Ensuring patient safety has been recognized as a major public health challenge. According to the Institute of Medicine (IOM), in the U.S. as many as 98,000 deaths per year are attributable to preventable adverse events that occur in the hospital setting, with annual costs (lost income, disability, and health care costs) of between $17 billion and $29 billion. Because the patient safety movement originated in and has focused on acute care settings, less is known about safety outside the hospital setting. A more recent IOM report concluded that the number of errors affecting outpatients is likely to far exceed those from the inpatient setting. As a result, the consequences and costs of medical errors in ambulatory settings may be comparable to or even greater than those in the inpatient setting, making ambulatory research and safety promotion all the more pressing.

Ambulatory visits constitute the overwhelming majority of medical care encounters, and with shorter hospital stays, patients cared for at home are sicker than in the past. Moreover, performing all recommended actions in the limited time of an office visit has become less feasible, increasing the potential for unsafe practices and errors. To advance ambulatory patient safety, we propose adapting the Chronic Care Model to frame the research, practice, and policy agenda. We employ clinical vignettes to illustrate the links between the Chronic Care Model and safe provision of ambulatory care and we use this adapted model to propose avenues for future research and intervention. We aim to link safety and self-management conceptually, so that the systems approach to safety can inform chronic disease management and the patient-centered approach to chronic disease management—one that emphasizes the primacy of the patient—can inform the patient safety movement.

### Contrasting Hospital and Ambulatory Safety

The terms patient safety, adverse events, and medical errors have all been used to describe morbidity and mortality associated with medical care and treatment. In this article, we use the IOM’s definition of patient safety: “the prevention of harm to patients.” The IOM further specifies that both errors of commission, such as prescribing a contraindicated medication, and errors of omission, such as failure to perform recommended medication monitoring, can each jeopardize patient safety. We acknowledge that the concepts of patient safety and quality of care overlap substantially; in fact, the IOM “strongly believes that patient safety is indistinguishable from the delivery of quality care.” However, the IOM definition of patient safety does not explicitly include patients as active participants in their care. Any argument that in the context of ambulatory care of chronic diseases, highlighting the patient’s central role in safe care is imperative.

In acute care settings, patients are under near-constant observation and often receive care as passive recipients. In contrast, ambulatory patients not only must navigate the health care system, they must actively obtain medical care and make critical self-care decisions. Although recent efforts such as The Joint Commission’s Speak UpTM initiatives (available at http://www.jointcommission.org/PatientSafety/SpeakUp/) have emphasized the need to activate hospitalized patients and inform about their role in promoting safety, this need also extends to ambulatory patients.

We have chosen to focus this discussion on safety for ambulatory populations with chronic diseases for several reasons. First, chronic disease care represents greater than 75% of all medical care. Enhancing patient safety in chronic disease care has clear public health relevance. Second, with today’s emphasis on aggressive treatment goals for chronic conditions, medication intensification and high-risk medication use routinely occur in ambulatory care, with corresponding reports of adverse events in chronic disease settings ranging from diabetes to organ transplantation. Third, chronic disease patients today take far more daily medications than was routine even a decade ago. Fourth, the high incidence of repeated adverse drug events (ADEs) in the same individuals supports the notion that those with chronic disease face espe
A Conceptual Model for Ambulatory Safety

The field of ambulatory safety research lacks a well-established conceptual model that takes into account the complex, longitudinal nature of chronic disease care. In this article, we extend Wagner’s Chronic Care Model2 using theoretical work in patient safety7 to develop a model for chronic disease safety, shown in Figure 1 (page 379). We propose adapting the Chronic Care Model because we believe that for patients with chronic diseases, multiple contributing factors interact in complex, often reciprocal ways, to produce a safe or unsafe state.

To describe the adaptation of this well-established model to ambulatory patient safety, we first discuss the community and health system. Second, we focus on the productive interactions between health systems and patients and providers, encompassing communication between patients and providers and among providers, and on transitions between different caregivers and settings. Third, we describe how behaviors on the part of patients and providers influence chronic disease safety in complex and reciprocal ways. Although safety threats often involve contributors within and across multiple levels from the model, to better elucidate the elements of this model we present case vignettes that highlight a particular component of the framework. These examples are drawn from actual cases that we have observed; identifying details (gender and initials) have been changed.

