; SMOG = Simplified Measure of Gobbledygook.					

Century Schoolbook.¹³⁴ In a descriptive survey of 60 elderly patients exposed to labels written with 5 different fonts, Scriptwriter font was considered the most difficult to read, and fonts that appeared larger were considered easier to read.¹²⁶ The survey by Bernardini et al.¹¹⁶ of patient preferences concerning CMI in Italy evaluated whether the color of print affects label readability. The investigators found that approximately 66% of respondents reported that, in general, they prefer labels to be printed in black and white. Yet the same patients noted that if colors were used, certain colors are more appropriate for certain sections of the patient leaflet; warnings and adverse effects were easier to identify when printed in red type. These findings did not suggest an overall preference for the use of color and did not address concerns about color-blindness.

Language

Two descriptive studies and one RCT have found that patients have more difficulty understanding vague versus precise medication directions.^{48,110,127} In a survey of medication leaflet comprehensibility for 30 commonly prescribed medications in 1060 Swedish patients, leaflets using more complex messages to communicate drug warnings and interactions were less comprehensible.¹¹⁰ In one RCT, researchers presented 260 students with medication labels that varied in the use of medical jargon and risk presentation.⁷⁷ The authors found that adherence intention was greater when the instructions were set in a negative frame (ie, the risks of nonadherence rather than the benefits of adherence) and when the language was simple and understandable, without medical terminology (ie, replacing "gastrointestinal problems" with "heartburn" on a label). The samples studied (Swedish and younger adults in the US) limit our ability to generalize the findings to a broader population.

Researchers in England performed a series of descriptive surveys to compare 2 risk communication approaches.⁷⁹ In 1998, the European Commission Pharmaceutical Guidelines required that every medicine be accompanied by a comprehensive leaflet, that a list of all known adverse effects be listed on those leaflets, and that the adverse effects be categorized into 5 verbal descriptors ranging from "very rare" to "very common." Researchers performed 4 patient surveys with a total of almost 850 participants to assess whether verbal versus numerical presentation of risk influences risk perception. In each of the surveys, patients substantially overestimated medication risks when they were presented in prose; estimation of risks was more accurate when they were presented numerically. While these studies evaluated the specific nomenclature adopted in Europe, concerns about the use of prose to communicate risk may be generalizable to other settings.

When presented with risk information, patients also request accurate benefit information. In a study of 203 pa-

tients presented with DTCA for common medications, patients were asked about their perceptions of the benefits of the medication.¹³⁷ Patients were then randomly assigned to receive the same DTCA with and without a "benefit box" that presented specific data concerning the expected benefits and risks of the drugs. Although patients had a lower perception of efficacy after reading the benefit box, approximately 93% reported that they preferred labels to include this risk and benefit information.

We found no evidence to assist with the problem of label production for patients who do not speak the languages used in the product information.

Use of Icons

Results concerning the use of icons have been mixed. One study found that a timeline icon improves patients' understanding of medication administration; however, it was helpful only when the icon was closely integrated with the text of the leaflet.¹⁰⁰ In children, icons were not found to improve understanding about medications.⁸⁵ In an RCT of 87 low-literacy patients in South Africa, patients given a leaflet with locally created, culturally sensitive icons were found to better understand (25% increase) and adhere to (18% increase) their medications compared with controls who received leaflets with no icons.¹²² Another study in the same population found that not all icons are equally effective, and patients understood locally created icons much better than typical icons from the US.¹²³

While one experimental study of 60 low-literate patients from South Africa found that the presence of icons significantly improved acquisition and comprehension of drug information,⁸⁶ another experiment with young and elderly adults in the US found that older patients have more difficulty understanding icons and icons did not improve readability in an elderly sample.¹⁰⁷ A more recent RCT found great variability in patients' interpretations of icons. A survey of 160 patients asked to interpret 10 icons found that patients interpreted between 7.5% and 90% correctly and that only 3 icons were understood by more than 85% of the participants.¹²¹ As a result, findings about icons are inconclusive, and further research is needed to explore the specific icons that most effectively communicate information to patients.

Containers

Three RCTs have evaluated the efficacy of methods to increase container label surface area. In one trial with young and elderly adults, container labels designed as tags or fold-out labels with greater surface area were easier to read and were preferred by patients.¹³³ When 60 older patients were exposed to a variety of OTC drug container designs, they preferred a design with a cap having an additional label that identified the drug and listed key informa-

tion.⁸¹ However, another trial evaluating the efficacy of fold-out labels found that they did not improve patient understanding about the medication.⁸⁷ The lack of consistent findings in these small studies with nonrepresentative samples makes it difficult to draw conclusions about the effect of newer container designs.

Discussion

This review of the literature points to several key components of both the content and format of prescription drug labels. When optimizing content, patients prefer information about the indication for the medication, expected benefits, duration of therapy, and a thorough list of potential adverse effects, in addition to typical information identifying the drug's name, directions for use, and warnings. When optimizing label format, lists, headers, and white space enhance readability, and content should be organized to follow the schema that patients use to understand medication information. The print should be the largest size possible of fonts that are easiest to read, and language should be simple, precise, and devoid of formal medical terminology. The evidence concerning the use of icons is mixed; only well-tested, culturally appropriate icons should be used and they should be carefully tested in elderly patients. New approaches to enhance container label surface area seem promising, but more study is needed. Table 3 summarizes label features for which we judged the evidence to strongly suggest benefit.

Although numerous studies have evaluated patients' perceptions about readability of medication labels and comprehension, there is limited evidence linking label design to patient outcomes such as adherence or safety. Our review is limited by our assumption of a significant relationship between readability, comprehension, and appropriate medication-taking behavior. While it seems reasonable to assume that if patients cannot read and comprehend medication labels they are less likely to be adherent, the nature of this relationship has not been well tested. Further studies evaluating the effects of label content and format should focus on their effects on medication-taking behavior (ie, adherence and error rates) and health outcomes. Additionally, many of the studies cited here were performed in a non-clinical setting; although many were randomized, they may not capture the true complexity of medication-taking in a real world setting in which patients may be taking multiple medications and have numerous competing demands. Future studies should be focused on the effects of label design in clinical settings.

Efforts to improve prescription drug labels are needed. A growing body of research has found that patients frequently misinterpret prescription drug labels. Challenges in reading and understanding labels may represent one cause for the high rates of medication errors and poor adherence. The extent to which deficits in labeling contribute to poor adherence or unsafe use of medications is unknown, but it is worth striving for improvements in these domains.

These findings come at an important time in the evolution of prescription drug labels. With the passage of the Medicare prescription drug benefit, the federal government plays an even greater role in purchasing prescription drugs. Federal payers will likely be increasingly interested in maximizing the safe and appropriate use of medications. To the extent that labeling practices can improve adherence and safety, efforts to improve prescription drug labels may have more traction. In addition, in 2007 the FDA will reevaluate whether quality and distribution guidelines for CMI are being met⁸⁸; evidence of poor outcomes could strengthen an argument for improving CMI. Future efforts to improve prescription drug labels should focus on the need for creative design but also should be grounded in the evidence about optimal label content and format.

These findings also raise important policy issues. Previous FDA policy has relied on private industry to self-regulate CMI and state laws to regulate container labels. Our findings suggest that certain content and format compo-

Table 3. Summary of Findings about Content and Format of Prescription Drug Labels

Items	Study Design	Outcomes Measured
Content to be included		
clinical indication for drug	3 observational studies	pt. preferences
administration instructions	3 observational studies	pt. preferences
thorough information about potential adverse effects	3 observational studies	pt. preferences
importance of adherence	2 systematic reviews	medication adherence
duration of therapy	1 observational study	medication continuation
language describing directions should be precise	2 observational studies and 1 RCT	pt. comprehension
information about benefits of medication	1 RCT	pt. preferences
numerical information about risk	4 observational studies	pt. comprehension
Format to be used		
lists	3 RCTs	label comprehension and recall
headers	3 RCTs	label comprehension, recall, and preferences
white space	1 RCT	pt. preferences
uniform schema that orders drug information	4 observational studies	medication recall
larger font size	2 RCTs and 1 observational study	label comprehension and recall
particular font styles	1 RCT and 1 observational study	label comprehension and recall

RCT = randomized controlled trial.

nents should be included on all labels, and minimum standards could be generated to enhance readability and comprehension of prescription drug information. The lack of any centralized oversight of CMI or container labels impedes the implementation of labeling improvements. Policymakers should consider developing clear standards for both the format and content of prescription drug labels to simplify patients' access to risk, benefit, and administration information about medications. Such strategies may improve the likelihood that patients will understand, safely administer, and adhere to their drug therapy.

Summary

We performed a systematic review of the published literature to evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. The evidence suggests that patients request information about a medication's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. There was little evidence to link label design or contents to measurable health outcomes, adherence, or safety.

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EXTRACTO

INTRODUCCIÓN: Los pacientes, especialmente los ancianos, tienen con frecuencia dificultades para leer y entender los prospectos, que pueden originar problemas con la adherencia a los tratamientos y con la seguridad de los mismos.

OBJETIVO: Intentamos evaluar las evidencias disponibles sobre el contenido y formato más adecuados de los prospectos para mejorar su legibilidad y comprensión y el uso de la medicación.

FUENTES DE DATOS: Se llevó a cabo una revisión sistemática de ensayos controlados aleatorios y revisiones sistemáticas de MEDLINE y la base de datos Cochrane (1990-junio 2005), también se revisaron las referencias bibliográficas de los artículos seleccionados y las referencias aportadas por un panel de expertos.

SELECCIÓN DE ESTUDIOS: Seleccionamos los estudios enfocados al contenido de la comunicación médico-paciente sobre medicamentos y al contenido y formato de los prospectos.

EXTRACCIÓN DE DATOS: Dos revisores extrajeron y sintetizaron los datos sobre diseño de los estudios, población, y resultados.

RESULTADOS: De 2009 artículos revisados, 36 de los orientados al contenido de la comunicación médico-paciente sobre los medicamentos y 69 relacionados con el contenido y formato de los prospectos cumplían los criterios de la revisión. Los pacientes solicitaron información sobre las indicaciones, los beneficios esperables, la duración del tratamiento, y los efectos adversos potenciales. Las evidencias disponibles sobre el formato del prospecto apoyan que el uso de letras de tamaño grande, listados con encabezado, espacios en blanco para separar los puntos relacionados, y la utilización de un lenguaje sencillo y una organización lógica de la información mejoran la legibilidad y la comprensión. No hay evidencias suficientes para apoyar el uso de pictogramas. Hay pocas evidencias que relacionen el diseño del prospecto a su contenido con resultados medibles en salud, adherencia a la medicación o seguridad de los tratamientos.

CONCLUSIONES: Existen evidencias que indican que un determinado formato y contenido de los prospectos facilita la comunicación y la comprensión de los pacientes. Los esfuerzos para mejorar los prospectos deben ser guiados por estos datos, aunque se necesitan estudios adicionales para valorar la influencia del diseño de los prospectos en la forma de tomar los medicamentos y en los resultados de salud. Existen distintas opciones para establecer normativas que exijan unos criterios mínimos para optimizar la terapéutica medicamentosa, particularmente teniendo en cuenta la nueva cobertura de medicamentos recetados de Medicare.

Juan del Arco

RÉSUMÉ

OBJECTIF: Les patients, plus particulièrement les personnes âgées, ont souvent de la difficulté à lire et à comprendre l'étiquetage des médicaments, ce qui pourrait causer des problèmes liés à leur utilisation. Nous avons évalué les caractéristiques du contenu et de format optimaux des étiquettes de médicaments qui pourraient augmenter la lisibilité, la compréhension, et l'utilisation des médicaments.

SOURCE DES DONNÉES: Revue systématique des essais contrôlés à répartition aléatoire, d'études observationnelles et de recherches systématiques dans MEDLINE et dans la Cochrane Database (1990-juin 2005), jumelées aux références croisées et à des listes de références fournies par des experts.

SÉLECTION DES ÉTUDES ET EXTRACTION DES DONNÉES: Les études portant sur la communication entre les patients et le médecin concernant les médicaments et le contenu et format des étiquettes. Deux réviseurs ont extrait et synthétiser les données relatives aux plans des études, populations, et résultats.

SYNTHÈSE DES DONNÉES: De 2009 articles ont été évalués; 36 articles retenus portaient sur la communication sur les médicaments, et 69 autres sur le format et le contenu des étiquettes. Il a été démontré que les patients demandent de l'information sur les indications des médicaments, les bienfaits attendus, la durée de la thérapie et sur les effets indésirables. Les données sur le format des étiquettes suggèrent que l'utilisation de caractères plus gros, de listes, d'en-têtes, et davantage d'espaces vides en utilisant un langage clair, et une organisation logique pourraient augmenter la lisibilité et la compréhension. Par contre, les données n'étaient pas suffisantes pour suggérer l'utilisation d'icônes et de pictogrammes. Peu de données ont mis un lien en cause entre le format des étiquettes et un impact sur la santé, les résultats de la thérapie, l'observance ou la sûreté des médicaments.

CONCLUSIONS: Les données suggèrent sur le contenu et format de l'étiquetage des médicaments facilitent la communication et la compréhension de la part des patients. Des efforts devraient donc être faits en ce sens, même si d'autres études sont nécessaires pour évaluer l'impact sur l'utilisation et sur les résultats de santé. Plusieurs législations existent pour définir les standards minimaux visant à optimiser la thérapie médicamenteuse, particulièrement dans le contexte du nouveau programme de médicaments Medicare.

Nicolas Paquette-Lamontagne

Executive Summary

Understanding is a two-way street. —*Eleanor Roosevelt*

ABSTRACT

I have a very good doctor. He takes the time to explain things and break it down to me. Sometimes, though, I do get stuff that can be hard—like when I first came home from the hospital and I had all these forms and things I had to read. Some words I come across I just can't quite understand (National Center for the Study of Adult Learning and Literacy, 2003).¹

Nearly half of all American adults—90 million people—have difficulty understanding and acting upon health information. The examples below were selected from the many pieces of complex consumer health information used in America.

- *From a research consent form: "A comparison of the effectiveness of educational media in combination with a counseling method on smoking habits is being examined." (Doak et al., 1996)*

¹All vignettes in shaded text in this report represent actual stories or materials. Names were omitted in most cases to protect the privacy of the author, and stories may have been edited for brevity and clarity. If not otherwise attributed, vignettes were drawn from the experiences of members of the committee.

- From a consumer privacy notice: "Examples of such mandatory disclosures include notifying state or local health authorities regarding particular communicable diseases."
- From a patient information sheet: "Therefore, patients should be monitored for extraocular CMV infections and retinitis in the opposite eye, if only one infected eye is being treated."

Forty million Americans cannot read complex texts like these at all, and 90 million have difficulty understanding complex texts. Yet a great deal of health information, from insurance forms to advertising, contains complex text. Even people with strong literacy skills may have trouble obtaining, understanding, and using health information: a surgeon may have trouble helping a family member with Medicare forms, a science teacher may not understand information sent by a doctor about a brain function test, and an accountant may not know when to get a mammogram.

This report defines health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Ratzen and Parker, 2000). However, health literacy goes beyond the individual obtaining information. Health literacy emerges when the expectations, preferences, and skills of individuals seeking health information and services meet the expectations, preferences, and skills of those providing information and services. Health literacy arises from a convergence of education, health services, and social and cultural factors. Although causal relationships between limited health literacy and health outcomes are not yet established, cumulative and consistent findings suggest such a causal connection.

Approaches to health literacy bring together research and practice from diverse fields. This report examines the body of knowledge in this emerging field, and recommends actions to promote a health-literate society. Increasing knowledge, awareness, and responsiveness to health literacy among health services providers as well as in the community would reduce problems of limited health literacy. This report identifies key roles for the Department of Health and Human Services as well as other public and private sector organizations to foster research, guide policy development, and stimulate the development of health literacy knowledge, measures, and approaches. These organizations have a unique and critical opportunity to ensure that health literacy is recognized as an essential component of high-quality health services and health communication.

INTRODUCTION

A two-year-old is diagnosed with an inner ear infection and prescribed an antibiotic. Her mother understands that her daughter should take the prescribed medication twice a day. After carefully studying the label on the bottle and deciding that it doesn't tell how to take the medicine, she fills a teaspoon and pours the antibiotic into her daughter's painful ear. (Parker et al., 2003).

Modern health systems make complex demands on the health consumer. As self-management of health care increases, individuals are asked to assume new roles in seeking information, understanding rights and responsibilities, and making health decisions for themselves and others. Underlying these demands are assumptions about people's knowledge and skills.

National and international assessments of adults' ability to use written information suggest that these assumptions may be faulty. Current evidence reveals a mismatch between people's skills and the demands of health systems (Rudd et al., 2000a). Many people who deal effectively with other aspects of their lives may find health information difficult to obtain, understand, or use. While farmers may be able to use fertilizers effectively, they may not understand the safety information provided with the fertilizer. Chefs may create excellent dishes, but may not know how to create a healthy diet. Indeed, health literacy can be a hidden problem—because it is often not recognized by policy makers and health care providers, and because people with low literacy skills or who are confused about health care may be ashamed to speak up about problems they encounter with the increasingly complex health system (Baker et al., 1996; Parikh et al., 1996). Without improvements in health literacy, the promise of scientific advances for improving health outcomes will be diminished.

The Institute of Medicine (IOM) convened the Committee on Health Literacy, composed of experts from a wide range of academic disciplines and backgrounds, to assess the problem of limited health literacy and to consider the next steps in this field. The committee addressed the following charge:

1. Define the scope of the problem of health literacy. The intent is to clarify the root problems that underlie health illiteracy. This would include identifying the affected populations and estimating the costs for society. Develop a set of basic indicators of health literacy to allow assessment of the extent of the problem at the individual, community, and national levels.

2. Identify the obstacles to creating a health-literate public. These are likely to include the complexity of the health care system, the many and often contradictory health messages, rapidly advancing technologies, limits within public education to promote literacy of adults as well as children, etc.

3. Assess the approaches that have been attempted to increase health literacy both in the United States and abroad. Identify the gaps in research and programs that need to be addressed. The focus should be on public health interventions attempting to increase health literacy of the public rather than on improving health provider/primary care interactions.

4. Identify goals for health literacy efforts and suggest approaches to overcome the obstacles to health literacy in order to reach these goals. These might include research or policy initiatives, interventions, or collaborations that would promote health literacy.

WHAT IS HEALTH LITERACY?

In this report, the committee accepted the definition of health literacy presented by the National Library of Medicine (Selden et al., 2000) and used in *Healthy People 2010* (HHS, 2000):

The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (Ratzen and Parker, 2000).

Health literacy is a shared function of social and individual factors. Individuals' health literacy skills and capacities are mediated by their education, culture, and language. Equally important are the communication and assessment skills of the people with whom individuals interact regarding health, as well as the ability of the media, the marketplace, and government agencies to provide health information in a manner appropriate to the audience.

The committee developed a framework for health literacy which identifies three major areas of potential intervention and forms the organizational principle of this report (see Figure ES-1). This framework illustrates the potential influence on health literacy as individuals interact with educational systems, health systems, and cultural and social factors, and suggests that these factors may ultimately contribute to health outcomes and costs. The proposed framework is a model, because available research supports only limited conclusions about causality. However, the cumulative effect of a body of consistent evidence suggests that causal relationships may exist between health literacy and health outcomes. Research is needed to establish the nature of the causal relationships between and among the various factors portrayed in the framework.

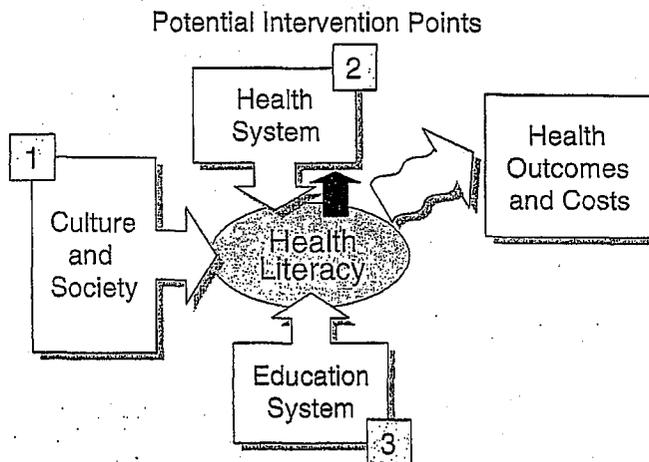


FIGURE ES-1 Potential points for intervention in the health literacy framework.

The committee reviewed the strengths and limitations of currently available measures of literacy and health literacy. Health literacy involves a range of social and individual factors, and includes cultural and conceptual knowledge, listening, speaking, arithmetical, writing, and reading skills. However, most of the tools currently available to measure health literacy primarily measure reading skills, and do not include other critical skills. Furthermore, adults' reading abilities are often estimated with a "grade level" measure, an estimate that is imprecise at best. Advancement of the field of health literacy requires the development of new measures which can be used to establish baseline levels and monitor change over time.

Finding 2-1 Literature from a variety of disciplines is consistent in finding that there is strong support for the committee's conclusion that health literacy, as defined in this report, is based on the interaction of individuals' skills with health contexts, the health-care system, the education system, and broad social and cultural factors at home, at work, and in the community. The committee concurs that responsibility for health literacy improvement must be shared by these various sectors. The committee notes that the health system does carry significant but not sole opportunity and responsibility to improve health literacy.

Finding 2-2 The links between education and health outcomes are strongly established. The committee concludes that health literacy may be

one pathway explaining the well-established link between education and health, and warrants further exploration.

Finding 2-3 Health literacy, as defined in this report, includes a variety of components beyond reading and writing, including numeracy, listening, speaking, and relies on cultural and conceptual knowledge.

Finding 2-4 While health literacy measures in current use have spurred research initiatives and yield valuable insights, they are indicators of reading skills (word recognition or reading comprehension and numeracy), rather than measures of the full range of skills needed for health literacy (cultural and conceptual knowledge, listening, speaking, numeracy, writing, and reading). Current assessment tools and research findings cannot differentiate among (a) reading ability, (b) lack of background knowledge in health-related domains, such as biology, (c) lack of familiarity with language and types of materials, or (d) cultural differences in approaches to health and health care. In addition, no current measures of health literacy include oral communication skills or writing skills and none measure the health literacy demands on individuals within different health contexts.

THE EXTENT AND ASSOCIATIONS OF LIMITED HEALTH LITERACY

Studies of health literacy or of literacy in health contexts suggest that limited health literacy skills, as measured by current assessment tools, are common, with significant variations in prevalence depending on the population sampled (see Chapter 3). People of all literacy levels may be able to manage texts that they frequently encounter and use for everyday activities, but will often face problems with difficult and confusing types of text (Kirsch et al., 1993).

Findings from the National Adult Literacy Survey (NALS) and International Adult Literacy Surveys (IALS) indicate that a large percentage of adults lack the literacy skills needed to meet the demands of twenty-first century society. More than 47 percent, or 90 million, of U.S. adults have difficulty locating, matching, and integrating information in written texts with accuracy and consistency. Of the 90 million with limited literacy skills, about 40 million can perform simple and routine tasks using uncomplicated materials. An additional 50 million adults can locate information in moderately complicated texts, make inferences using print materials, and integrate easily identifiable pieces of information. However, they find it difficult to perform these tasks when complicated by distracting information and complex texts (Kirsch, 2001; Kirsch et al., 1993).

These findings have serious implications for the health sector. Over 300

studies, conducted over three decades and assessing various health-related materials, such as informed consent forms and medication package inserts, have found that a mismatch exists between the reading levels of the materials and the reading skills of the intended audience. In fact, most of the assessed materials exceed the reading skills of the average high school graduate (Rudd et al., 2000a).

Studies suggest that while individuals with limited health literacy come from many walks of life, the problem of limited health literacy is often greater among older adults, people with limited education, and those with limited English proficiency (e.g., Beers et al., 2003; Gazmararian et al., 1999; Williams et al., 1995). For individuals whose native language is not English, issues of health literacy are compounded by issues of basic communication and the specialized vocabulary used to convey health information.

Associations with Health Knowledge, Behavior, and Outcomes

Research linking limited health literacy as it is currently measured to health knowledge, health behaviors, and health outcomes is accumulating. Patients with limited health literacy and chronic illness have less knowledge of illness management than those with higher health literacy (Kalichman et al., 2000; Schillinger et al., 2002; Williams et al., 1998a, b). Compared to those with adequate health literacy, patients with limited health literacy have decreased ability to share in decision-making about prostate cancer treatment (Kim et al., 2001), lower adherence to anticoagulation therapy (Lasater, 2003; Win and Schillinger, 2003), higher likelihood of poor glyce-mic control (Schillinger et al., 2002), and lower self-reported health status (Arnold et al., 2001; Baker et al., 2002; Kalichman and Rompa, 2000; Kalichman et al., 2000; Williams et al., 1998a, b).

Financial Associations of Limited Health Literacy

The limited amount of data available suggests that there is an association between health literacy, health-care utilization, and health-care costs. Baker and others (2002) found that public hospital patients with limited health literacy had higher rates of hospitalization than those with adequate health literacy. This increased hospitalization rate may be associated with greater resource use. Another analysis (Friedland, 1998) concluded that the additional health expenditure attributable to inadequate reading skills (as identified by the NALS) in 1996 was \$29 billion. This estimate would increase to \$69 billion if as few as half the individuals with marginal reading skills were also not health literate. Weiss and Palmer (2004) reported on a direct measure of cost in a small sample of Medicaid patients in

Arizona. Patients with reading levels at or below third grade had mean Medicaid charges \$7,500 higher than those who read above the third grade level.

For this report, David Howard examined the expenditure data collected in association with the Baker and colleagues (2002) utilization study (see Appendix B). He found that predicted inpatient spending for a patient with inadequate health literacy was \$993 higher than that of a patient with adequate reading skills. A difference of \$450 remained after controlling for health status, although the causality of the associations between health status and health-care cost could not be determined. In both analyses, higher emergency care costs were incurred by individuals with limited health literacy compared to those with marginal or adequate health literacy as measured by the Test of Functional Health Literacy in Adults (TOFHLA), while pharmacy expenses were similar and outpatient expenditures lower.

Although a robust estimate for the effect of limited health literacy on health expenditures is lacking, the magnitudes suggested by the few studies that are available underscore the importance of addressing limited health literacy from a financial perspective.

Finding 3-1 About 90 million adults, an estimate based on the 1992 NALS, have literacy skills that test below high school level (NALS Level 1 and 2). Of these, about 40–44 million (NALS Level 1) have difficulty finding information in unfamiliar or complex texts such as newspaper articles, editorials, medicine labels, forms, or charts. Because the medical and public health literature indicates that health materials are complex and often far above high school level, the committee notes that approximately 90 million adults may lack the needed literacy skills to effectively use the U.S. health system. The majority of these adults are native-born English speakers. Literacy levels are lower among the elderly, those who have lower educational levels, those who are poor, minority populations, and groups with limited English proficiency such as recent immigrants.

Finding 3-2 On the basis of limited studies, public testimony, and committee members' experience, the committee concludes that the shame and stigma associated with limited literacy skills are major barriers to improving health literacy.

Finding 3-3 Adults with limited health literacy, as measured by reading and numeracy skills, have less knowledge of disease management and of health-promoting behaviors, report poorer health status, and are less likely to use preventive services.

Finding 3-4 Two recent studies demonstrate a higher rate of hospitalization and use of emergency services among patients with limited literacy. This higher utilization has been associated with higher health-care costs.

THE CONTEXTS OF HEALTH LITERACY AND OPPORTUNITIES FOR INTERVENTION

Culture and Society

The hi'ola said Mom should confess to me and before God Jehovah. She did. She asked me to forgive her and I did. I wasn't angry. . . . And later Mom's sickness left her. Of course, she still had diabetes, but the rest—being so confused and miserable—all that left her (Shook, 1985: 109).

Culture is the shared ideas, meanings, and values that are acquired by individuals as members of a society. Culture is socially learned, continually evolves, and often influences us unconsciously. We learn culture through interactions with others, as well as through the tangible products of culture such as books and television (IOM, 2002). Culture gives significance to health information and messages, and can shape perceptions and definitions of health and illness, preferences, language and cultural barriers, care process barriers, and stereotypes. These culturally influenced perceptions, definitions, and barriers can affect how people interact with the health care system and help to determine the adequacy of health literacy skills in different settings.

The fluid nature of culture means that health-care encounters are rich with differences that are continuously evolving. Differing cultural and educational backgrounds between patients and providers, as well as between those who create health information and those who use it, may contribute to problems in health literacy. Culture, cultural processes, and cross-cultural interventions have been discussed in depth in several recent IOM reports and represent possible nexuses of culture and health literacy (IOM, 2002, 2003a).

It is important to understand how people obtain and use health information in order to understand the potential impact of health literacy. Information about health is produced by many sources, including the government and the food and drug industries, and is distributed by the popular media. Commercial and social marketing of health information, products, and services is a multibillion dollar industry. People are frequently and repeatedly exposed to quick, often contradictory bits of information. This

inundation with information has increased as the Internet has become an increasingly important source of health information. Socioeconomic status, education level, and primary language all affect whether consumers will seek out health information, where they will look for the information, what type of information they prefer, and how they will interpret that information. Limited health literacy decreases the likelihood that health-related information will be accessible to all (Houston and Allison, 2002).

Finding 4-1 Culture gives meaning to health communication. Health literacy must be understood and addressed in the context of culture and language.

Finding 4-2 More than 300 studies indicate that health-related materials far exceed the average reading ability of U.S. adults.

Finding 4-3 Competing sources of health information (including the national media, the Internet, product marketing, health education, and consumer protection) intensify the need for improved health literacy.

Finding 4-4 Health literacy efforts have not yet fully benefited from research findings in social and commercial marketing.

The Educational System

Adult education is an important resource for individuals with limited literacy or limited English proficiency. A major source of support for American adult education programs in literacy is the U.S. adult basic education and literacy (ABEL) system. ABEL programs provide classes in topics that support health literacy including basic literacy and math skills, English language, and high school equivalence, and predominantly serve students with literacy and math skills in NALS Levels 1, 2, or the low end of NALS Level 3. Sadly, these programs serve far fewer than the millions of Americans who could benefit.

Both childhood literacy education and childhood health education can provide a basis for health literacy in adulthood. Although most elementary, middle, and high schools require students to take health education, the sequence of coursework is not coordinated. The percentage of schools that require health education increases from 33 percent in kindergarten to 44 percent in grade 5, but then falls to 10 percent in grade 9, and 2 percent in grade 12. The absence of a coordinated health education program across grade levels may impede student learning of needed health literacy skills. Furthermore, only 9.6 percent of health education classes have a teacher

who majored in health education or in combined health and physical education (Kann et al., 2001).

In 1995, the Joint Committee on National Health Standards published the *National Health Education Standards* with the subtitle *Achieving Health Literacy*. These standards describe the knowledge and skills essential for health literacy, and detail what students should know and be able to do in health education by the end of grades 4, 8, and 11. They provide a framework for curricula development and student assessment. Unfortunately, these standards have not been widely met.

Finding 5-1 Significant obstacles and barriers to successful health literacy education exist in K-12 education programs.

Finding 5-2 Opportunities for measuring literacy skill levels required for health knowledge and skills, and for the implementation of programs to increase learner's skill levels, currently exist in adult education programs and provide promising models for expanding programs. Studies indicate a desire on the part of adult learners and adult education programs to form partnerships with health communities.

Finding 5-3 Health professionals and staff have limited education, training, continuing education, and practice opportunities to develop skills for improving health literacy.

