

Grant Final Report

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**Maximizing the Effectiveness of E-Prescribing
Between Physicians and Community Pharmacies**

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Abstract

Purpose: To test the interoperability of electronic prescribing (e-prescribing) standards, certification processes and pilot testing; and to evaluate the implementation of the standards from multiple perspectives using a mixed-method approach.

Scope: The Medicare Modernization Act (MMA) calls for the adoption of standards to enable electronic prescribing (e-prescribing). Six e-prescribing physician software vendors agreed to code, implement, and deploy e-prescribing software standards in FL, MA, NJ, NV, RI, TN. Two hundred eighty-three prescribers were recruited; focus groups (n=64) including 270 prescribers and staff were conducted. Patients (n=1,100) and pharmacy personnel (n=1,094; 276 pharmacies; 7 pharmacy chains) were surveyed.

Methods: A mixed-method study included a performance analysis of e-prescribing in physicians' office, i.e. surveys of clinicians and staff using e-prescribing (web-based and paper); focus groups with clinicians and staff (45-60 minutes), semi-structured interviews with staff; and observation in the physician practices for half a day. Follow-up surveys were conducted. Pharmacy personnel documented interventions relating to e-prescriptions and participated in a survey of attitudes and issues related to e-prescribing. Key stakeholders were surveyed to assess the proposed RxNorm and Structured and Codified SIG standards.

Results: Initial standards deemed ready for implementation include: Formulary and benefit, Medication history, and RXFILL. Initial standards requiring more testing before implementation include: Structured and Codified SIG, RxNorm, and Prior Authorization. Improvements in the implementation of the standards in physician and pharmacy software applications are needed to achieve optimal realization of efficiency and patient safety gains associated with e-prescribing.

Key Words: e-prescribing standards, pharmacy, electronic prescribing, physicians

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Final Report

Purpose

The aims of the study include:

- (1) To test the interoperability of the standards, certification processes and pilot testing;
- (2) To evaluate the implementation of the standards from multiple perspectives using a mixed-method approach;
- (3) To evaluate the extent to which the proposed MMA e-prescribing standards work effectively and efficiently within a variety of practice, technology, and geographic settings around the country;
- (4) To determine what changes need to be made to the MMA e-prescribing standards to improve their effectiveness (if some of the standards are not found to work well in a representative cross section of settings);

Originally, the project had two additional aims:

- (5) To evaluate the extent to which prescriber and vendor software characteristics predict prescriber uptake and dropout from e-prescribing;
- (6) To determine “best features” of vendor software in relation to expected gains in medication-related patient safety outcomes and to quantify the extent to which the gains with respect to medication-related patient safety outcomes are modified by provider organizational and implementation factors

Formal evaluation of specific aim 5 was not feasible as we did not have a sufficient number of physicians who agreed to participate in our study, completed the required surveys and adopted e-prescribing, but who dropped out from e-prescribing during the follow-up period. Several providers transitioned to full EMR and several reported dropping e-prescribing because the volume of e-prescribing did not justify its cost. Several recruited clinicians agreed to initiate e-prescribing, but neither adopted the technology, nor completed the baseline survey. The reviewers pointed out that specific aim 6 had limited statistical power given the small number of physician software vendors participating in the project. As such, we provided descriptive information and did not attempt to make inferences regarding this aim. Appendix A- Parts I, II, and III include SureScripts Implementation and Certification Guide, EDIFACT Implementation Guide, and Medication History Draft Guide. These documents are critical to understand how specific aim 1 was achieved.

Scope

Background

While electronic prescribing (e-prescribing) is not a requirement of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), stipulations included in Section 1860D-4(e) of the Social Security Act require that prescriptions transmitted electronically must comply with final uniform standards adopted by the Secretary of Health and Human Services. Section 1860D-4(e)(4)(C) of the Social Security Act, as added by the MMA, generally requires pilot testing of standards prior to promulgation of the final uniform standards to provide for the efficient implementation of the standards.

Context

CMS, with the advice and assistance of the National Committee on Vital and Health Statistics (NCHVS), has identified ten e-prescribing standards that provide the functionality deemed essential to e-prescribing for the Medicare Part D program and thus are subject to pilot testing in 2006 as required by the MMA. NCVHS members and CMS staff are well aware that several of the standards recommended for e-prescribing under Medicare are not widely implemented, some have not completed the process of becoming nationally recognized standards, and some are in the early stages of becoming standards. Different evaluation strategies were used for each standard as a function of where the standard was in the development process during the study period. With approval from our project officer, this project did not evaluate the prior authorization document set (X12 278, X12 275 and HL7 Pharmacy attachment). Institutional review boards at Brown Medical School, University of Arizona, Midwestern University – Glendale, and the New England IRB reviewed and approved components of the project as appropriate.

Settings

Six states (Florida, Massachusetts, New Jersey, Nevada, Rhode Island and Tennessee) were identified based upon a combination of factors including level of e-prescribing experience, state and/or community level support for health information technology, pharmacy support, and existing or committed users of e-prescribing. The states were also selected to provide geographic diversity. For the pharmacy component of the study, high volume e-prescribing pharmacies in New York, Maryland, and Pennsylvania were included.

Participants

Physician Software Vendor Participants. Six e-prescribing physician software vendors agreed to code, implement, and deploy various initial e-prescribing software standards. As part of their participation, the software vendors also assisted in the recruiting of clinicians using their products. The physician software vendors participating in the study included: OnCallData, InstantDX, LLC, Gaithersburg, MD; PocketScript, Zix Corporation, Dallas, TX; Rcopia, DrFirst,

Inc., Rockville, MD; Care360, Medplus, Inc., Mason, OH; eMPowerx, GoldStandard Multimedia, Inc., Tampa, FL; Touchworks, AllScripts, LLC, Chicago, IL. The vendors have been de-identified (to the extent possible) for reporting purposes, but the same coding scheme (A through F) has been applied uniformly throughout this report. Using functional recommendations for the capabilities of e-prescribing software to improve patients' health developed using a modified Delphi expert panel process,¹ Table B1 shows the characteristics of the physician e-prescribing software. Compared to a recent field study,² the e-prescribing software represented in the current study had a greater percent of the functional recommendations fully implemented (range of fully implemented: 62% (Vendor C) to 83% (Vendor B) vs. field study: 30% (Non-EHR) to 60% (EHR)).

Prescriber Participants. Within these states, six e-prescribing technology vendors identified practices servicing a mix of at least 25% Medicare eligible patients for participation in this study. Interested clinicians signed a detailed participation agreement reviewing all components of the study and detailing the steps necessary to receive a \$500 incentive. Eligible clinicians included physicians, nurse practitioners, and other prescribers, who were actively using one of six software products. Table B2 shows the distribution of recruited clinicians by physician software vendor and state and participation rates by various study components. In total, 283 clinicians in 96 practices signed participation agreements; however, ultimately 235 clinicians in 88 clinics were active study participants. The practice characteristics are shown on Table B3. Family and internal medicine had the greatest representation, with 17% of practices multi-specialty and 20% solo practices. The range of pharmacy faxes and call backs, as well as patient calls regarding prescriptions per week, was wide. Figure B1 shows the mix of clinical and non-clinical survey participants. Among prescribers, 12% were nurse practitioners, 5% residents, 8% physician assistants and 75% physicians. Non-clinician survey participants included a diverse mix of medical assistants, nurses, and office staff. Sixty-four focus groups were conducted on site and included both clinical and non-clinical staff using e-prescribing software. Figure B4 shows the gender and job position distribution of participants. Sixty four percent were prescribers, with physicians in practice an average of 15.7 years. The average size of focus groups was four. Figure 5 shows that the average age of focus group participants was 43 years.

Patient Participants. Table B4 shows the age and gender distribution of patients receiving at least one new prescription for each physician software vendor and a random sample. By design, practices were selected that had at least a 25% Medicare population. As such, that the age distribution differs from that of the random sample is not surprising. Table B5 provides the gender distribution and average number of new prescriptions stratified by three age categories among the elderly population. No significant pattern of the number of new prescriptions filled electronically by age was apparent. Table B6 shows the socio-demographic characteristics of the patients who voluntarily participated in a self-administered e-prescribing survey available in participating practices. It was not necessary for survey respondents to have had an e-prescription. Despite this, the gender and age distributions appeared similar. Although the survey was available in Spanish in every practice, 2% completed the Spanish version.

