oversight
measurement
culture improvement
health care providers
systems
collaboration technology initiatives
progress coordination
measures communication
patients respect hospitals
strategies clinicians reporting organizations
errors **patient safety**
action policymakers metrics quality
outcomes efforts workforce
nurses care continuum research
systems national tools
patients & families staff information technology
change
patient engagement
interventions lessons
burnout leadership

Free from Harm

Accelerating Patient Safety Improvement
Fifteen Years after *To Err Is Human*

Report of an Expert Panel Convened by
The National Patient Safety Foundation

NPSF
National Patient Safety Foundation®

About the National Patient Safety Foundation®

The National Patient Safety Foundation's vision is to create a world where patients and those who care for them are free from harm. A central voice for patient safety since 1997, NPSF partners with patients and families, the health care community, and key stakeholders to advance patient safety and health care workforce safety and disseminate strategies to prevent harm.

NPSF is an independent, not-for-profit 501(c)(3) organization. Information about the work of the National Patient Safety Foundation may be found at www.npsf.org.

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Contents

Executive Summary

Patient safety is a serious public health issue. Like obesity, motor vehicle crashes, and breast cancer, harms caused during care have significant mortality, morbidity, and quality-of-life implications, and adversely affect patients in every care setting. Although patient safety has advanced in important ways since the Institute of Medicine released *To Err Is Human: Building a Safer Health System* in 1999, work to make care safer for patients has progressed at a rate much slower than anticipated.

Despite demonstrated improvement in specific problem areas, such as hospital-acquired infections, the scale of improvement in patient safety has been limited. Though many interventions have proven effective, many more have been ineffective, and some promising interventions have important questions still unresolved. The health care system continues to operate with a low degree of reliability, meaning that patients frequently experience harms that could have been prevented or mitigated.

While the release of *To Err Is Human* significantly heightened the focus on patient safety, the expectation at the time was that expanded data sharing and implementing interventions to solve specific concerns would result in substantial, permanent improvement. In the intervening decade and a half, it has become increasingly clear that safety issues are far more complex—and pervasive—than initially appreciated. Patient safety comprises more than just mortality; it also encompasses morbidity and more subtle forms of harm, such as loss of dignity and respect. It involves more than inpatient care; it includes safety in every care setting: ambulatory care clinics, freestanding surgical and diagnostic centers, long-term care facilities, and patients' homes as well as hospitals and other locations.

Although our understanding of the problem of patient harm has deepened and matured, this progress has been accompanied by a lessening intensity of focus on the issue. Patient safety must not be relegated to the backseat, proceeding haphazardly toward only those specific harms currently being measured and targeted for improvement

by incentives. Advancement in patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety. Adopting such an approach would mean leadership consistently prioritizing safety culture and the well-being and safety of the health care workforce. It means more complete development of the science, measurement, and tools of patient safety. To ensure maximal impact, moving from competition on safety to coordination and collaboration across organizations will be important. Such an approach also means thinking about safety in all aspects of care across the continuum, not just in hospitals. To ensure that the patient voice is heard, it must also include partnering with patients and families at all points along the journey.

This report recognizes areas of progress, highlights remaining gaps, and most importantly, details specific recommendations to accelerate progress. These recommendations are based on the establishment of a total systems approach and a culture of safety:

1. **Ensure that leaders establish and sustain a safety culture**
2. **Create centralized and coordinated oversight of patient safety**
3. **Create a common set of safety metrics that reflect meaningful outcomes**
4. **Increase funding for research in patient safety and implementation science**
5. **Address safety across the entire care continuum**
6. **Support the health care workforce**
7. **Partner with patients and families for the safest care**
8. **Ensure that technology is safe and optimized to improve patient safety**

Success in these actions will require active involvement of every player in the health care system: boards and governing bodies, leadership, government agencies, public-private partnerships, health care organizations, ambulatory practices and settings, researchers, professional associations, regulators, educators, the health care workforce, and patients and their families. Our hope is that these recommendations and the accompanying specific tactics for implementation will spur broad action and prompt substantial movement towards a safer health care system. Patients deserve nothing less.

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Acknowledgments

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ACKNOWLEDGMENTS: EXPERT PANEL (cont)

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Endorsements

The organizations listed below have endorsed the content of this report. Additional endorsements are pending.

Organizations interested in endorsing this report should contact **info@npsf.org**.

Alliance for Quality Improvement and Patient Safety

American Academy of Nursing

American Association for Physician Leadership

American Association of Critical-Care Nurses

American Nurses Association

Anesthesia Patient Safety Foundation (APSF)

Association of periOperative Registered Nurses

Aurora Health Care

Baptist Easley Hospital

Baptist Health South Florida

Boston Children's Hospital

Buffalo Hospital, part of Allina Health

Canadian Patient Safety Institute

Carolina Pines Regional Medical Center

Center for Medical Simulation

Children's Hospitals' Solutions for Patient Safety (SPS)

Cincinnati Children's Hospital Medical Center

Citizens for Patient Safety

Collaborative for Accountability and Improvement

Collaborative Latin America Forum in Quality and Patient Safety (CICSP)

College of Healthcare Information Management Executives

Corizon Health

CoxHealth

Emergency Medicine Patient Safety Foundation

Fairview Health Services

Franciscan Alliance

Hampton Regional Medical Center

HIMSS

Hospital Quality Institute

Informed Medical Decisions Foundation

Institute for Clinical Effectiveness and Health Policy (IECS)

Institute for Healthcare Improvement

Institute for Safe Medication Practices

John D. Stoeckle Center for Primary Care Innovation

Massachusetts Coalition for the Prevention of Medical Errors

Medical University of South Carolina

Memorial Hermann Health System

MHA Keystone Center

Minnesota Alliance for Patient Safety

National Association for Healthcare Quality

National Partnership for Women & Families

NHS Improvement

Oregon Patient Safety Commission

Pacific Business Group on Health

Society of Hospital Medicine

Society to Improve Diagnosis in Medicine (SIDM)

Spartanburg Regional Healthcare System

The Task Force for Global Health

Tennessee Hospital Association

Tidelands Health

Trident Health

Vidant Health

Virginia Mason Health System

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National Patient Safety Foundation
Vision Statement

Creating a world where patients and those who care for them are free from harm

Preface

In June 1998 the Institute of Medicine (IOM) convened the Committee on Quality of Health Care in America to explore and report on the performance of health care in the United States. The group's initial publication, *To Err Is Human: Building a Safer Health System*, released in late 1999, focused on patient safety, and it captured attention like few other IOM reports before or since, in part because it estimated that as many as 98,000 hospitalized patients in the US die each year as a result of patient safety failures (IOM 2000). Although the mortality statistics cited in the report have sometimes been questioned, no doubt remains that mortality and morbidity related to patient harm are far too high, and several subsequent studies have suggested that the IOM numbers were underestimates (James 2013). Regardless of how the estimates were calculated, they served an important purpose by attracting much needed attention to patient safety.

In the decade and a half since the publication of *To Err Is Human*, the health care community has learned a great deal about problems in patient care and has celebrated areas of improvement. However, we now understand that the problem is far more complex than we initially appreciated. This report represents findings from an expert panel that the National Patient Safety Foundation convened to discuss the current state of patient safety.* We were fortunate to count among our panelists three individuals who served on the original IOM committee.

To Err Is Human stated, "The status quo is not acceptable and cannot be tolerated any longer" (IOM 2000). Unfortunately, this statement remains valid today. Although awareness has grown, patients still experience preventable harms during their interactions with the health care system. Much more work remains to be done. Achieving true safety is a journey. It may never be possible to eliminate harm altogether—there will always be new technologies and treatments with new risks, and protecting patients from one harm may increase their risk of another, which may lead to trade-offs. What we want is for

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* This report represents the opinions of the expert panelists; it is not reflective of an exhaustive literature review, although wherever possible it is based on published evidence.

health care to make safety a focus to the point that: (1) effective prevention strategies are in place for many of the current, common preventable harms that we know about, and (2) learning organizations are preoccupied with the possibility of preventable harm in order to be poised to identify problems and develop corrective actions. This report's title, "Free from Harm," is our aspiration—one that we must retain as our North Star as we move toward safer systems.

 Today we must not let the many competing priorities in health care divert our attention from the important goal of preventing harm to patients. On the contrary—we need to keep our eyes on the road and step on the accelerator. In this report, we strive to highlight both progress in patient safety and serious gaps that remain. Writing on behalf of the expert panel, we suggest action steps that all stakeholders should take for patient safety to improve thoroughly. For the sake of patients everywhere, we should not lose sight of our goals or falter in our commitment to achieving them.

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Important Definitions in Patient Safety

Based on AHRQ PSNet Glossary [nd], Runciman et al. 2009, and others as noted.