Health Systems

Health systems in the United States are complex and often confusing. Their complexity derives from the nature of health care and public health itself, the mix of public and private financing, and the variations across states and between types of delivery settings. An adult's ability to navigate these systems may reflect this systemic complexity in addition to individual skill levels. Even highly skilled individuals may find the systems too complicated to understand, especially when these individuals are made more vulnerable by poor health. Directions, signs, and official documents, including informed consent forms, social services forms, public health information, medical instructions, and health education materials, often use jargon and technical language that make them unnecessarily difficult to use (Rudd et al., 2000b). In addition, cultural differences may affect perceptions of health, illness, prevention, and health care. Lack of mutual understanding of health, illness and treatments, and risks and benefits has implications for behavior for both providers and consumers, and legal implications for providers and health systems. Imagine having to face this complexity if you

are one of the 90 million American adults who lack the functional literacy skills in English to use the U.S. health care system.²

Health literacy permeates all areas of the provider–consumer information exchange, and provides a common pathway for the successful transfer of information. A number of emerging areas are likely to increase the burden of limited health literacy on those entering and using the health-care system. These include demands inherent in chronic disease management, increased use of new technologies, decreased time for patient/provider discussions, and legal and regulatory requirements.

Many different interventions and approaches that may hold promise for addressing limited health literacy are being attempted across health-care systems, professional organizations, federal and state agencies, educational institutions, and community and advocacy groups across the United States and in other countries. Those profiled in the report are indicators of the creativity and promise for future improvements in countering the effects of limited health literacy. However, few of these approaches have been formally evaluated, and most are fragmented single approaches rather than part of a systematic approach to health literacy. In order for progress to be made, many more systematic demonstrations must be funded and rigorously evaluated.

Finding 6-1 Demands for reading, writing, and numeracy skills are intensified due to health-care systems' complexities, advancements in scientific discoveries, and new technologies. These demands exceed the health-literacy skills of most adults in the United States.

Finding 6-2 Health literacy is fundamental to quality care, and relates to three of the six aims of quality improvement described in the IOM Quality Chasm Report: safety, patient-centered care, and equitable treatment. Self-management and health literacy have been identified by IOM as cross-cutting priorities for health-care quality and disease prevention.

Finding 6-3 The readability levels of informed consent documents (for research and clinical practice) exceed the documented average reading levels of the majority of adults in the United States. This has important ethical and legal implications that have not been fully explored.

VISION FOR A HEALTH-LITERATE AMERICA

The evidence and judgment presented in this report indicate that health literacy is important to improving the health of individuals and popula-

²See Finding 3-1.

tions. This is supported by the conclusions and statements of others. Health literacy was one of two cross-cutting factors that affect health care identified by the IOM in its recent report *Priority Areas for National Action in Quality Improvement* (IOM, 2003b). The Surgeon General recently stated that "health literacy can save lives, save money, and improve the health and well being of millions of Americans . . . health literacy is the currency of success for everything I am doing as Surgeon General" (Carmona, 2003).

More needs to be known about the causal pathways between education and health, the role of literacy, and the discrete contribution of health literacy to health. With this knowledge we will be able to understand which interventions and approaches are the most appropriate and effective. This Committee believes that a health-literate America is an achievable goal. We envision a society within which people have the skills they need to obtain, interpret, and use health information appropriately and in meaningful ways. We envision a society in which a variety of health systems structures and institutions take responsibility for providing clear communication and adequate support to facilitate health-promoting actions based on understanding. We believe a health-literate America would be a society in which:

- Everyone has the opportunity to improve their health literacy.
- Everyone has the opportunity to use reliable, understandable information that could make a difference in their overall well-being, including everyday behaviors such as how they eat, whether they exercise, and whether they get checkups.
 - Health and science content would be basic parts of K-12 curricula.
 - People are able to accurately assess the credibility of health information presented by health advocate, commercial, and new media sources.
 - There is monitoring and accountability for health literacy policies and practices.
 - Public health alerts, vital to the health of the nation, are presented in everyday terms so that people can take needed action.
 - The cultural contexts of diverse peoples, including those from various cultural groups and non-English-speaking peoples, are integrated in to all health information.
 - Health practitioners communicate clearly during all interactions with their patients, using everyday vocabulary.
 - There is ample time for discussions between patients and health-care providers.
 - Patients feel free and comfortable to ask questions as part of the healing relationship.
 - Rights and responsibilities in relation to health and health care are presented or written in clear, everyday terms so that people can take needed action.

- Informed consent documents used in health care are developed so that all people can give or withhold consent based on information they need and understand.

While achieving this vision is a profound challenge, we believe that significant progress can and must be made over the coming years, so that the potential for optimal health can benefit all individuals and populations in our society.

Recommendation 2-1 The Department of Health and Human Services and other government and private funders should support research leading to the development of causal models explaining the relationships among health literacy, the education system, the health system, and relevant social and cultural systems.

Recommendation 2-2 The Department of Health and Human Services and public and private funders should support the development, testing, and use of culturally appropriate new measures of health literacy. Such measures should be developed for large ongoing population surveys; such as the National Assessment of Adult Literacy Survey, Medical Expenditure Panel Survey, and Behavioral Risk Factor Surveillance System, and the Medicare Beneficiaries Survey, as well as for institutional accreditation and quality assessment activities such as those carried out by the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance. Initially, the National Institutes of Health should convene a national consensus conference to initiate the development of operational measures of health literacy which would include contextual measures.

Recommendation 3-1 Given the compelling evidence noted above, funding for health literacy research is urgently needed. The Department of Health and Human Services, especially the National Institutes of Health, Agency for Healthcare Research and Quality, Health Resources and Services Administration, the Centers for Disease Control and Prevention, Department of Defense, Veterans Administration, and other public and private funding agencies should support multidisciplinary research on the extent, associations, and consequences of limited health literacy, including studies on health service utilization and expenditures.

Recommendation 4-1 Federal agencies responsible for addressing disparities should support the development of conceptual frameworks on the intersection of culture and health literacy to direct in-depth theoretical explorations and formulate the conceptual underpinnings that can guide interventions.

4-1.a The National Institutes of Health should convene a consensus conference, including stakeholders, to develop methodology for the incorporation of health literacy improvement into approaches to health disparities.

4-1.b The Office of Minority Health and Agency for Healthcare Research and Quality should develop measures of the relationships between culture, language, cultural competency, and health literacy to be used in studies of the relationship between health literacy and health outcomes.

Recommendation 4-2 The Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Indian Health Service, the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration should develop and test approaches to improve health communication that foster healing relationships across culturally diverse populations. This includes investigations that explore the effect of existing and innovative communication approaches on health behaviors, and studies that examine the impact of participatory action and empowerment research strategies for effective penetration of health information at the community level.

Recommendation 5-1 Accreditation requirements for all public and private educational institutions should require the implementation of the National Health Education Standards.

Recommendation 5-2 Educators should take advantage of the opportunity provided by existing reading, writing, reading, oral language skills, and mathematics curricula to incorporate health-related tasks, materials, and examples into existing lesson plans.

Recommendation 5-3 The Health Resources and Services Administration and the Centers for Disease Control and Prevention, in collaboration with the Department of Education, should fund demonstration projects in each state to attain the National Health Education Standards and to meet basic literacy requirements as they apply to health literacy.

Recommendation 5-4 The Department of Education in association with the Department of Health and Human Services should convene task forces comprised of appropriate education, health, and public policy experts to delineate specific, feasible, and effective actions relevant agencies could take to improve health literacy through the nation's K-12 schools, 2-year and 4-year colleges and universities, and adult and vocational education.

Recommendation 5-5 The National Science Foundation, the Department of Education, and the National Institute of Child Health and Human Development should fund research designed to assess the effectiveness of different models of combining health literacy with basic literacy and instruction. The Interagency Education Research Initiative, a federal partnership of these three agencies, should lead this effort to the fullest extent possible.

Recommendation 5-6 Professional schools and professional continuing education programs in health and related fields, including medicine, dentistry, pharmacy, social work, anthropology, nursing, public health, and journalism, should incorporate health literacy into their curricula and areas of competence.

Recommendation 6-1 Health care systems, including private systems, Medicare, Medicaid, the Department of Defense, and the Veterans Administration should develop and support demonstration programs to establish the most effective

Continued

tive approaches to reducing the negative effects of limited health literacy. To accomplish this, these organizations should:

- Engage consumers in the development of health communications and infuse insights gained from them into health messages.
- Explore creative approaches to communicate health information using printed and electronic materials and media in appropriate and clear language. Messages must be appropriately translated and interpreted for diverse audiences.
- Establish methods for creating health information content in appropriate and clear language using relevant translations of health information.
- Include cultural and linguistic competency as an essential measure of quality of care.

Recommendation 6-2 The Department of Health and Human Services should fund research to define the needed health literacy tasks and skills for each of the priority areas for improvement in health care quality. Funding priorities should include participatory research which engages the intended populations.

Recommendation 6-3 Health literacy assessment should be a part of health-care information systems and quality data collection. Public and private accreditation bodies, including Medicare, the National Committee for Quality Assurance, and the Joint Commission on Accreditation of Healthcare Organizations should clearly incorporate health literacy into their accreditation standards.

Recommendation 6-4 The Department of Health and Human Services should take the lead in developing uniform standards for addressing health literacy in research applications. This includes addressing the appropriateness of research design and methods and the match among the readability of instruments, the literacy level, and the cultural and linguistic needs of study participants. In order to achieve meaningful research outcomes in all fields:

- Investigators should involve patients (or subjects) in the research process to ensure that methods and instrumentation are valid and reliable and in a language easily understood.
- The National Institutes of Health should collaborate with appropriate federal agencies and institutional review boards to formulate the policies and criteria to ensure that appropriate consideration of literacy is an integral part of the approval of research involving human subjects.
- The National Institutes of Health should take literacy levels into account when considering informed consent in human subjects research. Institutional Review Boards should meet existing standards related to the readability of informed consent documents.

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Low Literacy Impairs Comprehension of Prescription Drug Warning Labels

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BACKGROUND: Adverse events resulting from medication error are a serious concern. Patients' literacy and their ability to understand medication information are increasingly seen as a safety issue.

OBJECTIVE: To examine whether adult patients receiving primary care services at a public hospital clinic were able to correctly interpret commonly used prescription medication warning labels.

DESIGN: In-person structured interviews with literacy assessment.

SETTING: Public hospital, primary care clinic.

PARTICIPANTS: A total of 251 adult patients waiting for an appointment at the Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) Primary Care Clinic.

MEASUREMENTS: Correct interpretation, as determined by expert panel review of patients' verbatim responses, for each of 8 commonly used prescription medication warning labels.

RESULTS: Approximately one-third of patients ($n=74$) were reading at or below the 6th-grade level (low literacy). Patient comprehension of warning labels was associated with one's literacy level. Multistep instructions proved difficult for patients across all literacy levels. After controlling for relevant potential confounding variables, patients with low literacy were 3.4 times less likely to interpret prescription medication warning labels correctly (95% confidence interval: 2.3 to 4.9).

CONCLUSIONS: Patients with low literacy had difficulty understanding prescription medication warning labels. Patients of all literacy levels had better understanding of warning labels that contained single-step versus multiple-step instructions. Warning labels should be developed with consumer participation, especially with lower literate populations, to ensure comprehension of short, concise messages created with familiar words and recognizable icons.

KEY WORDS: literacy, warning labels, prescription drug labels, medication error, patient comprehension, lexile.

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Adverse events resulting from improper medication administration are a serious concern.¹ Patients are increasingly managing multiple prescription and over-the-counter medications; therefore, patient understanding is essential for proper adherence.^{2,3} This issue is relevant to the majority of adults in the United States; two-thirds of all adults use prescription drugs, representing 16% (\$73 billion) of all health care expenditures.⁴ According to the Medical Expenditure Panel Survey (MEPS), the average adult in the United States

fills 9 prescriptions annually. This number is even higher among adults over 65 years of age, who fill an average of 20 prescriptions a year.⁴

Low literacy may be an overlooked contributing factor to patient misuse of prescription medications. The Institute of Medicine's recent report, *A Prescription to End Confusion*, indicates that 90 million adults in the United States have trouble understanding and acting on health care information.⁵ Shame may prevent individuals with limited literacy from telling providers they need help with medication instructions.⁶ The recently released National Assessment of Adult Literacy (NAAL), the most accurate measurement of literacy in America today, found that adults who are socioeconomically disadvantaged belong to racial/ethnic minority groups, and/or are elderly are disproportionately hindered by such literacy barriers.⁷ These individuals are also more likely to be in poorer health and may be taking multiple medications.

The purpose of this descriptive study was to identify factors associated with patient understanding of prescription drug warning labels (PWLs). We hypothesized that low literacy would be associated with incorrect interpretations of PWLs.

METHODS

Subjects

Study participants were patients aged 18 and older attending the Primary Care Clinic (PCC) at Louisiana State University Health Sciences Center—Shreveport (LSUHSC) during July 2003. Patients were ineligible if they had severe visual or hearing impairments, were too ill to participate, or were non-English speaking. The LSUHSC Institutional Review Board approved the study and all patients gave informed consent for participation. A total of 276 patients were approached before the medical encounter, and 273 consented to participation. Twenty-two patients were excluded based on self-reported impairments with hearing ($n=5$) or vision ($n=12$), English as a second language ($n=3$), or incomplete information ($n=2$). A total of 251 patients participated in the study.

Structured Interview and Literacy Assessment

Interviews with community pharmacists ($N=9$) and primary care physicians ($N=5$) were conducted to identify the most important PWLs for patients to understand. Through consensus, 8 PWLs were identified for study inclusion; all were developed by the most commonly used pharmaceutical labeling software package.⁸

A trained research assistant (RA) administered a structured interview that included self-report of sociodemographic

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information (age, gender, race/ethnicity, education, source of payment for medications). Color copies (actual size) of each of the 8 PWLs were then shown in the same order to all of the patients for review. To assess patient comprehension, the RA asked "what does this label mean to you?" for each PWL. The RA then documented the verbatim response on a separate form. A panel of physicians and pharmacists trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message. For quality assurance, an additional RA, blinded to patient information (including literacy) and following the same panel guidelines, independently reviewed all patient responses to the 8 labels ($N=2,008$). The RAs were unable to score 317 (15.8%) responses as either correct or incorrect. An expert panel that included 3 physicians, a clinical psychologist, and a pharmacist reviewed and graded the uncoded responses. Each member was blinded to subjects' literacy level, and decisions were made by majority rule.

After the patient had provided his or her interpretation on all of the PWLs, the RA administered the Rapid Estimate of Adult Literacy in Medicine (REALM), a health word recognition test that is the most common measure of adult literacy in medical settings.^{9,10} The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (TOFHLA).^{9,11}

Lexile Score

We used a measure of reading difficulty termed Lexile Framework to gauge reading level for the text on each PWL.¹²⁻¹⁵ Lexile scores are based on sentence length and word frequency in the popular literature, with higher values indicating higher levels of reading difficulty. The possible range of these scores is from below 0 (representing a beginning reading level) to 2000. A program available to registered users over the internet, called the Lexile Analyzer, calculated the Lexile score for each warning label text.¹² These values can be easily translated to corresponding reading grade levels. For instance, a Lexile value of 300 corresponds to a 2nd-grade level of reading difficulty, 400 to 3rd grade, and 1,300 to a 12th-grade level.

Analysis Plan

All statistical analyses were performed using STATA, version 8.0 (College Station, TX). Descriptive statistics were calculated for each variable. Chi-square or ANOVA tests were used to evaluate the association between literacy, sociodemographic characteristics, and correct interpretation of each of the 8 PWLs. In multivariate analyses, the 8 binary repeated responses per subject were modeled using a generalized linear model with logit link. A generalized estimating equation (GEE) approach was used to adjust model coefficients and standard errors for within-patient correlation.^{16,17} The final multivariate model included potential confounding variables age, gender, race/ethnicity, number of medications currently taken, and the additional risk factor of Lexile score. Patient literacy was classified either as low (6th grade and below), marginal (7th to 8th grade), or functional (9th grade and higher). Patient age was categorized by tertiles (<45, 45 to 64, ≥65), and Lexile score by quartiles (2 labels per category; ≤3rd grade, 4th to 5th grade, 6th to 7th grade, and ≥8th grade).

RESULTS

Among the 251 respondents, 70.9% were female and 66.1% African American. Patients ranged in age from 18 to 86, with a mean age of 47.2 years (S.D. =14.9). Patient literacy was limited; 29.5% were reading at or below a 6th-grade level (low literacy) and 31.1% were reading at the 7th to 8th grade level (marginal literacy). Forty-two percent of patients reported that they did not graduate from high school or receive a graduate equivalency diploma (GED).

Respondents were taking an average of 3 prescription medications, and nearly two-thirds (64.5%) lacked insurance for prescription medications. Low literacy was associated with male gender ($P<.05$), African-American race ($P<.001$), and less education ($P<.001$) (Table 1). No significant differences were reported between literacy level and age or source of payment for medications.

Lexile scores for each PWL were calculated and are listed in Table 2. Correct interpretation of the warning labels varied according to reading difficulty and complexity, with correct interpretation rates ranging from 83.7% for the simplest label (*Take with Food*, Lexile =beginning reading) to 7.6% for a label with multistep instructions (*Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*, Lexile =1,110). Patients with low literacy skills were less able to correctly interpret the meaning of 7 of the 8 warning labels, with the exception of the most basic single-step instruction, *Take with food* (Table 2). Patients who were 65 years of age and older were less able to correctly interpret the PWL, *Do not drink alcoholic beverages when taking this medication* ($P<.05$). No statistically significant differences in rates of correct interpretation of PWL were noted by number of prescription medications currently taken by patients. Verbatim examples of the most common incorrect interpretations for each of the PWLs by patients are detailed in Table 3.

Table 1. Patient Characteristics by Literacy Level

Characteristic	Literacy Level			P value
	≤6th grade (n=74)	7th to 8th grade (n=78)	≥9th grade (n=99)	
Age, mean (SD)	50.0 (15.5)	47.6 (15.0)	44.9 (14.2)	NS
Female, %	60.8	70.5	78.8	<.050
Race/ethnicity, %				<.001
African American	89.2	76.9	40.4	
White	9.5	20.5	56.6	
Other	1.3	2.6	4.0	
Education, %				<.001
Grades 1 to 8	21.6	6.4	4.0	
Grades 9 to 11	42.0	37.2	20.2	
Completed high school/GED	33.8	43.6	40.4	
>High school	2.7	12.8	35.4	
Payment source for medications, %				NS
Private insurance	5.4	6.4	12.1	
Medicaid	5.4	7.7	9.1	
Out of pocket	58.1	71.8	63.6	
Other	16.2	14.1	15.2	
Medications taken daily; mean (SD)	2.9 (0.62)	3.5 (0.40)	2.8 (0.21)	NS

NS, not significant ($P>.05$).

GED, graduate equivalency diploma.

Table 2. Percent of Respondents Correctly Interpreting Warning Labels by Literacy Level

Label (Lexile, Grade Level)	Literacy Level			P value
	≤ 6th grade (n=74)	7th to 8th grade (n=78)	≥ 9th grade (n=99)	
One-step instructions				
Take with food (<0, BR*)	78.4	85.9	85.9	NS
Do not chew or crush, swallow whole (600, 5th grade)	46.0	84.6	77.8	<.001
Medication should be taken with plenty of water (520, 4th grade)	36.5	73.1	65.7	<.001
Do not drink alcoholic beverages when taking this medication (870, 8th grade)	41.9	65.4	59.6	<.010
For external use only (100, <1st grade)	8.1	64.1	77.8	<.001
Multi-step instructions				
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication (1,300, 12th grade)	4.1	35.9	35.4	<.001
Refrigerate, shake well, discard after (date) (800, 7th grade)	8.1	18.0	22.2	<.050
Do not take dairy products, antacids, or iron preparations within 1 hour of this medication (1,110, 10th grade)	0.0	6.4	14.1	<.010

*BR, beginning reading; Text with a Lexile score of 0 or below.
NS, not significant ($P > .05$).

Multivariate analyses identified low literacy as a significant independent predictor of incorrect interpretation of warning labels (adjusted odds ratio [AOR] 3.4, 95% CI 2.3 to 4.9). Other factors associated with incorrect interpretation of PWLs included older age (65 and older), higher Lexile score (6th-grade reading difficulty and above), and male gender (Table 4). No interactions between literacy, Lexile

score, age, number of medications taken, and race were significant.

DISCUSSION

This is the first study to our knowledge to evaluate the relationship between patient literacy skills and correct

Table 3. Common Examples of Misinterpretations of Prescription Drug Warning Labels

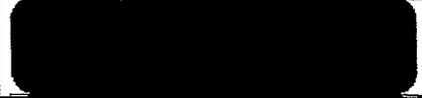
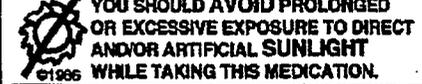
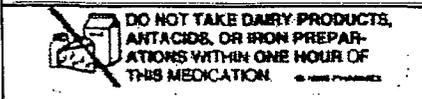
Labels	Misinterpretations
 TAKE WITH FOOD © 1990	Don't take food
	Chew pill and crush before swallowing Chew it up so it will dissolve, don't swallow whole or you might choke Just for your stomach
 MEDICATION SHOULD BE TAKEN WITH PLENTY OF WATER © 1976	Don't take when wet Don't drink hot water Don't need water
	Don't drink and drive Don't drink alcohol, it's poison and it'll kill you
	Use extreme caution in how you take it Medicine will make you feel dizzy Take only if you need it
 YOU SHOULD AVOID PROLONGED OR EXCESSIVE EXPOSURE TO DIRECT AND/OR ARTIFICIAL SUNLIGHT WHILE TAKING THIS MEDICATION. © 1986	Don't leave medicine in the sun Don't leave [medicine] in sunlight, but a cool place
 REFRIGERATE-SHAKE WELL DISCARD AFTER _____	Keep medicine chilled Mix it well, discard when done
 DO NOT TAKE DAIRY PRODUCTS, ANTACIDS, OR IRON PREPARATIONS WITHIN ONE HOUR OF THIS MEDICATION. © 1986 PHARMACEUTICALS	If allergic to dairy, don't take medicine Don't eat for one hour after taking medicine

Table 4. Generalized Estimating Equation (GEE) Model for Incorrect Interpretation of Warning Labels

Variable	OR	95% CI	AOR	95% CI
Literacy level				
≥ 9th grade (Functional)	1.0	Referent	1.0	Referent
7th to 8th grade (Marginal)	1.1	0.8, 1.4	0.9	0.7, 1.3
≤ 6th grade (Low)	3.2	2.4, 4.3	3.4	2.3, 4.9
Age, y				
< 45	1.0	Referent	1.0	Referent
45 to 64	1.0	0.8, 1.3	1.1	0.8, 1.4
≥ 65	1.6	1.0, 2.4	1.7	1.1, 2.8
Race				
White	1.0	Referent	1.0	Referent
African American	1.8	1.4, 2.3	1.3	0.9, 1.8
Gender				
Female	1.0	Referent	1.0	Referent
Male	1.4	1.0, 1.8	1.3	1.0, 1.8
Number of prescription medications currently taken				
≥ 3	1.0	Referent	1.0	Referent
1 to 2	0.9	0.7, 1.2	1.0	0.7, 1.3
None	1.1	0.8, 1.5	1.3	0.9, 1.9
Lexile score, reading level				
≤ 3rd grade	1.0	Referent	1.0	Referent
4th to 5th grade	1.1	0.9, 1.4	1.2	0.9, 1.5
6th to 7th grade	3.7	3.0, 4.7	4.3	3.3, 5.6
≥ 8th grade	10.4	8.0, 13.6	12.9	9.6, 17.5

OR, odds ratio; CI, confidence interval; AOR, adjusted odds ratio.

interpretation of warning labels routinely used with prescription medications. Low literacy was significantly associated with more than a 3 times greater likelihood of incorrect interpretation of PWLs. Our findings indicate that these warning labels are not likely to be useful to patients in their current form, especially those with low literacy skills, and could result in misuse of medications (e.g., the text message: *Do not chew or crush, swallow whole* vs the patient interpretation of *Chew pill and crush before swallowing*).

The Lexile score (reading difficulty) attributed to each PWL was also a significant independent predictor of patient comprehension. Labels with text written at the 6th- to 7th-grade level were 4.3 times more likely to be interpreted incorrectly, and PWLs that had text written at the 8th-grade level and above were 12.9 times more likely to be interpreted incorrectly compared with PWLs that had text written at the 3rd-grade level or below. These findings suggest that existing recommendations by health educators that patient information materials be written below an 8th-grade level should be revised.¹⁸⁻²⁰ Instead, a more appropriate goal for health information in print might be a Lexile score below a 6th-grade level.

Most patients in our study were able to understand simple, routine tasks using uncomplicated words, such as the label, *Take with food*. However, the single-step label, *For external use only*, was written at a 1st-grade level and yet proved difficult for many patients, especially those with low literacy skills. Possibly this was due to the fact that this PWL does not clearly state a specific action to be taken and uses unfamiliar wording or concepts. Over half of low literate patients could not properly interpret moderately complicated messages such as *Do not drink alcoholic beverages when taking this medication* (written at a 7th- to 8th-grade level), and people across all literacy levels found it challenging to fully comprehend unfamiliar and complex, multistep health instructions written at a high school level (e.g., *Do not take dairy products, antacids, or iron preparations within 1 hour of this medication*).

The awareness of the impact of low literacy on health and health care has led to increased attention to "health literacy." Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.⁵ The IOM Patient Safety Report (2000), *To Err is Human*, stresses that health literacy is an essential aspect of addressing patient safety and is fundamental to quality care.¹ The 2004 IOM Report on Health Literacy and recent literature note a growing discordance among individual reading skills and the increasingly complex demands of the health care system, particularly the demands on patients and families in managing chronic diseases.^{5,21,22} Low literacy has been strongly linked to higher rates of hospitalization and use of emergency services,^{23,24} poorer understanding of one's medical condition,^{25,26} poorer adherence to medical instructions,^{27,28} and worse health outcomes.^{21,29} In our study, low literacy is related to limited understanding and misinterpretation of warning labels, and therefore may be a factor in unintentional nonadherence and therapeutic failure. Incomplete understanding of labels may be an unrecognized contributor to the estimated 2% to 11% of hospital admissions in the United States caused by misuse of prescription medications.³⁰

The elderly may be especially vulnerable to misunderstanding of prescription labels and instructions. Our finding that adults over 65 were less likely to interpret PWLs correctly is supported by previous studies that examined comprehension of medication instruction labels.³¹⁻³⁴ The elderly comprise an increasingly larger portion of the population and consume 2 to 3 times more medication than the general public. They are also more likely to have lower literacy skills.⁷

Study limitations should be noted. First, participation was limited to patients proficient in the English language. However, 2 of 3 prescription medication warning labels currently used by the majority of pharmacies in the United States are only available in English.⁸ Second, patients were sampled from a public hospital, which may limit the generalizability of findings. However, patients in the sample reflect a group disproportionately affected by poor health outcomes, and whose health and health care is targeted for improvement by Healthy People 2010.³⁵ Finally, sample size may have limited the ability to detect significant and clinically meaningful relationships in the multivariate analyses.

The Food and Drug Administration (FDA), the American Pharmaceutical Association (APA), the American Society of Health-System Pharmacists (ASHSP), and the National Association of Boards of Pharmacy (NABP) are increasingly directing attention to the quality of drug labels and accompanying patient educational handouts.³⁶⁻⁴² All of these organizations agree that for the information to be useful for the consumer, it must be read and understood before it can be acted upon. However, evidence-based evaluation of these goals is limited.⁴³⁻⁴⁵

Our findings suggest that there is a need for improving prescription drug warning labels. The U.S. Food and Drug Administration (FDA) has supported the development of useful consumer information and established standard guidelines for over-the-counter medication. Similar standards are needed for PWLs. The development process for warning labels needs to involve consumers, especially those with low literacy, and take advantage of tools such as the Lexile Framework and knowledge gained through patient education literature to produce warning labels that convey information that all patients can understand.

Misunderstanding of prescription drug warning labels among patients with low literacy

MICHAEL S. WOLF, TERRY C. DAVIS, HUGH H. TILSON, PAT F. BASS III, AND RUTH M. PARKER

Nearly half of the adult population in the United States lack the reading and numeracy skills required to process, understand, and act on health information.¹ Forty million U.S. adults are reading at the lowest levels of literacy proficiency and may have profound difficulty understanding health information for their own or a loved one's needs.^{2,3} Prior studies have linked low literacy to a poor understanding of one's medical condition and nonadherence to medical instructions.⁴⁻⁷

Individuals with low literacy skills may be at particular risk for misunderstanding information on pharmaceutical drug labels and package inserts, thus misusing these medications.^{8,9} Recent concern over patient safety has increased awareness of the poor quality of consumer information describing proper use of medications and associated risks.^{10,11} This has led to an expanded interest in the causes of medication-related errors, from a focus on physician or health care system failure to analysis of potential patient errors.⁸⁻¹² As health care delivery continues to shift from

Purpose. The common causes for misunderstanding prescription drug warning labels (PWLs) among adults with low literacy were studied.

Methods. A total of 74 patients reading at or below the sixth-grade level and receiving care at the primary care clinic at the Louisiana State University Health Sciences Center in Shreveport were recruited to participate in structured interviews. Patients were asked to interpret and comment on eight commonly used warning labels found on prescription medications. Correct interpretation was determined by expert panel review of patients' verbatim responses. Qualitative methods were employed to code responses and generate themes regarding the misunderstanding of these PWLs.

Results. Among this sample of patients with low literacy skills, rates of correct interpretation for the eight warning labels ranged from 0% to 78.7%. With the exception of the most basic label, less than half of all patients were able to provide adequate interpretations of the warning label mes-

sages. Five themes were derived to describe the common causes for misunderstanding the labels: single-step versus multiple-step instructions, reading difficulty of text, use of icons, use of color, and message clarity. Labels were at greater risk for being misunderstood if they included multiple instructions, had a greater reading difficulty, included unfamiliar terms, or used confusing icons that were discordant with text messages. Participants also frequently imposed an incorrect meaning on label colors, which led to further confusion.

Conclusion. Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

Index terms: Comprehension; Labeling; Patients; Prescriptions; Readability
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inpatient to outpatient settings, the burden of quality control over proper medication use will also shift from provider to patient.^{1,9,13,14} An alarm-

ing trend has already emerged as a result: between 1983 and 1993, there was a ninefold increase in deaths due to outpatient medication errors in

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the United States.¹⁵ A recent study reported that 28% of emergency department visits are drug related, with over two thirds of these visits deemed preventable and 24% resulting in hospital admission.¹⁶

The Food and Drug Administration (FDA), along with the American Pharmacists Association, the American Society of Health-System Pharmacists, and the National Association of Boards of Pharmacy (NABP), is directing greater attention to the quality of labels on prescription and nonprescription drugs and accompanying patient educational handouts and package inserts.¹⁷⁻²³ In 1997, the Keystone Dialogue, initiated by the Department of Health and Human Services and the abovementioned organizations, was charged with developing an action plan for improving medication information and labeling.²⁴ One of the many recommendations made was to directly involve consumers to ensure that information included on medication labels and package inserts could be properly understood by patients across all literacy levels.

