

Study of Expanded Use of an Automated Delivery Device

30 January 2014



UC San Diego
HEALTH SCIENCES

Study Intent

To study the role of the automated delivery device on patient adherence and consultation behaviors

- Principal Investigator:

Charles E. Daniels, R.Ph., Ph.D.

Professor of Clinical Pharmacy & Associate Dean

Skaggs School of Pharmacy and Pharmaceutical Sciences

University of California

- Associate Investigators:

Kim Allen, SRS Pharmacy

Sheila M, SRS Pharmacy

Study Rationale

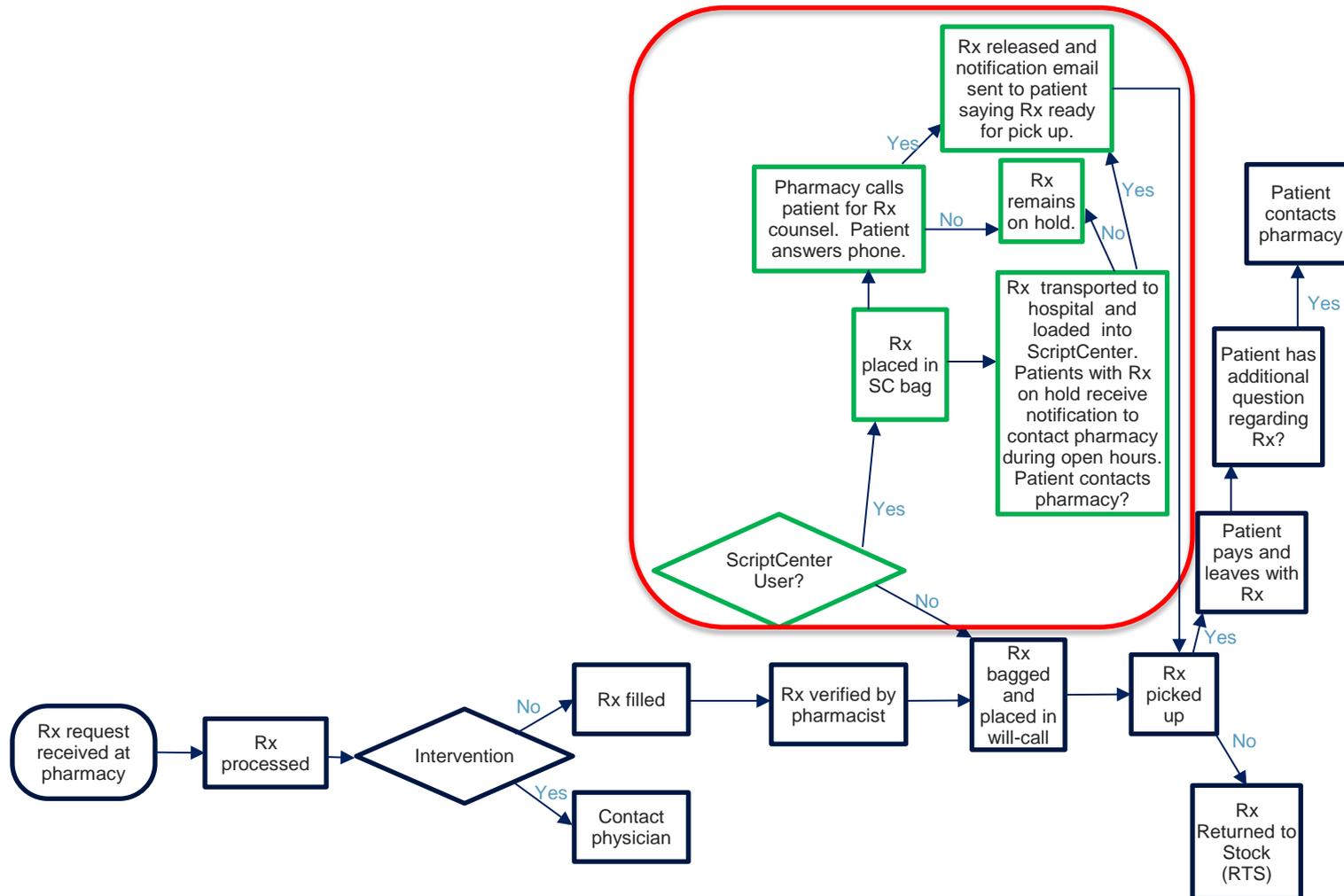
- One component of patient adherence behavior is related to their ability to have timely access to medications after prescribing
- Patient access to medications at their place of work will improve their ability to start quickly, and refill regularly
- A dispensing pharmacy at most places of work is not practical
- Use of an automated delivery device may provide more timely access to prescribed medications

Research Questions

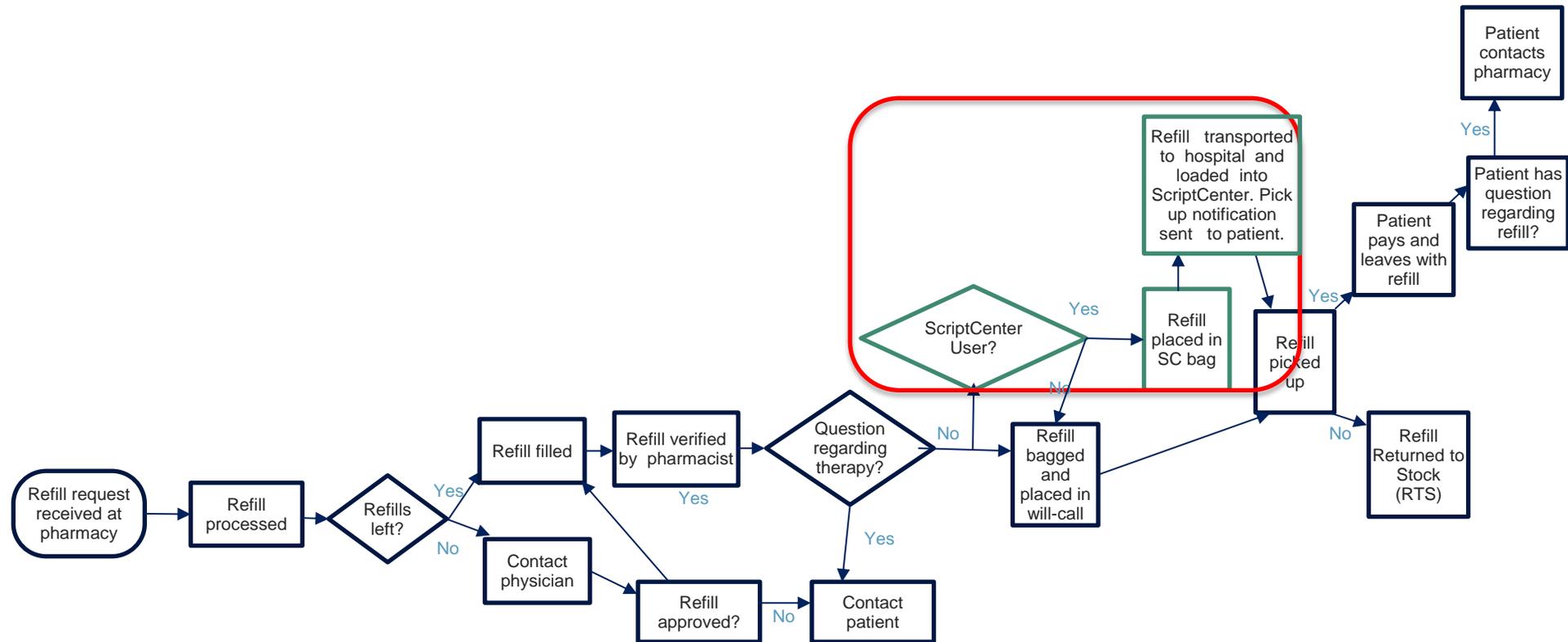
Primary: Is patient adherence improved with an on-site automated delivery device?

Secondary: Does the nature of patient consultation questions change when prescriptions are obtained from an automated delivery device?

SRS Pharmacy Process for New Prescriptions



SRS Pharmacy Process for Refill Prescriptions



Methods & Measures

- Adherence proxy will be prescription return to stock rate in pre-kiosk period, and in both kiosk pick-up and pharmacy pick-up in post kiosk period.
- Time from Rx fill, to kiosk availability, and to patient pick-up with comparison to time from fill to in-pharmacy pick-up
- Consultation question log will be used to document timing and nature of patient consultation requests

Sample Size Calculation

- Mean Return to Stock Rate (Dec 2012-Nov 2013)
 - 5.51%
- S.D. Return to Stock Rate (Dec 2012-Nov 2013)
 - 0.648
- Sample size requirement for alpha of 0.05 and power of 0.9

Projected Timetable

- Q2 2014
baseline data collection
Invitation to participate in new program
- Q4 2014
Implement kiosk
refine data collection tools and process
- 2 month
Ramp-up period
- Q1 & Q2 2015
Post-implementation
data collection and analysis
- Q3 2015
Report to Board

Population for Study

- Employees and dependents of Sharp Memorial Hospital
- Volunteers

Patient Issues

Risks to Kiosk Participants

- May not routinely come to pharmacy for face-to-face interaction
- May be concerned about use of phone consultation and reduce # of questions

Benefits to Kiosk Participants

- Rapid & convenient access to new prescriptions following phone consultation
- Convenient 24/7 access to refill medications

Other Study Issues

Human Subjects Research Approval

- Sharp Healthcare Institutional Review Board
 - Submitted for approval without requirement for individual patient consent based upon; awaiting results
- UCSD Institutional Review Board
 - Will be submitted after results of Sharp IRB review completed

Declaration of Conflicts of Interest

- Principal Investigator has no relevant conflicts of interest
- Associate Investigators have no relevant conflicts of interest

Sharp Memorial Hospital



Kiosk placed in employee entrance hallway of licensed facility within close proximity of information desk and telephone.