Adverse drug event: An adverse event involving medication use.

Adverse event: Any injury caused by medical care. Examples include pneumothorax from central venous catheter placement, anaphylaxis to penicillin, and postoperative wound infection. Identifying something as an adverse event does not imply "error," "negligence," or poor quality care. It simply indicates that an undesirable clinical outcome resulted from some aspect of diagnosis or therapy, not an underlying disease process. Preventable adverse events are the subset that are caused by error.

Error: An act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome. For instance, ordering a medication for a patient with a documented allergy to that medication would be an act of commission. Failing to prescribe a proven medication with major benefits for an eligible patient (e.g., low-dose unfractionated heparin as venous thromboembolism prophylaxis for a patient after hip replacement surgery) would represent an error of omission.

Harm: An impairment of structure or function of the body and/or any deleterious effect arising therefrom, including disease, injury, suffering, disability and death, and may be physical, social, or psychological.

Just culture: A culture that recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A just culture also recognizes many individual or "active" errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts "no blame" as its governing principle, a just culture does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).

Patient safety: Patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events.

Safety culture: The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures (Health and Safety Commission 1993).

Safety culture refers to both (a) the intangible sharing of the safety value among organization members and (b) the tangible results of this shared value in the forms of behavior and structure (Groves 2014).

Total systems safety: Safety that is systematic and uniformly applied (across the total process) (Pronovost et al. 2015).

Abbreviations Used in this Report

ACGME	Accreditation Council for Graduate Medical Education
AHRQ	Agency for Healthcare Research and Quality, US Department of Health and Human Services
CDC	Centers for Disease Control and Prevention
CLABSI	central line–associated bloodstream infection
CMS	Centers for Medicare and Medicaid Services
CPOE	computerized physician order entry
EHR	electronic health record
FAA	Federal Aviation Administration
FDA	US Food and Drug Administration
HAI	hospital-acquired infection
health IT / HIT	health information technology
HHS	US Department of Health and Human Services
IOM	Institute of Medicine
ISMP	Institute for Safe Medication Practices
LLI	National Patient Safety Foundation's Lucian Leape Institute
NHS	National Health Service (UK)
NPSF	National Patient Safety Foundation
NQF	National Quality Forum
NRC	US Nuclear Regulatory Commission
OIG	Office of the Inspector General, US Department of Health and Human Services
ONC	Office of the National Coordinator for Health Information Technology, US Department of Health and Human Services
PSO	patient safety organization
SPS	Children's Hospitals' Solutions for Patient Safety
VA	US Department of Veterans Affairs, Veterans Health Administration
VTE	venous thromboembolism

Introduction: Patient Safety Is a Public Health Issue

The Institute of Medicine* (IOM) report *To Err Is Human: Building a Safer Health System* motivated individuals and organizations to take a serious look at harms caused by medical care—harms that many in health care had traditionally regarded as unavoidable (IOM 2000). Health care professionals and the public alike were activated to focus on reducing harms in hospitals, including adverse drug events (ADEs), surgical injuries, preventable deaths, falls, burns, pressure ulcers, and mistaken patient identities.

Despite progress in the past 15 years, patient safety remains an important public health issue. Preventable harm remains unacceptably frequent—in all settings of care and among all patient populations. Recent studies suggest that the overall toll exacted by safety problems remains high (Landrigan et al. 2010; OIG 2010; Classen et al. 2011; James 2013). Harms caused during care carry significant mortality, morbidity, and quality-of-life implications, no less than obesity, airplane or motor vehicle crashes, and breast cancer.

Despite progress in the past 15 years, patient safety remains an important public health issue.

To understand the full impact of patient safety problems, we must look at both mortality and morbidity. This change is analogous to the shift in focus over the past few decades from acute care medicine to chronic disease management. The bulk of threats to patient safety are less like heart attacks and strokes that kill quickly, and more like diabetes and hypertension—chronic, more complex, and significantly affecting health and well-being. This evolution in thinking will be critical to achieving real change.

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* The Institute of Medicine was recently incorporated as a program unit of the National Academies of Sciences, Engineering, and Medicine, in which form it continues its traditional consensus study and convening activities.

In addition, although hospital safety remains an important target, protecting patients from harm during care involves more than reducing or preventing safety issues during hospitalization. Patients receive more care in settings outside the hospital—ambulatory care clinics, freestanding surgical or diagnostic centers, long-term care facilities, their homes, and other locations—and they deserve safe care in every setting, as well as when transitioning between settings.

While the mortality estimates related to patient safety issues in hospitals grabbed attention 15 years ago (and continue to be controversial), we now also recognize broader problems that cause significant harm to patients of all ages, in all fields of health care, and in all health care settings. These problems are more insidious

All health care stakeholders should recommit to and prioritize patient safety in general and the goal of eliminating harm to patients in particular.

and less dramatic than deaths due to safety issues, but they are hugely important given their impact on patients' lives and the performance of the health care system. (For a summary, see fig. 1.) All health care stakeholders should recommit to and prioritize patient safety in general and the goal of eliminating harm to patients in particular. Every one of us—whether patient, family member, caregiver, health care professional, taxpayer, or payer for care—deserves nothing less.

This report provides strategic recommendations for driving patient safety improvements through the next decade and beyond. Our hope is that these recommendations will spur broad action and galvanize the field to move forward with a unified view of the future of patient safety.

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Figure 1.

FREE FROM HARM:

ACCELERATING PATIENT SAFETY IMPROVEMENT FIFTEEN YEARS AFTER *TO ERR IS HUMAN*

Report of an expert panel convened by the National Patient Safety Foundation argues for looking at morbidity as well as mortality caused by medical errors and going beyond hospitals to improve safety across the continuum of care.
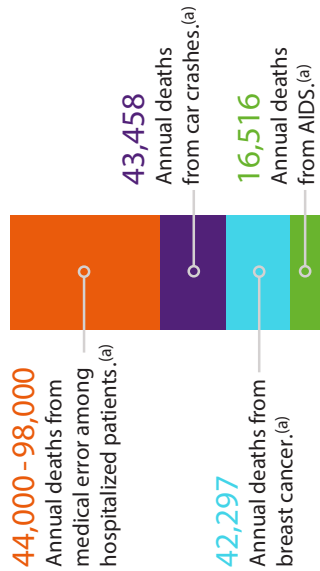
TO ERR IS HUMAN FRAMED PATIENT SAFETY AS A SERIOUS PUBLIC HEALTH ISSUE (1999 ESTIMATES)

44,000 – 98,000
Annual deaths from medical error among hospitalized patients.[a]

42,297
Annual deaths from breast cancer.[a]

43,458
Annual deaths from car crashes.[a]

16,516
Annual deaths from AIDS.[a]

TO UNDERSTAND THE FULL IMPACT OF PATIENT SAFETY PROBLEMS, WE MUST LOOK AT BOTH MORTALITY AND MORBIDITY

1 in 10
patients develops a health care acquired condition (such as infection, pressure ulcer, fall, adverse drug event) during hospitalization.[b]

BY SOME MEASURES, HEALTH CARE HAS GOTTEN SAFER SINCE TO ERR IS HUMAN

1.3 Million
Estimated reduction in hospital-acquired conditions (2011–2013) as a result of the federal Partnership for Patients initiative.[b]

BUT WE MUST LOOK BEYOND HOSPITALS TO THE FULL CARE CONTINUUM
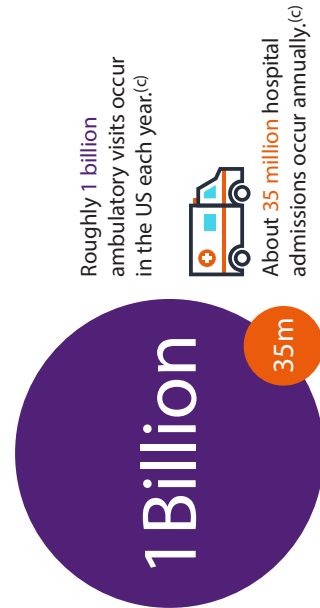
1 Billion
35m

Roughly 1 billion ambulatory visits occur in the US each year.[c]

About 35 million hospital admissions occur annually.[c]

ADVANCEMENT IN PATIENT SAFETY REQUIRES AN OVERARCHING SHIFT FROM REACTIVE, PIECEMEAL INTERVENTIONS TO A TOTAL SYSTEMS APPROACH TO SAFETY[d]

1. Ensure that leaders establish and sustain a safety culture.

2. Create centralized and coordinated oversight of patient safety.

3. Create a common set of safety metrics that reflect meaningful outcomes.

4. Increase funding for research in patient safety and implementation science.

5. Address safety across the entire care continuum.

6. Support the health care workforce.

7. Partner with patients and families for the safest care.

8. Ensure that technology is safe and optimized to improve patient safety.

Sources: (a) Institute of Medicine. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press, 2000. (b) 2013 Annual Hospital-Acquired Condition Rate and Estimates of Cost Savings and Deaths Averted From 2010 to 2013. Rockville, MD: Agency for Healthcare Research and Quality; October 2015. AHRQ Publication No. 16-0006-EF. http://www.ahrq.gov/professionals/quality-patient-safety/pfp/index.html. (c) National Center for Health Statistics. Faststats A-Z. Ambulatory Care and Hospital Utilization. Available at: http://www.cdc.gov/nchs/fastats/. (d) National Patient Safety Foundation. Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human. Boston, MA: National Patient Safety Foundation; 2015. Available at: http://www.npsf.org/free-from-harm.

