Relationship Between Patient Harm and Reported Medical Errors in Primary Care: A Report from the ASIPS Collaborative

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Abstract

Context: Harm associated with primary care medical errors is not well described. **Objective:** The objective of this project was to investigate the relationship between primary care medical errors and patient harm. **Main Outcome Measures:** The principal outcome measures for this study were: association between specific attributes of medical errors and levels of patient harm and frequency of harm classified hierarchically into five categories: (1) unknown or no known harm, (2) unstable or too early to tell if harm has occurred, (3) patient discomfort or inconvenience, (4) increased risk to patient or others, and (5) known clinical harm to the patient. **Results:** Clinical harm to the patient was reported in more than 10 percent of the 608 medical error reports. Prescription-related errors were most frequently associated with clinical harm (OR 5.25; 95 percent CI, 3.0-9.19; P <0.01). **Conclusion:** Errors in certain processes and systems are associated with patient harm in primary care. These findings might help prioritize the key areas of clinical care that warrant further study and intervention to improve patient safety.

Introduction

Patient safety reporting systems (PSRS) are useful tools to understand the scope of errors that occur during medical care.[1, 2, 3, 4] To date, research on errors in the primary care setting has focused principally on the types of errors that occur in primary care offices and less on the consequences of those errors.[5, 6, 7, 8] Makeham, et al., described broad categories of errors that led to hospitalization or death, as reported to an international primary care error reporting system.[1] They found that errors involving clinical decisions (as opposed to system process errors) were more likely to lead to serious consequences. However, this and a second brief report by Dovey, et al.,[9] did not describe whether and how harm relates to specific attributes of an error.

In this paper, we examine harm associated with the medical errors reported to the Applied Strategies for Improving Patient Safety (ASIPS) reporting system. The purpose of this study is to investigate the relationship between the attributes of medical errors in primary care settings and patient harm.

Methods

Study Population

The ASIPS project, a multi-institutional demonstration project, collected and analyzed medical errors in primary care ambulatory practice.[10] The ASIPS Patient Safety Reporting System (ASIPS PSRS) collected error reports from clinicians and staff in two practice-based research networks: the Colorado Research Network (CaReNet) and the High Plains Research Network (HPRN). The participating practices are located in urban, suburban, rural, and frontier regions of Colorado and represent over 500 clinicians, who receive approximately 400,000 visits per year from a patient population diverse in terms of age, race, ethnicity, socioeconomic status, and medical problems. The ASIPS protocol was approved by the Colorado Multiple Institutional Review Board (COMIRB) and other applicable institutional review boards.

ASIPS Patient Safety Reporting System

The core of the ASIPS PSRS is a Web-based data collection and data management system, described in detail elsewhere.[11] Briefly, the system accepted both anonymous and confidential reports of "medical events you don't wish to have happen again, that might represent a threat to patient safety." This definition included near-miss events and events that led to varying degrees of patient harm. All clinicians and staff members of participating practices were encouraged to report errors. Through August 2003, 67 percent of reports were from clinicians; 24 percent were from other clinical staff; and 7 percent were from nonclinical staff;[12] 66 percent of the reports were submitted confidentially.[10] Research personnel conducted telephone followup interviews with people who submitted confidential reports of interest to gather more detailed information about the report.

Error Coding and Classification

All error reports were reviewed and then coded by teams of at least three members, including one physician, using a multi-axial taxonomy, Dimensions of Medical Errors (DMO).[13] The DMO taxonomy provides a detailed description of the processes and individuals involved in adverse events or adverse patient outcomes, including events with and without identified errors, across all locations of medical care. Whereas the DMO taxonomy includes 5 domains and 38 axes, the ASIPS project only used 4 domains and 10 axes. Within each axis are numerical codes that correspond to descriptions of process steps (including causation), associated diagnoses, associated tests, associated medications, participants, outcome(s), individual(s) who discovered the event, and the setting(s). These descriptions and labels are collectively referred to here as "error attributes." Codes are arranged hierarchically within axes, ranging from 3-digit upper-level codes through 7-digit detailed, subordinate codes.[14] Because we wanted to use all relevant taxonomic axes to describe each error, multiple attributes could be assigned to the same error.