Thank You!

UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES

PROJECT PROPOSAL

The purpose of the project is to study the safety and efficacy of an automated prescription delivery device (Asteres ScriptCenter®) as a means to deliver finished prescription medications to employees and their dependents of Sharp Memorial Hospital in San Diego, California. Currently, several barriers exist that make it difficult for patients to access the Sharp outpatient pharmacy during regular business hours. Increased accessibility to prescription medications through the use of automated delivery devices has the potential to increase medication adherence resulting in improved health outcomes and decreased healthcare expenditure by decreasing exacerbations of disease states.

This proposal outlines the request for the pilot of one ScriptCenter at Sharp HealthCare. ScriptCenter will be placed in the secured, licensed facility and serviced by a California licensed pharmacy. In accordance with regulation 1706.5, the experimental program will be monitored and reported on by an accredited school of pharmacy, UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences. ScriptCenter will be accessible anytime by the California State Board for board inspection and evaluation. Monthly updates will be provided to the California State Board of Pharmacy during the duration of this research study.

REGULATION SECTION 1713

In 2005 and 2006, the California State Board of Pharmacy granted a waiver to allow the use of automated delivery devices in pharmacies to deliver refill medications even after the pharmacy has closed. Regulation 1713 section D has since been written to allow for these types of devices in California pharmacies. Current regulations allow the delivery of prescriptions to employees at their work site.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

The two areas Regulation Section 1713 that we are requesting a waiver:

Current regulation: (d)(6) The device is located adjacent to the secure pharmacy area.

Proposed Change: *Allow for placement of the device in a secured area located inside a building serviced by a current pharmacy licensee in an alternate location with access readily available for Board of Pharmacy inspection.*

Current regulation:(d) A pharmacy to use an automated delivery device to deliver previously dispensed prescription medications.

Proposed Change: *Allow for new prescriptions to be delivered from the automated delivery device after mandatory patient consultation and proper documentation have taken place.*

BACKGROUND

Sharp HealthCare recognizes that managing employees' health and wellness is important in maximizing workforce productivity. Today only 5% of Sharp HealthCare employees are using the Sharp Rees Stealy Pharmacy. Sharp Rees Stealy (SRS) Pharmacy can improve prescription medication adherence of Sharp employees at the workplace by providing improved access to prescriptions. This effort would improve employee health, productivity and control overall healthcare cost.

Studies show that patients have difficulty filling prescriptions due to the following barriers; lack of transportation, difficulty affording medications, and long wait times at the pharmacy. Therefore, the emerging technology will improve access to employees' prescriptions. Approximately 5.7% of all prescriptions filled at SRS Pharmacy are never picked up by the patient. In a small sample of patients who failed to pick up their prescriptions, failure of communication was



the primary reason cited and convenience of location was the secondary reason. By providing a secure and convenient method of prescription pick up for Sharp employees, they will have better access to their prescription without leaving the workplace, therefore decreasing the number of prescriptions returned to stock (RTS) for patients utilizing the automated delivery device.

RESEARCH PROPOSAL

The research study will be conducted by UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences. The intent of the research is to study the role of the automated delivery device on patient adherence and consultation behaviors. One component of patient adherence behavior is related to their ability to have timely access to medications after prescribing. Patient access to medications at their place of work will improve their ability to start quickly, and refill regularly. A dispensing pharmacy at most places of work is not practical, so we feel the use of an automated delivery device may provide more timely access to prescribed medications.

Research Questions:

Primary: Is patient adherence improved with an on-site automated delivery device?

Secondary: Does the nature of patient consultation questions change when prescriptions are obtained from an automated delivery device?

The methods and measurements along with the specific details of the research study including sample size and patient confidentiality can be found in the included IRB narrative and application. The study has been submitted to the Sharp Healthcare IRB and is awaiting approval. Once approved, it will be submitted to the UCSD IRB.

Principal Investigator: C. Daniels, RPh, Ph.D., FASHP

Program manager: Kim Allen, RPh, SRS Pharmacy Manager

PATIENT COUNSELING

ScriptCenter 'On-Hold':

New prescriptions loaded into ScriptCenter by authorized personnel will automatically be placed on hold until the patient has been counseled. Counseling will take place over the phone during pharmacy hours. The prescription will remain on hold until the patient is counseled during pharmacy hours. Authorized pharmacists in the pharmacy will have access to AsteresCentral® to change the on-hold status of a prescription. Refill prescriptions may also be placed on hold if the pharmacist feels the patient needs further counseling or information (*see reference materials page 7*).

New Prescriptions:

All new prescriptions will receive mandatory counseling before the medication is released from ScriptCenter. The will contact the patient and notify them they need to pick up their prescription at the pharmacy. The patient will also receive a notification via email and/or text notifying them they need to contact the pharmacy for consultation.

Refill Prescriptions:

The pharmacist will use their professional judgment and ensure that any refill prescription will receive a pharmacist consult if appropriate by placing the prescription on hold until the patient has been contacted.

Access to pharmacist 24/7:

ScriptCenter patients are presented with a 24 hour telephone number on the ScriptCenter screen and receipt connecting them with a Sharp HealthCare licensed pharmacist. The pharmacist will answer questions, but all counseling will occur during pharmacy hours (per the January 10th Enforcement Committee Meeting).

SCRIPTCENTER INSTALLATION

ScriptCenter location: Sharp Memorial Hospital - 7901 Frost Street, San Diego, CA 92123 (*see 'security measures'*)

ScriptCenter will be serviced by Sharp Rees-Stealy, 2929 Health Center Dr., San Diego, CA (0.2 mi.).



Device will be serviced once daily, Monday – Friday. SRS pharmacy is open Monday-Friday 8:30am-5:30pm.

SECURITY MEASURES

ScriptCenter will be placed within a 24 hour secured and monitored building. The hallway where ScriptCenter will reside is the employee entrance to the hospital and is patrolled by a security guard on a regular basis. The employee entrance doors are locked each night from 2200-0500. There is an information desk with a phone line within close proximity of the kiosk.

ScriptCenter is 1,300 lbs and is bolted to the floor. It is also equipped with an interior camera that photographs each person completing a transaction and keeps a photographic log on file (*see reference materials page 9*).

Asteres ScriptCenter has successfully delivered over 750,000 prescriptions to date without one known break-in or delivery error.

POLICY AND PROCEDURE

SRS Pharmacy will maintain written policies and procedures pertaining to the automated delivery device that include:

1. Maintaining security of automated delivery device and dangerous drugs within the device.
2. Determine and apply inclusion criteria regarding which medications are appropriate for placement for the device and for which patients including mandatory consultation for all new prescriptions, and immediate patient consultation via telephone upon request.
3. Ensure that patients are aware of mandatory consultation for every new prescription and that a Sharp HealthCare licensed pharmacist is available 24/7.
4. Description and workflow of responsibilities, training material for SRS pharmacy personnel, regarding the maintenance and filling procedures for the automated delivery device. Pharmacy personnel train with HIPAA certified Asteres employees. Pharmacy personnel are given a role by the pharmacy administrator with varying levels of access. Pharmacy personnel logging into ScriptCenter are tracked and a complete audit trail of all ScriptCenter activity is recorded (*see reference materials page 8*). After loading prescriptions into ScriptCenter, pharmacy staff is required to return a confirmation slip to the pharmacy for verification and sign off (*see reference materials page 4*).
5. Orient participating patients on the use of the automated delivery device, notify patients when expected prescriptions medications are not available in the device, and ensure patients use the device
6. Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program.

CONCLUSION

Implementation of the ScriptCenter solution at Sharp Memorial Hospital, will allow Sharp Healthcare to provide better access to medications and service for their employees. Sharp HealthCare is dedicated to providing wellness services to their employees to provide convenient 24/7 prescription pick up for Sharp employees. The intent of the research conducted by UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences is to study the role of an automated delivery device on patient adherence and consultation behaviors. The study results will be shared with the board along with monthly progress reports to ensure the health and safety of those involved in the pilot.



REFERENCE MATERIALS

Regulation Section 1713

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be to or from Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

(7) The device is secure from access and removal by unauthorized individuals.

(8) The pharmacy is responsible for the prescription medications stored in the device.

(9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).

(e) Any pharmacy making use of an automated delivery device as permitted by subdivision

(d) shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.

(5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.

(g) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.

