Final Report

APPLIED STRATEGIES FOR IMPROVING PATIENT SAFETY (ASIPS)

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Abstract

Purpose: Applied Strategies for Improving Patient Safety (ASIPS) was a collaborative effort among Colorado organizations and agencies to increase error reporting by primary care clinicians, analyze the causes and effects of those errors, and reduce the incidence of errors.

Scope: ASIPS collected and analyzed medical error reports from clinicians and staff in two practice-based research networks—CaReNet and the High Plains Research Network. Patients were not participants.

Methods: We categorized reports of errors using a proprietary taxonomy and analyzed these coded reports. Secondary data sets were reviewed to help understand the scope of errors in primary care. A Clinical Steering Committee and Learning Groups reviewed results, recommending next steps and relevant interventions.

Results: The 3-year ASIPS reporting period yielded 854 voluntary reports submitted by telephone (9%), web (28%), and paper (63%). Diagnostic test errors appeared in 47% of reported events; medication errors appeared in 35.4%; and communication errors appeared in 70.8%. Nonclinician staff were willing to report errors. Confidential reports were more likely to provide complete information about errors, and 67% of reports were made confidentially. A subanalysis of 608 reported events showed that 6.4% were associated with discomfort or inconvenience to patients, 9.0% were associated with an increased risk to the patient or others, and 10.2% were associated with known clinical harm to the patient. Although participants reported that the system was easy to use, lack of time and competing demands were barriers to reporting. Two small technology-based interventions failed to demonstrate improvement in targeted errors.

Key words: medical errors, practice-based research, primary healthcare

Purpose

Applied Strategies for Improving Patient Safety (ASIPS) was a collaborative effort among numerous organizations and agencies in Colorado to increase error reporting by primary care clinicians, analyze the causes and effects of those errors, and reduce the incidence of errors. The setting for ASIPS was two practice-based research networks, CaReNet and High Plains Research Network. ASIPS used a newly created voluntary error reporting system that permits us to sort and analyze reported incident data. ASIPS analyzed these error data and other data sets in order to develop interventions to correct systemic conditions from which errors arise. Ultimately, ASIPS aims to reduce the incidence and mitigate the effects of medical errors.

Specific aims of the project were to:

1. Enhance the efforts of the CU DFM and the clinical sites to collect medical error data by assessing the ability of a newly created incident reporting system to collect meaningful information.
2. Assess attitudes among clinicians and staff toward the data collection system.
3. Compile and compare shared data from Colorado organizations concerned with patient safety.
4. Develop a multidimensional approach to medical error analysis that will result in an improved understanding of medical errors and their root causes.
5. Develop and evaluate a system to inform patients about selected errors in collaboration with the University of Colorado Health Sciences Center Trust (HSC Trust).
6. Reduce the number of medical errors and near misses in our clinical sites.

Scope

BACKGROUND

Patient safety and medical errors have been the focus of much attention over the past several years. Although quality—its assurance, management, and improvement—have long been topics of interest in medicine, the focus on medical errors has been much more recent. This focus has grown, largely as a result of the increasing realization that medical errors occur much more frequently than initially thought. Medical errors and the threats to patient safety they represent result more from systemic conditions in and characteristics of the medical setting than from the negligence or "fault" of the provider, and management and control of the systemic environment can do more to improve patient safety than can blaming and punishing the provider.

A growing body of knowledge on medical errors/patient safety is beginning to emerge, particularly in the primary care setting; however, at the time this project began, there had been no attempt at identifying recurring systems errors in primary care. Given the recognition that, when a systems approach is taken, error reduction effects are both widespread and long lasting, anonymous reporting systems are insufficient to the task. It is clear that most of what is known about medical error comes from studies of inpatients and that what little we do know about primary care errors is not particularly helpful in developing preventive measures.

CONTEXT

This demonstration project extended patient safety/medical error knowledge to ambulatory primary care settings—the settings in which most healthcare is delivered and therefore which affect the largest number of patients. The ASIPS project incorporated and analyzed medical error data from a network of primary care practices all using the same reporting system and taxonomy,

and all data were analyzed by the same approach to error modeling. Furthermore, the reporting system was comprehensive, collecting reports of a wide range of errors attributable to a wide range of root causes and resulting from a wide range of event chains. Thus, it provided results that can be generalized across a range of ambulatory primary care settings and conditions.

SETTING

The setting for this demonstration project was a combination of two practice-based research networks, CaReNet and the High Plains Research Network (HPRN).

CaReNet was funded for 2000-2001 by AHRQ's practice-based research network development award (grant # HS11228-01 1P20, Wilson Pace, MD, principal investigator). CaReNet's purpose is to improve health and well-being by the application of scientific methods to questions important to primary care physicians, their patients, and their communities. CaReNet is committed to questions with the potential to understand health, disease, illness, and the roles and values of primary care, with a particular focus on disadvantaged populations. Twelve practices were CaReNet members at that time, including one pediatric practice, five family medicine practices, five family medicine residency training sites, and one independent nurse practitioner office. By the end of this study, CaReNet consisted of 34 practices and approximately 400 clinicians.

CaReNet provides an excellent population for studying healthcare delivery among disadvantaged populations. At the beginning of this project, CaReNet practices cared for approximately 100,000 active patients who made approximately 250,000 visits annually. Current CaReNet practices care for approximately 200,000 patients who make approximately 750,000 visits per year. Using NAMCS methods, we found that 30% of CaReNet patients are Hispanic and 47% either are uninsured or receive Medicaid benefits. The network has a sufficient patient base to study problems with a frequency greater than three per 1000 patient visits (or a problem seen about 10-12 times per year by an average full-time physician).

