Rady Children's Hospital San Diego EPCS Pilot
Evaluation Report

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Executive Summary

Rady Children's Hospital San Diego (RCHSD) is the third of three grantees participating in the California HealthCare Foundation (CHCF) Electronic Prescribing of Controlled Substances (EPCS) project. It is the largest children's hospital in California and the sixth largest in the United States. It is the San Diego region's only designated pediatric trauma center and the only hospital in the San Diego area dedicated exclusively to pediatric health care. Eighty-five physicians are affiliated with its Primary Care Medical Group, and 229 are affiliated with Rady Children's Specialists of San Diego. RCHSD's electronic health record (EHR) vendor is Epic, which has significant market share among California provider organizations, particularly the largest health care systems. The implementation of EPCS on Epic at RCHSD is also the first Epic EPCS implementation in the nation; therefore, understanding RCHSD's experience is expected to have significant benefit to other health care systems.

RCHSD offered a unique opportunity to evaluate EPCS implementation in a large provider organization on an EHR platform that is in broad use in California. RCHSD's incorporation of two-factor authentication required by the US Drug Enforcement Administration (DEA) also offered the opportunity to evaluate use of a biometric pattern (fingerprints) as one of the two required authentication factors.

This evaluation focuses on RCHSD's EPCS pilot implementation in its Neurology Department. In sum, clinical staff is very pleased with the EPCS process, including the relative effectiveness and efficiency of the two-factor authentication required for each e-prescription of a controlled substance. Prescribers believe that EPCS provides important patient convenience and safety benefits. Clinicians note that giving patients the opportunity to choose an EPCS-certified pharmacy requires

changing the current clinical workflow. Participating pharmacies note the improved patient safety associated with the elimination of difficult-to-read prescriptions and of the convenience to patients. Possible problems identified in advance of the pilot (pharmacy readiness, two-factor authentication failures) have not materialized. The pilot is viewed as successful and is serving as the foundation for a rollout to other RCHSD departments.

The pilot has also identified important challenges to EPCS implementation in California and nationally. A primary issue concerns ensuring full compliance with the DEA rules governing EPCS adoption. Specifically, RCHSD is taking steps to insure that its EPCS process, including the prescriber registration process and the performance of its two-factor authentication hardware and software, satisfy DEA process requirements and technical standards.

I. Introduction

Electronic prescribing (e-prescribing or eRx) is a key technology that can improve the quality and efficiency of health care delivery. Despite this potential, California is consistently near the bottom in Surescripts' annual SafeRx rankings, which measure states' adoption and use of e-prescribing. One of the barriers to increased use of e-prescribing has been the prohibition of the electronic prescribing of controlled substances (EPCS). Controlled substance prescriptions account for about 11% of all prescriptions. Thus, prescribers have needed to maintain parallel prescribing processes—a paper one for controlled substances and an electronic one for other medications. These dual workflows also create patient safety issues. A 2010 study found 37 errors for every 100 handwritten prescriptions, compared to 7 errors for every 100 electronic prescriptions. While the majority of these errors are not serious, it is estimated that about 7% have the potential to do harm.

In June 2010, the US Drug Enforcement Administration (DEA) issued an Interim Final Rule (IFR) permitting EPCS, subject to stringent security and audit requirements.[1] Despite the issuance of federal regulations permitting EPCS, implementation has been slow due largely to an initial slow rate of EPCS certification by e-prescribing and EHR systems as well as pharmacy systems.

As more software vendors achieve EPCS certification, interest in EPCS is growing among physicians, hospitals, and pharmacies, and it is unclear what challenges they may face when implementing EPCS. Some are concerned with achieving full

compliance with DEA rules that are difficult to interpret and fear that they may be replacing an imperfect paper-based process with a cumbersome and largely untested electronic process.

The purpose of the CHCF EPCS project was to pilot EPCS in up to three ambulatory provider organizations (medical groups, community clinics, etc.) to better understand the issues and challenges with implementing federal regulations that affect physicians, community pharmacies (independent and chain), and the health information networks that enable the communication of prescription-related information. The goals are to identify implementation challenges and to share the lessons learned broadly in California and nationally to facilitate the widespread adoption of EPCS.