How Do the Community and Health System Affect Patient Safety?

Case 1. Health Information Decentralization. Mr. J, a patient with severe degenerative joint disease who is cared for by a rural physician, is referred to an orthopedist at an urban center. He receives a chest x-ray as part of the preoperative evaluation for knee replacement. The chest x-ray shows a mass, and his knee surgery is cancelled. The orthopedic surgeon is on vacation the following month, and the radiology report is never sent to the primary care physician. Mr. J follows up three months later with his primary care physician, who learns of the chest x-ray from Mr. J. He is found to have a primary lung cancer, which is successfully removed with surgery.

Mr. J’s delayed cancer diagnosis did not cause him harm, making this event a near miss, but only because the patient himself reported the test result to his physician. In ambulatory health systems, lack of information availability is a common problem. Poor information availability can lead to delays in diagnosis and treatment, which can then lead to errors and poor health outcomes.26 Studies of ambulatory medical errors identify diagnostic delays29 and lack of real-time information30,31 as important contributing factors.

Health information technology (IT), such as digitized radiology images and reports with remote-access capability, could have reduced the diagnostic delay for Mr. J. However, because ambulatory practices typically lack the personnel and resources that hospitals can provide, health IT–driven information systems remain out of reach for all but the largest ambulatory care networks.2 Although strategies such as computer physician order entry and computer medication monitoring are integral to patient safety guidelines,32 they remain the exception rather than the rule. Although health IT has been shown to facilitate reporting and detection of safety problems,33–38 both over- and under-detection of safety threats occur,39,40 and clinical outcomes and quality of care may not improve.37,41,42 Nevertheless, we believe that expanding and rigorously evaluating health IT innovations, particularly across disparate ambulatory systems, comprises a necessary step toward improving ambulatory safety.

In addition, accreditation requirements are far less stringent for ambulatory practices than for hospitals. For example, in the inpatient setting, the Joint Commission requires multidisciplinary investigation, including root cause analysis, into certain types of adverse events. Most ambulatory practices are not subject to such accreditation and do not have a mechanism for investigating adverse events, even in the unlikely event that providers submit reports. This lack of scrutiny makes understanding current safety conditions and achieving uniform safety standards a challenge. A root cause analysis of Mr. J’s near-miss situation might uncover fixable processes to deliver information. We propose careful development and implementation of safety-focused accreditation requirements for ambulatory practices.

How Do Interactions Affect Safety in Ambulatory Care?

Case 2. Transitions. Mr. F, who has diabetes, hypertension, and heart failure, sees a primary care physician, an endocrinologist, and
Mr. F is at high risk for patient safety problems because he has multiple chronic conditions and because he makes transitions among multiple providers. Transitions among care settings and among primary care, specialty care, pharmacy, other providers, caregivers, and home care all pose a risk for adverse events. At each point, patients must understand and carry out the plan of care, and providers must develop a plan even when lacking relevant, complete information. The concept of a medical home with coordinated care seeks to address the risks to safety inherent in these frequent transitions.

For patients with multiple chronic conditions, clinicians may need to alter their medication-prescribing behavior, for several reasons. First, each additional medication increases the likelihood of patient errors in medication administration. Second, patients with multiple chronic illnesses also face increased risk for medication interactions that can lead to ADEs. Third, more general frailty may lead to more severe ADEs. For example, Mr. F’s low serum sodium may cause him to fall and sustain a serious injury, whereas a comparable abnormality may not cause as much distress in a healthier individual. Finally, because of competing effects of multiple chronic conditions on morbidity and mortality, meeting all condition-specific performance measures may lead to unnecessarily aggressive treatment goals, as shown in studies of rational screening practices.

**Case 3. Inadequate Health Literacy.** Mrs. P, a patient with long-standing diabetes, has had worsening glycemic control during the past few months, although she reports being adherent to her dia-
Mrs. P's inability to read and correctly interpret medication labels, a common problem, led to months of poor diabetes control and placed her at risk for chronic acetaminophen toxicity. The adequacy of communication between patients and caregivers/providers is crucial to patient safety. Suboptimal clinician-patient communication in chronic disease care is a consequence of multiple influences at the practice and system levels, including medication labeling procedures and the communication practices of physicians and pharmacists.