CaReNet consists of three distinct types of practices. The majority of our practices are federally qualified community health centers operating in a family practice model. These practices typically include nurse practitioners, physician assistants, and nurse midwives and often include dentists, mental health workers, social workers, and other allied support staff. Some of the community health centers run specific entitlement programs out of their offices, such as well-child clinics and prenatal clinics. The second most common office setting is residency training offices for family medicine residents. These sites are large practices with multiple ancillary providers, including nurse practitioners or physician assistants, psychologists, patient educators, dietitians, and social workers. The third practice type includes smaller private practices associated with organizations whose overall mission is to serve disadvantaged populations. Clinicians at these practices are family physicians, general internists, and nurse practitioners.

The High Plains Research Network consists of 11 hospitals and associated outpatient clinics in rural, northeast Colorado. The hospitals vary in size from six to 40 beds, with a total of about 175 hospital beds. The closest tertiary care center is 50-180 miles from HPRN sites. Forty-three percent of patients in HPRN hospitals are women. HPRN sites are located in counties where the Hispanic population ranges from 8% to 31% of the total population. The Hispanic population fluctuates significantly throughout the year as seasonal farm workers migrate in and out of northeast Colorado. The northeast region of Colorado is largely rural and agricultural, includes nearly 15,000 square miles, and has a population of approximately 80,000. Associated with these hospitals as part of HPRN are 23 family practices with approximately 75 physicians. It is these

physician practices that participated in the ASIPS project. Most of these practices are located in frontier areas.

PARTICIPANTS

Participants included all office clinicians and staff in the participating primary care offices. Practices included family medicine, internal medicine, urban/suburban, rural/frontier, and residencies, community health centers, and university-affiliated clinics. Directors of participating clinics in both networks were asked to sign a "Letter of Agreement" outlining the project, expectations for voluntary reporting and follow up, and an affirmation to foster an environment that did not discourage reporting. Individual participants were asked to sign consent forms to allow us to gather survey data about the reporting system (not specific reports), but signed consent was not required for submitting reports to the reporting system or for participating in Learning Groups or piloting office interventions. Patients were not participants in this study.

INCIDENCE / PREVALENCE

At the time of this initial grant submission, very little was known about the incidence of medical errors in outpatient settings. Bhasale et al. collected errors from over 300 general practitioners in Australia for almost 2 years.[1] Slightly over 800 events were reported during this time, or fewer than two errors per physician per year. Over 75% of those errors were considered preventable, and 27% had the potential for severe harm. Fischer and colleagues reviewed malpractice incident reports from primary care offices.[2] Though a low number of incidents were reported, over 80% of the reports were considered preventable and due to errors. Dovey et al. completed a study of errors in family practices in the United States,[3] collecting over 300 errors over 20 months from 42 physicians. Forty-five percent of the errors had adverse consequences. More than 80% were considered due to system failures. Both Dovey's and Bhasale's systems accepted only anonymous errors, so no follow-up analysis of system failures could take place.

Methods

STUDY DESIGN

Overview of the ASIPS Design

Errors occur in a broad spectrum of situations and facilities, with a varied (yet generally not described) population of patients, care providers, and support staff. Healthcare is such a complex phenomenon that, in order to create a more complete picture of medical errors, we must approach error recognition and analysis systems from various levels. On one level is the existing infrastructure of error reporting that a number of agencies require. On a second, more robust level is an incident reporting system such as ours, which allows a more detailed examination of error-related incidents. The ASIPS project features expert analysis both levels of data:

1. Primary data collected from the Patient Safety Reporting System, a telephone-, web-, and paper-based voluntary error reporting system used in primary care, and
2. Secondary data aggregated from various groups' existing databases.

Analyzing these two levels of data helped us work toward a comprehensive understanding of how and why medical errors occur and possible ways to prevent them. After carefully analyzing the types of errors that occur, we developed a set of interventions with the help of a Clinical Steering Committee and Learning Groups. We implemented interventions and examined if the intervention reduced the incidence of errors.

DATA SOURCES / COLLECTION

Primary Data Collection: The Patient Safety Reporting System

The **Patient Safety Reporting System** (PSRS) provided a vehicle for the confidential or anonymous reporting of errors or near misses by clinicians and administrative/support staff. A person who believed she or he knew of a medical error or near miss could report the error to the Patient Safety Hotline or the Patient Safety Website or could mail in paper forms describing the error. For confidential reports, users provided minimal information about themselves, the patient, and the incident. More detailed information was collected during a follow-up interview. For anonymous reports, users provided detailed information concerning the incident, the patient, and the context in which the incident occurred.

The Patient Safety Reporting System was relatively new to the participating practices at the time this study began. In order to reinforce use of the system to the clinicians and staff, CU DFM study staff visited each practice to describe the system, answer questions, and place posters that described the system and served as a daily reminder to report incidents. We created a quarterly ASIPS newsletter to publicize the system.

We provided guidance to clinicians and office staff about what constitutes an error in the primary care office. We discussed the range of possibilities from missed immunizations or failure to follow up for a chronic disease in a timely fashion to more overt actions or nonactions.

We carefully considered the need to protect people who complete error reports; thus, a system to de-identify confidential reports, along the line of the FAA system, was developed. The database did not store errors chronologically. We collected all additional information within 10 working days of the report and then removed all identifying information. The errors were coded and de-identified within this time frame.

Determining What Errors to Study Further

Criteria were developed to screen confidential error reports and prioritize them for follow-up investigation. These criteria were used when the system became overloaded with more reports than could be followed up within our 10-day time frame.

- Likelihood that error could lead to significant patient harm
- Likelihood that error resulted from systems problem
- Frequency of this general error type, particularly from the anonymous data

These criteria were rarely used, as we were able to handle the volume of error reports during the vast majority of the project.

Coding the Data

We categorized error reports using a proprietary taxonomy, the “five-decimal version” (version 00-1204) of the Victoroff taxonomy.[4] By using the Victoroff taxonomy, we consolidated data collection and research into the epidemiology of medical errors. The taxonomy was complete yet portable, and the hierarchical nature of the taxonomy allowed for the general classification of conditions and events when more specific details were unknown. During the project, the taxonomy was extensively refined. This method allowed us to bring credible objectivity to a generally subjective topic.

