Final Report:

Risk-Informed Interventions in Community Pharmacy: Implementation and Evaluation

Principal Investigator:
Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon)

Team Members:
Judy L. Smetzer, RN, BSN, FISMP
Donna M. Horn, RPh, DPh
John E. Westphal, BS
Sharon Conrow Comden, BS, MPH, DrPH

Organization:
Institute for Safe Medication Practices
200 Lakeside Drive, Suite 200
Horsham, PA 19044

Project Dates:
10/01/2008 — 06/30/2012

Federal Project Officer:
James B. Battles, PhD

This study is supported by the Agency for Healthcare Research and Quality
Contract # R18HS017910

Abstract

Purpose: Develop and test three risk-informed interventions in community pharmacies: 1) scripted patient counseling for targeted high-alert medications, 2) a readiness assessment for barcode product verification systems, and 3) a simplified risk-assessment tool to identify and quantify vulnerabilities, determine how to reduce risks, and estimate the impact of selected interventions.
Scope: Community pharmacy organizations.
Methods: To study patient counseling, a nonequivalent comparison-group design, direct observation, and self-reported data were employed. For assessing readiness of barcode verification systems, self-reported data were analyzed. To build and study a simplified risk assessment tool, a software development and testing process was utilized.
Results: The counseling rate for high-alert medications was 93.9% in pharmacies that provided scripted patient counseling and 29.6% in pharmacies using traditional counseling methods. Counseling rates were higher (83.6%-94.4%) when consumers were told that a pharmacist would like to speak with them and lower (3.1%-5.2%) when staff asked if they had any questions. Most consumers (85%) felt they were less likely to make a mistake after reading the safety tips handout. Most pharmacists (90%) found the handouts to be of high value, and 80% believed the scripted counseling could be sustained in community pharmacy practice. Mean scores for the barcode readiness assessments were 65% (leaders) and 77% (staff). Leaders and staff scored highest in domains related to drug information, culture, and the environment (physical and technology). Testing of HAMMERS™ verified the accuracy of its estimates of preventable adverse drug events.
Key Words: patient counseling, barcode product verification systems, high-alert medications, risk assessment

Purpose

The purpose of this study was to develop and test three risk-informed interventions in community pharmacies intended to identify, quantify, eliminate, reduce, and/or mitigate the risks associated with dispensing high-alert medications. High-alert medications bear a heightened risk of causing patient injury when they are misused.[1] The three interventions were:

Intervention 1: Scripted patient counseling by a pharmacist for consumers who picked up a prescription for high-alert medications, including warfarin, enoxaparin, fenta**NYL** patches, **HYDRO**codone with acetaminophen, oxy**CODONE** with acetaminophen, methotrexate, and five types of insulin analogs
Intervention 2: An assessment tool to determine community pharmacy readiness for implementation of a barcode scanning system to verify product selection
Intervention 3: A simplified risk-assessment—risk-intervention tool for high-alert medications based on socio-technical probabilistic risk assessment (ST-PRA) models of the pharmacy dispensing process

The three interventions were chosen in response to a prior study by the authors[1] that demonstrated significant improvements in medication safety when pharmacists counsel patients, when pharmacies employ barcode scanning for product verification, and when ST-PRA risk models are used to reveal important system relationships, unintended consequences of behavioral choices, and valuable risk-reduction interventions that can guide and accelerate community pharmacy safety improvements.

The study was approved by an Institutional Review Board of Temple University School of Pharmacy.

Scope and Significance

Intervention 1: Patient Counseling

The effectiveness of patient counseling as an error detection and prevention strategy has been well documented in the literature.[1-3] Given that all necessary information about the patient is rarely included on the prescription, the counseling session provides the pharmacist with an opportunity to learn about the patient's chronic and acute health issues, height, weight, allergies, and prior medication use history. Providing pharmacists with these data improves their ability to detect known allergy errors, contraindicated drugs, and out-of-range dosing errors.[3-4] The counseling interaction also allows the pharmacist to detect a possible data entry or drug selection error, verify what the prescriber has told the patient, and assess the consumer's

knowledge of the drug. A 2010 meta-analysis of 43 studies demonstrated a clear link between patient counseling and positive clinical outcomes, such as blood pressure control and quality-of-life outcomes.[5] Effective patient counseling can also significantly reduce patient nonadherence to prescribed therapy, which leads to treatment failures and wasted health resources costing up to $150 billion annually.[2-3,6-7]

Studies have placed patient counseling rates between 8% and 42% according to patient surveys[7-10] and between 43% and 63% according to observational studies.[6,11] However, in a study by Feifer et al.,[12] more than half (58%) of 100 patients contacted by telephone within a week of starting a new medication did not even recall an offer for counseling. Another 11% declined the offer, yielding 69% of patients who did not receive counseling. An additional 12% (39% of patients counseled) were not satisfied with the information received. Of the 81% of patients who did not receive counseling or were dissatisfied with counseling, 75% accepted the calling pharmacist's offer to counsel by telephone.

Another study[13] found that 91% of patients felt that pharmacist-provided counseling was necessary and that written information alone is not enough. But *patient*-requested counseling occurs very rarely, even when no perceived barriers to a pharmacist exist.[14] A study by Kimberlin et al.[15] demonstrated that patients engaged in counseling sessions and asked questions more often if a *pharmacist* was the person who handed the filled prescription to the patient at the point of sale. In fact, having a pharmacist hand the medication to the patient was the strongest predictor of patient counseling, followed by strict state regulations specifying that pharmacists must counsel all patients who fill a new prescription.[15]

These studies suggest several important points: 1) patients may not recognize the offer to counsel, which is often veiled when patients are simply told to "Sign here" without knowing they have declined an offer to counsel, or when patients are asked "Do you have any questions?"; 2) the offer to counsel alone is inadequate to engage the patient in counseling, as is expecting the patient to initiate the counseling; 3) patients are more likely to ask questions if a pharmacist hands them their medication(s); 4) patients are often dissatisfied with the information received during counseling sessions; and 5) most patients are receptive to counseling.

Within the past decade, there has been a shift in the role of the patient, from a passive recipient to an active consumer of health information. An interactive communication process and recognition of the "expertise" patients bring to the encounter is desired,[2] particularly by internet-savvy patients.[16] A literature review of 40 studies[17] (1993-2007) found that information on directions for use, dose, the medicine's name, and indication were more frequently provided during counseling sessions than information on adverse effects, drug interactions, precautions, contraindications, and storage/disposal. However, the information patients desire most with new prescriptions is about adverse effects (58.2%), basic instructions (32.6%), and drug interactions (31%).[13] Within this context, we have designed and evaluated a scripted patient counseling intervention that focuses on safe use of targeted high-alert medications.

Intervention 2: Barcode Scanning Technology and Readiness Assessment

Numerous studies prove the effectiveness and cost benefits of using barcode scanning technology for product verification during the drug dispensing process.[1,18-21] Thus, after the US Food and Drug Administration (FDA) mandate to provide barcodes on most drugs by 2006, many expected a rapid increase in the use of barcode product verification systems. According to a 2006 cross-sectional study of 3,000 community pharmacies from 18 US metropolitan areas, only 53.5% of community pharmacies utilize a barcode scanner for verification/identification of medications.[22] The study also revealed a significantly lower rate of adoption in independent pharmacies (11.5%) compared with chain pharmacies (62.6%). By 2008, 80% of chain pharmacies surveyed used barcode scanners in the prescription process, and two thirds of these chains scanned medications in every store.[23]

Based on the latest available data, the Institute for Safe Medication Practices (ISMP) estimates that the adoption of barcode verification technology in 2012 during manual filling of prescriptions in all community pharmacies is hovering around two thirds, with greater penetration in chain pharmacies (85%) and less penetration in independent pharmacies and supermarket or mass merchant markets (33%). Based on the sheer number of community pharmacies in the US—about 59,000, bar-coding technology for product verification has a long way to go before the market fully penetrates the nearly 19,000 remaining pharmacies.

A 2003 survey by the National Community Pharmacy Association (NCPA) showed that three quarters (78.2%) of respondents believed that barcode technology was somewhat or very important to enhance accuracy and efficiency in pharmacy dispensing.[24] Of those who were not using the technology, almost half (42.2%) thought it was too expensive and one third (30.7%) were satisfied with their current system. Additional details were provided in a 2009 survey[25] of community pharmacies, which showed other factors associated with decisions to implement the technology, including the ease with which the technology fit with the pharmacy workflow, to gain a competitive edge within the industry, and to improve the accuracy in billing third-party payors (thereby decreasing exposure of third-party payor audits on payments). The 2009 survey also provided insight into why community pharmacies have not implemented the technology, other than cost, including uncertainty regarding the 'right' vendor product for their practice site, concerns about inefficient use of staff time, and anticipated difficulties with staff training.

