Abstract

Purpose: The study aims were: 1) to test the interoperability of the initial standards with the proposed foundation standards; 2) to study the effects of ePrescribing (computerized physician order entry [CPOE] with electronic transmission) on patient safety and 3) to study the effects of ePrescribing on office workflow.

Scope: MA-SHARE and CSC Consulting developed a community utility, the Rx Gateway to facilitate ePrescribing transactions. We studied clinics during both a baseline (CPOE without ePrescribing) and intervention (ePrescribing) period.

Methods: Data from the CPOE applications, electronic medical records (EMR), RxHub and Surescripts were used to compare prescription (Rx) orders to dispensed medications. Laboratory testing was conducted on standards determined insufficiently mature to support live implementation. Suspected medication errors (MEs) and adverse drug events (ADEs) were rated by physicians. Direct observations of office practices were conducted using time-motion techniques. Outcome measures included Rx callbacks.

Results: Most of the tested ePrescribing standards were interoperable and we support their use. We also found several standards insufficiently mature or unsatisfactory to recommend use in their current formats for Medicare Part D ePrescribing. The clinical trial of ePrescribing was well accepted by clinicians and office staff. Currently, our findings are incomplete and do not permit us to report on the impact of ePrescribing on ADE rates and ME.

Key Words: Electronic prescribing, medication safety, computerized order entry
A. Purpose

Our study objectives or aims were threefold.

1. To test the interoperability of the initial standards with the proposed foundation standards, and in addition examine standards produced during the study period, and to catalogue and analyze issues identified during field usage of these standards.

2. To study and compare ePrescribing to computerized provider order entry (CPOE) without electronic transmission with respect to accurate Rx transmission, and in addition to evaluate the effects of ePrescribing on patient safety, quality and efficiency.

3. To study and compare ePrescribing to CPOE (without electronic transmission) with regards to business processes such as provider efficiency and the number of prescription (Rx) callbacks.

B. Scope

I. Background

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), through Title 1, will require participating drug plans to support and comply with e-prescribing standards for the Medicare Part D program. Standards testing are required by Section 1860D-4(e)(4)(c) of the Social Security Act and before final uniform standards are completed. This pilot project will test standards developed by the Centers for Medicare and Medicaid Services (CMS; rule 42 CFR 423) as well as additional standards produced during the study period. The CMS standards are the “initial standards” that include the proposed “foundation standards”.

More than 3 billion Rxs are written annually in the United States and Rx medications are used by nearly two-thirds of US citizens. Therefore, even small improvements in the safety, quality and efficiency of the medication prescribing process can be expected to result in substantial benefits.

II. Context

A combined team from MA-SHARE, Beth Israel Deaconess Medical Center (BIDMC), and CSC Consulting designed, developed, and deployed ePrescribing capability supporting new retail Rxs and provider-initiated Rx renewals for BIDMC physician practices. This deployment provided the intervention period data for evaluation of outcomes for Aims II and III by Brigham and Women’s Hospital’s (BWH) research team and the foundation for the Aim 1 results reported here.

This deployment completed the first live release of a community ePrescribing utility known as the Rx Gateway. The Rx Gateway provides standards-based connectivity among providers, payers, pharmacy benefit managers (PBMs), vendors of ePrescribing services, electronic medical record (EMR) vendors, and other MA healthcare stakeholders. The first release supported transmission of electronic Rxs (eRxs) from physicians using BIDMC’s EMR system, webOMR (online medical record), to retail pharmacies via SureScripts Messenger Service.

III. Settings

We tested the ePrescribing standards in Greater Boston area outpatient medical practices and local retail pharmacies and mail order fulfillment firms that have agreements to participate in a common linking electronic infrastructure, the “eRx Gateway”. We used
BIDMC practices that already have advanced to a mature outpatient EMR and CPOE environment; most clinicians have been prescribing medications by computer for years. We studied 3 office practices sites in BIDMC’s system, one very large teaching on-campus practice (Clinic A) and 2 smaller practices, a small on-campus geriatrics practice (Clinic B) and an off-campus non-teaching site (Clinic C).

We originally planned to split Clinic A, which includes 4 distinctly separate pods/units in half, such that each half of the large practice site and one of the small practice sites would be randomized into a control arm and the remaining sites into an intervention arm. However, the large practice now uses a centralized telephone call-in and nurse response system for managing all Rx-related telephone calls and refill/renewal requests and therefore could not be divided into control and intervention halves (see below). We therefore randomized Clinic A as the intervention unit v. Clinics B and C as the control units.

IV. Participants

Clinic A includes 224 providers, 62 are attending physicians, many part-time, and the remaining are housestaff or nurse practitioners (NP). During the intervention study, 21 attendings consented to participate in ePrescribing. The Rx workflow is centralized in one location within the clinic and is managed by two experienced clinical nurses and one practice assistant. The clinical nurses handle all Rx refills / renewals. The practice assistant manages PA requests. Nurses within this practice utilize approved phone treatment protocols for certain conditions. Clinic B has 9 clinicians including 7 attendings, a fellow and a NP. Physicians manage Rx workflow with assistance from practice assistants; therefore physicians in this site processed most tasks associated with Rx refills. Clinic C has 5 attendings. Two clinical nurses manage the Rx refill process. Prescription refills are faxed directly to retail pharmacies, unless the patient requests otherwise, but not to mail order pharmacies.

V. Incidence

Baseline statistics for Rxs and pharmacy callbacks are included in the results section and appendix. In 2005, the 3 clinics had 99,834 patient visits. We determined prior to the study that the 3 clinic sites generated an average of 4500 Rxs a week, including 700-900 Schedule II-V Rxs that are excluded from ePrescribing. During 2005-6, Clinic A had 100,000 annual visits as compared to 3200 and 15,000 for Clinics B and C, respectively.

VI. Prevalence

Not applicable.

C. Methods

We conducted a baseline evaluation from Jan. 1, 2006 - Feb. 28, 2006 followed by a controlled trial from Sept. 18, 2006 – Nov. 18, 2006 to evaluate ePrescribing and transmission (but until Oct. 18, 2006 for the ADE monitor). During the trial, the control groups continued to order medications with the computer (CPOE) but without changes to the mode of Rx handling / transmission and other workflow practices. During the intervention, only clinicians who consented to participate in ePrescribing were studied. Practice leaders recruited the busiest prescribers to participate in order to achieve robust sample sizes.
I. Study Design

Aim I: We tested the interoperability of the initial standards with the foundation standards from four perspectives: accuracy, completeness, coherence and usability. We tested or evaluated the standards using varied approaches dictated by each standard’s maturity and the organizational and technical resources available to our team. We did not test the standard supporting pharmacy-payer eligibility request because the standard is a foundation standard that is widely deployed and used in the marketplace. Our study was largely provider-centric and we did not undertake pharmacy testing and evaluation. For each standard, we developed an approach, methods, and tools to accomplish the testing. Factors that influenced this design included the maturity of each standard, the practicality and degree of sponsorship of the MA-SHARE community for live implementation in 2006, and the constraints of budget, resources, and time. A summary is presented here with full details in the Appendix.