Secondary Data Collection: Data from ASIPS Partner Organizations

ASIPS researchers coordinated with the Colorado Patient Safety Coalition, which meets informally to discuss contemporary issues in patient safety improvement. Representatives from

the Colorado Health Department, the Colorado Medical Society, CHA, the Colorado Board of Medical Examiners, and medical malpractice insurers make up the Coalition.

Purpose of Secondary Data

The collection and subsequent analysis of data from secondary sources were critical for the ASIPS project to assess the specific incidents and trends that may or may not have been reported to the CU DFM as well as trends occurring in larger populations of practices for comparison with our clinical sites' activities. More specifically, the secondary data sets were tested by researchers to see if they could identify consistencies or "matches" between reported incidents and sentinel event occurrences to determine the predictive value of secondary data. We expected that, in many cases, this would require individual practices to review medical records and provide information for use in tying practice-level information to incident data. This activity was not possible from the secondary data we obtained. We also used secondary data in an attempt to identify specific sentinel events that may have their root cause in errors that are not recognized or not reported by clinical sites. Secondary data analysis was used by the Clinical Steering Committee to determine the nature and scope of interventions needed. Reported incidents, alone, did not provide the full picture of errors or error-related outcomes.

Approved extensions of the project

During year 4, with the approval of the project officers, the ASIPS project and the AAFP Developmental Center for Education and Research in Patient Safety were allowed to combine their data sets to determine if additional analyses would be possible.

INTERVENTIONS

Interventions to Reduce Medical Errors

Two rounds of interventions were attempted over the course of the project. These interventions were not disciplinary or punitive in any way; rather, they focused on a collaborative and supportive mechanism to reduce specific errors.

The ASIPS project staff prepared information concerning incidents, errors, and sentinel events for presentation to and prioritization by a Clinical Steering Committee. In addition, ASIPS staff provided recommendations to the committee for interventions based on the analyses. The committee oversaw the development and implementation of specific interventions.

Designing Interventions

A "learning group" approach was employed to increase practice awareness of the Patient Safety Reporting System (PSRS), increase buy-in and ownership of this quality improvement effort, and develop a Patient Safety Team. Each practice identified patient safety leaders (at least one physician and one staff member) to lead meetings, encourage practice goals, and coordinate designed improvements in error reporting and identification and patient safety improvements. Meetings were held to help teams review data in order to identify practice goals and implementation plans for discussion, modification, and endorsement.

MEASURES

PSRS Reports

The ASIPS primary measure was reports submitted to the reporting system.

Participant Survey

Two surveys of participants' views of the PSRS were conducted.

Pharmacy Callbacks
Data were collected by practice staff concerning reasons pharmacists call primary care offices to clarify prescriptions. This concept developed as a result of analysis of error reports during the project.

Missing Information in Ambulatory Care
Clinicians collected data about the frequency and potential harm from missing clinical data during primary care encounter. This concept developed as a result of analysis of error reports during the project.

Patient Survey
Data were collected from community-dwelling individuals in designated rural areas. The concept developed as a result of an analysis of error reports during the project.

LIMITATIONS

The ASIPS project relied on reported events from busy clinicians. This meant that many observed errors went unreported. This occurrence appeared to be particularly true after individuals had reported a similar error several times previously. This means that the PSRS was not a valid means of understanding the rate of specific errors within the network or a practice. The system was better positioned to understand the error types that were most likely to cause harm.

The secondary data, particularly the Medicaid data, proved difficult to clean with the cleaning process, resulting in significant signal loss. The malpractice qualitative data was also difficult to transfer in a confidential format, though the use of the same taxonomy allowed analysis between the malpractice and the PSRS data at the code level.

Practice members and the Clinical Steering Committee were most interested in technology-related interventions. The project had no specific funding for interventions, so the project team struggled to meet participants' requests concerning interventions. Nonetheless, we did manage to undertake two rounds of technology-based interventions, though the number of practices involved was low and the ability to support the interventions was limited.

Results

PRINCIPAL FINDINGS

Patient Safety Reporting System (PSRS)
ASIPS demonstrated that it is feasible to implement a voluntary primary care error reporting system that securely collects anonymous and confidential reports, follows up on confidential reports, codes reports, and analyzes these coded reports. Our system successfully accepted and processed reports submitted by webphone or telephone. By the study's end, 481 clinicians and staff from 35 practices consented to participate in the study. Over the 3-year period, 854 reports were submitted. Of those reports, 758 were considered relevant primary events for overall analysis. Reports were received through the following systems: telephone, 9%; web, 28%; and paper, 63%.

We conducted more in-depth analyses of 608 coded reports. Overall, our data show the preponderance of errors associated with diagnostic tests---47% of events reported. Medication errors appeared in 35.4% of reports, and both a diagnostic testing and a medication error appeared in 13.6% of reports. Communication errors were identified in 70.8% of reports. We also analyzed our reports from harm. Two thirds of reported events

were associated with no known harm; for 7.7% of reports, it was too early to tell if harm occurred. In terms of nonclinical harm, 6.4% of reports were associated with discomfort or inconvenience to patients, and 9.0% were associated with an increased risk to the patient or others. Just over 10% (exactly 10.2%) of reports were associated with known clinical harm to the patient. Among reported errors, those most likely to be associated with clinical harm (odds ratios [ORs] greater than 3.00, 95% CI) included medication prescribing; errors related to disclosure to, explanation of, or follow up with a patient; delays in therapy; examination errors; and errors in clinician judgment or knowledge.