Although researchers have studied the changes in work activities following implementation of new technologies in pharmacy practice,[26-27] little guidance is available to pharmacies on how to best prepare *before* implementing this work-transforming technology. Within this context, we have created a readiness assessment to assist community pharmacies with the planning and implementation of a well-built foundation upon which to support barcode product verification technology. Readiness assessments coupled with action based on the results is an effective strategy for building a resilient foundation and culture before adoption of technologies.

Intervention 3: Prospective Risk Assessment and a Simplified Risk Assessment Tool

Healthcare systems have traditionally relied on root cause analysis (RCA) and failure modes and effects analysis (FMEA) to understand the risks involved in prescribing, dispensing, and administering medications.[28] RCA and FMEA are the most basic types of risk analysis that focus largely on system and process errors. Both offer qualitative information about risk and error, but neither helps quantify the level of risk or model the dependencies and effects of combinations of risks and failures.[29-30]

Sociotechnical probabilistic risk assessment (ST-PRA) is a prospective technique that advances the qualitative work of FMEA and RCA into a quantitative realm by linking process failures with estimates of human error and behavioral norms, yielding a more accurate picture of why and how often these failures affect patient outcomes.[28-31] After quantifying and ranking all relative risks, "what if" scenario testing is used to prioritize interventions that demonstrate an impact to ensure that limited resources are concentrated on interventions with the most benefit. ST-PRA has been used to support decision making in many complex, high-risk industries, because the process allows multiple failures to be considered in combination with one another.[30-33] The process also permits the examination of harmful events of both high and low frequency.[30]

The ST-PRA process begins with a team that possesses deep knowledge about the processes under assessment. The team first builds a detailed process map that shows how work inputs, outputs, and tasks are linked. The process map is used to build an event tree, a graphical risk model that represents the complex relationships among every small process step, the organizational culture, human errors, equipment failures, behavioral norms, and undesirable outcomes.[28-31] The event tree is very detailed and includes all the different combinations that a single task can entail. The event tree links all possible events through an "and" gate or an "or" gate. An "and" gate is used to link events that must all happen (A and B) to produce the studied adverse outcome. An "or" gate is used to link events for which only one of the events must happen (A or B) to produce the adverse outcome. The event tree also displays the order of events and dependencies between them, and it defines the event sequences that could lead to a specific undesirable outcome based on what is currently known about the processes given certain conditions that shape performance.

The ST-PRA team then quantifies the probability of failure or the frequency of occurrence for each event using actual data, when available, or Bayesian statistical methods, which work directly with estimated probabilities. Estimated probabilities are required, because actual rate data for underlying basic events are infrequently available in the precise form needed for classical statistical methods.[1,34] Event tree software then calculates the combinations of failures and the total combined probability of occurrence of the undesired outcome. All unique combinations, often 10,000 or more, that could lead to the undesired outcome are identified and ranked, producing a "risk portfolio" that defines which components of the system are truly important to risk in that they contributed most frequently to the undesired outcome. The risk portfolios are then used to identify the interventions with the greatest impact.

Although the application of ST-PRA in healthcare is relatively new,[1,28-30,35-36] two previous studies using ST-PRA to model medication system risk in long-term care[29] and community pharmacy[1] strongly suggest that it can be used successfully in healthcare to assess risk and the impact of system and behavioral changes on these risks. However, the process is time consuming and requires facilitation by leaders with expertise in ST-PRA risk modeling, group dynamics, human factors, and probability theory. Even with the necessary expertise and time, it may not be practical for every healthcare organization to conduct its own ST-PRA process from start to finish. Thus, we adapted a series of previously developed and validated ST-PRA risk models associated with prescribing and dispensing errors in community pharmacies[1] to create and test a streamlined tool for high-alert medications. The tool, High-Alert Medication Modeling and Error-Reduction Scorecards™ (HAMMERS™), offers community pharmacies a simple yet effective way to identify risks, estimate how often these risks result in potentially harmful errors that reach customers, rank which system features and behaviors most often contribute to the risks, and quantify anticipated change if interventions are implemented.

Methods

Intervention 1: Scripted Patient Counseling

Study Design

This descriptive study used an intervention group and a nonequivalent comparison group to test the frequency, quality, and effectiveness of a loosely scripted counseling intervention for patients who picked up prescriptions at community pharmacies for 11 targeted high-alert medications: warfarin, enoxaparin, oral methotrexate, fenta**NYL** transdermal patches, **HYDRO**codone with acetaminophen, oxy**CODONE** with acetaminophen, insulin glulisine, insulin detemir, insulin glargine, insulin lispro, and insulin aspart. The nonequivalent comparison group included 45 pharmacies, and the counseling intervention group included 18 pharmacies. One day of observation was conducted at each participating pharmacy in both groups. The units of analysis were the point of sale where an offer to counsel may have been made and the counseling session between the pharmacist and patient. Self-reported data were also collected from pharmacists and patients in the counseling intervention group.

Sample Selection and Recruitment

The nonequivalent comparison group of 45 community pharmacies was recruited from a convenience sample in four large cities and nearby suburbs across the US: Phoenix, Minneapolis, Boston, and Philadelphia. Three of the four US census bureau regions were represented: West, Midwest, and Northeast. The patient counseling intervention group of 18 pharmacies was recruited from a convenience sample in three large US cities and nearby suburbs: Philadelphia, Boston, and Boise. Two of the census bureau regions were represented: West and Northeast. Each participating pharmacy was offered a $250 honorarium. The comparison group provided patient counseling according to the pharmacy's current and usual practices. The intervention group provided patient counseling based on the interventional methodology.

Counseling Intervention Methodology

The counseling intervention group was instructed to tell patients who picked up a prescription for one of the targeted medications that a pharmacist would like to speak to them about their medication. For patients who agreed, a pharmacist would provide patient counseling while referencing a safety tips handout designed for consumers that was a component of the intervention. The drug-specific safety tips handout included 10 key actions to help patients detect and prevent medication errors when taking that drug along with key clinical information about the drug. The counseling sessions were loosely scripted in that the pharmacist was asked to select several key safety tips on the handout to discuss with the patient and then encourage the patient to read the safety tips handout in its entirety. The counseling sessions also included details about the drug and directions for use deemed important by the pharmacist or responsive to patient questions. Patients who declined speaking with the pharmacist still received the safety tips handout.

Safety Tips Handouts for Consumers

The safety tips handouts (**Appendix A**) were created and evaluated for accuracy, understandability, and value in improving medication safety. The 10 key actions to help patients detect and prevent medication errors were derived from reports of actual errors submitted to various national and state reporting programs, including the ISMP National Medication Errors Reporting Program, the Pennsylvania Patient Safety Reporting System, the

US Food and Drug Administration MedWatch program, and several commercial databases. The drug information facts were gleaned from reliable drug information resources, including the product labeling. Face validity and content validity of the safety tips and drug information were ensured via review by a professional drug information specialist and an online drug information vendor. Readability, usability, and perceived value of the handouts were determined via survey instruments.

Data Collection Techniques

Direct, undisguised observation was used to collect data at the point of sale and during patient counseling sessions. The observers were healthcare professionals who were oriented to the observation method and trained to be unobtrusive and nonjudgmental to minimize the effects on pharmacy staff. As the pharmacy staff interacted with the patient at the point of sale, the observer recorded data about the offer to counsel the patient and counseling sessions that were carried out. Additional data and field notes were collected regarding the patient identification process and the pharmacy environment. Written informed consent was obtained from pharmacists prior to observation, and verbal informed consent was obtained from patients prior to observation of a counseling sessions. Patients also received a letter with information about the study.

Two survey instruments were created to obtain self-reported data from pharmacists and patients in the intervention group. The patient survey included 21 items within four categories: the visit to the pharmacy, the encounter with the pharmacist, the safety tips handout, and responder demographics. The items were designed to elicit information about the quality and value of the counseling session and handout as well as new information learned about the prescribed medication. The pharmacist survey included 48 items within five categories: demographics about the pharmacy and the pharmacist, the patient counseling encounter, the safety tips handout, and the overall impression regarding the intervention. The items were designed to elicit perceptions about the value of the safety tips handouts and the value of the intervention, its sustainability in community pharmacies, the patient's response to counseling, and the barriers and facilitators to patient counseling. Patients were offered a $10 pharmacy coupon for completing the survey, which could be returned to the pharmacy or submitted anonymously online through a secure web-based survey database. Pharmacists were offered a $10 stipend for completing the survey, which also could be submitted anonymously online.