Live implementation: The MA-SHARE, CSC Consulting, and BIDMC project teams started the project with limited real-world experience with developing and implementing ePrescribing capabilities. We decided to begin by implementing the foundation standards for New Prescription (New Rx) transmission and drug eligibility and benefits to provide a robust platform for expansion of the Rx Gateway community utility as well as a real-world platform for testing interoperability with the initial standards. To provide data required by the BWH research team for Aims II and III, we worked with SureScripts to leverage their new Med Hx offering to provide data on dispensed drug Hx. We were unable to complete live implementation of formulary access and display early enough in the year to permit study of the clinical and business impacts by the BWH research team. This was due to delays in our earlier implementations for New Rxs and Med Hx and unanticipated complexity in the design for formulary. We report our experiences and findings in the areas of design, development, implementation, operation, and interoperability of new e-Rxs, provider-initiated Rx renewals, drug eligibility checking, formulary access and display, and Med Hx retrieval and content. The ePrescribing Pilot Architecture is further detailed in the Appendix.

Laboratory testing and research: We did not consider the initial standards supporting Prior Authorization (PA), RxNorm, and Structured and Codified Sig to be sufficiently mature for live implementation in the Rx Gateway community utility. For these standards, we designed laboratory testing methods that allowed us to present the standards to expert users and technical implementers in interviews and work groups for their review and comment on the standards’ value and usability. In the case of PA, we worked with RxHub, BCBSMA, and Express Scripts to implement the standard using test harnesses at both CSC and RxHub to simulate the required provider-payer interactions. For Structured and Codified Sig, we developed a stand-alone test harness used to compare entry of free-form text with entry of structured, codified instructions. In addition, we used a sample of approximately 28,000 de-identified Sigs to assess the adequacy of the standard’s terminology. For RxNorm, we developed tools for analyzing the adequacy of the standard’s content in the context of a selection of de-identified Med Hx records for approximately 7,000 BIDMC patients. We also mapped the structure and content of the initial standards to the foundation standards to identify potential interoperability issues. We viewed the standards for Rx Renewal/Refill, Fill Status Notification, Change, and Cancel as variants of the New Rx foundation standard that might be developed and deployed subsequent to the success of the live implementations described earlier. For these standards, we mapped the structure and content to the foundation standards and to each other to identify potential interoperability issues, and we conducted interviews and work group sessions with expert users and technical
implementers to assess their clinical and business utility and considerations for live
implementation. During the project, we learned about the foundation standards themselves
as well as the initial standards and their interoperability. Where a finding or conclusion
applies to multiple standards, we have reported it under the most pertinent standard and
included cross-references in the other sections.

**Aim II:**

Our study design employed a baseline evaluation followed by a controlled trial to
evaluate ePrescribing and transmission. During the trial, the control sites (Clinics B and C)
continued to order medications with the computer (CPOE) but without changes to the mode
of Rx handling / transmission and other workflow practices. Medication Rxs in the control
group continued to be produced in the paper format and either faxed to the pharmacy or
given to the patient.

Medication orders were collected from webOMR. We used the pharmacy, retail and
mail order, databases to review the Rxs that have been dispensed. The dispensed
medications were compared by a research nurse or pharmacist to the original medication
order as to the accuracy of the medication name, form (pill, liquid), dose, frequency, patient
instructions, amount to dispense and number of refills. In order to complete the review within
the studies timeframe, we limited the number of Rxs for review to 10 per visit. If a suspected
incident (MEs and ADEs) was identified on Rx review, a chart review was performed to
determine if the patient suffered any harm from the error. In order to assist identification of
ADEs, we modified BWH’s ambulatory ADE monitor for BIDMC’s webOMR to detect events
(see below). Suspected incidents found by research staff conducting Rx and chart reviews
were entered into an electronic rating tool (see below) used by MD reviewers to classify
incidents.

Medication Hx reconciliation was conducted using records provided by webOMR and
SureScripts. Prescriptions with associated dispensing Hx within 30 days of the written date
as recorded in webOMR were reviewed for dispensing errors. The prescribing Hx and
dispensing Hx were considered associated if the active moiety (drug chemical) of both
records matched. If multiple Rxs for a single moiety were dispensed within 20 days, the
dispensing Hx with the least number of days elapsed between writing and dispensing was
considered the associated dispensing Hx. Medical record numbers which we did not have
dispensing information were excluded. Prescriptions in which the active moiety was not
dispensed within 30 days of the written date as recorded in webOMR were excluded.

The following outcomes of interest described in our proposal were not completed in
time for this report either because of software development challenges or technical and
programmer personnel challenges needed to modify webOMR: 1) we did not create a
computerized rules monitor to search pharmacy databases for formulary substitution data
nor assess the appropriateness of substitutions and compliance rates; 2) we did not assess
prescribing – dispensing efficiency due to the lack of real time pharmacy dispensing
information and 3) while we successfully implemented a new decision support tool warning
clinicians when prescribing drugs contraindicated in patients ages 65 and older, known as
the Beer’s criteria, we were unable to assess the impact on patient safety. We plan to study
the impact of this alert in the next few months.

**Aim III**

Continuous observation was conducted at Clinica A and C. Due to study time
constraints, we were unable to complete observations at Clinic B, the least active site for Rx
renewals and pharmacy call backs. Also, Clinic B relied far less on office staff to manage Rx
renewals/ callbacks (see above). The method consisted of a trained observer passively
shadowing office staff (nurses and medical assistants) while capturing the amount of time spent on each activity performed. Patient information was not collected. The data collection tool is described below. Observation sessions lasted two to four hours and during the busiest time of day for handling Rx renewals /callbacks. Staff members were asked to voluntarily permit confidential observations. Office staff consented to be observed during several medication prescribing processes, including but not limited to, pharmacy call backs, patient refill requests, telephone orders and documentation related to prescribing. The data collection tool is described below and illustrated in an Appendix. Study of physician ePrescriber uptake, both enrollment and disenrollment was limited due to the study timeframe constraints and the IRB requirements that resulted in a limited (and biased) subset of clinicians who agreed to be the initial participants.

II. Data Sources/Collection

See Study Design for Aim 1 data collection. The EMR and CPOE system used in the study office practice sites is webOMR. WebOMR is a comprehensive web-based ambulatory care system that includes full results reporting, medication ordering, lab/radiology ordering, charting and CDS. As medications are entered, allergies, drug/drug interaction, and therapeutic substitution are checked. Doses are defaulted and pull-downs are used to enforce minimum/maximum dosing. Renal dose adjustment is automatically displayed for certain medications.