Importantly, our project demonstrated that staff are willing to report errors and that participants will submit confidential reports, despite knowing that identifiable information (name and phone number) would be collected and stored for up to 10 days. In fact, 67% of the reports were submitted as confidential reports. We also determined that confidential reports are more likely to include sufficient information to allow detailed coding.

We analyzed both closed- and open-ended responses to an anonymous self-report survey mailed to participants. We received completed surveys from 130 of 322 clinicians and office staff who consented to be surveyed, a response rate of 40%. Of respondents, nearly all (95%) had heard of the ASIPS reporting system; 30% indicated that they had reported at least one event to the system in the previous 6 months. The majority of respondents agreed that the system was easy to use (69%), allowed them to report candidly (79%), and has the potential to improve patient care (88%). Clinicians and residents indicated significantly greater concern with the time it takes to make a report ($p = .01$); office staff members were significantly more likely to express concern about others finding out they made a report ($p = .006$) and how their practice might react to their reporting of events ($p = .03$). Common identified barriers to using the ASIPS reporting system included time, understanding what to report, and the constant pressures of other, more important and competing, priorities of patient care. Many respondents reported that ASIPS raised their awareness of safety issues in their own practice.

Our mixed-methods approach allowed us to efficiently and effectively extract patient safety lessons from our error reporting system. We used this approach to quantitatively examine relationships between aspects of error events and qualitatively identify intervention opportunities in the cascade of events leading to and flowing from an error. The quantitative and qualitative analyses complement each other, with the former providing breadth and the latter providing depth. Combined, they provide more information than either analysis provides individually. For example, we conducted a qualitative analysis of reported events that were initially coded using the taxonomy as “ameliorated.” The qualitative assessment yielded insights into how some error cascades are stopped before reaching or affecting patients. From in-depth analysis of 60 events, we found that ameliorators included doctors, nurses, pharmacists, diagnostic laboratories, and office staff. Additionally, patients or family members may be ameliorators by recognizing the error and taking action. Ameliorating an event after an initial error requires an opportunity to catch the error by systems, chance, or attentiveness. Correcting the error before it affects the patient requires action directed either by protocols and systems or by vigilance, power to change course, and perseverance on the part of the ameliorator.

Furthermore, with the guidance of our Clinical Steering Committee’s review of early findings on types of errors reported and additional review by two Learning Groups, we implemented a process by which practicing clinicians and staff identified and prioritized problem areas; developed relevant, practice-specific interventions to improve patient safety; and implemented the interventions in practices.

Secondary Data

Medical claims data

We obtained Medicaid claims data through an agreement with the State of Colorado Department of Health Care Policy and Financing. The Colorado Medicaid Program provided claims history information for all outpatient encounters for the Colorado clinical sites from 1999 to July 2004. Our findings were largely inconclusive. Our analytical plan included a strategy to identify a sentinel event (e.g., hospitalization events for asthma, drug-related illness) from which to base a review of claims activity (both before and after the event) to determine if any medical error occurred and, if so, the nature of the error.

Though we were able to isolate pediatric admissions for asthma, we struggled to find any administrative claims information that pointed to the occurrence of an error that may have led to the hospitalization. With regard to the review of drug-induced illness claims (as a search for prescription errors), we initially found numerous events to review. However, in the opinion of our clinical reviewers, many or most of the events that we reviewed involved the inappropriate use of narcotics by patients. Informally, many clinicians believed that were looking at claims resulting from patient abuse of these substances—including possible suicide attempts.

As we worked with the claims data, we came to the conclusion that our ability to extract meaningful information related to errors from these stand-alone secondary data sets was extremely limited. If we had something to link with the claims data (e.g., reported laboratory errors or alarm values, prescription drug errors of dosage/route/administration), we believe that the opportunity to use the claims information to trace the impact of error would be greatly increased.

We continue to believe that the review of administrative claims data for possible medical error information remains a worthwhile goal (and is the current topic of a DEcIDE Task Order funded by AHRQ), if it could be guided by additional patient- or provider-specific error information. We will watch with interest as this work progresses.

Malpractice claims data

We obtained malpractice claims data to compare the types of reports submitted to ASIPS versus those submitted to a malpractice insurer covering the same geographic area. Similar taxonomies were used to code events from the ASIPS patient safety reporting system and a malpractice insurer. We coded and analyzed 608 ASIPS events; separately, we analyzed 2225 malpractice events that were already coded. Thirteen taxonomy-derived constructs were analyzed to assess types of events that involve patient harm. Frequencies of types of errors and odds ratios were calculated to establish risk of harm.

The most common ASIPS events were drug errors (60%), mistimed procedures (53%), and judgment/knowledge errors (42%). The most common malpractice events were patient care outside the office (18%), imaging/lab tests (9.2%), and drug errors (9.1%). Among ASIPS events, drug errors, delays in therapy, and communication errors were most likely to involve patient harm (ORs of 5.26, 5.2, 4.03, respectively); transfers of care, delays in therapy, and decisions based on incomplete/faulty information were most likely to involved patient harm (ORs of 3.93, 2.87, 2.43, respectively) in malpractice events. Despite the differences in the two systems, there exist similarities in the risk of harm from certain types of events, especially delays in therapy, drug errors, and transfers of care.

Other data sources

Patient Preferences for Normal Laboratory Test Results

We conducted 30-minute guided interviews with 20 adult patients recruited from practices participating in ASIPS. A semi-structured interview elicited the participant's experience with and preference for laboratory test result notification. Quantitative descriptive statistics were generated for demographic and preference data. Qualitative results were analyzed using a template approach and editing approaches. Ninety percent of participants wanted to be notified of all tests results. Important issues related to notification included privacy, responsive and interactive feedback, convenience, timeliness, and provision of details. Telephone notification was preferred, followed by regular mail. Electronic notification was perceived as uncomfortable because it was not secure. Although 65% preferred being notified by a provider, participants acknowledged that this may be impractical; thus, they wanted to be notified by someone knowledgeable enough to answer questions. Participants do not normally discuss their preferences for test result notification with their providers.