Intervention 2: Barcode Verification System Readiness Assessment

Instruments

***Readiness Assessment*.** The readiness assessment is composed of 94 self-assessment items organized around five domains: environmental factors; drug labeling, packaging, and nomenclature; drug information; staff competency and education; and culture, quality improvement, and risk management (**Appendix B**). The two domains with the most assessment items—environmental factors, and culture, quality improvement, and risk management—are further categorized into subsections. The 94 assessment items are divided into two sections, one for pharmacy leadership or owners (59 items), and the other for pharmacy staff (35 items). The items in the pharmacy staff assessment are the same or related to the items in the pharmacy leadership/owner assessment, although the latter tool for leaders includes items that are not on the staff assessment. Each assessment is either a prerequisite—a required item that should be in place before implementing a barcode product verification system—or a facilitator—an item not required but which would make it easier to implement a barcode product verification system. The assessment tool includes appendices that provide elements to consider during vendor selection and associated costs.

One pharmacy leadership/owner assessment was completed by each participating pharmacy organization. One or more pharmacy staff assessments were completed, depending on the number of pharmacies owned by the participating pharmacy organizations. The results were entered into a web-based database built and controlled by the authors. Participating pharmacies were able to generate pharmacy-specific or pharmacy organization-specific reports from the database. The assessment workbook provides details to help pharmacies utilize the assessment findings to improve readiness for barcode scanning technology.

Evaluation Survey. Two survey instruments, one for pharmacy leaders and one for pharmacy staff, were used to learn about the perceived value of the assessment tool from participating pharmacies. The leadership survey included 54 items within 10 categories. The staff survey included 40 items within eight categories. The items were designed to elicit perceptions about the tool's purpose, goals, value, directions for use, assessment

items, appendices, and other details. The leadership survey also inquired about the value of the confidential reports generated from the database. Each participating leader and staff was asked to complete a survey.

Scoring Methods

Readiness Assessment. Each self-assessment item had five possible responses using a Likert-type scale, with 1 representing no activity and 5 representing full implementation (**Table 1**). Participants could also choose "Not Applicable" for any of the assessment items. Participating pharmacies received numerical scores based on the numerical value of each response choice after entering their findings into the database, including a total maximum score, total average score for each leadership and staff assessment, component average scores for each domain and subcategory, and an average Likert scale score for each assessment item. The data reports allowed participants to quickly view any differences between leader scores and staff scores for items on both assessments.

For the purpose of descriptive analysis of the aggregate assessment results, the average Likert scale scores were converted to percentages, much like a score that appears on a report card between 1% and 100%. These average scores are often presented in the narrative results in parentheses or listed in tables as the "Average Score." The percent of distribution among the five answer choices, 1-5, is also provided occasionally for clarification within the narrative. The percent of distribution among answer choices has been grouped as follows:

- All **1** and **2** responses are grouped together to describe the percent of participants who had not implemented the item.
- All **3** and **4** responses are grouped together to describe partial implementation of the item.
- All **5** responses are used to describe full, widespread, and/or consistent implementation of the item.

Evaluation Surveys. The survey instruments used a five-point Likert scale to measure the respondents' agreement or disagreement with the assessment items. The surveys also included open-ended questions to determine what the user learned while using the assessment tool and how the tool could be improved.

Sample Pharmacies

Readiness Assessment. A convenience sample of 12 pharmacies representing both chain and independent pharmacies was invited to participate in the readiness assessment. Pharmacy associates, staff pharmacists, pharmacy managers, and pharmacy leadership within these pharmacies were asked to complete the assessment and the evaluation survey.

Intervention 3: Simplified Risk Assessment Tool—HAMMERS™

Software Development

A core team from ISMP and Outcome Engenuity, LLC, which includes experts in medication safety, community pharmacy practice, ST-PRA risk modeling, human factors, and software programming, was formed to develop the HAMMERS™ software. Five ST-PRA risk models developed during a prior study[1] were chosen for use with different types of medication errors. These five master risk models were then used to create Scorecards.

For each Scorecard, a map of every event in the master risk model was created. Each event represented a task, subtask, behavior, system component, or error capture opportunity for which frequency data would be required to compute the metrics of the Scorecards. For events with frequencies that would not vary regardless of the drug prescribed or dispensed, pharmacy characteristics, or staff member attributes, probability values established in evidence-based literature were preset in the software. For events with frequencies that could vary depending on the drug, pharmacy, or staff member, assessment questions were developed and tested for face validity and content validity. Mathematical formulas were written for events that could be calculated by the software based on answers to associated questions.

Working with a conceptual model of the software, the team developed and tested several mathematical models for computing the estimated frequency of occurrence of an undesirable outcome once data populated all the events in a Scorecard. A business logic for software development was created and tested. Data files with preset values, input values, or calculated values for each event in the five Scorecards were created. Sample screen shots were designed, which included user instructions, assessment questions, answer choices, and directions to the software programmer. Answer choices ranged from zero to 100 percent, although upper or

lower control limits on answer choices were set for some assessment questions to prevent over- or under-estimation of the frequency of an at-risk behavior or error capture opportunity. Tables that provide evidence-based error rates, at-risk behavior rates, and failure rates for capturing errors were compiled to help guide the probabilities selected to answer the assessment questions (**Appendix C**). Scoring guidelines were provided to aid with questions that might be misunderstood or not applicable.

Once each Scorecard was developed, a sensitivity analysis was performed to determine the events most predictive of safety and risk. The results of the analysis were used to ensure the output of each Scorecard focused on the most crucial vulnerabilities to be addressed and recommended risk-reduction strategies with a measurable impact. Usability testing of the HAMMERS™ software was conducted, and perceptions regarding the extent to which the software could be used by community pharmacists to achieve the tool's goals were used to modify the software.

Software Testing

Computations using the HAMMERS™ software were tested for accuracy by comparing the top-level risk values obtained with the HAMMERS™ software to risk values calculated by a commercial database software program and a commercial event tree analysis software program. To conduct the comparison to the commercial database software, individually calculated risk values for up to 23,500 different combinations of events that could lead to the top-level risk were entered into the commercial program, and all the risk values were summed. To conduct the comparison to the commercial event tree analysis software, the master risk models were used to create the fault tree structure, and each event in the fault tree was populated with the same or very similar value assigned to it in the HAMMERS™ tool. For up to three input values, the exact probability assigned to an event in the HAMMERS™ tool could not be used in the commercial software due to limitations on the available range from which to select the values. In these circumstances, the estimate closest to the HAMMERS™ tool value was selected. The commercial software then calculated the top-level risk by summing all events under "and" gates [A+B] and by summing, multiplying, and subtracting events under "or" gates [A+B – (AxB)].

Results

Intervention 1: Scripted Patient Counseling

Demographics

***Comparative Group*.** The 45 pharmacies in this group were diverse with regard to location, setting, prescription volume, hours of operation, drive-through services, and staffing on the day of observation (**Table 2**). Sixty percent of the pharmacies were located in states (Massachusetts and Pennsylvania) that require an offer to counsel patients when dispensing prescription medications, and 40% were located in states (Minnesota and Arizona) that mandate patient counseling with all new prescriptions. Observations were conducted between the hours of 7:00 a.m. and 10:00 p.m. for a minimum of 5 hours in each pharmacy, which included observations on Saturday and Sunday. In total, 71 pharmacists were observed in the 45 pharmacies. The pharmacists were diverse with regard to educational credentials, experience, ethnic background, and gender (**Table 3**).

***Intervention Group*.** The 18 pharmacies in this group were diverse with regard to setting and staffing on the day of observation (**Table 2**). Intervention pharmacies were less diverse than the comparative group with regard to location, prescription volume, hours of operation, and drive-through services. Most intervention pharmacies were from the Philadelphia area, filled 701-3,000 prescriptions per week, and were in a state that required an offer to counsel upon dispensing medications. Observations were conducted between 7:00 a.m. and 10:00 p.m. for 5 hours in each pharmacy, which included observations on Saturday. In total, 25 pharmacists were observed in the 18 pharmacies (**Table 3**). The pharmacists were diverse with regard to experience and gender; however, the intervention pharmacists were less often PharmD prepared (16%) than the comparative group of pharmacists (61%) and more often Caucasian (96%) than the comparative group (69%).

Observations at the Point of Sale

Between March and May 2010, 2,733 observations at the point of sale were made in 45 comparison-group pharmacies during which patients and family members or friends picked up filled prescription medications. Between April and May 2012, 487 observations at the point of sale were made in 18 intervention pharmacies.

The consumers who picked up medications in both the comparison and intervention pharmacy groups were diverse with regard to age, gender, and ethnic background.

Observations of Patient Counseling in All Pharmacies

In total, 519 consumers in the comparison-group pharmacies and 111 consumers in the intervention pharmacies were counseled by a pharmacist when picking up a prescription medication. Most consumers received counseling at the pharmacy counter. The drugs for which patients were counseled varied, numbering more than 125 different products. The targeted high-alert medications comprised between 2% and 7% of all the medications for which patients were counseled. Almost all the counseling sessions (93%) were conducted in the open in both intervention- and comparison-group pharmacies.

