



Patient Safety in the Office-Based Practice Setting

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Executive Summary

The issue of medical errors caught the attention of policymakers in 1999 when the Institute of Medicine (IOM), now called the National Academy of Medicine, published "To Err is Human: Building a Safer Health System" and its 2001 follow-up "Crossing the Quality Chasm." The "To Err Is Human" report found that between 44,000 and 98,000 people died each year due to medical errors (1). The report initiated a national conversation about patient safety and prompted policymakers to issue studies and new commissions and develop value-based purchasing policies and prompted researchers to test and develop patient safety improvement strategies. Despite the increased focus and some evidence of improved outcomes in the 15 years after the release of the IOM report, medical errors continue to be a serious problem. One 2016 study estimated that medical errors are the third leading cause of death in the United States, with over 251,000 people dying each year from medical mistakes (2, 3). A 2010 U.S. Department of Health and Human Services Inspector General report found that adverse events contributed to the deaths of approximately 180,000 Medicare beneficiaries and increased government health care costs by about \$4.4 billion annually (4).

The 1999 IOM report states that "safety is defined as freedom from accidental injury. This definition recognizes that this is the primary safety goal from the patient's perspective. Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (1). Errors can occur in the diagnostic (such as an error or delay in diagnosis), treatment (error in the performance of an operation, procedure, or test), and preventive (inadequate monitoring or follow-up of treatment) domains. Errors reported by primary care physicians involve complications from misdiagnosis, poor communication, medicines, and broader organizational or system issues (5).

Patient safety in the ambulatory setting was largely ignored over the decade following release of the IOM's report. One commentator called it a "lost decade" in ambulatory safety (6). While much attention has been directed to addressing medical errors that occur in the hospital, outpatient setting errors are just as, if not more, prevalent (7). More health care interactions occur in the outpatient than inpatient setting. More than 922 million physician office visits occurred in the United States in 2013, and 53% of them were primary care visits (8). By contrast, there were about 33 million inpatient admissions to community hospitals in 2014 (9). The high volume of outpatient care increases the potential for error. An analysis of paid medical malpractice claims from 2005 to 2009 found that of the nearly 11,000 paid claims on behalf of physicians, 43% were for outpatient setting events (10). Many of these events had tragic outcomes, with 36% ending in major injury and nearly 31% of events leading to the death of the patient. In 2009, \$1.3 billion in malpractice claims for outpatient errors were paid.

Attention to outpatient sector safety is growing, partly because of health care consolidation and the gradual move to more systems-based care where collaboration and communication across the continuum of care can be achieved (11). However, existing patient safety practices that may be effective in the inpatient setting may not work or be relevant to ambulatory care. Outpatient errors are a particularly vexing and complex problem, because there are thousands of outpatient care clinicians, many of whom do not have the time or resources to support dedicated patient safety efforts. Most private-public partnerships and accreditation bodies like the Joint Commission have given limited attention to addressing outpatient safety issues (12). Legislative efforts to address patient safety issues are generally not relevant to care that occurs outside of the hospital. This is beginning to change as the Joint Commission's 2017 National Patient Safety Goals include ambulatory care and the Agency for Healthcare Research and Quality (AHRQ), the primary federal agency for patient safety research, is devoting more attention to the issue (13).

In this policy paper, the American College of Physicians offers recommendations on improving patient safety in the ambulatory setting, with particular focus on office-based practices.

Recommendations

Recommendation 1: ACP believes that physicians and health care organizations have a responsibility to promote a culture of patient safety within their practices and among colleagues with whom they collaborate.

- Patient safety goals must be embedded in the daily activity of the health care team and office staff.
- Medical error reporting efforts should encourage accuracy, confidentiality, and compliance and ensure that information is useful, actionable, and non-punitive (just culture) and is focused on actual events and near-misses.
- A culture of safety can be encouraged by adopting liability protections that protect physicians and the health care team from being penalized for reporting errors and working with patients to address safety issues.

Recommendation 2: ACP recommends that physicians and other health care professionals, payers, government, and other relevant stakeholders should conduct research and work to address physician stress, burnout, and organizational culture that may impact medical errors.

Recommendation 3: Patient and family education, engagement, and health literacy efforts are needed to educate the public about asking the right questions and providing the necessary information to their physician or other health care professional. Materials should reflect the linguistic and cultural characteristics of the audience.

Recommendation 4: ACP supports the continued research into and development of a comprehensive collection of standardized patient safety metrics and strategies, with particular attention to primary care and other ambulatory settings. Domains could include medication safety, diagnosis, transitions, referrals, and testing issues. ACP recommends expanded patient safety research efforts to better understand the ambulatory medical errors and the efficacy of patient safety practices.