(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707 .2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written

1706.5 Experimental Programs

In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, teaching, research, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board enacts the following:

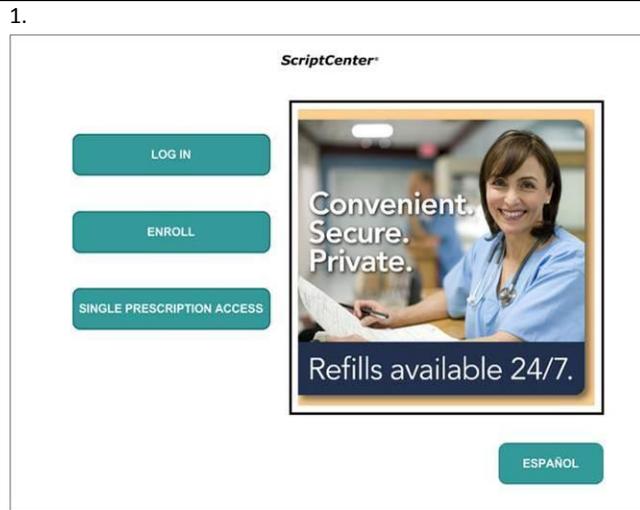
(a) The application of particular provisions of the Pharmacy Rules and Regulations contained in Title 16, California Administrative Code, Chapter 17, may be waived as to an accredited school of pharmacy recognized by the Board if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(b) Any plan or program approved by the Board shall have: definite time limitations; progress reports which shall be filed as required by the Board.

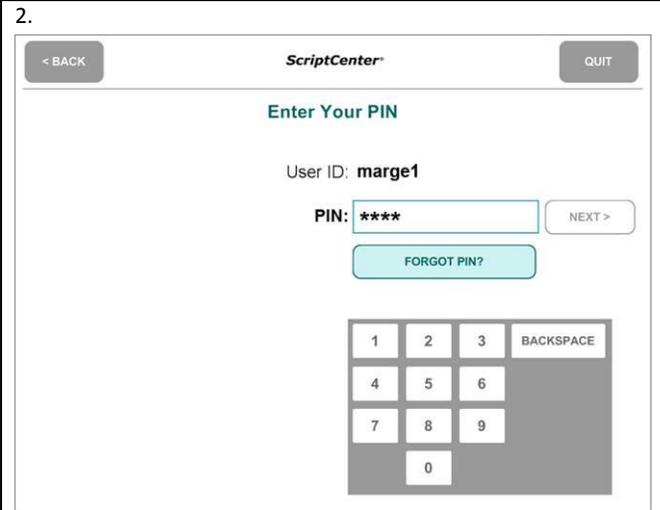
(c) The Board may rescind approval and terminate said plan or program at its discretion, at any time it may deem the public interest is not fully protected; nor shall any such plan or program be approved by the Board if such proposal might jeopardize public health or welfare or conflict with provisions of Chapter 9, Div. 2, Business and Professions Code.

Automated Delivery Device Screens

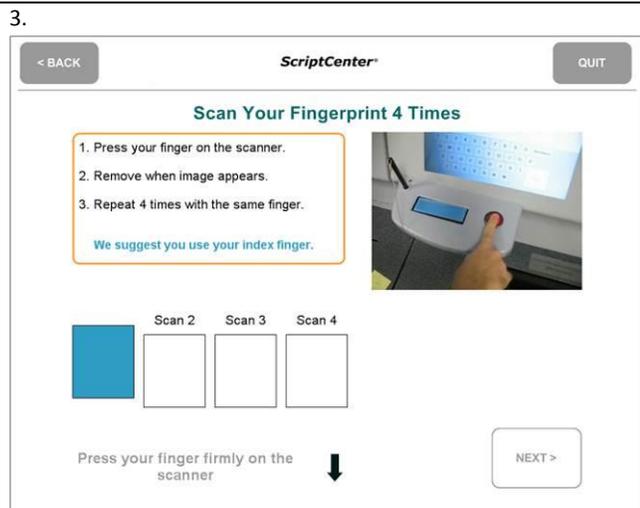
Enrollment:



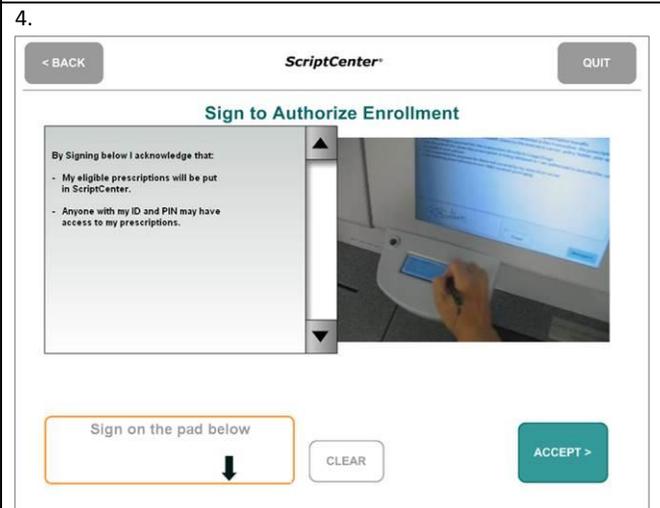
Patient/Employee selects 'Enroll'.



Patient/Employee enters their prescription number (one prescription number needed for enrollment) and creates their ID and PIN.



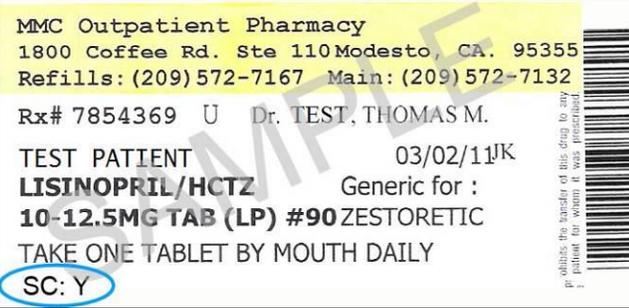
Patient/Employee adds their fingerprint for quicker login (optional).



Patient/Employee signs.

Pharmacy:

1.



MMC Outpatient Pharmacy
1800 Coffee Rd. Ste 110 Modesto, CA. 95355
Refills: (209) 572-7167 Main: (209) 572-7132

Rx# 7854369 U Dr. TEST, THOMAS M.
TEST PATIENT 03/02/11 JK
LISINOPRIL/HCTZ Generic for :
10-12.5MG TAB (LP) #90 ZESTORETIC
TAKE ONE TABLET BY MOUTH DAILY
SC: Y

Prohibits the transfer of this drug to any patient for whom it was prescribed.

Prescriptions with the ScriptCenter indicator get put in a separate bin for for ScriptLinking.



ScriptCenter prescriptions are put into a ScriptCenter containers.



Prescription is ScriptLinked to ScriptCenter container using a barcode scanner.

4. Prescriptions are transported to ScriptCenter via authorized pharmacy personnel.



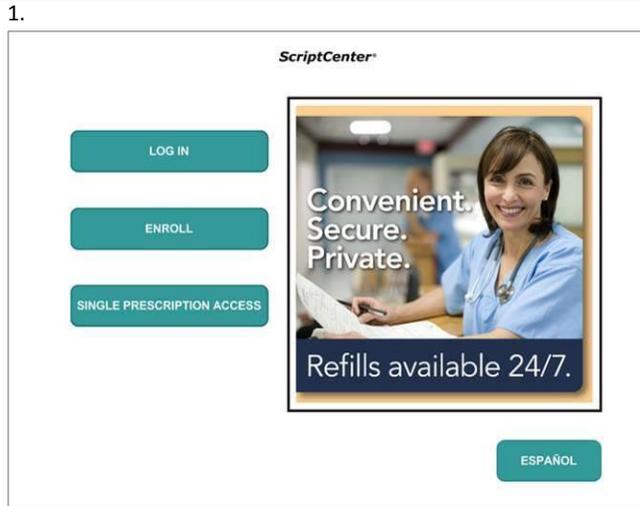
Pharmacy staff logs into ScriptCenter kiosk using unique ID and PIN or fingerprint and loads prescriptions.

6.

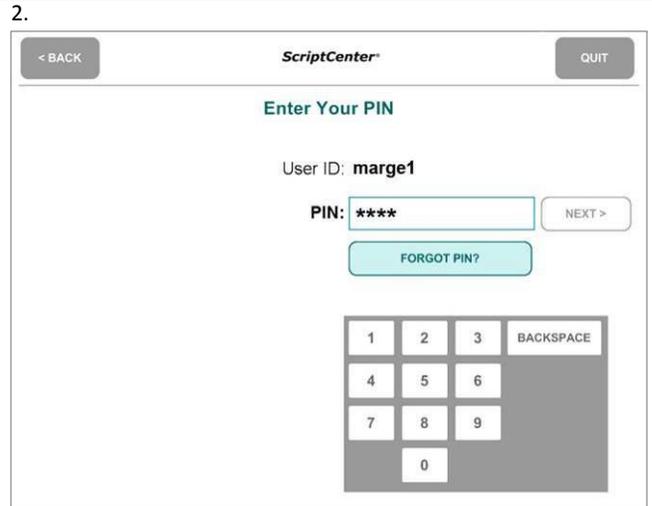
ScriptCenter Inventory Status	
Total Packages:	171
New Packages Loaded*:	19
Packages Unloaded*:	16
Ready to Unload:	5
Unknown:	5
Incomplete Orders:	0
<hr/>	
Trays to Inspect:	0
Missing Trays:	0
<hr/>	
<small>*Since 6/27/2013 12:58 PM.</small>	
Run by Sara Lake at 1:02 PM on 6/27/2013.	