The most common categories of information provided during the counseling sessions in both the comparison (**Table 4**) and intervention (**Table 5**) pharmacies were directions for use, dose, and drug indication. The least frequent information provided included when to call a doctor, side effects, generic and/or brand names, and special precautions. During the counseling sessions, the pharmacist asked the patient at least one question during 20% of the sessions in comparison-group pharmacies and during 41% of the sessions in intervention pharmacies. The patients asked the pharmacist at least one question during 17% and 24% of the sessions, respectively. The medication vial, bottle, or carton was opened to view the actual product during counseling sessions more often in intervention pharmacies (28%) than in comparison-group pharmacies (2%).

An error or potential error was detected during five of the counseling sessions in the comparison-group pharmacies and during two of the counseling sessions in the intervention pharmacies. Examples include an allergy to the prescribed medication, an inability to swallow the prescribed capsules, incorrect verbal directions from the physician, a wrong medication called into the pharmacy, and a potential self-administration error. Four of the five errors were detected when the medication vial, bottle, or carton was opened to view the actual product.

Overall, consumer attentiveness during counseling was high in all pharmacies, particularly for new prescriptions, and did not vary significantly based on pharmacy characteristics, patient characteristics, or pharmacist characteristics. In the comparison-group pharmacies, the sessions lasted a mean of 1.30 minutes, with 73% conducted in less than 1 minute and 25% lasting 1 to 2 minutes. In the intervention pharmacies, the mean length of the sessions was 1.94 minutes, with 39% lasting less than 1 minute, 34% running 1 to 2 minutes, 20% lasting 3 to 5 minutes, and 6% lasting longer than 5 minutes. The overall quality of the counseling sessions was assessed to be high or moderately high in all but 25% or 23% of the comparison and intervention pharmacies, respectively.

The observers assessed the impact of counseling on pharmacy workload in comparison and intervention pharmacies to be low (60%) or moderate (29%) in most cases. No counseling sessions were judged to have a high impact on pharmacy workload in intervention pharmacies, even when counseling sessions lasted longer than 5 minutes. About 12% of the counseling sessions were judged to have a high impact on workload in comparison-group pharmacies.

Patient Counseling Rates

All medications. In comparison-group pharmacies, patient counseling occurred with 19.0% (519/2,733) of consumers who picked up a prescription medication (**Table 6**); in intervention pharmacies, 22.8% (111/487) of consumers were counseled. Insignificant differences in counseling rates were observed in comparison and intervention pharmacies based on consumer presentation at the pharmacy counter or drive-through window or on consumer demographics, such as age or gender. Variables that resulted in significant differences in patient counseling rates included ethnic and social diversity of the population served by the pharmacies, how the offer to counsel the patient was made, and pharmacy location—particularly with respect to state pharmacy regulations on counseling in comparison-group pharmacies and geographic setting in intervention pharmacies.

Targeted high-alert medications. Patient counseling rates were significantly higher for the targeted high-alert medications dispensed from intervention pharmacies than from comparison-group pharmacies (**Table 6**). Among comparison-group pharmacies, 29.6% (16/54) of consumers who picked up one or more of the targeted high-alert medications were counseled by a pharmacist. Among all intervention pharmacies, 93.9% (31/33) of consumers who picked up one or more of the targeted high-alert medications were counseled by a pharmacist.

Two patients declined to be counseled when picking up prescriptions for **HYDRO**codone with acetaminophen, stating they had taken the medication previously and did not need to be counseled.

Counseling Details by Targeted High-Alert Medication

Insulin analogs (**Table 7**)***.*** In the comparison-group pharmacies, consumers who were counseled by a pharmacist when receiving an insulin analog were primarily educated about whether the insulin was long- or short-acting (100%), the onset of action (50%), timing of insulin administration with meals (33%), and how to store the drug (67%). Consumers counseled in the intervention pharmacies received significantly more information. All (100%) of the observed counseling sessions included education about the drug action, how to measure the dose and inject the medication, timing of drug administration with meals, glucose monitoring, and important safety tips (including checking the insulin before leaving the pharmacy, keeping a log of glucose levels and insulin doses, and calling the doctor about any illness, changes in habits, or new medications). Half (50%) of counseled patients were also educated about mixing insulins, how to differentiate various types of insulin, how to store insulin, safe disposal of syringes, the signs and treatment of hypoglycemia, and what to do if the patient will not be eating due to illness or a medical procedure.

Methotrexate (oral) (**Table 8**)***.*** In the comparison-group pharmacies, consumers who were counseled by a pharmacist when receiving methotrexate were most likely to be asked whether the directions on the medication vial or package matched the doctor's directions (33%) and to be educated about choosing one day of the week to start therapy (33%), never taking the drug for more than 7 consecutive days (33%), common side effects (33%), and when to report side effects to the doctor (33%). In all (100%) observed counseling in the intervention pharmacies, patients were educated about the onset of symptom relief, to never take extra doses to treat symptoms, and which medications to avoid while taking methotrexate. All (100%) were advised to ask their doctor to list the reason for the medication on future prescriptions, request special packaging to promote weekly dosing, tell their doctor and pharmacist about over-the-counter medications they take, choose a consistent day of the week (other than Monday) to take or start the weekly doses, and avoid sunlight. Two thirds (67%) of the patients were also advised to be sure the pharmacist's directions match what the patient has been told by the prescriber, to never take the medication for more than 7 days in a row, and to know the side effects that should be reported to the prescriber.

Warfarin (**Table 9**)***.*** In comparison-group pharmacies, consumers who were counseled by a pharmacist when receiving warfarin were most often instructed to take the medication the same time each day (67%) and to follow the doctor's instructions for periodic lab tests (67%). Some patients (33%) were also educated to keep a record of all dose changes, to keep the instructions near the medication, to call the doctor if they don't hear back about dose changes after holding the medication, to let their doctor know if they start or stop taking any medications, to avoid taking aspirin and NSAIDS, and about bleeding precautions. Consumers who were counseled by a pharmacist when receiving warfarin in an intervention pharmacy were less likely to be counseled about taking the medication the same time every day, keeping a record of dose changes near the medication, and getting regular blood tests. They were more often advised to avoid taking extra doses, tell the doctor about the strength on hand if the daily dose changes, call the doctor if they don't hear back about dose changes after holding the medication, maintain regular exercise and eating habits, follow bleeding precautions, know signs of bleeding or clot formation, and tell their doctor about any medications they start or stop (including aspirin, NSAIDS, and herbals).

Enoxaparin (**Table 10**). In intervention pharmacies, consumers who were counseled by a pharmacist when receiving enoxaparin were all (100%) advised to take the medication the same time each day, avoid the use of aspirin and NSAIDS, tell their physician when they start and stop medications, follow bleeding precautions, know the signs of bleeding or clot formation, and call the physician for injection-site issues. Consumers were also educated about preparing a dose without expelling the air bubble. No consumers were observed being counseled about enoxaparin in the comparison group.

FentaNYL transdermal (**Table 11**)**.** Three quarters (75%) of consumers who were counseled by a pharmacist when receiving fenta**NYL** transdermal in an intervention pharmacy were warned that the drug should be taken by opioid-tolerate patients for chronic pain only. Half (50%) were advised to avoid placement of a patch on broken skin, to take the patch off before applying a new one, to dispose of the patch safely, and to report signs of an overdose to their physician. One quarter (25%) were given application instructions and advised to avoid

patch exposure to heat sources and to avoid wearing the patch during an MRI. No consumers were observed being counseled about fenta**NYL** patches in the comparison group.

HYDROcodone with Acetaminophen/oxyCODONE with Acetaminophen (**Table 12**). Consumers who were counseled by a pharmacist when receiving one of these opioid analgesics in an intervention pharmacy were most often taught to avoid other acetaminophen products (78%), including acetaminophen-combination products (71%), and to prevent and treat constipation (63%). About half were informed about the maximum daily limit of acetaminophen (52%), to read the active ingredients on medication labels to avoid acetaminophen-containing drugs (46%), and to take precautions (46%) due to sleepiness from the effects of the drug. About one third were advised to tell their doctor and pharmacist about all medications they take (33%), check the medication before leaving the pharmacy to avoid a mix-up (35%), know signs of an overdose (39%), and call their doctor for unrelieved pain (38%). Signs of dependence and withdrawal (25%) and safe disposal of unused tablets (30%) were the least frequent information points provided to consumers. No consumers were observed being counseled for these drugs in the comparison group.

Counseling Details by Pharmacy Characteristics

Pharmacy Regulations. In the comparison-group pharmacies, counseling rates varied among the states in which the pharmacies were located (**Table 6**). Counseling rates were below 5% for pharmacies in two cities—Philadelphia (4.2%) and Boston (2.2%)—where only an offer to counsel patients is required by state pharmacy regulations. The counseling rate in Minneapolis was 16.4%, where pharmacy regulations require patient counseling for new medications. The counseling rate was 61.0% in Phoenix pharmacies, where regulations to counsel all patients with new prescription medications is actively monitored by the pharmacy board.