II. How EPCS Differs from E-Prescribing for Non-Controlled Substances

Other documents associated with the CHCF EPCS project show diagrammatically how EPCS differs from e-prescribing of non-controlled substances.[2] For the purpose of this evaluation report, two DEA EPCS requirements are described below due to their important impact on implementation planning and execution by provider organizations:

Requirements for identity proofing, issuing two-factor authentication credentials, and configuring logical (computer) access controls for all prescribers — DEA registrants must follow explicit DEA-prescribed processes for proving they are who they say they are, receiving two-factor authentication credentials, and being permitted to use the EHR's EPCS functionality.

Requirements for integrating two-factor authentication technology (hardware and software) with the EHR's e-prescribing functionality — An authorized prescriber must, in the simplest terms, sign each EPCS by using two of the following three factors: something she knows (e.g., a password), something she has (e.g., a device or hard token separate from the computer), and something she is (i.e., a biometric pattern — fingerprint, voice, retina).

There are various two-factor authentication technologies that satisfy DEA requirements and are available for integration with the provider organization's EHR's e-prescribing functionality. So, important implementation factors are, first,

the choices an EHR vendor makes among the available technologies for integration with its e-prescribing functionality and, second, the preferences of the provider organization among the available technologies.

III. Rady Children's Hospital San Diego

In early 2013, CHCF made a grant to Rady Children's Hospital San Diego in support of EPCS implementation in its affiliated ambulatory care clinics.

RCHSD is the largest children's hospital in California and the sixth largest in the United States. It is the San Diego region's only designated pediatric trauma center and the only hospital in the San Diego area dedicated exclusively to pediatric health care, providing care to 88% of children in San Diego County, as well as children in Imperial and Southern Riverside Counties. RCHSD comprises one main hospital campus, five satellite hospital locations, and 40 clinic locations that include 32 physician specialties represented by 85 physicians affiliated with the Children's Hospital Primary Care Medical Group and 229 affiliated with Rady Children's Specialists of San Diego.

RCHSD's EHR vendor is Epic, which has significant market share among California provider organizations, particularly the largest health care systems. The implementation of EPCS on Epic at RCHSD is also the first Epic EPCS implementation in the nation; therefore, understanding RCHSD's experience is expected to have significant benefit to other health care systems.

IV. RCHSD's EPCS Planned and Actual Implementation Summary

Originally, RCHSD leadership planned to implement EPCS according to the schedule in Table 1.

Table 1: Initial EPCS Implementation Work Plan

Key Activity	Planned Completion Date	Actual Completion Date
Complete two-factor authentication technology selection.	February 2013	June 2013

Select EPCS pilot group.	March 2013	March 2013
Complete testing of two-factor authentication/EHR technology, and identity proof all DEA registrants in pilot group.	April 2013	August 2013
Complete training of pilot group and "go-live" and begin identity proofing all RCHSD-affiliated DEA registrants for planned rollout or "big bang" implementation.	May 2013	September 2013
Assess pilot results, including two-factor authentication process.	June 2013	October 2013
Complete identity proofing for DEA registrants who work in departments not included in the pilot, and complete procurement and setup for two-factor authentication technology for EPCS rollout on Linux workstations.	July–September 2013	Not completed

A number of factors delayed the planned implementation by approximately four months. First, an initial delay of approximately six weeks was caused by an unanticipated, highly visible, high-priority project that required the full attention of RCHSD leadership.

Second, RCHSD leadership took more time than planned to complete selection of two-factor authentication technology. The EHR vendor, Epic, did not identify which two-factor authentication vendors' devices should be integrated with its software, and since no other Epic customer had implemented EPCS, RCHSD leadership worked carefully through the process of selecting, configuring, and testing a two-factor technology, in consultation with Epic.

Third, RCHSD leadership similarly needed to fully understand and comply with the DEA rules for identity proofing, issuing two-factor authentication credentials, and configuring logical access controls. This required a good deal of time, especially since the process was dependent on the selection of the two-factor authentication technology.