Pharmacy Chain Organization Participants. Seven pharmacy chain organizations participated in this pilot: Ahold (Giant and Stop & Shop), Brooks/Eckerd, CVS/pharmacy, Longs,

Rite Aid, Walgreens and Wal-Mart. Table B7a shows the distribution of NEWRX messages by participating pharmacy and location for all e-prescriptions during the study period January 1, 2006 through August 31, 2006. Table B7b shows the number of NEWRX transactions initiated by study participants by state and pharmacy chain organization and the distributions of the number of pharmacies involved. Eleven pharmacy chain organizations as well as over 500 independently owned pharmacies were identified as involved in the transaction analysis portion of this study. The number of transactions processed by each pharmacy chain organization varied substantially.

Pharmacy Participants—Survey. Although all participating pharmacy chain organizations were offered participation in this component of the study, one pharmacy chain organization with 95 eligible pharmacies ultimately agreed to distribute the survey to only 25 due to concerns related to ongoing changes in computer systems and management resulting from the recent acquisition of a competing chain. Another chain with 111 eligible pharmacies subsequently decided to limit distribution of the survey to 50 pharmacies due to concerns about disruptions in workflow. Thus, from an initial sampling frame of 553 high volume e-prescribing pharmacies (5 or more e-prescriptions per day), surveys were ultimately made available to personnel in 422 pharmacies. Responses were received from one or more personnel at 276 pharmacies for a response rate of 65.4% of participating pharmacies. The survey sample of 276 pharmacies yielded 1,094 responses for an average of four responses per pharmacy (range = 1 to 21). Technicians represented the largest respondent group at 605 (55.3%), followed by 446 pharmacists (40.8%), 35 student interns (3.2%) and 8 personnel classified as ‘Other’ (0.7%). Figure B5 shows the distribution of pharmacy personnel responses across the seven participating pharmacy chain organizations. The majority of pharmacist respondents were baccalaureate-trained (72.2%) and female (56.9%). A substantially smaller proportion (22.4%) were doctoral trained (i.e., Pharm.D), and several also had advanced graduate degrees (e.g., M.S., Ph.D.). Pharmacists responding to the survey had been practicing pharmacy for an average of 13.9 years, with a mean of 3.4 years at their current location. Technician respondents were predominantly female (86.4%) with a HS diploma / GED or some college (68%), although 26.7% had completed either a baccalaureate or associates degree. Technicians had worked as pharmacy technicians for an average of 5.7 years, of which 3.2 years was at their current location.

Incidence/ Prevalence

With ~62% of outpatient office visits resulting in at least one prescription (average of 2.4 medications prescribed per medication-related office visit)³, clinicians have important opportunities to educate and motivate patients to improve the use of the ~1.3 billion new prescriptions³ prescribed annually in the outpatient setting. Adverse drug events have been estimated to occur in 27.4% of community dwelling adults,⁴ and estimates are higher among Medicare beneficiaries visiting an outpatient physician practice.⁵ A recent study conservatively estimated the annual cost of preventable adverse drug events (ADEs) among Medicare enrollees aged 65 years and above and occurring in ambulatory settings at \$887 million.⁶ The impact of e-prescribing on the reduction of medication errors and improving patient safety remains unknown. While no direct measurement of ADEs were proposed in this study, it provides a qualitative assessment of the patient safety gains and quantifies use of inappropriate medication use in e-prescribing transactions.

Methods

Study Design

We used a performance analysis to evaluate the implementation of the standards. Performance analysis is a process used in the field of human development to collect both formal and informal data about job-related performance and performance strategies to define the nature of the performance and its workplace context. Focus is on the work, the worker and the workplace.⁷ The current state of skills, values, behaviors and challenges are garnered both by direct observation and interviews with key personnel, supervisors and managers and consumers. The work performance under study is examined from the perspective of what is happening, and what should be happening. Multiple perspectives on the performance, potential problems and opportunities, and barriers and facilitators for successful performance are investigated.⁸⁻¹⁰ Exemplary performers are identified and work performance is then described in terms that are measurable to enable comparison. The process of performance analysis includes specific observation and questioning tasks. We developed a standardized protocol, defining exactly what processes are to be observed, and which personnel are targeted for interviews. For observational tasks, specific goals and guidelines were developed to ensure a systematic approach. For example, observation of the e-prescribing process may focus on ease of use, ancillary materials employed, time required, mistakes and re-dos, concurrent activities, etc. For questioning tasks, the protocol specified queries for each type category of personnel.¹⁰ Questions ranged from open-ended to specific focusing on individual perspectives, opinions, experiences, challenges and suggestions. Performance analysts were trained in the theory and practice of performance analysis as well as the details of the prescribed protocol. The site visits required spending significant time at the worksite completing multiple observations and interviewing a range of personnel.

Data Sources/Collection

Physician Practices. We used a mixed-methods approach that includes quantitative (surveys) and qualitative data collection and analysis. Direct observation of the e-prescribing process including context and ease of use, ancillary materials employed, time required, mistakes and re-dos, concurrent activities provided text for qualitative review, as did semi-structured formal and informal interviews with practice personnel, focus groups with prescribers and other users of e-prescribing software in the practice.

Recruitment. The six software vendors recruited clinicians for participation in this study. All participating clinicians signed participation agreements (Appendix C – I (Participation Agreement – Clinicians)).

Site Visit Protocols. The site visit protocols for physician practices are provided in Appendix C- II Part a and Appendix C-II Part b. Site visits were conducted between April 2006 and August 2006. A typical site visit included a half-day of observation and a focus group (with a meal provided). Focus groups were held before hours, at lunch, or after hours at the discretion of the practice. A team of two highly trained research assistants (RAs) attended each site visit

with defined roles for primary and secondary RAs. The primary RA always led the focus group with the secondary RA collecting consents and demographic surveys, taking notes, keeping time, and running recording equipment. The primary RA observed clinical interactions and e-prescribing issues in clinical rooms (if the practice allowed) while the secondary RA observed staff and their use of e-prescribing software. Both primary and secondary RAs attending a site visit completed a site visit report. These reports documented observations, insights, discussions and informal interviews conducted at the practice. Interviews reported in this manner were not verbatim. RAs followed standard format when recording their site visit notes. Reports were written using Microsoft Word. Appendix C-II Part b includes the format for site visit reports that were written for each site visit. Also included in this section of the Appendix is the protocol for the pharmacy call back logs. Baseline surveys (shown in Appendix C-III) included a clinician survey, a non-clinician survey and a primary contact person survey (available as web-based or paper), and patient surveys (available in English and Spanish). Interviews and focus groups following the site visit protocol were conducted in 64 participating practices. Only selected interviews with key practice personnel were recorded. These interviews were more formal and conducted in private (as opposed to informal interviews conducted during clinic observations). Typically, recorded interviews were with lead physicians in the practice. At the beginning of the session, consent forms and demographic surveys were collected, and a sign listing the main topics for discussion was placed on the table for participants to view. An open ended approach was used, but specific areas for discussion were provided with probing questions to encourage discussion about important details. The areas covered in the focus group protocol included many topics relating to e-prescribing. Two digital recorders with PZM microphones were used for redundancy. Research staff downloaded audio files to laptop computers daily and submitted tapes to a transcription service. Once all digital recordings were transcribed, RAs double-checked every transcript for potential errors and corrected them as needed. To ensure coding accuracy, 19% of transcripts were double coded (that is, a pair of coders independently coded the same transcript). In a preliminary qualitative data review, passages coded by each coder commonly appeared twice, indicating effective coding among these transcripts. After reviewing initial focus groups, a coding scheme and code book were developed. The passages were coded to the code book instructions and quality control conducted. A code book defined all codes and their relationships (Appendix C, IIc). Follow-up surveys (included in Appendix C-IV) were conducted after standards were implemented (October through November 2006) and were available as web-based, paper or conducted by trained telephone interviewers.

Pharmacy Personnel Survey. Appendix C-V shows the self-administered survey (available in paper and web-based format) constructed to collect data from pharmacists and technicians who practice in chain community pharmacies that routinely receive, process and dispense e-prescriptions. Pharmacies for the sampling frame were identified from among stores those operated by seven participating pharmacy chain partners in the study states. Eligibility for the survey required that the pharmacy dispense an average of five or more e-prescriptions each day. This was done to ensure that pharmacy personnel were sufficiently familiar with e-prescription processing to provide meaningful responses to survey questions. In most pharmacy chain organizations pharmacy personnel do not have access to the Internet. In the few chains where personnel do have Internet access, restrictions and firewalls prevent them from accessing unauthorized non-corporate sites. As a result, although a few online surveys were submitted by pharmacy personnel who accessed the Internet from their homes, the distribution and collection

of surveys was conducted almost entirely via fax or mail using the paper version. In six of the chains the survey was faxed to pharmacies from corporate headquarters. The manager in each pharmacy was instructed to make the necessary photocopies of the survey, distribute to staff, and fax the completed surveys back to the investigators. In one chain, district supervisors were directed to fax the survey to designated pharmacies in their area then pick up completed surveys during a subsequent visit and mail them back to the investigators in bulk. One chain converted the paper survey to an internal electronic version for distribution to pharmacies then provided the investigators with a file (Excel) that contained staff responses.