Overall, pharmacies in states that require an offer to counsel provided significantly less information to patients during the counseling sessions than pharmacies in states that require counseling for all new prescriptions (**Tables 4** and **5**). Use of a collaborative tone during counseling, the number of errors detected during the counseling sessions, and the overall quality of the counseling sessions were higher in pharmacies in states that require counseling, not just an offer to counsel.

Setting. In comparison-group pharmacies, the counseling rate did not differ significantly among those located in urban and suburban settings (**Table 6**). No pharmacies were located in rural areas. The impact of counseling on pharmacy workload was rated highest in urban pharmacies, where customer attentiveness as well as length and quality of the counseling session were also high. In intervention pharmacies, the overall counseling rate was highest (29.8%) in pharmacies located in rural settings and lowest (17.9%) in pharmacies located in urban settings. Minor differences with consumer attentiveness, length and quality of the counseling session, and impact on workflow were observed in pharmacies in urban, suburban, and rural areas, but a clear pattern that favored counseling in one location over another did not emerge (**Tables 4** and **5**).

Prescription Volume. In both comparison and intervention pharmacies, the length and quality of the counseling sessions and their impact on pharmacy workflow often increased as the weekly prescription volume increased, up to 6,000 prescriptions per week (**Tables 4** and **5**). In comparison-group pharmacies, pharmacists in very-low-volume and very-high-volume pharmacies used a more collaborative tone while counseling, asked patients more questions, and were asked more questions by consumers. In intervention pharmacies, pharmacists in pharmacies with prescription volumes greater than 1,500 per week also used a more collaborative tone, asked patients more questions, and were asked more questions by consumers. However, in contrast, pharmacists in pharmacies with prescription volumes less than 700 per week never used a collaborative tone and never asked patients any questions.

Location of Counseling. In comparison-group pharmacies, patients being counseled at the pharmacy counter and at a pharmacy drive-through window received very similar types and amount of information about their prescription medications (**Table 4**). Consumers at the counter were more attentive during the counseling sessions, and they asked and were asked more questions than consumers counseled at the drive-through window. The mean length and quality of the counseling sessions at the counter was also higher, but the impact on pharmacy workload was assessed to be higher when counseling occurred at the drive-through window. There were too few observations of counseling at the drive-through window at intervention pharmacies to obtain useful data for comparison.

Counseling Details by Prescription Characteristics

Type of prescription (**Tables 13** and **14**)***.*** In both comparison and intervention pharmacies, consumer attentiveness and the overall quality of the counseling sessions were higher with new prescriptions than with refills. The mean length of the sessions and their impact on pharmacy workload were also higher when counseling consumers for new prescriptions in comparison-group pharmacies. In both pharmacy groups, more information was provided to consumers who were counseled for refills. In both groups, pharmacists also infrequently opened the vial, bottle, or carton to view the actual product while counseling patients for refills.

Counseling Details by Patient Characteristics

Consumer Attentiveness (**Tables 13** and **14**)***.*** Overall, customer attentiveness during counseling sessions was high in both the comparison and intervention pharmacies. In both pharmacy groups, when consumer attentiveness was highest, so was the mean length and quality of the sessions. Consumer interest waned as the length and quality of the sessions decreased. In both groups, the least-attentive consumers received less information overall about the medications compared with the most-attentive consumers. In the intervention pharmacies, the vial was opened more often with highly attentive consumers. In both pharmacy groups, all the errors identified during counseling occurred with the most-attentive consumers.

Ethnic and Social Diversity of Patients (**Tables 13** and **14**)***.*** In both comparison and intervention pharmacies, higher rates of patient counseling were observed in pharmacies that served populations with low or moderate ethnic and social diversity than in pharmacies with a highly diverse patient population. In the comparison group, consumers asked the most questions about their medications during the counseling sessions. However, the overall quality of the counseling sessions decreased as ethnic and social diversity in the patient population increased. In the intervention group, counseling sessions in pharmacies that served the highest diversity of patients were lowest in mean length (1.17 minutes) and quality.

Counseling Details by Pharmacist Characteristics

Education (**Tables 13** and **14**)***.*** In the comparison-group pharmacies, there were no significant differences overall between PharmD- and BS/MS-prepared pharmacists' counseling, particularly with regard to the type of information provided, customer attentiveness, the length and quality of the counseling sessions, and the impact on pharmacy workflow. In the intervention pharmacies, BS/MS-prepared pharmacists tended to provide information regarding brand names, drug indication, dose, directions for use, special precautions, and when to call the doctor more often than PharmD-prepared pharmacists, whereas PharmD-prepared pharmacists tended to provide the generic name and side effects more often than BS/MS-prepared pharmacists.

Years of Experience (**Tables 13** and **14**)***.*** In comparison-group pharmacies, consumer attentiveness tended to decline as the counseling pharmacists' years of experience increased. Pharmacists with more than 15 years of experience held the shortest counseling sessions and scored lowest regarding overall quality of the sessions. The opposite was true in the intervention pharmacies. Pharmacists with fewer than than 10 years of experience had less-attentive consumers during counseling than did pharmacists with more than 10 years of experience. They also asked fewer questions of patients and scored lower on the mean length and quality of the sessions than did pharmacists with more than 10 years of experience.

How the Offer to Counsel Was Made (**Table 6**)***.*** In both comparison and intervention pharmacies, patient counseling rates were significantly higher (83.6% and 94.4%, respectively) when consumers were told by the sales clerk or pharmacy technician that a pharmacist would like to speak with them or when a pharmacist initiated the counseling session at the point of sale. Significantly lower counseling rates (range 0% to 9%) were observed in all pharmacies when the sales staff asked patients if they had any questions or would like to speak to a pharmacist or when consumers were asked to sign a paper or electronic form to decline counseling.

Patient Survey Instrument Results

During a 4-week period in April and May 2012, 267 patients from the 18 intervention pharmacies completed an evaluation survey regarding the safety tips handout and/or their experiences during patient counseling. Patients were diverse with regard to gender, age, educational level, and race, although respondents were more often white, female, and between the ages of 36 and 55 and had a high-school education or some

college education. All but six patients (2%) received a safety tips handout during the pharmacy visit. The medication about which they were counseled was newly prescribed for 20% of the patients.

Patients' overall impressions of the counseling sessions and safety tips handouts were positive (**Tables 15** and **18**). Ninety-seven percent of patients rated the counseling session as excellent (78%) or good (19%). Fifty-nine percent of patients reported learning something new about the medication during the counseling session, and 82% felt they were less likely to make a mistake after being counseled. Patients receiving methotrexate were more undecided or less confident that the counseling session would help reduce the risk of an error.

The safety tips handout provided to patients was read in its entirety by 57% of respondents and in part by another 26% before completing the survey. Of the 15% who had not read the handout before completing the survey, 91% reported that they intended to read it later. Two percent (four patients) of respondents said they did not intend to read the handout, citing prior knowledge of the drug from long-term use or familiarity with the drug as a healthcare professional. Ninety-four percent of patients felt the handouts provided great information (34%) or good information to know (60%). Overall, 97% felt the information in the handouts was provided in a way they could understand. The patient's education level, ranging from unfinished high school to a doctorate or professional degree, did not account for significant differences in understanding the information among all respondents, nor did ethnicity.

Similar to the perceived effectiveness of the counseling sessions, 54% of all patients reported learning something new after reading the handout (**Tables 15** and **18**). Examples can be found in **Table 16**. Differences in learning between patients new to the drug therapy and those who had taken the drug previously were significant. Eighty-two percent of patients taking the drug for the first time learned something new after reading the handout, whereas 48% of patients who had previously taken the medication reported learning something new after reading the handout. Overall, 85% felt they were less likely to make a mistake with the medication because they had read the handout. Seventy-six percent of patients felt they would keep the handout for occasional reference; 6% would not keep it; the remaining 18% were uncertain.

Additional details regarding patients' impressions of the counseling sessions and safety tips handouts for each targeted medication can be found in **Tables 17** and **18**.

Pharmacist Survey Results

Nineteen of approximately 50 pharmacists from the 18 participating pharmacies completed the evaluation survey, for a response rate of about 38%. Respondents' pharmacies were diverse with regard to prescription volume and setting, and respondents were diverse with regard to gender, educational background, and experience, which ranged from less than 1 year in community pharmacy to more than 16 years (median 11-15 years). Half (53%) of the responding pharmacists reported that they were able to always or often counsel patients picking up the targeted high-alert medications.

Recognizing that responses may have differed among patients, participating pharmacists reported an overall positive response to the counseling sessions and the safety tips handouts (**Table 19**). Participating pharmacists' overall impression of the safety tips handouts from the consumer's perspective was positive; 95% felt the information in the handouts was great or good information to know. The strongest barriers to patient counseling (**Table 20**) included high pharmacy workload, a hurried consumer, prior patient knowledge of prescribed medication, and lack of access to patients who had family or friends pick up their prescription. The weakest barriers to patient counseling included pharmacist disinterest, unreimbursed pharmacist time, and lack of privacy for counseling. Consumer disinterest, an ill patient, child, or family member, and refusal to be counseled were perceived as moderate or uncertain barriers. Pharmacist disinterest was perceived by BS/MS-prepared pharmacists to be a stronger barrier to patient counseling than reported by PharmD-prepared pharmacists, all of whom said it was never a barrier.