Ethnic and linguistic diversity and health literacy also influence communication and play a central role in ambulatory safety. Individuals with limited health literacy and language barriers report greater problems across a range of communication domains, including informed consent, shared decision making, and elicitation of concerns. Patients with limited health literacy experience greater medication miscommunication that can pose a threat to patient safety in the context of chronic disease management. Effective interventions such as visual medication schedules and tailored medication education should be more widely implemented for chronic disease patients.

### Case 4. Patient-Physician Communication.

Mr. M is brought into the emergency department after collapsing on the sidewalk. He is found to be hypoglycemic, and after treatment, explains that he is Muslim and fasting for Ramadan but still taking all his diabetes medicines. He did not discuss his eating patterns for Ramadan with his physician.

Although Mr. M's religious beliefs affected his diabetes self-management, his hypoglycemic episode was preventable. His medication regimen could have been adjusted to accommodate his altered eating pattern during his religious observance. This would have required the patient to be an active communicator, conveying his religious requirements to his primary care provider in advance. In turn, this would have to be followed by appropriate medication adjustment, diet self-management on the part of the patient, and close provider follow-up.

### What Patient and Provider Behaviors Enhance or Jeopardize Safety in the Ambulatory Setting?

Both patient and provider behaviors, influenced by the community, health system, and interactions in care, directly affect patient safety. As an example, ambulatory patients must perform a series of actions for appropriate medication use, including making decisions in an office encounter, obtaining a prescription, bringing the prescription to a pharmacy, receiving the medicines and instructions, taking the medication correctly at home on an ongoing basis, monitoring oneself for side effects, and following up with laboratory testing or provider visits. Problems at any of these junctures may lead to ADEs.

**Case 5. Caregiving and Medication Misuse.** Mrs. S, an 80-year-old woman with hypertension, mild dementia, and arthritis, suffers from insomnia. Because she has had several recent illnesses, including a hospitalization for pneumonia, her insomnia has not been discussed at primary care visits. On a night with particularly troubling sleep problems, her son (and primary caregiver) gives her one of his own sleeping pills. In the early morning hours Mrs. S awakens confused and falls on her way to the bathroom, fracturing her hip.

Caregiving further complicates ambulatory medication management, as in the case of Mrs. S, whose son's well-intentioned attempt to help his mother contributed to a fall and resultant morbidity from hip fracture. This case involves problems with the health system, including poor access to/knowledge of after-hours medical advice, and with communication, because a bothersome symptom—insomnia—was not discussed in recent visits. Importantly, this example illustrates how patient and caregiver errors, in this case taking someone else's medication, can lead to harm.

**Case 6. Symptom Recognition.** Mrs. K has rheumatoid arthritis, for which she is treated with methotrexate and etanercept. She presents for routine follow-up with her primary care physician, and as she is leaving, mentions that she must be approaching menopause, because she has been experiencing progressively severe headaches and “hot flashes.” Further history reveals shaking chills and frontal headache for the last month that wakes her from sleep. The patient is sent to the emergency department for further work-up, where she is found to have severe bacterial sinusitis that requires hospital admission and intravenous antibiotics.

Mrs. K did not recognize symptoms of an infection, which is a particularly important aspect of self-care in patients on chronic immunosuppressive medication such as etanercept. Although it is not possible to avoid all ADEs, there are medications that are known to cause many ADEs, including insulin and warfarin, and others with less common, but known, serious adverse effects, such as methotrexate and amiodarone. For these medications, symptom recognition is a crucial aspect of self-management, and appropriate
communication must be the standard of care. Medication management is only one aspect of patient self-management, which also includes appropriate diet and exercise, appointment adherence, and recognition of symptoms.