Medication Therapy Intervention(MTI). A Medication Therapy Intervention (MTI) documentation form was constructed to collect data on e-prescribing problems identified by pharmacists practicing in chain community pharmacies that routinely receive, process and dispense e-prescriptions (Appendix C – Part VI). Eligibility required that the pharmacy dispense an average of at least five e-prescriptions each day to ensure that personnel were sufficiently familiar with e-prescription processing and were routinely reviewing a sufficient number to allow for analysis. Training materials in the proper completion of the form (Appendix C – Part VI) were subsequently sent to the manager at each pharmacy to provide additional detail regarding what would be expected of participants. Training materials were distributed to participants in multiple formats including e-mail, standard post or express postal service, fax, and on-line formats. Participating pharmacists were asked to complete 14 consecutive days of observation in their pharmacies. As a result of limitations and restrictions regarding Internet access by employees in pharmacy chains, only one pharmacy chain authorized in-pharmacy access to the interactive online version of the Medication Therapy Intervention form, and pharmacists at even this chain eventually elected to submit the majority of MTI reports via fax.

RxNorm. One physician application vendor, one pharmacy chain organization and SureScripts worked together to pilot test the RxNorm database in a laboratory environment to ensure no safety issues were introduced to a live production environment. RxNorm values were applied to a set of real, de-identified prescription records in the test so that review and analysis was conducted regarding the accuracy and viability of RxNorm for future potential use in a live environment. RxNorm was evaluated by: 1) Verifying the accuracy of the RxNorm database as a cross reference to textual Medication Name/Strength/Form; 2) Verifying the completeness of the RxNorm database to fully represent the prescribers and pharmacist's medication dispensing selection; 3) Using RxNorm as an additional verification tool to compare the prescriber's original intent to the pharmacist's dispensing decision; 4) Evaluating RxNorm as a potential replacement in the future for the textual medication name used to communicate the prescriber's intent in electronic prescriptions today; and 5) Survey of stakeholders using RxNorm.

Lab Environment Testing. SureScripts created a de-identified Original Prescription File that contained a record for each prescription to be analyzed as it was transmitted via e-prescription to the participating pharmacy chain. This provided the data for the prescriber's original intent for each prescription. SureScripts only included data originating from one physician software vendor in this file. The physician software vendor and their database vendor mapped the textual drug descriptions in these e-prescriptions to the RxNorm Semantic Clinical Drug Codes (SCD) using the proprietary drug database vendor codes in this file and returned it to SureScripts. The physician software vendor provided analysis of this mapping. The

participating pharmacy chain created a Dispensed Prescription File containing a record for each prescription analyzed as it was actually dispensed in the pharmacy. This provided the data for the pharmacist's dispensing selection for each prescription. The pharmacy chain and their drug database vendor mapped the textual drug descriptions to the RxNorm SCD using the proprietary vendor codes in the prescription dispensing record file behind the scenes. The mapping to the RxNorm SCD codes done by both vendors was based of the NLM generated RxNorm 2 August 2006 Concept Names and Sources file. SureScripts independently analyzed the mapping, highlighted the benefits or discrepancies uncovered during the mapping and explored alternative explanations for discrepancies in matching.

RxNorm Survey. We assembled an expert panel of the five leading drug database companies that compile, edit and disseminate drug databases for use by pharmacies, pharmacy benefit managers, and other entities. Through their work, these companies have had cause to examine the strengths and weaknesses of the RxNorm system as they have attempted to incorporate and assimilate RxNorm codes into their databases. We developed an e-mail survey (Appendix C-Part VII) administered in November 2006. A \$100 incentive was offered for completion of the seven page survey. Eighty-percent responded to questions regarding availability and ease of access of RxNorm, interoperability, and unambiguous prescribing.

Structured and Codified SIG Survey. We conducted a survey of e-prescribing and pharmacy vendors to examine the efficiency characteristics (or lack thereof) associated with the proposed NCPDP Structured and Codified Sig Standard. For both the physician solution and pharmacy systems side, eligible participants included organizations either currently certified on the SureScripts system or in the certification process as of September 1, 2006. For each organization, the key informants most closely involved in standards implementation were identified for inclusion in the survey process. Technical staff evaluated the proposed NCPDP Structured and Codified Sig Standard, which was provided electronically with the survey. The survey elicited feedback on each organization's evaluation of the appropriateness, complexity, and efficiency of the proposed standard, in addition to an estimate of the effort that might be involved in implementing the proposed standard. The survey asked each vendor to share any recommendations for changes to the proposed standard that they might think necessary, if any. The survey was conducted via email (Appendix C – Part VIII), with a \$100 incentive for participation offered. Responses were faxed or emailed to Brown University. Email reminders were sent several times to increase the response rate. Eight pharmacy chain organizations responded (response rate: 89%), six pharmacy management system vendors responded (response rate: 30%), and 20 physician application vendors responded (response rate: 47%).

Analysis of SureScripts Transactions. SureScripts e-prescribing transactions from January 1, 2006 through October 31, 2006 were analyzed to report on the total volume of transactions included in the study sample, as well as provide a comparison of study participants to a random sample of non-participants. Appendix C- Part IX, Table C1 a through f shows the month of first transaction in 2006 for each participating prescriber stratified by vendor, the number of NEWRX messages, REFREQ and REFRES messages and an average number of transactions per month per participant. A comparison of study prescribers to a non-study prescriber random sample within the same state and physician software vendor shows that participants in the study were higher volume e-prescribers relative to a random sample.

Intervention (SureScripts Certification Process)

An overview of the SureScripts Certification Process is provided. The complete certification guides are provided in Appendix A. The Pharmacy Health Information Exchange™ operated by SureScripts® is configured to work with all pharmacy and physician practice management systems. The only requirement is that the healthcare provider's system adheres to the specifications of the SureScripts Implementation Guide(s) and supporting documentations. The documentation and Implementation Guides utilize the NCPDP (National Council for Prescription Drug Programs) SCRIPT Standard for electronic prescriptions, medication history and formulary messaging. Additionally, SureScripts also publishes other guides based on the ANSI X12, 270/271, XML and HL7 Standards. For a detailed overview, please refer to the "SureScripts Implementation Guide", "SureScripts Certification Process Guide" in the appendices of this document. The SureScripts implementation and certification process is comprised of four general steps including Initiation, Application Modification, and Testing and Production; and, generally lasts five months from Initiation to final 'go-live'.

Implementation Process. The *initiation* of this process includes appointing a SureScripts Implementation Manager to serve as central point of contact during Implementation and Certification. A technology assessment pre-certification questionnaire is completed and weekly/biweekly calls are scheduled. The latest guides and documentation including Certification guide, Implementation guide, Directories guide, Admin Console guide and Solution document are provided. The *requirements and analysis phase* involves connectivity set up. Healthcare provider vendors select a communications interface and determine whether to connect directly to SureScripts network or through an aggregator. A portal is established in the SureScripts staging environment. An initial Best Practice (BP) call is held to overview the following items: Certification Checklist, Gateway Layer, Application Layer and DB Layer. A system demonstration is required and conducted at the early stage of the implementation. The Technical Interview (TI) is coordinated and conducted by the SureScripts Operations department to gain an early insight into the participant's solution including Internet connectivity, network and application infrastructure, vendor operations and security. The next phase includes modification of the application. The Network Participant must first demonstrate the ability to upload/download directory information used for pharmacy and prescriber network participant routing. Depending on the implementation—electronic prescribing, medication history, eligibility or formulary—the participant begins building these message types. The system build consists of ensuring that the new electronic data formats easily fit into the existing application and user workflow. As the Network Participant completes initial builds (beta) on the directories, messaging and system, unit testing in the staging environment commences. Once initial build and testing has neared completion, a system demonstration call / WebEx is scheduled for different SureScripts team members. This is considered a pre-certification application system demo. During this process a readiness review is conducted. This is the step just before the formal certification process. It involves sending / receiving messages and corresponding screenshots. At least two messages and screenshots are required for each message type. If any issues are found, the Network Participant needs to fix these issues before being allowed to continue on to Final Certification.