Recommendation 5: Team-based care models, such as the patient-centered medical home, should be encouraged and optimized to improve patient safety and facilitate communication, cooperation, and information sharing among team members.

Recommendation 6: Health information technology systems should be tailored to emphasize patient safety improvement.

Recommendation 7: ACP supports the establishment of a national effort to prevent patient harm across the health care sector. A national entity could be charged with coordinating and collaborating with stakeholders, defining the problem, setting national goals, and developing and assisting in the implementation of a patient safety action plan with attention given to the ambulatory setting.

Background

Medical Errors in the Office-Based Practice Setting

Patient safety occurrences include adverse drug events, improper infusions, suicides, restraint-related injuries or deaths, falls, burns, pressure ulcers, and amputation errors. Although intensive care units (14), emergency departments (15), and operating rooms (16) are especially high-risk settings for medical errors, they occur in the office setting as well. The more prevalent ambulatory setting errors—diagnostic, medication, communication, and transition or referral errors—are discussed below.

Diagnostic Errors

Diagnostic errors are the most common type of error that occurs in the ambulatory setting. Although definitions and terminology for diagnostic errors vary (17), the IOM has developed a patient-centered definition of diagnostic error: “the failure to (a) establish an accurate and timely explanation of the patient’s health problem(s) or (b) communicate that explanation to the patient” (18). The IOM committee explained that the first part of its definition relates to accuracy and timeliness of a diagnosis while the second part reflects the “key responsibility of the diagnostic process,” accurate and timely communication of the health problem in a manner that reflects the patient’s level of health literacy and informs understanding. Singh and colleagues frame diagnostic error as a “missed opportunity” to make a correct or timely diagnosis, arguing that this definition encourages stakeholders to move away from attributing blame to learning opportunities (19).

According to the IOM, at least 5% of all U.S. adults who receive outpatient care each year will experience a diagnostic error and most people will likely experience a meaningful diagnostic error in their lifetime (18). A population-based study estimated that the rate of outpatient diagnostic errors is 5.08%, or about 12 million U.S. adults every year (20). The IOM estimated that 10% of patient deaths are attributable to diagnostic errors and found that most paid malpractice claims for the outpatient setting were attributable to diagnostic errors. Bishop and colleagues’ study also found that most paid claims for outpatient errors (43%) involved diagnostic services (10). A 2017 study conducted by the Mayo Clinic found that 21% of patients who had received a second opinion regarding a diagnosis had their original diagnosis completely changed and 66% of patients saw their original diagnosis better defined or redefined; only 12% of original diagnoses were complete and correct (21). In a 2006 review of paid malpractice claims for diagnosis errors that resulted in adverse outcomes, 59% were associated with a major or significant physical adverse outcome and 30% were associated with death (22). The diagnoses missed were cancer (59%, with 24% involving breast cancer), infections (5%), fractures (4%), and myocardial infarctions (4%). Eighty-five percent of errors occurred in physicians’ offices. A 2013 study used electronic medical record triggers to detect primary care diagnostic errors and found that pneumonia, decompensated congestive heart failure, and cancer were the most common diagnoses missed (23).

Adverse Drug Events and Medication Errors

Medication errors, defined by AHRQ as an “error (either of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when a patient actually receives a medication” are also relatively common in outpatient care (24). The IOM estimates that 1 in 131 outpatient deaths are associated with medication errors (1). These may include errors that occur from prescribing, dispensing, and monitoring medications, as well as from failure to note harmful drug interactions or discontinue a patient’s prescription when necessary (25). Adverse drug events (ADEs), which are defined by AHRQ as “harm experienced by a patient as a result of exposure to a medication,” account for 700,000 emergency department visits and 100,000 hospitalizations each year (24), although many ADEs are not preventable and are not associated with clinician error. Each year, 4.5 million adverse drug event-related ambulatory

visits occur and are more likely to be reported in primary care than specialty visits (26). In 2007, the IOM evaluated the literature on medication errors in the ambulatory care setting. The report found that 21% of prescriptions contained at least 1 prescription writing error, documentation errors including current medications per patient missing from patient record, and 15% of prescription renewals missing from patient record (27). Computerized provider order entry (CPOE) systems may help to address medication errors, as discussed under Recommendation 6. Treatment or medication errors accounted for nearly 30% of outpatient errors in Bishop and colleagues' study (10), not including those that were attributed to both inpatient and outpatient settings. Medication errors may also include problems arising from patient nonadherence. Twenty to thirty percent of prescriptions are never filled and on average, half of prescriptions taken for chronic diseases are used incorrectly (28). Patients who take multiple prescriptions (polypharmacy) are especially at risk for medication errors (29, 30).