Fourth, Epic's EPCS functionality was incorporated into a software release that also included the new federally required SCRIPT standard 10.6. The simultaneous implementation of this standard with EPCS implementation was not originally anticipated.

Notwithstanding these delays, the "pilot group" was identified on schedule: the Neurology Department, with approximately 20 prescribers. This department was selected largely because it generated a substantial number of controlled substance prescriptions.

Also, from February through September 2013, three major chain pharmacies that received the vast majority of "external" prescriptions from RCHSD and that were EPCS certified and activated were notified, nationally and locally, of the EPCS pilot and its scheduled implementation. For these pharmacies, the RCHSD pilot was essentially the first time that EPCS would be transmitted in RCHSD's market area. One major chain pharmacy committed to collect key EPCS data, and an Epic "cross pharmacy" report was developed to measure EPCS use across all EPCS-activated pharmacies.

Prescribers in the department went live with EPCS in the last week of September 2013 using biometric pattern technology as part of the two-factor authentication process.

V. Evaluation Results: Pre- and Post-Pilot Interviews with Key Stakeholders

This evaluation is based on interviews that were conducted with 23 key RCHSD and external pharmacy stakeholders before (August 2013) and 17 after (November 2013) the pilot.

Table 2: Pre- and Post-Pilot Interviews

Pre-Pilot Interviews	Post-Pilot Interviews
	Albert Oriol, RCHSD CIO and executive sponsor
RCHSD neurology physician lead	RCHSD neurology physician lead
RCHSD pharmacist in chief	RCHSD pharmacist in chief
RCHSD chief medical information officer	RCHSD chief medical informatics officer and chair, Pediatrics Department
RCHSD Neurology Department clinical support staff (3)	RCHSD Neurology Department clinical support staff (2)
RCHSD Neurology Department physicians (4)	RCHSD Neurology Department co-chair (1)
RCHSD IT portfolio management office, including project manager (2)	RCHSD IT portfolio management office, including project manager (3)
RCHSD Credentialing Department (medical staff and GME) (3)	RCHSD Credentialing Department (medical staff)
RCHSD EPCS project team (5)	RCHSD EPCS project team (5)
Walgreens pharmacist, El Cajon	Walgreens pharmacist, El Cajon
Walgreens pharmacist, Escondido	Walgreens pharmacist, Escondido
CVS pharmacist, Escondido	
CVS pharmacist, San Diego	

A number of themes emerged from the interviews. These themes are presented for the pre-pilot interviews for three key groups: clinicians, administrative staff, and external pharmacies, and are followed by a general summary of post-pilot views.

Pre-Pilot Interview Results

Clinicians

All clinicians interviewed stated that a primary expected benefit of EPCS was increased patient convenience — especially for patients requiring a controlled substance Schedule II medication, since they would not be required to drive to the department to pick up a paper prescription. Clinicians also indicated that the two-factor authentication process constituted a much more secure prescribing process than the manual process it was replacing. Neurology Department clinical support staff said that they expected to save time by avoiding printed prescriptions and telephone and fax communication with pharmacies. Clinicians also indicated that EPCS would improve the completeness of the patient's EHR medication record. A patient safety benefit was also cited: EPCS would likely result in more conservative prescribing of Schedule II medications for patients whose needs are difficult to predict, since additional prescriptions could be authorized electronically for direct patient pickup at the pharmacy.

Clinicians also expressed several concerns, including these:

- EPCS may cause the e-prescribing functionality to break down.
- The chosen two-factor authentication process — a password and a fingerprint — would not work well and/or would be very time-consuming ("It's easier to write a paper script").
- External pharmacies will not be ready to process the prescriptions (special concern was expressed about one major chain pharmacy).
- The Epic pharmacy directory will not accurately list EPCS-activated pharmacies.
- RCHSD's in-house ambulatory pharmacy is not EPCS certified.