Pharmacy personnel prints inventory slip and returns to pharmacy to hand in for confirmation.

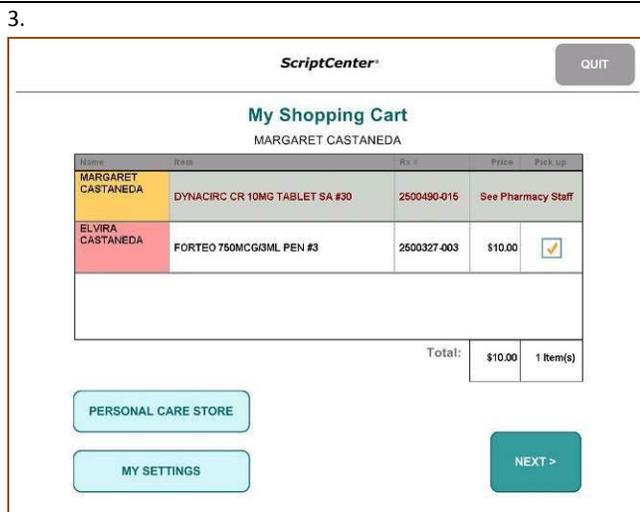
Delivery:



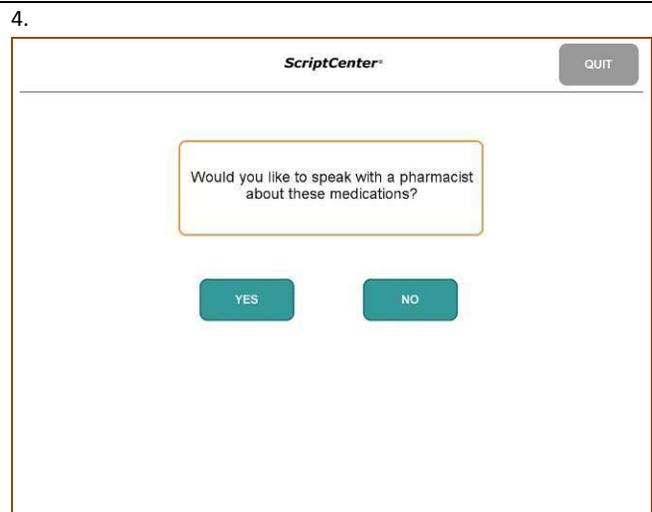
Employee logs in and discharge patient uses unique code for one-time pick up.



ID and PIN or fingerprint and PIN used for employee login.



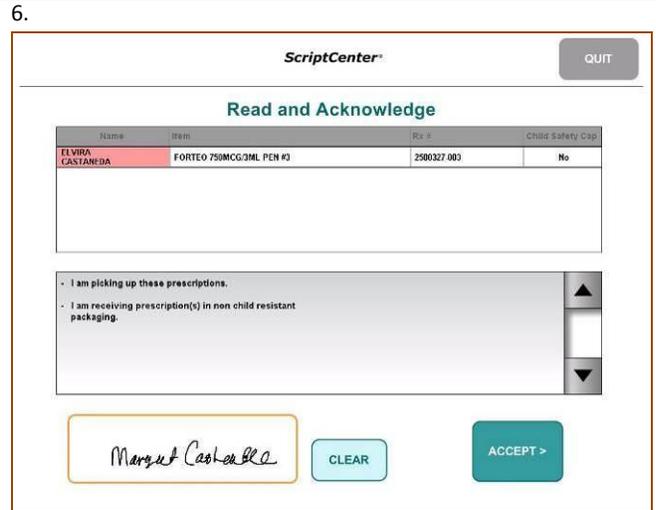
Prescriptions reviewed for pick up. Note that family members can be added to an account for quick and convenient pick up. Prescriptions on-hold requiring consultation are presented as 'See Pharmacy Staff'. A 'See Pharmacy Staff' slip also prints from ScriptCenter.



Offer for consultation presented.



Directions for consultation provided. A log is kept for those who decline consultation.



Employee/patient signs for prescription(s).



Employee/patient pays for prescription(s) and picks them up from the delivery bin. Prescriptions left behind are flushed into a secure bin on accessible by pharmacy.

Hold and Release in AsteresCentral®:

Welcome staff | Dashboard | Logoff

AsteresCentral® 3.4.0 (310) (2004/9/27/12)

Dashboard Reports **Patients** ScriptLink™ Access Product Link Holds

Patient: FIGUEROA, ELISA

Birthdate: **7/8/1980** Home Phone: **4760717950** User ID **ELFIGU**
 Post Code: **74130** Mobile Phone: **Not Provided** Fingerprint: **Not On File** [Clear Registration](#)
 Email:

Prescriptions Pick Up Lists Edit Patient Data

Hold	Select	Rx #	Fill	Location	Container	Medication	Status
<input type="button" value="Hold"/>	<input type="checkbox"/>	4471455	004	7-2-6	000000182	LEXAPRO 20MG TABLET	Deliverable
<input type="button" value="Release"/>	<input type="checkbox"/>	1010303	006	7-2-5	000000181	SYNTHROID 150MCG TABLET	Deliverable

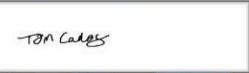
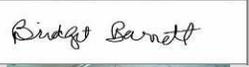
[Back](#)

AsteresCentral® Reports:

Asteres Activity						
48 Transactions						
Filter: "Today"						
Date and Time	Transaction Type	Container No.	Rx Number	Fill	User / Shopper	Patient / Product
08/10/10 09:57:24	UNLINKED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
08/10/10 09:56:42	UNLOADED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
The package was moved from location 6/4/10 to the holding area.						
08/10/10 09:55:43	SERVICE_REQUEST		Unknown		LAKE, SARA	
[sara] Sara Lake issued a request to unlock the back door by Bio ID.						
08/10/10 09:50:26	DELIVERED	002001028	2500469	002	GODINEZ, LUPE	GODINEZ, LUPE
The package at location 4/3/5 was delivered.						
08/10/10 09:48:47	UNLOADED	002001053	2500581	001	LAKE, SARA	JOHNSON, GARY C
The package was moved from location 6/5/6 to the holding area.						
08/10/10 09:48:46	ACCESSED	002001052	2500580	001	LAKE, SARA	LIMON, STACEY
The package at location 6/5/1 was accessed.						
08/10/10 09:48:45	ACCESSED	002001192	2500673	001	LAKE, SARA	HEUPEL, SANDRA
The package at location 6/5/5 was accessed.						
08/10/10 09:48:41	LOADED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
The package was moved from the holding area to location 6/4/10.						
08/10/10 09:48:23	ACCESSED	002248974	OTC		LAKE, SARA	Schick Quattro
The package at location 5/2/8 was accessed.						
08/10/10 09:48:23	ACCESSED	002248973	OTC		LAKE, SARA	Schick Quattro
The package at location 5/2/7 was accessed.						
08/10/10 09:48:23	ACCESSED	002248948	OTC		LAKE, SARA	Gillette MACH3 Turbo
The package at location 5/2/5 was accessed.						
08/10/10 09:47:53	DOOR_CLOSED		Unknown		Unknown	
Back door was closed.						
08/10/10 09:47:31	DOOR_OPENED		Unknown		Unknown	
Back door was opened.						
08/10/10 09:47:16	SERVICE_REQUEST		Unknown		LAKE, SARA	
[sara] Sara Lake issued a request to unlock the back door by Bio ID.						
08/10/10 09:46:57	LINKED	002001095	3500502	002	LAKE, SARA	VANCE, WARREN
08/10/10 09:44:13	MOVED	002001031	2500475	001	Unknown	AGUILERA, ANA
The package was moved within ScriptCenter from location 4/5/9 to location 4/4/3.						
08/10/10 09:43:45	MOVED	002001018	2500439	001	Unknown	KELLEY, TIM
The package was moved within ScriptCenter from location 5/4/2 to location 5/6/7.						
08/10/10 09:41:15	ACCESSED	002010063	2500326	001	DEYSHER, CHERYL	GAXIOLA, HILDA
The package at location 1/3/6 was accessed.						
08/10/10 09:41:14	ACCESSED	002010069	2500339	001	DEYSHER, CHERYL	NEAL, CHARLES
The package at location 1/3/5 was accessed.						
08/10/10 09:41:14	ACCESSED	002010075	2500354	001	DEYSHER, CHERYL	JUSTICE, FRANCES
Asteres Activity - Mira Main Street						
			August 10, 2010		9:58 am	
Page 1 of 3						

Photo Capture Log

Filter: Date Signed is between '6/25/2009' and '6/26/2009'

RX #	Fill	Date Signed	Time Signed	Medi-Cal Relationship	Third Party	Co-Pay	Credit/Debit Card	POS ID	Photo
2500302	1	6/25/2009	1:32:52PM		SBHA	\$20.00			 
2500228	1	6/26/2009	9:27:18AM			\$10.00			 
2500302	2	6/26/2009	9:46:09AM		SBHA	\$10.00			 
2500301	1	6/26/2009	9:47:36AM		CRK	\$15.00			 
2500306	1	6/26/2009	10:04:31AM		PACS	\$10.00			 



