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Enabling E-Prescribing and Enhanced Management of Controlled Medications

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Abstract

Purpose:

To demonstrate safety, security, quality, and effectiveness of electronic prescribing of federally controlled substances (EPCS) in the ambulatory setting.

Scope:

A collaboration of diverse healthcare organizations joined to implement a model for EPCS, develop mechanisms to monitor non-medical use/abuse of controlled medications, support enhanced patient-clinician communication and safe medication access and evaluate provider perceptions of electronic prescribing and the impact of EPCS.

Methods:

In 2008-2009, 189 providers and 9 pharmacies registered with U.S. Drug Enforcement Administration (DEA) joined this study. After technical partners established communications between the prescribing and pharmacy systems, prescribers received hard tokens allowing the use of two-factor authentication to create and transmit EPCSs. Providers not using prescribing systems were not issued tokens until later in the project.

E-prescribers were surveyed concerning their systems and perceptions regarding EPCS before its implementation and, again, 6 months later. Non-users were surveyed before and after implementation, and after they received their tokens. All prescribing providers received training and support throughout the study. The project worked with the Massachusetts Prescription Monitoring Program (MA PMP) to develop a model for reconciling e-prescribed and dispensed controlled substances prescriptions.

Results:

Physicians' concerns about security measures were not realized after adoption. As providers gained confidence with requirements, EPCS usage increased dramatically. At the community level, adoption depends upon a critical mass of pharmacies being capable of dispensing electronically transmitted controlled substances prescriptions. Finally, diversion/abuse potential requires stringent system controls across software vendors resulting in complex communication networks that must be interoperable.

Key Words:

Electronic Prescribing of Controlled Substances; e-Prescribing; EPCS

Final Report

Purpose

The project was developed to expand, within the participating providers' practices, the adoption and diffusion of electronic prescribing by (1) incorporating the capability of electronically creating and transmitting prescriptions for federally controlled substances and, (2) improving medication management by ambulatory care clinicians at the point-of-care. Since e-prescribing is a key component of health information technology (HIT) and electronic health records (EHR), introducing this capability into the prescribing work flow may increase the adoption of e-prescribing and EHR technology. Expansion of the e-prescribing system to cover federally controlled substances (e.g., narcotics, stimulants, sedatives) was intended to demonstrate a mechanism for increasing needed access to and reducing risks of dangerous pharmaceuticals, particularly for patients with chronic medical conditions who are frequently prescribed such medications. This was to be accomplished through the following aims:

Aim 1: Develop, implement and verify a system of safe and secure electronic transmission of prescriptions for federally controlled substances in an ambulatory care setting.

Aim 2: Develop and test the interfacing of the e-prescribing system developed in Aim 1 with the MA PMP to monitor for prescription fraud and non-medical use and abuse of controlled medications, while supporting enhanced patient-clinician communication, medication access and safety of patients with chronic medical conditions.

Aim 3: Conduct systems process and outcomes evaluations of improvements to patient care, risk reductions, patient and clinician benefits, patient safety and information privacy and confidentiality expected to ensue from the implementation of Aims 1 and 2.

Aim 4: Develop and implement a plan for dissemination of findings for Aims 1, 2 and 3.

Scope

Background

E-prescribing has the potential to significantly improve patient safety and clinician practice through processes that both enhance medication management and reduce risks.[1] The technical capability to implement e-prescribing on a broad scale already exists and the challenges to clinician adoption of e-prescribing are much less than for EHR such that it is seen as an evolutionary step to implementation of EHR.[2] While clinician adoption rates for e-prescribing have been historically low, more recent usage rates have improved according to reports from SureScripts.[3] While numerous systemic barriers to adoption of e-prescribing exist, one of the most rudimentary and significant has been the lack of standards for electronic transmission of prescriptions for federally controlled substances. This void set up an untenable paradigm in which e-prescribing has been a fractured system at the point of-care, comprising a combination of electronic and paper-based prescriptions in which controlled substances were required to be written or manually signed by the prescriber while non-controlled medication prescriptions were transmitted electronically. Given the risks of introducing additional variables to an already compromised system, provider resistance to implementing e-prescribing systems has been understandably high. While federally controlled substances represent only 11 percent of all prescriptions, they are issued by 90 percent of prescribers.[4] Thus, with a perceived barrier to overcome and adoption rates of e-prescribing by clinicians improving, the intent of the project has been to demonstrate how this barrier to adoption of e-prescribing could be eliminated.

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[1] Institute of Medicine, *Preventing Medication Errors*, National Academies, July, 2006.

[2] Halamka J. et al. E-Prescribing Collaboration in Massachusetts: Early Experiences from Regional Prescribing Projects, *J. Am. Med. Inform. Assoc.* 2006;13:239-244. http://www.jamia.org

[3] SureScripts: *National Progress Report on e-Prescribing and Interoperable Healthcare:* 2010. http://www.surescripts.com/about-e-prescribing/progress-reports/national-progress-reports.aspx

[4] Gallagher C., *Electronic Prescribing*. National Association of Controlled Substances Authorities Annual Educational Conference, Oct., 2006, San Antonio, TX. http://www.nascsa.org

Controlled substances in Schedules II–V, such as narcotics, stimulants and anxiolytics, are those prescription pharmaceuticals determined by the U. S. Drug Enforcement Administration (DEA) and the U.S. Food and Drug Administration (FDA) to have the highest potential for abuse and dependence and are consequently among those most sought for illicit and inappropriate (non-medical) use. Prescription fraud, other forms of drug diversion and the resulting abuse and misuse of prescription drugs are issues that persistently challenge DEA, FDA, the Massachusetts Department of Public Health (MDPH) and other federal and state public health and public safety agencies. To reduce and ultimately eliminate opportunities for drug diversion and abuse, it is necessary to impose a higher level of security and accountability for prescribing and dispensing of federally controlled substances than for non-federally controlled, "legend", prescription medications (e.g., antibiotics, vaccines, anticoagulants, and lithium).

Context

In order to establish a system for safe and secure transmission of EPCSs, MDPH secured the participation of DrFirst, Inc., one of the leading e-prescribing application vendors in the industry, the Berkshire Health Systems, Inc., and Emdeon/eRx Network (Emdeon), an e-prescribing network provider. Emdeon joined after the original e-prescribing network provider withdrew from the project, thus significantly limiting the number of pharmacies available to participate. At that point it became clear to the project team that success would be dependent on multiple key entities collaborating closely to achieve the goals of the study. Additionally, in order for the providers in the study to create and transmit EPCSs, the DEA issued a waiver to the Controlled Substances Act (CSA), thereby allowing their registrant providers to participate in the study. It should be noted that this project was the only effort to address this subject in a community based non-governmental setting in the United States prior to the promulgation of the DEA's 6/1/2010 Interim Final Rule (IFR) on EPCS.

Participants

The participants in the project included:

Project Partner	Role
MA Department of Public Health, Drug Control Program, Boston, MA	AHRQ Grantee and Project Sponsor
DrFirst, Inc., Rockville, MD	e-Prescribing System
Emdeon/eRx Network, Fort Worth, TX	e-Prescribing Network
Brandeis University, Schneider Institutes for Health Policy, Waltham, MA	Project Evaluator
Berkshire Health Systems, Inc.(BHS), Pittsfield, MA	Major Healthcare Provider in Berkshire County
U. S. Department of Justice, Drug Enforcement Administration, Alexandria, VA	Federal Regulator of creating, transmitting, and dispensing controlled substances prescriptions
187 Berkshire Health System affiliated physicians, Nurse Practitioners, and Physicians Assistants (NOTE: During the course of the study, 40 providers withdrew or did not actively participate due to relocation, system incompatibility, and death).	Providers eligible participate in the project
9 Berkshire County pharmacies (4 independent; 2 regional grocery store-based;1 affiliated with a national retail chain, and 2 hospital based pharmacies serving BHS's 3,345 employees.	Pharmacies eligible to receive controlled substances prescriptions created and transmitted electronically
3 Pharmacy software applications	Pharmacy systems supporting the 9 participating pharmacies. (QS/1, Cerner Etreby, and PDX)

Methods

Study Design

Aim 1 System Implementation

Implementation

DEA Waiver. From the outset, conducting the study was dependent upon the DEA granting MDPH the necessary waivers to the Controlled Substances Act (CSA) so as to allow providers to electronically prescribe federally controlled substances. An initial Memorandum of Agreement (MOA) was signed on 9/18/2008. Subsequent MOA's were executed in 12/2010 and 2/2011 addressing waivers relating to the DEA's 6/1/2010 IFR governing EPCS.