The Landmark IOM Report

To Err Is Human: Building a Safer Health System projected the human toll and the financial costs associated with safety problems. It estimated the scope of the problem, citing that as many as 98,000 hospitalized patients in the US die each year as a result of problems related to their care (IOM 2000). By citing safety issues as causing more deaths than motor vehicle crashes, breast cancer, or AIDS, it redefined harms related to safety as being analogous to preventable diseases.

The report recommended a four-pronged effort to improve safety:

- Establishing a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety

- Identifying and learning from errors by developing a nationwide public mandatory reporting system and by encouraging health care organizations and practitioners to develop and participate in voluntary reporting systems

- Raising performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care

- Changing from punishing individuals for errors to implementing safety systems in health care organizations to ensure safe practices

Publication of *To Err Is Human* was a watershed event, focusing attention on patient safety to an unprecedented degree. Many people credit the report as being a catalyst for the modern patient safety movement.

Beyond Mortality: The Multitude of Harms

- Despite increased focus and some indications of improvement, about *1 in 10 patients* develops an adverse event, such as a health care–acquired infection, pressure ulcer, preventable adverse drug event, or a fall, during hospitalization (AHRQ Efforts 2014).

- Recent research has found that roughly *1 in 2 surgeries* had a medication error and/or an adverse drug event (Nanji et al. 2015).

- More than *700,000 outpatients* are treated in the emergency department every year for an adverse event caused by a medication—adverse events severe enough in *120,000* of these patients to require hospitalization (Budnitz et al. 2006).

- More than *12 million patients* each year experience a diagnostic error in outpatient care, half of which are estimated to have the potential to cause harm (Singh et al. 2014).

- Globally, there are *421 million hospitalizations* and approximately *42.7 million adverse events* each year (Jha et al. 2013).

- About *one-third of Medicare beneficiaries* in skilled nursing facilities experienced an adverse event; half of these events were deemed preventable (OIG 2014).

The Current State of Patient Safety: Progress and the Need to Accelerate

The IOM report stimulated momentum in patient safety and has led to gains over the past 15 years. Although the current evidence regarding overall improvement in patient safety in the US and internationally is mixed (Landrigan et al. 2010; Baines et al. 2013; Baines et al. 2015; Shojania and Marang-van de Mheen 2015), the majority of the panel felt that overall health care is safer than in the past.

In an anonymous survey of our expert panel members regarding perceptions of patient safety, participants were asked if they believed that care was safer now than it had been and why.* The majority responded affirmatively and pointed to various positive advances to support their claim, such as the creation of standard practices and metrics, more organizations adopting high reliability theory, improvements in medication safety, and efforts to improve culture. Indeed, much of the language and the concepts of the systems approach now permeate health care. Moreover, we now know that multiple factors are critical to achieving patient safety, including transparency, communication, teamwork, human factors engineering, patient engagement, and organizational safety culture.

Much of the language and the concepts of the systems approach now permeate health care.

Beyond the specific improvements, general thinking has also evolved. Patient safety now receives far greater attention from organizational leaders, patients, health care professionals, policymakers, and the media—a notable accomplishment in itself, considering the plethora of competing priorities in health care. As one survey respondent put it, "Safety is now firmly ensconced in the lexicon of all care providers. People understand human factors and team training and the need to use checklists, other aids, and technology."

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* A summary of the panel's survey responses is available at **http://www.npsf.org/free-from-harm**.

In addition, previously under-recognized aspects of safety are now receiving more focus, such as the importance of addressing safety in ambulatory settings, where the majority of care is provided; the importance of considering underuse and overuse of treatment, misdiagnosis, and complications of care; and the need to address workforce support as an integral component of health care safety. Moreover, the importance of incorporating patient safety in education is better recognized, with patient safety requirements increasingly being included in curricula across disciplines and at various levels of training.

The quest for safety is not antithetical to pursuing aspects of quality or cost effectiveness—safety is an essential building block for achieving high performance in other areas. The connection between safety and other dimensions of quality, such as effectiveness, family-centeredness, timeliness, efficiency, and equity is now more appreciated (IOM 2001). This interconnectedness reflects another important lesson of the past 15 years: the various dimensions of quality interconnect, and addressing one may impact the others. For example, some safety best practices may lead to tradeoffs between safety and efficiency.

The increased use of evidence-based care marks another notable improvement. Interventions have successfully reduced hospital-acquired infections (HAIs) and adverse events related to drugs and surgical procedures. Barcoding has been shown to reduce medication administration errors (Poon et al. 2010). Team training in surgery has been shown to reduce mortality by 50% compared with control sites (Neily et al. 2010). A handoff communications process reduced medical errors by 23% and preventable adverse events by 30% (both P<0.001) (Starmer et al. 2014). A recent report on the large-scale "Partnership for Patients" safety initiative indicated that it had reduced hospital-acquired conditions by 1.3 million[*] (US DHHS 2014).

This amount of progress is notable, particularly for a field that is only 15 years old, is still developing its scientific foundations, and has received limited investment compared with other major biomedical endeavors, such as the "War on Cancer," heart disease, diabetes, genomics, and personalized medicine, among others. These other examples have made modest, incremental improvements over decades of well-supported research with a well-established scientific foundation—the product of decades of basic research and work by institutions and scientists. That progress in the field of patient safety has not been more complete and pervasive, while perhaps disappointing, is hardly surprising. The patient safety field is still early in its evolution, and improving patient safety is a complex problem that requires work by diverse disciplines to solve.

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[*] Some have questioned this study's methodology and lack of external review, raising uncertainty about the results' validity (Pronovost and Jha 2014).

As the health care system reforms, patient safety should remain a top priority. In some situations, safety may interact with other quality elements. Recognizing and understanding these interrelationships is imperative, as is prioritizing previously unrecognized issues, such as diagnostic errors. In addition, new contributing factors now need attention, such as the potential to introduce errors via electronic health records (EHRs) (IOM 2012) and alarm fatigue from countless equipment signals (ECRI 2013, Joint Commission 2013).

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Future Progress Depends on a Total Systems Approach to Safety

In the early years after *To Err Is Human* appeared, disparate views on the best approach to improvement were advanced. Some experts on the IOM committee called for emulating processes and philosophies that have worked in other industries, such as incident reporting, checklists, teamwork, human factors engineering, and a systems approach (Leape et al. 2002). Others argued that a better strategy would be to characterize specific safety problems and identify mechanisms to prevent them (Shojania et al. 2002, Brennan et al. 2005).

The latter approach ushered in an era in which clinicians and researchers focused on reducing or eliminating specific harms, such as venous thromboembolism (VTE), surgical complications, and central line–associated bloodstream infections (CLABSIs). While this approach has been successfully applied to some situations (Pronovost et al. 2006, Haynes et al. 2009), it has not reaped rewards in others (Urbach 2014, Reames 2015). Moreover, this project-by-project approach did not lead to widespread, holistic change.

To generate such holistic change, we need to embrace a wider approach to safety rather than focusing on specific, circumscribed safety initiatives. To achieve success, some project-based initiatives, such as the CLABSI checklist, required major changes in teamwork and culture (Pronovost et al. 2006). It is telling that most initiatives succeed only when they implement tactics using a broader approach. In fact, a fundamental finding from the past 15 years is that patient safety initiatives can advance only by making teamwork, culture, and patient engagement a key focus.

By embracing safety as a core value, other industries have moved beyond competition to a stage of cooperation. Health care organizations should also make this shift.

By taking into account systems design, human failures, human factors engineering, safety culture, and error reporting and analysis, the systems approach epitomizes a more comprehensive view.

By embracing safety as a core value, other industries have moved beyond competition to a stage of cooperation. Health care organizations should also make this shift. While some health care organizations have begun to work cooperatively with each other to advance patient safety, a commitment to share safety data and best practices is most

evident among pediatric hospitals. For example, the Children's Hospitals' Solutions for Patient Safety (SPS) network has seen significant improvements in patient safety metrics as a result of collaboration (Lyren et al. 2013). Unfortunately, many other health care organizations seem to believe they must differentiate themselves based on their safety record. Organizations should not compete on safety; such competition slows progress in patient safety by blocking the free flow of information crucial to preventing harm.