Institutional Review Board
 8695 Spectrum Center Blvd
 San Diego, CA 92123
 (858) 499-4836 (phone) / (858) 499-3105 (fax)
<http://sharpnet/irb/> / www.sharp.com/research
 E-mail: research@sharp.com

For IRB Staff Use Only:
 IRB #: _____
 Principal Investigator: _____
 Meeting Agenda Date: _____
 Section: _____
 Date Submission Received: _____

INITIAL IRB REVIEW APPLICATION

Sponsor's protocol number (if applicable):	Sponsor's Name (if applicable):
Title (or Humanitarian Use Device name): Experimental Program/Research Study on Automated Delivery Systems (Asteres ScriptCenter Kiosk) in a Licensed Facility for Employee Prescriptions	
Indication: Other If "Other", Specify: Automated Delivery System at Sharp Memorial Hospital	

Local Investigative Site Information

Indicate local sites where subject recruitment, enrollment, and other activities will occur:

- | | | |
|--|---|---|
| <input type="checkbox"/> Coronado | <input type="checkbox"/> Mary Birch | <input type="checkbox"/> California Institute of Renal Research |
| <input type="checkbox"/> Chula Vista | <input checked="" type="checkbox"/> Memorial / OPP | <input type="checkbox"/> eStudySite |
| <input type="checkbox"/> Grossmont | <input type="checkbox"/> Mesa Vista | <input type="checkbox"/> San Diego Cardiac Center |
| <input checked="" type="checkbox"/> Rees-Stealy | | |
| <input type="checkbox"/> Medical Oncology Associates - San Diego | <input type="checkbox"/> Cancer Center Oncology Medical Group | |
| <input type="checkbox"/> South County Hematology/Oncology | <input type="checkbox"/> North County Oncology Medical Clinic, Inc. | |
- Other – **Only complete the information below for local sites that are not selected above.** If more than one site is "Other," submit a separate sheet answering the questions below for each site listed. Complete the following only for sites listed as "Other".

Name of Study Location:
 Address: (street, city, state, postal code)

What type of facility is this site?
 If Other, specify: _____

What resources are available at this site to treat emergencies resulting from activity-related procedures? (check all that apply):

- ACLS trained personnel and crash cart
- Emergency drugs and supplies to stabilize subject until emergency personnel arrive
- Emergency response team within hospital
- Other - Specify: _____
- N/A

If your site is not a hospital, name the medical facility to be used in an emergency: _____ Or N/A

Does the PI or a sub-investigator have staff privileges at the facility to be used in an emergency?

Yes N/A

No (explain each of the following):

How will subjects be referred for hospitalization? _____ Or N/A

Have you made arrangements for a physician to attend to patients in an emergency? Yes No N/A

Have you taken measures to assure that attending physician(s) will communicate with the PI? Yes No N/A

Site Personnel

Submit each of the following for **all site personnel** listed on this application:

Completed, signed, dated Financial Disclosure Statements (FDS) (*sponsored activities only*)

Current Curriculum Vitae (CV) or resume (*if not previously submitted*)

Copy of current Medical License (*if not previously submitted*)

NIH training completion certificate or other research subject protection training program certificate (*to be completed within the past 24 months*)

Completed Demographic Form (DF) (*if not previously submitted or if person's information has changed*)

Has/have your site(s) and/or any site personnel been audited by the FDA, OHRP, sponsor, CRO and/or any other regulatory agencies?

Yes No

Has/have your site(s) and/or site personnel received a Form FDA 483, Warning Letter, and/or any other notification of regulatory issues?

Yes No

Have there been any professional disciplinary or legal actions involving your site(s) and/or site personnel?

Yes No

If yes to any of the above, provide copies of **all Form FDA 483s and/or correspondence** with application materials.

Attached Previously submitted (*The IRB may ask for additional information.*)

Principal Investigator (PI) Information

First Name: Sheila	Last Name: Alignay- Rivera	Degree: PharmD
If the PI is a student, resident or fellow, identify the site personnel responsible for oversight of PI:		
Is the PI a member of the Sharp HealthCare (SHC) Medical Staff or a SHC employee**?		
		No <input type="checkbox"/> Yes <input checked="" type="checkbox"/>
Specialty:	Pharmacy	
Company:	Sharp Rees Stealy Pharmacy	
Mailing Address:	2929 Health Center Drive	
City, State, Zip	San Diego, CA 92123	
E-mail address: sheila.rivera@sharp.com	Phone: 858.939.6586	Fax: 858.636.2999

Study Coordinator Information (*Will be primary contact for this activity.*)

Is there a designated study coordinator (other than the PI) for this activity?

No Yes - Complete the following:

First Name: Sheila	Last Name: Alignay-Rivera	Degree: PharmD
Is coordinator a member of the SHC Medical Staff or a SHC employee**?		
		Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Specialty:	Pharmacy	
Company:	Sharp Rees Stealy Pharmacy	
Mailing Address:	2929 Health Center Drive	
City, State, Zip	San Diego, CA 92123	
E-mail address: sheila.rivera@sharp.com	Phone: 858-939-6586	Fax: 858-636-2999

Site Personnel

<u>First Name</u>	<u>Last Name</u>	<u>Degree</u>	<u>Role</u>	<u>SHC Medical Staff member or Employee? **</u>

- b. Is there a CRO? No Yes Name: _____
- c. Does the Sponsor/CRO agree to cover subjects' costs for research related injuries?
 No Yes – Include in contract and consent.
- d. Does the Sponsor/CRO allow the Investigators to freely publish study results?
 Yes No - If no, describe any restrictions: _____
- e. ClinicalTrials.gov Identifier: _____ N/A - Sponsor's rationale: _____

Federally funded Research

Federal Agency: _____

Cooperative Group: _____ Or N/A

Foundation (*specify*):

Sharp HealthCare Foundation

Coronado Hospital Foundation

Grossmont Hospital Foundation

NOTE: If any one of the above is selected, the activity is considered "Sponsored" and individual FDS forms are required. Grant-funded activities also require individual FDS forms. In most cases, the selections below do not require Financial Disclosure Statements.

If none of the above, check all that apply below:

Investigator Initiated

Department Funded (*specify*): _____

No Support Required

Other: _____

Review Fees – Send check payable to Sharp HealthCare IRB to the address on page one of this application.

Initial Full Committee Review	\$3,000 (IRB and entity Administrative review)
Initial Expedited Review	\$1,000 (IRB and entity Administrative review)
Initial Humanitarian Use Device Review	\$1,000 (IRB and entity Administrative review)
System Antibiotic Review Committee Review	\$500 (SARC review fee is in addition to IRB and administrative review fees)

If internal Sharp HealthCare research site, provide SHC cost center number: _____

IRB and administrative review fees may be waived for unfunded research.

Site Personnel Financial Disclosure Statement

Is this sponsored research?

No - Skip to "Summary of Research Activity" section.

Yes - If any site personnel responded "Yes" to the corresponding questions on their individual FDS, select "Yes" below.

Financial Compensation from or Management Responsibilities in Related Businesses

No Yes

Equity Interest in Related Businesses

No Yes

Intellectual Property and Related Businesses

No Yes

Executive Relationship

No Yes

Business Ownership

No Yes

Other Relevant Financial Interests

No Yes

Summary of Research Activity

Is summary available in protocol, research narrative or study/project plan?

Yes – Page numbers _____ - Skip to “Expense to Subjects” and “Compensation to Subjects” sections.

No - Complete all Summary sections.

Explanation/Purpose:

Provide a brief description of the purpose of this activity and the hypotheses, or describe the purpose of the HUD. Specific aims may be used if they clearly define the purpose and intent of the activity.

Background and Significance:

Briefly describe the relevant background supporting the conduct of this activity or use of this HUD. Provide a summary of results obtained by others pertinent to this activity or HUD. Appropriate references should be included.

Design and Methods:

Describe the design and the procedures to be used to accomplish the specific aims of the activity. Define in clear terms exactly what will be done to the human subjects, source and types of data to be collected, and/or samples to be taken. Describe how the informed consent will be presented to potential subjects. Be sure to indicate which procedures are part of routine care, required for employment, and/or which procedures are experimental. Provide a precise description of the planned data collection, proposed analyses, and hypothesize activity results. This should include criteria for determining statistical significance and sample size.

Potential Risks:

Describe any potential or known risks - physical, psychological, social, legal or other - and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be available to the subjects.

Risk Management:

Describe the procedures for protecting against or minimizing potential risks. Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject. Also, where appropriate, discuss the provisions for monitoring the data collected to ensure the security of subjects' PHI.

Potential Benefits:

Benefits may be gained by:

- the individual subject: No Yes - Explain: **Increased access and medication adherence**
- society in general: No Yes - Explain: **Decreased healthcare costs**

Expense to Subject:

Does the research activity involve any added expense to subjects (e.g., longer hospitalization, additional tests, blood draws, travel, etc.)? No Yes - Explain:

Has the FDA authorized the drug or device sponsor to charge subjects or their insurance for the experimental drug, device, or intervention? No Yes (provide a copy of the authorization letter from the FDA with this application)

Will there be charges to subjects, or their third-party payers, for study-related procedures that are considered standard of care? No Yes - Explain:

Does the informed consent clearly outline the added expense to subjects?