Discussion

These real-life vignettes illustrate both the problems with and opportunities for patient safety in ambulatory chronic disease management. A goal of eradicating all adverse events is clearly impossible, especially with the presence of difficult-to-change factors at the community and health-system levels and the high prevalence of chronic diseases. Our aim is to highlight the many preventable events, or those in which harm to patients could have been reduced. We believe that improving patient safety could significantly reduce chronic disease morbidity and mortality.

Ambulatory Health Systems Need More Surveillance for Patient Safety Problems

Currently, we detect most patient safety problems through passive reporting at patients’ provider visits or when events lead to acute care utilization. In ambulatory settings, systems for detection of adverse events are underdeveloped and under-utilized. Unlike acute care systems, for which accreditation and regulatory agencies impose minimum standards for incident reporting and investigation, ambulatory reporting systems are of variable, often inadequate, quality.7,26,65-68 These methods reveal the tip of the iceberg of patient safety problems; we need a clearer understanding about how patients manage their chronic illnesses at home, between visits. A recent study using between-visit telephone surveillance of diabetes patients found frequent adverse events and potential adverse events, most of which were unknown to primary care physicians but were preventable.9 This suggests that active surveillance in ambulatory settings would likely identify a greater number and different kinds of safety problems than do existing methods. Future studies should investigate and compare methods for detection of adverse events, including active surveillance linked to between-visit self-management support, active and passive provider-directed event reporting, and innovative use of ambulatory administrative data.

For chronic diseases, patients themselves are the key to safety. Their everyday actions to manage their health are crucial to achieving positive health outcomes and avoiding safety problems. Because of the proliferation of between-visit self-management support programs for chronic disease patients,69,70 purposefully linking these programs with safety monitoring and promotion is a novel and promising approach. As an example, we are embarking on an innovative program to link diabetes self-management support with real-time safety surveillance to investigate adverse events prospectively. This patient-centered approach to safety can take advantage of quality improvement efforts for chronic disease care.

Providers and Policymakers Must Examine the Safety Consequences of Chronic Disease Treatment Intensification

Although failure to deliver indicated treatments can contribute to both inadequate quality of care and may represent a patient safety issue, aggressive pursuit of quality metrics may lead to inappropriate treatment intensification that actually worsens safety and outcomes.71 Evidence that adverse drug reactions are related to the overall number of medications prescribed62,72-74 suggests that complex regimens, as well as high-risk medicines such as warfarin and insulin, should be considered a safety risk. For instance, aggressively lowering blood glucose or blood pressure, for example, in hopes of reducing risk of future complications or meeting performance goals/quality metrics, may increase adverse treatment effects such as symptomatic hypoglycemia or syncope, respectively. Yet, it is these goals that are increasingly assessed as indicators of clinician quality and as rewards for superior performance. Such quality measures may need to take into account patient capacity and characteristics such as age and comorbid illness. Moreover, any intervention to improve chronic disease care quality through aggressive treatment should incorporate rigorous safety monitoring and build in safeguards such as patient education.

All Stakeholders Must Attend to Chronic Disease Disparities to Improve Patient Safety

Finally, to have the broadest public health impact, research on safety should focus on patients with a disproportionate chronic disease burden. We need further work for those with multiple chronic diseases, with direct examination of the safety consequences of competing health demands. Because low-income, ethnically diverse, and limited health literacy patients suffer disproportionate chronic disease complications, these populations should be the focus of both research and intervention efforts.1
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References


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The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during “minor” surgery due to a drug mix-up.1

These horrific cases that make the headlines are just the tip of the iceberg. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.2 In Colorado and Utah hospitals, 8.8 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.

When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.3 The results of the New York Study suggest the number may be as high as 98,000.4 Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th leading cause of death.5 More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).6

Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between $17 billion and $29 billion, of which health care costs represent over one-half.7

In terms of lives lost, patient safety is as important an issue as worker safety. Every year, over 6,000 Americans die from workplace injuries.8 Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.9
Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly. One recent study conducted at two prestigious teaching hospitals, found that about two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of $4,700 per admission or about $2.8 million annually for a 700-bed teaching hospital. If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about $2 billion for the nation as a whole.