Classification of Harm Level

In addition to identifying error attributes, we classified all errors hierarchically into one of five ordinal harm categories (Table 1). An earlier harm classification from the ASIPS Collaborative appeared in Fernald, et al.,[10] with detailed descriptions in the online appendices. Errors with

Table 1. Harm classification

Harm category	Example
Known clinical harm to the patient	A positive herpes simplex culture of the eye, not handled over the weekend; by Monday the patient has severe eye pain and visual changes.
Increased risk to patient or others	A missed diagnosis of diabetes for several years; or an Rh-negative woman, who is sensitized due to failure to check a blood type during a spontaneous miscarriage.
Patient discomfort or inconvenience[a]	A patient who must undergo a second skin biopsy due to a lost specimen.
Unstable or too early to tell	A patient with atrial fibrillation and a missed low PT/INR that is reported prior to correcting the problem.
Unknown or no known harm	An unlabeled lab specimen for gonorrhea and *Chlamydia* PCR is discovered by the lab after the patient has been started on antibiotics.

a Used only if report specifically mentioned discomfort or convenience.

multiple harm outcomes (involving either more than one patient or multiple outcomes for a single patient) were assigned to the category that represented the highest level of harm. For example, errors that involve both known clinical harm and patient inconvenience were classified as "known clinical harm."

Data Analysis

We calculated frequency distributions of error attributes for each harm category. We tested for bivariate associations between harm categories and each error attribute using chi-square tests. To measure the strength of the associations between "harm" and individual error attributes, crude odds ratios (ORs) and 95 percent confidence intervals (CI) were calculated with "no known harm/unknown" as the reference group. These analyses included only error attributes that were coded in at least 20 reports to reduce the possibility that someone could identify a particular event, provider, or practice because the attributes of that event were so unusual. Statistical analyses were performed using SPSS®, Ver. 12.0 (SPSS, Inc., Chicago, IL).

Results

Of the 708 events reported to ASIPS, 608 reports were coded using the ASIPS refined version of the taxonomy[13, 14] and analyzed for harm. (We determined that the remaining 100 reports did not describe medical errors.) Of the 608 errors, 405 (66.6 percent) were associated with no known harm; for 47 error reports (7.7 percent), it was too early to tell whether harm had occurred; 39 error reports (6.4 percent) were related to discomfort or inconvenience for the patient; and 55 error reports (9.0 percent) were related to increased risk to the patient or others; finally, 62 error reports (10.2 percent) were associated with clinical harm to the patient.

Types of Errors Associated with Harm

For purposes of the following analysis, we concentrated on the two highest levels of harm ("known clinical harm" and "future risk of clinical harm"), reasoning that these errors represent the greatest potential threat to patients' welfare. We identified four main categories of errors significantly associated with one or both of these highest levels of harm: (1) prescription drug errors, (2) coordination of care errors (specifically errors involving communication), (3) errors in clinical activities (generally timing of these activities), and (4) errors related to cognition (Table 2). As previously stated, in describing the likelihood of clinical harm or future risk of clinical harm that we observed in each of these categories of error (Table 2), crude odds ratios (ORs) and 95 percent confidence intervals (CIs) were calculated with "no known harm/unknown" as the reference group.

Prescribing errors. Prescription-related errors, reported in 165 events (27.1 percent), were more than three times as likely to be associated with increased risk of future harm to patients and were more than five times as likely as other types of errors to be associated with clinical harm (the strongest association observed). Prescription errors included instances of (1) the wrong drug or device selected; (2) the incorrect administration, dosage, or timing of the correct drug; and (3) not prescribing a drug or device that was needed. Of those 165 events, in 99 (16.3 percent) the correct drug or device was prescribed, but there was an error in dosage, administration, or timing. This subset of errors was associated with increased risk of future harm (more than three times as likely than all other reported errors) and clinical harm (nearly six times as likely).

Coordination of care errors. Reported errors that were grouped under the heading "coordination of care" included (1) errors involving participants outside of the office, (2) problems with communication from another office, and (3) errors related to disclosure, explanation, or followup with a patient.

Errors involving participants outside the office were reported in 137 events (22.5 percent) and were nearly three times as likely to be associated with clinical harm. Errors involving communication from other offices were reported in 73 events (12.0 percent) and were also nearly three times as likely to be associated with clinical harm. Errors involving disclosure, explanation, or followup with patients were reported in 55 events (9.9 percent) and were approximately four times as likely to be associated with increased risk to the patient or others and with clinical harm.

Errors in clinical activities. Clinical activity errors included mistimed procedures, examination errors, diagnostic errors, and delays in therapy. Errors involving mistimed procedures were reported in 244 events (40.1 percent) and were more than twice as likely to be associated with clinical harm. Examination errors were reported in 38 events (6.3 percent) and were more than three times as likely to be associated with clinical harm.

Diagnostic errors were reported in 74 events (12.2 percent) and were more than twice as likely to be associated with increased risk to the patient or others. Delays in therapy were reported in 81 events (13.3 percent), were nearly five times as likely to be associated with increased risk to patient or others, and were more than five times as likely to be associated with clinical harm.