No added expense Yes - provide page #:

Compensation to Subject:

Will subjects be compensated in any way?

No

Yes - Provide payment schedule or other compensation to be provided (include this information in the informed consent document(s) as well):

Subjects / Humanitarian Use Device (HUD) Recipients

Estimated number of subjects* to be enrolled at your site(s): **300**

(*Subjects = people (including HUD recipients), specimens, charts, etc.)

Is this a multi-center trial (or HUD)?

No Yes - Provide the total number of subjects to be enrolled at all sites: _____

Subjects will be (check all that apply):

Outpatients Inpatients Healthy Volunteers Employees/Medical Staff
 Students Records Biological specimens

Will this activity involve subjects from the following "vulnerable" categories? No Yes - Check **all** that apply:

Pregnant women Neonates - {if neonates involved, choose from list}
 Fetuses Placenta (after delivery)
 Dead fetuses (after delivery) Fetal material (after delivery)
 Prisoners Children - Ages: _____ to _____

Will this activity involve any of these other potentially vulnerable subjects? No Yes - Check **all** that apply:

Mentally ill Persons in detention Nursing home residents
 Institutionalized Chronic condition Terminally ill
 Hospitalized Limited literacy Limited English
 Poor/uninsured Medical, pharmacy, dental or nursing students
 Students of PI or study staff Students to be recruited in their educational setting, i.e. in class or at school
 Employees directly supervised by PI or sub-investigator
 Employees of Research Site or Sponsor
 Cognitively or Decisionally Impaired
 Others vulnerable to coercion (Specify) _____

Recruitment of Subjects

Explain how prospective subjects will be identified and/or pre-screened and/or recruited (check **all** that apply):

Personal contact (e.g., patients, students, employees)
 Referrals
 Medical Records
 Database from which subjects have given prior permission to be contacted for research studies
 Advertising (Submit all recruitment materials, including letters, posters, brochures, etc., with application materials)
 Written or verbal pre-screening materials
 Other (specify): _____

Are you using any written or verbal screening materials to screen subjects prior to enrollment in the research (e.g., telephone call scripts, written or web-based questionnaires or pre-screening forms)?

No Yes (Submit with application materials.)

Confidentiality of Protected Health Information (PHI) / HIPAA

What precautions will be used to maintain the confidentiality of identifiable subject information?

- Paper-based records will be kept in a secure location and accessible only to persons involved in the study.
- Computer-based files will be available only to persons involved in the study through the use of access privileges and passwords.
- Prior to accessing any PHI, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable health information.
- Whenever feasible, identifiers will be removed from study-related information.
- Other - *Specify*: _____

Coded - Provide example of code (*e.g., initials, relative's DOB, etc.*): **N/A**

Will there be a key that links the code to the subject? Yes No

Who will maintain the key? _____

Who will have access to the key? _____

How will the key be kept secure from improper use and disclosure? _____

Provide anticipated date when identifiers will be destroyed*? _____

(**To be done at earliest opportunity, unless there is a health or research justification for retaining the identifiers; or if such retention is otherwise required by law.*)

How long will data collected for this activity be stored at local site? **5** years after close of activity.

Does, or will, this research have a [Certificate of Confidentiality](#)? (*Issued by the National Institutes of Health (NIH) or other agencies for certain types of research.*) No Yes (*submit with application materials*)

Informed Consent / Assent

The Sharp HealthCare IRB expects that the subject consent / assent process will be conducted under the following conditions:

Will take place without undue influence or coercion.

Will allow subjects adequate time to consider the activity before signing.

Will be conducted in a private place and manner.

Will be conducted with words understandable to subjects (*goal is to have documents written at or below 8th grade reading level*).

The person obtaining consent will invite questions from the subject.

The subject will be allowed to take home an unsigned copy of the consent form to share with family and friends prior to enrollment.

If enrolled, the subject will be given a signed and dated copy of the consent form for their records.

Non-English speaking subjects will be provided with a certified translation of the approved consent form in the subject's first language. The translated document(s) are to be approved by the Sharp HealthCare IRB.

Indicate the **informed consent procedure(s)** to be used for this activity (*check all that apply*):

- The consent process will meet all of the above conditions. (*Separate PHI Authorization may be needed.*)

And/Or

- The consent process will **take place in emergency situations** and will therefore not satisfy all of the above conditions. Briefly explain the proposed consent process and complete the Emergency Research Section of the application:

And/Or

- Short form written consent** will be presented orally to some or all potential subjects, or their legally authorized representative.

Requirements when this method is used (45 CFR 46.117(b)(2)):

- Impartial witness to the oral presentation.
- Submit written summary to IRB of what is to be said to the potential subject or their representative. At minimum, the summary shall include the elements of informed consent described in the beginning of this section.
- Short form itself is to be signed by the subject or the representative.
- Impartial witness shall sign both the short form and a copy of the summary.

- Person actually obtaining consent shall sign a copy of the summary.
- A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

And/Or

Request for **waiver** of **signed** informed consent may be allowed **if at least one** of the following conditions are met (*separate PHI Authorization may be needed*):

- The only record linking the subject and this activity would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; and/or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

And/Or

Request to **alter***, or not include, some required elements of informed consent (*separate PHI Authorization may be needed.*)

And/Or

Request for **complete waiver*** of the requirement to obtain informed consent.

***Complete waiver and/or Alteration of informed consent** may be allowed if **all** of the following conditions are met.

Explain:

- Why the activity will not adversely affect the rights and welfare of the subjects, and will involve no more than minimal risk to the subjects: _____
- Why the activity cannot be conducted without the waiver or alteration: _____
- Whether or not the subjects will be provided with additional pertinent information after participation.
 - No
 - Yes - Explain the plan for providing information to subjects: _____

Who will conduct the consent / assent interview? (**check all that apply**)

Principal Investigator Co-Investigator(s) or Sub-Investigator(s) Coordinator Or N/A

Will consent be obtained from, and/or other decisions made by, some form of substitute decision-maker?

No Yes - Describe the categories of people from whom you will accept substituted consent.

If any of the subjects will be cognitively impaired, describe how capacity for consent will be determined:

- Capacity assessment by _____
- Other (*specify*): _____

Describe how the consent process will be conducted with cognitively impaired subjects:

Or

Provide a copy of your Standard Operating Procedure for consenting subjects with these vulnerabilities:

Attached Previously submitted (*The IRB may ask for additional information.*)

NOTE: *If the consent form will be read to the subject, an impartial witness not affiliated with the research or study doctor (or treating physician in the case of HUD recipients) to be present for the consent discussion and shall sign the consent document.*

Complete this section if this activity involves children (< 18 years of age).

Describe the assent plan for children (*check all that apply*):

- Children will be capable of providing assent. Describe the assent plan:
 - Separate assent to be signed by the minor; or
 - Assent collected by minor signing the parents' permission form; or
 - Other - *Specify*: _____

Children are not capable of providing assent.

Waiver of assent is requested (*specify*):

- Capability of minor is limited therefore they cannot reasonably be consulted; and/or
- Activity holds out a prospect of direct benefit that is important to the health or well-being of the child, and is available only in the context of the activity.

Drug(s) or Biologic(s)

Does this study involve any drugs or biologics? No Yes - Complete the following information:

Phase of research: **[choose from list]**

Investigational Drug or Biologic name(s) and/or number(s): _____ **or** N/A

Investigational New Drug (IND) number(s): _____

Sponsor of the IND: _____

If an IND is not available, explain why not:

List the names of any drugs or other agents required for the study that do not require an IND. Submit current Prescribing Information or Package Insert(s) with application materials.

Describe who will be responsible for storage, monitoring and dispensing of study drug(s):

Device(s) (Excluding Humanitarian Use Devices (HUDs))

Does this study involve the use of any devices? No Yes - Complete the following information:

Is the device to be used in this study FDA-approved? No Yes

Investigational device name(s): Device not an IDE (see below)

Manufacturer(s) of the device(s): _____

Investigational Device Exemption (IDE) number: _____ (*Submit FDA letter granting an IDE for the proposed use.*)

IDE Sponsor(s):

Or

510(k) number: _____ (*Submit FDA letter granting 510(k) and designation of substantial equivalence for the proposed use.*)

Categorization of the device (*check one of the following*):

Significant risk (SR)

Per 21 CFR 812.3(m), an SR device is an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Non-significant risk (NSR); Does not meet the definition for an SR device study.

List the names of any devices required for the study that do not require an IDE. Submit current Instructions for Use or User Manual(s) with application materials.