These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total costs. More care and increasingly complex care is provided in ambulatory settings. Outpatient surgical centers, physician offices and clinics serve thousands of patients daily. Home care requires patients and their families to use complicated equipment and perform follow-up care. Retail pharmacies play a major role in filling prescriptions for patients and educating them about their use. Other institutional settings, such as nursing homes, provide a broad array of services to vulnerable populations. Although many of the available studies have focused on the hospital setting, medical errors present a problem in any setting, not just hospitals.

Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided. It is impossible for the nation to achieve the greatest value possible from the hundreds of millions of dollars spent on medical care if the care contains errors.

But not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

Yet silence surrounds this issue. For the most part, consumers believe they are protected. Media coverage has been limited to reporting of anecdotal cases. Licensure and accreditation confer, in the eyes of the public, a “Good Housekeeping Seal of Approval.” Yet, licensing and accreditation processes have focused only limited attention on the issue, and even these minimal efforts have confronted some resistance from health care organizations and providers. Providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors.  

The decentralized and fragmented nature of the health care delivery system (some would say “nonsystem”) also contributes to unsafe conditions for pa-
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Tens of thousands of patients, and serves as an impediment to efforts to improve safety. Even within hospitals and large medical groups, there are rigidly-defined areas of specialization and influence. For example, when patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrong than when care is better coordinated. At the same time, the provision of care to patients by a collection of loosely affiliated organizations and providers makes it difficult to implement improved clinical information systems capable of providing timely access to complete patient information.

Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.

Lastly, the context in which health care is purchased further exacerbates these problems. Group purchasers have made few demands for improvements in safety. Most third party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality.

The goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort. “First do no harm” is an often quoted term from Hippocrates. Everyone working in health care is familiar with the term. At a very minimum, the health system needs to offer that assurance and security to the public.

A comprehensive approach to improving patient safety is needed. This approach cannot focus on a single solution since there is no “magic bullet” that will solve this problem, and indeed, no single recommendation in this report should be considered as the answer. Rather, large, complex problems require thoughtful, multifaceted responses. The combined goal of the recommendations is for the external environment to create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety. At the same time, there is a need to enhance knowledge and tools to improve safety and break down legal and cultural barriers that impede safety improvement. Given current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years.

In this report, 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. According to noted expert James Reason, errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct, (an error of planning). Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition
of the patient. While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). For example, if a patient has surgery and dies from pneumonia he or she got postoperatively, it is an adverse event. If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution). But the analysis may conclude that no error occurred and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event).

Much can be learned from the analysis of errors. All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals (some experts, such as Deming, believe improving processes is the only way to improve quality). The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems and has been doing so since World War II. Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century. In 1998, there were no deaths in the United States in commercial aviation. In health care, preventable injuries from care have been estimated to affect between three to four percent of hospital patients. Although health care may never achieve aviation’s impressive record, there is clearly room for improvement.

To err is human, but errors can be prevented. Safety is a critical first step in improving quality of care. The Harvard Medical Practice Study, a seminal research study on this issue, was published almost ten years ago; other studies have corroborated its findings. Yet few tangible actions to improve patient safety can be found. Must we wait another decade to be safe in our health system?

RECOMMENDATIONS

The IOM Quality of Health Care in America Committee was formed in June 1998 to develop a strategy that will result in a threshold improvement in quality over the next ten years. This report addresses issues related to patient safety, a subset of overall quality-related concerns, and lays out a national
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agenda for reducing errors in health care and improving patient safety. Although it is a national agenda, many activities are aimed at prompting responses at the state and local levels and within health care organizations and professional groups.

The committee believes that although there is still much to learn about the types of errors committed in health care and why they occur, enough is known today to recognize that a serious concern exists for patients. Whether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself. This report is a call to action to make health care safer for patients.

The committee believes that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. But the interaction between factors in the external environment and factors inside health care organizations can also prompt the changes needed to improve patient safety. Factors in the external environment include availability of knowledge and tools to improve safety, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements. Factors inside health care organizations include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

In developing its recommendations, the committee seeks to strike a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations. No single action represents a complete answer, nor can any single group or sector offer a complete fix to the problem. However, different groups can, and should, make significant contributions to the solution. The committee recognizes that a number of groups are already working on improving patient safety, such as the National Patient Safety Foundation and the Anesthesia Patient Safety Foundation.