Our research team previously investigated the quality of prescription drug warning labels (PWLs) that appear as stickers placed on the outside of medication bottles.⁸ These adhesive labels are widely used and provide important information regarding the safe administration of prescription medications. Failure to heed the warnings or special instructions on these labels could lead to a loss of drug potency or a change in the rate of absorption of the medication. As a consequence, patients may become ill or gain little or no treatment benefit from taking the prescribed drug.²⁵ For example, many long-acting antihypertensive agents should be swallowed whole, as chewing or crushing them would intensify the dose and could possibly cause acute hypotension.

Our findings revealed very low rates of comprehension of PWLs and

that low literacy was a significant independent predictor of an incorrect interpretation of their meaning. In the present study, the causes for misunderstanding text and icons found on eight commonly used PWLs among patients reading at or below the sixth-grade level (low literacy) were explored.

Methods

Subjects. Study participants were adult patients who attended the primary care clinic (PCC) at the Louisiana State University Health Sciences Center—Shreveport (LSUHSC) in July 2003. The PCC is a public hospital clinic that serves an indigent adult population. Seventy-five percent of PCC patients are African American, 50% are female, 25% receive Medicaid, and 5% have private insurance. Patients were ineligible for study inclusion if they were under 18 years of age; if a physician or a trained research assistant (RA), through the course of an interview, identified them as having hearing problems or a visual impairment not correctable with eyeglasses; if they were too ill to participate; or if they did not speak English.

The LSUHSC institutional review board approved this study, and oral informed consent was obtained from all participants. Patients were approached by one of five RAs immediately after seeing their physician for a routine, scheduled visit. Each RA had been specifically trained by one of three study investigators to administer a literacy assessment, conduct a structured research interview, and objectively rate patient interpretations of PWLs. The RA described the study to patients and sought their participation. If patients agreed, the RA orally reviewed informed-consent procedures and administered the survey instrument and literacy assessment.

Structured interview and literacy assessment. A structured interview was developed to assess correct in-

terpretation of eight common medication warning labels developed by Pharmex, the largest U.S. pharmacy supplier of adhesive warning labels. After patients orally consented to the study, an RA administered the structured interview that included self-report of sociodemographic information (age, sex, race, education, and source of payment for medications). Color copies (actual size) of each PWL were then shown to each patient in the same order. After the patients had provided their interpretation of all eight PWLs, the RA administered a brief literacy assessment, concluding the interview. The entire protocol took approximately 15 minutes per patient.

To assess patient comprehension for each PWL, the RA asked each patient what the label meant. The RA would follow by asking several probing questions about specific attributes of the label (i.e., what is the picture saying?, is the picture helpful?, what do you think about the color of the label?, do the different colors mean different things to you?). The RA then documented the verbatim responses on a separate form, and these responses were later transcribed for content analysis.

The RAs rated each response as either correct or incorrect, using stringent guidelines developed by a panel of pharmacists and physicians. The panel trained the RAs to give a correct score only if the patient's response included all aspects of the PWL message and an incorrect score if the patient's response was inaccurate or contained only a partial meaning of the message. For quality assurance, an additional RA, blinded to patient information (including literacy) and following the same panel guidelines, independently reviewed all patient responses to the eight labels. If the two RAs produced discordant ratings, an expert panel consisting of a pharmacist, two general internal medicine physicians, and two behavioral scientists with expertise in

health literacy made a determination based on majority rule.

At the end of the structured interview, patients' literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test of 66 health-related words.²⁶ Reading recognition tests are useful predictors of general reading ability of English. Using the REALM, raw scores (0–66) can be converted into one of four reading grade levels: third grade or less (0–18), fourth to sixth grade (19–44), seventh to eighth grade (45–60), and ninth grade or above (61–66). The REALM, which can be administered and scored in less than three minutes, is the most commonly used test of patient literacy in medical settings.²⁷ The REALM is highly correlated with standardized reading tests, including the Wide Range Achievement Test—Revised (WRAT-R) ($r = 0.88$), the Slosson Oral Reading Test—Revised (SORT-R) ($r = 0.96$), and the Peabody Individual Achievement Test—Revised (PIAT-R) ($r = 0.97$).^{26,27} The REALM is also highly correlated with the Test of Functional Health Literacy in Adults (TOFHLA) ($r = 0.84$).²⁸

Lexile score. We used a Lexile framework to gauge the reading level for the text on each PWL.²⁹ Lexile scores are based on sentence length and word frequency in popular literature, with higher values indicating higher levels of reading difficulty. The possible range of scores is below 0 (representing a beginning reading level) to 2000. A program available to registered users over the Internet, called the Lexile Analyzer (Metra-Metrics, Inc., Durham, NC), was used to calculate the Lexile score for each label's text. These values can be easily translated to corresponding reading grade levels. For instance, a Lexile score of 300 might correspond to a second-grade reading level, 400 to a third-grade level, and 1300 to a 12th-grade level.

Data analysis. Statistical analyses were conducted using STATA, ver-

sion 8.0 (Stata Corp., College Station, TX). Descriptive statistics were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and correct interpretation (yes or no) of each of the eight PWLs. For qualitative analyses, a grounded theory approach was used to explore the basis for patients' incorrect interpretations of each of the eight PWLs using their documented verbatim responses. Grounded theory, according to Strauss and Corbin,³⁰ is a systematic method for generating theoretical statements from case studies. Based on our qualitative, cognitive interviews, grounded theory guides the inductive process of organizing content derived from patient responses. For this study, patients' misinterpretations were reviewed and classified using both predetermined and emergent coding schemes. The qualitative data were coded according to predetermined factors, including text difficulty, use of icons, and use of color. Responses were then examined for additional coding of emergent factors.

Results

Of the 1162 patients seen at the PCC in July 2003, 276 were asked to participate in the study. Of these, 3 refused participation, 17 were excluded based on self-reported impairments with hearing ($n = 5$) or vision ($n = 12$), 3 were excluded because English was their second language, and 2 were excluded due to incomplete information. A total of 251 patients were assessed for literacy. Of these 251, 74 were reading at the sixth-grade level or below and were included in our study.

The characteristics of study participants are detailed in Table 1. The mean \pm S.D. age for the participants was 50.0 ± 15.5 years (range, 19–81 years). Most patients were African American, older, and female, with the average REALM score corre-

sponding to approximately the fifth-grade reading level. Approximately one third of patients had completed high school or received a general equivalency diploma. The mean \pm S.D. number of prescription medications patients were taking was 2.9 ± 0.6 (range, 0–15).

Label comprehension. Rates of correct interpretation of the eight PWLs ranged from 0% to 78.7% (Table 2). With the exception of the label "Take with food," less than half of all patients were able to provide adequate interpretations of the warning labels' messages. None of the respondents were able to correctly interpret the label "Do not take dairy products, antacids, or iron preparations within one hour of this medication."

Compared with patients reading at the fourth- to sixth-grade level, those with very low literacy skills (reading at or below the third-grade level) were less able to correctly interpret six of the eight labels (Table 3). No significant differences in correct interpretation were noted by age, sex, number of years of education, race, payment method, number of medications currently taken, or the two literacy categories.

Causes of misunderstandings.

The types of misunderstanding of PWLs by patients with low literacy were first determined by preselecting a coding scheme for the likely cause leading to misunderstanding and then allowing additional causes to emerge within the qualitative review process. Predetermined causes included single-step versus multiple-step instructions, reading difficulty of text, use of icons, and use of label color. One emergent cause of misunderstanding PWLs was identified and referred to as message clarity.

Single-step versus multiple-step instructions. Three of the eight PWLs were considered by the expert panel as having multiple precautions or steps instructing proper use of the medication. These included "Refrigerate, shake well, discard after

(date),” “Do not take dairy products, antacids, or iron preparations within one hour of this medication,” and “You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this

medication.” Rates of comprehension among patients were the lowest for these PWLs (8.0%, 0%, and 5.3%, respectively). Respondents frequently became confused when interpreting the multiple-step instructions or did

not address all messages of the PWL in their response (Table 2).

Reading difficulty of text. Overall, comprehension was lowest for two PWLs that had higher Lexile scores: “You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication” (Lexile score = 1300) and “Do not take dairy products, antacids, or iron preparations within one hour of this medication” (Lexile score = 1110). Both labels were written at a high school level or higher. Comprehension was highest for the label “Take with Food,” which was written at below the first-grade level.

Use of icons. Many of the icons used on the PWLs appeared to confuse patients. This was especially true if the text was difficult to comprehend. On the label “For external use only,” the pictogram was often interpreted as “radioactive,” “chills or shaking,” or “take anywhere.” One patient’s interpretation clearly relied on the pictogram and not the text: “Medicine will make you feel dizzy.” For the label “Do not chew or crush, swallow whole,” interpretations of the icon itself included “someone

Table 1. Participant Characteristics (n = 74)

Characteristic	No. (%)
Female	45 (61)
Race	
African American	66 (89)
White	7 (10)
Other	1 (1)
Literacy level	
3rd grade or below	28 (38)
4th–6th grade	46 (62)
Highest grade completed	
Grades 1–8	16 (22)
Grades 9–11	34 (46)
High school or GED ^a	21 (29)
Secondary education	3 (4)
Payment source for medications	
Private insurance	16 (22)
Medicaid	5 (7)
Self-pay	45 (61)
Other	8 (11)
Sources of medication information ^b	
Physician	53 (72)
Pharmacist	33 (45)
Family	16 (22)

^aGED = general equivalency degree.

^bParticipants could list multiple sources.

Table 2. Prescription Drug Warning Labels and Respondent Interpretations (n = 74)

Label	Lexile Score/ Grade Level	No. (%) Participants With Correct Interpretations	Incorrect Interpretations
Take with food	BR ^a	58 (78)	Don't take food; bread with food
For external use only	100/1st grade	7 (9)	Use extreme caution in how you take it; medicine will make you feel dizzy; take only if you need it; for adults not kids
Medication should be taken with plenty of water	520/4th grade	28 (38)	Don't take when wet; don't drink hot water; don't need water
Do not chew or crush; swallow whole	600/5th grade	35 (47)	Chew it up so it will dissolve; don't swallow whole or you might choke; just for your stomach; have something on medicine before you take it
Refrigerate—shake well. Discard after _____	800/7th grade	6 (8)	Keep medicine chilled; mix it well, discard when done; put in refrigerator
Do not drink alcoholic beverages when taking this medication	870/8th grade	31 (42)	Don't drink and drive; don't drink alcohol, it's poison and it'll kill you
Do not take dairy products, antacids, or iron preparations within one hour of this medication	1110/10th grade	0	If allergic to dairy, don't take medicine; don't eat for one hour after taking medicine
You should avoid prolonged or excessive exposure to direct or artificial sunlight while taking this medication	1300/12th grade	4 (5)	Don't leave medicine in the sun; don't leave [medicine] in sunlight, but a cool place

^aBR = beginning reading, the term used in the Lexile Framework to convey a reading level below the first grade.

Table 3.
Literacy Level of Respondents Who Correctly Interpreted Prescription Drug Warning Labels

Label	No. (%) Participants		p
	Third Grade or Below (n = 28)	Fourth to Sixth Grade (n = 46)	
Take with food	17 (61)	41 (89)	0.003
For external use only	0	7 (15)	0.032
Medication should be taken with plenty of water	4 (14)	24 (52)	0.001
Do not chew or crush, swallow whole	5 (18)	30 (65)	<0.001
Refrigerate, shake well, discard after (date)	0	6 (13)	0.049
Do not drink alcoholic beverages when taking this medication	6 (21)	24 (54)	0.004
Do not take dairy products, antacids, or iron preparations within one hour of this medication	0	0	NS ^a
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	1 (4)	2 (4)	NS

^aNS = not significant.

swallowed a nickel," "indigestion," and "a bladder." For PWLs that conveyed multiple steps for proper compliance, such as "Refrigerate, shake well, discard after (date)," icons were not able to convey all aspects of the text. The icon (a refrigerator) used on this label addressed only the first step of the instruction, and common incomplete responses to the PWL were subsequently limited: "keep medicine chilled" and "put in refrigerator."

Use of label color. Many patients attributed the use of color to the severity of the label's message. Patients reported that red meant danger; yellow translated to caution; and blue, white, and green labels were viewed as "recommendations" that were not as severe or important as the instructions on red labels. Thirty-one patients (41.9%) applied this cognitive valuation of color to the PWLs.

Message clarity. Text messages on certain PWLs, regardless of Lexile score, were not understood by most patients. For example, "For external use only" had a very low Lexile score (approximately first-grade level) but proved difficult for 90.7% of respon-

dents. For other labels, it was apparent that only a part of the message could be interpreted. For the PWL "Do not chew or crush, swallow whole," some patients provided interpretations that suggested they had read some but not all of the words on the label (e.g., "do not swallow whole," "chew it up so it will dissolve"). Often, patient interpretations of several PWLs were reliant on the pictogram, which led to discordance between the text and icon messages. For instance, many patients derived opposing meanings for the PWL "Do not chew or crush, swallow whole," such as "Don't swallow whole or you might choke."

Discussion

Adhesive PWLs were originally developed to highlight important instructions for the safe use of a medication that were contained within the longer package insert and to be visible every time the patient picked up the medication bottle. These labels are important, considering that many consumers report not reading the longer and more complicated package insert.^{31,32} Among our sam-

ple of patients with low literacy skills, less than a third (28.7%) reported reading the package inserts that are routinely distributed with prescription medications.

Overall, the eight PWLs in this study were not helpful to patients with low literacy skills. The majority of patients misinterpreted all labels with the exception of "Take with food." The causes for misunderstanding were attributed to one or a combination of problems associated with label text (word choice, message length, and number of steps for action), icons, and color. In fact, our findings indicated that some PWLs may inadvertently promote a misunderstanding of safety information that could potentially lead to hazardous administration of the drug and an adverse reaction. This scenario was most notable on the label "Do not chew or crush, swallow whole," which was interpreted as "do not swallow whole" and "chew it up so it will dissolve."

The example above also highlights a cognitive process that is common among individuals with low literacy skills. These patients may seek out and identify one or two words in print materials that they tentatively recognize and induce meaning from these words.³³ This often leads to an improper placement of the message context, as "swallow" or "chew" was recognized but the opposite action was interpreted. Similarly, adults with low literacy may misread a central word in the message, such as the word "external" in "For external use only." Several patients interpreted the message as "use extreme caution." In this scenario, these adults recognize the first few letters of the word and make an educated guess to decipher the whole word. These individuals lack the vocabulary and reading skills to further grasp the entire content of the message. Adults with low literacy skills may therefore rely more heavily on icons and colors to interpret the meaning of labels, but

these may also mislead or confuse patients.

Though all of the text on the PWLs was brief, some was unnecessarily complex (“You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication”) or vague (“medication should be taken with plenty of water”). Some terms reflect lay or professional jargon and may not be universally understood (“iron preparations,” “dairy products,” “antacids”). Consumers with low literacy need more concrete and specific instructions to respond accordingly.³³⁻³⁵ In addition, the font size and boldfacing of words varied widely, and often the words emphasized were not central to the action requested. This may cause patients with reading difficulties to take these messages out of context. Finally, all letters in these PWLs were capitalized, despite recommendations that uppercase and lowercase text be used to improve accessibility among beginning readers.³³⁻³⁵

Limitations. This study had several limitations. First, participation was limited to English-speaking patients. However, the majority of PWLs currently used in the United States are only available in English. Second, patients were sampled from one public hospital, which may limit the generalizability of findings. However, patients in the sample reflected a group disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010.³⁶ Finally, the sample size limited the ability to detect significant and clinically meaningful relationships within subgroups, such as differences across age groups. Previous studies found that older adults were less able to comprehend prescription labels compared with younger adults.^{37,38} Another study found that 67% of elderly persons did not fully understand the information on the drug labels.⁹ Less than 5% of patients in

our sample were 75 years of age or older.

Opportunities for improvement. Over the past decade, improvements have been sought to make the general prescription drug label and any patient information included in package inserts more accessible to all consumers.^{1,10,39} We offer the following steps as a road map to move from policy to practice, providing direction for the development of new messages, icons, and labels to better convey these important warnings and dosage instructions.

Develop standards, regulations, and guidelines. The Federal Food, Drug, and Cosmetic Act of 1938 provides FDA with regulatory oversight to mandate reform for the general drug label and package inserts.⁴⁰ However, these adhesive warning labels have not been viewed within the scope of this act, were not included in the Keystone Dialogue, and have largely been ignored by FDA, manufacturers, and other organizations. The development and use of PWLs should become an essential component of package labeling and should receive regulatory oversight to ensure that standards are in place for their continued development and use. Recognizing that such national regulation will take time, and realizing the urgency posed by the clear evidence of misunderstanding and the potential for harm, concerted voluntary action is needed. NABP and the Pharmaceutical Research and Manufacturers of America should develop consensus guidelines to ensure safe and consistent messages through PWLs.

Involve consumers. Consumers need to be actively involved in the development of new PWLs to ensure that the icon design, words, and formatting are useful to all individuals, including those with low literacy. Intensive cognitive testing of patients of all literacy levels should be conducted to confirm the appropriate meaning of text, icons, and color.

Feedback from pharmacists and physicians, who may counsel patients on the safe administration of prescription medications and eventually distribute and explain the revised labels, should also be sought.

Seek universal acceptance and consistent use of label icons. Several companies currently produce PWL stickers for U.S. pharmacies. As a result, different icons have been developed to convey similar messages regarding medication administration. Therefore, patients may be exposed to multiple PWLs and icons for the same medication if they fill prescriptions at more than one pharmacy or if their pharmacy changes label vendors. Icons should be consistent and universal acceptance of their meaning sought.

Train professionals in literacy issues and communication. Pharmacists, physicians, and other health care professionals should be oriented to this approach to supplemental labels to ensure that they, too, are communicating a consistent message. Specifically, the pharmacist may be the first to recognize problems with patient literacy and proper understanding of how to safely use prescription medications. However, pharmacists should be educated to the larger problem of health literacy and learn simple ways for both recognizing patients at risk and responding accordingly.⁴¹ Low literacy communications training modules currently exist that could provide pharmacists with useful skills, such as the “teach back” technique to confirm patients’ understanding of medication instructions, including those listed on warning labels.⁴²

Simplify text used on labels. Reading difficulty formulas, such as the Lexile Framework, should be used as a starting point to gauge the complexity of the print message on PWLs. However, these formulas should be used with more comprehensive assessments³³⁻³⁵ that focus on other contributing factors to reading

ease, such as organization, complexity, and clarity.³³

Minimize the action sought per label. Our findings suggest that multiple-step instructions on PWLs should be avoided when possible. For instance, the PWL "Do not take dairy products, antacids, or iron preparations within one hour of this medication" might be divided into three separate messages. For the label "Refrigerate, shake well, discard after (date)," it may be important to include multiple icons rather than one that only addresses the first action.

Give meaning to color and standardize its use. Consumers, like those in our study, may impose a "traffic light" color scheme to a label and its message. We recommend limiting the number of colors used and applying a consistent color scheme to different messages. For instance, messages conveying a warning or restriction might use red and yellow colors, and PWLs that provide instructions could be printed on white labels.

Aim for message concordance across languages. While some PWLs have translations in Spanish, many do not, and it is not clear how message concordance was achieved across languages for these labels. A systematic approach to the development and translation of PWLs across languages needs to be established. Existing resources are available to guide the translation process.⁴³ Cultural considerations should specifically be addressed, including semantic differences associated with both text and icons within a language.

Conclusion

Patients with low literacy skills demonstrated a lower rate of correct interpretation of the eight most commonly used PWLs than did those with higher literacy skills. Multiple-step instructions, reading difficulty of text, the use of icons, the use of color, and message clarity were the common causes of label misinterpretation.

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Literacy and Misunderstanding Prescription Drug Labels

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Background: Health literacy has increasingly been viewed as a patient safety issue and may contribute to medication errors.

Objective: To examine patients' abilities to understand and demonstrate instructions found on container labels of common prescription medications.

Design: Cross-sectional study using in-person, structured interviews.

Setting: 3 primary care clinics serving mostly indigent populations in Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois.

Patients: 395 English-speaking adults waiting to see their providers.

Measurement: Correct understanding of instructions on 5 container labels; demonstration of 1 label's dosage instructions.

Results: Correct understanding of the 5 labels ranged from 67.1% to 91.1%. Patients reading at or below the sixth-grade level (low literacy) were less able to understand all 5 label instructions. Although 70.7% of patients with low literacy correctly stated the instructions, "Take two tablets by mouth twice daily," only 34.7%

could demonstrate the number of pills to be taken daily. After potential confounding variables were controlled for, low (adjusted relative risk, 2.32 [95% CI, 1.26 to 4.28]) and marginal (adjusted relative risk, 1.94 [CI, 1.14 to 3.27]) literacy were significantly associated with misunderstanding. Taking a greater number of prescription medications was also statistically significantly associated with misunderstanding (adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥ 5 medications).

Limitations: The study sample was at high risk for poor health literacy and outcomes. Most participants were women, and all spoke English. The authors did not examine the association between misunderstanding and medication error or evaluate patients' actual prescription drug-taking behaviors.

Conclusions: Lower literacy and a greater number of prescription medications were independently associated with misunderstanding the instructions on prescription medication labels.

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Reducing adverse events associated with medication errors in the ambulatory care setting remains an important patient safety objective for physicians and for the health care community at large (1-7). Although much attention has been directed to medication-related errors attributed to physician or system failure (1, 8-10), patient-initiated errors in medication use have received less recognition. As the focus on health care delivery continues to shift from inpatient to outpatient settings, the practice of quality control over medication use is becoming more the responsibility of the patient and less the responsibility of the provider. Yet, patients do not always take medications as prescribed, and as a result, outpatient adverse drug events are common (4-6).

Previous studies have found that many patients are not receiving oral or written instructions from their physicians and pharmacists on how to appropriately manage prescription medications (11, 12). As a result, instructions on the prescription container label assume greater importance. The Institute of Medicine (13) estimates that 90 million adults in the United States may have trouble understanding and acting on health information. Medication container labels, in particular, may be confusing and difficult to comprehend for many patients (14-18).

The incidence of patient medication errors is likely to increase, because Americans are taking more prescription medications annually (19). The physician and the pharmacist may assume that their patients can read, understand, and act on brief instructions found on prescription medication labels, but this may not be the case (11-13). The

purpose of this study was to examine whether adult primary care patients were able to read and correctly state how they would take various medicines after reviewing label instructions on actual pill bottles. We hypothesized that low literacy would be associated with higher rates of misunderstanding and incorrect demonstration.

METHODS

Participants

Study participants were adult patients who attended 1 of 3 outpatient primary care clinics that predominantly serve indigent community populations in 3 distinct cities and states (Shreveport, Louisiana; Jackson, Michigan; and Chicago, Illinois). Participant recruitment took place in Shreveport, Louisiana, during July 2003 and at the remaining 2 sites during July 2004. In Shreveport, the primary care clinic was situated within a public hospital, whereas the clinics in Chicago and Jackson are both federally qualified health centers that provide care to medically underserved neighborhoods.

See also:

Print

Editors' Notes 888
Editorial comment 926

Web-Only

Conversion of tables into slides

Context

Low literacy contributes to medical and drug nonadherence.

Contribution

The authors tested patients in indigent communities to see how well they understood pill bottle labels. Patients with lower literacy levels and those taking a greater number of medications were less able to understand the meaning of the labels. Even among patients who understood the labels, only a minority could correctly demonstrate how to take the pills.

Cautions

Patients' actual drug-taking behaviors were not observed, so the authors could not demonstrate a link between misunderstanding and medication errors.

Implications

Lower literacy and a greater number of medications being taken were associated with patient misunderstanding of pill bottle labels.

—The Editors

Patients were considered eligible for the study if they were 18 years of age or older and were considered ineligible if the clinic nurse or study research assistant (during the course of the interview) identified a patient as having 1 or more of the following conditions: 1) severely impaired vision, 2) hearing problems, 3) illness too severe to participate, and 4) inability to speak English. The institutional review boards at all locations approved the study. All participants provided informed consent. A total of 458 patients were approached in the order they arrived at the clinics and before the medical encounter; 446 consented to participate in the study. Seventeen patients were excluded on the basis of self-reported impairments in hearing ($n = 5$) or vision ($n = 12$). Nine patients were excluded because they spoke English as a second language, and 25 additional patients were excluded on the basis of incomplete information. In all, 395 patients participated in the study. A response rate was determined following the American Association for Public Opinion Research standards (20), which estimated that 91.6% of approached eligible patients participated in the study.

Structured Interview and Literacy Assessment

A structured "cognitive" interview protocol was developed to assess patients' understanding the instructions of 5 common prescription medication container labels. Interviews were conducted with 6 primary care physicians and 1 hospital pharmacist to identify common medication prescriptions for acute and chronic health conditions. Through these interviews, a consensus was reached and 5 medications were identified for the study, including 2 anti-

biotics (amoxicillin [for pediatric use] and trimethoprim); an expectorant (guaifenesin); an antihypertensive, channel-blocking agent (felodipine); and a diuretic (furosemide).

After patients consented to participate in the study, a trained research assistant administered the structured interview that included self-report of sociodemographic information (age, sex, race and ethnicity, education, source of payment for medications, and number of prescription medications currently taken daily). Actual prescription pill bottle containers with labels were then shown in the same order to all of the patients for review. Once the patient provided his or her interpretation of all of the labels, the research assistant administered a brief literacy assessment, which concluded the interview.

Understanding Medication Container Label Instructions

To assess patient understanding of the instructions on each of the 5 prescription medication labels, the research assistant asked, "How would you take this medicine?" The patient's verbatim response was then documented on a separate form. All patient responses ($n = 1975$) to the instructions for each of the 5 medications were then independently rated as either correct or incorrect by 3 general internal medicine attending physicians from 3 academic medical centers. Each physician-rater was blinded to all patient information and was trained to follow stringent coding guidelines previously agreed on by the research team. Specifically, correct scores were to be given only if the patient's response included all aspects of the label's instruction, including dosage; "timing"; and if applicable, duration. Responses were given an incorrect score if they were inaccurate or if they did not contain all aspects of the instructions.

Interrater reliability was high among the 3 physicians who coded the patient responses ($\kappa = 0.85$). The 147 responses (7.4%) that received discordant ratings among the 3 reviewers were sent to an expert panel for further review. This panel included 3 primary care physicians and 2 behavioral scientists with expertise in health literacy. Each panel member, also blinded to patient information, independently reviewed and coded the responses as correct or incorrect. For 76.2% ($n = 112$) of the 147 responses, a consensus ruling was achieved among the 5-member panel for a final ruling on the coding of those responses. For the remaining 35 patient responses, a majority rule was imposed and the rating by a minimum of 3 panel members was used to determine the scores.

In a final review, responses that were coded as incorrect were qualitatively reviewed by 3 research assistants, who were trained by the expert panel members to code the responses according to the nature of the misunderstanding (incorrect dosage, incorrect frequency, incomplete response, navigation difficulty as defined by stating information on the container other than the primary label instruction, and no attempt because of self-reported reading

difficulties). Interrater agreement was high among the research assistants ($\kappa = 0.82$).

Attendance to Auxiliary Label Instructions

We also investigated the patient's attentiveness to the auxiliary or "secondary" warning labels on the pill bottles. These labels provide supplementary instructions, such as "Take with food" or "Do not chew or crush, swallow whole," which support the safe administration of the medications. Research assistants were instructed to document whether patients attempted to interpret the auxiliary label along with the primary label, or whether they physically turned the bottle to inspect the color stickers on which these warning messages are placed. Patient attendance to the auxiliary label was coded as "yes" if his or her response or behavior was noted by the reviewer and "no" if the label was disregarded. Our research team has previously investigated patients' understandings of these auxiliary labels (21).

Understanding versus Demonstration

A substudy was conducted among all patients to test whether those who could accurately read and state the instructions for guaifenesin ("Take two tablets by mouth twice daily") could correctly demonstrate how many pills were to be taken daily. After patients answered the first question, "How would you take this medicine?" they were asked, "Show me how many pills you would take [of this medicine] in one day". The medication container was filled with candy pills for patients to dispense and count out the correct amount. Responses were coded as correct if their answer was "4" and incorrect if any other response was provided.

Literacy Assessment

Patient literacy was assessed by using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test comprising 66 health-related words (22–24). This is the most commonly used test of patient literacy in medical settings (24). Raw scores can be converted into 1 of 3 reading levels: sixth grade or less (score, 0–46), seventh to eighth grade (score, 45–60), and ninth grade and above (score, 61–66). The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (14).

Statistical Analysis

All statistical analyses were performed by using SAS software, version 9.1 (SAS Institute, Inc., Cary, North Carolina). Descriptive statistics (percentage, mean, and SD) were calculated for each variable. Chi-square tests were used to evaluate the association between sociodemographic characteristics and patient understanding of primary label instructions of 5 prescription medications and attendance to the auxiliary labels. In multivariate analysis, the 5 binary repeated responses of understanding per patient were modeled by using a generalized linear model with a complementary log-log link function. A generalized estimating equation approach was used to adjust model coefficients

and standard errors for within-patient correlation by using PROC GENMOD (SAS Institute). Wald 95% CIs were calculated for adjusted relative risk ratios by using the robust estimate of the standard error as detailed by Liang and Zeger (25). The final multivariate model included the potential confounding variables: age, sex, race (white vs. African American), education, and number of medications currently taken daily. Although education is associated with literacy, it was examined separately but included in the final model to present conservative estimates of the effect of literacy on rates of understanding. This issue has previously been reviewed by Wolf and colleagues (26) and the same method was used in our study. Site was also entered into the model to adjust for any potential differences across study locations. In multivariate analyses, patient literacy was classified as low (sixth grade and below), marginal (seventh to eighth grade), or adequate (ninth grade and higher). For the substudy analyses, chi-square tests were used to evaluate the association between sociodemographic characteristics and correct demonstration of the specified medication instructions. A multiple logistic regression model was used to examine the relationship between literacy and comprehension of the medication labels while controlling for the previously mentioned confounding variables and study site. Model fit was assessed by using the *c*-statistic from the receiver-operating characteristic curves and the Hosmer–Lemeshow goodness-of-fit chi-square test.

Role of the Funding Sources

The study was internally funded by the Health Education and Literacy program at Louisiana State University Health Sciences Center and by a career development award from the Centers for Disease Control and Prevention.

RESULTS

The mean age for all respondents ($n = 395$) was 44.8 years (SD, 13.7; range, 19 to 85 years). Fifty-seven percent of patients were recruited from Shreveport, Louisiana; 25% from Jackson, Michigan; and 18% from Chicago, Illinois. Two thirds (67.8%) were women, approximately half were African American (47.4%) and half were white (48.4%), and 28.4% reported less than a high school level of education. Patient literacy was limited; 19.0% read at or below a sixth-grade level (low literacy), and 28.6% read at the seventh- to eighth-grade level (marginal literacy).

Patients were taking an average of 1.4 prescription medications, and 22.8% lacked insurance for these medications. Low literacy was associated with older age ($P < 0.001$), African-American race ($P < 0.001$), and less education ($P < 0.001$) (Table 1). No statistically significant differences were reported between literacy level, sex, source of payment for medications, or number of prescription medications taken daily.