Administrative Staff

IT Department leadership indicated that the Neurology Department had been chosen because a large proportion of its prescriptions were for controlled substances and that the physicians were interested in piloting EPCS. Expected benefits include most of those expressed by clinicians; however, concern was expressed regarding the IT and administrative challenges posed by EPCS implementation:

- How to comply with the DEA IFR's confusing requirements associated with identity proofing, issuing two-factor authentication credentials, and configuring logical access control for DEA registrants
- Managing IT resource use with parallel focus on migration to SCRIPT standard 10.6 and planned implementation of formulary and refill messaging
- Managing a tight installation and training timeline for prescriber use of fingerprint peripherals due to delays in finalizing contractual arrangements for two-factor authentication technology
- Longer term, and assuming the chosen two-factor technology works well, uncertainty regarding whether this technology can be made compatible with RCHSD's Linux platform. (The Neurology Department was migrated to a Windows platform for testing the HealthCast biometric technology.)

External Pharmacies

Pharmacists at four local pharmacies (representing two major chain pharmacies) all indicated that key benefits of EPCS included increased patient convenience (prescriptions will be ready when patient arrives), safety (elimination of illegible paper prescriptions), and increased efficiency (reduced telephone call-backs to prescribers). Most pharmacists felt that EPCS is generally more secure from drug fraud or diversion due to DEA requirements for both prescribers and pharmacies. Pharmacists did not identify any concerns regarding EPCS implementation.

The pharmacists appreciated notification regarding when the Neurology Department prescribers were "going live," especially since none of the pharmacists had received any EPCS since the DEA issued its rules. All pharmacies requested a listing of the prescribers in the department. In all cases, no pharmacy-based training specific to EPCS was necessary — only notification that EPCS was finally starting.

Post-Pilot Interview Results

The post-pilot opinions of key stakeholders were generally consistent for both RCHSD clinicians and administrative staff. However, due to the small number of prescribers and the many pharmacies to which EPCS scripts were sent, the volume of EPCS scripts at the pharmacies participating in the interview process was too low to be noticeable, and post-pilot interviews with the pharmacists were not productive.

General feedback from all RCHSD stakeholders indicated that EPCS had been smoothly implemented and that clinicians are very happy with how well it is working. In particular, one clinician observed that it took only a few seconds to complete the two-factor authentication protocol. Clinicians were very pleased with the increased patient convenience associated with EPCS.

Due to the success of the pilot, Neurology Department prescribers are now requesting remote access to expand EPCS functionality, and IT staff are evaluating technology options for two-factor authentication. Other RCHSD departments (e.g., general surgery) are requesting EPCS. Also, positive experience with EPCS was so strong that prescribers are increasingly interested in migrating RCHSD's in-house pharmacy to software that is EPCS certified.

A number of concerns were expressed about Epic's EPCS functionality, necessary changes to clinical workflow, and the EPCS policies of one major chain pharmacy.

First, regarding Epic EPCS functionality, clinicians believe there may be an issue with how quickly notification of a failed transmission is received by the prescriber. Some clinicians thought that they had successfully transmitted an EPCS; however, notification of a failed transmission is apparently not reported immediately but is transmitted to the prescriber's Epic inbox. In these instances, the patient arrives at the pharmacy and is told that no prescription has been received. At this point, the prescription is handled the "old way," through telephone communication with the department's clinical support staff. One clinician observed that this problem may be caused by prescribers not noting whether the pharmacy to which the EPCS is being transmitted is EPCS activated. This information is clearly shown (by *Y* or *N*) in the Epic software. However, support staff observed that there may be an error in the Epic software, describing a number of daily instances of the EPCS being transmitted as "normal" but later reverting to "print" (a reference to a paper prescription). Since this is the first implementation of EPCS on Epic software, the RCHSD EPCS team, which includes Epic representation, will be looking at this issue closely.

Second, clinicians indicated that there likely needed to be modifications in clinical workflow, or in how patients are processed through the visit. Once in the examination room and before seeing the prescriber, a patient's medical record is created or updated by a medical assistant. This process includes asking the patient to identify a preferred pharmacy. Eventually, when the prescriber sees the patient and orders a controlled substance prescription, the previously selected pharmacy,

which may or may not be EPCS activated, is shown. One clinician indicated that this may be the instance when a prescriber attempts to send an EPCS to a non-EPCS-activated pharmacy.