The recommendations contained in this report lay out a four-tiered approach:

- establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.
Leadership and Knowledge

Other industries that have been successful in improving safety, such as aviation and occupational health, have had the support of a designated agency that sets and communicates priorities, monitors progress in achieving goals, directs resources toward areas of need, and brings visibility to important issues. Although various agencies and organizations in health care may contribute to certain of these activities, there is no focal point for raising and sustaining attention to patient safety. Without it, health care is unlikely to match the safety improvements achieved in other industries.

The growing awareness of the frequency and significance of errors in health care creates an imperative to improve our understanding of the problem and devise workable solutions. For some types of errors, the knowledge of how to prevent them exists today. In these areas, the need is for widespread dissemination of this information. For other areas, however, additional work is needed to develop and apply the knowledge that will make care safer for patients. Resources invested in building the knowledge base and diffusing the expertise throughout the industry can pay large dividends to both patients and the health professionals caring for them and produce savings for the health system.

RECOMMENDATION 4.1 Congress should create a Center for Patient Safety within the Agency for Health Care Policy and Research. This center should

- set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
- develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

To make significant improvements in patient safety, a highly visible center is needed, with secure and adequate funding. The Center should establish goals for safety; develop a research agenda; define prototype safety systems; develop and disseminate tools for identifying and analyzing errors and evaluate approaches taken; develop tools and methods for educating consumers about patient safety; issue an annual report on the state of patient safety, and recommend additional improvements as needed.

The committee recommends initial annual funding for the Center of $30 to $35 million. This initial funding would permit a center to conduct activities in goal setting, tracking, research and dissemination. Funding should grow over time to at least $100 million, or approximately 1% of the $8.8 billion in health care costs attributable to preventable adverse events. This initial level of
funding is modest relative to the resources devoted to other public health issues. The Center for Patient Safety should be created within the Agency for Health Care Policy and Research because the agency is already involved in a broad range of quality and safety issues, and has established the infrastructure and experience to fund research, educational and coordinating activities.

**Identifying and Learning from Errors**

Another critical component of a comprehensive strategy to improve patient safety is to create an environment that encourages organizations to identify errors, evaluate causes and take appropriate actions to improve performance in the future. External reporting systems represent one mechanism to enhance our understanding of errors and the underlying factors that contribute to them.

Reporting systems can be designed to meet two purposes. They can be designed as part of a public system for holding health care organizations accountable for performance. In this instance, reporting is often mandatory, usually focuses on specific cases that involve serious harm or death, may result in fines or penalties relative to the specific case, and information about the event may become known to the public. Such systems ensure a response to specific reports of serious injury, hold organizations and providers accountable for maintaining safety, respond to the public’s right to know, and provide incentives to health care organizations to implement internal safety systems that reduce the likelihood of such events occurring. Currently, at least twenty states have mandatory adverse event reporting systems.

Voluntary, confidential reporting systems can also be part of an overall program for improving patient safety and can be designed to complement the mandatory reporting systems previously described. Voluntary reporting systems, which generally focus on a much broader set of errors and strive to detect system weaknesses before the occurrence of serious harm, can provide rich information to health care organizations in support of their quality improvement efforts.

For either purpose, the goal of reporting systems is to analyze the information they gather and identify ways to prevent future errors from occurring. The goal is not data collection. Collecting reports and not doing anything with the information serves no useful purpose. Adequate resources and other support must be provided for analysis and response to critical issues.

**RECOMMENDATION 5.1** A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should
• designate the Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
• require all health care organizations to report standardized information on a defined list of adverse events;
• provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and
• designate the Center for Patient Safety to:

  (1) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and
  (2) receive and analyze aggregate reports from States to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

RECOMMENDATION 5.2 The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should

• describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
• convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
• periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
• fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

The committee believes there is a role both for mandatory, public reporting systems and voluntary, confidential reporting systems. However, because of
their distinct purposes, such systems should be operated and maintained separately. A nationwide mandatory reporting system should be established by building upon the current patchwork of state systems and by standardizing the types of adverse events and information to be reported. The newly established Forum for Health Care Quality Measurement and Reporting, a public/private partnership, should be charged with the establishment of such standards. Voluntary reporting systems should also be promoted and the participation of health care organizations in them should be encouraged by accrediting bodies.