Certification Testing Process. Certification ensures that an implementation conforms to the SureScripts' Implementation Guide(s) and supporting documentation. This process consists of the Network Participant completing a number of test case scenarios through their application and comparing their results to the expected outcomes noted. The test cases cover are based on implementation and consist of NEWRX, REFREQ/RES, ERROR, STATUS messages (all required for baseline certification) and VERIFY, RXHREQ/RXHRES, RXCHG/CHGRES, CANRX/CANRES, 270/271, and Formulary Files (depending on individual implementation). Each transaction type is tested for requests and responses, with and without errors, using simple (min) and complex (max) test cases. A portion of the testing scenarios are conducted using use case scenarios that are provided prior to the Network Participant. The SureScripts Manager also utilizes the SureScripts testing suite to generate randomized min/max test messages. These test messages are generated randomly (algorithmic) and cannot be altered. The final certification was conducted over the telephone. SureScripts sends the test scenario(s) just before the scheduled test and the Network Participant is asked to send messages based on the information in the test scenario(s). Once completed, the SureScripts Manager also generates completely randomized test messages that are also reviewed. As a final step, the Network Participant must send screen shots that the manager reviews in conjunction with the raw message data. As each test scenario is executed, the Network Participant provides screen prints/shots to the SureScripts Certification Administrator in order to compare the findings against the expected outcome for that test. The Certification Administrator reports any issues detected during the testing process to the Network Participant for failed case(s). Each test case is reviewed for expected data results, expected error handling, and appropriate application recognition of message transaction types. All test case results (pass or fail) are documented in the Certification Evaluation Checklist. If the criteria for a given test case are not met, the Certification Administrator documents the issues found. This documentation occurs on the Certification Evaluation Checklist for the failed test case. If the Network Participant has failed Certification and has known issues, our Certification Review Board reviews the Network Participant's request for certification and approves or denies the certification. If denied, the Implementation Manager works through recommended changes with the Network Participant for Certification. If problems are fixed, the Implementation Manager then moves to retesting with the Network Participant. Once the Network Participant has communicated to the Certification Administrator that the corrections have been made, a re-test is conducted using similar scenario(s). This process continues until the test case(s) have been completed successfully. Just prior to final certification, the Implementation Manager engages Support and Deployment representatives to prepare for eventual production support. Network Participants have one hour introductory calls with each respective group to prepare for Production / Go-Live. Once final certification notice is sent, the Network Participant's account and portal are set up in production. If the Certification Administrator deems all certification and Go-Live test cases as "Successful", the Network Participant receives a final Certification Approval email within five (5) business days following the successful final test(s). This email is a Network Participant's notification that they publicly may state that they are a 'SureScripts Certified Solution Provider'. This email is also distributed internally within SureScripts to ensure that SureScripts Operations, Deployment, Marketing and Reporting staff can prepare for the Production/Live support. Table C2 in Appendix C, Part X shows the dates of progression through the certification process for each vendor.

Measures

Patients, clinicians, non-clinician staff, and pharmacy staff provided responses to questions in the following conceptual domains: patient safety, effectiveness of patient care, efficiency of patient care, communications with the patient, communications with the physician / prescriber, and effect on relations with the patient. In the follow-up questionnaire of prescribers and their staff, specific questions relating to the enhancement of the e-prescribing software and quality of the data provided after the updated software were included on the survey. Measurement of ADEs was not proposed. Using the SureScripts transaction data sample, we hoped to evaluate medication-related quality measures derived from a sample of pharmacy transaction files only. We focused on inappropriate medication use in the elderly and medication persistence. An inappropriate drug is one that offers greater risk than benefit, taking into consideration its adverse effects. Usually, the drug might have an existing, safer alternative or that a preferable medication might be available.¹¹ In 1991, Beers et al. developed explicit criteria that defined the use of inappropriate medications for the elderly.¹¹ These criteria were developed by a consensus of internationally recognized experts in geriatric medicine for the elderly population, and updated and expanded in 1997, and revised again in 2003.^{12,13} No diagnosis data were available on transactions, as such we focused on medications generally avoided in the elderly independent of diagnosis. Unique medications were identified using manual drug searches for drug names of interest by an R.Ph., PhD. Medication persistence is the accumulation of time from initiation to discontinuation of therapy.¹⁴ For feasibility purposes, we chose to focus analyses on two distinctive classes of medications: bisphosphonates (for osteoporosis) and HMG-CoA reductase inhibitors, or statins, (for cholesterol abnormalities). We selected these two classes of medications as both are chronic therapies for prevalent chronic conditions for which long-term therapy is essential, both focus on disease states that can be asymptomatic for the patient, and both classes appear widely in the literature such that a historical comparison of our estimated numbers to a similar population prior to the era of e-prescribing may be available. Multiple methods to measure persistence have been proposed and vary by the class of drug assessed and the clinical interest of the analyses. Measuring persistence requires identification of new users and sufficient length of follow-up. Given that we had a sample of nine months of SureScripts transaction data, we used three months to identify new users of therapy and six months as the follow-up period. The choice of treatment gaps is variable. While an extensive literature review revealed that most select 30, 60 or 90 days of gap, other methods have been proposed. To assist in comparability to published work, we required the time from initiation of drug therapy to the beginning of a gap of therapy lasting at least 30 days. Persistence was defined as the number of days from first fill to first gap of at least thirty days plus the final day's supply of the last fill divided by the length of follow-up period (6 months). Preliminary analysis of the data revealed that application of traditional persistence measures to e-prescribing transaction data is hampered by lack of flow of information on refills.

Limitations: Participant Selection

Physician Practices. Although the data are from a geographically diverse group of physician practices, all practices in this study were currently using e-prescribing and thus do not represent a random sample. Many of the physicians were potentially “early adopters” of e-prescribing technology and therefore it is possible that included physicians may not be representative of all physicians. Indeed, relative to a random sample of e-prescribers (selected from the same state and physician software vendor) not participating in the study, the prescribers participating in the study were higher volume e-prescribers. The extent of bias introduced by non-random selection of physicians is unknown.

Patients within Physician Practices. The patients surveyed as part of this study were also a convenience sample and thus may not be generalizable. It is plausible that patient responses to the survey were influenced by a positivity bias (i.e. the propensity of persons to be overly optimistic of their lives). The extent that positivity bias may have affected our results is immeasurable given the current study design and therefore the results of the patient survey may be overly affirmative.

Pharmacies- Personnel Survey. Although the sampling frame of pharmacies included all locations of seven pharmacy chain organizations dispensing an average of five or more e-prescriptions per day within the six states in the study, not all pharmacy chain organizations were able to adhere to the research protocols. One chain with 95 eligible pharmacies ultimately agreed to distribute the survey to only 25 due to concerns related to ongoing changes in computer systems and issues resulting from the recent acquisition of a competing chain. Another chain with 111 eligible pharmacies subsequently decided to limit distribution of the survey to 50 pharmacies due to concerns about disruptions in workflow. Of the remaining pharmacies, the response rate was 65.4%. The extent to which the deliberate adjustments to the sampling frame by the chain organizations and non-response influenced the study findings is unknown.

Pharmacies- Medication Therapy Intervention Study. Of the seven chain organizations, five identified 122 pharmacies to participate, of which 55.7% of pharmacists agreed to participate. Despite participation agreement, only 33% of expected data were received by the research team. The extent to which the refusal, non-response, and partial participation in the data collection activities biased the findings is unknown.

Limitations: Methodological Issues

Positivity Bias. The surveys performed within the workplace context and administered through workplace channels may offer some degree of positivity bias. While some of the surveys administered as part of this study permitted the flexibility of completing the survey from a non-work environment through web-based portals, we cannot rule out this source of bias.

Survey Method. While ramifications of design elements on issues of validity need to be better understood, there is some evidence to support that multiple waves of surveys tend to capture a more diverse (both socioeconomic and racial/ethnic) population. For some of the

surveys in this study (pharmacy personnel, patient), we were only able to have one wave of survey request.

Attrition Bias. For the physician practice component of the study, 20.5% some eligible physician practices did not participate in the follow-up aspect of the protocol. The follow-up period was extremely short due to the delays experienced in the roll out of the new standards by the physician software vendors and the time restrictions imposed by the funding agency.

Limited Experience with Standards. Given the unanticipated delays in the roll out of the standards to the physician practices, we acknowledge that the physician practices involved in the study may not have had the optimal length of time to work with the new software. Our original design required follow-up surveys to occur four to six weeks post implementation to assure that we would not be measuring outcomes during a learning curve. Yet, we were unable to adhere to this ideal given the aggressive time frame for the study.

Inability to Evaluate Standards Individually. Although our original application proposed evaluating groupings of standard implementations, we were unable to implement the desired protocols owing to the technical challenges experienced by all the participating parties. Some of the participating vendors did not implement all of the standards, thus part of the follow-up evaluation was not confounded by too many simultaneous enhancements.

Loss of Physician Software Vendor Participant. One of the participating software vendors was unable to roll out the agreed upon software for the standards testing. As such, physician practices in Nevada and Tennessee were not eligible to participate in the follow-up.