Conditions that strongly facilitate patient counseling (**Table 21**) included using the safety tips handouts as a counseling guide and telling patients that a pharmacist wanted to talk to them rather than asking if they had any questions. Pharmacists also believed that their interest in teaching and their patients' trust in them helped to bring about patient counseling, although PharmD-prepared pharmacists found these factors to be stronger facilitators than BS/MS-prepared pharmacists. The patient's interest in learning, particularly about a new

medication, and familiarity with the pharmacist were ranked as moderately strong facilitators. BS/MS-prepared pharmacists were less likely to believe that familiarity between a pharmacist and patient facilitated the counseling process.

Ninety percent of the pharmacists found the safety tips handouts for patients and the counseling sessions to be of high value, and the remaining 10% found them to be of moderate value (**Table 19**). More than three quarters reported that the safety tips handouts were also highly useful to the pharmacist to help guide the counseling process; 5% reported low usefulness for this purpose. Most participating pharmacists also reported positive responses from patients and confidence that the counseling sessions and handouts would reduce the risk of medication errors. Eighty-eight percent of pharmacists reported a high (76%) or moderate (12%) belief that patients would be less likely to make a mistake when taking the medication after counseling and/or reading the safety tips. Eighty-nine percent reported high (58%) or moderate (31%) confidence that patients learned something new from the counseling session or safety tips handout that would help them take the medication properly. All but 5% of pharmacists reported that patients seemed interested in learning about the targeted medications.

In general, most pharmacists reported that pharmacy workload was manageable despite the increased frequency of patient counseling for high-alert medications. If provided with safety tips handouts for high-alert medications after the study, all responding pharmacists reported that they would continue to counsel patients and provide handouts, particularly for new prescriptions. Eighty percent of the pharmacists believe that such a practice could be sustained in community pharmacy practice.

Intervention 2: Barcode Verification System Readiness Assessment

Sample Pharmacies

Readiness Assessment. A convenience sample of five pharmacies from five states—Massachusetts, Maine, New Hampshire, Washington, and Florida—participated in the assessment intervention from among a subset of 12 pharmacies initially invited to participate, yielding a 42% response rate. This sample included supermarket chain pharmacies, independent pharmacies with a single store, and independent pharmacies with multiple stores. The volume of prescriptions filled at these stores ranged from less than 700 up to 6,000 prescriptions per week. Refer to **Tables 22**, **23**, and **24** for a complete respondent profile. Compared with a national profile, the set of pharmacies that participated in the assessment was not representative of all US community pharmacies, given the small sample size. The five participating pharmacies each completed one leadership assessment (n=5) and one or more pharmacy staff assessments (n=13), for a total of 18 assessments.

Evaluation Survey. Among the five participating pharmacies, 13 of 18 leaders and staff (n=4 leaders, n=9 staff) completed an evaluation survey after utilizing the readiness assessment to provide feedback regarding the perceived value of the assessment tool, yielding a 72% response rate. Staff participants included pharmacy associates, staff pharmacists, pharmacy managers, and pharmacy leadership.

Readiness Assessment

General Results. Individual scores for perceived readiness by pharmacy leaders/owners ranged from 41% to 80% (mean 65%). The scores for the staff readiness assessment ranged from 59% to 91% (mean 77%). Both leaders and staff scored themselves highest in domains related drug information (staff 92%, leaders 72%), the culture (staff 86%, leaders 71%), the physical environment (staff 81%, leaders 76%), and the technology environment (staff 80%, leaders 79%) (**Table 25**). Overall, scores for the domains and the entire assessment tended to be higher for staff than leaders in large part because the staff assessment contained fewer items, particularly those associated with resource allocation and use of data from the technology to improve safety. If the additional items in the leadership assessment are removed so that both are measuring the same items, the scores are much closer: an average of 71% for leaders compared with an average of 77% for staff. The lowest and highest scoring individual items, and those with the largest gap between staff and leader scores, can be found in **Table 26**.

Environmental Factors. Most items related to the technology environment, including successful prior experiences with technology and its integration, received high scores from both staff and leaders. However, leaders (88%) were more confident than staff (65%) that recovery and back-up plans associated with

technology failures were being regularly tested in pharmacies. The results may indicate that certain frontline staff are not involved in this process. However, the differences in scores may also suggest that leaders need to apprise frontline staff of technology failure back-up plans and involve them in their testing so they can function effectively in the event of a failure.

Most items related to the physical environment also received high scores from both leaders and staff, although staff (82%) appeared to be more certain than leaders (64%) that consideration had been given to where computer terminals, docking stations, battery chargers, and other associated equipment would be placed to support the natural workflow.

One of the lowest staff scores (35%) for any assessment item was associated with whether the impact of a barcode product verification system on time requirements, work rhythm, and job responsibilities had been evaluated. The assessment item suggested comparing a flowchart of the hypothetical dispensing process with barcode scanning against a flowchart of the current dispensing process without the technology. Overall, 39% indicated that such a comparison had not occurred, 15% said it had been done in part, and 15% said a full comparison had been accomplished throughout the pharmacy organization. Also, leaders (68%) were less sure than staff (88%) that pharmacists and pharmacy associates were consistently following existing processes. Variations in the way prescriptions are filled, checked, and dispensed make the application of technology difficult.

Labeling, Packaging, and Nomenclature. Overall, staff scored items in this domain higher than leaders, mainly because leaders had four additional assessment items not scored by staff. Several of these items received low scores, including anticipating the need to place a bar-coded label on return-to-stock products (48%) and identifying procedures for testing barcodes on new products to ensure they are scannable and accurate (48%). Leaders and staff generally agreed that wholesaler labels, auxiliary or warning labels, and any markings placed on opened stock bottles do not typically hide the manufacturer's barcode. Scores were variable for staff (60%) and leaders (40%) for establishing a method to add pharmacy-compounded drug products to the drug file so that a scannable barcode on the label can be generated, suggesting that frontline staff may be an excellent resource when developing new procedures associated with technology.

Drug information. On average, staff (94%) believed that drug information updates, which include national drug code (NDC) numbers and product images, were received and loaded in the pharmacy computer more consistently than leaders (72%) associated with the same pharmacies. Only 40% of the leaders, but 77% of staff, indicated that both NDC and UPC codes are listed for all drugs in the pharmacy computer. Because the leaders and staff work in the same five participating pharmacies, the variation suggests possible overestimation by staff and uncertainty by leaders.

Staff Competency and Education. Staff and leaders agreed that the periodic use of pharmacy agency staff or per-diem staff is minimized, with 23% and 40%, respectively, noting at least partial compliance with such a policy and another 60% or more indicating full compliance in all stores. The lowest scores in this domain for both staff (34%) and leaders (52%) are associated with whether, in the past year, interactive discussions have been held with frontline pharmacy staff about potential anxieties and job dissatisfaction related to the use of barcode technology. Examples provided in the assessment tool include anxieties and job dissatisfaction related to loss of control over certain aspects of the job that were previously important to staff, degradation of clinical skills that are replaced by technology, suspicions about technological capabilities, concern about potential tracking of individual medication error rates, and unchecked optimism and complacency due to reliance on technology. If these issues are not addressed, the risk of circumventing or ignoring the technology is high. Low scores (ranging from 52% to 58%) were also observed for items associated with educational programs or discussions with both staff and pharmacy managers about the value of barcode technology.

Culture, Quality Improvement, and Risk Management Processes. The leadership planning category under this domain uncovered numerous weaknesses in planning for barcode scanning technology. Whereas high scores (88%) were received for leadership's commitment to expanded use of proven technology, low scores (60%) were received for leadership's commitment to allocating the necessary resources for the technology. Without allocation of appropriate resources, leadership's commitment to barcode scanning technology is meaningless. Leaders also reported low compliance (32%) with establishing criteria for evaluating vendors'

stability, experience, service, and specific technological characteristics of a barcode scanning system. Many leaders (at least 40%) reported that they had not established a core team to make recommendations regarding vendor selection, clinical support, and technology requirements or to visit other pharmacies currently using any barcode scanning systems under evaluation.

The culture category under this domain generally received high scores from both leaders and staff. Staff scores were generally higher than leader scores for the same items. For example, more staff (97%) than leaders (84%) felt that pharmacy leadership had created a safe environment for pharmacy staff to report risks and errors. Likewise, more staff (97%) than leaders (80%) said that staff report and openly discuss errors without undue embarrassment or fear of reprisal from peers or leadership. The leaders' scores were lower primarily because numerous participants had selected the lowest possible score for this item, whereas all staff had selected the highest score. The lowest scoring item (32% leaders, 58% staff) in this section evaluated whether discussions had been held with frontline pharmacists and pharmacy associates to prepare them for increased error detection capabilities with barcode product verification systems. Such efforts are crucial to prevent defensive attitudes when the data becomes available after technology implementation is reviewed.