Pharmacy Callbacks

A cross-sectional study of 22 primary care practices participating in ASIPS was performed. Callbacks from pharmacies were logged for 2 weeks to determine reasons for callbacks (most frequently involved drug classes), whether issues were resolved on the same day of the call, and variability of callbacks among practice types. Practices recorded 567 clarification calls, most frequently for prior authorization issues (n = 209, 37%), formulary issues (n = 148, 26%), and unclear/missing prescription dosages (n = 117; 21%). Drug classes most frequently requiring clarifications were gastrointestinal (n = 122; 21.7%), cardiovascular (n = 278; 13.9%), and analgesic/anesthetic (n = 74; 13.2%) agents. Issues were resolved on the same day 62% of the time. Residency practices averaged more issues per call ($p < .001$).

After-Hours Telephone Calls

A previous study looking at after-hours calls to primary care offices provided an additional opportunity to apply our taxonomic coding to another set of event reports. We combined resources to evaluate the actual outcomes for patients when their phone call was not forwarded to the on-call physician. All telephone calls made after hours (5 p.m. to 8 a.m. weekdays and all day on weekends/holidays) to a freestanding, community-based family practice training program were collected for the 12-month period between April 2000 and March 2001. For this analysis, we evaluated 288 after-hours phone calls (n = 288) during a 1-year period that were not forwarded to the physician on call. A final sample of 119 patient calls regarding a clinical concern was used to abstract event data for coding using the ASIPS taxonomy. When the patient call was not forwarded to the physician, 51% had an appointment within 2 weeks after their call, 4% visited an emergency department within 2 weeks, and 2% were admitted to the hospital within 2 weeks. Analysis of the taxonomy harm codes revealed that 3% suffered some degree of harm and 26% experienced discomfort due to the delay in receiving timely care for their problem. Although 66% required no intervention, 1% required emergency transport, 4% required a medication change, and 4% required an ED visit.

Missing Information in Ambulatory Care

A cross-sectional survey of 253 clinicians in 32 primary care clinics participating in ASIPS was conducted between May and December 2003. For every visit, during one half-day session, each clinician completed a questionnaire about patient and visit characteristics and stated whether important clinical information had been missing ("missing information"). The questionnaire collected the type of missing clinical information, the frequency, and the presumed location; perceived likelihood of adverse effects, delays in care, and additional services; and time spent looking for missing information. Multivariate analysis was conducted to assess the relationship of missing information to patient, visit, or clinician characteristics, adjusting for potential confounders and effects of clustering.

From 1614 patient visits, clinicians reported missing clinical information in 13.6% of visits; missing information included laboratory results (6.1% of all visits), letters/dictation (5.4%), radiology results (3.8%), history and physical examination (3.7%), and medications (3.2%). Missing clinical information was frequently reported to be located outside their clinical system but within the United States (52.3%), to be at least somewhat likely to adversely affect patients (44%), and to potentially result in delayed care or additional services (59.5%). Significant time was reportedly spent unsuccessfully searching for missing clinical information (5-10 minutes, 25.6%; > 10 minutes, 10.4%). After adjustment, reported missing clinical information was more likely when patients were recent immigrants (odds ratio [OR], 1.78; 95% confidence interval [CI], 1.06-2.99), were new patients (OR, 2.39; 95% CI, 1.70-3.35), or had multiple medical problems compared with no problems (1 problem: OR, 1.09, 95% CI, 0.69-1.73; 2-5 problems: OR, 1.87, 95% CI, 1.21-2.89; > 5 problems: OR, 2.78, 95% CI, 1.61-4.80). Missing clinical information was less likely in rural practices (OR, 0.52; 95% CI, 0.29-0.92) and when individual clinicians reported having full electronic records (OR, 0.40; 95% CI, 0.17-0.94).

Patient Experiences Following an Error

Patient perceptions of patient-provider communication after an adverse medical event were examined through four patient focus groups. Participants were recruited from a statewide post-injury program run by an ASIPS collaborator (COPIC). We found that complex issues and processes were involved in resolution attempts. Effective communication was an important factor in whether professional relationships continued after an adverse event. The communication nature and quality influenced whether patients defined event as an “honest mistake” or an “error.” Two types of trauma (physical and emotional) were expected and found. A third (financial) was uncovered and proved in some cases the most salient factor influencing patients’ subsequent actions. Caring, honest, quick, personal, and repeated provider responses were linked to patient satisfaction.

Samples Use Card Study

This study assessed the frequency, motivation for, and safety of manufacturer-provided medication sample use in primary care practices. Sample medication processes were evaluated and compared with Institute for Safe Medication Practices (ISMP) standards. Eighteen urban and rural ASIPS practices participated in a 1-day, prospective, observational evaluation. A card study assessed provider motivation and sample dispensing. A simultaneous card study assessed patient knowledge of their sample(s). During 18 days of evaluation, 57 samples were dispensed during 54 (9.2%) of 585 patient encounters. Sixty-five percent were new medications. Motivations for dispensing included availability (57.1%), cost (20%), and patient request (20%). Providers also stated their plan to continue the medication through written prescriptions (54.9%) and more samples (28.6%). Seventy-two percent of patient card studies were returned and indicated that verbal instruction alone was the primary means of patient education for dose and frequency of use (68%), precautions (68%), and side effects (60%). Twelve percent of patients received no education related to side effects. Of 1233 samples inventoried, medication for hypertension were most prevalent (17.7%) followed by cold/allergy (9.0%), dyslipidemia (6.9%), bacterial infections (6.8%), asthma (6.7%), diabetes (5.4%), and depression (5.3%). Labels were either absent or incomplete in all 18 practices.

These preliminary data suggest that sample medications are dispensed in approximately 9% of primary care visits, with availability being the strongest impetus for use. Patient education and labeling were not compliant with ISMP standards, potentially increasing the risk for medication errors.