Advancing patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety in which safety is systematic and is uniformly applied across the total process (Pronovost et al. 2015). Such a shift would have seismic effects. A total systems approach would mean a constant prioritization of safety culture by leadership. It would mean considering safety across the entire care continuum and addressing both the increased mortality and substantial morbidity that safety failures cause. It would mean prioritizing the well-being and safety of the health care workforce. It would mean avoiding heaping more, potentially disjointed, initiatives onto an already stressed delivery system and caregivers. Meaningful advancement in patient safety can occur only when a total systems approach underpins improvement initiatives.

Advancing patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety.

To move effectively toward a total systems approach to safety, we make eight targeted recommendations with specific action steps (see fig. 2 and the summary in the appendix). The remainder of this report outlines these recommendations and associated tactics that are needed in order to make fundamental, widespread improvement in patient safety.

Recommendations:

1. **Ensure that leaders establish and sustain a safety culture**
2. **Create centralized and coordinated oversight of patient safety**
3. **Create a common set of safety metrics that reflect meaningful outcomes**
4. **Increase funding for research in patient safety and implementation science**
5. **Address safety across the entire care continuum**
6. **Support the health care workforce**
7. **Partner with patients and families for the safest care**
8. **Ensure that technology is safe and optimized to improve patient safety**

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Figure 2.

EIGHT RECOMMENDATIONS FOR ACHIEVING TOTAL SYSTEMS SAFETY

1. ENSURE THAT LEADERS ESTABLISH AND SUSTAIN A SAFETY CULTURE

Improving safety requires an organizational culture that enables and prioritizes safety. The importance of culture change needs to be brought to the forefront, rather than taking a backseat to other safety activities.

2. CREATE CENTRALIZED AND COORDINATED OVERSIGHT OF PATIENT SAFETY

Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations.

3. CREATE A COMMON SET OF SAFETY METRICS THAT REFLECT MEANINGFUL OUTCOMES

Measurement is foundational to advancing improvement. To advance safety, we need to establish standard metrics across the care continuum and create ways to identify and measure risks and hazards proactively.
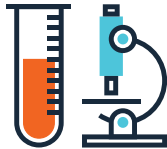
4. INCREASE FUNDING FOR RESEARCH IN PATIENT SAFETY AND IMPLEMENTATION SCIENCE

To make substantial advances in patient safety, both safety science and implementation science should be advanced, to more completely understand safety hazards and the best ways to prevent them.

5. ADDRESS SAFETY ACROSS THE ENTIRE CARE CONTINUUM

Patients deserve safe care in and across every setting. Health care organizations need better tools, processes, and structures to deliver care safely and to evaluate the safety of care in various settings.

6. SUPPORT THE HEALTH CARE WORKFORCE

Workforce safety, morale, and wellness are absolutely necessary to providing safe care. Nurses, physicians, medical assistants, pharmacists, technicians, and others need support to fulfill their highest potential as healers.

7. PARTNER WITH PATIENTS AND FAMILIES FOR THE SAFEST CARE

Patients and families need to be actively engaged at all levels of health care. At its core, patient engagement is about the free flow of information to and from the patient.

8. ENSURE THAT TECHNOLOGY IS SAFE AND OPTIMIZED TO IMPROVE PATIENT SAFETY

Optimizing the safety benefits and minimizing the unintended consequences of health IT is critical.

Recommendation 1: Ensure That Leaders Establish and Sustain a Safety Culture

Improving safety requires an organizational culture that enables and prioritizes safety. Since the appearance of *To Err Is Human*, experts have called for widespread culture change in all health care organizations (Sexton et al. 2006, Singer et al. 2007, Sorra and Dyer 2010). The concept of safety culture originated outside health care, in studies of high reliability organizations, which "consistently minimize adverse events despite carrying out intrinsically complex and hazardous work. High reliability organizations maintain a commitment to safety at all levels, from frontline providers to managers and executives," with a commitment by leadership to achieve consistently safe operations (AHRQ PSNet Safety Culture 2014). In health care, a strong safety culture is one in which health care professionals and leaders are held accountable for unprofessional conduct yet not punished for human mistakes; errors are identified and mitigated before they harm patients; and strong feedback loops enable frontline staff to learn from previous errors and alter care processes to prevent recurrences. Indeed, "improving the culture of safety within health care is an essential component of preventing or reducing errors and improving overall health care quality" (AHRQ PSNet Safety Culture 2014).

Improving safety requires an organizational culture that enables and prioritizes safety.

The importance of culture change needs to be brought to the forefront, rather than being treated as one among various safety activities. The expert panel felt this to be the most important recommendation of this report: that leadership (boards/governing bodies as well as executives) must establish a safety culture as the foundation to achieving total systems safety. Generating and maintaining the necessary large-scale culture shift requires strong leadership. Some data exist on effective strategies for advancing organizational norms that foster improved patient safety, and distributed leadership and strong

staff support have been identified as critical to establishing a solid safety culture (McKee et al. 2013, Dixon-Woods et al. 2014)

Leaders should be educated in the importance of safety culture, and they need tools to help create this culture. Tools are available to effect culture change, such as organizational compacts, respect training, strategies for addressing disruptive behaviors, culture surveys, and executive WalkRounds™ (IHI 2004, Joint Commission 2008, Kaplan 2013). However, these tools are not simple to implement; in some circumstances, executive WalkRounds have not been effective at improving safety (Martin et al. 2014, Rotteau et al. 2014, Singer and Tucker 2014). In addition, many organizations now use standard surveys to measure culture, although many struggle with how to improve in low-scoring areas.

Improved culture is not the means to an end but an end itself.

Even though tools for developing a safety culture are available, a common set of best practices is needed. One can envision the development of a "culture bundle," analogous to the bundle of interventions that drastically reduced ventilator-associated pneumonia (Resar et al. 2005). Such a culture bundle would include evidence-based strategies that leadership and teams across an organization could implement to drive meaningful culture change.

To help begin the process of transformation, hospital boards should be engaged to demand that leaders recognize a culture of safety as a priority and an activity for which they are responsible. The role of effective leaders is to establish safety culture by defining the goals and values of the organization—health care leaders must clearly and relentlessly communicate that safe care is a primary, non-negotiable goal (Leonard and Frankel 2012).

Improved Culture: An End Itself

Knowledge often moves in three phases: first a superficial simplicity; followed by confusing complexity, as underlying, previously unidentified problems surface; and finally, profound simplicity (Schutz 1982). The superficial simplicity in patient safety began as the notion that we should emulate aviation and other high-risk industries with incident reporting, culture change, and attention to communication and teamwork. The confusing complexity represents the current state: safety initiatives are focused on a broad array of specific safety targets with interventions for each one—checklists for surgery, bundles for central lines, computerized physician order entry (CPOE), and barcoding. In this phase, teamwork, communication, and culture are the means to an end, such as successful implementation of the surgical checklist or central line bundle.

Now we are beginning to realize the profound simplicity phase: improved culture is not the means to an end but an end itself. For example, we know that superficial implementation of a surgical checklist doesn't work (Urbach et al. 2014). However, a major teamwork and culture intervention that also included checklists (rather than the other way around) reduced mortality by 50% more than secular trends (Neily et al. 2010). Thus, according to this checklist example, a core focus on culture (with checklists as a tool) can improve outcomes. This example helps explain why the panel felt leadership and culture are crucial to accelerating progress in patient safety.

We recommend that leaders and other key stakeholders leverage the following tactics to develop and sustain a culture of safety.

Recommendation 1: Ensure that leaders establish and sustain a safety culture

Tactics		Rationale	Audience
1.1	Refocus the boards of organizations to guide and be accountable for patient safety through governance, goal setting, and ensuring that executives and all levels of management value and prioritize safety (e.g., ensure that safety data and stories are presented at every board meeting).	A culture of safety is fundamental to driving improvements in patient safety, and more attention is needed for improvement.	Boards/Governing Bodies Leadership
1.2	Ensure that leadership and governance bodies develop and implement robust processes to initiate and sustain transformation to a culture of safety and respect, specifically one that encourages honesty, fosters learning, and balances individual and organizational accountability.		Boards/Governing Bodies Leadership
1.3	Develop and implement operational culture change "playbooks," based on existing practices and operational experience with successful culture change efforts.	Leaders need practical, tactical strategies to actually change culture.	Boards/Governing Bodies Leadership Safety Organizations
1.4	Create a new norm that every trustee, leader, and regulator completes a foundational program in patient safety science (e.g., just culture, systems).	Boards, leaders, and regulators (e.g., state agencies) need sufficient education in the fundamentals of safety science to foster culture efforts.	Boards/Governing Bodies Educators Leadership Regulators

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Recommendation 2: Create Centralized and Coordinated Oversight of Patient Safety

Although the authors of *To Err Is Human* called for coordinating patient safety efforts at the national level 15 years ago, their recommendation remains unfulfilled. Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations. Many experts have highlighted examples in other high-risk industries as models for health care to emulate. A common safety element in various fields is a central independent agency that is responsible for conducting incident investigations. The central agency employs or consults with multiple experts who look across incidents to develop recommendations, some of which then become mandatory across the industry. In the US, the Federal Aviation Administration (FAA) oversees the aviation industry in this manner; the Nuclear Regulatory Commission (NRC) plays

Optimization of patient safety efforts requires the involvement, coordination, and oversight of national governing bodies and other safety organizations.

a similar role for the nuclear power industry. These central agencies investigate safety issues and create and disseminate best practices to drive effective improvement.