Multiple Methods for Follow-Up. To increase the response rates during the follow-up period, we provided a phased survey approach. In the initial phase, we implemented a protocol that resembled the baseline procedures (i.e. paper or web-based survey response). If respondents did not respond in a timely fashion, we engaged Brown's survey center and permitted the completion of the surveys over the phone.

Qualitative Validation Methods not Feasible. Cumulative validation (i.e. comparison to previous research) was not possible, as to our knowledge, this is the first study of its kind. We were unable to perform respondent validation (i.e. a technique to determine the level of correspondence between the researcher's account with those of the research subjects) as the time table for project completion was too aggressive to permit this level of validation.

Persistence Analyses. Transactions appear in the data source only when communication between pharmacist and prescriber is necessary. Further analyses of persistence should be performed on the medication history records.

Analysis of Potentially Inappropriate Medications. Diagnoses are usually not available on e-prescribing transaction files. As such, estimation of potentially inappropriate medications is limited to medications for which an indication is not required. Further, some potentially inappropriate medications are controlled substances. By federal law, controlled substances may not be electronically prescribed. Thus, estimates of potentially inappropriate medications should

be lower than what is observed based on insurance claims files. Lastly, sample sizes were too small to evaluate individual classes of inappropriate medications. Each of these limit the comparison of potentially inappropriate medication use to estimates reported in the literature.

Results

Principal Findings

Prescriber-specific details on the volume of e-prescription transactions in our sample are provided in Appendix C Part IX for new and refill message types. Table D1 in Appendix D demonstrates the volume of transactions by message type and vendor in our sample. Figure D1 shows the distribution of NEWRX transactions by vendor type. Table D2 shows an analysis of duplicate transactions. Vendor A had 1.4% of total NEWRX messages with one exact duplicate message to 5.4% among Vendor D. The maximum of exact duplicate NEWRX messages sent through the SureScripts network ranged from 5 (Vendor A) to 29 (Vendor E). These multiple transmissions were more prevalent among refill responses from physicians to pharmacies. Among Refill Request message types, the maximum of exact duplicate messages sent through the SureScripts network ranged from 3 (Vendor C) to 14 (Vendor F) with 3.5% of Vendor A Refill Requests exact duplicate messages and 2.3% of Vendor D messages. For refill responses, 8.9% of Vendor E message types were exact duplicates, whereas only 0.6% of Vendor A had exact duplicates. Information from participating physicians obtained during office visits/interviews may provide some insight into reasons for this phenomenon and help to highlight practices that may prevent this from occurring. We evaluated the time from Refill Request to Refill Response (n=163,840). Approximately 66.4% had an electronic response within the same week and an additional 13.4% in the following week. Response times varied widely by vendor and ranged from a few minutes to a maximum of 12 days, with an average response time of approximately 19 hours. Table D3 and D4 describe the demographic profile of patients included in the study who received e-prescriptions and the average number of e-prescriptions received for the entire population and those at least 65 years of age. Although estimated processing times from prescriber to SureScripts network were calculated by transaction type and vendor (not shown), the extent to which the prescriber transaction time represented a universal time code was unclear. A standard-by-standard summary of the findings is presented.

Structured and Codified Sig

The Structured and Codified Sig survey findings are shown in Table D5, Figures D2 Panels a through e stratified by respondent type (Pharmacy Chain, Pharmacy Management System Vendor, and Physician Software Application Vendor). There is overall agreement in concept that standards are necessary and 68% agreed that the NCPDP approach is appropriate for standardization. Yet many respondents reported that the proposed standards (the 99/1 approach) are too complex and would represent a significant burden to implement, with one third indicating that the developmental effort to implement would be excessive. The average FTE-month

equivalents to implement the 99/1 standard overall was 145; with pharmacy chain organizations reporting on average 19 FTE-month equivalents would be needed to implement the standard, 39 FTE-month equivalent for pharmacy management system vendors, and 235 FTE-month equivalents for physician software vendor applications. Despite this, respondents clearly recognized the value of increasing complexity with respect to reduction of errors and increasing patient safety (Figure D2; Pharmacy-based research – Appendix F). Nevertheless, 85% agreed that there is a point of diminishing returns on investment. The average threshold where return on investment was insufficient to warrant additional effort was 82%.

RxNorm – Survey

The survey findings revealed that more testing of RxNorm is needed before testing of the standard in a live environment. Accuracy and mapping issues were cited as being problematic. (See Appendix E.1 for details.) One respondent estimated that 95% of NDC codes provided in the attribute file is accurate, with the other respondents unable to judge. With respect to multiple SCD RxNorm concepts mapping to the same NDC code, the problem occurs when pooling information from multiple data sources or multiple RxNorm concepts are similar such that one cannot be sure what the correct concept to represent the drug is. Suggested solutions to minimize this error included: retiring or make obsolete concepts that are the same or similar to other RxNorm concepts, do not allow two ambiguous terms to co-exist, or link by NLM of the NDC to a unique SCD. All respondents said that it would be extremely helpful if NLM or another credible regulatory authority (e.g. FDA) maintained an up-to-date readily available NDC-RXCUI mapping file. All respondents indicated that they wanted SCD mapped to the NDC code, three of the four wanted SBD mapped to NDC code, one respondent wanted SCDC mapped to NDC, and one respondent suggested Semantic Clinical Drug Dosage Form (SCDF). Of the three respondents that answered, all reported that given the current RxNorm structure, the RxNorm concept(s) are not detailed enough to potentially replace the drug description free form text and explicitly convey the prescriber's intent.

RxNorm – Lab Environment

Of the 14,005 transactions meeting the eligibility criteria for analysis, ~85% (n= 11,893) had the same RxNorm SCD codes in the physician software application file (Multum) and the pharmacy chain organization file (FDB), 11.95% had mismatched RxNorm SCD codes but matching drug name descriptions, 0.3% had mismatched drug name descriptions provided, 1.16% had differing drug strengths and/or dosage forms in the drug description, and the remaining 1.69% of records had completely different drug names from the physician software application and the pharmacy chain organization. The 0.3% of mismatched RxNorm SCD codes and drug name descriptions may be due to an anomaly in the data extracting process on the physician vendor side and we have requested a re-extract of the data to confirm. The 1.16% of records with differing drug strengths and/or dosage forms in the drug description could be due to the unavailability of the prescribed drug strength or the dosage form in the pharmacy. In this case the pharmacist would most likely then dispense a different strength and adjust the patient directions accordingly to accurately reflect the prescriber's original intent or would call the prescriber to seek permission for change of the original order and document this interaction on the hard copy as a verbal order. We did not have access to dispensed patient directions or hard

copy prescriptions and hence were unable to validate our hypothesis. It is possible that the 1.69% of records with different drug names were incorrectly matched as the pharmacy chain organization did not store the SureScripts unique message ID. Flaws in the matching logic may be one explanation of these findings. Although our analysis of data collected in the evaluation of RxNorm is ongoing, the inability to rule out the alternative hypotheses owing to methodology of this analysis severely limits the interpretability of these analyses.

Prior Authorization

While direct testing of this standard in a lab or live environment was not proposed in this study, clinician (and their staff) focus group participants were generally enthusiastic about the possibility of electronically submitting for prior authorization, particularly if the process were standardized, quick, and time saving. An immediate decision in real time while the patient was still in the office was considered ideal. However, since in many practices support staff actually do most of the prior approval processing, prescribers wanted staff to continue to handle most of the work and did not want the responsibility for this duty shifted to the physician. Less enthusiastic participants thought that the potential prior authorization function “might be useful” particularly when the patient and the chart are available – however less useful with patients in a nursing home, for example, or if the “chart is offsite.” Another prescriber did not think the function would be useful because it would not be conducive to the PDA format used in that practice for e-prescribing.

The following standards were tested in a live environment:

Change and Cancel Transactions (RXCHG/CHGRES/CANRX/CANRES)

Though already designated foundation standards by CMS in 2005, it was considered appropriate in this pilot to attempt to test the NCPDP Change and Cancel transactions. One physician software vendor and two pharmacy chain organizations successfully certified for these transactions on the SureScripts network proving that these transactions work in a laboratory environment. Although scheduled for live implementation and evaluation, the physician software application vendor was not able to deploy the updates in time for evaluation. Qualitative research, an evaluation of the SIG code e-prescribing transactions, and research from the Medication Intervention Therapy study (Appendix F.2; Table 4) confirm the need for such transactions from the pharmacy and prescriber perspective as persons using the software have developed workarounds in the absence of the ability to communicate changes and cancels. For example, 992,380 transactions were reviewed to identify possible workarounds being used by e-prescribing physicians. Prescribers attempted to communicate with pharmacists to discontinue a medication in ~0.2% of new prescriptions (range 0.1% - Vendor C to 1.3% Vendor B and D).