Overall, the 395 patients gave a total of 1975 responses for the 5 medication labels. Of these responses,

Table 1. Sample Characteristics Stratified by Literacy Level*

Characteristic	Literacy Level			P Value
	Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Mean age (SD), y	42.6 (13.6)	44.9 (13.5)	50.8 (12.7)	<0.001
Female, %	60.0	68.1	70.5	0.25
Race, %				<0.001
African-American	29.0	63.7	73.3	
White	65.2	32.7	25.3	
Other	5.8	3.6	1.4	
Education, %				<0.001
Grades 1-8	1.9	2.7	14.7	
Grades 9-11	11.6	34.5	41.3	
Completed high school/GED degree	43.0	45.1	40.0	
>High school	43.5	17.7	4.0	
Payment source for medications, %				0.43
Private insurance	18.8	14.2	12.0	
Medicaid	46.4	55.8	58.7	
Out-of-pocket	24.6	19.5	22.7	
Other	10.2	10.5	6.6	
Mean medications taken daily (SD), n	1.4 (1.1)	1.5 (1.1)	1.4 (0.9)	0.37
Study site, %				<0.001
Shreveport, Louisiana	60.0	68.1	43.0	
Jackson, Michigan	14.0	19.5	20.3	
Chicago, Illinois	26.0	12.4	36.7	

* GED = general educational development.

374 (18.9%) were coded as incorrect. Almost half (46.3%) of patients misunderstood 1 or more of the prescription label instructions, and the prevalence among patients with adequate, marginal, and low literacy was 37.7%, 51.3%, and 62.7%, respectively ($P < 0.001$). The rates of understanding individual labels ranged from 67.1% for the instructions for trimethoprim ("Take one tablet by mouth twice daily for seven days") to 91.1% for the instructions on the label for felodipine ("Take one tablet by mouth once each day"). Patients with low literacy were less able to understand the meaning of all 5 medication labels than those with adequate literacy (Table 2). No statistically significant differences in rates of understanding the medication labels were noted by either age or number of prescription medications currently taken.

The majority (51.8%) of incorrect patient responses reflected an error in dosage (that is, tablespoon vs. teaspoon), and 28.2% stated the wrong dose frequency (that is, "one tablet each day for seven days" instead of "Take one tablet by mouth twice daily for seven days"). For the instruction, "Take one tablet by mouth twice daily for seven days", 11.1% of responses omitted the duration of use. In 5.8% of the incorrect responses, patients had difficulty finding the instructions on the prescription label, and in 3.2% of incorrect responses, the patient acknowledged to the interviewer that he or she was unable to read.

Multivariate analyses identified low and marginal lit-

eracy as statistically significant independent predictors of misunderstanding the primary medication label instructions (adjusted relative risk, 2.32 [CI, 1.26 to 4.28] for low literacy and adjusted relative risk, 1.94 [CI, 1.14 to 3.27] for marginal literacy) (Table 3). Patients who took more prescription medications were also independently found to be more likely to misunderstand the labels (adjusted relative risk, 2.29 [CI, 1.16 to 4.54] for 1 to 2 medications; adjusted relative risk, 3.22 [CI, 1.53 to 6.77] for 3 to 4 medications; and adjusted relative risk, 2.98 [CI, 1.40 to 6.34] for ≥ 5 medications) (Table 3). No statistically significant interactions were found between literacy, age, number of medications taken, sex, and race.

One-way sensitivity analyses were conducted to account for responses that were coded as incorrect because of incomplete information on duration of use ($n = 41$ [11.1% of incorrect responses]). When these responses were recoded as correct, no substantial differences were noted for the association between misunderstanding and low literacy (adjusted relative risk, 2.29 [CI, 1.29 to 3.34]) or marginal literacy (adjusted relative risk, 1.84 [CI, 1.11 to 4.26]).

Substudy Analyses

A substudy analysis compared the percentage of patients who accurately read and correctly stated the label instructions for guaifenesin ("Take two tablets by mouth

twice daily") compared with the percentage of patients who correctly demonstrated the number of pills to be taken. Patients at all literacy levels were more able to read label instructions than to demonstrate the correct number of pills to be taken. Among patients with adequate literacy, 89.4% were able to read the instructions, whereas 80.2% properly demonstrated the correct number of pills to be taken. Differences in the ability to read versus the ability to demonstrate use were larger among patients with marginal (84.1% vs. 62.8%) and low literacy (70.7% vs. 34.7%). In multivariate analysis, low literacy was the only statistically significant independent predictor of correct demonstration of the label instructions (adjusted relative risk, 3.02 [CI, 1.70 to 4.89]). The model was tested for interactions; none were found to be statistically significant.

DISCUSSION

Physicians may assume that patients can understand instructions on prescription medication containers, because their appearance suggests that they are simple and clear. However, in this multisite study of primary care patients, approximately half (46.3%) were unable to read and correctly state 1 or more of the label instructions on 5 common prescriptions. Rates of misunderstanding were higher among patients with marginal and low literacy, yet more than one third (37.7%) of patients with adequate literacy skills misunderstood at least 1 of the label instructions.

This is cause for concern, because patient misunderstanding could be a potential source of medication error.

The instructions on the 5 prescription labels were typical in that they were short and used seemingly simple words. Nonetheless, the information was not clear for many patients. Mistakes were more common when the instructions had several components with varying numerical information (for example, "Take one tablet by mouth twice daily for seven days" vs. "Take one tablet by mouth once each day"). Misunderstanding was less frequent for the label with the most explicit dosing instructions ("Take one tablet in the morning and one at 5 p.m."), and differences by literacy did not reach statistical significance. However, this is probably the result of a higher rate of comprehension among patients with marginal literacy, because the difference between patients with adequate and low literacy skills was still similar to that found for other labels with less explicit instructions. Beyond the clarity of the instructions, patients may misread labels as a result of haste or limited literacy. Twenty-two percent ($n = 23$) of the patients with incorrect responses to the instructions, "Take one teaspoonful by mouth three times daily," misinterpreted the dose as "tablespoon" rather than "teaspoon."

Among the patients correctly stating the instruction, "Take two tablets by mouth twice daily" ($n = 333$ [84.3%]), one third were unable to demonstrate the correct number of pills to take per day. This was most pronounced

Table 2. Percentage of Patients Understanding Primary Prescription Drug Label Instructions and Attending to Auxiliary Labels* by Literacy Level

Drug Name	Instruction	Literacy Level			P Value
		Adequate ($n = 207$)	Marginal ($n = 113$)	Low ($n = 75$)	
Amoxicillin					
Correctly interpreted primary label	Take one teaspoonful by mouth three times daily	82.6	65.5	58.7	<0.001
Attended to auxiliary labels		5.3	4.4	0.0	0.130
Trimethoprim					
Correctly interpreted primary label	Take one tablet by mouth twice daily for seven days	73.0	66.4	52.0	<0.001
Attended to auxiliary labels		7.8	7.1	1.3	0.144
Guaifenesin					
Correctly interpreted primary label	Take two tablets by mouth twice daily	89.4	84.1	70.7	<0.001
Attended to auxiliary labels		14.1	7.1	0.0	<0.001
Felodipine					
Correctly interpreted primary label	Take one tablet by mouth once each day	94.7	87.6	86.7	0.032
Attended to auxiliary labels		12.6	10.6	4.0	0.115
Furosemide					
Correctly interpreted primary label	Take one tablet in the morning and one at 5 p.m.	91.3	91.2	82.7	0.092
Attended to auxiliary labels		14.5	8.9	2.7	0.011

* The multicolored labels that provide auxiliary instructions, such as "Take with food" and "Do not chew or crush, swallow whole."

Table 3. Risk Factors for Misunderstanding Prescription Medication Label Instructions*

Variable	Relative Risk (95% CI)	P Value	Adjusted Relative Risk† (CI)	P Value
Literacy level				
Adequate	1.00		1.00	
Marginal	1.59 (1.12–2.26)	<0.001	1.94 (1.14–3.27)	0.014
Low	2.38 (1.64–3.45)	<0.001	2.32 (1.26–4.28)	<0.001
Age, y				
<40	1.00		1.00	
40–49	1.18 (0.81–1.74)	0.39	1.18 (0.70–2.03)	0.53
50–59	1.26 (0.84–1.89)	0.26	0.63 (0.33–1.19)	0.155
≥60	1.42 (0.89–2.27)	0.146	1.09 (0.58–2.08)	0.78
Sex				
Female	1.00		1.00	
Male	1.65 (1.21–2.23)	<0.005	1.43 (0.95–2.14)	0.083
Race				
White	1.00		1.00	
African-American	1.46 (1.08–1.98)	0.016	0.99 (0.63–1.55)	0.95
Education				
>High school	1.00		1.00	
Completed high school or GED degree	1.09 (0.76–1.58)	0.63	1.07 (0.64–1.80)	0.79
Grades 9–11	1.46 (0.97–2.19)	0.075	0.89 (0.48–1.65)	0.70
Grades 1–8	2.53 (1.31–4.87)	<0.001	1.83 (0.85–3.99)	0.121
Medications taken daily, n				
None	1.00		1.00	
1–2	1.60 (1.05–2.44)	0.032	2.29 (1.16–4.54)	0.022
3–4	1.77 (1.13–2.76)	0.012	3.22 (1.53–6.77)	<0.005
≥5	1.63 (1.01–2.62)	0.054	2.98 (1.40–6.34)	<0.001

* GED = general educational development.

† Multivariate adjusted relative risks derived from generalized estimating equation regression models, adjusting for site in addition to all variables shown.

among patients with low literacy—fewer than half—who correctly stated the instruction were then able to count the right number of pills. This may reflect more of a patient's numeracy skills than reading proficiency; however, numeracy is an aspect of functional literacy. According to the National Adult Literacy Act of 1991 (27), functional literacy is defined as "the ability to read, write, and speak in English, and compute and solve problems at levels of proficiency necessary to function on the job and in society, to achieve one's goals, and develop one's knowledge and potential." Our finding that patients may be able to read label instructions but not correctly demonstrate the number of pills to be taken suggests that numeracy may be a more difficult literacy task than decoding relatively simple words (28).

Currently recommended methods for confirming patient understanding include the "teach-back" technique in which patients are asked to repeat instructions to demonstrate their understanding (29). This may be inadequate for identifying potential errors in medication administration, because study results documented a gap between a patient's ability to correctly state instructions and his or her ability to correctly demonstrate the correct number of pills to be taken daily. A system approach in which someone (pharmacist, nurse, clinic assistant, or physician) verifies that patients can accurately demonstrate or articulate specific

correct medication taking behaviors is important to ensure quality care. A recent report from the Institute of Medicine (7) notes the importance of providers having enhanced discussions with patients as a means of improving medication safety. This study suggests that medication review needs to verify that patients, or their surrogates, can accurately describe and demonstrate how to take medications safely.

Most patients did not pay attention to the auxiliary (warning) labels, and those with low literacy were more likely to ignore them. Lack of attention to the warning labels has been recognized as a problem (21). In a previous study, patients reported that they rarely attended to warning labels. This may be attributed to a limited effort by physicians or pharmacists to counsel patients about the importance of these labels. Nonetheless, failure to heed the special instructions on these labels could potentially lead to a loss of drug potency; change in the rate of absorption of the medication; or in certain formulations, cause such adverse events as gastrointestinal bleeding (30).

In addition to limited literacy, the greater number of prescription medications taken by patients was a statistically significant, independent predictor of misunderstanding label instructions. It is possible that as patients take more prescription medications, the complexity and possible confusion of managing multiple instructions may be greater. It is also possible that the number of medications

taken is a proxy for a greater number of comorbid conditions. Previous studies have shown that poorer health status is not only associated with more prescription medications in one's regimen but also with low literacy skills (26). This is noteworthy in light of recently reported trends. According to the Medical Expenditures Panel Survey (19), the average number of prescription medications filled annually by adults in the United States increased from 7 to 10 prescriptions between 1996 and 2003. An earlier study reported parallel trends in the increase of hospitalizations and deaths associated with medication errors (31).

Few studies have assessed actual patient understanding of medication instructions, and those that have more often focused solely on the elderly, a population especially vulnerable to misunderstanding prescription labels and instructions (17, 18, 32, 33). Senior citizens consume 2 to 3 times more medicine than does the general public, are more likely to have lower literacy skills, and have repeatedly been found to have poorer comprehension and recall of information on medication labels (28, 33). Although these studies have identified problems among elderly patients, our findings show that patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs.

Our study has limitations. We investigated patient understanding only of the primary label on prescription medications. The association between misunderstanding of label instructions and medication error was not examined. We also did not study the patients' actual prescription drug-taking behaviors. Motivation, concentration, and comprehension might have been greater if the patients were reporting on their own medication given by their physician for conditions they or their children actually had. Because the study design did not include a chart review, we could not identify whether patients had actual experience with the study medications.

Patients in our study were socioeconomically disadvantaged persons from 3 primary care clinics in diverse areas of the United States. Recruitment solely at clinics mandated to serve indigent populations was intentional. Our sample addresses those persons who are disproportionately affected by poor health outcomes and whose health and health care are targeted for improvement by Healthy People 2010 (34). The generalizability of our findings is further limited because the participants in our study were predominantly women (an accurate depiction of the clinic patient populations) and participation was limited to those who were proficient only in English. This was due in part to criteria for using the REALM as our literacy assessment. Additional research is needed to examine the language barrier to understanding instructions on prescription drug labels.

Our estimated prevalence of misunderstanding 1 or more prescription container labels (46.3%) was very similar to the estimates published by the National Assessment of Adult Literacy of 2003 (28), which reported that 43%

of adults in the United States read at the lowest levels of reading proficiency. Previous studies suggest that misunderstanding instructions on prescription medication labels is more common among elderly persons (17, 18, 33). Only 12% of patients in our sample were older than 60 years, and it is possible that we underestimated this relationship.

The Institute of Medicine Patient Safety Report (1) and a more recent report (7) stress the importance of addressing patient safety as a critical first step in improving quality of care. Our study found hidden health literacy problems with seemingly simple prescription medication labels. Although the prescriptions we examined have a relatively wide therapeutic margin, errors in their use have clinical importance. Moreover, it is probable that the rates of misunderstanding would be similar among medications with a more narrow range for clinical efficacy and safety. These medications may have similar dosing instructions to those we studied but possess greater risks for serious treatment failure or adverse events if taken incorrectly.

In summary, patients of all ages would benefit from additional efforts to improve the clarity and comprehensibility of labeling on prescription drugs (35–37). The text and format of existing primary and auxiliary labels on prescription medication containers should be redesigned and standardized. Less complex and more explicit dosing instructions may improve patient understanding; however, more research is needed to properly evaluate different instructional formats.

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EDITORIAL

Misunderstanding Prescription Labels: The Genie Is Out of the Bottle

► Dean Schillinger, MD

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The U.S. health care system largely operates under the assumption that all patients have high English-language literacy skills (1). In fact, many patients do not. In this issue, Davis and coworkers (2) carefully show that a substantial proportion of users of the U.S. health care system don't understand the instructions on prescription bottle labels and are unable to correctly execute these instructions. For those interested in improving health care quality and safety for vulnerable populations, this multisite study has important implications for practice, research, and policy. It forces us to focus on developing better "operating instructions" for medication taking. We are left wondering whether we could improve current labeling practice to communicate instructions about taking medication. I know that we can. So, who should be accountable for implementing a better system?

Briefly, in a sample of ethnically diverse primary care patients from community health centers, the investigators demonstrated a high rate of misunderstanding instructions on prescription labels for 5 common medications. Although the highest rates of misunderstanding across each of the 5 bottle labels (13% to 48%) occurred among patients with the lowest literacy levels, misunderstanding was common even among those with the highest literacy levels (5% to 27%). In multivariate analyses, lower literacy and greater number of prescription medications taken were associated with misunderstanding. Even worse, among those who seemed to understand a standard prescription label—by correctly reading and restating the instructions—far fewer correctly demonstrated how they would take the medication at home. Specifically, participants were asked to show how many pills they would take in 1 day, using candy pills from the bottle. Lower literacy was also associated with failure to correctly execute pill-taking instructions.

Does the authors' evidence fully support their conclusion that poor reading skills were responsible for poor understanding? In fact, the evidence is incomplete because the authors did not account for patients' cognitive function or visual acuity—each of which can impair reading comprehension and could explain poor understanding of labels. However, although this oversight may undermine the strength of the association between low literacy and poor understanding, it does not weaken the conclusion that many patients do not comprehend prescription labels and cannot act on their instructions. Some may argue that it is not surprising that doing poorly on a formal literacy "test" is associated with doing poorly on another form of literacy test: reading a prescription label. They would claim that this study confirms that poor test-taking skills beget poor test-taking and that the results of this particular test may not adequately reflect patients' behaviors at home. Although the authors did not assess actual

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medication-taking behaviors, other research has found that misunderstanding one's own warfarin prescription label, as measured by a similar test, is associated with limited literacy and unsafe anticoagulant outcomes (3), providing support for Davis and colleagues' conclusion that low literacy can have clinical consequences.

Do the findings of Davis and coworkers apply to other populations? While study participants were recruited from sites that serve the economically disadvantaged, the prevalence of low literacy was similar to that documented in a recent national assessment of literacy. This study categorized 36% of the U.S. population as having basic or below-basic literacy skills as regards to health-related tasks (4). The nature of the study design by Davis and colleagues was somewhat artificial—the authors asked participants to read, interpret, and demonstrate how to follow instructions from hypothetical sample prescription bottles and labels for commonly prescribed medications. This approach was necessary to standardize the test of prescription label reading, but it may raise concerns that the results do not reflect a "true" understanding of a patient's own prescription bottle labels—labels that patients arguably have learned to read and interpret correctly despite poor reading skills. However, more than one third of patients who take warfarin cannot demonstrate how to follow label instructions on their own medications (5), which suggests that the results from the study by Davis and coworkers do apply to patients' own prescription medications. Finally, the patients in the study were atypical: They took few medications regularly (mean, 1.4 medications), were relatively young, and spoke fluent English (6). Rates of misunderstanding in a typical internal medicine practice are probably even higher, because greater medication burden, older age, and limited English-language proficiency are all associated with misunderstanding prescription labels (5).

Davis and colleagues move the health literacy field forward considerably by developing improved research methods. The investigators' rigorous method for determining agreement between patients' and clinical investigators' interpretations of the same instructions will be useful for future descriptive and intervention studies. In addition, the researchers were able to tease out the "understanding" component of task performance, as measured by having participants verbally interpret prescription label instructions, from the "demonstration" component, as measured by having participants actually show how many pills they would take of the medicine in 1 day.

The study has several important implications. First, for the practitioner, it confirms that detailed medication reconciliation—ensuring that the patient knows which medications have been prescribed and can demonstrate how to correctly use all of them—must be part of routine practice. Medication reconciliation is important for all patients, but may be especially so for patients taking several medications, those taking medications that require stringent adherence, or those taking medications that cause adverse events if taken incorrectly. The best way to efficiently assess comprehension and elicit correct demonstration as part of the reconciliation process is unclear (5). The methods will probably include interactive communication strategies (7, 8) and using information from multiple sources (patient verbal report, demonstration of correct medication taking, and pharmacy records). However, in the absence of significant changes in prescription labeling and/or development of a more robust and standardized prescription communication system, medication reconciliation will usurp a substantial portion of clinical visit time, thereby infringing on the practice of a more relationship-centered type of care.

Second, from the perspective of patient safety research, the study findings challenge the fields of health communication, human cognition, and ambulatory medication safety to do better. For example, 2 related methods for assessing comprehension used in this study provided divergent results (many patients who correctly stated the instructions could not correctly demonstrate how to take the medications). This study was not designed to show which types, design, or formatting of label instructions is particularly challenging or effective, which should now be an area for intense scientific inquiry. Although the study did not examine the relationship between misunderstanding prescription labels and adverse events, research from our group has clarified this causal link. We found that providing a visual aid that shows the weekly pill regimen seems to increase comprehension of prescription labels and reduce the risk for medication-related adverse events (9).

Finally, this study has profound implications for health policy. In the United States, transmission of information on written prescriptions occurs in 4 ways (William Shrank, MD, MSHS, personal communication; 16 October 2006). The first is the label affixed to the bottle, the focus of the current study. The U.S. Food and Drug Administration (FDA) and state boards of pharmacy jointly regulate the content—but not the format—of this label. Not

surprisingly, practices within and among states vary. Second, pharmacies voluntarily provide consumer medication information in the form of nonstandardized, privately developed information leaflets delivered with most filled prescriptions. Consumer medication information is entirely unregulated and is often of poor quality. Third, package inserts, which are heavily regulated by the FDA, are intended for the use of the prescribing physician, are rarely delivered with prescriptions, and offer little benefit to patients (10). It is the prescribing physician, in his or her capacity as a "learned intermediary" between the drug manufacturer and the patient, who ultimately is accountable for successfully transmitting information about prescription medications. However, physician communication of basic prescription information to patients is notoriously spotty, and physicians do not seem to make a greater effort to communicate with less educated patients (11). Finally, in the past decade, the FDA has required the development of patient-directed medication guides for particularly high-risk medications (often those with "black box warnings"). In a recent study of a representative sample of such guides, none met federal readability recommendations, and nearly all were unsuitable for the average user (12). Nonetheless, the FDA's action to require medication guides at least provides a regulatory template within which we can operate as we develop more effective strategies to ensure effective and consistent prescription communication.

Why don't we have a standardized system to transmit medication instructions that all patients can understand and act on? Perhaps it is because the field of health literacy is in its infancy and research findings have not yet been translated into policy changes. To date, we have invested too little in generating the scientific evidence to show that 1 labeling practice or communication system is superior to another (5, 9). Furthermore, because the framework for regulating the content of prescription labels and accompanying materials is inadequate, patients and clinicians are suffering. With this study, the genie is out of the bottle.

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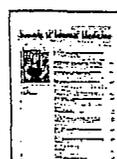
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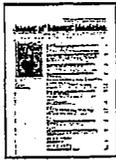
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To err is human: Patient misinterpretations of prescription drug label instructions

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Abstract

Objective: To examine the nature and cause of patients' misunderstanding common dosage instructions on prescription drug container labels.

Methods: In-person cognitive interviews including a literacy assessment were conducted among 395 patients at one of three primary care clinics in Shreveport, Louisiana, Jackson, Michigan and Chicago, Illinois. Patients were asked to read and demonstrate understanding of dosage instructions for five common prescription medications. Correct understanding was determined by a panel of blinded physician raters reviewing patient verbatim responses. Qualitative methods were employed to code incorrect responses and generate themes regarding causes for misunderstanding.

Results: Rates of misunderstanding for the five dosage instructions ranged from 8 to 33%. Patients with low literacy had higher rates of misunderstanding compared to those with marginal or adequate literacy (63% versus 51% versus 38%, $p < 0.001$). The 374 (19%) incorrect responses were qualitatively reviewed. Six themes were derived to describe the common causes for misunderstanding: label language, complexity of instructions, implicit versus explicit dosage intervals, presence of distractors, label familiarity, and attentiveness to label instructions.

Conclusion: Misunderstanding dosage instructions on prescription drug labels is common. While limited literacy is associated with misunderstanding, the instructions themselves are awkwardly phrased, vague, and unnecessarily difficult.

Practice implications: Prescription drug labels should use explicit dosing intervals, clear and simple language, within a patient-friendly label format. Health literacy and cognitive factors research should be consulted.

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Keywords: Prescription; Drug; Medication; Dosage; Instructions; Warnings; Misunderstanding; Health literacy

1. Introduction

According to the Institute of Medicine (IOM) 2006 report, *Preventing Medication Error*, more than one third of the 1.5 million adverse drug events that occur in the United States each year happen in outpatient settings [1]. Problems with

prescription drug labeling were specifically cited as a leading root cause of a large proportion of outpatient medication errors and adverse events, as patients may unintentionally misuse a prescribed medicine due to improper understanding of instructions. The prescription container label, in particular, is often the sole, tangible source of specific dosage/usage instructions given to and repeatedly used by the patient. Despite their potential value, problems are clearly evident with container labels [2–5]. Dosage instructions on the label can vary, as they are dependent on what the prescribing physician writes, as well as how the pharmacist interprets them [6,7]. With little guidance available to providers, instructions

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commonly found on prescription drug labels may not always be clearly stated. In prior studies, half of adults in outpatient primary care settings misunderstood one or more primary and auxiliary prescription instructions and warnings they encountered [2–4]. Patients with limited literacy skills and those managing multiple medication regimens made more errors.

Improving prescription drug container label instructions is both a matter of health literacy and *patient safety* [1,8,9]. This is especially true since other sources of patient medication information are insufficient. Prior studies have found that physicians and pharmacists frequently miss opportunities to adequately counsel patients on newly prescribed medicines [10–12]. Other supplementary sources, such as consumer medication information sheets and FDA-approved medication guides that may be dispensed with a prescribed medicine are too complex and written at a reading grade level too high for the majority of patients to comprehend [13]. As a result, these materials are not read [13–15]. Patients' ability to decipher the brief text instructions on the container label itself takes on greater importance to ensure proper use.

1.1. Sources of comprehension failure: a conceptual model

The ability to read and understand prescription label instructions may appear to be a simple task, yet van den Broek & Kremer describe various sources of failure in comprehension that are particularly applicable for the abbreviated text on container labels [16–18]. These include readers' cognitive characteristics, constraints on the reading situation, and the nature of the presented health information. The influence of the latter set of factors is particularly applicable to the truncated text on container labels, and may include text complexity, formatting and organizational issues. Failure may also occur if instructions are not explicit, or if purpose is not evident, such as providing an indication for use on the bottle label itself (i.e. "take for diabetes"), which is not part of routine practice for either physicians to add to the script or pharmacists to include on the dispensed container label. The presence of distracting information may limit comprehension of the pertinent dosage/usage instructions and auxiliary warnings that patients need to understand in order to safely use a medicine. This might include the more prominently displayed pharmacy logo, phone number, serial number and drug code, and other provider-directed content on the label.

1.2. Purpose of study

The purpose of this study was to investigate how patients approached and interpreted prescription drug label instructions, and to document the nature of misunderstanding that may contribute to the high prevalence of medication error. We took a health literacy perspective towards the problem of misunderstanding prescription medication instructions. From this view, it was hypothesized that misunderstanding would be the result of both patient literacy limitations and the ambiguity and inherent difficulty of label instructions themselves.

2. Methods

The methods and quantitative findings from this research study that detail the relationship between patient literacy and misunderstanding prescription label instructions have been reported upon previously [2].

2.1. Subjects

Subjects were adult patients who attended one of three outpatient primary care clinics serving low-income community populations in Shreveport, Louisiana, Jackson, Michigan and Chicago, Illinois. Recruitment took place over consecutive summers beginning July 2003. Patients were eligible if they were 18 or older, and ineligible if the clinic nurse or study research assistant identified a patient as having one or more of the following conditions: (1) blindness or severely impaired vision not correctable with eyeglasses; (2) deafness or hearing problems uncorrectable with a hearing aid; (3) too ill to participate; (4) non-English speaking. Institutional Review Boards at each location approved the study.

A total of 458 patients were approached in the order they arrived at the clinics and prior to the medical encounter. Twelve patients refused participation 26 were deemed ineligible, and 25 had incomplete information, leaving 395 patients participating in the study. A response rate was determined following American Association for Public Opinion Research (AAPOR) standards; 92% of approached eligible patients participated in the study [19].

2.2. Structured interview and literacy assessment

A structured, cognitive interview protocol was developed to assess understanding of different label dosage instructions placed on five common prescription medications. This process has been widely used by the research team, among others [2–4,20,21]. These included two antibiotics (amoxicillin (for pediatric use) and trimethoprim), an expectorant (guaifenesin), an anti-hypertensive, channel blocking agent (felodipine), and a diuretic (furosemide). A trained research assistant (RA) at each site administered the interview to consenting patients that included self-report of sociodemographic information (age, gender, race/ethnicity, education) source of payment for medications, and number of prescription medications currently taken daily. Actual prescription pill bottle containers with labels were then shown to patients, one at a time, for review. Once patients provided their interpretation on all of the labels, the RA administered a brief literacy assessment, ending the interview.

2.2.1. Understanding of medication primary container label instructions

To assess patient understanding of prescription medication instructions included on the container primary labels, the RA asked "how would you take this medicine?" This question was often followed by one to two short probes (i.e. "anything else?", "exactly how would you take the pills [medicine]?") to

initiate more detailed description of administration. The RA documented the verbatim response on a separate form. Responses to the instructions for the five medications ($N = 1,975$) were then independently rated correct or incorrect by three general internal medicine attending physicians from three different academic medical centers. Each physician rater was blinded to all patient information and was trained to follow stringent coding guidelines agreed upon previously by the research team. Correct scores were to be given only if patient responses included all aspects of the label's instruction, including dosage, timing, and if applicable, duration.

Inter-rater reliability was high ($\kappa = 0.85$). The 147 responses (7.4%) that received discordant ratings between the three reviewers were sent to an expert panel that included three primary care physicians and two health literacy experts for further review. Each panel member, also blinded to patient information, independently reviewed and coded responses as correct or incorrect. For 76.2% ($n = 112$) of the 147 responses, consensus was achieved among the five-member panel. A majority rule was imposed for the remaining responses ($n = 35$).

2.2.2. Attendance to auxiliary (secondary) warning label instructions

Attentiveness to the auxiliary or "secondary" warning label on the pill bottles by patients was also investigated. These labels provide supplementary instructions supporting the safe administration of the medications, such as "take with food" or "do not chew or crush, swallow whole." RAs were instructed during the interview to document (yes or no) whether patients either attempted to interpret the auxiliary label along with the primary label, or physically turned the bottle to inspect the color stickers on which these warning messages are placed.

2.2.3. Reading versus demonstrating instructions

Patients were further tested on their functional understanding of the primary label instruction for guaifenesin ("take two tablets by mouth twice daily"). They were asked to demonstrate how many pills were to be taken on a daily basis. After patients answered the first question, "how would you take this medicine?" they were asked, "show me how many pills you would take [of this medicine] in one day". The container was filled with candy pills for patients to dispense and count out the correct amount. Responses were coded as correct if their answer was "four", and incorrect if any other response was provided.

2.2.4. Literacy assessment

Patient literacy was assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a reading recognition test comprised of 66 health-related words [22]. The REALM is the most commonly used test of patient literacy in medical settings [23]. In healthcare studies where patients need only be categorized as low (scores 0–44), marginal (scores 45–60) or adequate (scores 61–66) readers, the information provided by the REALM is generally sufficient. The REALM is highly correlated with standardized reading tests and the Test of Functional Health Literacy in Adults (TOFHLA) [23,24].

2.3. Analysis plan

Mixed methods were used. Chi-square tests were calculated to examine bivariate associations between health literacy (adequate, marginal, low), sociodemographic variables (age, gender, race, education, number of medications currently taken), and understanding (yes or no) primary label instructions and attendance (yes or no) to the auxiliary warning instructions. Quantitative analyses were conducted using Stata 9.0 (College Station, TX).

For qualitative analyses, a grounded theory approach was used to explore the basis for patients' misunderstanding of each of the five dosage instructions using their documented verbatim responses [25]. Grounded theory is a systematic method for generating theoretical statements from case studies. Based on our qualitative, cognitive interviews, grounded theory guides the inductive process of organizing content derived from patient responses. Patient misunderstandings were first reviewed by investigators (MSW, TCD, RMP) and classified using both selective and *in vivo* coding schemes [26]. Data were then reduced by one of the lead investigators (MSW) through detailed a priori coding to classify the reason for error in understanding (label language, complexity, explicitness of instruction, presence of distracters, and label familiarity). These predetermined codes were based on previous studies and the conceptual model of sources of comprehension failure [16]. The reduced data was confirmed based on the a priori coding scheme, and *in vivo* codes were allowed to develop based on emergent themes in responses. Agreement among investigators was sought prior to classifying patient responses with any new themes. Open coding techniques were used [27]. Qualitative analyses were supported by NVivo 7 software (QSR International; Doncaster, Australia).