We employed the following 4 approaches to the data collection for Aim II: 1) we compared medication orders to Rxs using the webOMR for the CPOE order data and the databases of Surescripts and RxHub for the Rx data; 2) we utilized the webOMR for access to the electronic visit notes. Notes were reviewed manually to assess medication history (Med Hx) reconciliation between the transmitted order and the chart; 3) we used stamps on CPOE entered orders and compared them to the electronically recorded times pharmacies used when labels were printed for dispensing. This data was used to study prescribing-dispensing efficiency; and 4) the webOMR’s database was electronically searched for ADEs using a sophisticated ADE monitor. Several rules were deleted because of low positive predictive values (PPV) found in our previous work. We originally reduced the time frame of post-Rx webOMR searching from 120 to 60 days, but had to cut that to 45 days in the baseline period and 30 days in the intervention period. These decisions were based on study timeframe requirements and delays (previously described in the interim reports) in obtaining BIDMC IRB approval. See appendix for additional details.

Suspected incidents (MEs and ADEs) were found by research staff conducting Rx and chart reviews and were entered into an electronic rating tool. The tool was used by two MD reviewers to classify suspected incidents as ADEs, potential ADEs (MEs with potential for harm), MEs, or exclusions. For Aims II, an electronic database was created in MS access. Previous ME and ADE studies performed by investigators in our group used 5 main paper dataforms to collect variables used in identifying incidents involving MEs, potential adverse drug events and actual adverse drug events. For this study, those paper dataforms served as a guideline for creating the primary data collection tool in Microsoft Access. Patient, physician and employee identifiers remained confidential and secure and all identifiers, except for assigned study ID numbers, will be removed from all data files at the conclusion of the study.

Due to challenges in the study timeline and other conditions discussed a month ago with the Project Officer, by necessity we did sampled analyses for Aim II in order to provide preliminary results at this time. Our sampling strategy in provided in the following table.
<table>
<thead>
<tr>
<th>Period</th>
<th>Baseline</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Control Site</td>
</tr>
<tr>
<td>Prescriptions (Rx)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Rx</td>
<td>24,763</td>
<td>15,581</td>
</tr>
<tr>
<td>All Rx meeting eligible for review: excludes Rx with disp =0, equipment, and duplicate prescriptions</td>
<td>22,943</td>
<td>NA</td>
</tr>
<tr>
<td>Rx sample selected for initial RN/RPh screening</td>
<td>19, 880</td>
<td>13,482</td>
</tr>
<tr>
<td>Baseline Medication Incidents sampled for MD classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For Control Site, all NMs and ADEs</td>
<td>299</td>
<td></td>
</tr>
<tr>
<td>For Intervention Site: All MEs, NM, and ADEs</td>
<td>309</td>
<td></td>
</tr>
<tr>
<td>Intervention Medication Incidents sampled for MD Classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention Site : All MEs NM, and ADEs</td>
<td>374</td>
<td></td>
</tr>
</tbody>
</table>

After initial prescription review screening by the Research RNs and RPH, the following prescription errors /medication incidents were designated as “Rule Violations” by Study Investigators and therefore did not receive further MD review for classification as follows: no length of rx errors; no amount dispensed errors; no prn errors no frequency or route abbreviation errors- all other abbreviation errors were included; no combinations (i.e Tylenol # 3) strength w/out units, or any strength without units where there was a / in the dose or strength; and no strength without units for Bactrim DS (only comes in 1 form).

**III. Interventions**

As previously described, the ePrescribing intervention was conducted during the intervention period at Clinic A and was compared to the baseline period findings as well as concurrently to the control Clinics (B and C). In addition to looking the entire clinic practices, we also compared the findings of only those physicians who consented to participate in the ePrescribing intervention to their baseline prescribing.

**IV. Measures**

*Aim I. (see appendix for details)*

1. Prescriptions
   A. *New Rx:* The new Rx implementation encompassed three key development components: 1) Prescriber upload - BIDMC periodically transmitted prescriber data sourced from BIDMC's provider credentialing system to the Rx Gateway, which then loaded the prescribers to the SureScripts prescriber directory; 3) Pharmacy download - the Rx Gateway performed nightly downloads of SureScripts pharmacy data to the Rx Gateway. Since our implementation did not use SureScripts' fax capability, we downloaded only those retail pharmacies SureScripts had identified as enabled to receive eRxs; and 3) BIDMC/Rx Gateway services and integration - BIDMC enhanced webOMR and other applications to leverage services provided by the Rx Gateway. These functions included: a) enabling selection of pharmacy and pharmacy favorites at the time of patient registration or at the time the Rx was written;
b) enabling the choice of medium for rendering the Rx; c) routing eRxs to a prescriber approval queue; d) delivering Rx data to the Rx Gateway for transmission to SureScripts; and e) displaying messages indicating the status of Rx delivery. This ePrescribing capability was live beginning in June, and more than 6,000 eRxs were processed by the end of 2006.

B. Medication History: We developed a process to obtain live Med Hx data from SureScripts for use by the BWH team to compare prescribed medications to dispensed medications. To accomplish this, we: 1) designed, developed, and implemented a process whereby BIDMC provided patient demographic data and SureScripts provided Med Hx data for those patients included in the study; 2) executed the process and delivered the data to BWH in August and December for baseline and intervention periods respectively; and 3) reviewed the Med Hx data with the BWH research team to identify data anomalies and interoperability issues. We mapped the Med Hx standard to the New Rx standard to identify potential interoperability issues and solicited input from our participating organizations regarding clinical, business, and implementation considerations.

C. Renewal/Refill, Fill Status Notification, Change, and Cancel: We mapped the four standards to the New Rx standard and to each other to identify potential interoperability issues. We conducted interviews to understand the work flows and issues associated with these transactions and to assess the business and clinical usefulness of the transactions and the implementation challenges that might be encountered.

2. Benefits

We evaluated the Eligibility and Benefits verification and Formulary and Benefits Download standards. We had originally planned to implement the eligibility and formulary live to permit study of the clinical and business impacts by the BWH research team, but delays in our earlier live implementations for New Rxs and Med Hx and unanticipated complexity in the formulary design and development prevented our achieving the goal of live implementation. The eligibility and formulary testing encompassed four key development components: 1) Eligibility verification - BIDMC transmitted patient information to the Rx Gateway, which queried RxHub for pharmacy benefit eligibility under the RxHub PBMs and plans. Data returned by RxHub was saved in the BIDMC applications to be used for viewing by the prescriber and to look up corresponding formulary data. BIDMC applications were enhanced to permit “batch” retrieval ahead of time for scheduled visits and real-time retrieval where the eligibility check had not been performed in the previous 24 hours; 2) Formulary download - the Rx Gateway performed periodic downloads of RxHub data; 3) Formulary lookup - webOMR transmitted drug data for drugs selected by the prescriber, and the Rx Gateway looked up the available corresponding formulary, coverage, copay, and alternatives data and transmitted it to webOMR; and 4) Eligibility and formulary display - webOMR displayed the patient eligibility data and the plan coverage and formulary data to the clinician.