Errors related to cognition or systems. Errors classified as having been related to judgment and knowledge or to systems issues were included within the cognition and systems grouping.

Judgment and knowledge errors were reported in 129 events (21.2 percent) and were three times as likely to be associated with clinical harm. Errors appearing to have been caused by either the failure or lack of a good system were reported in 72 events (11.8 percent) and were more than twice as likely to be associated with clinical harm.

When coding errors, the ASIPS team considered many repetitive office activities as "systems," even if the office staff did not at times recognize the system construct. If an office indicated it had a formal process for handling a specific activity and if training was provided to new employees in the area, the process was considered a "system." Likewise, repetitive activities for which an office did not have a systematic or standardized process were considered "system absences." Therefore, system-related harm would include reported failures to follow up on missing laboratory or imaging results, either because the office did not track this information (lack of a system), the office system was used intermittently (inadequate system), or the system output was ignored by the staff (system overridden or ignored).

Participants in Errors Associated with Harm

People in certain roles were more often involved in reported errors. The clinician of record was reported to be involved in 267 events (43.9 percent), compared with licensed staff within the office (118 events, 19.4 percent); patients or individuals associated with the patient (65 events, 10.7 percent); and providers of patient care outside the office (137 events, 22.5 percent). Patients were included as participants only if their conscious action or inaction was related to the error (e.g., knowing about a drug allergy but not reporting it to the clinician).

Multiple roles could be involved in any single error event. Errors involving the physician of record were nearly twice as likely to be associated with increased risk of harm to the patient or others and were more than twice as likely to be associated with clinical harm than were errors not involving the clinician of record (Table 2).

Discussion

These results indicate what many have long suspected[15] and what smaller studies[9] have suggested: errors that occur in primary care can result in harm to patients and others. The types of errors for which we found harm were similar to previous reports concerning ambulatory medical errors.[15, 16]

The strongest associations with clinical harm involved reported prescription-related errors. The high prevalence of errors involving prescription medications makes this finding a particular concern. Gandhi and colleagues' survey and chart review of primary care patients identified 162 adverse drug events, 13 percent of which were serious.[6] The analysis by Zhan, et al., of National Ambulatory Medical Survey (NAMCS) data on outpatient visits by elderly patients found that 2.58 percent (95 percent CI = 2.44 - 2.72) of visits that included prescription medications had one or more inappropriate drug-disease combinations.[17]

The results of the present study suggest that certain types of errors might be good candidates for the development of systems, such as those that can facilitate reliable communication within and between offices, as well as with other external organizations (e.g., labs and pharmacies). As part of the ASIPS project, our research team designed interventions to improve systems in primary

Table 2. Attributes of errors related to harm (N = 608)

Error type	Error attributes [N (%)]	Future risk of harm to patient or others [Frequency (%)] OR (95% CI) (N = 55)	Known clinical harm to patient [Frequency (%)] OR (95% CI) (N = 62)
Prescription error	Any prescription drug or device error 165 (27.1)	26 (47.3) 3.18 (1.78 - 5.68)[b]	37 (59.7) 5.25 (3.00 - 9.19)[b]
	Correct drug selected, but other prescribing error 99 (16.3)	17 (30.9) 3.41 (1.78 - 5.61)[b]	27 (43.5) 5.88 (3.27-10.57)[b]
Coordination of care error	Error participants outside of the office 137(22.5)	NS	25 (40.3) 2.88 (1.64 - 5.06)[b]
	Problems with communication from another office 73 (12.0)	NS	15 (24.2) 2.91 (1.50 - 5.67)[b]
	Errors relating to disclosure to, explanation to, or followup with a patient 55 (9.9)	11 (20) 3.80 (1.75 - 8.25)[b]	13 (21) 4.03 (1.94 - 8.40)[b]
Errors in clinical activities	Mistimed procedures 244 (40.1)	NS	33 (53.2) 2.18 (1.27 - 3.73)[b]
	Examination errors 38 (6.3)	NS	8 (12.9) 3.60 (1.47 - 8.82)[a]
	Diagnostic errors 74 (12.2)	10 (18.2) 2.35 (1.09-5.06)[b]	NS
	Delays in therapy 81 (13.3)	17 (30.9) 4.88 (2.50 - 9.55)[b]	20 (32.3) 5.20 (2.75 - 9.83)[b]
Errors related to cognition	Judgment and knowledge 129 (21.2)	NS	26 (41.9) 3.40 (1.93 -5.98)[b]
	Systems issue 72 (11.8)	NS	11 (17.7) 2.08 (1.00 - 4.33)[a]
Error participant	Clinician of record 267(43.9)	31 (56.4) 1.84 (1.04 - 3.25)[a]	39 (62.9) 2.42 (1.39 - 4.20)[a]

a *P* <0.05.

b *P* <0.01 in chi-square test.

care offices, such as automated tracking of orders for diagnostic tests to ensure receipt of results and electronic prescribing to reduce errors in the prescribing process.[18] However, further research is required to learn if these efforts can reduce the medical errors that result in clinical harm.