Communication and Flow of Information Errors

Poor communication contributes to diagnostic errors, medication errors, and problems related to delay in delivery of preventive care. Communication errors can occur among patient/family, clinician and office staff members and along the chain of communication from patient to primary care provider to subspecialist (31). One literature review found that although data are scant, there is some evidence of information gaps during outpatient to acute care transitions (32). Lack of communication between hospital staff and a patient's primary care physician at the point of discharge can have a negative effect on the quality of follow-up care (33). Missing laboratory, imaging, and other test reports can also lead to communication lapses (31). Relatedly, a systematic review found that failure to follow up on test results in part due to communication deficits among providers or to alert patients of laboratory and other test results also contribute to patient safety problems (34).

Transitions Among Health Care Clinicians and Referral Issues

According to the Joint Commission, transitions of care "refer to the movement of patients between health care practitioners, settings, and home as their condition and care needs change" (35). According to the World Health Organization (WHO), clinical handovers are the transfer of care among health care clinicians; transition of care is a broader term that considers the patient's contact with their health care professional and activity inside and out of the health care sector and how the patient experience, needs, and other variables may affect care (36). Much attention has been focused on hospital discharge transitions, where risk for an error-prone patient transfer is high; for example, adverse drug events after discharge are relatively common (37). Other evidence found medication continuity errors, work-up errors, and test follow-up errors due to discontinuity of care problems after patients were discharged to outpatient care (38). Errors also occur during transitions among ambulatory health care professionals, ambulatory and emergency department transitions, skilled-nursing facility to hospital transitions, among other examples (25,39).

Why Do Errors Occur?

Preliminary findings from a WHO report on patient safety and primary care determined that communication between health care professionals and patients, teamwork issues, laboratory and diagnostic imaging investigations, data management issues, patient transitions between health care professionals at different levels of care, and chart and patient record completeness warranted attention as sources of patient safety occurrences (40).

The IOM identified many system-level factors that contribute to the problem of medical errors, including the fragmented health system that impedes collaboration among physicians and health care professionals and creates unsafe conditions, licensing and accreditation processes that do not emphasize error prevention, a "deny-and-defend" medical liability system that discourages health care

professionals from admitting mistakes, and lack of incentives from payers to address errors (41).

The diagnostic process is very complex and is affected by variables outside of the physician's control; if a patient provides an incomplete medical history, the physician is not equipped to consider past interventions or undisclosed health risks that may lead to unintended errors. There are tens of thousands of diseases and thousands of laboratory tests but a relatively limited number of symptoms that can point to a vast number of health problems (42). Gandhi and colleagues list the leading "breakdown points" that lead to diagnostic errors, including failure to order a proper diagnostic test, (55% of cases), failure to create a proper follow-up plan (45%), failure to obtain an adequate history or perform an adequate physical examination (42%), and incorrect interpretation of diagnostic test (37%) (22). Similarly, a study of closed medical liability claims involving primary care physicians determined that most diagnostic errors were related to acquisition and updating of patient and family history, physical examinations, and symptom evaluation; ordering or failure to order diagnostic or laboratory tests; and referral management and patient follow-up (43).

Prescriber-related medication errors may occur due to communication problems (such as illegible prescriptions, use of confusing abbreviations) and cognitive issues (such as confirmation bias, where a physician selects an intervention based on an initial decision or familiar beliefs). Other risks include substitution errors and confusion due to drug label changes (44). Medication errors may also occur due to the health care professional's lack of training, knowledge, and experience with the drug; inadequate knowledge of the patient; perception of risk; fatigue or stress; or poor patient-clinician communication (45). In contrast to inpatient care, ambulatory care disproportionately relies on the patient to manage their own care. Patient-related factors that may influence risk for medication errors include a patient's level of literacy or language barriers and number of medications involved (45). Actively monitoring patient adherence between office visits or other patient-clinician interactions is very difficult; the physician or other health care professional can only assume that the prescription was filled properly, the dose is correct, and the patient is administering it correctly. In a study evaluating root causes of medication errors, 56% of cases were tied to patient error (46).

Care transition errors may occur due to communication breakdowns among members of the patient's care team, insufficient patient education, or accountability breakdowns. (35). Patients with multiple chronic illnesses, the elderly, people with cognitive impairments, and individuals with limited English proficiency are among those who are particularly vulnerable to transition-related errors (47).

Progress on Reducing Medical Errors and Improving Patient Safety

The bulk of patient safety initiatives over the last 20 years have focused on the inpatient setting. The IOM established a target to cut medical errors by 50% by 2004, but that goal was not realized, owing in part to lack of effective communication and information tools, poor incentives, and resistance to change (48).