3. Prior Authorization

We developed a four-pronged approach to comprehensively test the electronic PA (e-PA) standards. First, we implemented the standards in the test harness to assess the usability, completeness, coherence and accuracy of the proposed e-PA process. The test harness was used to: 1) understand and implement the standards by a) developing a service to issue initial e-PA requests using the X12.278 EDI transaction; b) developing a service to issue an additional information attachment X12.275 EDI transaction and c) generating an HL7 Computer Decision Variant message; 2) Create a user interface that entails selecting a drug and reviewing formulary information, issuing an initial e-PA request, viewing the status of PA requests sent, issuing a 275 transaction with additional information provided and creating a NewRx with a PA code and 3) devise 120 test scenarios to execute
in the test harness by a) using twelve in-scope BCBSMA forms to design test scenarios, we varied values in form fields and created ten scenarios per form; and b) issuing test scenarios using only the four LOINC forms available for use by BCBSMA in the test harness. Second, we mapped fields from the 278 and 275 transactions to evaluate the coherence and completeness of the e-PA standards. The purpose of the data map was threefold: 1) to identify redundant elements, i.e., elements that were included in both transactions, 2) to determine which elements would be required for implementation, and 3) to assess which elements would be necessary to link transactions together. Third, we conducted a series of in-depth interviews with information technology (IT) professionals from provider groups to assess the usability and completeness of these standards and introduction of e-PA. Finally, we conducted both one-on-one interviews with clinicians and a focus group with providers, pharmacists, and BCBSMA. The purpose of these conversations was to understand how prescribers view PA, identify issues that might arise from the implementation of e-PA, and devise appropriate recommendations that address these concerns.

4. Structured and Codified Sig

To evaluate Structured and Codified Sig, we engaged in interviews with IT professionals, researched codified Sig methods currently in practice, examined the vocabulary of the SNOMED database that comprises the standard, and mapped the standard to SCRIPT 8.1. To understand the implementation of Structured and Codified Sig standard within an EMR, we originally planned to develop a Sig UI in our laboratory. Our intention was to deploy a test harness to assess the accuracy and usability of the model through an interactive survey tool. The survey would have asked clinicians to compare free text Sigs with Structured and Codified Sigs. However, due to strong negative initial reaction by physicians to the drop-down menus for Structured and Codified Sig, we amended our approach. Instead, we interviewed providers to solicit their reactions to the standard. Thus, our test approach involved the following: 1) Interviewed the Structured and Codified Sig task group leader to gain a deeper insight into the development of the standard; 2) Compared the unique terms from 28,000 live Sigs to the terms contained in the SNOMED database that comprises the Structured and Codified Sig standard to determine the adequacy of the database; 3) Interviewed IT professionals to assess how Sigs are currently entered into scripts, to solicit feedback around the concept of Structured and Codified Sig, and to gain insight into how they would envision the implementation of the standard; and 4) Manually mapped Structured and Codified Sig to SCRIPT 8.1 to determine whether the two standards are interoperable.

5. Rx Norm

To evaluate the RxNorm standard, we conducted a set of interviews, implemented an RxNorm database, used the database to obtain drug strings, and analyzed the standard’s interoperability with formulary and NewRx. To assess the usability, completeness, and accuracy of the standard, we interviewed representatives from the RxNorm task group, IT professionals, pharmacists, and clinicians. To evaluate further the usability, completeness, and accuracy of the standard, we implemented an RxNorm database. We then used a sample of Med Hx for approximately 6,000 BIDMC patients to match NDC codes from the sample to either RxNorm Semantic Clinical Drug (SCD) or Semantic Branded Drug (SBD) strings, as appropriate. Next, a pharmacist compared a sample of the strings obtained from RxNorm with those drug names from Med Hx. Finally, we examined the interoperability of the RxNorm standard with the Formulary and SCRIPT 8.1 NewRx standards to determine the coherence of the standard. This entailed assessing whether Formulary and NewRx contained fields that were available for, and compatible with, RxNorm codes.
Aim II

For this aim, we compared ePrescribing to CPOE (without eRx transmission) for their capacity to effectively and unequivocally communicate the correct and necessary information from the sending physician or other prescribing clinician to the receiving pharmacy responsible for dispensing the medication to the patient. The unit of analysis is the Rx / medication order. Medication errors are errors during ordering, transcribing, dispensing, administering, or monitoring. During this study, medication errors associated with transcribing and dispensing were most likely impacted by the addition of ePrescribing with electronic transmission. Not all medication errors have the potential to harm a patient. A near miss or potential adverse drug event (PADE) is a medication error that has the potential to cause harm but does not either because it is intercepted or reaches the patient and because of lack does not cause harm. Adverse drug events (ADEs) are injuries due to medications and are classified as preventable (associated with a medication error) or non-preventable. The “Rx for dispensing” is defined as the Rx to be dispensed by the pharmacist or PBM and is entered by the pharmacy (retail and mail-order) into their databases and results in the printed Rx label on the medication given to the patient. For this study, we did not interview patients nor examine Rx bottle labels or contents.

For the Medication Hx analyses, we used the following definitions: Dispensing Hx Not Available – dispensing Hx not found for a prescribed active moiety (e.g. active chemical) within 30 days of the written date; No Error – the medication was dispensed as written within 30 days of prescribing; Prescribing Error Corrected – dispensing data differed from prescribing data and suggesting an error was corrected, likely by the pharmacist; Dispensing Error – dispensing data differed from prescribing data in either the product dispensed or Sig field such that the dispensing and prescribing information were not therapeutically equivalent; and As Directed when Inappropriate - pharmacy label direction for use field read “as directed” when more explicit directions appeared in the Rx in webOMR.

Aim III

The outcomes of interest were: Prescription related-calls – this is the primary outcome we will measure for Aim 3 –and include 3 types: 1) Rx renewal requests from patients; 2) pharmacy calls for Rx renewals and 3) pharmacy callbacks - for Rx clarification. Secondary outcomes of interest included Prescription related call impact on office workload – the amount of person –hours required to manage the calls.

We do not have the following outcomes (described in our proposal) to report at this time: office costs of Rx related calls nor the office efficiency savings of ePrescribing and ePrescribing physician disenrollment. The intervention study started only months before this report and to date there has been no disenrollment. In addition, this finding is biased by BIDMC’s IRB requirement for this study that only physicians who consented to be studied during ePrescribing were available to the research team. We cannot comment on disenrollment by other physicians in BIDMC.