**RECOMMENDATION 6.1** Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

The committee believes that information about the most serious adverse events which result in harm to patients and which are subsequently found to result from errors should not be protected from public disclosure. However, the committee also recognizes that for events not falling under this category, fears about the legal discoverability of information may undercut motivations to detect and analyze errors to improve safety. Unless such data are assured protection, information about errors will continue to be hidden and errors will be repeated. A more conducive environment is needed to encourage health care professionals and organizations to identify, analyze, and report errors without threat of litigation and without compromising patients’ legal rights.

**Setting Performance Standards and Expectations for Safety**

Setting and enforcing explicit standards for safety through regulatory and related mechanisms, such as licensing, certification, and accreditation, can define minimum performance levels for health care organizations and professionals. Additionally, the process of developing and adopting standards helps to form expectations for safety among providers and consumers. However, standards and expectations are not only set through regulations. The actions of purchasers and consumers affect the behaviors of health care organizations, and the values and norms set by health professions influence standards of practice, training and education for providers. Standards for patient safety can be applied to health care professionals, the organizations in which they work, and the tools (drugs and devices) they use to care for patients.

**RECOMMENDATION 7.1** Performance standards and expectations for health care organizations should focus greater attention on patient safety.
• Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.
• Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

Health care organizations are currently subject to compliance with licensing and accreditation standards. Although both devote some attention to issues related to patient safety, there is opportunity to strengthen such efforts. Regulators and accreditors have a role in encouraging and supporting actions in health care organizations by holding them accountable for ensuring a safe environment for patients. After a reasonable period of time for health care organizations to develop patient safety programs, regulators and accreditors should require them as a minimum standard.

Purchaser and consumer demands also exert influence on health care organizations. Public and private purchasers should consider safety issues in their contracting decisions and reinforce the importance of patient safety by providing relevant information to their employees or beneficiaries. Purchasers should also communicate concerns about patient safety to accrediting bodies to support stronger oversight for patient safety.

RECOMMENDATION 7.2 Performance standards and expectations for health professionals should focus greater attention on patient safety.

• Health professional licensing bodies should
  (1) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
  (2) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

• Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should
  (1) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
  (2) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
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(3) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;

(4) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and

(5) collaborate with other professional societies and disciplines in a national summit on the professional’s role in patient safety.

Although unsafe practitioners are believed to be few in number, the rapid identification of such practitioners and corrective action are important to a comprehensive safety program. Responsibilities for documenting continuing skills are dispersed among licensing boards, specialty boards and professional groups, and health care organizations with little communication or coordination. In their ongoing assessments, existing licensing, certification and accreditation processes for health professionals should place greater attention on safety and performance skills.

Additionally, professional societies and groups should become active leaders in encouraging and demanding improvements in patient safety. Setting standards, convening and communicating with members about safety, incorporating attention to patient safety into training programs and collaborating across disciplines are all mechanisms that will contribute to creating a culture of safety.

RECOMMENDATION 7.3 The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and post-marketing processes through the following actions:

- develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
- require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
- work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.

The FDA’s role is to regulate manufacturers for the safety and effectiveness of their drugs and devices. However, even approved products can present safety problems in practice. For example, different drugs with similar sounding names can create confusion for both patients and providers. Attention to the safety of products in actual use should be increased during approval processes and in
post-marketing monitoring systems. The FDA should also work with drug manufacturers, distributors, pharmacy benefit managers, health plans and other organizations to assist clinicians in identifying and preventing problems in the use of drugs.

Implementing Safety Systems in Health Care Organizations

Experience in other high-risk industries has provided well-understood illustrations that can be used to improve health care safety. However, health care management and professionals have rarely provided specific, clear, high-level, organization-wide incentives to apply what has been learned in other industries about ways to prevent error and reduce harm within their own organizations. Chief Executive Officers and Boards of Trustees should be held accountable for making a serious, visible and on-going commitment to creating safe systems of care.