Our findings about the harm associated with communication problems are consistent with a recent analysis of error cascades (one error leading to another) by Woolf, et al.[19] and also one of the first studies of primary care errors by Bhasale, et al.[20] The cascade analysis found that 80 percent of the errors that set off cascades involved informational or personal miscommunication, and two of three errors in treatment or diagnosis were actually set in motion by errors in communication.[19] The earlier study found that one of the most common factors contributing to incidents of potential or actual harm was poor communication between patients and health care professionals (23 per 100 incidents).[20] While improving interpersonal communication appears to be a useful goal, systematic intervention may be necessary. Smith et al. reported that clinical information was unavailable in 13.6 percent of primary care visits and that this missing information was at least somewhat likely to adversely affect patients 44 percent of the time.[21] We found that communication with other offices appears to be especially problematic, particularly for clinicians attempting to fulfill what the Institute of Medicine and others consider the defining task of primary care, coordinating comprehensive care across the health care system.[22, 23, 24]

We also found errors associated with patient harm that might be less amenable to systematic intervention, namely, the errors in judgment and knowledge. Woolf et al., found that over three-quarters of errors reported by family physicians to a primary care error reporting system were mistakes in treatment or diagnosis;[19] Bhasale and colleagues reported that errors in judgment were common factors contributing to poor outcomes.[20] Our results show that errors in judgment and knowledge were more than three times as likely to result in clinical harm to patients as errors not involving this lapse. Educational interventions that address the way physicians in training frame clinical hypotheses and confront inconsistencies with their hypotheses, such as those proposed by Borell-Carrió and Epstein,[25] might address some of the diagnostic and other clinical errors that lead to harm. In the meantime, very specific, effective interventions to address cognitive errors (e.g., decision support) are needed.

We acknowledge that there are a number of limitations associated with our research, including the fact that the error data collected and analyzed were self-reported by clinicians and office staff. Reports of the errors themselves and any clinical harm (or lack of harm) associated with each error could not be independently verified. In addition, the frequency—and thus the number—of reported errors resulting in harm was also a limiting factor in our analysis. Large-scale studies with more reported events would allow for the development of a fuller understanding of the relationships of specific categories of errors to overall harm and to one another. Finally, the ASIPS data, which were reported to a voluntary reporting system, might not be representative of all errors that occur in primary care or the harm associated with those errors, and they likely underestimate the occurrence of medical errors.[26] Until we can create a culture that embraces learning from our mistakes, including implementing comprehensive error reporting, we will understand only a fraction of all medical errors and their associated harm.

Despite these limitations, this study is among the first primary care studies to document the potential patient harm of ambulatory primary care medical errors. Better understanding of what distinguishes errors that are associated with patient harm from those that are not is essential in our attempts to improve patient safety. Additional, efficient methods of identifying and studying medical errors in primary care are necessary. Detailed mapping of specific processes within primary care settings that correspond to those areas most associated with patient harm is

necessary for the development and evaluation of specific interventions designed to reduce the harm caused by medical errors.

Conclusion

Across inpatient and outpatient care settings, the utility of medical error reporting systems is being recognized. However, the resultant data can present researchers and practitioners alike with large data sets containing hundreds or even thousands of carefully analyzed and coded errors. The challenge is to determine how to best use these data to improve patient safety. The ASIPS project team developed one such approach using a mixed methods strategy,[27] but certainly other approaches exist.

Our efforts have shown that it is possible, using reporting systems and coding methods designed to capture the presence of patient harm, to isolate the attributes of certain reported medical errors that are most frequently associated with harm. We posit that this is a step in the critical path toward identifying and isolating those clinical processes that warrant our closest attention. By incorporating these data into a clinical quality improvement framework, quality and safety improvement efforts can focus on isolating the root causes of the most dangerous medical errors and identifying the critical control points or workflows that could be changed to reduce or eliminate future hazards.

The areas of clinical harm and risk of future harm identified by our analysis might not come as a surprise to experienced clinicians or researchers who have long been concerned about the harm associated with prescribing errors and those errors related to communication with entities outside the physician's office. By increasing our ability to capture information about patient harm in medical error reports and by assessing the association of harm with specific types of errors, we believe our efforts to become better "detectives" to identify the problems within our clinical processes will be enhanced, and our interventions will become more targeted, more appropriately evaluated, and thus, more effective in the future.

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