Many of the IOM's recommendations have come to fruition. AHRQ has a Center for Quality Improvement and Patient Safety that is charged with conducting research on patient safety, developing and distributing reports on quality measurement, and working with health care system stakeholders to implement evidence-based patient safety and quality improvement practices (49). AHRQ's Patient Safety Organization (PSO) program provides a means for physicians and other health care professionals to report medical errors and work with patient safety experts on strategies to reduce errors in a confidential manner protected from the threat of liability (50). The ACP New York Chapter's near-miss registry was introduced in 2006 and operated through 2012 under state data protections. Near-misses are defined by AHRQ as "an unsafe situation that is indistinguishable from a preventable adverse event except for the outcome. A patient is exposed to a hazardous situation, but does not experience harm either through luck or early detection" (51). The near-miss registry subsequently operated under the protection of federal PSO statute in collaboration with ACP through 2016. The registry has now returned to operating solely in New York and includes the

potential to track near-misses in ambulatory practice settings in addition to those that occur in hospital and training areas. The Patient Protection and Affordable Care Act called for the creation of a National Quality Strategy, which lists improved patient safety among its priorities (52). The public-private Partnership for Patients initiative seeks to reduce hospital-acquired conditions by 40% and hospital readmissions by 20% over 3 years compared with 2010 levels. Participants can join the Hospital Improvement Innovation Networks to share patient safety strategies with like-minded hospital systems. ACP is affiliated with the Coalition to Improve Diagnosis, which is dedicated to increase awareness, action, and attention to the problem of diagnostic error (53).

Although a national error reporting system has yet to be authorized, 28 states now require hospitals (and some ambulatory facilities) to report adverse events (54). Patient safety measures, checklists, and guidelines have been developed (with help from AHRQ funding), including those seeking to address pressure ulcers, reduce diagnostic errors, and prevent central line infections, and have become ingrained in practice norms (55). The Joint Commission established the National Patient Safety Goals program and has made accreditation contingent on adopting patient safety standards, and payers, such as Medicare, have pegged reimbursement to patient safety performance (56, 57). Other independent efforts, such as the Institute for Healthcare Improvement's 100,000 Lives Campaign and the Protecting 5 Million Lives from Harm projects, Blue Cross Blue Shield of Michigan's Michigan Regional Collaboration Improvement Program, and Johns Hopkins University's Comprehensive Unit-Based Safety Program have focused on determining and disseminating best practices to ensure patient safety.

The 2015 AHRQ National Healthcare Quality and Disparities Report Chartbook on Patient Safety indicates that outcomes have improved overall, but many problems persist. The data show that during the period of 2002-2003 through 2013, over 60% of patient safety measures with trend data available had shown improvement; however, for approximately one third of patient safety measures, white and higher-income individuals received higher-quality care than African American, Asian, and lower-income households (52, 58). The report found that hospital-acquired condition rates, such as adverse drug events and pressure ulcers, dropped by 17% from 2010 to 2014, possibly due to payment incentives (such as the Centers for Medicare & Medicaid Services' [CMS] policy to not reimburse "never events" like wrong-side surgery), public reporting of hospital-level results, value-based payment models that connected payment to safety goals, better research to determine what interventions work, and the Department of Health and Human Services' Partnership for Patients initiative (59,60,48). Similarly, Wang and colleagues reviewed trends in patient safety related to acute myocardial infarction, congestive heart failure, pneumonia, and conditions requiring surgery. From 2005 to 2011, adverse events for acute myocardial infarction and congestive heart failure dropped, but reductions were not apparent for pneumonia and conditions requiring surgery (61). Hospital-acquired conditions are also decreasing.

The National Patient Safety Foundation (NPSF) released a report, "Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after 'To Err is Human,'" that outlined the nation's progress on addressing patient safety and highlighted gaps. The report calls for a "total systems approach" to improving patient safety and specifically recommends encouraging a culture of safety, coordinated oversight of patient safety efforts, development of safety measures, funding for patient safety research, workforce education and morale support, improved health information technology (IT), and better patient and family engagement (62).

Recommendations

Recommendation 1: ACP believes that physicians and health care organizations have a responsibility to promote a culture of patient safety within their practices and among colleagues with whom they collaborate.

- **Patient safety goals must be embedded in the daily activity of the health care team and office staff.**
- **Medical error reporting efforts should encourage accuracy, confidentiality, and compliance and ensure that information is useful, actionable, and non-punitive (just culture) and is focused on actual events and near-misses.**
- **A culture of safety can be encouraged by adopting liability protections that protect physicians and the health care team from being penalized for reporting errors and working with patients to address safety issues.**

A culture of safety ensures that all staff in an organization is committed to safety and the reduction of adverse events. The concept of safety culture comes from other “high reliability organizations,” such as the aviation industry and the military, where constant attention is given to safety despite the complex, potentially dangerous work. Because unexpected safety issues are constantly emerging, “high reliability organizations work to create an environment in which potential problems are anticipated, detected early, and virtually always responded to early enough to prevent catastrophic consequences” (63). According to AHRQ (64), key characteristics of safety culture in health care include:

- “acknowledgment of the high-risk nature of an organization’s activities and the determination to achieve consistently safe operations
- a blame-free environment where individuals are able to report errors or near misses without fear of reprimand or punishment
- encouragement of collaboration across ranks and disciplines to seek solutions to patient safety problems
- organizational commitment of resources to address safety concerns.”