A similar type of inter-organizational sharing, coordination, and oversight is needed for patient safety on a national level. To avoid unnecessary duplication and ensure that valuable lessons are shared across all stakeholders, a coordinated approach should include collaboration among public agencies and private organizations whose activities support patient safety. This collaboration would include priority setting, identification of risks, and creation and dissemination of best practices.

In addition to encouraging greater collaboration and coordination, the designation of a central agency would also provide greater centralized leadership and accountability

for work that is under way in the field. One important lesson from the events at Mid-Staffordshire in the National Health System (NHS) in England, in which the provision of substandard care was found to have contributed to patient death, is that when responsibility is diffused across groups, it is not owned (National Advisory Group 2013). Specifically, the National Advisory Group on the Safety of Patients in England found that "responsibility for oversight and remedy for quality and safety concerns was, and is still to some extent, diffused in the NHS, with that responsibility divided among many agencies, and with unclear or at times non-existent lines of coordination, communication, pattern-recognition and follow-up for action." The advisory group concluded that "when so many are in charge, no one is" (National Advisory Group 2013).

Various bodies have initiated nationwide efforts that have shown value. In the US, at the federal level, the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) have shown active leadership on many patient safety initiatives. For example, in 2008 CDC launched the PROTECT initiative to reduce the risk of unintentional medication overdose among children (CDC 2012). In 2010, CMS launched the Partnership for Patients, a public-private partnership focused on reducing preventable hospital-acquired conditions and improving care transitions. Preliminary data demonstrate the collaboration has been effective, achieving a 17% decline in hospital-acquired conditions between 2010 and 2013* (CMS 2013).

Other illustrations of collaboration to advance patient safety include regional, national, and international groups. Some health care organizations are uniting to improve care, including those operating in the same market segments and some potentially competing organizations. SPS, a collaborative of pediatric hospitals in Ohio, has enabled sharing data, best practices, and documented improvements in safety, such as reducing the number of cardiopulmonary arrests outside the intensive care unit (ICU) by 46% (Children's Hospitals' Solutions for Patient Safety [nd]).

Patient safety organizations (PSOs), which are regulated by the US Agency for Healthcare Research and Quality (AHRQ), were created to promote shared learning to enhance quality and safety nationally by conferring confidentiality protections (AHRQ PSO [nd]). The intention for these organizations is that they capture incident report data using common formats, to inform a centralized government effort and also aid in measurement. While conveying information back to their clients, PSOs also can serve as liaisons between the central effort and their clients. However, the current effectiveness of PSOs in communicating patient safety information to clients and working with them to reduce errors requires rigorous examination (Frankel 2011).

Central coordination could also add significant value to incident reporting. In aviation and other industries, the most serious incidents and accidents are reported to and

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* However, some have questioned this study's methodology and lack of external review, raising uncertainty about the results' validity (Pronovost et al. 2014).

investigated by an entirely independent safety team to ensure that system-wide causes and required improvements can be impartially identified (Macrae 2015). England's NHS is currently working to implement a similar model. Voluntary practitioner reporting of certain types of events to external organizations, such as the US Food and Drug Administration (FDA), the independent non-profit Institute for Safe Medication Practices (ISMP), the CDC, and others, have been an important approach for centrally capturing and applying information about adverse events and developing strategies to address them. Such reporting also has had a broad effect on FDA regulations, industry practices, health care standards, national patient safety goals, and targeted medication safety best practices (Michael Cohen personal communication Nov 2015).

In addition to these safety organizations and collaboratives, health care includes numerous regulatory bodies involved in patient safety activities and oversight. These groups include the FDA; US Office of the National Coordinator for Health Information Technology (ONC); the US Department of Health and Human Services (HHS), which includes AHRQ, CMS, CDC, and the Office of the Inspector General (OIG); and the National Quality Forum (NQF), to name a few. In addition, several patient advocacy groups focus on patient safety, as well as non-profit safety organizations such as the National Patient Safety Foundation, the Leapfrog Group, and the Institute for Healthcare Improvement (IHI).

Within the US, however, there is no dedicated central group and no national strategy to align all of the organizations involved in patient safety. Without a primary group to galvanize will and act as a focal coordinating point to prioritize patient safety efforts, patients and health care professionals suffer from fragmentation and duplication of efforts, absence of effective advocacy, lack of ultimate accountability, and competition for funding.

To fill this void, the preferred solution would be to form a new organization, analogous to the FAA or NRC, to act as a focal point for safety efforts and to develop a national strategy to align and coordinate these efforts across public and private organizations. In the current political climate, achieving such a solution seems unlikely. A potential alternative would be to expand the role of an existing organization to serve the lead coordinating role. Given the known rates of patient harm in health care, we need to elevate the conversation about patient safety to make it a public health priority. We need the same coordination and focus that other public health initiatives have—for example, the use of seatbelts and the reducing of cigarette use, where policy makers, industry, and frontline organizations all work together. A national patient safety oversight structure could represent the aforementioned disparate groups and become an effective interface between the government, other safety stakeholders, and the public regarding all aspects of health care safety.

We recommend that stakeholders exercise the following tactics to facilitate national coordination and oversight of patient safety activities.

Recommendation 2: Create centralized and coordinated oversight of patient safety

Tactics		Rationale	Audience
2.1	Align and harmonize national safety activities by designating or creating a central coordinating body.	Lack of coordination between numerous federal agencies and safety organizations leads to a lack of a national strategy and harmonization of efforts on patient safety.	Congress HHS
2.2	Expand and accelerate collaborative improvement efforts (e.g., regional or specialty-specific coalitions) in patient safety across the care continuum.	Lack of sharing data and best practices limits efforts to drive effective improvement.	Health Care Organizations HHS Professional Societies Public-Private Partnerships Safety Organizations

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Recommendation 3: Create a Common Set of Safety Metrics That Reflect Meaningful Outcomes

Measurement is foundational to advancing improvement. It helps clarify goals, establish a shared sense of purpose, and confirm that organizations are heading in the right direction over time. However, measurement also carries the potential for unintended negative effects. Inaccurate measurement obscures the true state of affairs, leading either to ill-advised complacency or efforts disproportionately targeted on minor problems. The quantity of measures now required by different regulatory bodies can distract attention from important goals, and the task of collecting and analyzing data is overwhelming. Another problem is the unintended use of metrics (e.g., AHRQ patient safety indicators, meant as a screening tool, being used for payment penalties) and unintended consequences of metrics currently in use (e.g., financial penalties to low-resourced hospitals as a consequence of readmissions measurement) (Joynt and Jha 2012), which can have deleterious consequences.

Measurement is foundational to advancing improvement.

Some progress has been made in measurement over the past 15 years. Measurement is now considered routine in many areas of health care in a way it was not previously. Organizations nationwide now regularly measure HAIs using reliable, validated definitions that have gained national consensus (Yokoe 2014, CDC Identifying 2015). Many states now require reporting of HAIs (CDC State-Based 2015). A growing number of measures now assess what matters to patients: the patient experience. The Hospital Consumer Assessment of Healthcare Providers and Systems survey and related tools provide standardized measurements of the patient experience of care, including some items directly related to patient safety such as discharge communication. These tools are widely used and are now tied to Medicare reimbursement, increasing their visibility and importance (CMS 2013, CMS 2014,). The past 15 years have also witnessed increased transparency in measurement. Mortality and complication rates of many hospitals are now posted publicly—an activity far less common prior to the IOM report (Ryan 2012).

Numerous measurement challenges are, however, very specific to patient safety. First, unlike with other aspects of quality, there are not widely used measures for safety. Administrative data doesn't work well for safety measures. The current measurement methodology, which often relies on retrospective surveillance via claims data or chart review, fails to detect all instances of errors, harms, and "never events" (Thomas and Classen 2014). Cross-cutting safety measures are not available from routine data; it is difficult to use large databases to find ADEs or diagnostic errors.