The largest gap between staff scores and leader scores was observed for the item associated with communicating and celebrating medication safety objectives when met. Apparently, staff (92%) communicate and celebrate safety successes on a local level more often than leaders (60%) do on a corporate level. The lowest scoring item for both leaders (56%) and staff (68%) asked whether leaders or their designees periodically hold focus groups with frontline staff for "off-the-record" discussions to learn about perceived problems with the dispensing systems. Such a format for sharing and learning about risks is invaluable when new technology is introduced.

In the leader-only section on using data to improve medication safety, most (84%) leaders reported that they were very interested in being able to intercept potential errors before they reach patients. Yet, many had not planned to allocate time and resources to analyze and use the data generated by the barcode technology to enhance and improve the medication dispensing system. Few leaders (28%) had anticipated the time and resources needed to analyze error data from the barcode scanning system. Even more revealing is that 40% of the leaders reported that a resource allocation plan for this purpose is "not applicable." Another 20% reported that only a partial analysis of the data is being considered. Data from barcode scanning technology are replete with information regarding system weaknesses and unsafe practice habits that should not be overlooked.

Post-Utilization Evaluation Survey

Analysis of the post-utilization surveys suggest that leaders and staff felt the directions for using the tool, entering assessment findings into the database, and generating reports were clear and easy to follow. Overall, they felt the tool included meaningful assessment items and was comprehensive and well organized, and they would recommend its use to colleagues. No suggestions were made for topics or items that should be removed or added to the tool. Minor edits were suggested and made for several of the Appendices. Participants provided numerous examples of new information learned from using the assessment tool (**Table 27**).

The lowest-scoring item among participating staff (4.0 of 5.0) was associated with agreement that the knowledge gained from completing the assessment was worthwhile. One respondent commented that he did not understand why frontline pharmacy staff need to complete the assessment, because they are not part of the decision-making process for technology implementation. As a result, the assessment directions were edited to better explain the need for participation of staff with first-hand knowledge of the pharmacy dispensing process, workflow, and division of labor among pharmacy staff.

The lowest-scoring item among pharmacy leaders (4.25 of 5.0) was associated with agreement that an Appendix that compiled basic information about the costs associated with different vendors' products was valuable. A participant suggested adding more detailed cost information, comparing the benefits that each vendor's product, and covering additional details for a few systems as examples. However, additional details regarding costs and comparisons of each vendor's system are considered proprietary information and were outside the scope of this intervention. Showcasing a few vendor's systems, which was suggested, also was not an option, given the appearance of unfair marketing advantage and misrepresentation that the systems selected for showcasing are endorsed by the authors or funding source (and those not selected are not endorsed).

Intervention 3: Simplified Risk Assessment Tool—HAMMERS™

Software Development

HAMMERS™ was developed through a Windows Presentation Foundation framework, using Sequel Server Compact Addition databases to store necessary information about the master risk models. The business logic, which includes programming codes for preset values, input values from responses to assessment questions, and calculation formulas, resides within the application, allowing intended users in a community pharmacy to download the software and use it as a freestanding application. Detailed instructions for use of the software were developed and tested for understanding, and a companion workbook (**Appendix C**) was created to guide the use of the software.

Five Scorecards are available in the application, each for use with a specific type of medication error, including prescribing errors, wrong patient and wrong drug data entry errors, prescription filling errors, and dispensing errors at the point of sale. A short description of each Scorecard can be found in **Table 28**.

With the exception of wrong patient errors, the Scorecards prompt users to choose a high-alert medication or class of medications on which to focus (**Table 29**). However, HAMMERS™ can be used to assess the risks associated with *any* medication or class/group of medications.

The tool requires pharmacy staff to answer predetermined questions about how often certain process steps and practices occur and how likely staff would be to detect an error, given the circumstances described in the questions. To populate the required fields, users are presented with a wizard-style dialog in a question-and-answer format. All assessment questions in the Scorecards were tested to ensure face validity and content validity by recognized subject matter experts, including community pharmacy practice pharmacists, pharmacy students, ST-PRA process experts, and medication safety experts.

Once all questions have been answered, the application generates a report using all inputs provided by the user and preset in the software (**Table 30**). The report includes:

- An estimate of how often the specific type of medication error with the chosen medication reaches patients, including a frequency based on prescription volume (e.g., 2.64 errors every month) and an overall error rate (e.g., 0.0045678);
- Various tables and bar graphs depicting the most frequent and significant process steps and practices contributing to these errors;
- A list of suggested interventions that can reduce the risks identified in the Scorecard.

The suggested interventions in the HAMMERS™ reports are informed by the results of a sensitivity analysis that identified the following strategies as producing the largest error minimization:

- Process changes associated with patient counseling
- Process changes associated with patient identification
- Redundancies, particularly associated with data entry
- Reductions in at-risk behaviors
- Improved access to information, particularly about the patient's clinical condition
- Use of certain technologies, including automated dispensing, barcode scanning, pill imaging, electronic prescriptions, and prescription scanning

Users are encouraged to test the impact of planned risk-reduction strategies by answering the assessment questions again, this time anticipating the effects of the planned strategies. A new report reflecting the planned strategies can be generated and compared with the initial report, thus demonstrating the anticipated overall impact of the planned strategies.

Software Testing

The results from testing the accuracy of HAMMERS™ computations can be found in **Table 31**. The differences in computation methods and range of available input values with the commercially available software and the HAMMERS™ tool explained slight variations among the results, which were deemed clinically insignificant and inconsequential for the intended purpose of the HAMMERS™ tool. Repeating the same test twice resulted in

unchanged outputs, suggesting consistently accurate HAMMERS™ computations that can be relied upon to guide the risk assessment process and choice of risk-reduction interventions.

Discussion

Community pharmacy practice entails much more than just dispensing medications. It involves preventing, identifying, and resolving drug safety problems and promoting health through safe and effective medication management therapy. The three Interventions tested in our study are at the very heart of these practices: patient counseling, building a strong foundation upon which to maximize barcode scanning technology, and an effective, streamlined risk assessment process that can identify vulnerabilities while accommodating unique differences from pharmacy to pharmacy and from time to time.

Intervention 1, mandatory scripted patient counseling, proved to be an effective and well-accepted model for patient education that should be considered in all community pharmacies. Given time constraints on pharmacists, patient counseling efficiency and impact can be improved by 1) providing tools for pharmacists to use during the counseling sessions to ensure they include the most crucial information, 2) providing materials that can be given to consumers before they leave the pharmacy, and 3) mandating patient counseling only for high-alert medications. Although all consumers should continue to be offered the opportunity for counseling, pharmacists may be able to prevent serious errors more often by concentrating counseling efforts on those taking high-alert medications. Furthermore, state boards of pharmacy should consider revisions in current regulations to mandate counseling when patients fill new prescriptions for a high-alert drug—an offer to counseling is not effective nor is a mandate without periodic evaluation of compliance by the licensing bodies.

Intervention 2, a Barcode Verification System Readiness Assessment, demonstrates the overall value of a readiness assessment and its ability to predict and thereby prevent technology problems when implementing the technology in community pharmacies. Prior studies show that more than 5% of medications first selected to fill prescriptions are wrong,[37] and at least 75% of these wrong drug or wrong dose errors are captured and corrected using barcode scanning technology.[19] In our study, use of the readiness assessment disclosed vulnerabilities along with numerous differences between the perceptions of staff and leaders regarding readiness for the technology that can be used to strengthen the foundation before implementing the technology. Healthcare technology failures and the organizational discord that follows are typically rooted in basic mismanagement and inadequacies in preparation.[38] The stories of technology failures are peppered with unrecognized system-based problems that led staff to circumvent the technology. The direct economic loss to the organization often exceeds its initial investment and includes less-tangible costs associated with lost opportunity. Assessing readiness for barcode scanning and using the results to plan for the technology are crucial steps every community pharmacy considering adoption of the technology should take.

Intervention 3, HAMMERS™, is a robust tool that helps community pharmacies uncover important and largely correctable dispensing system vulnerabilities identified by the people who work within those systems. The tool quantifies human error probabilities and at-risk behavior frequencies that combine and contribute to dispensing system failures and the overall incidence of preventable adverse drug events. The tool allows community pharmacies, perhaps for the first time, to identify pathways prone to technological, process, or behavioral failures; important system relationships; unintended consequences of behavioral choices; and valuable risk-reduction interventions that can guide and accelerate community pharmacy safety improvements. The Scorecards represent a tool for shared understanding of the failure pathways that lead to harm, facilitating communication, shared goals, trust, and agreement among staff, because everyone's contributions are represented. HAMMERS™ allows providers to identify which system attributes and failures have the highest impact on errors so that they can focus their resources on interventions most likely to benefit patients. Community pharmacies will be more willing to adopt proposed interventions, because they can appreciate the causes of errors and perceive the utility, in quantifiable terms, of the recommended interventions and best practices. Given that this level of detail is not currently available from any other source, HAMMERS™ has the potential to become the foundation of safety improvement programs in community pharmacies.