Automated Delivery System (Asteres ScriptCenter Kiosk)

Describe the inventory control procedures for storage, monitoring and dispensing of study devices:

The Asteres ScriptCenter kiosk uses barcode technology to track and monitor finished prescriptions. The device knows at all times where any given prescription is located. ScriptCenter also takes a photo and signature of each patient during their prescription pick up. These reports are available real-time through a web based application called AsteresCentral®. Pharmacy staff is given role specific access to ScriptCenter reports on AsteresCentral. For examples of ScriptCenter reports, see "Asteres User Guide" and

"Asteres Policies and Procedures". **See attached "Asteres User Guide"**

Describe the training procedures for personnel to ensure the safe handling of the study devices:

Pharmacy personnel is trained by Asteres staff before the go-live of the ScriptCenter kiosk. They are provided the Asteres Policies and Procedures document that is kept available at the pharmacy at all times. Asteres also provides a toll free customer care number where pharmacy staff can call for additional help or questions. For more on staff training, see "Asteres Policies and Procedures"

If an IDE is not available and the device is not approved, provide one of the following:

Letter from sponsor stating that the study is a non-significant risk device study and fulfilling the abbreviated requirements under 21 CFR 812.2(b)

Or

Letter from sponsor explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2(c)

Humanitarian Use Device (HUD)

Is this a request for use of a Humanitarian Use Device? No Yes - Complete the following information:

Name of the device: _____

Manufacturer of the device: _____

Humanitarian Device Exemption (HDE) number: _____

Submit:

- FDA approval order(s) granting HDE for the proposed use
- Summary of Safety and Probable Benefit
- Patient labeling and informed consent
- Professional labeling
- Any other consumer information

Describe the inventory control procedures for storage, monitoring and dispensing of HUD:

Describe the training procedures for personnel to ensure the safe handling of the HUD:

Emergency Research

Is this Emergency Research (21 CFR 50.24) which involves the following?

- An Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) is required,
- Subjects who have a life-threatening medical condition (*for which available treatments are unproven or unsatisfactory*),
- Subjects who, because of their condition (*e.g., unconsciousness*) cannot give informed consent,

And

- To be effective, the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible.

No (*if fewer than four of the above are checked*) Yes (*if all four of the above are checked*) – Complete the following:

What additional protections will be provided to subjects in this emergency research?

(check all to confirm and provide explanation of how conditions will be met for each):

- Consultation (*including, where appropriate, consultation carried out by the IRB*) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn:

Provide explanation:

- Public disclosure of plans for the investigation and its associated risks and benefits to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation:

Provide explanation:

- Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results:

Provide explanation:

- Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation:

Provide explanation:

And

- If obtaining informed consent is not feasible within the therapeutic window, and a legally authorized representative is not reasonably available, the investigator will attempt to contact subject's family member to ask whether he or she objects to the subject's participation in the clinical investigation:

Provide explanation:

NOTE: *Studies involving an exception from the informed consent requirements may proceed only after a sponsor has received prior written authorization from FDA. The IRB shall find and document that these specific conditions have been met. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.*

List of Items Submitted

List the items submitted exactly as they are to be listed on the approval letter. For example, "Protocol (Version 1.0; Dated: 09Jul2010)".

NOTE: Please do not list site personnel information in this section as these items will not be listed on the approval letter.

Name of person who prepared this submission: **Sheila Alignav- Rivera**

Phone #: **858-939-6586** e-mail address: **sheila.rivera@sharp.com**



Your time is valuable and a complete application packet helps avoid delays!

**A complete application package includes
the completed application and all required attachments.**

Use the checklist on the following page to make sure that your application packet is complete before submitting.

INITIAL IRB REVIEW APPLICATION CHECKLIST

<p>IRB forms are designed to be completed electronically (typed). Please submit completed forms electronically, in the same format forms were provided to you (.doc or .docx).</p> <p>Documents that require signatures (e.g., PI Attestation, FDS) should be scanned and submitted electronically (or faxed to (858) 499-3105 if you don't have access to a scanner).</p>	Are the items below complete & ready for submission?		
IRB SUBMISSION	Yes	No	N/A
Application Form - All sections are complete and Principal Investigator has reviewed before submitting.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Principal Investigator's (PI) Attestation – To be signed and dated by the PI.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Site Personnel Information – Submit the following for all site personnel listed on this application: Completed, signed and dated Financial Disclosure Statements (FDS) (<i>sponsored activities only</i>) Current Curriculum Vitae (CV) or resume (<i>if not previously submitted</i>) Copy of current Medical License (<i>if not previously submitted</i>) NIH training completion certificate or other research subject protection training program certificate (<i>to be completed within the past 24 months</i>) Completed Demographic Form (DF) (<i>if not previously submitted or if person's information has changed</i>). Any Form FDA 483s, Warning Letters, and/or any other notification of regulatory issues for site or site personnel (<i>if not previously submitted</i>)	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>
Completed, signed, dated Form FDA 1571 (for investigator-initiated studies, treatment IND, or treatment protocol using investigational drug(s))	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Completed, signed, dated Form FDA 1572 (for Phase I, II, or III studies of investigational drugs only)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Study Protocol (Drug or Device studies), Research Narrative or Study Plan (<i>if not imbedded in application</i>) <i>Or</i> Summary of Probable Risks and Benefits (Humanitarian Use Devices only)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Grant Application (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Investigator's Brochure (Investigational Drugs) <i>And/or</i> Package Insert(s) (FDA-Approved Drugs) <i>And/or</i> User's Manual (Investigational or FDA-Approved Devices) <i>And/or</i> Instructions for Use (Investigational or FDA-Approved Devices)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Other supporting documents, including but not limited to the following: Informed Consent / Assent, PHI (HIPAA) Authorization, Informed consent letter, Case Report Forms, data collection forms, surveys, questionnaires, measures, and any other documents/tools/forms to be used to carry out the study.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FINANCE AND ADMINISTRATIVE REVIEW			
Review Fees – Send check payable to Sharp HealthCare IRB to the address on page one of this application. Initial Full Committee Review - \$3,000 (IRB and entity Administrative review) Initial Expedited Review - \$1,000 (IRB and entity Administrative review) Initial Humanitarian Use Device Review - \$1,000 (IRB and entity Administrative review) System Antibiotic Review Committee Review - \$500 (in addition to IRB and Administrative review fees)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Service Agreement - Call 858-499-4830 for assistance in determining whether a Service Agreement is needed.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sharp Medicare Coverage Analysis Form – Submit completed form to clinicaltrials@sharp.com to determine when a trial is considered qualified to bill Medicare.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Contract Contact Sharp's Legal Secretary, Jenna Haynes at jenna.haynes@sharp.com or (858) 499-4023 to determine if a contract is needed.			
Review by Hospital/Medical Group Administration IRB Office staff will submit the application packet to representative(s) of Administration at each Sharp entity where this project is to be conducted. Please see "Required Approvals for Research Activities" for more information.			

SUBMIT COMPLETE APPLICATION PACKET ELECTRONICALLY TO Research@Sharp.com

**Experimental Program/Research Study on an Automated
Delivery Device (Asteres ScriptCenter[®]) in a Licensed
Facility for Employee Prescriptions**

**C. Daniels, RPh, Ph.D., FASHP, K. Allen, RPh, S. Alignay-Rivera, Pharm.D., N. Khoja, RPh, MSc.,
E. McPherson, Pharm.D. Candidate, D. Laufer, Pharm.D., H. Morales, Pharm.D.**

**Sharp Rees Stealy Pharmacy
UCSD School of Pharmacy
Sharp Memorial Hospital**

2014-2015

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Introduction

This study examines the effectiveness and safety of an automated prescription delivery device (Asteres ScriptCenter[®]) as a new method for picking up finished prescriptions. ScriptCenter is an approach to simplify prescription pick up to improve medication adherence.

We postulate that if prescription medications are available for pick up at all times, even when the pharmacy is closed, patients' compliance with their treatment plan will improve and potential medical complications will decrease.

Hypothesis

Does better access lead to better adherence? We predict that the presence of an automated delivery device, available 24 hours a day, 7 days a week, for Sharp Memorial Hospital (SMH) employees will be advantageous for picking up prescriptions at any time with the same level of access to a pharmacist for consultation, which ultimately will lead to better adherence.

Background and Significance

In the past ten years, pharmacy has incorporated automation technology¹. Automation includes barcoding for filling, restocking, returns and dispensing in order to improve efficiency, safety and accuracy².

In 2005 and 2006, the California State Board of Pharmacy granted a waiver to allow the use of automated delivery devices in pharmacies to deliver refill medications even after the pharmacy has closed³. Regulation 1713 section D has since been written to allow for these types of devices in California pharmacies⁴.

In addition, states such as Arizona⁵ and Illinois⁶ have adopted their own regulations to allow for the delivery of not only previously dispensed prescriptions but also new prescriptions after appropriate counseling has taken place and the placement of these devices away from the pharmacy.

Research shows that low or non-adherence to medication therapy is a major healthcare cost and quality problem. One method to measure the success of pharmacy automation is to measure medication adherence. It is important to understand factors that lead to low adherence but also effectively evaluate clinical and economical outcomes⁷. The cost of non-adherence to the U.S healthcare system is estimated at \$100- \$300 billion annually⁸.

The problem and the solution

Sharp HealthCare recognizes that managing employees' health and wellness is important in maximizing workforce productivity⁹. Today only 5% of Sharp HealthCare employees are using the Sharp Rees Stealy Pharmacy. Sharp Rees Stealy (SRS) Pharmacy can improve prescription medication adherence of Sharp employees at the workplace by providing improved access to prescriptions. This effort would improve employee health, productivity and control overall healthcare cost.