Fill Status Notification Function (RXFILL)

Two vendors successfully certified and deployed RXFILL and 37,646 transactions were processed. Prior to implementing the RXFILL functionality, we assessed opinions on the value of this new feature among focus group participants (clinicians and their staff). Of the sixty-three

percent of comments about potential usefulness of such a feature, 22% were negative (legal trap, don't want responsibility, burdensome, "ignorance is bliss") and 15% were equivocal (might be useful on a selected basis, seems useful but could become overwhelming). Among the positive comments, participants referred to the feature's clinical usefulness in addressing patient compliance including monitoring the use of controlled substances and managing chronic conditions such as diabetes, asthma, heart disease, hypertension or depression. It was also seen as helpful in identifying other patient problems such as inability to afford prescription drugs or misunderstanding of dosing instructions. One participant also noted that documentation of noncompliant patients could protect physicians from malpractice suits in the event of an adverse outcome, and could also become a factor in quality measures used for physician reimbursement. Among those who were not enthusiastic about RXFILL, concerns focused primarily on potential liability and additional work generated for clinicians and staff. Although some also conceded that it could provide good clinical information that would probably improve quality of care, most were concerned about the large volume of work that might result. Figures D3 through D6 show the survey results after implementation. Among clinician respondents, 47% found the functionality very useful and an additional 42% found it somewhat useful. Only 9% of prescribers indicated that they would not want this information for any medications. Eighty percent indicated that if a medically necessary medication was not filled, they would call the patient. Regarding notification that a patient has NOT picked up a prescription, more than half of clinicians indicated that cardiovascular (66%), antidiabetics (64%), anticoagulants (61%), antidepressants (60%), antibiotics (59%), and antipsychotics (53%) were important to be informed about. Forty-four percent were very concerned about liability issues. Fifty-four percent wanted fill information on the active medication lists, 20% desired alerting messages when a prescription was filled, and 26% preferred the information be available via medication history. Despite concerns regarding work increases with RXFILL, only 1% reported that the changes in the software made their jobs a lot more difficult, and 8% reported that changes made their jobs a little more difficult. The majority reported no change in job in relation to the implementation of RXFILL. Additional suggestions for optimizing implementation of this functionality included: allow for selective checking/alerting of medication pick-ups, have a mechanism to call non-adherence to the clinician's attention, have the pharmacy trigger calls to the patient when prescriptions are not picked up, have an option to send an automatic reminder to the patient, and allow to turn on a "close monitoring" feature for certain patients.

Formulary and Benefit Information

Formulary and benefit information was evaluated at baseline (with flow of information provided by one network) and at follow-up after three physician software vendors (A, D, E) enhanced the flow of information with SureScripts provided formulary and benefit information. During the pilot testing, 19,226 formulary and benefit transactions were processed (Table D1). At baseline, 80% of e-prescribing users reported using the formulary and benefit information. Most focus group participants found formulary and benefit functions within e-prescribing software good, helpful, "a great idea." Many noted that having formulary and benefit information reduced the number of pharmacy call backs when the prescription was not covered or patients objected to the co-pay. "It's a big help because we'd have a lot more work if we weren't using it." "Half of my day is taken up calling back different prescriptions because it's not covered under somebody's insurance." Some participants did not use formulary and benefit

functions because they feel it would take too much time and generate too much work. In the case of refills, these participants felt that changing the prescription due to formulary concerns could generate a significant amount of staff work. With new prescriptions, a change might require re-negotiation and re-education of patients about a treatment regimen already settled upon. Constant changes and increasing complexity of formulary and benefits was also seen as generating more work for prescribers. Other participants say they do not use the formulary and benefit feature because they never see it – the formulary information is displayed when their staff enter the prescription. Others believe prescription cost “doesn’t concern me.” The concept of knowing a patient’s current and correct formulary and benefit information was welcome. However, in practice, there were problems such as not having actual cost information, not knowing what the alternate formulary options might be, not having up-to-date or accurate information, and patients changing prescription plans or having both primary and secondary coverage that cannot be handled simultaneously by e-prescribing software. Real cost information on formulary alternatives would be a welcome addition. Some participants report that some patients get angry when a higher cost drug is prescribed unbeknownst to the prescriber. Rapidly changing formularies was a concern of many participants. Formularies available on e-prescribing might be two to four or more months out of date, incomplete or missing entirely. This is particularly concerning with regard to Medicare Part D with multiple products, differing formularies, and patients with limited income.

Results of the follow-up survey relating to formulary and benefits are shown in Figures D7 through D13. Frequency of using formulary and benefit functionality did not change during the follow-up period (Figure D7), however most reported they found formulary and benefit information at least somewhat useful in making medication decisions at the point of prescribing (Figure D8) and discussing and evaluating costs with patients (Figure D9). While 72% of participants reported no change in the accuracy of formulary and benefit information, 25% reported improvements in accuracy after the integration of supplemental SureScripts provision of formulary and benefit information (Figure D10). Similar estimates were expressed for change in amount of information provided (Figure D11) and number of patients for whom information was provided (Figure D12). Despite the increases in accuracy, amount, and number of patients for whom formulary and benefit information was provided in the follow-up period, Figure D13 shows that no appreciable differences in the frequency of patient related medication cost discussions were documented.

Medication History (RXHREQ/RXHRES)

PBM-based medication history was evaluated at baseline (with flow of information provided by solely payers). At baseline, 85% of e-prescribing users reported using the formulary and benefit information. Figure D14 shows that one third of respondents indicated that they always view PBM-based medication history, but the frequency with which PBM-based medication history was viewed varied depending on physician e-prescribing software (from 7.7% to 74.2%). Figure D15 shows that for the two e-prescribing technologies that permitted non-clinicians to view medication history, more than 75% viewed it; with slightly over 50% always using medication history. Accuracy and legibility were noted as benefits of reviewing medication history. The variability in use was corroborated by the variation in comments with respect to frequency of use and value of the functionality in the focus groups. Reflective of the quantitative data, some respondent’s do not use or reported negatively about the PBM-based medication

history - “I can’t say that I’ve ever used that function....” Positive comments related to accessibility of information, ability to view medications across multiple prescribers, ability to detect prescription drug abuse and doctor shopping, assistance in medical decision making, and reviewing the medication list with patients. Analysis of the focus groups revealed that clinicians generally value the ability to access data from home, hospital, or other off-site location. The efficiency of accessing the data, even while in the office, is also valued. Having information on what other doctors prescribe is a valued aspect of PBM-based medication history as it helps prescribers confirm therapies with the patient and improve their own care. This is particularly important with new patients, patients who see several different doctors, patients who are seen rarely, or patients who are poor historians. Clinicians reported catching drug interactions that were unknown to them from other physicians prescribing. A timely, accurate, relevant and complete medication history aids in clinical decision-making. This includes both decisions about the most effective course of therapy to try, the origin of a certain side effect, or whether previous therapies have been effective. Some physicians found medication history particularly useful for discovering potential prescription drug abuse among patients and doctor shopping. Accuracy of medication history information is essential as comments made in focus groups underscore. “Sometimes you trust that it’s accurate when it’s not totally up to date... Sometimes you are lulled into a false sense of security.” The need is for accurate, complete, and timely information. Having medication history on all patients was desired. Negative comments with respect to PBM-based medication history related to: 1) not having medication history on all patients; 2) not having enough information on people with at least some medication history covered (e.g. short duration); and 3) not having accurate information. Non-clinicians also valued medication history owing to legibility issues. Figure D16 shows the frequency that clinicians used medication history to review/update the active medication list with patients. Figure D17 confirms that relative to patients in practices without e-prescribing capabilities, patients of practices with e-prescribing capabilities more frequently report discussions regarding adherence and updating medication lists. Medication history also permits drug alerting programs to run prescriptions in the history with over-the-counter, samples, herbals, and medications administered in the office. Few prescribers use e-prescribing software to enter OTC, samples, thus limiting the potential for patient safety gains in this area. Drug alerting is available at the point-of-prescribing and physician software applications run the alerts against medication history. Figures D18a and D18b show that overriding drug alerts relating to dose- and drug-interactions is a common occurrence.

Five physician software vendors (A, C, D, E, F) implemented the flow of SureScripts provided community pharmacy-based medication history. During the pilot testing, 43,485 medication history transactions were processed (Table D1). Despite this volume, Figure D19 shows that only 25% of participants overall realized they could view prescriptions written by clinicians outside of their practice, however, 75% of participants using software from Vendors D and F reported such capability. Overall, 54% reported an increase in the number of patients for whom medication history was available (Figure D20a), 44% reported improved accuracy in the medication history (Figure D20b), and 88% indicated that more comprehensive medication history was provided (Figure D20c). Great variability by physician software vendor and locale was observed and may be due to timing of deployment versus evaluation and training provided with deployment. The extent to which enhancing PBM medication history with community pharmacy-based medication history would result in greater overriding of drug alerts was explored. Figure D21 shows that ~17% of participants did report an increase in the volume of

drug alerts, with a trend in most vendor applications towards greater frequency of overriding drug-drug interaction alerts (Figure D22a) and dose alerts (Figure D22b) in the follow-up period. While the vast majority of respondents indicated no change in the usefulness of drug alerts at the point of prescribing in the follow-up period, those who reported a change in the usefulness of the alerts were more likely to indicate that the drug alerts were more useful relative to being less useful (Figure D23).