Provider and Pharmacy Recruitment. In addition to the technical partners in the study, it was clear that providers and pharmacies were critical to the success of the effort. Consequently, the project engaged members of the provider and pharmacy community, bringing them into the study via a Memorandum of Understanding (MOU) with MDPH delineating their responsibilities and providing material which included detailed reference documents about the project.

The 187 providers recruited into the study represented a wide range of specialties, including most prominently Internal Medicine (36), Family Practice (21), Psychiatry (14), Neurology (8), and Pediatrics (6). During the course of the project, 40 withdrew or did not actively participate due to system incompatibility (27), relocation (6), job change (5), and health issues (2). In consideration of their participation in the project, providers' DrFirst e-prescribing software license and support fees and the cost of the hard tokens[5] were paid for by the grant's funding during their time in the study.

Initially, the project planned on including all 30 Berkshire County pharmacies in the study. For business reasons, SureScripts, the original intermediary partner in the project, withdrew in June, 2008, which made 21 pharmacies unavailable to participate in the project. Subsequently, the Project Team reached out to Emdeon which, after extensive discussions regarding the objectives of the project, joined the study to undertake the intermediary responsibilities. For purposes of this project (and the IFR), the intermediary is "any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy."[6] The nine pharmacies were likewise diverse, representing independent (4), grocery (2), hospital employee (2), and national chain (1) segments of the industry.

The provider/pharmacy MOU was also the vehicle through which providers and pharmacies could confirm their agreement to abide by the terms and conditions of the MOA with the DEA. The DEA required that this (signed) affirmation take place before the project could enroll a provider or pharmacy into the study. While the pharmacies did sign an MOU for participation, the vendors providing pharmacy systems did not, as all parties felt the vendors would be brought into the study through their contracts with the participating pharmacies. As the study evolved and the needs for data and additional reporting from the pharmacy systems became more complex, their ability and interest in devoting resources was not as strong as originally anticipated and this proved to be a limiting factor in the pharmacy component of the study.

Network Communication. In order for the EPCS network to function, DrFirst, the prescribing system; Emdeon, the intermediary; and the three pharmacy systems needed to have the ability to communicate with each other. As such, considerable time was devoted by the respective technical teams to test the necessary links that would securely transmit the EPCSs from the prescribers to the pharmacies. The work flow encompassing the creation and transmission of EPCSs included prescriber credentialing and identity verification, two factor authentication with a hard token, transmission to the pharmacy through an e-prescribing network (intermediary), weekly DEA's CSA data base provider verification, and confirmatory faxes to the pharmacies for each EPCS.

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[5]Hard token means a cryptographic key stored on a special hardware device (*e.g.,* a PDA, cell phone, smart card) rather than on a general purpose computer. (Federal Register, March 31, 2010, Vol. 75, No. 61, p. 16277)
[6] Federal Register:*Electronic Prescriptions for Controlled Substances; Final Rule 21CFR Parts 1300, 1304, 1306, and 1311*. 2010 Mar 31 75(61):16305.

The initial security measures of the MOA with the DEA were similar to the measures proposed in the initial Notice of Public Rulemaking (NPRM) on EPCS, published on 6/28/2008 in the Federal Register and applied to each of the major partners in the project, including the prescribing system, the pharmacy systems, the prescribing providers, the pharmacies, and the intermediary. In addition to these baseline requirements, the intermediary added three supplementary security controls to assist the pharmacies in confirming the legitimacy of the EPCSs: (1) a confirming fax for each EPCS; (2) a message string in the free text field noting that the prescription was part of the MDPH EPCS project and (2) a web site for the pharmacies to access as a secondary source of confirmation in the event there was a question about a particular prescription.

Train, Monitor, Adapt. Concurrently, with the establishment of the communication network, the providers were identity-proofed by DrFirst through an authentication process that establishes identity of requesting individual. This occurred when prescribers were registered in the EPCS system by the Project Liaison as being authorized to create and transmit EPCSs. At this time, they were also oriented to the EPCS technology and authenticated to the system.[7] Prior to activating provider hard tokens, which were used throughout the study, the Project Liaison re-confirmed each provider's identity and trained them on the EPCS system. Orientation included the security requirements of the system, its effect on prescribing work flow, the process of using two-factor authentication, and reporting breaches of security. Authentication can involve something the user knows (e.g., a password), something the user has (e.g., a smart card), or something the user "is" (e.g., a fingerprint or voice pattern). Single-factor authentication uses only one of the three forms of authentication, while two-factor authentication uses any two of the three forms.[8]

Each provider signed a receipt for the token and an acknowledgement of training on the system. When issues with the authenticating token and EPCS software arose, DrFirst technical staff assisted with identification and resolution. As with its non-controlled substance e-prescribing, the DrFirst monitoring staff were available as instances of prescription rejection occurred and communicated these to the respective providers' offices. Several meetings were held with the group of participating pharmacy managers/owners to address questions, resolve issues, and communicate information regarding the IFR.

IT Security

During the course of the project, there were two scheduled system security reviews and two reviews of unanticipated events that required the system to be deactivated for short periods of time.

Scheduled Reviews. Global Sage Group (GSG) (Salem, NH), the IT security firm engaged to participate in the security design and evaluation conducted two scheduled reviews of the EPCS system. A pre-implementation review was conducted in the summer of 2009, prior to the 9/2009 activation of the system for transmitting the initial test EPCS. In determining the extent to which this review would be conducted, the project recognized that in the information technology industry, there are models for comprehensive security audits of software systems such as Rcopia (DrFirst), Emdeon, and the pharmacy systems servicing the participating pharmacies. While compliance audits may be appropriate for future projects involving EPCS, this type of review was not considered for the study, and as such, the initial and follow up reviews were conducted within a scope that provided the information needed and the available budgeted funds.

In the pre-implementation review, GSG examined the processes developed by the prescribing system and the intermediary to ensure they were in compliance with the terms and conditions of the MOA with the DEA. A similar review was conducted for the pharmacy that was initially designated to go live in 9/2009. Subsequently, GSG participated in the testing prior to and after activating each additional participating pharmacy in the EPCS network.

GSG also conducted a post implementation review, examining reports with data fields from EPCSs transmitted between 1/20/2010 and 7/23/2010. The intent of this review was to assess the flow of transactions from the provider to the intermediary and finally to the pharmacies. Approximately 2,100 EPCS transactions transmitted by participating providers to five of the nine participation pharmacies were reviewed, using the National Council for Prescription Drug Programs (NCPDP)

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[7] This process met the requirements for National Institute of Standards and Technology (NIST) SP 800-63 Level 3 compliance, as referenced in the 9/18/2008 MOA with the DEA.

[8] Department of Homeland Security:*DHS Sensitive Systems Policy Directive 4300A*, March 14, 2011: 7.
https://www.dhs.gov/xlibrary/assets/foia/mgmt_directive_4300a_policy_v8.pdf

SCRIPT Transaction Control Reference Number (UIB-030-010) as a common indicator for tracking purposes. It was determined most of the prescriptions were accounted for in the prescribing system–to-intermediary segment of the work flow. However, the consultants found fewer matches when they attempted to reconcile the EPCSs transmitted from the intermediary to the pharmacy system data base. It was subsequently learned that the Transaction Control Reference Number, which was not required by MDPH to be part of the work flow until 1/1/11[9], had not been passed on to the pharmacy systems by the intermediary until July, 2010. Unfortunately, when this gap was discovered, there was insufficient time left in the project and no available resources on the part of the prescribing and pharmacy systems to develop the data for follow up on a more current set of EPCS transactions. The analytic model used by the consultant could be tested further in a future study of EPCSs.

It was also noted that due to limited access to logs of the prescribing systems, the intermediary, the pharmacy systems, and corresponding meta data, a more robust review of these systems was not possible. The Project Team notes that the minimum requirements for this type of review, however, can be found in the June 1, 2010 DEA IFR, which requires these systems to undergo and pass a third-party audit conducted by a firm qualified to perform a SysTrust or WebTrust audit, Certified Information Systems Auditor (CISA), or DEA approved certification organization before they can process EPCSs. In July, 2011, DrFirst received third party certification of its EPCS 2.0 system for handling controlled substances prescriptions electronically and at the close of the project one pharmacy system announced that it had also successfully undergone a third party certification audit.

System Deactivations. At the beginning of the study, the Project Team recognized the potential for needing to deactivate the EPCS system and therefore developed a Critical Incident Examination and Response Process. There were two instances of the system being deactivated for periods of 8 and 6 weeks, respectively, as a result of processing issues the Project Team determined could adversely affect the integrity of the study. In the first instance, a provider reported that she was able to transmit an EPCS without inserting her hard token. In the second, a provider reported the system allowed an EPCS to be transmitted without a hard token when the *Send/Print* icon was clicked. During each of these periods, GSG received and assessed information from the prescribing system and created incident reports detailing issues and remediation. After reviewing the material, discussing modifications with the prescribing system, and determining that the issues causing the situation had been corrected, it was recommended that the project be reactivated.