Overall, health system leadership has been slow to embrace patient safety as an overarching goal. The paradigm shift toward a culture of safety has not been realized in ambulatory care, although transformation has progressed in the inpatient setting. Lack of collaborative spirit, “turf issues” that discourage cooperation and effective communication, a “culture of low expectations,” fear of litigation, and poor interoperability of health technology have stymied the full embrace of the patient safety mission (64, 65).

According to Weaver and colleagues’ review of inpatient safety culture, “multiple components that incorporate team training and mechanisms to support team communication and include executive engagement in front-line safety walk rounds” have shown to be effective in creating a climate of safety (66). In the office setting, building a safety culture should be a multidisciplinary effort and include all staff that interacts with the patient, from the physician to the front office workers. A crucial element is that physicians, health care professionals, and medical office staff must feel comfortable in reporting errors and confident that they will be treated fairly and not be severely punished if an unintentional mistake is made (67). Patients and family members should also be considered critical members of the health care team.

A group of clinics affiliated with a hospital in Washington state took initial steps to address patient safety issues by forming a patient safety committee that was represented at all staff levels (68). A patient safety survey was taken to better understand the existing climate, including whether staff felt the practices could prevent, identify, and correct problems that could harm patients; whether staff felt they could openly discuss office problems; whether error prevention strategies were discussed; and willingness to report mistakes. Once survey information was gathered, it was determined that an error reporting system and reporting protocols and standards were implemented. Staff was educated on the merits of

error reporting, and clinic leaders were charged with reminding their staff of the importance of reporting. Monthly reports summarizing errors that were reviewed, investigated, and closed were distributed. To address errors, the clinic system adopted the Just Culture system, which “recognizes that competent professionals make mistakes and acknowledges that even competent professionals will develop unhealthy norms (shortcuts, ‘routine rule violations’), but has zero tolerance for reckless behavior” (69). As errors were reported and tabulated, staff identified problem areas (in this case, vaccination errors and problems with test specimen labeling) and took action to address them. Ongoing efforts to measure errors and progress, train staff in addressing problems, and assist as needed to achieve improvement were also crucial. To assist medical offices in assessing and building a safety culture, AHRQ has developed a Medical Office Survey on Patient Safety Culture to aid practices in gauging how staff perceives the culture of safety (70) and has assembled a collection of resources for offices that use the survey (71). It is important to note that any such program or survey should be implemented in a manner that actively assesses the administrative tasks involved to ensure that they are not excessively burdensome—a framework and taxonomy for how to analyze these tasks has been outlined in an ACP position paper “Putting Patients First by Reducing Administrative Tasks in Health Care” (72).

Although the issue of medical liability is outside the scope of this paper, many physicians and other health care professionals are hesitant to report errors because of fear of litigation. One potential way to address this is the testing of apology and disclosure approaches where the physician is encouraged to disclose that an error has occurred, apologize to a patient, and resolve the case (73, 74). Legal protections are afforded to the physician so their admission of error is not admissible in a court of law. In its 2014 paper “Medical Liability Reform: Innovative Solutions for a New Health Care System,” ACP expressed support for testing disclosure and apology programs (75).

Recommendation 2: ACP recommends that physicians and other health care professionals, payers, government, and other relevant stakeholders should conduct research and work to address physician stress, burnout, and organizational culture that may impact medical errors.

Physician stress and burnout, “a syndrome characterized by emotional exhaustion, depersonalization, and decreased professional effectiveness,” is growing and is associated with medical errors, medical liability lawsuits, and other negative consequences (76). A 2012 survey found that nearly half of U.S. physicians surveyed experience at least 1 symptom of burnout, and the prevalence of burnout is higher among physicians than other workers (77). General internal medicine physicians and other front-line physicians were among specialties reporting the highest amounts of burnout. Subsequent surveys indicate that the problem is worsening (78).