3. Results

3.1. Description of study sample

Table 1 describes the study sample in detail, stratified by literacy. The mean age was 45 years (S.D. = 14; range 19–85 years). Fifty-seven percent of patients were recruited from Shreveport, Louisiana, 25% from Jackson, Michigan, and 18% from Chicago, Illinois. Two-thirds (68%) were female, approximately half of patients were African American (47%) and half white (48%), and 28% reported less than a high school level of education attainment. Patient literacy was limited; 19% were reading at or below a sixth grade level (low literacy) and 29% were reading at the seventh to eighth grade level (marginal literacy).

Patients were taking an average of three prescription medications, and 23% lacked insurance to cover these prescribed drugs. The physician was the most likely source of medication information for patients (71%). Low literacy was associated with older age ($p < 0.001$), African American race ($p < 0.001$), and less education ($p < 0.001$); differences were also noted by site ($p < 0.002$). No significant differences

Table 1
Sample characteristics stratified by literacy level

Characteristic	Literacy level			p-Value
	Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Age, mean (S.D.)	43 (14)	45 (14)	51 (13)	<0.001
Female (%)	60	68	71	0.25
Race (%)				<0.001
African American	29	64	73	
White	65	33	25	
Other	6	4	1	
Education (%)				<0.001
Grades 1–8	2	3	15	
Grades 9–11	12	35	41	
Completed High School/GED	43	45	40	
>High School	44	18	4	
Payment source for medications (%)				0.43
Private insurance	19	14	12	
Medicaid	46	56	59	
Out of pocket	25	20	23	
Other	10	11	7	
Source of support for understanding prescription medication instructions (%)				
Physician	71	72	68	0.81
Nurse	10	12	19	0.12
Pharmacist	45	53	57	0.35
Family member	22	9	4	<0.001
Number of medications taken daily, mean (S.D.)	2 (1)	2 (1)	1 (1)	0.37
Misunderstanding 1 or more dosage instructions (%)	38	51	63	<0.001

were reported between literacy, gender, source of payment for medications, or number of prescription medications taken daily.

3.2. Prevalence and associations of misunderstanding dosage instructions

Overall, 46% of patients misunderstood one or more dosage instructions. The prevalence of misunderstanding among patients with adequate, marginal and low literacy was 38%, 51%, and 63%, respectively ($p < 0.001$). The rates of misunderstanding individual labels ranged from 8% for the instructions on the label for Felodipine (“Take one tablet by mouth once each day”) to 33% for the instructions for Trime-thoprim (“Take one tablet by mouth twice daily for 7 days”; Table 2). Patients with low literacy were less able to understand instructions compared to those with adequate literacy.

3.3. Reading versus demonstrating dosage instructions

The ability to read dosage instructions did not always preclude the ability to demonstrate a functional understanding of prescription drug use (Fig. 1). When asked how pills were to be taken in a given day for the instruction, “Take two tablets by mouth twice daily”, one third of patients were unable to correctly state “four pills”. Rather, the most common incorrect answer was “two pills”. Patients with low literacy were less able to state the correct number of pills taken daily compared to those with marginal and adequate literacy (35% versus 63%

versus 80%, $p < 0.001$). No statistically significant associations were noted by number of medications or age.

3.4. Nature of patient misunderstanding label dosage instructions

The 374 (18.9%) total responses that were coded as incorrect were qualitatively reviewed and coded using the pre-selected

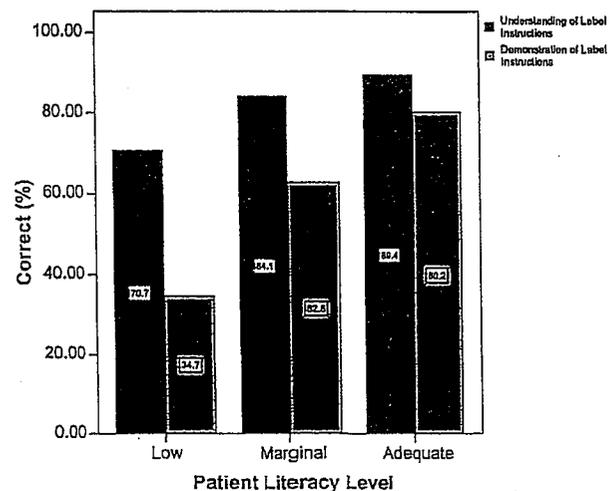


Fig. 1. Rates of correct understanding vs. Demonstration for the primary label instruction, “Take two tablets by mouth twice daily”.

Table 2
Rates of understanding primary label instructions and attendance to auxiliary warnings, stratified by literacy level

Generic drug name (dose)	Primary instructions and auxiliary warnings ^a	Literacy level			p-Value
		Adequate (n = 207)	Marginal (n = 113)	Low (n = 75)	
Amoxicillin					
Correctly interpreted primary label	Take one teaspoonful by mouth three times daily	86	66	59	<0.001
Attended to auxiliary label(s)	Refrigerate, shake well, discard after [date]	5	4	0	0.13
Trimethoprim					
Correctly interpreted primary label	Take one tablet by mouth twice daily for 7 days	73	66	52	<0.001
Attended to auxiliary label(s)	You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medication	8	7	1	0.14
Guaifenesin					
Correctly interpreted primary label	Take two tablets by mouth twice daily	89	84	70	<0.001
Demonstrated understanding		80	63	35	<0.001
Attended to auxiliary label(s)	Medication should be taken with plenty of water	14	7	0	<0.001
Felodipine					
Correctly interpreted primary label	Take one tablet by mouth once each day	95	88	87	0.03
Attended to auxiliary label(s)	Do not chew or crush, swallow whole	13	11	4	0.11
Furosemide					
Correctly interpreted primary label	Take one tablet in the morning and one at 5 p.m.	91	91	83	0.09
Attended to auxiliary label(s)	Do not take dairy products, antacids, or iron preparations within 1 h of this medication	15	9	3	0.01

^a Included behavioral demonstration for Guaifenesin only.

coding scheme of likely causes for error in interpretation (Table 3). One emergent cause, referred to as attentiveness to label instructions, was included in addition to the predetermined causes of label language, complexity of instructions, implicit versus explicit dosage, presence of distracters, and label familiarity.

3.4.1. Label language

Certain common phrases used on medicine labels seemed confusing and unfamiliar to patients within the context of the instruction itself. Errors that appeared to be the result of label language were most prevalent on the instruction, "Take two tablets by mouth twice daily". The repetitiveness between dosage ("two") and frequency ("twice") often led to the common interpretation "Take a pill twice a day", whereas dosage would go ignored. This was confirmed in the follow-up demonstration task, "How many pills would you take in one day" with the common incorrect response of "two" (72% of incorrect responses).

Many terms commonly used on prescription labels had exceptionally poor recognition rates by patients. Specifically, among patients reading at the 6th grade level and below

(n = 75), 79% of these patients could not recognize and pronounce "antibiotic", 73% "orally", 70% "teaspoonful", 48% "medication", 45% "prescription", and 35% the word "dose". Poor word recognition may have contributed to patients misreading words on labels, such as "tablespoon" instead of "teaspoon". This accounted for 9% of errors (n = 34).

Interestingly, feedback documented by RAs from patient interviews recommended the use of numeric symbols within the instruction rather than the written word equivalent (i.e. "2" versus "two") for further reading ease.

3.4.2. Complexity of instructions

Instructions ranged in complexity, both with regards to the calculation of the number of pills and times to be taken daily (i.e. "Take one pill by mouth once each day" versus, "Take two tablets by mouth twice daily") and in the amount of content to be retained (dosage, frequency, and/or duration, as in "Take one tablet by mouth twice daily for seven days"). Patients found simpler dosing regimens to be easier to understand, while more complex regimens had more errors in their interpretation (Table 2). Eleven percent (n = 41) of incorrect responses

Table 3
Examples of the most common misunderstandings, by dosage instruction

Dosage instruction	Misunderstanding
Take one teaspoonful by mouth three times daily	Take three teaspoons daily; take three tablespoons every day; you should drink it three times a day
Take one tablet by mouth twice daily for 7 days	Take two pills a day; take it for 7 days; take one every day for a week; I'd take a pill every day for 7 days
Take two tablets by mouth twice daily	Take it every 8 h; take it every day; take one every 12 h
Take one tablet by mouth once each day	Take it as directed
Take one tablet in the morning and one at 5 p.m.	I would take it every day at 5 o'clock; take it at 5 p.m.

omitted duration of use from the specified instruction. The inclusion of duration on the label instruction also led to a loss of other aspects of the instruction. For the label, “Take one tablet by mouth twice daily for seven days”, the second most common error made was an incorrect interpretation of dosing frequency ($n = 34$; i.e. “I’d take a pill every day for seven days”).

3.4.3. Implicit versus explicit dosage intervals

Patients were better able to interpret more explicit dose frequencies as in “Take one tablet in the morning and one at 5 p.m.” (90%), compared with the more vague “Take two tablets by mouth twice daily” (83%), and “Take one teaspoonful by mouth three times daily” (73%). For the latter two instructions, patients varied in their interpretation of “twice daily” and “three times daily”. For example, patients interpreted “twice daily” as both “every 8 h” and “every 12 h”, and “three times daily” ranged from “every 4 h” to “every 8 h”.

3.4.4. Presence of distracters

In 6% ($n = 21$) of the incorrect responses, patients had difficulty navigating the label content itself and identifying the instructional content. Rather than describing the dosage of the medicine, responses detailed provider-directed content that surrounded and may have obscured the dosage instructions (i.e. stated combinations for the name of the drug, physician’s name, refill and date). Patients turned the bottle to acknowledge auxiliary warnings, as they were also recited along with the provider-directed content instead of the dose and frequency for use (i.e. “Take it with Food”; “I would take them every day but not with dairy products, antacids, or iron preparations”; “I would stay out of the heat”).

3.4.5. Label familiarity

Auxiliary instructions are often placed as stickers surrounding or in back of the primary label. Very few patients were familiar with these instructions. Less than 10% of patients physically turned any of the bottles to examine these stickers (Table 2). Sixteen percent of patients attended to at least one auxiliary instruction, and 2% made the action part of the routine inspection of the prescription bottle for all five medicines.

3.4.6. Attentiveness to label instructions

Several patients provided detailed responses that verbally “implemented” the regimen (“It’s an antibiotic, and I would take one pill in the morning when I wake, and another pill after dinner—I would do that for a week”). Even though tasks were not timed, many patients appeared to have responded quickly, and by doing so made simple mistakes. When answers were provided in haste, patients often skipped or omitted dosage information (“Take two a day”; “I’d take three pills daily”).

Patients with adequate literacy were more likely than patients with low literacy to omit the duration of use for the instruction, “Take one tablet by mouth twice daily for seven days” ($n = 41$; 44% versus 18%, $p < 0.001$). They were equally likely to make errors wherein dose and interval were inverted for the same instruction and for “Take one teaspoonful by mouth three times daily” ($n = 60$; 39% versus 43%, $p = 0.65$).

Mistaking “teaspoon” for “tablespoon” was more common among patients with limited literacy, but one third of these errors were made by patients with adequate literacy ($n = 12$).

4. Discussion and conclusion

4.1. Discussion

Although there may be a finite number of ways a physician can prescribe a medicine, the same dose and frequency schedule may be written in several different ways (i.e. every 12 h, twice daily, in the morning and evening, 8 a.m. and 5 p.m., etc.). This becomes especially problematic as many patients may have more than one healthcare provider prescribing medicine [28]. The ability to follow instructions is crucial in ambulatory care, since the patient assumes the bulk of responsibility for medication safety. Our present research offers timely evidence classifying the nature and causes of patient misunderstanding of commonly-written dosage instructions that could potentially lead to errors and adverse events [1].

Our prior studies have repeatedly shown that limited literacy significantly impairs one’s ability to read and demonstrate an understanding of instructions and warnings found on commonly prescribed medicines [2–5]. While individual differences in reading ability may be related to a greater risk for misunderstanding, problems are clearly evident with the label itself, and the implicit nature and syntax of instructions. Improving the reading ease of dosage instructions is therefore warranted.

Many patients might presume the task of reviewing prescription drug labels to be overly simple. As a result, they may not allot adequate time to process and understand the information. This could explain why a majority of patients were able to read back the instruction, while far fewer could demonstrate a proper understanding when probed further. An earlier study by Morrell and colleagues found that older adults, who on average manage more medications than younger patients, spent less time processing dosage instructions and consequently made more errors in interpretation [29]. These mistakes could lead to compromised health outcomes, such as under-treatment (i.e. taking two rather than four pills a day) or possible harm (i.e. taking too much of a medicine or not attending to warnings).

The manner in which physicians write dosage instructions requires patients to make inferences as to when to specifically implement the prescribed regimen (i.e. Take two tablets by mouth twice daily; Take one teaspoon by mouth three times daily). Our findings suggest that patients’ interpretations may widely vary when dosing intervals are presented in vague terms as “twice daily” or “three times daily”, which may stray from the original intent of the prescribing physician. Park and colleagues suggest that making inferences is a complex cognitive process, and the elderly may have greater difficulty when faced with these types of tasks [30].

Some misunderstandings appeared to be the result of container label organization. The prescription labels were

typical of the order in which most pharmacies present drug information, often emphasizing (by yellow highlight, large font, bold text) content that is irrelevant to the patient. The inclusion of such distracting information may be particularly problematic for individuals with limited literacy, who face greater reading difficulty in less familiar and technical contexts [31].

4.2. Limitations

We investigated patient understanding of prescription drug label instructions, not whether a medication error occurred. Patients' actual prescription drug-taking behaviors were not examined. Patients' motivation, concentration and comprehension might have been greater if they reported on their own medicine. Similarly, we interviewed patients before their medical encounter. It is also possible that the reason for the medical visit altered patients' concentration, although patients were offered the opportunity to refuse and anyone too acutely ill was not interviewed. We also did not conduct a chart review, and thereby could not identify if patients had actual experience with any of the study medications. Only patients who were proficient in the English language were also included. This was due in part to criteria for using the Rapid Estimate of Adult Literacy in Medicine (REALM) as our literacy assessment. Further research should investigate the effect of cultural differences and language barriers on misunderstanding prescription drug label instructions.

4.3. Conclusion

Prescription drug labels often are the only print source of dosage instructions received by patients. Given the tangible nature of the prescription bottle, these label instructions may be the 'last line' of informational support detailing how and when a patient should administer a prescribed medicine. Yet many of the common phrases used to describe dosage instructions are inadequately written and contribute to misunderstanding. Patients with limited literacy may face greater difficulty when attempting to infer and interpret instructions. Research is needed to evaluate the use of enhanced strategies of communicating dosage information and warnings for improving comprehension among patients across all literacy levels. In the end, all patients would benefit from more clearly presented prescription drug information.

4.4. Practice implications

Unfortunately, there are only minimal standards and regulations set by state boards of pharmacy that dictate any recommendations for content and organization of prescription drug labels [32]. As such, rules vary by state. Our research study provides initial guidance for improving the dosage instructions on prescription bottles, and 'best practices' can be derived from our study. These are supported by health literacy principles and cognitive/human factors research [31–33].

4.4.1. Use explicit language when describing dose intervals.

Three previous studies also found more explicit instruction improved comprehension [34–36]. This might help pace patients and allow them to direct necessary attention for processing each component of dosage. For instance, the actual dose (number of pills to be taken at a time) could be separated from the interval (times per day), as in the example "Take 2 tablets in the morning, and take 2 tablets in the evening."

4.4.2. Organize label in a way to minimize distracters

The label should be re-organized, separating distracting elements that often comprise provider-directed content (pharmacy logo, drug serial number, pharmacy address and phone number) away from dosage instructions. Auxiliary instructions might also be placed in a set location (i.e. backside of label), instead of being stuck on in various locations, so patients can have routine expectations of their location.

4.4.3. Simplify language

Doak, Doak, and Root (1993) offer guidance as to how to make health information more suitable for patients with limited literacy, such as dosage instructions and warning messages on auxiliary labels. The use of numbers rather than the text equivalent should be promoted for reading ease, and unclarified medical jargon (i.e. antibiotic) or awkward terms (i.e. twice) avoided.

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Prescription for Improving Patient Safety: Addressing Medication Errors

An Executive Summary of the The Medication Errors Panel Report

Pursuant to California Senate Concurrent Resolution 49 (2005)

About the Medication Errors Panel:

Recognizing the significant and growing public health concern of medication errors, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution (SCR) 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to study the causes of medication errors in the outpatient setting and to recommend changes to the healthcare system that would reduce errors associated with prescription and over-the-counter medication use.

The Medication Errors Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, Panel members gave a tremendous effort to this study and met at the state capitol 12 times to hear and discuss testimony from 32 invited speakers who included many widely respected state and national leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

The following is the Executive Summary of the Panel's report complete with its consensus recommendations.

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing¹, transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds \$177 billion per year.² Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.³ Extrapolating these figures to California suggests that on an annual basis, the problem costs our state \$17.7 billion and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

Reducing Errors through a “Systems Approach”

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual “wrong doers,” but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took a “systems approach” for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/ processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

- 1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).
- 2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.
- 3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.
- 4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

- 1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.
- 2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and provider licensing/oversight Boards.
- 3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements**, with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

- 1) *Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.*
- 2) *Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.*
- 3) *Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.*
- 4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

- 5) *Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.*
- 6) *Establish an on-going public education campaign to prevent medication errors,*

targeting outpatients and persons in community settings.

- 7) *Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.*

C. **Pharmacy Standards and Incentives**, with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

- 8) *Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.*
- 9) *Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.*

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

- 10) *Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.*

E. **Research**, with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

- 11) *Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.*

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

- 12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

Acknowledgements

This project has benefited from the generous contributions of many individuals and organizations. In particular the Panel would like to thank former Senator Jackie Speier who authored the resolution; Lynn Rolston of the California Pharmacists Association which sponsored SCR 49 (2005); Judith Babcock of the Pharmacy Foundation of California which managed funding for the Panel and arranged for administrative support; the Kaiser Family Foundation and California HealthCare Foundation which funded the Panel; Sandra Bauer, Michael Negrete and Ronald Spingarn who provided staff support for the Panel; and of course all of the Panel members listed on the following page with special thanks to Carey Cotterell for helping to write this report.

End Notes and References

¹While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

²Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc* 2001;41:192-9.

³Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series*. P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

*Prescription for
Improving Patient Safety:
Addressing Medication Errors*



A report from
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Pursuant to California Senate Concurrent Resolution 49 (2005)

March 2007

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EXECUTIVE SUMMARY

The Problem of Medication Errors

A medication error is any preventable event occurring in the medication-use process, including prescribing, transcribing, dispensing, using and monitoring, that results in inappropriate medication use or patient harm. These errors and their consequences present a significant public health threat to Californians.

While most consumers and healthcare providers do not often associate poor health outcomes with adverse drug events – frequently the result of medication errors – the human and financial costs of the problem are staggering.

The most recent estimate of costs associated with drug-related morbidity and mortality in the US exceeds \$177 billion per year. Amazingly, this amount is significantly greater than the amount actually spent on prescription drugs during the same year. In terms of patient harm, the Institute of Medicine projects that at least 1.5 million Americans are sickened, injured or killed each year by medication errors. Extrapolating these figures to California suggests that on an annual basis, the problem costs our state \$17.7 billion dollars and causes harm to 150,000 Californians.

Perhaps the most concerning aspect of these errors is that the tremendous human and financial costs are not the result of some serious disease, but rather, well-intentioned attempts to treat or prevent illness.

In an effort to address this significant and growing problem, in 2005 Senator Jackie Speier authored Senate Concurrent Resolution 49, sponsored by the California Pharmacists Association. This resolution, adopted September 14, 2005, called for the creation of an expert panel to 1) study the causes of medication errors in the community setting, and 2) recommend changes in the health care system that would reduce errors associated with over-the-counter and prescription medications in the outpatient setting.

The Panel, assembled in 2006, consisted of two Senators, two Assembly members and 13 persons representing academia, consumer advocacy groups, health professions (medicine, nursing, public health and pharmacy), health plans, the pharmaceutical industry, and community pharmacies. Throughout 2006, the Panel met at the state capitol 12 times to hear and discuss testimony from 32 leaders in the fields of pharmacy practice, medicine, medical technology, healthcare regulation, academia, and the pharmaceutical industry.

Reducing Errors through a “Systems Approach”

Testimony provided to the Panel indicated that efforts to address errors are best targeted not at a particular group of individual “wrong doers,” but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. Consequently the Panel took

a “systems approach” for studying the problem and developing its recommendations.

After spending considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component, the Panel identified four key medication-use systems/processes and three key stakeholder groups which served as the focus of its recommendations.

Key Processes and Stakeholders

The four key processes which the Panel believes could be better designed to reduce and prevent medication errors are those related to:

- 1) **The transcription and transmission of prescriptions** (i.e. the methods prescribers use to document a prescription order and communicate that order to the pharmacy where it will be filled).
- 2) **The education of the consumer** regarding the purpose of the treatment, the effective use of the medication, and the monitoring of signs and symptoms that may indicate efficacy or toxicity.
- 3) **Healthcare provider payments and incentives** which can directly or indirectly influence providers to pursue behaviors designed to reduce medication errors.
- 4) **Healthcare provider training and licensure** which could foster a better understanding among providers about the seriousness of medication errors and the behaviors to adopt that will reduce them.

The three key stakeholder groups which the Panel believes will be critical in affecting the necessary changes to these processes are:

- 1) **Consumers and consumer oriented organizations** such as the California Department of Consumer Affairs; advocacy organizations (e.g. AARP, American Heart Association); community-based organizations; and private and public foundations.
- 2) **Healthcare providers and related organizations** such as academic institutions, professional societies and advocacy groups, and licensing/oversight Boards.
- 3) **Healthcare purchasers, payers, regulators and related organizations** such as the State of California, its Department of Health Services and the Medi-Cal program; private purchasers of health care such as employers; commercial insurance companies which administer health benefits for both public and private sector purchasers; the

California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Based on the analysis of these four key processes and three key stakeholder groups, the Panel developed 11 consensus recommendations within five subject areas, and a twelfth recommendation to further consider and address issues that went beyond the scope of the Panel's purpose.

Recommendations

A. **Communication Improvements**, with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients. Specific recommendations are:

- 1) *Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies to use electronic prescribing.*
- 2) *Require that the intended use of the medication be included on all prescriptions and require that the intended use of the medication be included on the medication label unless disapproved by the prescriber or patient.*
- 3) *Improve access to and awareness of language translation services by pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.*
- 4) *Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain medication consultation from a pharmacist.*

B. **Consumer Education** to increase consumer awareness regarding the proper use – and dangers of misuse – of prescription and over-the-counter medications. Specific recommendations are:

- 5) *Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.*
- 6) *Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.*

7) *Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.*

C. **Pharmacy Standards and Incentives**, with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety. Specific recommendations are:

- 8) *Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.*
- 9) *Establish standards for Medication Therapy Management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers.*

D. **Training and Education for Healthcare Providers** on various medication safety practices. The specific recommendation is:

- 10) *Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.*

E. **Research**, with a focus on obtaining information about the incidence, nature, and frequency of medication errors in the community setting. The specific recommendation is:

- 11) *Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.*

In addition to these five subject areas, the Panel identified a sixth that needs to be addressed but which it determined was beyond its scope. This issue relates to the many obstacles that pharmacists face in providing drug consultation to their patients which encompasses a variety of factors such as manpower shortages and the lack of payment systems to cover the time and expense associated with these tasks. Before additional duties can be imposed on pharmacists practicing in outpatient settings, the Panel recognizes that these issues must be addressed. Therefore the Panel put forth a twelfth recommendation:

- 12) *Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.*

SECTION I: REPORT OF THE PANEL

Background & Overview

The Problem of Medication Errors

For the purpose of its work, the SCR 49 Panel defined a medication error as “any preventable event occurring in the medication-use process, including prescribing¹, transcribing, dispensing, using and monitoring, which results in inappropriate medication use or patient harm.”

Errors involving prescription and over-the-counter medications represent an enormous public health problem. When an error occurs, the best possible outcome is for a medication to simply not elicit an adverse result. Even under this best-case scenario, medication errors have a significant negative impact on the US healthcare system, contributing to increasing costs for consumers, employers and other persons who pay for health care. Even worse than the financial cost is the harm to consumers’ health and well-being caused by medication errors, which can range from mild to life-threatening and even death.

The scope and severity of medication errors and the related consequences have been documented by many health researchers. For the year 2000, experts estimated the overall cost of drug-related morbidity and mortality to be in excess of \$177.4 billion.² That amount greatly exceeds the \$120.8 billion spent on prescription drugs during that year.³ In terms of patient harm from medication errors, the Institute of Medicine (IOM) estimates that at least 1.5 million Americans are sickened, injured or killed each year by medication errors.⁴ Extrapolating these figures to California suggests that on an annual basis, the problem costs our state \$17.7 billion dollars and causes harm to 150,000 Californians.

¹While the Panel identified drug and dose selection as a process (i.e. prescribing) where errors can occur, its analysis and recommendations were focused on the areas of the medication-use process that occur *after* the point where prescribers consciously make such decisions.

²Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: updating the cost-of-illness model. *J Am Pharm Assoc* 2001;41:192-9.

³US Office of the Actuary National Health Expenditure Data. 2000.

⁴Institute of Medicine (IOM). (2007). *Preventing medication errors: Quality chasm series*. P. Aspden, J. Wolcott, J. L. Bootman, & L. R. Cronenwett (Eds.). Washington, DC: The National Academies Press.

Perhaps the most disturbing aspect of medication errors is that these tremendous human and financial costs are not the result of some serious disease, but rather well-intentioned efforts to treat or prevent illness.

The Importance of Addressing Errors in Community Settings

When imagining places where medication is dispensed and taken or “administered,” many people think of hospitals or other health care facilities. But, in fact, the vast majority of medications are taken by out-patients in “community settings,” including homes, schools, offices, independent living facilities, and children or adult day care centers. Last year, over 5,000 licensed “community” pharmacies in California filled about 400 million prescriptions for community dwelling individuals.

In community settings a person often has a prescription written by his or her health care provider, usually a doctor, and has it filled at a community pharmacy, often a neighborhood drug-store, supermarket or other retail outlet. After a consumer receives medication from a community pharmacy, they or their caregiver is largely left on their own to take/administer the medication and monitor for signs and symptoms of efficacy or toxicity.

Compounding the problem of medication errors in community settings are the increasing numbers of consumers that buy and use over-the-counter medicines, herbals or other alternative treatments. While many consumers believe the “all-natural” or non-prescription status of these therapies suggests inherent safety, these products do have the potential to cause adverse effects and interact with prescription medications or each other.

In spite of incredible potential for medication errors to occur in the community setting, much of the attention paid to the problem thus far has focused on hospital and other institutional settings. In fact, there are already many state and national efforts underway aimed at reducing errors in these settings. This, coupled with evidence regarding the magnitude of the problem outside of institutional settings, led the Panel to focus on making recommendations about medication errors that occur in the community.

U.S. and California Medication Error Data

There is no organization responsible for maintaining comprehensive data about medication errors in the United States or California. Several national organizations collect information related to medication errors, but their data is not comprehensive and has many limitations – it may focus on health care professionals, not consumers or on health care facilities, not community settings – or organizations may mix data about medication errors with other data – for example, data about “medical” errors or “adverse drug events.” Also, organizations often define “medication error” differently, creating challenges with combining or comparing data.

Finding medication error data specific to California is even more challenging. One could extrapolate from data at the State’s Board of Pharmacy and Medical Board, although neither body is charged with actively monitoring medication errors or collecting comprehensive error data. They simply document and respond, as appropriate, to complaints made by health care professionals or consumers about medication errors and other issues related to their areas of oversight.

California-specific research studies identified by the Panel did not include information about community-settings, only hospitals and residential care settings. National organizations, including the federal Food and Drug Administration (FDA) and the nonprofit Institute for Safe Medication Practices (ISMP), contacted by the Medication Errors Panel staff were unable to report medication error data specific to California.

Types of Medication Errors

In the community setting, there are three general types of medication errors that can occur: those related to the prescribing process; those that occur when the medication is dispensed at the pharmacy; and those related to the consumer’s use of the medication.

Prescribing Errors

The first step in obtaining a prescription medication occurs when a consumer visits a physician, or other health care professional with prescribing authority, and receives a prescription.

In order to avoid selecting a drug that could be inappropriate or harmful to a patient, it is important for

the prescriber to have access to the patient’s complete health information record at the time the patient is being seen. The patient information should include all medicines the patient is taking, lab test results, other physicians the patient has seen, and any past hospitalizations or drug allergies.

The Panel heard testimony that prescribers in California often do not have ready access to vital patient information at the time that a prescription is written. This is largely due to continued reliance on paper-based documentation systems which lend themselves to having important patient information be missing, inaccessible, illegible and inaccurate – all of which can contribute to prescribing errors.

While the Panel identified drug and dose selection as a place where errors can occur, it decided to focus its analysis and recommendations on areas of the medication-use system that occur *after* the point where such decisions are made. From a prescribing standpoint, this includes practices related to the transcription and transmission of prescription information which may contribute to patients not receiving the intended medication or dose. More information on these types of errors is included in the next section of this report.

Dispensing Errors

Dispensing errors occur when a patient is given a medication other than the one intended by the prescriber. These types of errors are often the result of sound/alike or look/alike drugs, according to testimony provided by Patricia Harris, Executive Officer of the California Board of Pharmacy. Ms. Harris noted that an increasingly reported mistake is the dispensing of the “right drug” to the “wrong person,” often the result of similar names shared by several members of a family, many of whom may speak limited English.

To help address errors such as these, the California Board of Pharmacy created a requirement in 2002 for every pharmacy to adopt a quality assurance program. Such programs require pharmacies to document and identify the cause of any errors that occur, and develop systems and workflow processes designed to prevent the same type of error from occurring in the future.

The Panel heard testimony regarding other types of dispensing errors from Michael Cohen, RPh, ScD, founder and director of the Institute for Safe Medication Practices (ISMP). His data is based on voluntary reports of errors received by the ISMP from health practitioners and consumers nationally over many years. A summary of all the major medication error causes identified by

ISMP is listed in Table 1. Causes of dispensing errors include confusing drug names, labels, and/or packaging (look/sound alike problems); environmental, staffing, or workflow issues (poor lighting, excessive noise, workload, interruptions); lack of quality control or independent verification systems; missing patient information (allergies, age, weight, pregnancy); and missing drug information (outdated references, inadequate computer screening).

In relation to the last two causes, it is pertinent to note a California regulation which requires pharmacies to maintain records on all patients who have prescriptions filled at their pharmacy for at least one year. These records must include "patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent".⁵ For the purposes of creating as complete a record as possible in one location, the Board of Pharmacy recommends that consumers use only one pharmacy when feasible.

By reviewing patient records, a dispensing pharmacist can determine whether a new medication the patient is being prescribed is appropriate and compatible (not contraindicated or in conflict with) with other medications the patient is already taking. Reviewing patient records in this way is called Drug Utilization Review (DUR) and is a very important safety feature.

Administration/Medication Use Errors

A key characteristic of the community setting that contributes to medication errors is that medications are administered by patients or other persons who are not health care professionals trained to do so. This is in sharp contrast to inpatient hospital settings where prescribers write orders for medications on patients' medical charts and drugs are subsequently administered by health care professionals. In hospitals, patients are often passive, and rely on others for their treatment. In community settings the opposite is true, and medication use is almost completely dependent upon consumer knowledge and motivation which can often be lacking. In fact, it has been estimated that people who are prescribed self-administered medications typically take less than half the prescribed doses.⁶

Many consumers simply do not understand what medications they are taking, their importance, their contraindications, or proper usage. In addition, consumers may not be asked by their health care professionals what non-prescription medications or supplements they are taking and may not know the importance of volunteering this information to avoid problems such as therapeutic duplications or interactions.