The metric denoted "total adverse events" is too heterogeneous to provide meaningful data for improvement, yet it is often used as a primary metric for assessing patient safety (Vincent and Amalberti 2015, Shojania and Marang-van de Mheen 2015). Measuring adverse events provides a general lay of the land, indicating what types of safety problems commonly arise and a rough sense of their relative frequency. However, for any given type of adverse event (HAIs, ADEs, surgical complications, diagnostic errors), we often do not measure reliably enough to be able to show improvement over time. Another problem is that the classification of adverse events may change over time; with new harms or changes in what reviewers regard as preventable, even if hospitals successfully lower many known preventable adverse events, the preventable adverse event rate might look unchanged (Vincent and Amalberti 2015). In addition, any category of adverse event has so many heterogeneous causes that any given intervention may not reduce the rate enough that a change is detected. Even for outcome measures that seem relatively straightforward, such as VTE rates, there can be inaccuracies (e.g., hospitals that screen and test more may look worse although giving better care) (Bilimoria et al. 2013).

Chart review is an alternative to administrative data, but it is extremely labor intensive. Even when simplified by using instruments such as the IHI Global Trigger Tool, these tools may be too blunt to detect improvement (Shojania and Marang-van de Mheen 2015, Wong et al. 2015). These tools can only identify the specific adverse events in the tool and can only detect events that are actually documented.

Significant effort has been spent on organizational reporting systems, which was a core recommendation of the original IOM report, but these efforts have often provided little value to organizations in terms of actual improvements. A recent study identified five barriers hindering the effectiveness of incident reporting: poor processing of incident reports, inadequate physician engagement, insufficient visible subsequent action, inadequate funding and institutional support of incident reporting systems, and inadequate use of emerging health information technology (health IT) (Mitchell et al. 2015). According to another report, "we collect too much and do too little," and we should refocus efforts to ensure that reports lead to actual improvement (Macrae 2015). Voluntary reporting to central organizations such as ISMP and the FDA has been more effective. For example, ISMP runs a centralized voluntary error-reporting program to which any care professional or organization can report medication errors. ISMP then uses its expertise to share feedback, best practices, and lessons learned from these errors very

broadly through alerts and newsletters. More work needs to be done to to optimize organizational reporting and determine how to expand effective centralized programs.

Finally, all of these methods (claims, chart review, reporting) are retrospective and reactive. In thinking about prevention, we need more and better ways to identify and measure risks and hazards in real time, or proactively, to potentially intervene before an adverse event occurs. For example, identifying patients at risk of an ADE based on number of medications taken and other factors would allow intervention with a pharmacist before the event occurs.

To turn the tide, the safety field needs to establish standard metrics that span the entire care continuum. Processes and tools also need to be developed to identify risks and manage hazards proactively (e.g., identify early signs of clinical deterioration). Safety reporting systems should be improved to ensure that appropriate systems improvements are implemented as a result of these reports. Better strategies are needed to increase measurement of outcomes that matter to patients via patient-reported outcomes or safety concerns. Finally, once the standard metrics are in place throughout the care continuum, incentives should be devised for innovation and further improvement.

We recommend that stakeholders use the following tactics to accelerate progress in patient safety measurement.

Recommendation 3: Create a common set of safety metrics that reflect meaningful outcomes

Tactics		Rationale	Audience
3.1	Create a portfolio of national standard patient safety process and outcome metrics across the care continuum and retire invalid measures.	Relevant measures of patient safety and harm are lacking, and some current measures are ineffective.	HHS (AHRQ, CDC, CMS) NQF Researchers
3.2	Develop processes and tools to identify and measure risks in real time to proactively manage hazards (e.g., identify the early signs of clinical deterioration).	Much of safety measurement is retrospective rather than prospective.	Researchers Vendors
3.3	Improve safety reporting systems to ensure that appropriate systems improvements are implemented and that timely feedback is provided to all involved.	While significant effort has been spent on reporting systems, often little value is added in terms of actual improvements. More work is needed to identify and better understand what forms of reporting work best to improve safety.	Health Care Organizations HHS Vendors
3.4	Develop measures of safety in settings throughout the care continuum and develop financial and non-financial incentives for innovation and improvement.	Very few measures of patient safety exist for settings outside of the hospital.	HHS (AHRQ, CDC, CMS) NQF Researchers

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Recommendation 4: Increase Funding for Research in Patient Safety and Implementation Science

To make substantial advances in patient safety, both safety science and implementation science should be developed more completely so that more is understood about safety hazards and the best ways to prevent them. Safety science investigates contributing factors and underlying causes of risk and harm, including errors and human factors. It includes many disciplines not typically considered part of health care. Safety science research recognizes the fundamental importance of system design in driving workforce behavior. In other industries, such as aviation and manufacturing, safety experts accept the tenet that human error is expected; it therefore must be anticipated and its effects mitigated. In addition to designing systems to prevent errors, health care should better understand and more actively apply the principles of safety science and human factors engineering to identify and mitigate errors before they cause harm.

> *In other industries, safety experts accept that human error is expected and therefore must be anticipated and its effects mitigated.*

Implementation science supplements patient safety science, focusing on delivery, scaling up, translation, and applying lessons learned in the laboratory or pilot setting. Identifying valuable practices and effectively implementing them are critical to success in the real world.

Progress in safety and implementation science includes increasing recognition that safety science exists, and clinicians and organizational leaders being open to opportunities to improve through partnership with disciplines outside of health care. For example, surgery teams have applied safety approaches from aviation and automobile racing to improve postoperative care (Catchpole et al. 2007). Forums have emerged that

encourage interdisciplinary work and large-scale collaboratives, in which peer organizations work together to learn and to improve (Berwick et al. 2006, IHI 2015). Additionally, some progressive health care organizations have shown that judiciously applying strategies and tools used to design and build automobiles can improve the quality, safety, and efficiency of health care delivery (McCulloch et al. 2010, Meyer 2010, Kaplan 2013).

In many settings, however, leaders and frontline clinicians have not been exposed to or do not effectively apply lessons culled from safety science. In other instances, the lessons about what works to remove defects in other industries are sometimes oversimplified, losing essential elements in their translation to health care and dooming some to failure. Sometimes one health care organization is able to achieve significant improvement, for example reducing mortality with surgical safety checklists (Haynes et al. 2009, Weiser et al. 2010), while others are unable to replicate such results (Urbach et al. 2014, Reames et al. 2015). An additional point is that some organizations can achieve gains in one area and yet, within the same organization, not achieve positive gains in other areas.

Training specifically focused on safety and quality is essential. Examples include the Interprofessional Fellowship Program in Patient Safety and the Chief Residents in Quality and Safety program run by the US Veterans Administration (VA) (Chang and Williams 2013, Watts et al. 2013). The former was modeled after the VA Quality Scholars Fellowship Program, which effectively prepares physicians to lead quality initiatives (Splaine et al. 2009). Interprofessional practice and education is also needed to change how we train future clinicians (University of Minnesota [nd]). In addition, there is a need to train researchers to conduct patient safety research and educate a workforce in implementation science to lead operational improvement efforts.

At times the regulatory environment has been slow to adapt to new care strategies and technologies. For this reason, the field lacks a sufficient number of transformative success stories to inform and inspire replication. Finally, the continually evolving nature of science inadvertently contributes to non-acceptance of safety and implementation science. For example, when an innovation shows initial promise but later studies fail to reproduce positive results, the public, policymakers, and clinicians may not only doubt the effectiveness of the specific intervention but also the larger approach. It is important to highlight and foster acceptance of this aspect of the scientific process to ensure that the will to improve can be sustained.

Substantial research in safety science and implementation science will require the commitment of sustained financial resources. However, the estimated 2015 budget of the National Institutes of Health (NIH) for patient safety research was $1.01 billion, which represents 3.4% of the total annual budget for medical research ($30.1 billion) (NIH 2015). In recent years, the budget of AHRQ, the major US federal funding source for

health care quality and safety research, has been at risk for being severely slashed. The lack of available funds for research and the precariousness of the funds available are serious obstacles to improvement in patient safety.

We recommend that stakeholders draw upon the following tactics to advance patient safety research and implementation science.