Interim Final Rule Compliance

On 6/1/2010, the DEA promulgated the anticipated IFR on EPCS in which requirements for creating, transmitting, and dispensing EPCSs were articulated. The DEA, recognized the IFR would require a replacement of the original MOA for the project. As such, the DEA worked with the Project Team to develop individual MOAs with MDPH for the sections of the IFR pertaining to the prescribing and pharmacy systems, respectively. In contrast to the original MOA, which set out the terms and conditions of the prescribers', pharmacies', prescriber system, pharmacy systems, and intermediary's EPCS conduct, the new MOAs specifically identified the sections of the IFR that were to be waived until such time that the respective party came into compliance. As of the end of the study, the following reflects the compliance status of the project partners:

- *DrFirst (Prescribing System)* – In May, 2011, DrFirst's Rcopia EPCS application underwent and successfully passed a third party IFR compliance audit. Formal notification of this came in late July, 2011. Additionally, DrFirst engaged federally approved firms to conduct identity proofing and issuance of authenticating credentials to its provider clients, both of which are required by the IFR.

- *Emdeon/eRx Network* – In August, 2011 Emdeon, the intermediary for the EPCS process, announced its intention to support the so-called "Option 2" in the IFR EPCS workflow. Under this transmission process, the intermediary receives the EPCS accompanied by an indicator in the transaction affixed by the prescribing system, digitally signs the prescription, and transmits it to the pharmacy. Upon receipt, the pharmacy system digitally signs the EPCS if it has the capability or accepts it with the intermediary's digital signature and the accompanying

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[9] Massachusetts Department of Public Health:*Massachusetts Prescription Monitoring Program Handbook*, September 10, 2010.
http://www.mass.gov/eohhs/docs/dph/quality/drugcontrol/pmp-handbook-20100924.pdf

indicator confirming the prescriber is authorized to create and transmit EPCSs.[10,11,12,13] As such, Emdeon, as the last entity to have possession of the EPCS before transmitting it to the pharmacy, will affix its digital signature to the EPCS. Using only Option 2 is consistent with the IFR and has direct applicability to the participants in this project.

- *Pharmacy Systems* – One pharmacy system had been certified and two were not anticipated to be prepared to support EPCS until mid to late 2012.

- *Pharmacies* – The participating pharmacies developed and signed a document affirming their compliance with the IFR to the extent that their software system allowed them, including setting logical access controls, performing daily audits, and identifying auditable events.

Aim 2 Reconciliation of EPCSs to Dispensed CS Prescriptions by the MA PMPs

PMP Interface/Pharmacy Reporting. Work on Aim 2 did not actively commence until after the prescribers began creating and transmitting EPCSs to participating pharmacies during Year 3. At this point, with an active data base of EPCSs to work with, MA PMP was in a position to develop an understanding of the EPCS content and work flow. The key to developing a meaningful reconciliation of prescribed EPCSs with those that have been dispensed is the availability of a common identifier that ties into the original electronic prescription. As such, the project initially worked with DrFirst to identify key information that could be provided and the manner in which it would be retrieved. The initial focus for the common identifier was a serial number found in the DrFirst system. Concurrently, pharmacy systems and the American Society for Automation in Pharmacy (ASAP) were addressing similar questions. As these discussions evolved, it became clear the identifier should come from the existing NCPDP SCRIPT standard fields. Numerous meetings of the ASAP Standards Committee were held, which included staff from MA PMP, and the decision was subsequently made to designate the NCPDP SCRIPT Transaction Control Reference Number (UIB-030-010) in the ASAP Standards (v. 4.1) for this purpose. DrFirst also agreed to provide this number to MA PMP in lieu of the original prescription serial number for the Aim 2 analysis.

Drug Control Program Reporting Requirements. In order to ensure the availability of the Transaction Control Reference Number to MA PMP for this and other purposes, the Massachusetts Drug Control Program revised its prescription reporting requirements to require the inclusion of data in this field for all EPCSs reported to MA PMP on or after 1/1/11.[14] While the nine pharmacies in the project were the only ones in the Commonwealth in a position to report this data, having the requirement in place allows for broader availability of this information once EPCS becomes more widely adopted in the Massachusetts medical community.

Reconciliation. The three pharmacy systems were identified as the primary sources of the dispensed prescription data on EPCSs and were therefore engaged in discussions concerning making the Transaction Control Reference Number information available to the MA PMP for reconciliation with original source prescriptions. With respect to work flow, upon receipt of this data element from both DrFirst and the pharmacy systems, MA PMP planned to perform a simple reconciliation of the prescriptions received from the two sources (DrFirst and the 3 pharmacy systems) on a weekly basis. Combined with other data resources MA PMP was using, its intention was to determine: (1) the extent to which EPCSs were transmitted but not dispensed and (2) the extent to which dispensed controlled substances prescriptions with an electronic transmission indicator did not have underlying EPCSs.

Aim 3 Evaluation

Survey Instrument
A baseline survey was fielded among all BHS prescribers prior to implementation of the pilot, focusing on the use of electronic prescribing, prescribing practices of controlled substances, and

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[10] Federal Register: *Electronic Prescriptions for Controlled Substances; Final Rule*, March 31, 2010, Vol. 75, No. 61, 21 CFR Parts 1300, 1304, 1306, and 1311:16260-61.

[11] Ibid., Section 1311.102(d)(2):16311

[12] Ibid., Section 1311.120(b)(17):16315

[13] Ibid., Section 1311.210(a)(1) and (b):16318

[14] *Massachusetts Prescription Monitoring Program Handbook*

expectations for EPCS. The survey development is described, and the results are published in an earlier paper [15] and elsewhere in this report. Questions were developed *de novo* for this survey to address expectations for EPCS specifically, and to correspond to components related to the Rogers model of technology adoption.[16] In addition, questions were adapted from the technology acceptance model used by Tamblyn and associates to assess familiarity with use of health technology.[17] The final survey had five domains: (i) current prescribing practice; (ii) current e-prescribing activities; (iii) current prescribing of controlled substances: potential issues with patient safety, convenience, and identifying non-medical use; (iv) expectations for the EPCS system (e.g., effect on workflow, patient safety, and potential barriers); and (v) perceptions regarding proposed security measures for use of EPCS.

The survey was pilot tested among five providers who were not part of the respondent population, in individual sessions. Providers were asked to indicate which questions were ambiguous or redundant, as well as the time involved in completing the survey. Revisions were made accordingly. Surveys were then administered in person by the BHS Project Liaison during regular medical departmental meetings and hand-delivered to additional prescribers not attending the meetings, and all mid-level prescribers and dentists with practices in the immediate geographic area.[18]

Data analysis
Descriptive statistics were generated on the survey categories of interest, including provider characteristics, degree of burden of each security measure, experience with particular features of EPCS, and overall satisfaction with the system. Experience with EPCS was compared to expectations at the prescriber level, using the McNemar test of paired proportions for nonparametric data.[19] The impact of EPCS on perceived patient safety issues was measured by comparing responses on a question asking prescribers how often several safety issues occurred. Post implementation responses were compared to baseline prior to implementation using the Wilcoxon sign rank test for pairs for non-parametric data.[20] Predictive Analytic SoftWare (PASW Statistic) version 18 was used for all analyses.

Exploratory factor analysis was conducted on items related to expectations for EPCS to identify conceptual themes, using Varimax with Kaiser Normalization method.[21] Factor analysis was completed for the follow up survey, and factors compared to responses obtained in the baseline surveys. The analysis on questions related to prescribers' experience of EPCS identified two themes: 1) improvement in patient management and 2) risk of EPCS technology to patient care. The variables associated with the two factors were then used to create a composite score for each factor which were then used in the predictive models.

A logistic regression model estimating predictors of overall satisfaction with the system was fitted based on theoretical concepts associated with diffusion of innovation, including provider characteristics, ease of use, and familiarity with the technology. The analysis assessed whether certain provider or medical practice characteristics (such as gender, age, reliability of and comfort with technology, number of patients seen in typical week) and factors associated with experience with EPCS during the pilot study were associated with respondents' overall satisfaction of EPCS.

The study protocol was approved by the Institutional Review Boards of Brandeis University, Berkshire Medical Center, and MDPH/Lemuel Shattuck Hospital.

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[15] Thomas C., M. L. Kim, et al. Prescribers' Expectations and Barriers to Electronic Prescribing of Controlled Substances. *J American Medical Informatics Association* 2012 **19**: 375-381.