Patient Reports of Medical Mistakes
With the assistance of the High Plains Research Network's Community Advisory Committee, we developed a survey and dissemination method to assess community members' experiences of harm resulting from a medical mistake. The survey included open-ended questions to elicit a broad response from community members about medical mistakes and any resultant harm. We distributed 11,500 surveys via inserts in four local newspapers in the region of the High Plains Research Network. nother 25 surveys were handed out following specific requests from community members within the targeted communities.

We received 284 completed surveys, of which 170 (60%) indicated that the respondent or a family member had experienced a medical mistake (33% responded that they had not experienced a medical mistake). Using a mixed-methods analytical approach, we found that community members reported that 155 mistakes resulted in harm (87%). Types of harm described by community members included emotional, financial, and physical harm. Responses also suggest that perceived clinician indifference to a bad outcome led to patients' loss of trust and a belief that the bad outcome was a result of a mistake.

We were able to code 88 event narratives that met our usual criteria for a reportable event using the ASIPS taxonomy. From these 88 events, we found that 62% involved a clinical event. Communication errors (39.6%) and medication errors (39.6%) were frequently reported. In over half of the 88 reports, physicians (53.4%) were active participants in the mistake; over a third of the time, both nonphysician providers and nursing staff (34.5%) were involved. Third-party participants were involved in 17.2% of the reports. Mistakes occurred in a variety of settings. Hospitals accounted for almost one third of all errors (32.6%), and ambulatory offices (20.7%) accounted for one in five errors. Other errors occurred in nursing homes (10.3%), emergency departments (13.8%), and pharmacies (10.3%).

Combined ASIPS-AAFP Data Set
Dr. Pace was a consultant to the AAFP group; during the late part of year 3 of the project, he became the director of the overall research organization within the AAFP. We initially worked on creating a crosswalk between the two taxonomies that were used to code these data sets. After many attempts to develop a usable crosswalk, we came to the conclusion that the two systems were so fundamentally different in their conception that a crosswalk was impossible. The two taxonomies resulted in numerous many-to-many relationships between codes that could only be resolved through direct human re-coding. This effort was finally abandoned. Instead, Dr. Pace and the ASIPS team convinced the AAFP group to code resultant harm within their entire lab error database using the ASIPS taxonomy's Outcomes axis. This has allowed an analysis of lab and imaging errors between the two sets of error reports.

OUTCOMES

The ASIPS project solidified the knowledge base concerning the breadth and consequences of primary care medical errors. High-risk errors were identified, and the information-intensive nature of primary care was highlighted. The role of communication as a central and recurring theme within primary care errors was also elucidated. A substudy within the project examined the rate of missing data within primary care clinical encounters and the possible consequences of this problem.

The powerful effect of a safety culture, and the lack of understanding of high-performance systems, was demonstrated to many clinicians in the project. Many offices spontaneously changed selected systems after examining selected error reports. Unfortunately, other offices, even when provided with simple, automated solutions to proven error-prone systems, could not see the benefit of change. This appeared to be particularly true if a practice clinical leader had not embraced safety as an essential part of care.

Learning Groups

Our Learning Groups yielded recommendations for high-priority, relevant interventions for two areas of primary care: diagnostic testing and medication safety.

Diagnostic Testing

1. Interventions should seek to minimize the number of steps required to complete a function.
2. The process for tracking test orders and receiving test results should be coordinated and clearly communicated to clinic personnel. Every effort should be made to ensure that the process does not rely solely on a single person but is understandable to all personnel.
3. The process for tracking test orders and receiving test results should rely upon a single information source (e.g., a central database or single tracking log).
4. Clinicians should record their test orders directly on the same form used to order the test from the laboratory.
5. If multiple forms (for multiple laboratories) are in use, the forms should be standardized.
6. A tracking system should be in place to:
    a. Track all tests sent out
    b. Track all test received (both complete and partial)
    c. Ensure sensitivity to time
    d. Ensure sensitivity to critical values
    e. Ensure that providers review results and act in a timely manner
    f. Ensure that patients are informed of results in a timely manner
7. Processes should incorporate a "feedback loop" to ensure their constant improvement.

Medications

1. Prescriptions should clearly state the drug, the dose, the frequency, the time of day (when indicated), the duration, and special instructions (e.g., take with food) in a manner that is understandable for clinicians, staff, pharmacy staff, and patients.
2. All prescriptions should include the indication for the drug therapy (i.e., the purpose of the medication).
3. Medication List: Practice personnel should be able to readily access a list of active and inactive medications (prescription, OTC, herbal) for any given patient.
4. If sample medications are used, they should be used in a manner that is consistent with the writing and filling of other prescriptions.
5. Practices should establish a reflective "feedback loop" to ensure the constant improvement of processes (e.g., regular staff meetings, discussion and documentation of process changes).

Pilot Interventions:

Interventions were designed to be responsive to the principles issued by the Learning Groups (above). As described below, we tested two interventions in a few participating ASIPS practices.

Diagnostic Test Tracking

We developed and tested a browser-based lab and imaging tracking system to replace paper-based systems in place in a number of practices. This system was pilot tested in one practice. Though the system was developed with the practice staff and appeared to handle a large volume of data efficiently (barcode scanning of labs ordered and returned, and powerful reporting), the practice staff frequently fell behind in the use of tracking system and eventually abandoned it in

favor of their old paper system. Staff indicated that the paper system was more efficient than the web-based system. Further review of the paper system indicted that it also was frequently not kept up to date, but the system was not easily audited, such that its performance could not be accurately monitored, as the electronic system allowed. The office administration and clinicians were not willing to confront the staff with this failure to complete this task. The other offices that were considering implementing the system then backed out of the intervention. Since then, all these offices have installed electronic medical records systems that do not track the return of ordered labs or imaging studies. Nonetheless, these systems make it impossible to operate the old paper-based systems in these offices; thus, lab tracking has entirely deteriorated despite ample evidence from our work that this is an essential activity within a safe office system.