Recommendation 4: Increase funding for research in patient safety and implementation science

Tactics		Rationale	Audience
4.1	Support collaboration between researchers in patient safety and researchers in safety sciences within other industries and sectors.	A formal method for learning and innovation to occur in health care around patient safety is needed.	HHS (AHRQ) Researchers
4.2	Identify and make available sustainable funding sources for safety and implementation research, including federal funding and public-private partnerships.	Patient safety lacks sufficient funding, relative to its impact on patients.	HHS (NIH, AHRQ) Congress Foundations/Other Funders Safety Organizations
4.3	Expand health care safety scholar programs to train researchers with safety science expertise and to train operational and implementation leaders.	A highly trained workforce is needed to conduct research in patient safety and lead operational improvement efforts.	HHS (AHRQ) Foundations/Other Funders
4.4	Encourage organizations that have successfully implemented safety innovations to establish learning labs and collaboratives to spread them to other organizations.	Spreading and sustaining innovations is critical to meaningful improvement in patient safety.	Foundations/Other Funders Health Care Organizations HHS Public-Private Partnerships Safety Organizations

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Recommendation 5:
Address Safety across the Entire Care Continuum

Patients deserve safe care in and across every setting. Roughly one billion ambulatory visits occur annually in the US compared with 35 million hospital admissions (NCHS 2015). Yet *To Err Is Human* was largely focused on care provided within hospitals, and the bulk of patient safety research has occurred in the inpatient setting (Gandhi and Lee 2010). Less research has focused on non-inpatient settings, including: physician offices; community pharmacies; clinics; ambulatory surgical, medical, and imaging centers; as well as long-term, hospice, and home care settings. A review of ambulatory patient safety research prepared for the American Medical Association (AMA) found the work to be "remarkably limited, both in quantity and the ability to generalize from the studies that were reported" (Lorincz et al. 2011). Written 10 years after the publication of *To Err Is Human*, the AMA report notes continued gaps in knowledge regarding the magnitude of safety issues and harms occurring outside of hospitals. A companion piece to the report refers to this time as a "lost decade" (Wynia and Classen 2011).

Patients deserve safe care in and across every setting.

Patient safety risks are substantial in outpatient settings. In one study, more than half of annual paid medical malpractice claims were for events in the outpatient setting, and two-thirds involved major injury or death (Bishop et al. 2011). A separate study found that one-quarter of primary care patients had an ADE and 11% were preventable (Gandhi et al. 2003). ADEs occurred in about 11% of discharged patients in a separate study, and 25% of these were preventable (Forster et al. 2005). Lack of coordination between care settings is also a major source of safety problems, especially at transitions. One report documented that about one-third of Medicare beneficiaries in skilled nursing facilities experienced an adverse event; half were deemed preventable (OIG 2014). Better understanding of the risks at transitions of care and identification of effective prevention tools are essential. Finally, diagnostic errors are another important source of preventable harm to patients cared for in the outpatient setting (Singh et al. 2014), as highlighted in a recent report from the Institute of Medicine (National Academies 2015).

Payers, policymakers, organizational leaders, and health care professionals now recognize the need for greater care coordination and better communication across the care continuum (Craig et al. 2011, Naylor et al. 2011). However, significant financial incentives currently hinder effective collaboration during care transitions. Many hospitals do not appropriately support health care professionals to reliably communicate with post-acute care facilities, such as nursing homes or rehabilitation centers, or compensate them for the time needed to do so.

Too little is known about the epidemiology of patient safety in settings outside of hospitals and about potential strategies for improvement. In addition, the infrastructure is far more limited in these settings; hospitals have personnel dedicated to quality and safety, reporting systems, peer review conferences, and other resources that may not exist in other settings. Health care organizations need better tools, processes, and structures to deliver care safely and to evaluate the safety of care in various settings. Additional research is needed to characterize more fully the risks in all settings across the care continuum.

We recommend that stakeholders leverage the following tactics to facilitate coordination and communication, and ultimately increase patient safety, across the entire care continuum.

Diagnostic Error Re-examined

Improving Diagnosis in Health Care, a new Institute of Medicine report, concludes that "most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences." For the purposes of the report, diagnostic errors are defined as diagnoses that are inaccurate, missed, or inappropriately delayed. Research indicates that such errors are widespread and are more common in outpatient settings (56% of all diagnostic errors) than in the emergency department (28%) or inpatient setting (16%). The report emphasizes that improved collaboration among health care professionals, patients, and families, coupled with enhanced clinical education and training on the diagnostic process, will be central to improvement (National Academies 2015).

Recommendation 5: Address safety across the entire care continuum

Tactics		Rationale	Audience
5.1	Increase funding for research to understand the epidemiology of patient safety in settings across the care continuum (e.g., primary care, specialty practices, ambulatory surgical centers, dialysis centers, nursing homes).	Little is known about the epidemiology of patient safety in settings outside of hospitals and about potential strategies for improvement, even though most care is delivered in these settings.	Congress Foundations/Other Funders HHS (AHRQ, NIH)
5.2	Expand infrastructure across the care continuum (e.g., safety expertise, reporting mechanisms, collaboratives) to identify and implement best practices for safety improvement.	Many settings across the care continuum lack the infrastructure for improvement.	Ambulatory Practices and Settings Health Care Organizations Leadership

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Recommendation 6:
Support the Health Care Workforce

Workforce safety, morale, and wellness are absolutely necessary to providing safe care. As discussed in *Through the Eyes of the Workforce: Creating Joy, Meaning, and Safer Health Care*, "workplace safety is . . . inextricably linked to patient safety. Unless care-givers are given the protection, respect, and support they need, they are more likely to make errors, fail to follow safe practices, and not work well in teams" (LLI 2013).

Members of the dedicated health care workforce—nurses, physicians, medical assis-tants, pharmacists, technicians, and others—need support to fulfill their highest potential as healers. Such support should include attention to both physical harm (e.g., physical injury, violence in the workplace, stress-related illness) and emotional harm (e.g., disre-spectful behavior, intimidation, and verbal abuse) (LLI 2013).

Members of the dedicated health care workforce need support to fulfill their highest potential as healers.

In 2011, US hospitals reported about seven work-related injuries and illnesses per 100 full-time employees, a rate almost twice that of private industry as a whole (OSHA 2013). In terms of days lost from work due to injury, hospitals are among the most haz-ardous job sites in the US. Health care workers are at risk for physical injuries on the job, sometimes inflicted by violent patients or families.

Bullying behavior among health care professionals has direct effects on workforce safety and patient safety. Many organizations do not address disrespectful behavior decisively; too often individuals in roles of power or influence are not corrected or reprimanded when they intimidate others (Joint Commission 2008). Health care workers who are bullied may be intimidated from speaking out when they observe safety violations or failures to complete safety-related tasks. Health care organizations should take steps to eliminate bullying behavior and address the security of the workforce.

Pockets of awareness about workforce support are emerging, as evident from the increase in research about workforce burnout and healthy work environments (Sainfort et al. 2001, Carayon et al. 2006, Linzer et al. 2014, Ulrich et al. 2014). Professional burnout is common. About half of physicians in primary care and some specialties report symptoms of burnout (Shanafelt et al. 2012, Roberts et al. 2014, Shanafelt et al. 2014). One study demonstrated that staff burnout affected more than half of neonatal intensive care unit staff in some organizations; units with higher proportions of burnout had worse safety culture scores (Profit et al. 2014).

The important role of joy and meaning in work for patient care outcomes was not widely recognized 15 years ago; its acknowledgement as a valid topic for research, and its discussion represents progress (LLI 2013). To find joy and meaning in their daily work, each employee should be able to affirmatively answer three questions each day: (1) Am I treated with dignity and respect by everyone? (2) Do I have what I need so I can make a contribution that gives meaning to my life? (3) Am I recognized and thanked for what I do? (LLI 2013) Moreover, a recent article cited the need to advance a "quadruple aim," with improving the experience of *providing* care added to the so-called triple aim of improving the individual experience of care, improving care of the population, and reducing per capita cost (Sikka et al. 2015)

Recent initiatives to nurture healthy work environments represent important steps forward. The Joint Commission and professional associations such as the American Association of Critical-Care Nurses (AACN) have disseminated guidelines for creating healthy work environments, especially as they relate to communication and interpersonal relationships (AACN 2005, Joint Commission 2012). The American Nurses Association recently announced the HealthyNurse™ initiative, which emphasizes the total wellness of nurses and the key role that nurses play in modeling health-promoting behaviors (ANA [nd]). Internationally, the Royal College of Physicians (UK) recently published a report delineating the link between staff well-being and high-quality patient care, and specifying recommendations for promoting the safety and well-being of the health care workforce (RCP 2015).