Health care sector-related risk factors for burnout include “time pressure, lack of control over work processes, role conflict, and poor relationships between groups and with leadership, combine with personal predisposing factors and the emotional intensity of clinical work to put clinicians at high risk” (78). Time pressure and increasing workloads may also undermine physician adherence to clinical guidelines (79). Health information technology (IT) can improve or have a negative effect on patient safety. Concerns have been raised about the association between electronic medical records (EMRs) and higher stress levels, less job satisfaction, and increased time pressure among primary care physicians (80). Alert fatigue due to the barrage of information delivered through CPOEs, EMRs, and other avenues may cause clinicians to tune out and become desensitized to information, potentially raising the risk for an adverse event (81). Error incident reporting can also pose an administrative burden, discouraging clinicians from reporting less severe mistakes (67).

Burnout and stress may affect patient safety in various ways. Emotional exhaustion, which is linked to standardized mortality ratios among intensive care units, may affect cognitive and physical ability to perform tasks and diminish

memory and attention, lessening ability to attend to details and process highly technical information; mental detachment and deficiencies in personal accomplishment may cause individuals to neglect duties or complete seemingly minor but crucial patient safety activities (82).

The National Patient Safety Foundation's report recommends that workforce support efforts attend to improving working conditions and staff resiliency and fostering mutual respect. Programs could also include fatigue management systems, and communication, apology, and resolution skills. The Minimizing Error, Maximizing Outcome Study recommends that primary care-based medical errors could be addressed by emphasizing communication and information systems, building a culture of quality, and addressing factors that make the office environment stressful and chaotic (83). Workflow redesign (such as changing call schedules and assigning certain tasks to nurses or medical assistants), improved communication among clinicians and staff (including teamwork building and monthly clinician meetings to enhance collegiality), and quality improvement projects directed at clinician concerns (like more automated prescription phone lines and medication reconciliation projects) may help to reduce burnout (84).

Recognizing the problem of burnout, stress and administrative burden on physicians, ACP's recent position paper "Putting Patients First by Reducing Administrative Tasks in Health Care" recommends that payers, governmental oversight organizations, and others assess administrative requirements, regulations, and programs to determine their effectiveness and viability and decide whether they should be changed or eliminated. The paper further recommends that necessary administrative tasks be streamlined and calls for research and the development of best practices related to administrative tasks (72).

Recommendation 3: Patient and family education, engagement, and health literacy efforts are needed to educate the public about asking the right questions and providing the necessary information to their physician or other health care professional. Materials should reflect the linguistic and cultural characteristics of the audience.

Among IOM's 21st-century health care system goals are that health care should be patient-centered, meaning "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions" (85). However, patients may not be actively engaged with their clinicians in their care, do not know what questions to ask their clinicians, and do not share in the decision making regarding their treatment.

Communication breakdowns between clinicians and patients may threaten patient safety. Use of medical jargon, health illiteracy, and limited understanding of information can increase the risk for problems (86). Further, patient confusion could lead to medication adherence problems that lead to adverse drug events. Evidence shows that patient engagement is associated with fewer inpatient adverse events (87) and can instigate best practices, such as high hand-washing rates among clinicians (88). The IOM has called for improved patient-clinician communication to reduce medication errors, noting that by taking such actions as double-checking prescriptions when dropping off and picking them up from the pharmacy, asking their prescribing clinician to clearly explain their medication regimen, and reporting any unexpected reactions after taking their medication, patients can reduce the potential for errors (89). The IOM has also stressed the importance of patient-clinician engagement in improving diagnosis, recommending that "health care professionals and organizations should partner with patients and their families as diagnostic team members and facilitate patient and family engagement in the diagnostic process, aligned with their needs, values, and preferences" by creating an environment that is conducive to patient engagement, making electronic health records and diagnostic testing results accessible to patients, and identifying opportunities to include patients and families in efforts to learn from diagnostic errors and near-misses (18).

Patient-centered care may be achieved through shared decision making. Shared decision-making efforts typically use patient decision-making aids to enable clinicians and patients to discuss their treatment options and guide patients to make informed decisions about their care based on their clinical needs and preferences. Evidence shows that compared with usual care, patient decision aids help patients be better informed about their treatment options and aware of the risks and benefits involved (90). However, evidence is mixed on whether informed patients are engaged in the decision-making process. Permitting patients to view their clinician's medical notes may prove to increase patient understanding and medical adherence (91, 92). One study found that when patients were granted access to their physician's notes through a protected electronic portal, they reported greater ability to adhere to medications as prescribed, better sense of control, and an enhanced understanding of their medical issues (93). Physicians did not experience increased workload due to the accessibility of notes, and the vast majority expressed that making the notes available was a good idea.