Studies show that patients have difficulty filling prescriptions due to the following barriers; lack of transportation, difficulty affording medications, and long wait times at the pharmacy¹⁰.

Therefore, the emerging technology will improve access to employees' prescriptions.

Approximately 5.7% of all prescriptions filled at Sharp Rees Stealy Pharmacy are never picked up by the patient. In a small sample of patients who failed to pick up their prescriptions, failure of communication was the primary reason cited and convenience of location was the secondary reason¹¹. By providing a secure and convenient method of prescription pick up for Sharp employees, they will have better access to their prescriptions without leaving the workplace, therefore decreasing the number of prescriptions returned to stock (RTS) for patients utilizing the automated delivery device.

Prescriptions not picked up are returned to stock by the pharmacy. We chose Sharp Rees Stealy Outpatient Pharmacy one of Sharp HealthCare's seven pharmacies as our study site. The automated delivery device will be used to deliver finished prescriptions to Sharp Memorial Hospital employees. Employees working at SMH do not currently have convenient 24/7 access to their prescriptions, therefore, by providing a secure and convenient prescription pick up method for employees, they will have better access to their prescriptions without having to leave work.

All new prescriptions will receive mandatory counseling before the medication is released from ScriptCenter. All employees picking up prescriptions will have access to a pharmacy consultation 24 hours a day, seven days a week. In addition, the filling pharmacist will use their professional judgment to ensure that any refill prescription will receive a pharmacist consult if appropriate.

Asteres ScriptCenter has successfully delivered over 750,000 prescriptions to date without one known break-in or delivery error.

Study aims

Primary Aim: To measure medication adherence by determining changes during a six month period after kiosk implementation in the number of new patients to the pharmacy and return to stock (RTS) numbers at Sharp Rees Stealy (SRS) Outpatient Pharmacy, which services employees at Sharp Memorial Hospital.

Secondary Aim: To measure the number of patients, in a six month period, who called the consultation service line at ScriptCenter as a means to show non-inferiority of the kiosk to the traditional method of prescription pick up. Measurement of the new technology will not affect the ability to provide healthcare information and pharmacist expertise on medications.

Stages of the study

Stage 1: Approval from the California Board of Pharmacy and project planning. 2-3 months.

Stage 2: Implementing ScriptCenter free of charge in SMH. 4-6 months.

Stage 3: Experimental study including measuring patient satisfaction. 6 months.

Study Design and Methods

Method

This will be an observational experiment, using a questionnaire type of survey as tool for data collection.

Questionnaire development

Because the subjects of this study are Sharp Memorial Hospital employees, it is assumed that they have a basic level of comprehension and understanding. Therefore, the questionnaire was developed and presented to be suitable for employee knowledge.

Study procedures

The study will distribute a pre-implementation questionnaire targeting Sharp Memorial Hospital employees to determine if better access to patient prescriptions leads to better adherence. The study will also include a second questionnaire after implementation to evaluate employee satisfaction rate.

Data collection will be six months in duration.

Sample size

It is anticipated that 300 patients will utilize the Asteres Scriptcenter at SMH

Sample recruitment procedures

A pre- implementation questionnaire will be distributed via email to Sharp Memorial employees with a brief description of the automated delivery device and will provide a Sharp Rees Stealy Pharmacy phone number to contact for further information. A pre-implementation questionnaire will be distributed via email to SMH employees to measure whether better access leads to patient prescriptions leads to better adherence

Informed Consent Process

The following reasons support the waiver of informed consent: minimal risk of harm to subjects and the lack of medical procedures involved.

Protected Health Information

Protected Health Information (PHI) is removed and reports are de-identified to protect the privacy of SRS patients per HIPAA regulations. Data will be kept on a password protected database and will be linked only with a study identification number for this research. There are no patient identifiers. All data will be entered into a computer that is password protected.

Potential Risks

A potential risk for this study may include loss of participant confidentiality. To prevent this, PHI will be removed and reports will be de-identified. This study presents minimal risk to the privacy of individuals.

Risk Management/Confidentiality

This study involves the analysis of survey reports that have been de-identified. Data will be prepared with privacy, and all research staff will have completed the human research training module and HIPAA module that provides training in regards to HIPAA regulations, research ethics, investigators responsibilities, IRB role etc. Data will be kept confidential and stored in the study investigator's locked cabinets, archived, and saved in password- protected electronic files that are backed up daily. Data will be maintained for a minimum of five years after the completion of the study. There will be no patient identifiers used or linked to any data for analysis or publications. Pre-implementation questionnaire will be emailed to ~2610 employees at SMH with the Survey monkey link. . Email will be sent by Sharp Marketing utilizing the SMH distribution list. Patient information data will be stripped or de-identified. Pre-implementation questionnaire is listed on page 9. Patients that utilize the ScriptCenter to pick up prescriptions will be given the option to participate in a Post implementation patient satisfaction survey at the kiosk. Patient

information data will be stripped or de-identified. Post implementation questionnaire is listed on page 10.

Potential Benefits:

SRS Pharmacy anticipates learning that the placement of an automated delivery device at Sharp Memorial Hospital will increase access to prescription medications for employees and their dependents, which could potentially increase adherence and lead to better outcomes.

Data and results from this study will enable SRS pharmacy to effectively and efficiently utilize information with the end goals of ensuring patient safety and delivering optimal health outcome for patients. The anticipated benefits for learning whether the effectiveness and safety of automated delivery devices would deliver these prescriptions with convenient access at SRS outweigh the potential risk of loss of confidentiality.

Security and Safety

ScriptCenter weighs more than 1,300 lbs and is bolted to the floor. It is equipped with a camera and collects a signature and photo for every pick up. The device includes reporting capabilities to track inventory and system access (both patient and pharmacy).

Study Timeline

The questionnaire will be delivered online using Survey Monkey (an online survey technology provider) through employees’ email. The survey will launch in the first quarter of 2014. A series of three reminder messages will be sent by e-mail to those who do not respond to the initial request to complete the survey. The survey will close after one month. A final thank you e-mail will be sent to all respondents at the end.

Statistical Analysis Plan

Aim of the study	Tool	Before Kiosk Implementation	After Kiosk Implementation
Primary Aim: To measure prescription medication adherence	Return to Stock (RTS) numbers at Sharp Rees Stealy (SRS) Outpatient Pharmacy	RTS% mean for 12 month period	Anticipate RTS% numbers to decrease at the kiosk compared with the Rx counter
Secondary Aim: To show non-inferiority of the kiosk to the traditional method of	Record the number of patients who called the consultation service	Numbers of patients who declined	Anticipate numbers to be the same or

prescription pick up*	line at the kiosk	counseling by pharmacist	show non-inferiority
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Conflict of interest

The ScriptCenter kiosk will be loaned to the SRS Pharmacy at no cost for the duration of the study and no third party funding will be received. This research study will be conducted by SRS Pharmacy and the UCSD Skaggs School of Pharmacy and Pharmaceutical Science. No aspect of the relationship between the research participants and Asteres may be considered an apparent conflict of interest.

Conclusion

Sharp employees would benefit from an automated delivery device located at Sharp Memorial Hospital. Sharp employees would pick up their medications at their workplace improving accessibility, patient care and medication adherence.

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Appendix

Questionnaire

Pre-Implementation emailed to Sharp employees

1. Do you use the Sharp Rees Stealy pharmacy for your prescriptions?

1. Yes
2. No

2. If no, what pharmacy do you use?

1. Mail order
2. Another pharmacy
3. I don't take any prescription medications

3. The ability to pick up prescriptions for you and your family at Sharp Memorial Hospital would be beneficial to you.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

4. Easier access to your prescriptions would lead to an increase in your adherence to your medications.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

5. Location or limited hours of the pharmacy is a barrier to picking up your prescriptions.

1. Strongly agree
2. Agree
3. Neutral
4. Disagree
5. Strongly disagree

Post – Implementation at the kiosk

1. How satisfied are you with the kiosk?

1. Strongly Satisfied
2. Satisfied
3. Neutral
4. Unsatisfied
5. Strongly unsatisfied

2. How important is it to have 24/7 access to your prescriptions?

1. Very important
2. Important
3. Neutral
4. Unimportant
5. Very unimportant

3. If this kiosk was not available would you still use Sharp Rees Stealy Pharmacy?

1. Yes
2. No

Characteristic	Population		Surveyed		Respondents		Non respondents	
	n	%	n	%	n	%	n	%
Sharp Memorial Hospital Employees	2800	100	2610	93.2				

From the Respondents:

	Yes		No	
	n	%	n	%
Do you use the Sharp Rees Stealy pharmacy for your prescriptions?				

	Mail order		Another pharmacy		I don't take any prescription medications	
	n	%	n	%	n	%
If no, what pharmacy do you use?						

	Strongly agree		Agree		Neutral		Disagree		Strongly disagree	
	n	%	n	%	n	%	n	%	n	%
The ability to pick up prescriptions for you and your family at Sharp Memorial Hospital would be beneficial to you.										
Easier access to your prescriptions would lead to an increase in your adherence to your medications.										
Location or limited hours of the pharmacy is a barrier to picking up your prescriptions?										