[16] Rogers, E. *Diffusion of Innovations, Fifth Edition.* New York: Simon & Schuster, Inc.; 2003

[17] Tamblyn, R., A. Huang, et al. The Development and Evaluation of an Integrated Electronic Prescribing and Drug Management System for Primary Care. *Journal of the American Medical Informatics Association* 2006 **13** (2): 150-159

[18] Thomas, et al

[19] Pagano M and K Gauvreau. *Principles of Biostatistics, Second Edition*. Pacific Grove CA, Duxbury Press. 2000

[20] Ibid.

[21] SPSS, Inc:. *PASW Statistics Base 18.0. Core System User's Guide*. Chicago, 2011.

Data Collection, Intervention, Measures and Limitations

Aim 1 System Implementation

Data Sources/Collection. The primary source of provider EPCS activity was the daily activity reports created by DrFirst that included the prescription number, the date of the prescription, a status indicator, the prescriber, the drug prescribed, and the pharmacy to which the EPCS was transmitted. Additional information was provided by Emdeon and the participating pharmacies. A master file of participating providers was maintained as well as a log of issues that were identified during the project and discussed on weekly Project Team conference calls. The most frequent operational issues were: 1) hard token drivers incompatibility with Windows 7/Vista; 2) hard token failure; 3) duplications of controlled substances prescriptions; 4) free/variable text overflow; 5) time outs at the pharmacy system server; and, 6) Buprenorphine (medication for opioid addiction) function lock out.

Interventions. As noted, there were two instances when the EPCS study was deactivated. The first occurred in November, 2009 after it was determined an EPCS was transmitted without a hard token inserted into the provider's computer. The second occurred in July, 2010, after the prescribing vendor became aware providers were able to transmit EPCSs without using their hard token to pharmacies by using the *Send/Print* key in the DrFirst EPCS program. In each instance, the prescribing system's technical team removed the code causing the problem and, before allowing the study to resume, the project's security evaluator confirmed that the issue causing the problem had been corrected.

The project also provided multiple training sessions for providers and pharmacists on the concept of EPCS as well as the 6/1/2011 IFR on EPCS.

Measures. The aggregate data collected from the EPCS system allowed the project to measure the volume of EPCSs and assess the use rate by providers over time. It also allowed the project to measure the use rate in the time period after the second hiatus in 2010 and the robustness of the providers' EPCS usage as opposed to the first prescribing period earlier in the same year. The project determined that 51.9 percent of providers who were assigned hard tokens used them during the study period. Discussions with providers not using the hard tokens revealed that many found the learning curve for EPCS to be difficult and the lack of a critical mass of pharmacies to be the primary reasons for their lack of activity. Specific metrics identified include provider demographics, their use of the hard tokens, their aggregate volumes, and the distribution of EPCSs according to controlled substance schedule.

Limitations. The project originally anticipated a total of 30 pharmacies in Berkshire County would participate in the study. Based on this assumption the Project Team planned for a more complete assessment of prescribing patterns and the impact on patient care practice patterns, practice efficiency and system costs, the introduction of e-prescribing for controlled substances on patient safety and quality of care, and the impact of EPCS on identifying and decreasing non-medical use and abuse of controlled substances. Unfortunately, with the SureScripts withdrawal from the study in June, 2008, the major pharmacies in Berkshire County (n=21) decided their organizations would likewise be unable to participate. Additionally, while the project made strides towards compliance with the IFR, because of the difficulty which the industry experienced with respect to confirming a third-party certification audit process, the project was limited in the extent to which it could fully accommodate the DEA's new EPCS requirements. Finally, as noted earlier, due to limited access to logs of the prescribing systems, the intermediary, the pharmacy systems, and corresponding meta data, a more robust review of these systems by GSG was not possible.

Aim 2 Reconciliation of Prescribed to Dispensed EPCSs

Data Sources/Collection. In 1/2011, and on a weekly basis through the end of the project, DrFirst made a CSV text file available to MA PMP consisting of agreed upon fields from EPCSs that had been transmitted to pharmacies by the participating providers. MA PMP had adopted the American Society for Automation in Pharmacy (ASAP) reporting standard (version 4.1) for PMP data and specified to pharmacies that when dispensing EPCSs the following ASAP fields were to be populated: the field indicating that it is an electronic prescription, the EPCS Transaction Control Reference number and, when available, the RXNORM number. If pharmacies complied with the MA

PMP reporting requirements, it was expected that reconciliation of EPCSs prescribed (as reflected by the DrFirst file) to EPCSs dispensed (as reflected by the regular pharmacy PMP report) would be clear cut based upon linkage of a combination of the prescriber DEA number and the Transaction Control Reference Number in both data sources.

Interventions. An MDPH member of the project team is a workgroup member of the ASAP PMP Standards Committee. In late 2010 he was able to influence the development of ASAP 4.1 to include EPCS data collection elements including Transaction Control Reference Number (DSP19) and RXNORM (DSP18). Effective 1/1/11 MA Drug Control Program publicized its adoption of ASAP 4.1 and specified that the EPCS fields be populated when relevant for Schedule II thru V controlled substances.[22] The DrFirst weekly prescribing file provided to MA PMP was also revised to include the Transaction Control Reference Number as an improved measure to facilitate unique comparison of prescribed to dispensed EPCS.

Upon MA PMP attempting to reconcile a sample of prescriptions with the data received from the pharmacies, it was discovered that 3 pharmacy system vendors were not accurately populating the Transaction Control Reference Number field (DSP19), thus impairing the reconciliation task. The vendors subsequently acknowledged broad misunderstanding of the requirements. Throughout the 2nd and 3rd Quarters of 2011, the Project Team conducted regular conference calls with each vendor to discuss creating the necessary modifications to correctly transmit DSP19 data to MA PMP. By the end of the project, only one pharmacy system (representing two pharmacies) was reporting this DSP19 field to MA PMP accurately.

Measures. The DrFirst file of prescribed EPCSs, provided to MA PMP weekly, included, among other fields, the Transaction Control Reference Number and the prescriber DEA number. When accurately included by the pharmacy systems, these two fields represent a unique compound key to link prescribed to dispensed prescription records.

Limitations. Because pharmacies were slow to remediate their inability to accurately report DSP19, the data analysis was hindered. Additionally, the limited data that was received from the one pharmacy system did not allow for the type of analysis the Project Team originally anticipated. This also had a negative impact on the ability to analyze the data for diversion under the project conditions and predict future analytic capabilities when EPCS becomes widely adopted. With the lessons learned, the project is therefore proposing additional areas of study may exist with respect to available EPCS information which may include the development of models for a more robust analysis of EPCS and ASAP data. These may be the basis for future studies of the effect EPCS has on diversion and patient care outcomes.

Aim 3   Evaluation

Data Sources/Collection. User and non-user provider surveys were the primary sources for the information reported for Aim 3. Surveys were conducted during 2009 (Q1 and Q2) and 2010 (Q2 and Q3). Additionally, supplemental information was gathered through interviews with providers and pharmacy managers during the course of the study.

Interventions. The initial survey was conducted at ambulatory care test sites based at or affiliated with Berkshire Health Systems (BHS), the primary provider of healthcare services in Berkshire County (MA), between January and July, 2009. BHS affiliated practices include nearly 400 physicians, dentists, nurse practitioners, physician assistants, and other clinicians. The target population for the survey included all prescribers of controlled substances in the BHS network (excluding resident physicians, and physicians in radiology, pathology, and anesthesia, due to limited outpatient prescribing). The initial survey served as a baseline for assessing experiences with EPCS. The survey was developed drawing from literature, past surveys, and interviews with providers. The participating providers were subsequently surveyed to identify changes in perception with respect to e-prescribing and EPCS.

Measures. The six-month follow-up survey was an abbreviated form of the initial survey, and it was fielded to those who were enabled to prescribe EPCS. Prescribers were asked to rate on an ordinal scale their experience with e-prescribing activities, issues with patient safety in the prior six months, current use of EPCS and experience with security measures (to compare expectations to experience),

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[22] Massachusetts Prescription Monitoring Program Handbook: 7 and 13.

and overall satisfaction with the system. For those individuals who were in the control group (prescribers without e-prescribing prior to being deployed with EPCS), an updated baseline survey was fielded to examine whether anything had changed in the practice, or in issues related to prescribing of controlled substances since the initial baseline survey was fielded.