Because the majority of medication errors in community settings are made by consumers, it is clear that real progress will require significant efforts to improve consumers' knowledge, skills and motivation to use their medications correctly. Health care professionals and others involved with prescribing, dispensing, administering and monitoring medication use in community settings can all help achieve these goals.

TABLE 1: Institute of Safe Medication Practices' Major Causes of Medication Errors

- Critical patient information is missing (allergies, age, weight, pregnancy, etc.)
- Critical drug information is missing (outdated references, inadequate computer screening, etc.)
- Miscommunication of drug order (illegible, incomplete, misheard, etc.)
- Drug name, label, packaging problem (look/sound alike, faulty drug identification)
- Drug storage or delivery problem
- Drug delivery device problem (poor device design, IV administration of oral syringe contents, etc.)
- Environmental, staffing, workflow (lighting, noise, workload, interruptions, etc.)
- Lack of staff education
- Patient education problem (Lack on patient consultation, non-compliance)
- Lack of quality control or independent check systems in pharmacy
- Physician knowledge is lacking (when a drug comes to market that replaces an existing one or several ones, i.e., a combination drug may mean that a person takes it once a week instead of daily)

⁵ California Code of Regulations, Title 16, Section 1707.1

⁶ Haynes RB, Yao X, Degani A, Kripalani S, Garg AX, McDonald HP. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev* 2005;(4):CD000011.

Working Towards Patient Safety: A Systems Approach

Several experts who testified to the Panel cited multiple reports indicating that efforts to address errors are best targeted not at a particular group of individual “wrong doers,” but rather at faulty systems, processes, and conditions that either lead people to make mistakes or fail to prevent them. The Panel consequently agreed to take a “systems approach” for studying the problem and developing its recommendations.

As a result, the Panel spent considerable time examining each part of the medication-use process – prescribing, dispensing, using (administering/self-administering) and monitoring – and the inter-relationships of each component. The Panel determined the medication-use system to be quite complex involving a multitude of stakeholders. A detailed explanation of the entire system is beyond the scope of this report, but through its work, the Panel identified four key processes and three key stakeholder groups which served as the focus of its recommendations.

Key Medication Use Processes

Prescription, Transcription and Transmission Processes

Once a prescriber decides what medication and dose to prescribe, he or she must find a way to communicate that information to the pharmacy where the patient will have their prescription filled. It is through this communication where a significant proportion of prescription errors occur.

Often, prescribing information is communicated via handwritten prescriptions which employ the use of Latin abbreviations that can sometimes be confusing. These prescriptions can be illegibly written and may be submitted to pharmacies via fax which can further contribute to legibility problems. The most frequent problems of this sort are related to medication names (particularly for drugs that have “look-alike” names such as those in Table 2), and medication strengths.

Table 2: Look-alike/Sound-alike Drug Name Examples	
Seroquel 200mg	Serzone 200 mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg

Alternatively, the prescription can be communicated to a pharmacy verbally over the telephone but this mode of communication is not without its own challenges, such as the confusion of “sound alike” drugs (see examples in Table 2). These problems can be exacerbated through the use of non-professional medical office staff who may not be familiar with drug names and medical terminology. It should also be noted that whenever a person other than the prescriber is used to communicate prescription information over the telephone, they are almost always reading information that was written by another individual, which of course is subject to the same legibility issues as hard-copy prescriptions.

Electronic or “e-prescribing” is, most broadly, the transmission of prescription information from a prescriber to a pharmacy using computer technology. While recent efforts have been made by some prescribers and pharmacies to adopt e-prescribing, medical offices has been slow to do so, predominantly because of high-costs and a lack of incentives for providers to change their practices. Compounding the situation is the fact that state and federal e-prescribing standards have not been set or are inconsistent or conflicting.

Even when medical offices have the technology to facilitate e-prescribing, most do not fully employ it. Rather, they simply use their electronic record systems to send computer generated prescriptions via fax.

While some persons may consider the transmission of a prescription from a computer to a fax machine as “e-prescribing,” others believe that transmitting a static image, picture or facsimile is of limited value to helping ensure information accuracy, quality control or data analysis. The benefit is maximized from e-prescribing only when prescriptions are transmitted in a manner so that a recipient may use and analyze the information without having to manually copy or enter the data received.

The end goal with e-prescribing should be full system connectivity between pharmacies and medical offices to allow for *two-way* communication. Such connectivity could better leverage pharmacy data and has the potential to notify prescribers of possible medication-related problems before they occur.

Another problematic aspect of the prescribing process is that it frequently does not engage the consumer to an appropriate degree. All too often patients leave the prescriber's office without having the adequate medication-related information effectively communicated to them. Of particular concern are the consumers who present to the pharmacy without knowing the most basic information such as the name of the medication or what it is for. Without this minimal knowledge, there is very little consumers can do on their own to identify errors – even the most obvious ones such as receiving the wrong medication.

Consumer Education Processes

At the center of the medication-use process is the consumer. In the community setting, successful medication use is heavily dependent upon consumer knowledge and motivation which can often be lacking. When a person is not well-informed and motivated to manage their therapy, they cannot be expected to take their medication correctly or be an active partner in screening for signs and symptoms of medication efficacy or toxicity. There are a variety of complex reasons why many consumers allow themselves to be passive participants in the medication use process but the most significant is that consumers are largely unaware of, or do not accept the personal risks associated with medication use.

In addition to the consumer education challenges that pertain to the prescribing process, the Panel identified other aspects of the medication use process that could be modified to provide patients with better information and tools to reduce medication errors.

Pharmacist Consultation

While pharmacists are widely known for their dispensing activities, they can also play an important role educating consumers to ensure that the patient or their caregiver knows what the medicine is for, how to take it correctly, and what signs/symptoms should be monitored to assess for efficacy and toxicity.

State regulation requires pharmacists to provide a verbal medication consultation to the patient or the patient's agent each time a new medication is dispensed, or whenever an existing medication therapy is dispensed with a change in dosage form, strength or instructions for use.⁷ This consultation is to include "directions for use and storage and the importance of compliance with the

directions." Also included should be a "discussion of the precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered."

In spite of these requirements, the Panel received testimony suggesting considerable variability in the quality of these consultations as well as the consistency to which they are offered by pharmacy staff and utilized by consumers. The reasons for this are not well defined but there appear to be contributing factors from both the pharmacist end (lack of time and incentives) and the consumer end (lack of awareness regarding availability and perceived value).

While there is not a lot of data about the effectiveness of this dispensing-related counseling, it is reasonable to assume that the significant number of consumer-related medication errors could be positively influenced by greater efforts in this arena, particularly with at risk populations including seniors and minority patients.

Prescription Labels and Labeling

The information that consumers need to know about their medication is often complex and may include unfamiliar language or concepts. Expecting a consumer to retain all the pertinent knowledge from a brief verbal encounter may not be reasonable in many instances. For this reason, it is important that consumers also receive written information regarding their prescription.

Often-times however, even this information can be forgotten and lost, and in those instances, the consumer may be left with nothing more than the prescription packaging and label to guide them. Testimony provided to the Panel identified many limitations related to the prescription label as an effective communication tool. These included the limited size of a prescription label (approximately 2 x 3 inches) which, due to established pharmacy systems, processes, and drug container variability would be functionally and financially difficult for the pharmacy industry to change.

Further complicating matters is the fact that there is already a significant amount of information required by California law to be printed on the label.⁸ The most recent label requirement went into effect on January 1, 2006 and was created to help consumers identify erroneously filled prescriptions by mandating that pharmacies include the physical description of the dispensed medication, including its color, shape, and

⁷ California Code of Regulations, Title 16, Section 1707.2

⁸ California Business and Professions Code 4076

any identification code that appears on the tablets or capsules.

While this requirement is obviously directed at reducing errors, one might question the utility of some of the other label requirements which include the date of issue, the name of the pharmacy, the address of the pharmacy, the prescription number or other means of identifying the prescription, the name of the patient, the name of the prescriber, the name of the medication, the name of the medication's manufacturer, the strength of the drug, the quantity dispensed, the expiration date of the drug, and of course the directions for use. Given the limited space available, are all of these elements the most valuable pieces of information for the patient?

Regarding the directions of use, even when individuals are able to read and repeat back the directions, they may still not understand how to take the medication. This is particularly a problem for individuals with limited health literacy (the ability to read, understand and act on health information). A recent study by Davis, Wolf and others showed that even though 70.7% of patients with low literacy could correctly read and repeat the instructions, "Take two tablets by mouth twice daily," only 34.7% could accurately demonstrate the actual number of pills to be taken daily.⁹ In this study the researchers found that it was common for consumers to make mistakes when dosing medicine for themselves, their elderly parents, and their children.

Tailoring and Targeting Consumer Education Efforts

To maximize the impact of consumer education activities, efforts will need to be tailored and targeted to individuals who are likely to achieve the greatest benefit. While the Panel did not come to consensus on the most important subset of consumers that are at "high risk" for medication errors, it did acknowledge that there are a variety of factors which may increase an individual's risk for experiencing a medication error.

In addition to 1) low health literacy, these can include; 2) limited English proficiency; 3) cultural incongruence with healthcare providers; 4) physical, cognitive and/or other impairments that make understanding and/or complying with medication instructions difficult; 5) age at either end of the age spectrum (the variability of a medication's response, metabolism and dose increases in children and seniors); 6) multiple medications; 7) multiple prescribers;

⁹ Davis TC, Wolf MS, Bass PF 3rd, Thompson JA, Tilson HH, Neuberger M. et al. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006;146:887-94.

8) non-prescription medication use (including herbals, dietary supplements alcohol and tobacco); and 9) medication procurement from more than one pharmacy including mail-order. These factors must be taken into consideration in the development of any consumer education efforts.

Provider Payment/Incentive Processes

Incentives that directly or indirectly influence the behavior of prescribers and pharmacists are a key aspect of the medication use system. Testimony provided to the Panel indicated that prescriber incentives are frequently not aligned to promote spending time educating patients about medication use, or to closely follow patient compliance and medication monitoring parameters.

A fairly recent collaboration between healthcare purchasers, payers and medical groups provides incentives byway of "pay-for-performance" and shows promise for realigning prescriber incentives to reward behavior that results in positive outcomes. However, it is clear that there is still room for improvement in this area, particularly as it relates to safe and effective medication use.

Similarly, pharmacy incentives appear to do little to encourage pharmacist activity in areas related to patient education and the promotion of safe and effective medication use. Since pharmacies generally only receive compensation when a product is dispensed, financial pressures may, in fact, be driving pharmacy processes and personnel to minimize any activities not directly related to product distribution. Ironically, the structure of this financial model may possibly create disincentives for pharmacists to identify and prevent prescriptions with prescribing errors from leaving the pharmacy.

Fortunately, testimony provided to the Panel suggests that the healthcare system may be in the very early stages of what could be a paradigm shift. It appears that increasing numbers of healthcare purchasers and payers are beginning to understand that there is more to consider when it comes to medication than the simple cost of distribution, and the speed and convenience by which it can be put into the hands of consumers. There is a growing recognition that no matter how cheaply a drug can be purchased, the cost is too great if it does not elicit the desired effect, or worse, causes patient harm.

In response to this growing recognition, more and more healthcare purchasers and payers are developing

specialized initiatives focused around improving medication use, particularly in target populations where safe, appropriate and effective medication use is critical. These “medication therapy management programs” have been developed for people with particular conditions such as diabetes¹⁰, individuals who have multiple chronic conditions and/or take multiple medications, and those whose medication costs exceed a certain threshold.

Perhaps the most prominent example of this early trend is the requirement placed in the Medicare Modernization Act for sponsors of the Medicare Part D drug benefit to have in place a medication therapy management program designed to promote optimal therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions.

While medication therapy management programs may hold significant promise for reducing medication errors, many issues will need to be resolved before the full potential of such programs can be known and realized. As with any new healthcare initiative, there is uncertainty regarding how the quality and financial returns-on-investment can be maximized by adjusting program variables such as:

- The types of services that are provided (e.g. patient education, medication compliance packaging and comprehensive medication reviews);
- The patient populations that are targeted (e.g. those with a particular condition, medication, cost, or combination thereof);
- The types of providers who deliver various services (e.g. physicians, nurses and pharmacists);
- Service delivery models (e.g. face-to-face, telephone or mail); and
- Payment and documentation methodologies.

Until there is more information and standardization around issues such as these, the spread of medication therapy management programs will likely be slower than perhaps it should. Nonetheless, the fact that innovative purchasers and payers of healthcare are developing novel models to incentivize physicians, nurses, and/or pharmacists to pursue behaviors that will decrease medication errors is a positive step in the right direction.

Healthcare Provider Training and Licensure Processes

Obviously, simply aligning incentives to encourage safe medication practices among healthcare providers is not enough. Providers must also be cognizant of the seriousness of medication errors, know the behaviors to adopt that will reduce errors, and possess the knowledge and skills to effectively execute those behaviors.

Healthcare providers undergo extensive training to become licensed practitioners. Subsequent to licensure, providers must continue training to maintain their licenses. The vast majority of this training is clinical in nature. Most providers receive little education on subjects such as healthcare administration, error prevention, patient communication, and effective, systematic approaches to medication therapy management.

While testimony provided to the Panel indicates that some formal education on topics related to medication errors may be included in provider training programs, the very size of the medication errors problem suggests that the current amount may not be enough. More education in these areas would likely promote greater awareness among providers about what they can do to protect consumers. Informed providers can also be powerful advocates of change in a variety of healthcare settings.

Key Stakeholder Groups

In addition to the four key processes, the Panel identified three key stakeholder groups believed to play critical roles in the development and implementation of initiatives designed to address medication errors.

Consumer-Oriented Organizations

Since the consumer is at the center of the medication use process, it is imperative that all relevant consumer organizations be solicited to join the effort to prevent medication errors. These organizations can play critical roles in educating consumers about medication errors and advocating for healthcare policy and practice changes that have the potential to reduce errors. These groups may be government-related (e.g. the California Department of Consumer Affairs), private foundations, member-benefit organizations (e.g. AARP), or public-benefit organizations.

¹⁰ Information was presented to the Panel on APhA Foundation's Asheville Project. Details can be found at www.aphafoundation.org/programs/Asheville_Project

Healthcare Provider Groups and Related Entities

Healthcare providers such as physicians, nurses and pharmacists are on the front lines of healthcare. In many respects, the burden of reducing medication errors will fall largely on their shoulders. A problem of this scope and size, however, cannot be solved by any single group of individuals, or even by a single sector of the healthcare system acting alone.

Any appreciable reduction in medication errors will require that the entities which support, direct, or influence provider behavior also be actively engaged in addressing this problem. These entities include the academic institutions and professional societies that train providers; the associations that advocate for them; the individuals that manage them; the companies that employ them; and the oversight boards that license and regulate them.

Healthcare Purchasers, Payers and Related Entities

The group that has perhaps greatest opportunity to influence the healthcare system consists of the entities that actually purchase and administer healthcare benefits

– and to some extent, those which regulate and oversee the activities of these groups. Many of these entities have the power to decide which healthcare-related behaviors and outcomes are truly of value, and they can create payment structures, non-financial incentives and/or requirements to drive processes and behaviors that seek to deliver those results.

Stakeholders in this group include: the State of California which uses taxpayer monies to purchase, and through its Department of Health Services, administer healthcare benefits through programs such as Medi-Cal; private purchasers of health care such as employers which purchase healthcare for a majority of Californians under 65; commercial insurance companies which administer health benefits for both public and private sector purchasers; the California Departments of Insurance and Managed Health Care which regulate these insurance companies; pharmacy benefit managers which focus specifically on the administration of pharmacy benefits; and, of course, the Legislature and Administration of the State of California which possess the potential to influence and/or establish accountability for these groups.

Conclusion

Based upon the information provided to the Panel, and the identification of these key processes and stakeholders, the Panel developed 12 consensus recommendations in the following subject areas:

- **Communication Improvements** with an emphasis on improving the quality and accuracy of communications between prescribers, pharmacists and patients;
- **Consumer Education** to increase consumer awareness regarding the proper use, and dangers of misuse, of prescription and over-the-counter medications;
- **Provider Standards and Incentives** with a focus on information and medication consultations given by pharmacists to their patients as a means of educating consumers about drug safety;
- **Training and Education for Healthcare Providers** on various medication safety practices;

- **Research** with a focus on obtaining information about the incidence, nature and frequency of medication errors in the community setting.
- **Other Topics to be Addressed** which were determined to be beyond the scope of the Panel but which the Panel recognizes must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

The recommendations are provided in their entirety in the next section of the report.

SECTION II: RECOMMENDATIONS

A. Communication Improvements

Background:

Improving the quality of communication among prescribers, pharmacists and patients is critical to the success of any effort aimed at decreasing medication errors. The existing process for communication among health professionals and their patients leaves much room for improvement, according to testimony received by the Panel. Indeed, California health practitioners have been slow in their adoption of computer-based patient records and electronic prescribing.

Currently, pharmacist-patient consultation is often compromised by the pharmacist's lack of knowledge of the prescriber's treatment objectives, including such basic information as the condition being treated. Confirming prescriber intent with the patient at the time of dispensing is an additional means of confirming that the medication treatment is understood and properly implemented.

In addition, prescribers' lack of writing legibility has long compromised pharmacists in their efforts to correctly dispense the desired drug product and provide accurate instructions for use. Addressing these two problems of communication between prescribers and pharmacists has been shown to substantially decrease medication errors.

In regard to communication between consumers and their health care providers, an important step would be to adopt techniques that bridge the language and cultural diversity of the patient population in California. This would provide the prescriber and pharmacist with the means to confirm that the medication treatment is understood and will be properly implemented.

Another important improvement in communication between health care providers and their patients would result from improved readability of drug labels and user-friendly packaging.

Goal 1: Improve prescriber-pharmacist communication quality and accuracy regarding prescriptions.

Recommendation 1

Improve legibility of handwritten prescriptions, and establish a deadline for prescribers and pharmacies (allowing for some exceptions) to use electronic prescribing.

Methods

- 1.1 Require each prescription to be legibly hand written or printed, computer generated or typed, and by 2010 that all prescriptions be computer generated or typed.

The California Board of Pharmacy and the California Medical Board shall review and seek modification of statutory and regulatory requirements as needed to implement adoption of computerized prescriber order entry (CPOE) systems and secure 2-way electronic communication between prescribers and pharmacies, with consideration for identified exceptions to the requirement.

- 1.2 Require the California Medical Board to collect and disseminate information in order to educate and assist physicians about the benefits of and ways to adopt electronic prescribing systems and supporting CPOE and secure 2-way transmission to pharmacies. Coordinate these efforts with related activities undertaken by the State. For example, Executive Order S-12-06 was issued by Governor Schwarzenegger on July 24, 2006 regarding efforts planned to make reforms regarding healthcare, especially regarding health information technology.
- 1.3 Require the California Medical Board to adopt regulations by January 1, 2008 that require

prescribers using electronic prescription systems to provide patients with a written "receipt" of the information that has been transmitted electronically to a pharmacy. The document should include at least the patient's name, the dosage and drug prescribed and the name of the pharmacy where the electronic prescription was sent, and should indicate that the receipt cannot be used as a duplicate order for the same prescription.

Goal 2: Improve prescriber-pharmacist and pharmacist-consumer communications to enhance understanding of the intended use of prescribed medication.

Recommendation 2

Require that the intended use of the medication be included on all prescriptions and require that the intended use of medication be included on medication label/labeling unless disapproved by the prescriber or the patient.

Methods

- 2.1. Require the California Board of Pharmacy and the California Medical Board to pursue necessary statutory and/or regulatory changes to require that by January 1, 2008 these entities coordinate efforts to develop plans to require prescribers to include the diagnosis, medical condition, symptoms or other indicators of the intended use of the medication on each prescription written, allowing for some exemptions.
- 2.2. Require the California Board of Pharmacy to pursue necessary statutory and/or regulation changes to require that the intended use of any prescribed medication be included on the medication label, unless the prescriber or consumer disapproves, and consumer disapproval is documented by the pharmacist.

Recommendation 3

Improve access to and awareness of language translation services by

pharmacists at community pharmacies and encourage consumers to seek out pharmacists who speak their language and understand their cultural needs.

Methods

- 3.1 The California Board of Pharmacy, Department of Health Services and/or the Department of Consumer Affairs should develop and implement methods, when possible in coordination with other state entities, that are designed to reduce barriers for pharmacists at community pharmacies to access and utilize language translation services. These entities should report their respective related activities planned and undertaken annually on their respective websites and to the Assembly and Senate health committees, beginning January 1, 2008. They should, but not be limited to distributing information to pharmacies about the pharmacies' obligations to provide language translation services and resources for pharmacies to do so via the telephone.

Messages related to this method and goal should be included in the public awareness campaign (Recommendation #6) to inform consumers about their right to use language translation services and availability of these services at community pharmacies and other health care providers.

Recommendation 4

Promote development and use of medication packaging, dispensing systems, prescription container labels and written supplemental materials that effectively communicate to consumers accurate, easy-to-understand information about the risks and benefits of their medication, and how and where to obtain a medication consultation from a pharmacist.

Methods

- 4.1 Require the California Board of Pharmacy to examine the existing requirements for prescription container labels, prescription containers, and supplementary consumer information, and to consider revising these requirements to encompass required, supplemental consumer information and California Board of Pharmacy contact information.

Require these finding be issued by January 1, 2009 and distributed to the Senate and Assembly Health committees, posted on the California Board of Pharmacy's website and that public notice be made by issuance of a press release.

4.2 Encourage prescription drug plans, health care service plans, and health insurance companies to develop strategies to provide incentives for pharmacies and drug manufacturers to package medications in a manner that increases medication compliance, safety and efficacy.

4.3 Require the California Board of Pharmacy to adopt regulations mandating all pharmacies, including non-resident pharmacies, provide written materials with all dispensed prescriptions that inform consumers of their right to receive a medication consultation from a pharmacist with any new or changed prescriptions. These regulations should include enforcement provisions and the California Board of Pharmacy should make enforcement a priority.

B. Consumer Education

Background:

There is a great need to increase consumer awareness of the proper use, and dangers of misuse, of prescription and over-the counter-medications. Consumers often do not appreciate the potency and risks involved in the use of drugs that are widely advertised and promoted on television, radio and print media.

The California Board of Pharmacy is in an excellent position to spearhead an educational effort directed toward the public concerning drug safety issues. In recent years, the Board has been recognized nationally for its consumer protection efforts. A Board program that capitalizes on their proven expertise in consumer safety and which takes into account health literacy and culturally appropriate communication could be very effective in alerting consumers to potential medication errors, and in motivating them to adhere to their drug treatment instructions. A commitment by the State of California to capitalize on this proven expertise will go far to aid consumers in understanding their role in recognizing potential medication errors and preventing injury from those that do occur.

Goal 3: Improve consumer awareness and knowledge about the risks of medication errors and about steps they can take to reduce their risk of medication errors.

Recommendation 5

Identify and disseminate information about best practices and effective methods for educating consumers about their role in reducing medication errors.

Methods

- 5.1 Propose legislation allocating funds to and requiring the California Board of Pharmacy to:
- a) Identify effective methods for educating consumers about ways to prevent and report medication errors. Include methods that are culturally and linguistically appropriate, especially addressing the needs of persons at high-risk for medication errors.
 - b) Develop guidelines and/or related regulations to define ways for effectively educating consumers to prevent medication errors. Include both verbal and written education strategies.
 - c) Disseminate information about the methods and guidelines/standards to specific relevant public and private sector entities, including mail-order (non-residential pharmacies) and pharmacies that dispense prescriptions to outpatients.
 - d) Improve public access to California Board of Pharmacy services (e.g., telephone, mail, and internet).

Recommendation 6

Establish an on-going public education campaign to prevent medication errors, targeting outpatients and persons in community settings.

Methods

- 6.1 Pass legislation allocating funds to and requiring the Department of Consumer Affairs and/or the California Board of Pharmacy to oversee development and implementation of a public education campaign to reduce medication errors. Public and/or private funds may be pursued.

The campaign shall be based on principles of public health practice and shall use methods that have been shown effective in educating consumers. The methods shall be culturally and linguistically appropriate and shall be developed in collaboration with other state entities.

The campaign shall develop messages that educate consumers about their medication use, risks, rights and responsibilities and shall include a consumer's right to basic consultation from a pharmacist with each new or changed prescription.

- 6.2 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with appropriate state entities and stakeholder groups, including but not limited to health plans, retail pharmacists, and consumer advocates representing persons at high risk for medication errors to:
- a) Develop an evidence-based "safe medication use curriculum" that is designed to be used for educating consumers, and promote its availability to intermediaries, such as health care service plans, colleges, high schools, health insurers, Medi-Cal providers, and healthcare providers throughout the state who can educate consumers.
 - b) Post the curriculum on the websites of the relevant state departments and promote its

availability through issuance of a press release and other public notice activities;

- c) Develop and disseminate suggested strategies, possibly unique to each intermediary, to encourage consumers to attend presentations based on the curriculum.
 - d) Create a web-based interactive version of the curriculum that will be posted on websites of designated state entities and require those entities to promote the availability of the curriculum via no or low cost methods, such as press releases, faxes and email.
 - e) Coordinate this activity with the efforts to educate health care professionals about medication errors and prevention issues in Goal 5, Recommendation 10.
- 6.3 Recommend that the California Medical Board and the California Board of Pharmacy encourage physicians and other prescribers to post notice in their offices informing consumers of their right to know, and the benefits of understanding the name of any medication prescribed and the indication(s) and instructions for use, in addition to their right to consult with a pharmacist.

Recommendation 7

Develop and implement strategies to increase the involvement of public and private sector entities in educating consumers about improving medication safety and effectiveness.

Methods

- 7.1 Require the California Board of Pharmacy and/or the Department of Consumer Affairs to collaborate with a cross-section of public and private sector entities, including prescription drug plans, health care service plans, health insurers, and/or mail-order pharmacies, to support and/or undertake efforts to educate consumers about safe medication use. Use legislative and regulatory means to ensure a joint effort is made by all agencies that regulate these entities to collaborate in these efforts.

C. Provider Standards and Incentives

Background:

The drug consultation given by a pharmacist to their patient, or the patient's agent, can be a powerful means for educating consumers about drug safety. However, current law regarding pharmacists' consultation contains only the minimal requirements that were established in the early 1990s. In light of the substantial changes the State's health care system has undergone since that time, a re-examination of the pharmacist's consultation requirement is in order.

The Panel recommends that the Board of Pharmacy establish new pharmacist consultation standards that would provide greater benefit and protections to the public. Consistency should be a key component of the new standards, and they should take into account the economic and workforce conditions that impact the ability of pharmacists to provide this essential service.

Medication therapy management programs (MTM) provide another important tool in avoiding medication errors. The purpose of these programs is to evaluate whether prescribed medications are yielding desired results and, if not, to recommend or implement adjustments to therapies to maximize outcomes. To properly protect consumers, MTM programs should meet minimum standards for provider qualifications and program design.

Goal 4: Improve the quality and availability of pharmacist-patient medication consultation.

Recommendation 8

Help ensure quality and consistency of medication consultation provided by pharmacists within and among pharmacies.

Methods

- 8.1 Require the California Board of Pharmacy to review and, as needed, revise current regulations regarding patient consultation to

focus on what would actually be useful to patients to help maximize their therapeutic outcomes and take their medications safely and effectively.

The California Board of Pharmacy shall invite stakeholders, including consumer representatives, to collaborate to develop minimal standards for required consultation. These deliberations should consider factors that reflect the current conditions of the business and healthcare environments, various types of pharmacy practices and practice settings (e.g. community, mail-order, extended care), and the "learning environment" available in those settings for providing consultation. The standards should be applied equally to all providers or entities dispensing medications to California consumers, including non-resident pharmacies.

Nothing in consideration of these standards shall preclude pharmacists from being paid for services that exceed these minimal standards.

These standards should address, at a minimum:

- a) Encouraging or providing incentives to pharmacists for providing patient medication consultation with prescription renewals, when appropriate.
- b) Re-examining the circumstances involved with patients' refusal of consultation, and what type of documentation is required, if any, for patients who refuse consultation. The Panel strongly emphasized that the following factors be considered as part of the re-examination process: (1) prohibiting any pharmacy employee from asking a patient or patient's agent if he/she wants pharmacist prescription consultation (i.e. no "screening" questions) and (2) requiring that the patient communicate the refusal of consultation directly to a pharmacist.

Recommendation 9

Establish standards for medication therapy management (MTM) programs and create incentives for their implementation and ongoing use by pharmacists and other healthcare providers

Methods

- 9.1 Require the California Board of Pharmacy to identify best practices and to develop evidence-based standards of care for MTM programs, and to disseminate these to known MTM providers, the Department of Health Services, Department of Managed Health Care, Department of Insurance, the Managed Risk Medical Insurance Board, CalPERS, California Medical Board, and to applicable professional and healthcare associations (e.g. California Medical Association, California Pharmacists Association, California Association of Health Plans).
- 9.2 Require the Department of Health Services, Department of Managed Health Care, Department of Insurance, Managed Risk Medical Insurance Board, California Medical Board, Board of Registered Nursing, Board of

Pharmacy, and appropriate private sector entities to develop and implement strategies to incentivize payers, pharmacists and other healthcare providers to implement and routinely use MTM standards of care. These public entities shall report their respective related activities to the Assembly and Senate Health Committees, and to notify the public by posting descriptions of their activities and/or any findings on their websites and notifying the public and media by issuing one or more press releases.

- 9.3 Consistent with the standards developed in this recommendation, require the Department of Managed Health Care, the Department of Health Services and the Department of Insurance to allow health plans, health insurers, and Pharmacy Benefit Managers flexibility in methods of implementing MTM programs, including via face-to-face interaction, call center advice lines, and secure e-mail communication.
- 9.4 Encourage state-funded programs (e.g., Medi-Cal and CalPERS) to establish financial and other incentives for healthcare providers and patients improving drug therapy compliance, including cases of over-use (including therapeutic duplication) and under-use of prescription medication.

D. Healthcare Provider Training and Education

Background:

Good communication skills are essential in the current health care environment, and are a key tool in reducing medication errors. Pharmacists and other health care professionals must take into account their patients' language skills and cultural characteristics in order to effectively convey essential information to them. There is therefore a need to educate prescribers and pharmacists concerning improved ways to help their patients understand the proper use of medications, the importance of complying with their treatment regimen, and the need to report any problems to their prescriber or pharmacist.

Considering the ever increasing numbers of patients who have conditions that can be managed with therapies that are frequently long-term and involve the use of multiple medications, healthcare providers are also likely to

benefit from more training and education around the intricacies of medication therapy management (MTM). While much of this information is already an integral component of pharmacist training, many of the skills needed to apply it are distinct from a pharmacist's traditional dispensing role. Consequently some pharmacists may have a need to obtain other types of training as well.

Goal 5: Improve education and training of pharmacists and other health care professionals about medication errors and prevention methods.

Recommendation 10

Create training requirements for pharmacists and other healthcare professionals that address medication safety practices and related programs, including medication consultation and medication therapy management programs.