Electronic Prescribing

We introduced into two practices that lacked EMRs a web-based, stand-alone electronic prescribing system. We worked with a nonprofit company, the Center for Drug Safety, to modify an existing web-based prescribing system to make it more suitable for our primary care practices and to be responsive to the principles mentioned above, especially item 2, "All prescriptions should include the indication…." We trained clinicians in both practices to use the system for all prescribing. Both practices used the system for a number of months but eventually found reasons to abandon the systems. We also evaluated the impact of prescribing following the installation of an EMR in another practice. The prescribing package in this EMR system was also modified to meet the principles described above.

This exercise highlighted a number of issues: 1) drug databases are woefully inadequate – for instance, neither system would recognize the generic name of a medication unless that medication was available commercially in a generic format; 2) clinical alerts are often of little import and are widely ignored by clinicians; 3) clinical alerts were poorly constructed to help clinicians understand which ones were important and which could be ignored; 4) despite the introduction of clinical alerting systems, drug-allergy and drug-drug interaction errors continued to be reported by these practices; 5) many pharmacies are not prepared for electronic prescribing and would not accept the faxed or electronically signed prescriptions; and 6) pharmacy callbacks for prescription clarifications did not decrease following the introduction of an electronic prescribing system, though the reasons for the calls shifted to a perhaps less risky set of concerns.

Dissemination of Findings to Participants

Throughout the study, we distributed an ASIPS *Newsletter* and *Alerts*. The *Newsletter* updated participants on study progress and findings of interest. We also included brief summaries of published manuscripts along with ideas for examining safety in practices. The *Alerts* were distributed to raise awareness about specific reports we received. These highlighted a particular safety concern that could occur in any practice and offered suggestions for improving safety. The *Alerts* focused on hepatitis A vaccinations, normal glucose alerts, D-dimer alert values, and using auto-fill picklists in computer applications.

Analysis of Combined ASIPS-AAFP Data Set

Our initial analysis compared the two taxonomies on identifying types of laboratory testing or imaging errors associated with harm. We believed that the two taxonomies would point to differing types of events being associated with clinical harm because of how the taxonomies are constructed and the language used to label types of events. Preliminary findings suggest that this may be the case. For example, the ASIPS lab/imaging errors associated with clinical harm include "Communication from other office/facility to [someone in the practice]" (O.R. 3.354) and "Disclosure, explanation or understanding to patient" (O.R. 8.712). The AAFP coding shows that "Errors in reporting investigations to office" were negatively associated with clinical harm (OR,

0.426) and “Notifying patients of investigation results” was not significantly associated with clinical harm. These events described by the taxonomic codes in the two taxonomies are likely similar processes but suggest different interpretations of which errors in primary care are likely to involve clinical harm. Consequently, this could suggest different focal points for interventions aimed at reducing harm related to diagnostic testing. Additional analysis would require a more thorough review of the text of the reports to understand more clearly how the interpretations based on taxonomic coding might (or might not) differ.

DISCUSSION

Assuming that the purpose of a patient safety reporting system is to reduce errors through changes in clinical practice, confidential reports appear to offer greater potential to understand the processes that are likely targets for intervention, especially in complex cases. Anonymous reports appear equivalent to confidential reports for understanding the risk (harmful outcome or not) associated with safety events. If patient safety reporting system data are used primarily to identify patterns of events that are candidates for additional data collection, then anonymous reports may suffice, even with a lower level of detail. Confidential reports require time for the research staff to collect a complete set of data. Although a complete data set allows for clarification and detailed information, it is also costly. It is possible that combined systems requiring a great amount of structured data entry, even when submitting confidential reports, could maintain the effectiveness of confidential systems while decreasing their cost. Greater structured data entry may also improve anonymous reports. Early in the learning process, structured data collection often slows the data-entry process. It will be important to be careful when designing system interfaces for long-term use, because our participants indicated that lack of time to create a report is a major barrier to system use.

Taxonomies developed to understand medical errors should be analyzed using quantitative and qualitative approaches to determine the useful level of detail based on empirical data, not just conceptual constructs. One of the important uses of codified error reports is to be able to sort events into categories for additional, typically qualitative, analysis and sense making. The ASIPS taxonomy allows for classification of events from several different perspectives to facilitate these activities. As taxonomies continue to evolve, developers should pay attention to how the construction of a taxonomy facilitates the analysis and elucidation of errors, meriting more examination and warranting the development of practicable interventions. The development of a taxonomy that contains varying levels of granularity may allow multiple users to converse with each other while maintaining local control over the extent and complexity of coding undertaken. More work is needed in developing such a taxonomy.

The use of the taxonomy for analyzing data is feasible; however, a mixed-method approach appears to yield more useful information. This approach allows a given report to be selected for and used in multiple analyses, rather than forcing an event into a single category to be analyzed from that perspective alone. A diagnostic testing error, for example, may involve a failed communication between a clinician and a medical assistant, allowing this case to be selected for analyses of diagnostic testing errors, communication errors, and errors involving clinicians and nonclinicians. The report does not belong to any one analysis, nor is it excluded from any analysis on the basis of being included in another. This protocol and the method we used for collecting and coding reports should be equally applicable to voluntary and mandatory reporting systems that allow for narrative reporting. It is best suited to large practices, groups of practices (e.g., PBRNs), or university- or hospital-affiliated practices that have the analytic and research expertise and staff to support it. It is also suited for use with federally designated patient safety organizations or with statewide or national coalitions or professional associations, which could collect and analyze reports centrally. This method, however, is time consuming and may not be

practical for smaller organizations or for individual practices interested learning about safety issues in their own practice. A simpler, more streamlined method for coding and analyzing events would be needed for those situations.