Limitations

This study tested three interventions in close to 70 community pharmacies across the US. However, results are not generalizable to all community pharmacies due to differences between the participating pharmacies and national demographics for all US community pharmacies. Recruitment of participants was not conducive to a

stratified random selection method and large sizes. Although the pharmacies, pharmacists, and consumers in the study were diverse, the participating pharmacies represent a convenience sample, and the participating pharmacists and consumers represent the demographics within the convenience sample, not necessarily the national aggregate. Constraints associated with conducting the study necessitated a convenience sample from just a few demographic regions. With Intervention 1, additional limitations include a study design using nonequivalent groups and 1 year between data collection within each group. With Intervention 2, the sample size of pharmacies that completed the barcode verification system readiness assessment was smaller than planned, given constraints associated with a small pharmacy chain that was unable to serve as a participant. Overall, the implication is that the study results could differ in pharmacies not included in the study.

Conclusion

This study demonstrates the strength and value of three interventions and their application in community pharmacies; their advantages over current practices and tools; and their capabilities to help prevent patient harm, particularly with high-alert medications. We anticipate that their use will vastly improve patient education, prepare for barcode scanning technology, identify risks, predict adverse outcomes, and evaluate the effectiveness of interventions. The broad applicability of patient counseling, barcoded product verification system readiness, and risk assessment should help secure interest in utilizing the interventions to improve community pharmacy practices nationwide.

References

1) Cohen MR, Smetzer JL, Westphal JE, et al. Risk models to improve safety of dispensing high-alert medications in community pharmacies. *J Am Pharm Assoc* 2012;52:584-602.

2) Shah B, Chewning B. Conceptualizing and measuring pharmacist-patient communication: a review of published studies. *Res Social Adm Pharmacy* 2006;2(2):153 -85.

3) Guirguis LM, Chewning BA. Role theory: literature review and implications for patient-pharmacist interactions. *Res Social Adm Pharmacy* 2005;1:483-507.

4) Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997: 277(4):312-7.

5) Nkansah N, Mostovetsky O, Yu C, et al. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns. *The Cochrane Collaboration* The Cochrane Library, 2010; Issue 7.

6) Svarstad BL, Bultman DC, Mount JK. Patient counseling provided in community pharmacies: effects of state regulation, pharmacist age, and busyness. *J Am Pharm Assoc* 2004;44(1):22-9.

7) Erickson J. The cost of medication noncompliance. *J Am Assoc Preferred Provider Organ* 1993: 3(2):33-4,38-40.

8) Perri M, Kotzan J, Pritchard L, et al. OBRA '90: the impact on pharmacists and patients. *Am Pharm* 1995;NS35:24-28,65.

9) Morris LA, Tabak ER, Gondek K. Counseling patients about prescribed medication: 12-year trends. *Med Care* 1997;35:996-1007.

10) Nau DP, Erickson SR, Medication safety: patient's experiences, beliefs, and behaviors. *J Am Pharm Assoc* 2005;45(4):452-7.

11) Flynn EA, Barker KN, Berger BA, et al. Dispensing errors and counseling quality in 100 pharmacies. *J Am Pharm Assoc* 2009;49:171-80.

12) Feifer RA, Greenberg L, Rosenberg-Brandt S, et al. Pharmacist counseling at the start of therapy: patient receptivity to offers of in-person and subsequent telephonic clinical support. *Popul Health Manag* 2010;13(4):189-93.

13) Kruger JL, Hermansen-Kobulnicky CJ. Patient perspective of medication information and barriers to asking pharmacists questions. *J Am Pharm Assoc* 2011;51(4):510-19.

14) Hirsh JD, Oen A, Robertson S, et al. Patient request for pharmaceutical counseling and satisfaction: automated prescription delivery system versus regular pick-up counter. *J Am Pharm Assoc* 2011;49(1):73-7.

15) Kimberlin CL, Jamison AN, Liden S, et al. Patient counseling practices in the US pharmacies: effects of having pharmacists hand the medication to the patient and state regulations on pharmacist counseling. *J Am Pharm Assoc* 2011;51(4):527-34.

16) McMullan M. Patients using the Internet to obtain health information: how this affects the patient-health relationship. *Patient Educ Couns* 2006;63(1-2):24-8.
17) Puspitasari HP, Aslani P, Krass I. A review of counseling practices on prescription medications in community pharmacies. *Res Social Adm Pharm* 2009;5(3):197-210.
18) Aspden P, Wolcott JA, Bootman JL, et al. editors. *Preventing medication errors: quality chasm series*. Institute of Medicine, Committee on Identifying and Preventing Medication Errors. Washington, DC: The National Academies Press; 2007.
19) Maviglia SM, Yoo JY, Franz C, et al. Cost-benefit analysis of a hospital pharmacy barcode solution. *Arch Intern Med 2007*;167(8):788-94.
20) Poon EG, Cina JL, Churchill W, et al. Medication dispensing errors and potential adverse drug events before and after implementing bar code technology in the pharmacy. *Ann of Int Med* 2006;145(6):426-34.
21) Flynn EA, Barker KN, Pepper GA, et al. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. *J Am Pharm Assoc* 2003;43(2):191-200.
22) Skrepnek GH, Armstrong EP, Malone DC, et al. Workload and availability of technology in metropolitan community pharmacies. *J Amer Pham Assoc* 2006; 46(2):154-60.
23) Lockwood W. The chain market report. *Computer Talk for Pharmacists* 2008. Accessed on July 15, 2012 at: www.computertalk.com/content/view/208/.
24) West DS, Carper B, Hoey D, et al. 2003 NCPA-Pfizer digest. National Community Pharmacists Association and Pfizer Inc. 2003. Accessed on June 15, 2012 at: www.ncpanet.org/members/pdf/2003digest.
25) Institute for Safe Medication Practices. ISMP survey on barcode scanning technology for medication selection verification. *ISMP Medication Safety Alert!* Community/Ambulatory Care Edition. September 2009;8(9):4.
26) Baker GE, Grussing PG, Stewart JE. Pharmacist work activities before and after pharmacy department computerization. *Am J Hosp Pharm* 1992;49:382–6.
27) Murray MD, Loos B, Tu W, et al. Effects of computer-based prescribing on pharmacist work patterns. *J Am Med Inform Assoc* 1998;5:546–53.
28) Battles JB, Kanki BG. The use of socio-technical probabilistic risk assessment at AHRQ and NASA. In: Spitzer C, Schmocker U, Dang VN, editors. *Probabilistic safety assessment and management*. 4th ed. Berlin: Springer; 2004;2212–7.
29) Comden SC, Marx D, Murphy-Carley M, Hale M. Using probabilistic risk assessment to model medication system failures in long-term care facilities. Accessed on July 1, 2012 at: www.ahrq.gov/downloads/pub/advances/vol2/Comden.pdf.
30) Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs: an introduction to socio-technical probabilistic risk assessment in healthcare. *Qual Saf Health Care* 2003;12(suppl 2):33–8.
31) Marx DA, Westphal JE. Socio-technical probabilistic risk assessment: its application to aviation maintenance. *Int J Aviat Psychol* 2008;18:51–60.
32) Stamatelatos M, Apostolakis G, Dezfuli H, et al. Probabilistic risk assessment procedures guide for NASA managers and practitioners. Accessed on October 1, 2012 at: www.hq.nasa.gov/office/codeq/doctree/praguide.pdf.
33) Garrick BJ, Christie RF. Probabilistic risk assessment practices in the USA for nuclear power plants. *Saf Sci* 2002;40:177–201.
34) Bier VM. Challenges to the acceptance of probabilistic risk analysis. *Risk Analysis* 1999;19:703–9.
35) Stockwell DC, Slonim AD. Quality and safety in the intensive care unit. *J Intensive Care Med* 2006;21:199–210.
36) Wreathall J, Nemeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *Qual Saf Health Care* 2004;13:206–12.
37) Koutnik E. Bar coding: working toward error-free pharmacy. *Pharmacy Times* Sept 1, 2003. Accessed on August 2, 2012 at: www.pharmacytimes.com/publications/issue/2003/2003-09/2003-09-7372.
38) Silverstein S. Examples of common, costly, and preventable information technology failures. Hospital Information and Communication Technology Projects 2007; Drexel University, PA: Philadelphia. Accessed on July 15, 2012 at: www.ischool.drexel.edu/faculty/ssilverstein/cases/.