Methods

- 10.1 Require that the licensing boards for relevant health care professionals (e.g., pharmacists, physicians, nurses, dentists and optometrists) establish specific requirements for training/education about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, and medication therapy management methods) as part of licensure, certification, and/or continuing education requirements. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.
- 10.2 Encourage the colleges, universities, and schools that provide degree programs for health care professionals (e.g., pharmacists, physicians, nurses, dentists, optometrists, pharmacy technicians) to establish and maintain specific curricular requirements about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).
- 10.3 Encourage employers of healthcare providers, as well as the healthcare professional associations (e.g., the California Medical Association, California Pharmacists Association, California Society of Health System Pharmacists, and California Nurses Association), to establish and maintain ongoing training and educational activities for their respective constituencies about medication safety practices (e.g., medication error reduction strategies, patient medication consultation, medication therapy management methods).
- 10.4 Require that the licensing boards of relevant healthcare professions (e.g. pharmacists, physicians, nurses, dentists and optometrists) evaluate the effectiveness of their respective licensing requirements (e.g. board examinations) in determining a licensee's ability to communicate medication-related information and instructions to consumers in a manner that reduces the risk of medication errors related to patient misunderstanding. Further, require these boards to report their findings and plans for improving their requirements in this regard to the appropriate cabinet-level position, the Assembly and Senate Health Committees, and the public through posting of the report on their websites and issuing one or more press releases.

E. Research about Prevalence & Occurrence of Medication Errors

Background:

Obtaining information about the incidence, nature and frequency of medication errors in the community setting is challenging. Most research on medication errors has been conducted in hospitals, even though the drugs administered in inpatient settings represent a very small proportion of medications dispensed. Indeed, there is comparatively little academic research available regarding medication errors occurring in the community setting. While it appears that this situation is beginning to improve, a greater emphasis on research related to medication errors in the community setting is definitely warranted.

Goal 6: Increase evidence-based information about the nature and prevalence of medication errors available to policy-makers, pharmacists, consumers, and other interested parties.

Recommendation 11

Establish and support efforts to collect data regarding the nature and prevalence of medication errors and prevention methods for reducing errors, especially focused on persons at high risk for medication errors and on community, ambulatory and outpatient settings.

Methods

- 11.1 Require by legislation, regulation, joint legislative resolution, and/or issuance of a Governor's Executive Order that the California Board of Pharmacy establish an agreement with a private sector organization, such as the Institute of Safe Medication Practices (ISMP), to establish a pilot project to collect and analyze data about the nature and prevalence of medication errors at California community-based pharmacies.

Require that the cost of this project to the State be negligible.

Require the California Board of Pharmacy to share data about medication errors reported to it with the entity responsible for implementing this recommendation and that the Board collaborate with the entity responsible for implementing this recommendation to promote the project to consumers, pharmacies and providers. The project should ensure that:

- a) Prescribers, pharmacists and consumers may voluntarily and confidentially report errors to the ISMP or other responsible entity.

- b) The entity responsible for implementing this recommendation report annually to the California Board of Pharmacy, the California Medical Board and the Senate and Assembly health committees, and that these reports indicate if an error occurred either under the auspices of a health care facility or in a community setting (i.e., retail pharmacy or private residence) and the severity of the error (i.e., if it resulted, contributed or may have been associated with death, hospitalization or serious injury).
- c) The information collected and reported by this project should not be used in any legal proceedings against prescribers and/or pharmacists.
- d) The project be designed to minimize conflict with existing systems that are used to collect data from pharmacies as part of their current California Board of Pharmacy Quality program.
- e) Efforts to inform consumers about this project include information handed out at pharmacies, on medication information sheets, and with related public education campaigns.
- f) The California Board of Pharmacy and the Medical Board post the reports produced by this project on their respective websites.
- g) Persons reporting errors to the entity responsible for implementing this recommendation be informed of their right to also report errors to the California Board of Pharmacy and the benefits of doing so.

F. Other Topics to be Addressed

Background:

The many obstacles that pharmacists face in providing drug consultation to their patients as required by law are exacerbated by the lack of a payment system that would compensate them for the time and expense associated with performing these mandated tasks. Before additional duties can be imposed on pharmacists practicing in the outpatient setting, changes to the health care financing/

reimbursement system must occur. This issue was beyond the charge of the Panel, but it was recognized to be an issue that must be addressed hand-in-hand with other practice enhancement efforts in order to assure success in the current and future marketplace and workforce environments.

Goal 7: Develop strategies designed to increase incentives for pharmacists to offer and provide medication consulting and medication therapy management services to consumers.

Recommendation 12

Convene a panel of stakeholders to identify and propose specific actions and strategies to overcome barriers to qualified pharmacists being recognized and paid as healthcare providers.

Methods

- 12.1 The Legislature should convene a panel of stakeholders representing California pharmacists, healthcare providers, consumer groups, payers, health plans and other perspectives to hold a series of public meetings and issue recommendations addressing the reimbursement of pharmacists for non-dispensing services.

Reimbursement for medication consultation should be based on standards of care (see recommendations and discussion under Goal 4). If such standards have not been adopted at the time that the panel is convened, then the panel should make recommendations to the California Board of Pharmacy about development of the standards.

In considering recommendations for reimbursing pharmacists for patient medication consultations, the panel should weigh factors based on patient-specific information, including, but not limited to time spent providing the consultation or complexity of the consultation (the number of medications taken by the consumer, the consumer's compliance challenges, language, literacy or translation needs, or patient diagnosis). Additionally, the panel should take into account the most current thinking on this subject from relevant regional or national entities such as the US Centers for Medicare and Medicaid Services, Quality Improvement Organizations, and pertinent payer and provider organizations.

SECTION III: APPENDICES

Appendix A: Panel Meeting Dates and Speakers

The Medication Errors Panel held 12 meetings in Sacramento, the first on May 5 and the last on November 16, 2006. Presentations were made to the panel by persons listed below on the dates indicated.

May 5

- Senator Jackie Speier, Panel Chair and Author of SCR 49
- Senator Sam Aanestad, Panel Member
- Lynn Rolston, CEO of CA Pharmacists Association
- Robert MacLaughlin, Aging and Long Term Care, Senate Health Subcommittee
- John Gilman, Assembly Health Committee
- Dawn Adler, Office of Assemblymember Betty Karnette
- Sang-ick Chang, M.D., San Mateo County Medical Center
- Michael J. Negrete, Pharm.D., Pharmacy Foundation of CA

May 19

- Eleanor M. Vogt, R.Ph., Ph.D., Health Sciences Clinical Professor and 2004 – 2005 Presidential Chair, UC San Francisco School of Pharmacy
- Patricia Harris, Executive Director, Board of Pharmacy
- John Gallapaga, SmartRx for Seniors
- Lisa Chan, Office of Assemblymember Wilma Chan

June 2

- Michael Cohen, R.Ph., MS, FASHP, founder of the Institute for Safe Medication Practices (ISMP)
- Patricia Harris, Executive Director, CA Board of Pharmacy
- Dave Thornton, Executive Director, CA Medical Board
- Dr. William Soller, PhD, Executive Director, Center for Consumer Self-Care, University of CA, San Francisco

June 16

- Bill G. Felkey, Professor, Pharmacy Care System, Auburn University, Alabama
- David Murphy, SureScripts
- Pam Bernadella, RPh, Manager, Pharmacy Professional Services, Target Corporation, Minnesota

June 30

- Victoria Bermudez, RN, CA Nurses Association
- Lori Hack, Interim CEO, CA Regional Health Information Organization
- Sharon Youmans, Pharm.D, MPH, Professor of Clinical Pharmacy, University of CA, San Francisco

August 11

- Dr. Robert E. Lee, Jr., Eli Lilly, and U.S. Food and Drug Administration Trademark Focus Group Member
- Tom Williams, CEO, Integrated Healthcare Association
- David Murphy, SureScripts and Get Connected CA
- Carmella Gutierrez, Lumetra
- Peter Boumenot, Lumetra, Electronic Health Records Implementation Consultant

August 25

- Paul Tang, MD, Vice President, Chief Medical Information Officer, Palo Alto Medical Foundation, Sutter Health

- Susan L. Ravnan, Pharm. D., Associate Professor, University of The Pacific Thomas J. Long School of Pharmacy and Health Sciences; CA Society of Health System Pharmacists representative

September 15

- Robert Friis, PhD, California State University Long Beach, Department of Health Sciences Chair, and American Public Health Association Southern California Chapter President
- Gurbinder Sadana, MD, FCCP - Director of Critical Care Services, Pomona Valley Hospital Medical Center; California Medical Association representative

September 29

- Panel committees begin work of drafting recommendations for final report

October 13

- J. Kevin Gorospe, Pharm. D., Chief, Medi-Cal Pharmacy Policy Unit
- Loriann De Martini, Pharm.D., Chief Pharmaceutical Consultant, Licensing and Certification Division, Department of Health Services

November 2

- Senator Jackie Speier, Panel Chair, met with the Panel to discuss major issues, and Panel's progress on developing final recommendations

November 16

- Final meeting of the Panel to discuss recommendations

Appendix B: Prior Legislative Efforts to Address Medication Safety

The following legislation relevant to the objectives of the Panel has been enacted:

- SB 1339 (Figueroa) became law in 2000 and requires pharmacies to establish quality assurance programs to reduce frequency of medication errors. Every pharmacy is required to have a system of tracking and assessing errors so that the proper steps can be taken to reduce the chance of a reoccurrence. It exempts any documents generated by the program from legal discovery proceedings.
- SB 1875 (Speier), 2000, requires hospitals and surgical centers to develop medication error reduction plans and submit the plans to the Department of Health Services. In order for a health facility or clinic to obtain a license it must complete a plan to eliminate or substantially reduce medication error by 2005.
- SB 292 (Speier) 2003, requires labels on pill bottles to include a written description of the drug that was prescribed, including its color, shape, and any identification code appearing on the tablets or capsules. (This bill initially sought to have a color image of the pill or tablet printed on the bottle label.)
- SB 151 (Burton), 2004, requires that tamper-resistant security forms be used for nearly all *written* prescriptions for controlled substances (Schedules II-V). This pre-printed and numbered form must contain at least ten security features and replaces the Schedule II triplicate prescription forms. Pharmacies must report Schedule III prescriptions to the CURES program.

There were six bills before the legislature during the 2005-2006 session that had objectives relevant to medication safety. They were the following:

- AB 71 (Chan) would have established the Office of the California Drug Safety Watch to administer a database of information about the safety and effectiveness of highly advertised prescription drugs. The database was to include reports of adverse drug reactions (ADRs) which would have been accessible to health professionals and the public. This bill is inactive.
- AB 657 (Karnette) would have required that the purpose or indication of a medication be listed on the prescription label if a prescriber had written it on the prescription. This bill is inactive.
- SB 1301 and SB 380 were both introduced by Senate Elaine Alquist in 2005. SB 1301 was chaptered September 29, 2006 and requires acute care facilities to report ADRs to the Department of Health Services within five days of the occurrence. SB 380 originally contained a mandatory reporting requirement to the federal Food and Drug Administration for all serious ADRs, but was amended to address a non-related issue.
- SB 329 (Cedillo) 2005, would have established the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency. The Commission would request assistance from a unit of the University of California and be a repository of information about prescription drug safety and effectiveness. In February 2006, this bill was returned to Secretary of Senate pursuant to Joint Rule 56.
- AB 72 (Frommer) 2005, would have established the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. On January 31, 2006, this bill died on the inactive file.

FROM: STEPHEN J. ROSATI, R.PH.

RE: 1707.5 LABEL AMENDMENTS

Based on the public comments and Board Discussions at the 10/22/09 Board Meeting, my 5 page document dated 10/22/09 that contains my proposed amendments to 1707.5, I am making the following recommendations to the Board's current proposal of 1707.5 that was posted on the website for today's meeting. I would also like today's documents to become part of the record:

- Section 1707.5(a) – change “drug containers” to “prescription containers”.
- Section 1707.5(a)(1)(B) –re-word the first sentence to read: “Name, strength and form of the drug dispensed”.
- Section 1707.5(a)(1)(C) – re-word to read “Directions for use. A minimum of 4 lines shall be allocated on the label for directions in 12-point typeface. Directions may be printed in less than 12-point typeface only if the directions from the physician or physician’s agent are longer than the 4 lines allocated for 12-point; the minimum typeface in such instances shall be no less than 8-point”.
- Add a new Section 1707.5 (a)(3) dealing with auxiliary/warning labels: “Auxiliary/Warning Labels or Print for a prescription container shall be a minimum of 6 point, san serif typeface”. *I believe that if a patient cannot read these warning/auxiliary labels, they will continue to utilize the prescription improperly. Plus, these labels are essentially part of the directions and need to be addressed in the same manner as the main directions!*
- Regarding the directions listed in Section 1707.5(a)(4), the following should be added:

--Take 1 tablet with breakfast	--Take 1 tablet every 4 hours
--Take 1 Tablet at noon	--Take 1 tablet every 6 hours
--Take 1 tablet with dinner	--Take 1 tablet every 8 hours
	--Take 1 tablet every 12 hours
- Add a new Section 1707.5 (e) dealing with advertising: “There shall be no form of advertising on the prescription label, container or container top; only the information required by the Board of Pharmacy and the name, address and phone number(s) of the pharmacy that filled the prescription”.
- Regarding the translation of the prescription container label’s information in another language: If the Board of Pharmacy ever requires this translation to occur on the actual label, rather than an oral translation, it is imperative that the pharmacy’s software shall include the ability to include the other language and its English translation simultaneously on the computer screen, located in the prescription pathway that establishes the directions for the prescription label. Even though this would not guarantee that the translation is correct, at least it would give the pharmacist, technician and clerk typist some indication of what it should mean – this will still be a dangerous situation if no one in the pharmacy speaks the patient’s language and will exert a great deal of liability on the pharmacist on duty, as well as the PIC and pharmacy. *Although many of today’s software programs may have this capability, it is imperative that pharmacy has this legal requirement to help the pharmacy staff have some kind of a chance at filling the prescription with the correct translation, or else I can guarantee that we will be creating a whole new category of dangerous errors/problems for the consumer.*

Thanks you very much for your serious consideration.



Effects of label format on knowledge acquisition and perceived readability by younger and older adults

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This research examines consumers' information acquisition and preference for labels of a simulated over-the-counter (OTC) medication. Twelve otherwise identical OTC drug bottles were compared with different back labels varying in (a) print size, (b) amount of white space between text, and (c) label design (standard vs extended/pull-out). A no back label condition served as a control. Older (mean age = 77.7 years) and younger (mean age = 21 years) adults were given one of the 12 bottles and asked to perform one of two information acquisition tasks: (a) they examined the bottle for 3 minutes and then completed a questionnaire with the bottle absent, or (b) they answered the same questionnaire while the bottle was present. Afterwards, participants were given all of the bottles and asked to rank them according to perceived readability. The younger adults' information acquisition performance was significantly better than the older adults' for all label conditions except the control condition where both groups' low performance did not differ. Specifically, the older adults' performance was significantly better in the medium and large print conditions than in the small print conditions – with the latter conditions not differing from the control condition. Younger adults showed no performance differences among the different print-size conditions. No substantial effects on knowledge acquisition performance from the white space manipulations were found. However, the perceived readability ranks showed that both groups preferred larger print size and white space. The white space effect was smaller than for print size, particularly for older adults. The extended/pull-out label design was facilitative for older adults in that it allowed the use of larger print. The results suggest that older consumers may be unable to acquire information in the 'fine' print frequently found in various kinds of product literature.

1. Introduction

In recent years, consumers have assumed more responsibility for their health and medical care. Accordingly, there has been increased interest in enabling consumers to acquire information from over-the-counter (OTC) non-prescription pharmaceutical labels (US Food and Drug Administration 1995). Consumer-targeted OTC drug information is provided in various ways such as on the exterior packaging, in inserts, and most commonly, on labels attached to the drug container itself (e.g. Wogalter *et al.* 1999). The US Food and Drug Administration (FDA) requires that OTC drug labels state: what the drug is used for; how to use the drug safely and effectively;

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warnings and drug interaction precautions; information on the drug's active and inactive ingredients; and what to do in case of emergencies (Nonprescription Drug Manufacturers Association 1996). The placement of this relatively large amount of information on the label can be a problem when the surface area of the product container is relatively small, as is usually the case for most OTC drugs.

Several approaches can be taken to remedy the problem. One is to decrease the print size so that all of the information fits on the container label. However, the resulting print size may be too small to be read by people with poor vision, such as older adults (seniors) who tend to consume more pharmaceuticals than other age groups (Vanderplas and Vanderplas 1980, Morrow *et al.* 1986, Watanabe 1994). A second way to deal with the limited label space issue is to omit certain (presumably, less important) information from the container label, and to place the remaining information elsewhere such as on the original packaging or in an insert. The problem with this approach is that the packaging and insert are frequently discarded or misplaced; thereby reducing their availability when the drug is used at later times (Wogalter *et al.* 1993).

A third way is to present the information via an alternative type of on-container label such as a tag or fold-out that extends the available surface area available to print information. Alternative label designs that expand the available surface area to print information are preferred by older adults and in some cases also by younger adults (Barlow and Wogalter 1991, Wogalter *et al.* 1993, 1996, 1999, Kalsher *et al.* 1996, Vigilante and Wogalter 1999). Also, younger adults complied more frequently to a glue-product warning that directed users to wear protective gloves when the warning was placed in an extended label design (a tag) compared with placement on a conventional container label (Wogalter and Young 1994). Furthermore, older adults' knowledge acquisition was benefited when the most critical information was printed onto a previously-unused surface area of an existing OTC bottle container (Wogalter *et al.* 1999). Thus, extended label designs would seem to be beneficial for presenting OTC drug information.

Recently, the FDA has recommended the use of labels that increase the space (e.g. extended labels or tags) on OTC drug containers that are too small to hold all of the necessary drug information (Federal Register 1999). Specifically, the FDA suggests extending a single panel on small OTC drug containers to increase the amount of label space for the necessary printed information (Federal Register 1999). One purpose of the present research is to determine empirically whether an extended panel label design for an OTC bottle label benefits consumers' knowledge acquisition and is preferred over a standard design.

Although characteristics of the textual print would seem to be an important factor in label design, there has been sparse research on the topic until recently. In the past decade, research activity has mainly focused on the effects of various print characteristics on people's ability and willingness to read warnings and other consumer information. Young *et al.* (1992) found that the width of the alphanumeric characters in printed warnings affects the perceived legibility and reading speed. The legibility of print with normal type widths (100% of the font size) was judged to be better than print with smaller type widths (60% and 35% of the font size). Reading speed also differed depending on type width, with thinner type (35% size) producing significantly longer reading times than the wider type (100% and 60% sizes). Anderton and Cole (1982) found that legibility is reduced as the spacing between

letters is reduced. Watanabe (1994) also found that legibility is negatively affected when characters are horizontally compressed.

Smither and Braun (1994) investigated the effects of medication label font type (Century Schoolbook, Courier, and Helvetica), font size (9, 12, and 14 point), and font weight (Roman and bold) on reading speed and various other dimensions. Participants were timed as they read the manipulated medication labels attached either to a medication bottle or to a flat piece of cardboard. They found that younger and older adults took longer to read the labels printed in 9 point font than in 12 or 14 point font. Also, the labels printed in 14 point font were judged easier to read than those in 9 and 12 point fonts. Similarly, Silver and Braun (1993) found that product labels printed in 10 point font were perceived as more readable compared to product labels printed in 8 point font. Young and Wogalter (1990) demonstrated that warnings printed more conspicuously with larger, wider-stroke print with orange highlighting were better recalled than warnings printed less conspicuously with smaller, thinner, non-highlighted print.

Together these results suggest that people generally do not prefer, nor perform well, with smaller print compared to larger print on consumer product labels. The most likely reason for these results is that smaller print is less legible and more difficult to read under certain conditions. For example, less legible print is more likely to produce perceptual difficulties under degraded environmental conditions (e.g. dim lighting) and by readers with reduced visual capabilities (e.g. older adults). Also, legibility may play a role in higher-level cognitive processes. Research (e.g. Chandler and Sweller 1996) indicates that people are less likely to engage in behaviour that produces a higher level of mental workload, such as reading densely-worded consumer information. In other words, people are less willing to expend the mental effort to read information that requires greater time and energy. With this as a consideration, the FDA has recently mandated that all information on OTC drug labels be printed in a font no less than 6 points (Federal Register 1999).

The present research examines whether there are differences in knowledge acquisition and preferences for OTC drug labels that are printed in several sizes (4, 7, and 10 points). The smallest size print is less than the FDA recommended size but is comparable to the font size found on many currently available product labels (Wogalter *et al.* 1999).

Recent FDA regulations also include the use of white spacing in OTC drug labels (Federal Register 1999). The purpose is to help separate and distinguish different sections of text in which each section is a conceptual grouping of information. Such formatting is in contrast to the conventional method of presenting text in continuous prose, or in other words, a single grouping of information. Much of the prior research related to white spacing is indirect, as in comparing textual layouts of a single group (or a few groups) of text versus more numerous groupings of related information. Wogalter and Post (1989) found that instructions in a list-type format produced better computer-task performance by experienced users than instructions that presented the same content in a prose-paragraph format. Morrow *et al.* (1998) found that prescription labels arranged in a list format produce better comprehension and recall performance by older and younger adults compared to labels arranged in a paragraph format. While younger adults generally performed better than the older adults, the difference in performance between the two age groups was smaller with the list format. Additionally, Hartley (1978, 1999) has shown that

increasing the vertical spacing between text facilitates reading comprehension. Research involving computer displays indicates that grouping text into separate conceptually-related sections can facilitate the search and acquisition of information (Tullis 1983). Together, the previous research indicates that labelling in list-type formats, which have greater amounts of white space, has benefits over paragraph-type formats, which have lesser amounts of white space. One potential reason is that separation of textual groups allows information to be shown in separate conceptual units within a context of some larger functional relationship. Conceptual grouping (or chunking) of information may aid in encoding processes because its structure makes it easier to assimilate the information into an existing memorial framework, and as such aiding knowledge acquisition (Frase and Schwartz 1979).

Thus, the grouping or chunking of related information by separating sections or lines with white spacing may be beneficial compared to a denser single grouping of information. The white space formats compared in the present study consisted of no spacing, section spacing, and line spacing. The specifics regarding these formats are described later.

The present research also employs two participant groups, younger and older adults. In general, older adults tend to use more medications than other age groups. Research has shown that sensory and cognitive impairments increase with age (see e.g. Park *et al.* 1999). The impairments include presbyopia, decreased transfer of short-term (working) memory to long-term memory, and reduced processing speed. Because of these age-related declines, older adults were not expected to perform as well as younger adults in the information acquisition tasks.

In summary, the present research examined the effects of available surface area, print size, and white spacing on knowledge acquisition of, and preference for, OTC drug labels. Twelve labels for an OTC medication with a fictitious name were constructed and attached to bottle containers. The labels varied in (a) label design (standard versus extended/pull-out), (b) print size (4 point, 7 point and 10 point) and (c) amount of white spacing between lines/sections of text (no spacing; section spacing that included a single line space between each major sections of information; and line spacing that consisted of each sentence starting on a new line using double spacing). A bottle with no back label served as a control.

Two groups of participants, older and younger adults, performed one of two knowledge acquisition tasks. One task required the participants to search a container label to answer a series of drug-related questions. This task was included to determine the effect of label design on information search. The other task required the participants to examine the container's labels for 3 minutes and then complete the same questionnaire from memory. This task was included to determine the effect of label design on participants' memory of the label information. Thus in one task the bottle was present (available) and in the other it was absent (unavailable) while taking the knowledge acquisition test. Later, after all of the knowledge acquisition testing was completed, participants were shown all 12 container-label variations and asked to arrange them in rank order according to perceived readability.

Most previous research on formatting has examined only a single kind of labelling characteristic in a given experiment. The present research examines multiple levels of three label characteristics (label design, print size, and white spacing) that enable the examination of the interactions among the factors. Also examined was whether the effect of these factors interacts with participant age group.

2. Method

2.1. Participants

Two different groups of participants were recruited totalling 210. One group comprised 101 older adults (23 males and 78 females) over the age of 65 from various community organizations and retirement communities in the Raleigh-Durham, North Carolina area (mean age = 77.7 years, $SD = 7.4$). The other group comprised 109 younger adults (61 males and 48 females) who were undergraduate students from introductory psychology courses at North Carolina State University who participated as part of a course requirement (mean age = 21 years, $SD = 4.2$).

Based on self-reports, 96% of the older adults reported that they needed glasses to read, whereas only 40% of the younger adults reported that they needed glasses to read. Of those participants who reported wearing glasses, 95% of the older adults and 86% of the younger adults wore their glasses during the experimental session. The highest educational level attained by the older adults was as follows: 16% completed high school, 27% had taken some college or trade school courses, 16% had a bachelor degree, 11% had some form of postgraduate study but no postgraduate degree, and 28% had a graduate degree. Eighty-five percent of the older adults reported having one or more medical ailments. These included: 50% arthritis, 12% cataract, 6% heart condition, 4% asthma, 3% high blood pressure and 10% other. Nineteen percent of the younger adults reported having one or more of the following ailments: 8% asthma, 5% arthritis, and 6% other.

2.2. Design

The 12 experimental label conditions were developed using a 3 (print size: 4 point, 7 point and 10 point) \times 3 (white spacing: no spacing, section spacing, line spacing) \times 2 (label design: standard/flat, extended/pull-out) design. The actual experiment was not a complete factorial design. The reason for this is that some of the possible label format combinations on OTC drug containers would not (or could not) be realistically implemented. The excluded conditions were the large print, line spaced extended label, and all of the large and medium print standard label designs. One reason for excluding these conditions was that there was no way to place all of the information content on the standard label using the larger print sizes. Moreover, while it is possible to put the large print, line spaced condition on an extended label, it would require a different or larger extended label design than the extended label design used in the present experiment.

The knowledge-acquisition dependent variable was analysed using a between-subjects (groups) model. The rank order data were analysed using a within-subjects (repeated measures) model. The data were also examined with respect to participant group (older versus younger adults).

2.3. Materials

2.3.1. *Bottles*: Twelve identical bluish-green plastic OTC medication bottles (commonly used to contain liquid antacid) with approximate dimensions of 19 cm high \times 9.5 cm wide \times 5.5 cm deep were used. The original labels were stripped from the bottles and replaced by labels designed for the present research. The front and side labels were identical on all 12 bottles. The label information and design were adapted from an actual OTC motion sickness medication; however a fictitious name, Marvine, was used. The front and side labels are shown in figure 1.



Figure 1. Front (a) and side views (b) of the OTC medication bottle.

Table 1. Descriptions of 12 label conditions as a function of print size, white space and label design.

Condition number	Print size	White space	Label design
1	Large (10 point font)	Section (paragraph format)	Extended/pull-out
2	Large (10 point font)	No spacing	Extended/pull-out
3	Medium (7 point font)	Line (sentence format)	Extended/pull-out
4	Medium (7 point font)	Section (paragraph format)	Extended/pull-out
5	Medium (7 point font)	No spacing	Extended/pull-out
6	Small (4 point font)	Line (sentence format)	Extended/pull-out
7	Small (4 point font)	Section (paragraph format)	Extended/pull-out
8	Small (4 point font)	No spacing	Extended/pull-out
9	Small (4 point font)	Line (sentence format)	Standard flat
10	Small (4 point font)	Section (paragraph format)	Standard flat
11	Small (4 point font)	No spacing	Standard flat
12	No label (control)		

The back labels were constructed to correspond to the 12 label conditions listed and described in table 1.

All of the back labels contained exactly the same printed material (except the control, which had no back label). Only the way the information was presented (i.e. via format and label type) varied. Figure 2 shows example back labels. The control condition was included to determine the level of background knowledge that participants had without having seen a back label in the experimental situation. The no-label control provides a baseline to compare to the other conditions in which some form of back label was given. The extent to which performance is higher for the back label present conditions is an indication that some information is being acquired from the back labels.



Figure 2. Example back labels. (a) Small print, no spacing, standard flat label. (b) Medium print, line spacing, extended label. (c) Large print, section spacing, extended label.

In the no spacing conditions, text was continuous prose. In the section spacing conditions, major sections of information (e.g. directions, warnings) were separated by a line space. In the line spacing conditions, each sentence started on a new line using double spacing.

There were two label designs that provided different amounts of labelling surface area. The standard label design was similar to conventional container labels, with all of the information printed on a single side (in this case, a relatively flat surface) of the back of the bottle. For the extended/pull-out label design the back label information was printed on three sides of a label that was folded in half. The front (or first) side of the label folded out like a book cover revealing the second and third page of the label. No information was printed on the back (fourth) side of the extended label as it was attached to the back surface of a bottle.

For all conditions, the back label information was printed in a Helvetica-Narrow (sans serif) font similar to that used on many OTC drug labels. Labels were constructed using a word processing program on an Apple Macintosh computer and printed using a black and white Postscript-enabled 800 dpi laser printer on white bond paper. When attached to the bottles, the paper labels were covered in a high-gloss clear plastic adhesive.

2.3.2. Forms: The forms included a consent form, a questionnaire assessing knowledge of an OTC motion sickness medication, and a demographics form. The demographics form asked questions about age, gender, educational background, and use of corrective lenses.

The knowledge questionnaire asked questions about the medication. Example questions include: (a) 'How many tablets does the bottle contain?' (b) 'Within what temperature range should the medication be stored?' (c) 'Who should not take this medication?' and (d) 'What is the proper dosage for children 12 and under?' Each correct answer was given 1 point totalling 37 points. Blank spaces were provided after each question for the participants' written responses.

2.4. Procedure

2.4.1. *Knowledge acquisition task*: Participants were assigned randomly to bottle-label and knowledge-acquisition task conditions according to a predetermined random assignment according to order of participation.

All participants were first given the consent form to read and sign. Next, they completed a demographics form. After completing this form, the experimenter read the following scenario to each participant:

Assume for the moment that you and a group are going on a one-day bus trip to the mountains. The group includes children as well as older adults. It will be a bumpy ride, with hills and winding roads. You have taken with you a bottle of medicine called Marvine to help you and others overcome any motion sickness that might occur. Knowing that others on the bus might have medical conditions that mean they should not use the drug, you will need to be careful to whom you give the Marvine.

This scenario is similar to that used in previous OTC knowledge acquisition research reported in Wogalter *et al.* (1999). After the scenario, participants were given additional instructions depending on the specific knowledge acquisition task to which they were assigned. The two knowledge acquisition tasks are described below: bottle available or unavailable.

2.4.1.1. *Bottle available task*: After reading this scenario, the experimenter instructed the participants assigned to the bottle available condition that they would be given a medication container to examine and a questionnaire to complete. These participants were instructed to take as much time as they needed to complete as many of the questions as they could based on their background knowledge about the drug and from the information found on the container. The experimenter then handed the participant the bottle and questionnaire and asked them to begin working on the items.

2.4.1.2. *Bottle unavailable task*: After reading this scenario, the experimenter instructed the participants assigned to the bottle unavailable condition that they would be given a medication container to examine for 3 minutes. They were told to carefully examine the information on the bottle and that after the 3-minute period, the bottle would be taken away and they would be asked to complete a questionnaire based on their background knowledge of the drug and from the information found on the container. The experimenter then handed the participant a bottle, asked them to begin, and began the timer. After 3 minutes the bottle was removed and the participants were given the questionnaire and asked to begin working on the items. All participants were timed from the time they started answering the questionnaire to the time they stated they were finished answering the questions.