Limitations. The limited number of participating pharmacies influenced the prescribers' ability to fully incorporate EPCS into their practice workflow. As such, the project was not able to analyze certain quality measures (impact on the quality of care and safety and on instances of non-medical use of controlled substances). The perceptions shared by providers in the two surveys suggested that the lack of a critical number of participating pharmacies influenced the extent to which they were not able to transmit more EPCSs. An additional shortcoming of the particular system used for this pilot was that the prescribing software was not integrated into the patient medical record (EMR) or the state PMP, so that prescriptions dispensed and prescribed by other prescribers would be known at the time of prescribing

Results

Aim 1 System Implementation

Principal Findings.

1. The study demonstrated that a safe, secure, and reliable system of EPCS can be easily adopted by a targeted medical community. It was also shown that the industry is ready to support this process using the recognized standards (NCPDP SCRIPT) with minor modification.

2. The number of pharmacies capable of handling EPCSs in a community will influence prescribing patterns and the extent to which providers will adopt EPCS. Even with the capability, many providers who received hard tokens created and transmitted controlled substances prescriptions to participating pharmacies manually. Anecdotal information from providers suggested this was the result of there not being a critical mass of participating pharmacies in the community. In one suburban community with four participating providers and one local pharmacy, the use rate was significantly higher (97.0%) than for providers in the major urban center (56.1%) with more pharmacy choices but less participating sites.

3. Creating and processing EPCSs is more complicated than for electronic prescribing of legend drugs due to security requirements associated with the interdependent IT systems. In particular, the hard token that was used experienced a high instance of failure due to compatibility issues with the prescribers' PC based operating systems. Identifying and correcting authenticating issues proved to be more labor intensive than anticipated for both the prescribing system technical staff and the project staff. Additionally, the technical partners found the root causes of EPCS rejections to be inter-systemic issues with accepting the prescription. Backup procedures within the prescribing process, however, ensured provider notification of the failed prescriptions and issuance of a hard copy for the patient.

4. After an initial transition period, EPCS had a net positive impact on the work flow of the pharmacists. While legibility of controlled substances prescriptions improved, instructions in free text fields were often inconsistent with the electronic SIG which precipitated calls to the provider for clarification.

5. As with legend electronic prescriptions, improved delivery of the EPCS script to the pharmacy was experienced. In many cases the prescription was ready when the patient arrived at the pharmacy.

6. While many data requests resulted in information that was helpful to the study, some vendors had difficulty in providing EPCS data for auditing purposes.

7. During the prescribing segment of the study, and considering the limitations of available pharmacies noted earlier, actively prescribing providers quickly adapted to EPCS as evidenced by the reported aggregate and average volumes before and after the 7/2010 deactivation period.

Process Outcomes

1. The project recruited, trained, and supported 187 providers of which 151 were issued hard tokens over the course of the project. Of the 151, 81 (53.6%) created and transmitted at least 1 EPCS.

2. Based on a sample of prescriptions successfully transmitted from 1/1/11 through 8/31/11, the EPCS usage rate (≥ 1 EPCS) for prescribers with hard tokens was 62.3 percent. The use rate was derived by calculating the ratio of EPCSs transmitted (Source: DrFirst prescribing system data) to all controlled substances prescriptions originating with the participating prescribers and dispensed by the participating pharmacies (Source: MA PMP data) during the period. No adjustment was made for prescriptions transmitted but not picked up. While Fischer, et al. found in a study that the non-adherence rate for legend medications was 24 percent[23], the clinical members of the Project Team felt this would be lower for controlled substances prescriptions. Once EPCS is fully adopted in a community with access to robust PMP reporting, this figure will be more readily derived.

3. Upon reactivation after a 6 week hiatus during the middle of the study, providers' prescribing patterns eventually leveled off with an average number of prescriptions/provider/week between 1½ to 2 times greater than the original prescribing period.

4. Overlaying the requirements of the IFR escalated the possibility of EPCS failure as evidenced by the issues experienced with the technology and transmission.

5. An issue often identified with e-prescribing of non-controlled medications is that providers "batch" transmission of e-prescriptions around the noontime hour and the end of the day, causing bottlenecks in the pharmacy workflow process. This phenomenon was also identified in the study and it is anticipated once providers adopt EPCS on a broader scale, and the percentage of electronic prescriptions increases proportionately, the impact of the additional volume at these times will exacerbate this pharmacy workflow issue.

6. On a review of the chain of possession for EPCSs during a sample period, GSG was able to account for only 22.7 percent of the EPCSs transmitted to 5 of the 9 pharmacies by the intermediary. This low return rate was influenced by the Transaction Control Reference Number not being transmitted during the assessment period. The role of a common identifier for a reconciliation audit between prescribing, intermediary, and pharmacy system systems was not fully understood by all parties in the EPCS "chain of possession," resulting in the achievement of a less than optimal data yield.

Discussion

Based on the experience of the participating partners in this controlled study, while the framework for the project was more complex than for e-prescribing of non-controlled substances, EPCS was accomplished in a safe and secure manner. The prescribing providers created and transmitted 9,874 EPCSs and for those who were active, an average of 15.5 EPCSs per prescriber per day were sent to the participating pharmacies during the last eight months of the study. The project found that after providers using the system became accustomed to the technology, their overall use rate was 62.1 percent. With respect to the prescribing process that required two-factor authentication with a hard token, the first generation device presented challenges for some providers because of compatibility issues with PC based operating systems. Other more reliable authenticating technologies requiring less support are available and will be used in the second generation of EPCS two-factor authentication that will be available to providers in 2012. The project also did not encounter any security breaches or reported instances of diversion. Unfortunately, time limitations and challenges facilitating a discussion with the DEA regarding an extension of the IFR waivers beyond the initial end date of the study precluded the project from assessing provider and pharmacy work flows under the terms and conditions of the IFR in a fully compliant EPCS setting.

There are areas that require additional study. Specifically, with new federal rules governing EPCS, additional study should build upon the research of this Project to assess workflow and security measures required by the DEA for prescribers and pharmacies. Since EHR data on EPCSs will be available, models for assessing the impact on quality of care, including adverse drug events and pick up compliance at the dispensing site should be more fully explored. While the project conducted

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[23] Fischer M A., et. al. Trouble Getting Started: Predictors of Primary Medication Nonadherence. T*he American Journal of Medici*ne, 2011 Nov, e9-1081.e22:1081.

baseline and follow up research on perceptions of prescribers related to EPCSs impact on their controlled substances prescribing patterns, further study is needed to assess barriers to full adoption under the new federal regulations. Finally, further study of the chain of possession, as proposed by GSG, should be undertaken to identify potential areas in the prescribing continuum that may be prone to security breaches.

Policy Impact

1. Based on the experience gained in the implementation of EPCS in Berkshire County, the Project Team contributed to the advancement of EPCS at the national level. The project also informed the DEA of its experience with EPCS during the study period. Additionally, the Principal Investigator provided written comments to the DEA on the project's experience in response to an invitation for feedback on the IFR.

2. The Project Team initiated informative discussions with the American Institute of Certified Public Accountants (AICPA), the entity responsible for developing and maintaining SysTrust, WebTrust, and SAS 70 guidelines referenced in the IFR. Specifically, these exchanges focused on the DEA's IFR and the role of the AICPA constituent CPA firms in conducting required third-party certification audits. As a result of these discussions, the AICPA's Trust Services Task Force commenced developing guidelines for audits that will be conducted on the third party software system application for compliance with the IFR. The final AICPA reporting guidelines were made available to the financial and IT systems auditing industry in May, 2012.[24] [25] [26]

3. The staff of the MA PMP was influential in the development of changes to the ASAP reporting standards as they relate to PMPs. As noted under Aim 2, the ability to reconcile prescribed EPCSs with those that have been dispensed is reliant upon the existence of a common indicator in the pharmacy record that remains with the record through the chain of possession from the prescribing system, to the intermediary, to the pharmacy system, and finally, to the PMP. Through the efforts of the MA PMP, on 1/1/2011, ASAP's reporting standards included a field for the NCPDP SCRIPT Transaction Control Reference Number (UIB-030-010), which was used for the reconciliation performed in Aim 2.

4. The project conducted a "gap analysis" of the prescribing and pharmacy system partners' IFR compliance, measuring their section by section status against the requirements of the IFR, leading to a list of waivers approved by the DEA for participating prescribing and pharmacy systems. An outgrowth from this analysis was a gap analysis evaluation tool and a Quick Reference Guide to the IFR for providers and systems to use in assessing IFR compliance.

Conclusions

1. In order for community wide adoption of EPCS, there must be a critical mass of pharmacies available to prescribers. While this will occur over time, early implementation dialogue between providers and pharmacies on this subject is likely to yield more robust community-wide adoption rates. Collaboration and "interoperability" involving prescribing and pharmacy system vendors, providers, independent and large chain pharmacies, and intermediaries will be the hallmark of successfully implemented communities.