V. Limitations

Limitations have been described within the report where applicable including the impact of the timeframe constraints on completion of components of the study. We contacted Dr. White about specific and unexpected challenges affecting our staff (illness) and their impact on the completion of the primary data collection and analyses. No cost extensions were not permitted for this grant.
D. Results

I. Principal Findings

II. Outcomes

Aim I (see appendix for details)

Prescriptions

We found the 6 transactions we evaluated—New Rx, Medication Hx, Renewal/Refill, Fill Status Notification, Change, and Cancel—adequate for transmitting generally complete and accurate Rx data and recommend their use for Medicare Part D ePrescribing. We believe the industry maturity and adoption of the New Rx, Medication Hx, and Renewal/Refill transactions strongly support their use. However, we believe the lack of adoption of the Fill Status Notification, Change, and Cancel transactions indicate that although the standards support their use, electronic implementation of these transactions should not be mandated. In our evaluation, we identified a number of improvements that should be considered, and we developed advice and recommendations for implementers. These points are summarized here.

1) The standards for the 6 transactions are generally consistent with each other in terms of structure and content. Segments, field names, code values, and message types are generally consistent, and the documentation is generally clear in describing their use. We encountered challenges in the use of concepts such as medications with durations, drug names, and the VERIFY message.

2) We found serious challenges when using the standard in an operational workflow because the standard does not call for the use of unique identifiers for Rxs and prescribers that would facilitate linking across the life cycle of the Rx, routing transactions to the right prescriber, and some improvements in efficiency.

3) Some useful concepts are not supported by the standard, including the ability to notify the pharmacy of when the patient will pick up the Rx or that the Rx should be filled at a later time or when certain conditions are met.

4) Legal restrictions, particularly regarding the transmission of eRxs for controlled substances, cause workflow inefficiencies.

5) Implementation of electronic processing for the full life cycle of a Rx will require significant effort by the provider organization to define, implement, and manage protocols for clinician coverage that will ensure appropriate and timely handling of new Rxs and downstream transactions. Routing, queuing, and redirecting transactions to the right clinician or the covering clinician will be needed to ensure safe and efficient processing.

6) We found some issues with the quality of retail pharmacy data entry of patient information. These issues can affect the linking of downstream transactions such as medication Hx, especially in the absence of a unique Rx identifier that is known to both the prescriber and the pharmacy.

7) Differences in vendor requirements for registering and exchanging prescriber and pharmacy data complicate the prescriber system interfaces for this data.

8) Level of support for eRxs varies among the retail pharmacies enabled to receive eRxs.

9) Introduction of ePrescribing in provider organizations must be carefully designed to minimize work for the prescribers by off-loading work to other staff.

10) We believe that increasing adoption of eRx transactions will over time improve the breadth and quality of data available to the clinician and can be expected to also yield...
improvements in patient safety and process efficiency.

11) The Medication Hx transaction response does not require the Hx data provider to transmit the patient data that is on file with the data source. Since Hx data providers may identify Hx for a patient through indirect matching, as in the case of probabilistic demographic matching, clinicians may not be confident that the Hx is for the right patient unless they are able to compare the patient demographics they have on file for the patient with the demographics on file with the data source.

12) Coverage of medication Hx data from various sources differs considerably based on legal restrictions related to the data sources, readiness of pharmacies to contribute data, restrictions imposed by health plans, lack of data sources for certain patients, and numerous other factors.

13) The coverage provided by pharmacy-sourced medication Hx data is relatively high. We found pharmacy-source medication Hx data for 67% of the patients we requested it for.

14) We found the response time to obtain pharmacy-sourced medication Hx data was reasonable - less than five seconds on average.

15) We found that the high volume of renewals and the relatively widespread adoption of electronic handling of pharmacy-initiated renewals make proceeding with this implementation highly desirable.

16) We found that the low usage volume, low level of industry adoption, and lack of industry best practice experience for the Fill Status Notification, Change, and Cancel transactions make proceeding with their implementation less desirable.

17) The Medication Hx transaction may render the Fill Status Notification transaction unnecessary since the Medication Hx transaction may be a more reliable and more readily available source for whether an Rx was dispensed to the patient.

Benefits

We found that the Formulary and Benefits Download standard adequately supports the transfer of formulary and benefits data from the data provider to the data consumer and recommend its use under Medicare Part D ePrescribing for those implementations where the data is to be periodically stored for subsequent lookup. Although we did not fully evaluate the 5010 version of the Eligibility and Benefits request/response transaction, we did find that it provides better support for pharmacy benefit data than the 4010 version; therefore, we recommend use of the 5010 version for Medicare Part D ePrescribing. We found that the 4010 version of the Eligibility and Benefits request/response transaction does not adequately support pharmacy benefit requirements and that the 5010 version provides better support.

1) We found that there is no central source for determining Medicare Part D medical eligibility and benefit information using the 270/271 transaction and recommend that CMS incorporate support for this information in the 271 response.

2) We found that the Formulary and Benefits Download standard adequately supports the transfer of relevant data from the data provider to the data consumer and is relatively easy to implement.

3) We found considerable variation in the level of detail at which the PBMs and health plans represent formulary data and considerable variation in the application certification requirements of PBMs and payers. This variation significantly increases design, development, and certification time for a provider organization. It would be helpful if the participants in the RxHub network were to define a uniform set of requirements and a single certification process that might also provide guidance for the industry as a whole.

4) We found that the complexity of formulary data and the volume of formulary data associated with some drugs will require considerable design and implementation effort to access and display the data for clinical use in real time.
Prior Authorization

The electronic PA (e-PA) standard has the potential to improve operational efficiencies for providers by standardizing payer processes and tracking capabilities. The proposed e-PA process could facilitate tracking of authorizations, automatically populate relevant patient information in applications, and simplify the overall system. However, some changes to the e-PA process will be required to further increase the usability of the standards and the efficiency of implementation. We do not recommend the use of these standards in their current state for Medicare Part D ePrescribing.

1) The LOINC standard does not contain all of the questions that payers require to conduct PA. Further, the LOINC standard forms ask questions not currently required by the payers. The LOINC standard should become more flexible to adapt better to the needs of the payers.

2) Payers currently require information on their PA forms that they already have through claims data, indicating that they may need a more streamlined PA process.

3) To minimize the potential increase in the physician’s role in completing requests for additional information using the proposed e-PA standards, the questions defined in the LOINC standard should be made more specific in order to facilitate autopopulation of relevant data.

4) The implementation of real-time PA adjudication is recommended to prevent potential delays in PA transactions caused by this asynchronous process.