AHRQ has developed patient safety resources to help patients become better partners in their care, including pamphlets and videos outlining important questions to ask your doctor (94). The Centers for Disease Control and Prevention (CDC) has information on what patients can do to avoid infections (95) and the Joint Commission's Speak Up campaign offers communication tips on various topics, including preventing ambulatory care errors (96). ACP's Center for Patient Partnership in Healthcare has developed resources to educate patients on talking with their doctor (97). For clinicians, AHRQ has developed a Guide to Patient and Family Engagement in Hospital Quality and Safety and is in the process of developing a similar resource for primary care. Among the interventions included are "Teach-Back," a resource to enable clinicians to explain medical information to patients, a communication toolkit for patients and their families, a medication management toolkit, and a guide to improving warm handoffs, where the transfer of care between clinicians occurs in the presence of the patient and family to allow for communication and engagement (98). To address language barriers, ACP has called for policies to encourage the use of availability and use of language services for patients with limited English proficiency, including clinician reimbursement for additional time and materials related to providing care for patients with limited English proficiency (99).

Recommendation 4: ACP supports the continued research into and development of a comprehensive collection of standardized patient safety metrics and strategies, with particular attention to primary care and other ambulatory settings. Domains could include medication safety, diagnosis, transitions, referrals, and testing issues. ACP recommends expanded patient safety research efforts to better understand the ambulatory medical errors and the efficacy of patient safety practices.

Although AHRQ, the Joint Commission, the National Committee for Quality Assurance, and the National Quality Forum have endorsed ambulatory patient safety measures, most measurement development has been focused on the inpatient setting and initiatives like the Value-Based Purchasing and Hospital-Acquired Conditions penalties continue momentum along this path. Of the 22 patient safety measures endorsed by NQF in 2016, only 4 were related to the ambulatory setting (100). If ambulatory care patient safety is going to improve, errors will have to be reported and compared with patient safety targets to help understand the epidemiology of errors and spur better outcomes. Development of process and outcomes measures for outpatient safety is difficult because patients are cared for by multiple clinicians in multiple settings, complicating coordination of care assessment, and real-time tracking of outpatient safety events is more difficult to achieve than in the inpatient setting (101). Also concerning is the issue of proper attribution to ensure physicians and other health care professionals are not blamed for errors outside of their control. Despite the complexity, AHRQ has recommended that measurement development efforts focused on medication

safety, diagnosis, transitions, referrals, and testing issues and has also called for rigorous research into intervention development (25). Of importance, measures need to be rigorously researched, tested, standardized, and harmonized across settings to eliminate duplication and adverse administrative burden. An evidence-based, patient-centered process to consider which metrics to improve, which to jettison, and which to innovate is necessary to ensure that metrics are working as intended.

A report by the American Medical Association (AMA) highlighted ambulatory patient safety research gaps over the 2000-2010 period: Patient safety studies often relied on malpractice claim data that exempted errors for which no claim was filed, research included events where no harm occurred, lack of standard taxonomy made comparing research results difficult, and research had been too focused on primary care and limiting the knowledge base for other settings (102). AHRQ calls for “prospective, large-scale studies in diverse ambulatory settings to develop and test ambulatory safety interventions” (25). The AMA report buttresses the call for more intervention research. Further, the IOM and AHRQ has noted the need to fund research into the diagnostic process and diagnostic errors.

Recommendation 5: Team-based care models, such as the patient-centered medical home, should be encouraged and optimized to improve patient safety and facilitate communication, cooperation, and information sharing among team members.

Safety improvement initiatives should consider the rapidly changing ambulatory care environment and emerging delivery system models. In its various reports on patient safety, the IOM has called for a patient-centered approach to patient safety, and evidence suggests that health care delivery system models that encourage better communication and collaboration among clinicians may be associated with safety improvements, such as those caused by communication breakdowns among physicians and other health care professionals.

Although evidence on the effect of reimbursement on diagnostic errors is limited, it may affect the diagnostic process (103). The fee-for-service model provides an unintentional financial incentive to order unnecessary diagnostic tests which could lead to false positives and inappropriate diagnoses, and there is no mechanism to encourage care coordination (18). Other payment approaches, such as capitation, may unintentionally cause clinicians to avoid delivering necessary services (104). Patient safety experts have noted that the patient-centered medical home (PCMH) model holds promise to facilitate patient safety practices and should be further studied (25). The PCMH seeks to improve coordination, communication, and continuity of care and may also cultivate patient and family engagement in such activities as review of medical information and treatment results, improved medication and treatment information sharing among settings, and encouraging patients to report adverse events and errors although more evidence is needed (105, 106). Clinical decision making can be supported through electronic health records and patient information embedded in the PCMH. Due to this potential, the IOM recommends that the CMS and other payers review the effect of delivery and payment system reform initiatives on diagnostic process and diagnostic errors and learning from such errors. Moreover, team-based care models where clinicians work to the top of their license may be better able to support patient safety initiatives in smaller practices where, unlike hospitals and large systems, they do not have the resources to support a dedicated quality or patient safety staff member.