2. Under the IFR, successful implementation of EPCS in a community will require all of the following: certified prescribing systems for providers, certified pharmacy systems, identity proofed providers, an intermediary capable of affixing a digital signature and transmitting EPCSs under either or both the IFR's approved scenarios, and state regulations that allow EPCS to occur.

3. Because of the issues experienced with hard tokens authenticated to provider-based computers and operating systems, the industry should focus on utilizing a one-time password or a biometric

[24] American Institute of Certified Public Accountants: Audit and Attest Services, 2012. New York, NY http://www.aicpa.org/INTERESTAREAS/FRC/AUDITATTEST/Pages/AuditAttestServices.aspx,
[25] American Institute of Certified Public Accountants: Industry Insights, 2012. New York, NY http://www.aicpa.org/INTERESTAREAS/FRC/INDUSTRYINSIGHTS/Pages/IndustryInsights.aspx
[26] American Institute of Certified Public Accountants:Reporting on a Pharmacy Application or an Electronic Prescription Application Used for Electronically Prescribing Controlled Substances, 2012. New York, NY http://www.aicpa.org/InterestAreas/FRC/AuditAttest/Reporting/DownloadableDocuments/DEA_Reports.pdf

two factor authentication process, both of which are referenced in the IFR as being acceptable alternatives.

4. Anticipating a 10-11 percent increase in EPCS prescriptions received electronically by pharmacies once full community adoption has been achieved by providers, pharmacies should take preemptive action to address work flow issues, including the prescriber practice of batching e-prescriptions identified in the study as occurring mid-day and at the end of the day. Discussions with the provider community could yield previously unidentified solutions to this issue.

5. Since EPCS requirements present new data handling processes for software systems, vendors will need to be prepared for reporting in sufficient detail to respond to information requests from outside auditors, law enforcement, and regulatory authorities.

6. Vendors will also need to be prepared for unanticipated mandatory deactivations of EPCS capabilities when reports of non-compliant system operations are reported, as required by the IFR.[27][28]

7. Because on-site support was available to the participating providers and pharmacies, the project was successful in gaining moderate to strong use rates of EPCS among participants choosing to use their hard tokens. Communities will, therefore, benefit by using available community resources to facilitate and support the inter-provider discussions necessary for successful adoption.

Significance

This project was the only one of its kind in the mainstream health care industry and, therefore, is the only source of experiential information and lessons learned for prescriber and pharmacy software system vendors, providers, pharmacies, PMPs, and regulators.

Implications

1. By eliminating manual and printed controlled substances prescriptions, and with the reduction in the opportunity for forged prescriptions, pharmacists may have more confidence in the legitimacy of controlled substances prescriptions presented electronically.

2. General adoption of EPCS technology will occur slowly on a community by community basis as various combinations of prescribing and pharmacy systems become certified. The lessons learned from this project may influence how quickly these implementations occur. The industry expects to begin general implementation of EPCS during the 2nd and 3rd Quarters of 2012.

Aim 2   Reconciliation of Prescribed to Dispensed EPCSs.

Principal Findings

1. Based on a limited sample of EPCSs and using the NCPDP SCRIPT Transaction Control Reference Number, it is possible for a state PMP to reconcile prescriptions transmitted by a prescribing system with prescriptions dispensed by a receiving pharmacy.

2. Pharmacy systems experienced misunderstanding of expectations with respect to the 2011 ASAP (version 4.1) reporting requirements for EPCSs in field DSP19 (i.e., UIB-030-010). As with the reporting for audits, more work must be done by agencies requiring controlled substances prescription data to clarify the key indicators for the source systems.

Outcomes

1. Through the efforts of MA PMP, the version 4.1 ASAP reporting standards for PMPs took effect 1/1/2011 in Massachusetts, and included an identifier that PMPs can use for the reconciliation of prescribed to dispensed controlled substances prescriptions.

2. The MA PMP, using the NCPDP SCRIPT Transaction Control Reference Number, reconciled 100 percent of the EPCSs transmitted by participating providers during the 8/1- 9/29/2011 timeframe with prescriptions dispensed by two receiving participating pharmacies. It should be

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[27] Federal Register:*Electronic Prescriptions for Controlled Substances; Final Rule 21CFR Parts 1300, 1304, 1306, and 1311.* 2010 Mar 31 75(61) Section 1311.102(e)-(k):16311-312
[28] Federal Register:*Electronic Prescriptions for Controlled Substances; Final Rule 21CFR Parts 1300, 1304, 1306, and 1311.* 2010 Mar 31 75(61) Section 1311.200(b)-(d)(i):16316-317.

noted that this was a small sample of EPCSs (N= 110), and as such, it was not possible to assess the data for potential diversion.

3. An analysis of EPCS adoption rates identified anomalies of one prescribing system which reported, in certain instances of mid-level provider prescribing, the name of the supervising physician as the prescriber of record rather than that of the mid level provider. This was an unexpected outcome and prompted immediate discussion with the pharmacy system vendor regarding remediating the system's incorrect reporting of the prescriber-of-record information.

4. The MA PMP identified communication interventions needed to promote accurate population of PMP EPCS related fields in the ASAP (v 4.1) report.

5. Further enhancements to EPCS-related fields were incorporated into the ASAP (v 4.2) reporting guidelines..

Discussion

The project initially assumed the availability of data from the prescribing and pharmacy system vendors would provide an opportunity to evaluate instances of diversion and improved quality care with respect to pickup compliance. Two of the three pharmacy systems experienced difficulty transmitting the required data field that would allow reconciliation, thus, the MA PMP was only able to assess a limited data set from one system. The project concluded, however, that the infrastructure exists to allow a more robust reconciliation once EPCS is more widely adopted. Additionally, the availability of this data to the other 42 PMPs in the country will create opportunities for additional research on how to best use the data for identification of diversion scenarios. Because state PMP programs may have different configurations and work flows, however, they need to engage prescribing and pharmacy system vendors in order to ensure the quality of the data received.

With respect to additional study, the project concluded further refinement of EPCS data use will produce models that can be adopted by other PMPs, particularly as it relates to identification of diversion. Whether this involves exception analysis, whereby dispensed medications without underlying EPCSs are reviewed, or the data is simply used for focused investigative purposes is an area for further inquiry.

Conclusions

1. As PMPs in 43 states continue to play a major role in curtailing the diversion of controlled substances, they must work closely with the prescribing and pharmacy software industries at the national level to identify consistent guidelines for reporting EPCSs from point of issuance and the point of dispensing.

2. The ability to provide prescribed to dispensed reconciliation information will be beneficial to both state controlled substances authorities as well as providers.

Significance

1. Industry reporting standards relating to PMPs are still incompatible at the national level. Currently, while most PMP reporting is done on a batch basis, there is no reporting outside of this project that relies on electronic prescribing. The work done in the study is helping to inform the discussion of establishing future industry standards.

2. At the local level, the availability of data on EPCSs has the potential to result in more effective analysis of prescribed and dispensed controlled substances data.

Implications

1. Uniformly adopted reporting standards for prescribed and dispensed EPCSs will improve the interstate efforts to identify instances of controlled substances diversion.

2. Having this information available to providers will also contribute to improving the quality of pharmacotherapy for patients needing controlled substances for legitimate purposes.

3. In some specialties, including those that treat for opiod addiction with buprenorphine, information related to pick-up compliance will be helpful to prescribing providers.

Aim 3 Evaluation

Principal Findings

1. While 33 percent of providers expected that carrying a security token at all times would be a large inconvenience, only 10 percent found it to be so (p<.001). Findings were similar for other security features, with the greatest burden experienced being the computer screen timing out, with 20 percent rating it so.

2. Prescribers using the system at least once (n=70) reported relative comfort in addressing issues related to controlled substances misuse. Of all respondents, 81.2 percent felt somewhat or totally comfortable with their ability to diagnose prescription drug abuse or dependence. 74.3 percent felt comfortable in their ability to identify if a patient is trying to obtain prescription drugs for the purpose of abuse or diversion, and 72.7 percent felt somewhat or totally comfortable with their ability to balance the needs of their patients in terms of risk of diversion with maximizing pain control. These responses did not differ significantly from responses provided by the same providers at baseline prior to the pilot.

3. Regarding the impact of EPCS on practice work flow and efficiency, practice management, and patient safety and care management, over half of prescribers found EPCS to be easy to use (72.9%), improve work flow (66.1%), improve accuracy of prescriptions (69.5%), improve monitoring of medications in the practice (59.3%), coordinate with pharmacists (55.9%), and led to fewer calls to pharmacists (54.2%). On most dimensions, EPCS experience did not meet high expectations reported prior to implementation. For several patient care related effects of EPCS (easier to identify diversion or misuse, improving medication management within practice with other prescribers, and pharmacists), expectations were much more positive than experience.