5) The element names should be made consistent between the 278 and 275 where the content is the same, and unnecessary redundancies should be eliminated.

6) The e-PA standard does not limit dropdowns based upon specific criteria, such as diagnosis, prior therapies, etc.

7) The e-PA standards should delineate an electronic process for patient notification when coverage is changed or when a final decision on a PA request has been rendered.

8) Payers and providers should develop more effective ways of communicating changes to PA rules, including incorporating changes into the e-PA process.

9) The e-PA standards need to address quality care dosing (QCD) overrides. Currently, there is no way for a physician to justify QCD overrides using the LOINC standard. The task group should incorporate a field for QCD justification into its existing forms or the 278 transaction if QCD will always require justification.

10) The workflow to generate the “additional information attachment form” is inefficient and challenging to complete. The process is piecemeal, involving the need to gather relevant LOINC codes from the 278 response, obtain LOINC code translations from the LOINC database, collect response codes from the code set database, and generate an HL7 message with both the question and the answer. The HL7 is wrapped in a 275 EDI and transmitted to the payer.

11) The documentation for e-PA standards should provide guidance on how to prioritize PA requests electronically to denote urgency.

Structured and Codified Sig

Discussions with providers and IT professionals demonstrated that Structured and Codified Sig addresses a need in the medical community. With additional development, the proposed standard format may provide a controlled vocabulary that reflects prescriber thinking, offers structure and simplicity, and improves communications between prescribers and pharmacies. We do not recommend its use for Medicare Part D ePrescribing in its current state.

1) The proposed Structured and Codified Sig standard format does not currently support prompt revision of its fields in the event of new methods of drug administration. One
recommendation is to create a line of communication between the FDA and the task
group in which the FDA would mandate a drug manufacturer to notify the Sig task group
when a new method of drug administration is being tested.

2) Structured and Codified Sig’s highly flexible design, coupled with a lack of explicit
guidance around the standard’s implementation, results in a system that may prove
difficult to understand and complex to execute. The Structured and Codified Sig
documentation might be improved if it delineated how to limit available fields and/or
terms within each dropdown menu based on a particular drug and provided more
clarification on the use of the free text box and on the standard’s potential for error
checking mechanisms. Such changes would need to take into consideration clinical
decision processes and tools, FDA regulations, ePrescribing systems capabilities, and
impact on implementation and user acceptance.

3) Currently, the proposed standard format requires both free text and codified Sig to be
sent to the pharmacy, where the free text is used to support correct interpretation of the
codified data. Transmission in both forms could result in inconsistencies between the
two. If the Industry Sig Task Group re-evaluates transmission of both Sig formats, the
re-evaluation will need to take into account potential compliance issues related to
ePrescribing.

4) The proposed standard format is designed to support transfer of information from
prescriber to pharmacy. It employs 1,300 terms and 14 segment types, each of which is
further broken down into subsegments. Providers have indicated that tabbing through
multiple fields, each with a large number of options available via dropdown menus, can
prove cumbersome. Providers have also expressed a preference for complete sentence
Sigs or “quick picks” for commonly prescribed medications.

5) The SNOMED terms contained in the proposed standard format’s database are difficult
to classify into the 14 segment types. Recognizing this, the task group provided a draft
classification in spreadsheet form.

6) The proposed standard format is supported by a database of SNOMED terms that did
not contain many terms used in our sample of live Sigs.

7) Providers regularly use ranges, dates, diagnosis codes, and lab test results in their Sigs.
The proposed standard format in some cases does not support these items or does not
provide sufficient guidance on how to enter this information into a Structured and
Codified Sig format.

8) The DRU segment of the ballotted and published SCRIPT 8.1 standard does not support
the Structured and Codified Sig proposed standard format.

RxNorm

RxNorm has the potential to simplify ePrescribing, create efficiencies, and reduce
dependence on NDCs. If the standard were used both within payer formularies and within
provider groups, it could decrease the complexities currently inherent in formulary lookup.
However, the dictionary standard requires further evaluation and refinement before it can be
deployed in a live setting. We do not recommend its use for Medicare Part D ePrescribing in
its current state.

1) There is no central repository containing a list of all NDC codes. Nor is there a reference
guide that indicates all of the NDCs associated with a particular drug.

2) RxNorm documentation requires further development to provide examples on RxNorm
usage within a provider setting and tracing data within the RxNorm RRF files. It should
also include a list of RxNorm’s limitations.

3) The RxNorm task group should continue to correct linkages between NDCs, Semantic
Clinical Drugs (SCDs), and Semantic Branded Drugs (SBDs), as well as create an
efficient method to use the RxNorm Database to match NDCs directly with SCDs and
SBDs. Approximately 12% of NDCs in our test sample could not be matched with an SCD or an SBD.

4) The significance of medication packaging and standardized dosage to Rx drugs requires further assessment. Currently, RxNorm text strings do not reflect packaging information and rely on normalized dosing.

5) If RxNorm is to be expanded internationally, differences in terminology between the US and other countries will need to be resolved.

6) The RxNorm documentation does not currently provide guidance on how to use the dictionary standard when prescribing compounded drugs.

7) A strategy for more widespread adoption of the RxNorm dictionary standard should be devised. One of the primary uses of RxNorm is for formulary lookup services. However, the standard does not contain terms relating to non-drug therapeutic devices such as wheelchairs and heart stents.

**Aim II**

The most common medication classes prescribed during the study were antibiotics (8.3%), allergy/cold/ENT (6.9%), narcotic analgesics (6.2%), cholesterol lowering agents/statins (6%), ACE inhibitors (5%), SSRIs (4.9%), diuretics (4.9%), and beta-blockers (4.8%). We were unable to complete nursing/pharmacist review of all Rxs and also physician review of all potential incidents that were screened positive by nursing/pharmacist review. The sampling strategy used for this report is provided in the Data Sources/Collection section.

The ME and ADE findings are in the following table. At this time we are unable to separate the results for the Intervention Period for those Rx that were ePrescribed and those that were not. We also do not have information for the control sites during the intervention period, though do not expect changes in their rates of MEs and ADEs.

<table>
<thead>
<tr>
<th>Medication Safety</th>
<th>Baseline Period</th>
<th>Intervention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control Site n (%)</td>
<td>Intervention Site n (%)</td>
</tr>
<tr>
<td>Medication Errors</td>
<td>50 (0.4)</td>
<td>89 (1.4)</td>
</tr>
<tr>
<td>Near Misses</td>
<td>130 (1)</td>
<td>70 (1.1)</td>
</tr>
<tr>
<td>Significant</td>
<td>53 (0.4)</td>
<td>35 (0.6)</td>
</tr>
<tr>
<td>Serious</td>
<td>68 (0.5)</td>
<td>32 (0.5)</td>
</tr>
<tr>
<td>Life-Threatening</td>
<td>9 (0.07)</td>
<td>3 (0.05)</td>
</tr>
<tr>
<td>ADEs*</td>
<td>6 (.04)</td>
<td>2 (0.03)</td>
</tr>
</tbody>
</table>

*ADE results do not include findings from the ADE monitor that are not yet completed. We expect to find many more ADEs from the monitor.*
The results of the ADE monitor are summarized below. We have not completed the physician review for confirmation of the presence or absence of actual ADEs and therefore cannot provide the positive predictive values for the triggers. Please see the Appendix for more information pertaining to the specific triggers used in the ADE monitor.