The length of time with experience using the enhanced medication history may have been too short as no clear increases in the frequency of reviewing medication history between baseline and follow-up was observed (Figure D24). Regardless, the value of having medication history at the point of prescribing was systematically documented by all prescribers (Figure D25). No clear changes from baseline to the follow-up period in the frequency with which providers communicate with other prescribers was observed (Figure D26). With respect to evaluating medication adherence, Figure D27 demonstrates that clinicians realize the value of this information stream. Figure D28 shows that the flow of medication history based on PBM and community pharmacy data did not systematically increase the frequency of discussions clinicians have with their patients related to adherence. Clinicians documented the perceptions regarding medication history to evaluate concomitant medication use (Figure D29) and reconciling the active medication list (Figure D30), although appreciable increases in frequency of reviewing medication history with patients to update active medication lists was not demonstrated (Figure D31). With the flow of medication history from PBMs and community pharmacies, many clinicians reported being very concerned about liability if they did not reconcile the discrepancies between medication histories and the information provided by insurance companies or pharmacies (Figure D32). Forty percent of participants thought medication history should go back ten to twelve months, with 27% requesting over one year of data.

Pharmacy Personnel Study

No differences were found among pharmacy personnel in their overall satisfaction with e-prescribing and the processing of e-prescriptions, as all were somewhat-to-moderately satisfied. The 2,235 written comments received provided information to support the standard-specific findings reported above. Of these, 57% (1,277) were negative features of e-prescribing, while 43% (958) were positive. Among the positive features, improved clarity and/or legibility of prescriptions was the most frequently cited advantage of e-prescribing, followed closely by improved speed or efficiency of processing. Prescribing errors, particularly wrong drug or directions, were the most commonly cited negative feature of e-prescribing (34.1%). Commonly cited among negative comments were delays in receiving e-prescriptions from prescribers and reduced communications with physicians and patients.

Medication Therapy Intervention Study

During the 312 observation shifts, pharmacists reviewed a total of 2,690 e-prescription orders (new = 83.0%, refill = 17.0%) and intervened 102 times for an overall intervention rate of 3.8%. The rate at which pharmacists identified problems on new e-prescriptions was found to be nearly twice that of refills at 4.1% and 2.2%. The problems were recognized by pharmacists (65.7%), the pharmacy's computer system (14.7%), the patient (6.9%) and the physician (4.9%). The most common reason for pharmacists' interventions was to supplement omitted information

(31.9%), especially missing directions. Other common problems included insufficient dose (9.7%) and excessive dose (8.0%). The most common response to e-prescribing problems was to contact the prescriber (64.1%), followed by consulting the patient's profile or medication history (12.8%) and interviewing the patient or the patient's representative (9.4%). In most cases, the e-prescription order was changed and the prescription was ultimately dispensed to the patient (56%). In 15% of cases, the e-prescription order was eventually dispensed as initially written following contact with and clarification by the prescriber. In 10% of cases the prescription was not dispensed. An additional 12% of prescription issues remained unresolved when the pharmacist reported these data. Twenty percent were dispensed with different directions.

Outcomes

Estimates of potentially inappropriate e-prescription transactions did not vary systematically throughout the study period. It is unlikely given the timeframe of the e-prescribing transaction data stream: January 1, 2006 through October 31, 2006 and the roll out of the enhancements to the software (October 2006) that improvements would be realized immediately. Figure D33 shows the proportion of NEWRX transactions generated for elderly persons that were for potentially inappropriate medications and Figure D34 displays the percent of elderly patients with a NEWRX whose prescription was for a potentially inappropriate medication by month and vendor. There was substantial variation by physician software application (Vendor A: ~5% of patients had an inappropriate medication; Vendor D: ~19%). Variation by vendor could be due to many factors including regional prescribing differences, case mix of patients, presence of controlled substance records in the transaction files, and differences in the built in decision support tools and drug alerting functions. Regardless, the observed estimates are much lower than what has been reported in the literature. Although many studies have been published with respect to potentially inappropriate prescribing in elderly populations, two studies provided the most relevant comparisons with respect to operational definitions, populations, and time frame.^{15,16} An estimated 34% of their persons aged 60 years and above was taking at least one inappropriate medication.¹⁵ In a population based survey of community dwelling elders (> 65) in a rural North Carolina county using face-to-face in-home interviewing, 26.6% of their population was taking > one inappropriate medication.¹⁶ There are several non-causal explanations why estimates derived from an e-prescribing sample were markedly lower than those reported in the literature. The most likely explanation is that federal laws prohibiting electronic prescribing of scheduled drugs (of which many potentially inappropriate medications are).

Discussion

Overall, satisfaction levels with e-prescribing from patients, pharmacists, and clinicians were high and not adversely affected by the introduction of new standards. Efficiencies realized were clear, although variations in implementation and gains achieved were observed. Patient safety claims for e-prescribing were not definitively quantified, as measures of ADEs were not part of this project, and analyses based on e-prescribing transactions data were limited by the availability of the information from this data source. Recommendations for improvement of efficiencies and patient safety were numerous and are listed below.

Efficiency. Pharmacy perspectives: While pharmacy computer systems should have an obvious indicator on the main prescription processing screen that immediately alerts staff when an e-prescription has been received and is awaiting processing, staff should also be trained and supervised to look for, and respond to, alerts that an e-prescription has been received and is awaiting processing. Information systems should allow pharmacy management to monitor the status of e-prescriptions awaiting processing, and should issue a reminder to staff if processing has not been initiated within a defined period of time. If physician e-prescribing applications adopted and used standard formats and procedures, a reduction in the need for physician call back and/or editing of e-prescriptions by pharmacy personnel is likely. Mechanisms should be implemented by physician e-prescribing applications and/or network switches to ensure that e-prescriptions are complete with respect to all information needed by pharmacies to process and dispense. Pharmacy e-prescription processing should evolve toward eliminating the routine printing of e-prescriptions that must be re-entered by pharmacy staff, thereby increasing costs and the opportunity for data entry error. Until this is done, e-prescriptions should be received by pharmacies in a format that is as similar as possible to the way that information is organized on paper prescriptions. Electronic “bundling” of e-prescriptions written, or a mechanism to tell the receiving pharmacy how many prescriptions are being transmitted for the patient, e.g., one of four, would assist in efficient processing of prescriptions. Pharmacists should have the ability to electronically request supplemental or clarifying information from the prescriber. Prescribers should be able to electronically respond to these queries and the information exchanged should be easily accessed and clearly displayed to users on both sides.

Prescriber Perspectives. Participants commented that the software was not as easy to use as they would like, which influenced their perceptions of the efficiency of e-prescribing. Inadequate training in the software exacerbates this problem. Prescribers requested simpler interface (e.g. fewer screens and ability to use a “back” button), increased flexibility, and speed. Physician software should permit flexibility in sorting preferences, threshold for alerts, how data are viewed, and the flexibility to recognize common misspellings of words. To maximize the utility of the formulary and benefit information, the information must be kept up to date, pricing information and cost differential between tiers should be placed on the screen, and if a drug is not on the formulary, suggest a comparable drug that is on the formulary. Physicians and their staff should engage patients as active and informed participants in e-prescribing to better ensure that their expectations at the receiving pharmacy are realistic. Many participants commented that they would like their e-prescribing software to run faster. It was unclear the extent to which the slow down in processing was owing to the software, the network, or the adequacy of the participants’ computing hardware. Participants noted that frequent password changes and short time-outs requiring logging back into the system slowed them down. In addition, participants expressed interest in getting a confirmation back from the pharmacy that the prescription was received. From pharmacists and physicians, permitting e-prescribing for all types of prescriptions is necessary for efficiency purposes. The Drug Enforcement Administration must continue to work with stakeholders to create legal ways to allow prescribers to issue, and pharmacies to receive and process, e-prescriptions for controlled substances.