4. For practice efficiency, expectations for financial savings were not high, but experience was even lower. While few prescribers said EPCS did not have advantages over the current system (15.3%), this is triple the number who expected no advantage.

5. Less than one-third of pharmacies in the market area participated in the pilot, and for the pilot prescribers who had few patients using participating pharmacies, work flow for a limited number of patients was disruptive. The vast majority of prescribers (70.9%) said that the small number of participating pharmacies was a barrier to any use of EPCS. This was followed by technical challenges related to the computer program (38.4%) and security token (34.5%).

6. Providers using EPCS reported that several safety problems occurred less often after implementation of EPCS, including: a) the provider was alerted that the pharmacy filled wrong drug, dose, strength or directions were incorrect, and b) the patient reported that he or she lost the prescription and required a placement. All other items occurring were reported to have been experienced fewer times than prior to the pilot, but the difference was not significant. In the survey results, 60% of prescribers in the pilot and responding to the survey reported that they were somewhat or very satisfied with the use of EPCS.

Discussion

The experience of EPCS in this pilot study was generally positive for those who used the system. In spite of the limitations of pharmacy participation and several technical problems related to the system, more than half of prescribers in the study rated EPCS as a positive activity. Open-ended comments, provided by 40 of the 102 respondents, were both positive and negative. Positive comments related mostly to the concept of EPCS, ease of implementation, and patient safety concerns while negative comments were more related to limitations of the pilot system and specific technical aspects in implementation of the pilot (e.g., not enough pharmacies, technical aspects such as unreliable system, or incompatibility with current computer operating system). No providers reported a concern with potential system breaches compromising patient safety, in spite of the fact that the pilot was halted at least once to address security-related matters (a prescription was sent without use of a security token).

Users of EPCS reported a significant decrease in some of the problems associated with written prescriptions for controlled substances (e.g., incorrect drug or dose was prescribed, prescription altered, or reported lost and required replacing), but not others (counterfeit prescription was discovered).   Perceived improvements are consistent with improvements identified with electronic

prescribing of any medications,[29] and with the speculations of others regarding the impact of EPCS.[30] Additionally, while physicians initially expected security items to be a large burden, especially carrying a security token, these requirements, in practice, were not a big barrier as expected. With the development of new approaches to two-factor authentication such as biometrics and one-time password technology, a security token such as the one used in this study may not be uniformly required as EPCS is adopted elsewhere.

However, there were certain barriers to successful implementation for all prescribers, that serve as lessons as other states and systems begin to implement EPCS in communities. Most important in this particular pilot, if a critical number of community pharmacies do not have systems in place to accept EPCS, physicians will not see the value in changing systems and office work flow to accommodate this practice. The vast majority of open-ended comments, both positive and negative, addressed the fact that not enough pharmacies participated to experience the full effect of EPCS on work flow. This strongly suggests a wide interest on the part of providers to incorporate EPCS as a tool for efficient practice and patient safety, when fully implemented in communities. Our finding that EPCS improved patient management underscores the clinical importance of successful use of this tool.

A shortcoming of the system used for this pilot was that the prescribing software was not integrated into the patient medical record (EMR) or the state prescription monitoring program (PMP), so that prescriptions dispensed and prescribed by other prescribers would be known at the time of prescribing. EPCS also has the potential to integrate several data sources to ensure safe prescribing, in addition to safe transmission of prescriptions. Immediate accessibility of a full patient record through integrated EMRs, prescribing systems, and health information exchanges (HIE) while prescribing, certainly improves the efficiency of practice and patient safety. Further, linking PMPs with EMRs (e.g., having a tab in the EMR system that automatically retrieves information from the PMP system rather than logging into a separate website) will ensure smooth integration into practice work flow. This will have a positive impact on patient care coordination, particularly in improvement in coordination of medication management with other prescribers and pharmacies.

The findings of this study provide important lessons to those implementing EPCS in the community, but certain aspects of this study are not generalizable beyond this pilot. First of all, as more communities and pharmacy systems implement EPCS on a community-wide scale, the limited number of participating pharmacies in this pilot would likely not be an issue. As well, the implementation of EPCS in this pilot fell within the time frame prior to EPCS regulations being issued by the DEA, so that providers and pharmacies worked under waiver rules that departed somewhat from the current regulations (electronic prescriptions were confirmed by fax to the pharmacies). Finally, because of the small sample, and the fact that prescribing systems were not integrated with EHRs, we could not examine the impact of EPCS on specific patient outcomes. Controlled substances safety issues were thus identified by provider recollection in the survey instrument.

Conclusions

Overall, our study found that the impact of EPCS in this pilot was positive in terms of outcomes, but implementation features were not always as expected. This was the first project in the nation to pilot a community wide electronic prescribing of controlled substances, and in the two years since the transmission of EPCSs began, providers and pharmacies have had time to address technical challenges. EPCS is a promising tool to improve public health and public safety by identifying diversion or misuse of controlled substances. It promises to become a major tool to prevent/curb the growing substance abuse epidemic, and contribute to patient safety, practice efficiency, and positive health outcomes.

Areas of future provider-based research include 1) assess the stringent operational work flows required by the IFR to determine barriers to provider adoption of EPCS in the practice setting, 2) assess in a fully implemented community (i.e., widespread EPCS adoption by providers and pharmacies) the impact of EPCS on certain quality measures, including patient pickup compliance

[29] Kaushal R., et. al., et al. Electronic prescribing improves medication safety in community-based office practices. *Journal of General Internal Medicine* 2010 **25**(6): 530-536.

[30] Figge HL and Fox BI, et al. Electronic prescribing of controlled substances. *American Journal of Health System Pharmacy* 2009 **66**(14):1311-1316.

and the effect on rated of adverse drug events (ADE), and 3) evaluate the effect of introducing EPCS on the diversion of controlled substances for non-medical use.

Aim 4 Dissemination

During the course of the study members of the project team participated in 40 presentations, 3 poster presentations, 2 webinars and produced 1 manuscript in a peer reviewed publication and 1 trade press article. In addition, the project conducted the first live demonstration of an EPCS transmission at the 2011 AHRQ HIT meeting. The following is a list of publications and presentations resulting from the project to date:

Publications

Journal of the American Medical Informatics Association, "Prescribers' Expectations and Barriers to Electronic Prescribing of Controlled Substances", Cindy Parks Thomas, PhD, et al., September 22, 2011.

Healthcare Financial Management Association Newsletter (Maine), "Electronic Prescribing of Controlled Substances: Preparing for Implementation in Maine", Stephen J. Kelleher, Jr., MHA, FACHE, September, 2011.

Presentations

Massachusetts Health Data Consortium, eRx Forum, Waltham, MA, September 27, 2007, Grant Carrow

Massachusetts Department of Public Health, Institutional Review Board, Boston, MA, October 22, 2007, Grant Carrow

Massachusetts Health Data Consortium, eRx Forum, Waltham, MA, November 29, 2007, Grant Carrow

Massachusetts Department of Public Health, IT Governance Committee, Boston, MA, December 4, 2007, Grant Carrow

Massachusetts Department of Public Health/Division of Health Care Finance and Policy, IT Business Steering Committee, Boston, MA, December 17, 2007, Grant Carrow

Massachusetts Executive Office of Health and Human Services, Chief Information Officer, February 4, 2008, Grant Carrow

Massachusetts Executive Office of Health and Human Services, Legal Office, and Department of Public Health, Legal Office and Privacy Office, February 14, 2008, Grant Carrow

Massachusetts Executive Office of Health and Human Services, Legal Office and Security Office, and Department of Public Health, Legal Office and Privacy Office, March 19, 2008, Grant Carrow

Massachusetts Health Council, Pharmacy Committee, Boston, MA, March 26, 2008, Grant Carrow

Massachusetts Health Data Consortium, eRx Forum, Waltham, MA, April 10, 2008, Grant Carrow and Stephen Kelleher

Pain Management Steering Committee, Berkshire Health Systems, Pittsfield, MA, May 9, 2008, Grant Carrow.

Joint Meeting of Executive Directors of Massachusetts Professional Boards of Medicine, Pharmacy, Nursing, Physician Assistants, and Dentists, Boston, MA, May 20, 2008, Grant Carrow and Stephen Kelleher.