<table>
<thead>
<tr>
<th>ADE Monitor</th>
<th>Baseline Period n (%)</th>
<th>Intervention Period n (%)</th>
<th>All Periods n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Clinics Control Clinics</td>
<td>Intervention Clinics</td>
<td></td>
</tr>
<tr>
<td>All Rxs (meds only)</td>
<td>25126 (3121)</td>
<td>4929 (33176)</td>
<td></td>
</tr>
<tr>
<td>No ADE Hit</td>
<td>21938 (87.3)</td>
<td>2685 (86.0)</td>
<td>4205 (85.3) 28828 (86.9)</td>
</tr>
<tr>
<td>ADE (+) Hit</td>
<td>3188 (12.7)</td>
<td>436 (14.0)</td>
<td>724 (14.7) 4348 (13.1)</td>
</tr>
<tr>
<td>Actual ADE</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

We found the rate of dispensing errors to be reduced for the intervention clinics only for those prescriptions ePrescribed (3%) and not for prescriptions still routed the traditional method (6.1%). Further analyses are provided in the Appendix.

<table>
<thead>
<tr>
<th>Medication/Dispensing Hx</th>
<th>Control Clinics Baseline n (%)</th>
<th>Intervention n (%)</th>
<th>Intervention Baseline n (%)</th>
<th>Intervention n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period</td>
<td>Baseline n (%)</td>
<td>Intervention n (%)</td>
<td>Baseline n (%)</td>
<td>Intervention n (%)</td>
</tr>
<tr>
<td>Electronically prescribed</td>
<td>no</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Rx in webOMR</td>
<td>5093 (40.0)</td>
<td>6354</td>
<td>19670 (47.8)</td>
<td>2179 (49.2)</td>
</tr>
<tr>
<td>Reviewed Rx</td>
<td>1313 (25.8)</td>
<td>2723 (42.8)</td>
<td>9695 (49.2)</td>
<td>1574 (72.2)</td>
</tr>
<tr>
<td>Dispensing Hx available</td>
<td>525 (94.7)</td>
<td>584 (92.3)</td>
<td>4603 (95.9)</td>
<td>608 (96.1)</td>
</tr>
<tr>
<td>No error</td>
<td>497 (21.4)</td>
<td>639 (92.3)</td>
<td>4371 (95.9)</td>
<td>608 (96.1)</td>
</tr>
<tr>
<td>Prescribing error corrected</td>
<td>6 (1.1)</td>
<td>8 (1.3)</td>
<td>42 (0.9)</td>
<td>6 (0.9)</td>
</tr>
<tr>
<td>Dispensing error</td>
<td>22 (4.1)</td>
<td>37 (6.3)</td>
<td>190 (4.1)</td>
<td>19 (3.0)</td>
</tr>
</tbody>
</table>

1, 2, 3 P values for Dispensing Errors: 1 – 0.11; 2 – 0.005; 3 – 0.004  
(2 and 3 are each compared to the intervention clinic during the baseline period)

_Aim III_

The following table provides the preliminary analyses of our observation study of office workflow management Rx callbacks / renewals.
<table>
<thead>
<tr>
<th></th>
<th>Baseline Period</th>
<th>Intervention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinic A</td>
<td>Clinic C</td>
</tr>
<tr>
<td>Observation Hours</td>
<td>41.7</td>
<td>41.3</td>
</tr>
<tr>
<td>Observation hours related to Rx activity</td>
<td>29.8</td>
<td>26.9</td>
</tr>
<tr>
<td>Total Rxs processed</td>
<td>1364</td>
<td>519</td>
</tr>
<tr>
<td>New non-narcotic</td>
<td>833 (61)</td>
<td>171 (33)</td>
</tr>
<tr>
<td>New narcotic</td>
<td>229 (17)</td>
<td>23 (4)</td>
</tr>
<tr>
<td>Existing Rx</td>
<td>219 (16)</td>
<td>260 (50)</td>
</tr>
<tr>
<td>Rx type not selected</td>
<td>83 (6)</td>
<td>65 (13)</td>
</tr>
<tr>
<td>Rxs processed per hour</td>
<td>45 / hour</td>
<td>19.3 / hr</td>
</tr>
<tr>
<td>Call Type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td>64</td>
<td>6</td>
</tr>
<tr>
<td>Email</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Fax</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Paper Message</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>In-person request</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Entry not selected</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Contact type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient</td>
<td>64</td>
<td>38</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>14</td>
<td>30</td>
</tr>
<tr>
<td>Health plan</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Ordering prescriber</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Other provider</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Entry Not selected</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Reason for Call</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renewal/refill</td>
<td>78</td>
<td>57</td>
</tr>
<tr>
<td>Rx clarification</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>New Rx</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>Prior auth. / confirm medical necessity</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Incorrect prescription</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Tasks for Rx Request/ Other Workflow Activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lookup patient medical Hx in webOMR</td>
<td>37</td>
<td>21</td>
</tr>
<tr>
<td>Perform patient care related activities</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Receive / review and document RX requests</td>
<td>22</td>
<td>24</td>
</tr>
<tr>
<td>Contact patients</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Clarify orders with prescribers</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Review standard guidelines</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Insurance approval</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Update patient med list in WebOMR</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Transmit order to pharmacy</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Update Rxs to new eRx format</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sending eligible eRx to MD queue for sign</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Looking up and entering pharmacy info</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
III. Discussion

Please see the results section (and Appendix) for the discussion regarding the standards testing.

Regarding Aims II and III, our results are incomplete. We have a considerable proportion of potential incidents requiring physician review. Therefore it is premature to make any conclusions regarding the impact of ePrescribing on rates of MEs and ADEs. In addition, we are still completing analyses of the workflow findings. We had insufficient time to provide a reliable analysis for this report, primarily due to the late start of the intervention period and the large volume of work needed to be done during the last month of the study.