To address this problem, another clinician indicated that he has revised his clinical workflow as follows:

- For existing patients with a controlled substance prescription, the medical assistant informs the patient of the new EPCS system and, if the patient's originally preferred pharmacy is not EPCS-activated, asks if the patient would like to have the prescription sent electronically to an EPCS-activated pharmacy. If so, a different pharmacy can be chosen.
- For patients with no past or current prescription for a controlled substance, the physician offers the EPCS-activated pharmacy choice to the patient as the physician is authorizing the prescription.

It is not clear how many of the prescribers have updated their clinical workflow to accommodate the EPCS pharmacy option for patients.

Third, while all three major chain pharmacies that are EPCS activated indicated readiness to process EPCS from the RCHSD Neurology Department, one major chain pharmacy maintained a policy of not processing EPCS from nurse practitioners unless the prescription includes approval by an authorizing physician. This policy was ultimately revoked by the pharmacy at the request of Rady Children's Hospital leadership and the EPCS project director. The other major chain pharmacies that are EPCS activated are routinely processing EPCS prescriptions from nurse practitioners.

Given the success of the EPCS pilot, RCHSD administrative staff is focusing on identifying the next steps for rollout to the entire medical staff. Key challenges are determining whether the biometric devices used for two-factor authentication can be made compatible with Rady's Linux platform, and deciding on the technology to be used for implementing two-factor authentication for prescriptions generated from remote locations. The goal is to achieve full rollout by July 2014.

Staff is also developing the plan for systemwide identity proofing, issuing two-factor authentication credentials, and configuring logical access controls for prescribers.

The guide[3] developed by Walter Sujansky & Associates is being used for development of this plan.

Based on discussions with the CHCF EPCS project director, RCHSD leadership is also focused on ensuring that all aspects of the EPCS process and associated technology satisfy the DEA's IFR. This involves conducting a review of Epic's third party EPCS certification report and also reviewing, with its two-factor technology vendor, DEA requirements for biometric devices.

VI. Data Regarding EPCS Use

Preliminary data[4] for the first five weeks of the pilot (September 24–November 30) indicate that, for the three major EPCS-activated chain pharmacies, 80% of controlled substance prescriptions from the RCHSD Neurology Department were transmitted electronically. Also, 72% of all controlled substance prescriptions are sent to EPCS-activated pharmacies.

VII. Conclusions

RCHSD's EPCS implementation has been successful, and the concerns regarding the inclusion of two-factor authentication technology in clinical practice have not materialized. This is particularly noteworthy, since the pilot demonstrates that biometric pattern (fingerprint) technology was successfully incorporated into clinical workflow and the EHR's eRx functionality. Prescriber support for EPCS is strong within RCHSD, with clinicians in other departments requesting activation.

RCHSD leadership is defining a technologic and administrative path to roll out EPCS to all prescribers while insuring that its EPCS process satisfies DEA requirements, especially with respect to the prescriber registration process and the technical performance of its two-factor authentication hardware and software. RCHSD leadership is also addressing a key barrier to full EPCS use: migrating its in-house pharmacy to EPCS-certified software.

Ronald C. Wacker is an independent consultant.

Notes

[1] 21 CFR Parts 1300, 1304, 1306, and 1311, "Electronic Prescriptions for Controlled Substances; Final Rule," Department of Justice Drug Enforcement Administration, March 31, 2010, http://www.gpo.gov/fdsys/pkg/FR-2010-03-31/pdf/2010-6687.pdf.

[2] See "Evaluation of the Electronic Prescribing of Controlled Substances Pilot, American Institutes for Research," December 2013, and "Guidelines for the Electronic Prescribing of Controlled Substances: Identity Proofing, Issuing Authentication Credentials, and Configuring Logical Access Controls," Sujansky & Associates, November 2013.

[3] Sujansky, "Guidelines."

[4] Epic-based prescription report.