RECOMMENDATION 8.1 Health care organizations and the professionals affiliated with them should make continually improved patient safety a declared and serious aim by establishing patient safety programs with defined executive responsibility. Patient safety programs should

- provide strong, clear and visible attention to safety;
- implement non-punitive systems for reporting and analyzing errors within their organizations;
- incorporate well-understood safety principles, such as, standardizing and simplifying equipment, supplies and processes; and
- establish interdisciplinary team training programs for providers that incorporate proven methods of team training, such as simulation.

Health care organizations must develop a culture of safety such that an organization’s care processes and workforce are focused on improving the reliability and safety of care for patients. Safety should be an explicit organizational goal that is demonstrated by the strong direction and involvement of governance, management and clinical leadership. In addition, a meaningful patient safety program should include defined program objectives, personnel, and budget and should be monitored by regular progress reports to governance.

RECOMMENDATION 8.2 Health care organizations should implement proven medication safety practices.

A number of practices have been shown to reduce errors in the medication process. Several professional and collaborative organizations interested in pa-
tient safety have developed and published recommendations for safe medication practices, especially for hospitals. Although some of these recommendations have been implemented, none have been universally adopted and some are not yet implemented in a majority of hospitals. Safe medication practices should be implemented in all hospitals and health care organizations in which they are appropriate.

SUMMARY

This report lays out a comprehensive strategy for addressing a serious problem in health care to which we are all vulnerable. By laying out a concise list of recommendations, the committee does not underestimate the many barriers that must be overcome to accomplish this agenda. Significant changes are required to improve awareness of the problem by the public and health professionals, to align payment systems and the liability system so they encourage safety improvements, to develop training and education programs that emphasize the importance of safety and for chief executive officers and trustees of health care organizations to create a culture of safety and demonstrate it in their daily decisions.

Although no single activity can offer the solution, the combination of activities proposed offers a roadmap toward a safer health system. The proposed program should be evaluated after five years to assess progress in making the health system safer. With adequate leadership, attention and resources, improvements can be made. It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives and meet the challenges ahead.

REFERENCES


Introduction to Atrial Fibrillation

During the learning day you will participate in a case about Mr. Filler, who suffers from atrial fibrillation (abbreviated a.fib.), which is a series of disorganized rapid contractions of the atria (the top two chamber of the heart). The ventricles contract well enough to maintain cardiac output as long as they are contracting slowly enough. Because the atria aren’t contracting normally, small clots may form in the walls of the atria. If these occur in the left atrium, they can break off and go through the arterial system to the brain, causing a stroke. The treatment of a. fib. is usually one of two choices: give the patient medications that attempt to convert the a. fib. into a normal sinus rhythm, which will decrease the risk of stroke; or leave the patient in a. fib. and give them medications to control their rapid heart rate, and in addition, treat them with anticoagulation to prevent clots from forming. There is considerable evidence that treating patients with a. fib. with anticoagulation prevents the vast majority of strokes. Neither treatment approach is ideal. The medications used to convert patients into normal rhythm can be dangerous and cause many side effects, including worsening of heart rhythms and sudden death; anticoagulation requires monitoring of the blood on a regular basis and requires very careful attention to adherence to the prescribed medication, which traditionally has been warfarin. Testing the blood on a regular basis can tell whether the amount of warfarin being taken is too much, causing the blood to be too thin and making the patient susceptible to bleeding, or not thin enough, in which case the patient might be at risk for a stroke. A new medication, dabigatran (Pradaxa) is given in a standard dose and does not require ongoing monitoring to keep patients appropriately anticoagulated. Additionally, it is not sensitive to the use of other medications, which can dramatically affect the anticoagulation effectiveness with the use of warfarin. However, dabigatran has another concern in that when patients do bleed, the effect of the drug cannot be quickly reversed; warfarin on the other hand can be quickly reversed by giving vitamin K.

When patients are undergoing surgery, or transitioning to an alternative anticoagulant, great care must be taken to make sure they are adequately anticoagulated for as much time as possible because of the significant risk of either bleeding or stroke.