We provide the following specific responses to questions from the NRC Evaluation Team not previously described:

Clinical outcomes
1. How did ePrescribing usage improve patient care from a prescriber perspective? In general, this seems to be viewed as a benefit for patient care by the physicians who have provided feedback to us. Some are extremely enthusiastic, while others have been somewhat more reserved, perhaps because of the workflow implications (see below), or because of the delays/missing Rxs that occasionally occur (see below).
2. How did ePrescribing usage improve patient care from a pharmacist perspective? We did not study pharmacists.
3. Hospital and Emergency use overall – we were unable to assess.
4. What was the impact on patient satisfaction? The physicians who have provided feedback to us have indicated that ePrescribing has generally been well received by patients. Of course, in those few cases where the Rx was delayed (e.g. because not noticed by the pharmacist) or lost by the pharmacy, patients were less satisfied.

Workflow outcomes
1. What was the effect on functionality with integration of other systems? We were able to incorporate the NewRx functionality with minimal changes to the user interface and MD ordering workflow. The flow worked just fine for new medications written by a physician, but two issues quickly surfaced. First, many Rx renewals are processed by nurses who are not authorized Rx signers. BIDMC had to make a policy decision as to whether electronic refills done by nurses should be viewed like calling Rxs to a pharmacy (no MD signature required) or like documenting an order (MD signature required). We opted for the latter and built a queue to allow MDs to sign and electronically route Rxs written by nurses. Second, in order to meet the technical requirements for the NewRx message, we had to modify Rx data entry so as to collect information in a slightly more structured format. This had little to no impact for new medications. For renewals, which are usually done with a single click, each medication had to be modified in order to collect the additional information. This modification is required only once to convert to the new format and takes anywhere from 15 seconds to a minute per medication, depending on whether physicians use the “quick pick” function. Physician reaction varied widely. Some thought it was a very minor issue, while others considered it a major barrier to entry.
2. Who were the primary users of the ePrescribing systems in the various pilot settings? What impact this may have on overall adoption. We are currently “live” in Clinic A and a second off campus site that did not participate in this study. We are currently working with BIDPO (our physician organization) to develop a roll out plan for the remaining webOMR users. We expect ePrescribing will be available to all webOMR users some time in March.
3. Was there a change in usage (retention rates), give reasons for increase or decreased participation. Aside from the expected dips around Thanksgiving and Christmas/New Years,
the number of Rxs per week has been stable or slowly increasing, as the number of users has remained constant. Spreadsheet below demonstrates the overall activity for BIDMC Clinics during Week 37 to Week 2 (September 2006 to January 2007). Excluding the initial week, the mean eRxs per week was 577.

<table>
<thead>
<tr>
<th>Number of ePrescriptions Per Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>600</td>
</tr>
<tr>
<td>800</td>
</tr>
<tr>
<td>400</td>
</tr>
<tr>
<td>200</td>
</tr>
<tr>
<td>0</td>
</tr>
</tbody>
</table>

Week 4.

Include any workflow models that you have created. We did not create models.

5. Other outcomes: please discuss any other relevant findings. Clinicians raised several issues of concern. ePrescribing presented challenges for Rxs that in the “paper world” was not possible to translate into the “digital world” with the current webOMR system. Firstly, “non” real time prescribing was problematic. For example, conditional prescribing, where patients are given an Rx to fill at a later date only under certain conditions, could not be operationalized for eRx (e.g. patient is given an Rx to fill only if a positive test result returns days after the visit or the condition worsens or does not improve days after the visit). Providing Rxs in advance also could not be operationalized (e.g. at the visit, unable to provide renewals for 3-month Rxs that could not be automatically renewed and to carry the patient until the next scheduled visit, 6-12 months later). The inability to ePrescribe narcotics and other Schedule II-V drugs created some work flow challenges but appeared to be accepted by patients and clinicians. Several pharmacy issues were discovered during our study. Despite current thinking, the vast majority of pharmacy chains stores in the Boston area did not carry out true ePrescribing. Pharmacies had the capability but in reality reported to us that they generally printed out the eRx routed through the Rx Gateway and re-entered the data in their pharmacy system. Therefore the intervention period was essentially not different in practice from the baseline (CPOE without electronic transmission) period at the level of the pharmacy. To our knowledge, only 1 pharmacy chain, estimated with 10% or less of the eRxs in our study, conducted end-to-end ePrescribing such that the Medication Hx and Rx-for-Dispensed were not affected by data-reentry at the pharmacy.

IV. Conclusions

During the project, we learned about the foundation standards themselves as well as the initial standards and their interoperability. We have provided preliminary findings with regard to medication safety and office workflow efficiencies. In addition, the MA-SHARE Appendix also provides additional observations and recommendations regarding the impact of the standards on office efficiencies. From an operations viewpoint, the intervention clinic initially had many concerns regarding the impact of ePrescribing on workflow and the reliability of eRxs reaching pharmacies and ultimately, patients. In the short time period of only a few months, clinicians and office staff have found the ePrescribing functionality built by the BIDMC and MA-SHARE team to be an asset and easy to use. It is expected that by
mid-2007, nearly all physicians at Clinics A, B and C will use ePrescribing. Therefore, in an environment already using CPOE, the introduction of ePrescribing has been seamless.

V. Significance

This project contributes to the body of knowledge concerning ePrescribing standards and their use in clinical settings. By using a unique community utility, the eRx Gateway, we have been able to study the standards in a common infrastructure that electronically connects existing prescribing components from clinicians at multiple locations and ultimately to the dispensing pharmacies, either retail or mail-order. Our study addressed the transmission standards in a real world setting within a premier health care system (BIDMC’s CareGroup) and using a robust EMR (webOMR). Our clinical and workflow findings are still preliminary. Following completion of our analyses in the months ahead, we look forward to learn if ePrescribing will clearly demonstrate enhanced medication safety and office efficiencies.

VI. Implications

E prescribing has great promise to improve the safety, quality and efficiencies of ambulatory prescribing and dispensing. Implementation of ePrescribing throughout a healthcare system, especially without preexisting CPOE, will be a costly and difficult process but an important investment despite the challenges associated with changing current prescribing practices. Future research will be needed to study different ePrescribing systems and office practice workflow adaptations, but also the pharmacy aspects associated with these important process changes. The standards are necessary requirements to insure successful ePrescribing interoperability.

E. List of Publications and Products

We plan to submit several manuscripts to peer-reviewed journals and present our findings at local and national meetings. Preliminary findings were presented at the Nov. 2006 Annual AMIA Symposium in Washington, DC in a panel (The Medicare ePrescribing Pilots: Updates on the eRx Gateway Project) and poster (Virk P, Bates DW, Halamka J, Fournier GA, Rothschild JM. Analyzing Transaction Workflow in an ePrescribing System. Proc AMIA Symp 2006:1129).

F. Appendices

2. Incident Rating Tool: Screen Shots
3. Time - Motion Data Collection Tool for the Workflow Analysis: Screen Shot
4. Adverse Drug Event Monitor: Detailed Methods and Results
5. Medication Hx: Detailed Methods and Results