CONCLUSIONS

- A safe and secure reporting system that relies on voluntary reporting from clinicians and staff can be successfully implemented in primary care settings, including frontier and rural settings.
- Information from confidential reports appears to be superior to that from anonymous reports and may be more useful in understanding errors and designing interventions to improve patient safety.
- Using mixed methods to study patient safety is an effective and efficient approach to data analysis that provides both information and motivation for developing and implementing patient safety improvements.
- Taxonomies developed to understand medical errors should be analyzed empirically, using quantitative and qualitative approaches to demonstrate their utility for describing medical errors as well as the level of detail required for varying uses.
- Using multiple data sources, locally developed and relevant quality improvement interventions to improve patient safety can be implemented in primary care. However, a clear understanding of the processes that require change is essential to successfully address implementation challenges and put interventions into routine use.
- Clinicians and office staff held generally favorable perceptions of the ASIPS reporting system and identified a few key areas for improvement. Survey data indicate the need to streamline reporting and reinforce the confidential nature of reports, particularly for office staff.
- Prescription-related errors are most frequently associated with clinical harm. Attributes of reported medical errors that are significantly associated with clinical harm included errors in which the provider of record is a direct participant; errors of judgment and knowledge; errors reported to occur outside the office, including communication from other offices, and errors with participants outside the office. Mis-timed procedures or delays in therapy were also associated with clinical harm.
- Prescription clarification calls made to primary care practices involve administrative and clinical issues potentially impacting patient safety. Pharmacy callback data can identify potential prescription concerns, thereby helping practices develop interventions aimed at reducing errors and improving patient safety.
- Provider communication timeliness and quality were important influences on patients' responses to adverse events. Confronting an adverse medical event collaboratively helped both patients and providers with patients' emotional, physical, and financial trauma and minimized the anger and frustration commonly experienced. Health organizations, providers, investigators, and policymakers should consider the patient experience when developing provider training or evaluating processes in patient resolution.

SIGNIFICANCE

Reporting System:

The ASIPS PSRS demonstrated that a voluntary error reporting system for primary care is feasible and delivers useful descriptive data about patient safety issues in primary care office. Importantly, these data can be used to direct practices to areas of focus for improvement. At the

time of the grant inception, few studies described errors in primary care. Our data have helped describe the types of errors occurring in primary care offices and corroborate findings from recently published studies conducted elsewhere.

Interventions:
Although much has been written suggesting computerized solutions as fixes for many types of errors in primary care offices, stand-alone electronic solutions to lab tracking and prescribing are not practicable interventions to reduce errors associated with diagnostic testing and medications. Furthermore, safety systems are not programmed into many current ambulatory EMRs. Implementation of these EMRs may displace existing safety systems without replacing them, further eroding office system safety.

Taxonomy:
ASIPS demonstrated that a theoretically derived, multi-axial taxonomy can be used to code and analyze errors in primary care settings. Furthermore, this taxonomy—with our revisions—provided useful details about the types of errors occurring in primary care, especially those associated with harm to patients. Furthermore, we have also demonstrated that the taxonomy can be used to code other event types reported through chart abstraction or community surveys (see *After-Hours Calls* and *Community Perceptions of Harm*, above) and yield useful data.

IMPLICATIONS

Reporting:
ASIPS has been able to describe commonly reported error types in primary care. Despite our efforts and those of others, *rates* of errors in primary care settings remains poorly understood. Yet, our study suggests areas for improvement in terms of system improvements that focus on diagnostic testing, medication, and communication errors in primary care. More narrowly focused interventions may seek to address errors that are strongly associated with harm, as indicated by our analyses.

To increase reporting by busy clinicians and staff, a critical point will be to ensure that useful, practice-specific feedback about types of events occurring in a practice can be provided in a timely fashion and that adequate legal protections can be assured.

Interventions:
Perhaps the most significant barriers to overcome are not related to the reporting of errors but relate to the analysis, which is time consuming and costly, and how to construct interventions that address barriers to fostering a culture of safety in primary care offices. Many currently designed office automation systems are not designed to improve safety monitoring. These systems do not inherently increase primary care office safety.

Taxonomy:
Taxonomic coding can be a lengthy process and may not be practicable for smaller practices or practice groups. A more streamlined approach to classification and analysis will be needed along with the ability to reflect on individual, illustrative cases. It is not clear that the taxonomy proposed by JCAHO will be useful for primary care practices.

Building a culture of safety:
Our reporting system data also suggest several implications for building a culture of safety in primary care. Surveys of participants indicate that reporting raises awareness of safety issues in offices, involvement of practice staff and clinicians in mapping diagnostic testing flow leads to

immediate change, and error cascades can be corrected before affecting patients. These findings suggest that raising awareness about offices processes and instilling observant, vigilant, and questioning behaviors in staff, physicians, and patients may lead to a wider culture of safety that reduces errors not prevented by systems. Failure to engage key office members, particularly key administrative staff and senior clinicians, will frequently dilute the effectiveness of other concerning individuals.

ASIPS investigators continue promoting safety efforts through a number patient safety activities regionally, nationally, and internationally. This involvement extends to the development and leadership of the Colorado Patient Safety Coalition (http://www.coloradopatientsafety.org), the IOM committee"Identifying and Preventing Medication Errors" (http://www.iom.edu/?id=22526&redirect=0), and international taxonomy development efforts.

List of Publications and Products

PUBLICATIONS

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PRODUCTS

Except where noted, more information about the following products can be obtained by contacting the Principal Investigator.

- Primary Care Patient Safety Reporting System
- Web-based coding system
- Reporting forms: event reports (confidential and anonymous) and pharmacy callback logs
- Principles for Process Improvement in Primary Care Offices
- Reporting system feedback survey
- Dimensions of Patient Safety: A Taxonomy. Available at: http://www.errorsinmedicine.net/

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