Project Information Meeting for Healthcare Providers and Pharmacists, Pittsfield, MA, June 24, 2008, Grant Carrow, PhD (PI); Peter Kaufman, MD, Chief Medical Officer, DrFirst; Nancy Coffey, New England Manager of Diversion Control, U.S. Department of justice, Drug Enforcement Agency; Cindy Parks Thomas, PhD, Senior Scientist, Schneider Institute for Health Policy, Brandeis University. (The Project Team conducted an information sharing meeting for 90+ healthcare providers and pharmacists targeted for participation in the project)

AHRQ Annual Conference, Health IT Session: "ePrescribing: Enabling Change and Measuring Impact", Bethesda, MD, September 8, 2008, Grant Carrow, PhD (PI).

AHRQ Annual Conference, Health IT Grantee Discussion, Bethesda, MD, September 8, 2008, Grant Carrow, PhD (PI), Peter Kaufman, MD (Chief Medical Officer, DrFirst), Stephen Kelleher, Jr., FACHE (Project Manager)

Massachusetts College of Pharmacy and Health Sciences, E-Prescribing Conference, Framingham, MA, October 7, 2008, Grant Carrow, PhD (PI)

National Association of State Controlled Substances Authorities (NASCSA), Annual Conference, Jacksonville, FL, October 23, 2008, Grant Carrow, PhD (PI) and Peter Kaufman, MD.

Meeting with DEA Senior Leadership, Springfield, VA, November 6, 2008, Peter Kaufman, MD.

Massachusetts Health Council, DPH Pharmacy Initiatives: Electronic Prescribing Project, January 28, 2009, Grant Carrow, PhD:(PI)

Massachusetts Health Data Consortium, eRx Forum, Comments on the Progress of the Project to the Membership of the eRx Forum (teleconference), March 12, 2009, Grant Carrow, PhD (PI)

Joint Meeting of DEA Regional Office, MDPH, Board of Medicine, Office of the Attorney General, MassHealth, March 13, 2009, Grant Carrow, PhD (PI)

The Medical Records Institute Annual Conference, Palm Springs, CA, Controlled Substances E-Prescribing: Preliminary Experience from a Pilot Project, February 3, 2009, Thomas Sullivan MD and Peter Kaufman, MD. (DrFirst)

Health Information and Management Systems Society (HIMSS) e-prescribing Work Group Teleconference *Update on the Enabling E-Prescribing of Controlled Substances Project*, November 10, 2009, Michael Blackman, MD, Chief Medical Information Officer, Berkshire Health Systems, Inc.

National Council for Prescription Drug Programs (NCPDP), NCPDP Script Work Group Meeting, New Orleans, LA, November 11, 2009, Richard Sage, Vice President for Clinical Services, eRx Network, an Emdeon company.

LSS Data Systems User Group, Minneapolis, MN, *Update on the Enabling E-Prescribing of Controlled Substances Project*, December 10, 2009, Michael Blackman, MD, Chief Medical Information Officer, Berkshire Health Systems, Inc.

Massachusetts Health Council Annual Pharmacy Conference, DPH *Pharmacy Initiatives: Electronic Prescribing Project,* Needham, MA, January 19, 2010, Grant Carrow, Ph.D. (PI).

Health Information and Management Systems Society (HIMSS) Annual Meeting, *Initial Experiences With e-Prescribing of Controlled Substances: How It's Done*, Atlanta, GA, March 3, 2010, Michael Blackman, MD, MBA, former Chief Medical Information Officer, Berkshire Health Systems, Inc and Peter Kaufman, MD, Chief Medical Officer, DrFirst, Inc.

Agency for Healthcare Research and Quality Annual Health IT Grantee and Contractor Meeting, *Live Demonstration of Electronic Prescribing of Controlled Substances*, Washington, DC, June 3, 2010, Thomas Sullivan, MD, Chief Strategic Officer, DrFirst, Inc.; Michael Blackman, MD, former Chief Medical Information Officer, Berkshire Health Systems, Inc.; and Allan Smith, Senior Product Engineer, Emdeon/eRx Network (NOTE: A video of the demonstration was produced for AHRQ)

Agency for Healthcare Research and Quality Annual Health IT Grantee and Contractor Meeting, Poster Presentation: *Early Experiences from Implementing Electronic Prescribing of Controlled Substances*, Washington, DC, June 2-4, 2010, Stephen J. Kelleher, Jr., MHA, FACHE, et. al.

Tufts HealthCare Institute Program on Opioid Risk Management, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Poster Presentation: Enabling Electronic Prescribing for Controlled Substances: Perspectives of Physicians and Other Prescribers, Boston, MA, June 3-4, 2010, Cindy Parks Thomas, PhD, et al.

Office of National Drug Control Policy, *Overview of the Prescription Monitoring Programs Center of Excellence of Brandeis University*, June 8, 2010, John Eadie, MPA (Member, EPCS Project Team), Washington, DC (reference to the EPCS project was included within Mr. Eadie's presentation regarding the PMP Center of Excellence at Brandeis University).

Academy Health Annual Research Meeting, Poster Presentation: *Enabling Electronic Prescribing for Controlled Substances: Perspectives of Physicians and Other Prescriber*, Boston, MA, June 28-29, 2010, Cindy Parks Thomas, PhD, et al.

Electronic Prescribing of Controlled Substances (EPCS): What You Need to Know, National Town Hall Webinar Sponsored by Emdeon, Inc., September 21, 2010, Grant M. Carrow, PhD, Peter N. Kaufman, MD, Stephen J. Kelleher, Jr., MHA, FACHE, Ann McDonald, RN, MN, and Richard B. Sage.

Implementing the 2010 Interim Final Rule for Electronic Prescribing of Controlled Substances, Participating Pharmacy Managers in Berkshire County Pittsfield, MA, September 26-27, 2010, Stephen J. Kelleher, Jr., MHA, FACHE and Ann McDonald, RN, MN.

Initial Experiences with Electronic Prescribing of Controlled Substances, Annual Meeting of the National Association of State Controlled Substances Authorities(NASCSA), Charleston, SC, October 20, 2010, Grant M. Carrow, PhD (PI).

Enabling Electronic Prescribing for Controlled Substances: Perspectives of Physicians and Other Prescribers (poster presentation), American Public Health Association (APHA) Annual Meeting, Denver, CO, November 6-10, 2010, Cindy Parks Thomas, PhD, et. al.

Implementing the 2010 Interim Final Rule for Electronic Prescribing of Controlled Substances (Part 2): Advanced Security Software Training, Participating Pharmacy Managers in Berkshire County Pittsfield, MA, December 1-2, 2010, Stephen J. Kelleher, Jr., MHA, FACHE and Ann McDonald, RN, MN.

Prescription Monitoring Integration with E- Prescribing and Health Information Exchange, PDMP East Regional Meeting. April 5, 2011, Washington, DC, Grant M. Carrow, PhD.

Update: Enabling E-Prescribing and Enhanced Management of Controlled Medications Massachusetts Board of Pharmacy, April 12, 2011 Boston, MA, Grant M. Carrow, Ph.D. (PI), Stephen J. Kelleher, Jr., MHA, FACHE, and Ann McDonald, RN, MN.

EPCS: Progress Report Since DEA IFR Became Law, National Council for Prescription Drug Programs Annual Technology and Business Conference, May 18, 2011, Phoenix, AZ, Richard B. Sage (Emdeon) and Stephen J. Kelleher, MHA, FACHE (Project Manager).

Electronic Prescribing for Controlled Medications: Prescriber Experience in a Community-wide Demonstration,(poster presentation) Agency for Healthcare Research and Quality Annual Conference, September 19, 2011, Bethesda, MD, Cindy Parks Thomas, PhD, et al.

EPCS Progress Report Since DEAs IFR Became Law, National Association of State Controlled Substance Authorities Annual Meeting, October 21, 2011, Portland, ME, Nathan Ludvigson, Emdeon.

Enabling e-Prescribing and Enhanced Management of Controlled Medications:From the Perspective of Providers and Pharmacies, National Association of State Controlled Substance Authorities Annual Meeting, October 21, 2011, Portland, ME, Ann McDonald, RN, MN, Berkshire Health Systems, Inc.

Electronic Prescribing for Controlled Medications: Prescriber Experience in a Community-wide Demonstration, National Association of State Controlled Substance Authorities Annual Meeting, October 21, 2011, Portland, ME, Cindy Parks Thomas, PhD, Schneider Institute for Health Policy, Brandeis University

Enabling e-Prescribing and Enhanced Management of Controlled Medications. AHRQ National e-Prescribing Webinar, September 5, 2012. Grant M. Carrow, PhD (PI) and Cindy Parks Thomas, PhD (Brandeis University)

E-Prescribing of Controlled Substances.... A Work in Progress. New England Pharmacists Convention, September 27, 2012, Ledyard, CT. Stephen J. Kelleher, Jr., MHA, FACHE (Project Manager) and Stanley Walczyk, RPh (Participating Pharmacy Owner/Project Team Member)