Patient Safety Gains. E-prescribing theoretically can improve patient safety in at least the following domains: legibility issues, drug alerting at the point of prescribing, providing more information to assist clinical intervention regarding non-adherence, and awareness of duplication

of therapy and concomitant medication use originating from multiple prescribers through medication history. While legibility gains have been documented, errors in drop down menu selections have emerged. To achieve optimal patient safety gains, physicians should either perform their own e-prescription data entry or carefully review e-prescriptions entered by support staff before allowing them to be transmitted to the pharmacy. Drug alerting at point of prescribing has the potential to improve patient safety in the outpatient setting, but our study revealed that the lack of specificity in the alerts result in frequent overriding of messages. This is consistent with previous research demonstrating that such alerts are frequently overridden (49 to 96% of cases) because of poor specificity and high volume of alerts.¹⁷ Prescribers in our study recommended: targeted messages, ability to suppress alerts for medication combinations tolerated by patients, and ability to set the threshold for alerts. These suggestions are reinforced by suggestions from the medical literature. The feasibility of designing drug alerting systems targeting specific issues and minimizing workflow disruptions has been shown to increase clinician acceptance of alerts in ambulatory settings.¹⁸ Although impact on patient outcomes is less clear, real-time alerts targeting medications contraindicated in elderly persons reduces prescribing of targeted medications.¹⁹ To improve the clinical utility of the drug allergy alerts, greater specificity must be employed.²⁰ Another suggestion to reduce alert overload is to suppress alerts for renewals of medication combinations that patients currently tolerate.²¹ With respect to the initial standards improving patient safety, participants in the pilot gave the following suggestions for optimizing implementation of RXFILL: allow for selective checking/alerting of medication pick-ups, have a mechanism to call non-adherence to the clinician's attention, have the pharmacy trigger calls to the patient when prescriptions are not picked up, have an option to send an automatic reminder to the patient, and allow to turn on a "close monitoring" feature for certain patients. Patient safety gains from providing medication history are realized by increasing communication between multiple providers prescribing for the same patient. Patients often do not remember or do not know their medications or doses, or do not tell their provider about medications (e.g. controlled substances). Timely, comprehensive, and accurate medication history can help prevent complications and improve patient safety. Enhancing payer-based medication history to include community pharmacy based information improves the completeness and accuracy of the data. Complete, accurate medication history is highly valued by prescribers and would be valued by pharmacists as well.

Accurate formulary and benefit information as well as actual drug costs is reported as important to clinical practice. Our study confirms the mismatch in provider and patient perceptions regarding communication about medication issues in ambulatory settings, and demonstrates that implementation of e-prescribing may provide needed information at the point of prescribing, but in and of itself may not be a panacea. The differences in the perceptions of medication-related discussions by patients and providers in this study are marked and consistent with previous research. Eighty percent of patients in our study reported that they would never tell their physician if they did not intend getting a prescription filled and physicians appeared oblivious to the extent to which this lack of communication exists. Only one in five physicians understand how much patients pay for their prescriptions.²² Lack of communication between providers and patients likely results in missed opportunities to identify resources to help patients at risk for underutilizing medications.²³ Physicians may be able to switch to less expensive drugs, provide free samples, identify resources for assistance or at a minimum provide guidance on which medications must not be skipped. In the absence of e-prescribing software, clinicians lack easily accessible information about insurance coverage. Theoretically, the availability of

formulary and benefit information at the point of prescribing may stimulate prescription cost discussions between patients and providers, though our data suggest that the mere existence of the information may not be enough. Providers may need training to assist them in incorporating this information into their practice.

National Provider Identifier (NPI). Although neither the RFA nor the grant award document required this pilot to study the use of the NPI as the provider identifier for the electronic prescription program under Medicare Part D, AHRQ has requested that this report provide input with respect to this suggestion. It is the opinion of this pilot team that the NPI could successfully be used as a provider identifier for the Medicare e-prescribing program, provided that it is modified to contain more detailed, specific provider location information. The two primary and essential functions that a provider identifier must fulfill in e-prescribing transactions are to: (1) identify who the provider is and (2) tell how the message must be routed in order to reach the provider. There is no question that the NPI will satisfy the first requirement, but as currently configured and being implemented, the NPI will not satisfy the second requirement. Having the first functionality without the second renders the NPI no more useful for e-prescribing than other potential identifiers, and less useful than others currently in use. Many prescribers work from multiple locations, so the NPI must have the capability to indicate the location to which an electronic prescription message is to be sent (private practice, clinic, hospital, etc.) It is strongly recommended that a prescriber with multiple locations have a single NPI, or core number, and then a suffix for each location that an electronic message can be sent to. If CMS were to see to it that the NPI was changed to include this type of routing information, it would make the NPI an excellent choice of a provider identifier for Medicare and other e-prescribing transactions.

Conclusion. Initial standards deemed ready for implementation include: Formulary and benefit, Medication history, and RXFILL. Initial standards requiring more testing before implementation include: Structured and Codified SIG, RxNorm, and Prior authorization. Foundation standards found technically viable but in need of broad implementation: Change and Cancel. Improvements in the implementation of the standards on the physician software application and the pharmacy organization sides are needed to achieve optimal realization of efficiency and patient safety gains associated with e-prescribing.

Significance. The primary significance of the findings of this pilot is that there is now empirical evidence that several of the initial e-prescribing standards that were identified by both NCVHS and CMS as potentially useful to Medicare e-prescribing are, in fact, ready for adoption by CMS and implementation by the health information technology industry. Thus, CMS should move forward with notice and comment rulemaking to adopt the initial standards that this pilot research has shown to be technically complete and efficacious. On the other hand, several of the initial e-prescribing standards studied in this pilot were shown to be ineffectual in their current form, and CMS should not recommend these standards for adoption until their Standards Development Organizations (SDOs) have mitigated the shortcomings that have been found.

Implications. Some e-prescribing processes in use today will become even more valuable to medical and pharmacy practitioners through the rapid adoption of the initial e-prescribing standards whose immediate use is supported by these findings. It is quite likely that the pilot

work that this and the other grantees conducted in 2006 will accelerate the acceptance of the initial e-prescribing standards that are ready for adoption beyond what it would have been had these pilots not been conducted. With respect to the initial standards that these findings say should not be used at this time, it is important to note that their absence will not create a significant burden at this time because their functions currently are being addressed in other ways. It will be far better for healthcare practitioners and the health information technology industry that the SDOs that created the initial e-prescribing standards not endorsed by these findings address the many concerns raised by this research before attempting to have said standards adopted for Medicare e-prescribing.

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List of Publications and Products

Presentations

Whittemore K, Lapane KL. Maximizing the effectiveness of e-prescribing between community pharmacists and physicians. AHRQ E-prescribing Meeting January 25, 2006.

Whittemore K. American Society for Automation in Pharmacy (ASAP), 2006 Industry and Technology Issues Conference, St. Pete Beach, FL, January 27, 2006

Whittemore K, Lapane KL. Maximizing the effectiveness of e-prescribing between community pharmacists and physicians. NCVHS Standards and Security Subcommittee, Meeting February 24, 2006.

Lapane KL, Dube C, Whittemore K. Toward the goal of maximizing the effectiveness of e-prescribing between community pharmacists and physicians: Evaluating the implementation of e-prescribing standards. AHRQ Health Information Technology Conference, June 4-7, 2006

Whittemore K. American Society for Automation in Pharmacy (ASAP), 2006 Midyear Industry and Technology Issues Conference, West Palm Beach, FL, June 23, 2006

Dube C, Lapane KL. Assessing the Impact of e-Prescribing on Physician Practice. AAPP October 2006

Lapane KL, Dube C. A collaborative relationship to understand how to maximize the effectiveness of e-prescribing between community pharmacists and physicians" submitted for 134th Annual Meeting & Exposition American Public Health Association, Boston, MA November 4-6, 2006.

Whittemore K. American Medical Informatics Association (AMIA), 2006 Annual Symposium, Washington, DC, November, 13, 2006

Whittemore K. National Council for Prescription Drug Programs (NCPDP) Fall Educational Summit, Dallas, TX, November 14, 2006

Rupp MT, Jackson T, Lapane K, Whittemore K, Dube C, Maximizing the Effectiveness of e-Prescribing Between Physicians and Community Pharmacies. ASHP Midyear Meeting. Anaheim, CA; December 4, 2006.

Rupp MT. "ePrescribing - Past, Present and Future" ASHP Midyear Clinical Meeting & Exhibition, December 6, 2006, Los Angeles, CA.

Rupp MT, "Evaluating the Impact of Technology on Pharmacy Practice" ASAP Annual Industry & Technology Issues Conference, January 11, 2007.

Publications

Lapane KL, Dube C, Schneider KL, Quilliam B. Patient Perceptions Regarding E-prescriptions: Is the Geriatric Patient Ready? Under review, *J Amer Geriatr Soc*

Lapane KL, Dube C, Schneider KL, Quilliam B. (Mis)Perceptions of Patients and Providers Regarding Medication Issues. Under review