The intended purpose of imposing a time limit was to simulate situations where users may allocate a relatively short period of time to examine a product label. Also, it was intended to represent situations where the user is somewhat rushed in examining a label before use (e.g. in a medical emergency). The time limit of 3 minutes was chosen because it represented the average time needed to read through the entire back label at a hurried reading speed by several undergraduate and graduate student pilot participants. The time limit also provided a control of the

maximum amount of time participants were exposed to the label information across all conditions. If a particular label condition was easier to read and acquire information than another label condition, it was expected that a relatively short, but constant time of exposure would be more apt to reveal a difference in a subsequent knowledge acquisition test.

2.4.2. Bottle label ranking: After all aspects of the knowledge acquisition test described above were completed, participants were then given all 12 OTC motion sickness medication bottles and told that all of the bottles were identical except for their back labels. The experimenter then orally described the format differences between the label conditions. The participants were instructed to provide a single rank order of the bottles according to a combination of several perceived readability criteria, specifically which label formats were easiest, fastest, and most comfortable to read. Participants were instructed to choose the bottle with the best label and place it to their left (assigned a rank score of one), then decide which label was next best (assigned a rank score of two) and so forth, down to the worst label condition (assigned a rank order of 12). Participants were allowed to change their rank orders until they were satisfied. Ties were also allowed.

Following the completion of these tasks, participants were debriefed and interviewed about their thoughts concerning the materials they had seen. Lastly they were thanked for participating.

3. Results

Analyses examined the knowledge acquisition and perceived readability rank scores separately.

3.1. Knowledge acquisition

3.1.1. Scoring reliability: The responses from the knowledge acquisition questionnaire were scored by two judges who were blind to experimental conditions and who used both strict and lenient criteria in their evaluations. The former required the exact wording found on the labels, whereas the latter allowed wording that was synonymous in meaning to the wording found on the labels. The judges were highly reliable in their scoring. The correlations were 0.97 and 0.98 between the judges for the lenient and strict criteria, respectively. In addition, the strict and lenient scores themselves were highly correlated, with $r > 0.96$. Because of these high correlations, the mean of the two judges' lenient scores are used in the analyses described below. Lenient scores were used instead of the strict scores because the former are more reflective of conceptual understanding as opposed to latter, which are more reflective of verbatim memory (cf. Young and Wogalter 1990). We were more interested in participants' understanding of the material than their recall of the exact words.

3.1.2. Factorial analysis: Because of the large number of factors investigated, several analyses were used to fully explore the data. Initially, the knowledge acquisition scores were submitted to a 2 (participant group: older adults, younger adults) \times 2 (task type: label available vs unavailable) \times 12 (bottle label conditions) between-subjects analysis of variance (ANOVA). Significant effects according to the ANOVAs were followed (when applicable) by simple effects analysis and subsequent comparisons among conditions based on the 0.05 probability level. The ANOVA showed that the participant group factor produced a significant main effect, $F(1,$

162) = 132.47, $MSe = 31.10$, $p < 0.0001$. Older adults ($M = 18.78$) acquired less information from the labels than the younger adults ($M = 27.73$). Task type also produced a significant main effect, $F(1, 162) = 188.27$, $p < 0.0001$. Knowledge acquisition scores were higher when the label was available for inspection while answering the questionnaire ($M = 28.59$) than when it was unavailable ($M = 19.92$). There was also a main effect of label condition, $F(11, 162) = 5.96$, $p < 0.0001$. Paired comparisons among the means showed that all of the medium and large print size conditions produced higher knowledge acquisition performance levels than two of the small print size conditions (the extended label with line spacing and the standard flat label with no white space). Also, the extended label with large print and no white space produced significantly higher scores than the standard flat label with small print and line white space. All 11 experimental (label-present) conditions produced significantly higher scores than the control condition.

The ANOVA also showed an interaction of label condition with participant group, $F(11, 162) = 2.62$, $p < 0.01$. Table 2 shows the knowledge acquisition means as a function of bottle label condition and participant group. Also shown are the significant differences between conditions as indicated by different superscript letters. (The table also shows data from the preference rank analysis in the two right-most columns. These data will be discussed later.) The table shows that older adults produced higher knowledge acquisition performance in the large and the medium

Table 2. Mean knowledge acquisition and perceived readability rank order scores as a function of bottle label and participant group.

Bottle label condition				Dependent measures			
				Knowledge acquisition		Perceived readability rank	
Condition number	Print size	White space	Label design	Older	Younger	Older	Younger
1	Large	Section	Extended	22.13 ^a	29.21 ^a	1.62 ^a	2.09 ^a
2	Large	No	Extended	24.56 ^a	28.51 ^a	1.98 ^a	3.33 ^{bc}
3	Medium	Line	Extended	23.90 ^a	27.86 ^a	3.56 ^b	2.72 ^{ab}
4	Medium	Section	Extended	21.10 ^a	30.64 ^a	4.03 ^{bc}	3.70 ^c
5	Medium	No	Extended	22.16 ^a	28.94 ^a	4.56 ^c	4.91 ^d
6	Small	Line	Extended	14.38 ^b	28.55 ^a	7.77 ^d	6.80 ^e
7	Small	Section	Extended	17.25 ^b	29.40 ^a	9.21 ^{de}	8.42 ^f
8	Small	No	Extended	18.00 ^b	28.36 ^a	9.50 ^e	9.87 ^g
9	Small	Line	Standard flat	16.81 ^b	28.58 ^a	7.27 ^d	6.28 ^e
10	Small	Section	Standard flat	16.40 ^b	29.21 ^a	8.27 ^{de}	8.07 ^f
11	Small	No	Standard flat	14.71 ^b	28.59 ^a	9.75 ^e	9.88 ^g
12	No label (control)			14.00 ^b	14.96 ^b	11.87 ^f	12.00 ^h

Print size: large (10 point), medium (7 point), small (4 point).

White spacing: no (no spacing), section (spacing between main sections), line spacing (between listed statements).

Label design: standard flat or extended (book cover).

Higher knowledge acquisition scores indicate better performance. Lower rank scores indicate greater perceived readability.

Mean scores with different superscript letters are significantly different from each other ($p < 0.05$).

print size conditions than the small print and control conditions. Performance in the small print conditions did not significantly differ from the control condition. The younger adults performed similarly across all 11 experimental label conditions, and all of which were higher than the control condition.

The ANOVA also showed a significant interaction of task type and bottle label condition, $F(1, 162) = 2.91, p < 0.01$. These means are displayed in table 3. When the label was available during the time the questionnaire was completed, knowledge acquisition performance in the large and medium print conditions was generally greater than in the small print conditions. When the label was unavailable during the time the questionnaire was being completed (i.e. from memory), there were no significant differences among the label-present conditions.

The participant group \times task type interaction was not significant, but the ANOVA showed a significant three-factor interaction of participant group \times label condition \times task type, $F(1, 162) = 1.84, p = 0.05$. These means are shown in table 4. When the bottle labels were available for inspection, the older adults produced better performance in the large and medium print conditions compared to the small print and control conditions, but no differences among conditions were apparent when the label was unavailable. The younger adults performed better than the older adults and better with the label available than unavailable.

3.1.3. *Subset factorial analyses:* In the preceding analysis, the entire set of 12 bottle label conditions was treated as a single factor. Because of the structure of the label manipulations it was not possible to examine all of the label factors simultaneously in a single factorial ANOVA. Therefore, three subsets of labels were analysed to determine main effects and interactions in smaller analyses with fewer conditions. These ANOVAs examined label type \times white spacing (using the small print conditions only) and print size \times white spacing (using two subsets of the extended label conditions).

Using only the six small print conditions (label conditions 6 through 11), a 2 (participant group: older adults, younger adults) \times 2 (label type: standard flat,

Table 3. Mean knowledge acquisition as a function of bottle label and task type.

Condition number	Bottle label condition			Task type	
	Print size	White space	Label design	Label available	Label unavailable
1	Large	Section	Extended	31.38	19.96
2	Large	No	Extended	34.39	18.69
3	Medium	Line	Extended	33.45	18.31
4	Medium	Section	Extended	32.70	19.04
5	Medium	No	Extended	33.63	17.47
6	Small	Line	Extended	25.13	17.80
7	Small	Section	Extended	26.63	20.03
8	Small	No	Extended	27.68	18.69
9	Small	Line	Standard flat	30.06	15.32
10	Small	Section	Standard flat	28.35	17.26
11	Small	No	Standard flat	23.25	20.05
12	No label (control)			16.50	12.46

Table 4. Mean knowledge acquisition as a function of bottle label, participant group, and task type.

Condition number	Bottle label condition			Task type			
				Label available		Label unavailable	
	Print size	White space	Label design	Older	Younger	Older	Younger
1	Large	Section	Extended	26.50	36.25	17.75	22.17
2	Large	No	Extended	32.38	36.40	16.75	20.62
3	Medium	Line	Extended	30.80	36.10	17.00	19.62
4	Medium	Section	Extended	30.50	34.90	11.70	26.38
5	Medium	No	Extended	32.38	34.88	11.94	23.00
6	Small	Line	Extended	16.25	34.00	12.5	23.10
7	Small	Section	Extended	17.25	36.00	17.25	22.80
8	Small	No	Extended	20.25	35.10	15.75	21.62
9	Small	Line	Standard flat	23.88	36.25	9.75	20.90
10	Small	Section	Standard flat	21.70	35.00	11.10	23.42
11	Small	No	Standard flat	13.12	33.38	16.30	23.80
12	No label (control)			15.88	17.12	12.12	12.80

extended) \times 3 (white space: no, section, line) between-subjects ANOVA showed only one significant effect. Younger adults ($M=28.6$) performed better than the older adults ($M = 16.26$), $F(1, 94)=63.5$, $MSe = 59.48$, $p < 0.0001$.

Using a subset of conditions of the extended label condition, two additional factorial ANOVAs were conducted. One was composed of a 2 (participant group) \times 2 (print size: small, medium) \times 3 (white spacing: no, section, line) design (using label conditions 1, 2, 4, 5, 7 and 8). The ANOVA not only showed a participant group main effect (with means similar to that noted above), but also a print size main effect, $F(1, 91)=4.24$, $MSe = 71.74$, $p < 0.01$. Performance was better for medium print ($M=26.1$) than for small print ($M=22.9$). (There were no large print conditions in this analysis.) The other analysis involving the extended label conditions was similar to the one just mentioned but used a somewhat different set of conditions (label conditions 3 to 8). The design was a 2 (participant group) \times 3 (print size: small, medium, large) \times 3 (white spacing: no, section) factorial. In this analysis, only the participant group main effect was significant.

3.2. Questionnaire completion time

The time taken by participants to complete the questionnaire from start to finish was examined. An ANOVA model identical to the first-described knowledge acquisition analysis showed only two effects. One was for participant group, $F(1, 161)=5.41$, $MSe = 135.85$, $p < 0.05$. The younger adults ($M=20.95$ s) completed the questionnaire faster than the older adults ($M=24.88$ s). The other was for task type, $F(1, 161)=108.41$, $MSe = 135.85$, $p < 0.0001$. Participants completed the questionnaire faster when the label was unavailable ($M=14.37$ s) than when it was available ($M=31.37$ s).

3.3. Perceived readability rank order

The perceived readability data consisted of rank order scores with lower numbers indicating greater perceived readability.

3.3.1. *Analysis across all label conditions:* Rank order as a function of condition was first tested using the non-parametric multi-condition within-subjects Friedman test, which was significant, $p < 0.0001$. The Wilcoxon Matched-Pair Signed-Rank test together with a Bonferroni correction (to maintain experiment-wise error at 0.05) was used to make paired comparisons. The mean ranks and significant differences are shown in the two right-most columns of table 2. The older adults' and younger adults' ranks were analysed separately. Only the significant comparisons are described below.

For the older adults, the large print conditions were preferred over medium print conditions, which in turn were preferred over the small print conditions. Within the medium and small print conditions, line spacing was preferred over no spacing. For the small print conditions, there were no significant differences between the standard flat and extended labels. The control label was the least preferred compared to all other conditions.

For the younger adults, a similar pattern of rank order means was shown. However, there were more differences that were significant between label conditions relative to those seen in the older adults' data. Large print with section spacing was preferred over all other conditions except for the medium print line spacing condition, which in turn was preferred over all other conditions except for large print no spacing. Large print no spacing was preferred over the medium print no spacing and all six small print conditions. Medium print section spacing was preferred over the medium print no spacing, which was in turn preferred over all six small print conditions. Within the six small print conditions, line spacing was preferred over section spacing, which in turn was preferred over no spacing. There were no significant differences between the standard flat and extended labels for the comparable small print conditions. The control label was the least preferred.

3.3.2. *Subset factorial analyses:* Like the analyses conducted on the knowledge acquisition data, three separate factorial analyses were conducted to examine main effects and interactions among different subsets of the bottle label conditions.

A 2 (participant group: older adults, younger adults) \times 2 (label type: standard flat, extended) \times 3 (white-spacing: no, section, line) mixed-model ANOVA (with the latter two factors repeated measures) comprised of only the six small print conditions was conducted (label conditions 6–11). The ANOVA showed significant main effects for all three factors. Younger adults ($M = 8.22$) gave lower ranks than the older adults ($M = 8.63$), $F(1, 201) = 12.64$, $MSe = 4.05$, $p < 0.001$. For these conditions, the standard flat label ($M = 8.25$) was preferred over the extended label ($M = 8.59$), $F(1, 201) = 6.19$, $MSe = 5.72$, $p < 0.05$. Comparisons for the white spacing main effect means indicated that line spacing ($M = 7.03$) was preferred over the section spacing ($M = 8.49$), which in turn was preferred over no spacing ($M = 9.75$), $F(2, 402) = 282.20$, $MSe = 2.66$, $p < 0.0001$. There were two significant interactions. One was for participant group and white spacing, $F(1, 402) = 14.67$, $MSe = 2.66$, $p < 0.0001$. While both groups preferred line spacing to section spacing and section spacing over no spacing, the older adults preferred the section and line spacing to a greater extent than the younger adults. The other significant interaction involved label type and white spacing, $F(2, 402) = 8.69$, $MSe = 2.09$, $p < 0.001$. The standard flat labels received lower ranks than the extended labels in both the section and line spacing, but there was no difference between the label designs with no spacing.

The second subset analysis of the ranks (using label conditions 1, 2, 4, 5, 7 and 8) was a 2 (participant group: older adults, younger adults) \times 3 (print size: small, medium, large) \times 2 (white-spacing: no, section) mixed-model ANOVA (with the latter two factors repeated measures). The ANOVA showed significant main effects for all three factors. The older adults ($M=5.15$) gave lower ranks than the younger adults ($M=5.39$), $F(1, 201)=7.12$, $MSe=2.42$, $p<0.01$. Print size comparisons showed that large print ($M=2.25$) was ranked significantly lower than medium print ($M=4.30$), which in turn was preferred over the small print ($M=9.25$), $F(2, 402)=2018.1$, $MSe=2.60$, $p<0.0001$. Section spacing ($M=4.85$) was preferred over no spacing ($M=5.69$), $F(1, 201)=147.49$, $MSe=1.47$, $p<0.0001$. There were two significant interactions. One involved participant group and print size, $F(2, 402)=14.67$, $MSe=2.66$, $p<0.0001$. Older adults gave significantly lower ranks for large print than the younger adults, but the two groups did not differ for small and medium print. The other interaction was between participant group and white spacing, $F(1, 201)=42.60$, $MSe=1.47$, $p<0.0001$. While section spacing was preferred over no spacing by both participant groups, the difference was larger for the younger adults compared to the older adults.

The third factorial analysis was a 2 (participant group: older adults, younger adults) \times 2 (print size: small, medium) \times 3 (white-spacing: no, section, line) mixed-model ANOVA (with the latter two factors repeated measures) using a subset of the extended label conditions (conditions 3–8). The ANOVA showed significant effects for all three factors. Younger adults ($M=6.07$) gave lower ranks than older adults ($M=6.44$), $F(1, 201)=16.49$, $MSe=2.47$, $p<0.0001$. Medium print ($M=3.91$) was preferred over small print ($M=8.59$), $F(1, 201)=2337.60$, $MSe=2.85$, $p<0.0001$. Line spacing ($M=5.21$) was preferred over section spacing ($M=6.34$), which in turn was preferred over no spacing ($M=7.21$), $F(2, 402)=186.17$, $MSe=2.19$, $p<0.0001$. The ANOVA also showed a significant participant group \times white spacing interaction, $F(2, 402)=19.91$, $MSe=2.19$, $p<0.0001$. While both groups preferred line spacing and least preferred no spacing, the difference was larger for the younger adults than the older adults. There was also a significant print size \times white spacing interaction, $F(2, 402)=14.73$, $MSe=1.48$, $p<0.0001$. Preference for medium print over the small print was smaller with line spacing than with the other two spacing conditions.

4. Discussion

This research examined the effects of label type, print size and white spacing given on the back labels of a fictitious OTC medication. Younger and older adults answered questions while one of the 12 manipulated labels was present or was absent (i.e. from memory). Later participants rank ordered all of the labels on perceived readability.

Both the knowledge acquisition and rank order scores showed that print size was a very important label factor for older adults but to a somewhat lesser extent for younger adults. In the knowledge acquisition task, older adults were only able to show higher knowledge acquisition than the no label control (a) when medium (7 point) or large (11 point) print was used but not when small (4 point) print was used, and (b) when the label was available to them when answering the knowledge test. For the younger adults, the print size manipulation had no effect. They performed equally well with all three sizes of print, producing knowledge acquisition scores higher than the control, not only when the label was present but also from memory.

However, the results from the rank order data suggest that both age groups preferred the larger print, followed by the medium print, over the small print. Larger print size was more strongly preferred by the older adults than the younger adults. For the younger adults, some of the medium print conditions were perceived as readable as the large print conditions.

Older adults also performed more slowly in answering the knowledge acquisition questionnaire. The latter result concurs with research showing that as age increases, performance on short-term/working memory and speed of cognition decreases (see e.g. Park *et al.* 1999). However, these cognitive processes cannot account for the decreased knowledge acquisition performance by the small print conditions. The most probable explanation for the decreased performance by older adults in the small print conditions is due to reduced visual capabilities relative to the younger adults. Presbyopia, a collection of vision problems in adults as they age, results in reduced acuity and a reduced ability to read small print (Watanabe 1994). Many products contain labels that are printed as small as or smaller than the small print condition in this study (e.g. Wogalter *et al.* 1999). This suggests that older adults may not be able to acquire information from many kinds of product documentation such as proper-use instructions, maintenance requirements, and safety information. Given that many older adults take one or more medications on a regular basis and also have reduced visual capabilities, it would seem essential to ensure that the size of the print is large enough to enable information transmission from the label to the receiver.

While the knowledge acquisition test failed to show any white spacing effects, the ranking task, however, showed that both participant groups preferred more white space. Line spacing (with the most white space) was preferred over section spacing, followed by no spacing. During the debriefing period, several of the participants commented that the line spacing made the labels easier to read and that the paragraph-type separation between sections of label text helped to differentiate the different parts of the label material.

Interestingly, the older adults showed a less pronounced white spacing effect compared to the younger adults. This indicates a lower degree of importance relative to print size. For younger adults, print size was less of an issue because they could extract information in the small print conditions, whereas older adults could not. An inability to read the material probably produced a strong negative bias on preference judgments. Thus, the older adults made their readability preference judgments on the basis of print size and less strongly with regard to white spacing. Probably for any given reader, if the print size is large enough to be read, increasing the size further is not likely to make much difference for that individual in the same circumstances except in noticeability. But if the print size is not large enough for that individual to read it, then there is a strong reduction in readability preference. This was found for the older adults more so than the younger adults.

The discrepancy between the knowledge acquisition scores and perceived readability scores is not unexpected. The research literature in psychology and human factors/ergonomics commonly shows that performance and subjective judgments do not always match, particularly when they are measuring different concepts (e.g. Wogalter *et al.* 1997, Wogalter and Dingus 1999). A generic finding is a small or no difference in performance with a larger difference in subjective judgments. Subjective judgments are often somewhat more sensitive in detecting differences among conditions than measures of memory and behaviour. With more

participants and more sensitive procedures, significant differences between the white spacing conditions in the knowledge acquisition scores might have been noted.

A ceiling effect (i.e. scores near maximum) was apparent in the younger adults' data when the label was available for inspection during the knowledge test. This concurs with the notion that when the print size is large enough to read, further increases of size will not further facilitate performance. However, this particular result is dependent on the task and the individuals participating. A ceiling effect was less obvious in the younger adults' performance in the label unavailable task, and was absent in the older adults' data.

The study also failed to show a direct effect of the extended label design compared to the standard flat design. Somewhat oddly, one analysis showed the standard flat design was better than the extended label. On the surface, this would appear to be a surprising finding. It is surprising since previous research (Kalsher *et al.* 1996, Wogalter *et al.* 1996) shows greater preference for and compliance to extended labels and tags compared to traditional container labels (Wogalter and Young 1994). This apparent conflict in the results is reduced when it is noted that a direct comparison between the two label-design types in the present research could only be made in the small print conditions. The extended labels with no spacing and section spacing produced considerable white space at the bottom of the panels. During the debriefing period, several participants commented negatively about the wasted label space in these two conditions, a perception that might have reduced their preference judgments.

Actually, an opposite conclusion, that the extended label is beneficial, can be drawn from other findings. The extended label design provides additional label space that could be used to increase print size on small containers. Larger print sizes could not otherwise be used on standard flat labels because the material would not fit. At debriefing, many participants agreed with the idea that an extended label design was a good way to include larger print and allow for white spacing. Thus, the extended label did, by proxy, yield positive effects in that it served as a vehicle to carry the larger and medium print labels, which were the conditions that showed significant knowledge acquisition benefits for older adults.

Many of the current findings support past research on print characteristics of consumer product labels. For example, there was support, in the form of user preference, for Morrow *et al.*'s (1998) finding that a list format (comparable to the line-spacing) aids reading comprehension, and for Hartley's (1984) recommendations for using white spacing between sections of text (comparable to section-spacing) on medication labels. The present research also confirms Smither and Braun's (1994) finding that people prefer and are able to read through more information in medication labels that use larger print fonts compared to labels that use smaller fonts.

The present results also correspond to the FDA regulations that concern the standardization of the formatting for OTC drug labelling (Federal Register 1999). The FDA has set the minimum print size for OTC medication labels to a 6 point font, although they encourage the use of larger font sizes. In the present study, a 4 point font was not legible to older adults, whereas the 7 and 11 point fonts were. The FDA also requires the use of a horizontal line to separate the information under each major OTC drug label heading and to use a bullet format to list chunks of information. The present study showed that greater separation between text is preferred as long as the print size is adequate. Finally, the FDA encourages the use

of an extended label design when surface area is limited on an OTC medication bottle. It was noted in the present study that the standard flat label was unable to accommodate the larger print that older adults could see. The FDA has also recently mandated that labels contain a certain ordering of sections (indications, warnings, directions for use) that are similar to those found by Vigilante and Wogalter (1997) in a consumer preference study. Although OTC drug labels served as the vehicle to examine label characteristics, the findings from this study are probably applicable to other kinds of product label, particularly for products that are complex and/or hazardous and which have limited surface space. Extended label designs, whether it is a pull-out or a tag, or simply making better use of existing surface space, can enable larger print and increased white space. Sufficiently large print is a necessary characteristic for older adults to read the material. While larger print is not as important to younger adults as it is to older adults, the data suggest that print size and white spacing can affect preferences and performance of both age groups.

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Title 16. Board of Pharmacy Proposed Language

To Add Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1707.5 Patient Centered-Labels on Medication Containers

(a) Labels on drug containers dispensed to patients in California shall conform to the following format to ensure patient-centeredness.

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~12-point, 10-point,~~ sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name, or the generic name and the name of the manufacturer.

(C) Directions for use.

(D) Purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy and its inclusion on the label is ~~desired~~ requested by the patient.

(2) For added emphasis, the label ~~may~~ shall also highlight in bold typeface or color, or use "white space" blank space to set off the items listed in subdivision (a)(1).

~~(3) The remaining required elements for the label specified in Business and Professions Code section 4076 and other items shall be placed on the container in a manner so as to not interfere with emphasis of the primary elements specified in subdivision (a)(1), and may appear in any style and size typeface.~~

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

- (A) Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
- (B) Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (C) Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (D) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning
- (E) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning
- (F) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning
- (G) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, and Take 1 ~~tablet~~ [insert appropriate dosage form] at bedtime
- (H) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 2 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (I) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, and Take 3 ~~tablets~~ [insert appropriate dosage form] at bedtime
- (J) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, and 1 ~~tablet~~ [insert appropriate dosage form] in the evening
- (K) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon, and 2 ~~tablets~~ [insert appropriate dosage form] in the evening
- (L) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, 3 ~~tablets~~ [insert appropriate dosage form] at noon, and 3 ~~tablets~~ [insert appropriate dosage form] in the evening
- (M) Take 1 ~~tablet~~ [insert appropriate dosage form] in the morning, 1 ~~tablet~~ [insert appropriate dosage form] at noon, 1 ~~tablet~~ [insert appropriate dosage form] in the evening, and 1 ~~tablet~~ [insert appropriate dosage form] at bedtime

Deletions to the regulatory text are indicated by double strike-through, thus: ~~deleted language~~. Additions to the regulatory text are indicated by a double underline, thus: added language.

(N) Take 2 ~~tablets~~ [insert appropriate dosage form] in the morning, 2 ~~tablets~~ [insert appropriate dosage form] at noon, 2 ~~tablets~~ [insert appropriate dosage form] in the evening, and 2 ~~tablets~~ [insert appropriate dosage form] at bedtime

(O) Take 3 ~~tablets~~ [insert appropriate dosage form] in the morning, 3 ~~tablets~~ [insert appropriate dosage form] at noon, 3 ~~tablets~~ [insert appropriate dosage form] in the evening, and 3 ~~tablets~~ [insert appropriate dosage form] at bedtime

~~(P) Take 1 tablet as needed for pain. You should not take more than _____ tablets in one day~~

~~(P) If you have pain, take _____ [insert appropriate dosage form] at a time. Wait at least _____ hours before taking again. Do not take more than _____ [appropriate dosage form] in one day~~

~~(Q) Take 2 tablets as needed for pain. You should not take more than _____ tablets in one day~~

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) Beginning in October 2010, the board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

~~(d) For patients who have limited English proficiency, upon request by the patient, the pharmacy shall provide an oral language translation of the prescription container label's information specified in subdivision (a)(1) in the language of the patient.~~

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open.

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either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

February 10, 2010

To: Board Members

SUBJECT: FOR DISCUSSION AND POSSIBLE ACTION. Board Action to Adopt New Section at Title 16 California Code of Regulations Section 1702 – Fingerprint Submissions for Pharmacists

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concluded February 15, 2010.

A copy of the proposed regulatory language is attached. To date the board has received three comments. Copies of the comments will be provided to the board during the meeting as well as suggested responses.

Title 16. Board of Pharmacy Proposed Language

To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after ([OAL insert effective date]).

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

February 10, 2010

To: Board Members

SUBJECT: FOR DISCUSSION AND POSSIBLE ACTION. Board Action to Initiate Rulemaking to Amend Title 16 California Code of Regulations Section 1732.2 – Awarding Continuing Education Credits.

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR §1732.05),

- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR §1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR §1732.2).

Additionally, the board previously voted to award CE for the following:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

This was included into the board's continuing education policy, but was never formally amended into regulation.

Following is a copy of the draft language for board consideration.

Title 16. California State Board of Pharmacy

Proposed Language

To Amend Section 1732.2. of Article 4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1732.2. Board Accredited Continuing Education

(a) Individuals may petition the board to allow continuing education credit for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.

(b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.

(c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists (pursuant to section 4200.2 of the Business and Professions Code) may annually be awarded six hours of continuing education credits for conducting a review of exam test questions as directed by the subcommittee. A subcommittee member shall not receive continuing education credits pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions as directed by the subcommittee.

(d) A pharmacist or pharmacy technician who attends a full day of a board meeting may be awarded up to six hours of continuing education on an annual basis. The board shall designate on its public agenda which day shall be eligible for continuing education credit.

(e) A pharmacist or pharmacy technician who attends a committee meeting of the board may be awarded up to two hours of continuing education on an annual basis. Such continuing education will be limited to attendance at two different committee meetings on an annual basis.

(f) A pharmacist who completes the Pharmacist Self-Assessment Mechanism (PSAM), administered through the National Association of Boards of Pharmacy, may be awarded up to six hours of continuing education.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4200.2, 4231 and 4232, Business and Professions Code.



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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

February 9, 2010

To: Members, Board of Pharmacy

Subject: Board Licensure of Clinics Pursuant to CA Business and Professions Code Section 4190

California Pharmacy Law allows the board to issue a "clinic permit" to "surgical clinics" as defined in Health and Safety Code section 1204(b)(1). The permit issued by the board allows the clinic to have a single drug stock for use by the facility. Without such a clinic permit, each practitioner must own his or her own drug stock and must dispense dangerous drugs only to the prescriber's own patients as mandated by Section 4170 of the Business and Professions Code.

Health and Safety Code Section 1204(b)(1) also determines what surgical clinics are subject to licensing by the Department of Public Health (CDPH). CDPH's regulatory authority over "surgical clinics" extends to the regulation of the facilities themselves, including establishment of minimum standards for safety including minimum staffing requirements, qualifications and equipment. (Health & Safety Code, §§ 1226, 1248.15.) As a result, to qualify for either a Pharmacy Board permit or a license issued by CDPH, an ambulatory surgical clinic must meet the definition of "surgical clinic" provided in Health and Safety Code section 1204(b)(1). Any clinic that does not meet the definition contained in Section 1204(b)(1) of the Health and Safety Code does not qualify for a clinic permit issued by the Board.

Health and Safety Code section 1204(b)(1) provides the following definition of what is considered a "surgical clinic":

*(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter: (1) A "surgical clinic" means a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. **A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure. (Emphasis added.)***

About three years ago, the California Department of Public Health was involved in a lawsuit regarding the regulation of a physician-owned ambulatory surgical clinic. In deciding that lawsuit, the California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to "...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this

ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as “surgical clinics” within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the “*Capen* decision,” the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the foregoing, the California State Board of Pharmacy cannot issue permits to ambulatory surgical clinics (ASCs) with physician ownership. These unlicensed ambulatory surgical clinics are outside the board's jurisdiction. The board has not issued a clinic license to physician owned clinics since 2007, since they lack the underlying Department of Public Health license. Several legislative remedies introduced since 2007 have not been enacted and were either vetoed or stalled in the Legislature.

Where a currently licensed ambulatory surgical clinic undergoes a change of ownership (i.e., a change of 50% or more), it is required to submit a change of ownership application to the Board of Pharmacy for its clinic permit (16 CCR § 1709). Under those circumstances, if the ambulatory surgical clinic has physician ownership (and thus no CDPH license), the Board cannot issue the facility a clinic permit. As a result, Business and Professions Code 4170 requires a prescriber at these ASCs to be responsible for his own drug stock at the location from which he/she dispenses. Thus, in order to continue to dispense drugs at the ASC site, each prescriber at the ASC must maintain his or her own separate drug supply in the absence of a board clinic permit. If the prescriber fails to maintain his/her own supply while the ASC continues to dispense drugs, such failure could subject the prescriber or the owners of the facility to sanctions by CDPH or the Medical Board for violation of Business and Professions Code section 4170.

At this meeting: The board is asked to review and evaluate its policy in this area. Our attorneys will be prepared to respond to questions.