Recommendation 6: Health information technology systems should be tailored to emphasize patient safety improvement.

Health IT systems can have a positive or negative effect on patient safety. An efficient, interoperable health IT system could facilitate health care team communication, efficient workflow, and delivery of educational prompts that improve

timeliness and accuracy of diagnoses, enhance care transitions, and referrals. Health IT could also facilitate patient-clinician communication outside of the office setting in ways that mitigate the potential for errors and improve patient self-management. ACP's 2017 Health IT Policy Strategic Plan calls for building systems that support patient-physician communication and decision making, improve multiclinician care, and enhance information visualization and anticipatory decision-support capabilities.

Computerized provider order entry systems have been shown to reduce medication errors caused by the point of ordering and transcribing and have been widely adopted in the hospital and outpatient setting following implementation of the federal HITECH Act and Meaningful Use program (107, 108, 109). Technologies, such as text-based and pager alerts, computerized decision-support systems, and decision-support algorithms, may help reduce diagnostic errors (110). On the other hand, there is evidence that CPOE systems can raise the risk for medication errors, such as "fragmented CPOE displays that prevent a coherent view of patients' medications, pharmacy inventory displays mistaken for dosage guidelines, ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system, separation of functions that facilitate double dosing and incompatible orders, and inflexible ordering formats generating wrong orders" (111).

Health IT may also support patient and family interaction: Preliminary evidence shows that providing patients with tools through a web portal to conduct medication reconciliation and discrepancy review may result in fewer adverse drug events (112). Trigger tools can help catch and alert clinicians of adverse events, but development of such tools for the ambulatory setting is limited (113, 114). Effective health IT systems should enable easy retrieval of data, have simple and intuitive displays, be easy to navigate, provide point-of-care decision-making support, enhance workflow, and reduce mundane tasks all while curbing increases in physical and cognitive workflow (115). Unfortunately, health IT systems do not always meet these goals, and many may increase the chance of patient errors (116). Although an extensive discussion on this complex area is outside of the scope of this paper, ACP maintains that health IT systems should be optimized to improve patient safety and enhance the quality of care by providing decision support, facilitating patient engagement, and promoting collaboration and communication among physicians and other health care professionals (117) in a way that reduces administrative burdens and workflow problems.

Recommendation 7: ACP supports the establishment of a national effort to prevent patient harm across the health care sector. A national entity could be charged with coordinating and collaborating with stakeholders, defining the problem, setting national goals, and developing and assisting in the implementation of a patient safety action plan with attention given to the ambulatory setting.

In its "Free from Harm" report, the NPSF calls for the creation of a centralized agency to coordinate patient safety efforts (62, 118). Such a body would function similar to the Federal Aviation Administration or the Nuclear Regulatory Commission and coordinate efforts, facilitate communication among stakeholders, provide direction, ensure accountability, and disseminate best practices. The IOM made a similar recommendation in its 1999 report to encourage collaboration among various government entities, payers, private sector, and the health care community. AHRQ, CDC, and CMS conduct much of the patient safety work at the federal level, and a coordinating agency could enhance cooperation among private and federal and state stakeholders. A centralized agency dedicated to patient safety would cull best practices, provide industry oversight, and ensure accountability. Establishing a regulatory agency would elevate the issue, broaden the focus from single patient safety initiatives, and help to break down silos that act as a barrier to system-wide patient safety improvement. The Federal Aviation Administration requires the submission of reports when serious incidents occur; the agency conducts an independent investigation and identifies causes and improvements.

In a 2017 position statement, the NPSF calls for designating preventable medical harm as a public health crisis (119). Based on the successful national campaign to eliminate health care-associated infections, the statement calls for the establishment of a national steering committee comprising various health care organizations and leaders to develop an action plan for the prevention of health care harm. Action plan activities would be coordinated across multiple sectors, patient engagement efforts would be enhanced, progress would be measured and monitored, relevant research would be conducted, and the health care workforce would be educated on issues like workplace conditions, a constructive work environment, staff resiliency, and medical liability disclosure, and apology and resolution programs. This effort would ensure that ambulatory medical errors receive the necessary attention are part of system-wide patient safety campaign.

Conclusion

As the health care system changes to encourage greater cooperation and collaboration across settings, advances in ambulatory patient safety could be achieved. However, the field is relatively nascent and advances in research are needed. It is important for physicians and other clinicians and policymakers to embrace and facilitate a culture of safety, where errors are reported, discussed, and addressed without fear of discovery. Further, as interventions are developed, they must be implemented across the care continuum and in a manner that minimizes unnecessary administrative tasks and systems that aggravate physician stress and lead to burnout.

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