Both joy in work and enhanced safety are possible if care professionals are sufficiently supported in their efforts to provide safe and effective care. Support should include ongoing training opportunities related to quality improvement tools and methods, safety culture, and implementation science, as well as resilience and dealing with disruptive

> **The Many Costs of Failure to Support the Health Care Workforce**
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> *Through the Eyes of the Workforce Creating Joy, Meaning, and Safer Health Care*, a report by the National Patient Safety Foundation's Lucian Leape Institute (LLI), describes how failure to support a healthy workforce in health care results in both physical and emotional harm. This harm is associated with a variety of adverse consequences that ripple across the health care system. "The costs of burnout, litigation, lost work hours, employee turnover, and the inability to attract newcomers to caring professions are wasteful and add to the burden of illness" (LLI 2013). The report emphasizes that lack of workforce support has adverse effects on everyone who touches the health care system: patients, families, health care professionals, administrators, and those who pay for health care.

behaviors. There is a clear appetite for quality and safety education among the workforce, and organizations should embrace and encourage it. For instance, the IHI Open School provides online training and tools for health care professionals and has seen more than 2 million online courses downloaded in the past four years. In addition, medical and nursing schools and residency programs are putting increased focus on quality and safety training (QSEN [nd], ACGME [nd]). By developing these skills, the front lines will have the knowledge and tools they need to create safer systems.

Workforce support should also include providing comprehensive training and addressing low morale, professional burnout, and lack of engagement. Organizations should endeavor to provide consistent, effective support after critical or adverse events to reduce the suffering of caregivers and staff who experience psychological harm after being involved in errors (Wu 2000, Seys et al. 2013). Health care organizations should consistently offer support for all caregivers, both routinely and after adverse events (Hu et al. 2012)

We recommend that stakeholders use the following tactics to better support the workforce.

Recommendation 6: Support the health care workforce

Tactics		Rationale	Audience
6.1	Organizations must adopt modern quality improvement tools and methods and train all professionals in safety culture and implementation science throughout their career trajectory.	Providing the knowledge and skills to improve safety may improve job satisfaction, engagement, resilience, and patient safety.	Accreditors Educators Health Care Organizations Health Care Workforce Health Professional Licensing Bodies Professional Associations Safety Organizations
6.2	Expand or develop resources that support the workforce, including initiatives to improve working conditions and establish an environment of respect; programs to support staff and improve resiliency; fatigue management systems; and communications, apology, and resolution programs.	Workforce safety is a precondition to patient safety; however, physical and psychological harm and burnout are highly prevalent in health care.	Boards/Governing Bodies Educators Health Care Workforce Leadership Professional Associations
6.3	Involve the workforce in identifying domains for measurement and creating workforce safety and wellness dashboards to be reviewed by leadership and boards.	Standardized measures of physical and psychological safety are not available for senior leaders to review.	Boards/Governing Bodies Health Care Workforce HHS (AHRQ) Leadership NQF

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Recommendation 7: Partner with Patients and Families for the Safest Care

Patients and families need to be actively engaged at all levels of health care. The term "patient engagement" can mean different things to different health care stakeholders and can be conceived of in different ways (Batalden et al. 2015). Common to most definitions are the ideas of partnership, communication, information exchange, and respect. Recent research focuses on patient emotional harm, which may result from disrespect. In particular, emotional harm is perceived as something that impacts a patient's dignity "by the failure to demonstrate adequate 'respect' for the patient as a person" (Sokol-Hessner et al. 2015), and some hospitals are starting to measure emotional harm as part of their safety efforts. At its core, patient engagement is about the free flow of information to and from the patient. Its foundation is an environment where patients and families are always treated with respect and their personal dignity is honored (Sokol-Hessner et al. 2015). Whereas in decades past, patients may have been discouraged from being vocal participants in their care, today we understand that optimal care *depends* on active involvement from patients and their families.

Patients and families need to be actively engaged at all levels of health care.

In the past several years, public awareness of the need for patient and family involvement in care has grown. The NPSF Lucian Leape Institute report *Safety Is Personal: Partnering with Patients and Families for the Safest Care* highlights the concept that patient engagement is critical for patient safety at all levels of health care (NPSF LLI 2014). An advisory group report on patient safety within the NHS in England highlighted the importance of true patient engagement: "Patient involvement means more than simply engaging people in a discussion about services. Involvement means having the patient voice heard at every level of the service, even when that voice is a whisper" (National Advisory Group 2013).

Some US states have taken steps to encourage patient engagement. Massachusetts requires hospitals to establish patient and family advisory councils (HCFA 2012), Washington encourages shared decision making, and other states are beginning to follow suit (NASHP 2012, IMDF [nd]). On the federal level, both the HITECH Act of 2009 and the Affordable Care Act of 2010 encourage and support much more meaningful engagement of patients, families, and communities in decision making and design for their care. Mechanisms include, for example, transparency, new roles in governance, patient-reported

outcome measures, patient-reported experience measures, and payment innovations that redirect attention to the entire experience of care. Some policymakers have even called for the health care system to partner with patients as *co-producers* of health (Batalden et al. 2015, Berwick et al. 2015). This shift is important to ensure safety and requires changed roles for patients and health care professionals. "What needs to happen is for doctors to come down off their pedestal and for patients to get up off their knees" (WHO 2012).

The degree of information sharing with patients has substantially increased in the US over the past 15 years. Shared decision making is a two-way process increasingly seen as the standard of care and a powerful lever for improved safety. Ensuring that patients have full information about their treatment choices and that health care professionals have a complete understanding of the patient's values and preferences can decrease errors (Elwyn et al. 2012). Lack of informed decision making can result in patients undergoing tests and treatments they would not have chosen were they fully informed about the risks and benefits (Sokol-Hessner et al. 2015). In fact, exposing patients to treatments that they would not have wanted if better informed can be viewed as a preventable adverse event (Brownlee et al. 2014, Stacey et al. 2014, Wynia et al. 2014, Wolfson and Mende 2015).

In addition, significant progress has been made in advancing disclosure of errors to patients and management of subsequent processes (Studdert et al. 2007, Mello et al. 2014). Several groups have studied the best way to disclose errors, including NQF, which endorsed full disclosure of "serious unanticipated outcomes" as a safe practice in 2006 (AHRQ PSNet Error Disclosure 2014). The measure includes standards for practitioners regarding the key components of disclosure.

> ## Recommendations for Engaging Patients and Families
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> The National Patient Safety Foundation's Lucian Leape Institute (LLI) convened two roundtables to develop recommendations for engaging patients and families in improving patient safety. The 2014 LLI report produced from that effort, *Safety Is Personal: Partnering with Patients and Families for the Safest Care*, states: "Engaging patients and families in improving health care safety means creating effective partnerships between those who provide care and those who receive it—at every level, including individual clinical encounters, safety committees, executive suites, boardrooms, research teams, and national policy-setting bodies" (NPSF LLI 2014). The report recommends actions for health care leaders, policy makers, and frontline providers to promote patient engagement at all levels of care.

Some health care organizations are increasingly providing patients with greater access to information about their health and health care, through patient portals, accessible health records including clinician notes, bedside rounding, and other initiatives (Delbanco et al. 2012). They are also providing consumers with more information than ever before through public reporting of quality and safety metrics (e.g., Leapfrog, Hospital Compare). (The LLI report *Shining a Light: Safer Health Care Through Transparency* provides more information on the role of transparency in patient safety.)

Health care organizations are increasingly seeking patient input to a degree that was unseen previously. In inpatient settings, patient and family engagement strategies include patient-activated rapid response teams (Winters et al. 2013), open visitation policies, and multidisciplinary rounding at the bedside. At the organizational level, many promote involvement of patients in quality improvement and safety committees and initiatives

as well as creation of patient and family advisory councils (NPSF LLI 2014). There is also increasing support for patient involvement in root cause analysis (Etchegaray et al. 2014). A recent report from NPSF highlighted the importance of interviewing patients and families during root cause analysis, as well as providing them feedback about its results (NPSF 2015).

Certain issues impede patient engagement. In too many instances, care is rushed, fragmented, and unresponsive to the needs of individual patients. Too often, transparency about patient options, medical harm, and performance outcomes is lacking. Patients and families need to be heard through access to the complete medical record (and the ability to annotate it), family-centered rounds, 24-hour family presence, and the ability for patients to alert providers when they observe an urgent situation. Patients and families should be encouraged more frequently to participate actively in care planning, delivery, and evaluation. In some cases patient and family advisory councils are established, but are not invited or enabled to do meaningful work. Patient involvement needs to be authentic. Meaningful measures of patient engagement should be developed to ensure that participation is not simply superficial.

We recommend that stakeholders draw upon the following tactics to better support and advance patient and family engagement and partnership.

Recommendation 7: Partner with patients and families for the safest care

	Tactics	Rationale	Audience
7.1	Provide communication training for all health care workers that includes concepts of shared decision making, cultural sensitivity, language literacy, effective listening, and respect in personal interactions.	Patient engagement is critical for patient safety, yet the training and tools for patients, families, and health care workforce are limited.	Educators Health Care Organizations Health Care Workforce Patients/Families
7.2	Ensure that patients and families have timely access to tools, resources, test results, and their full medical records.		Health Care Organizations Health Care Workforce Patients/Families
7.3	Ensure that committees and governing bodies include members of the local patient and family community (representative of the patient population), and these members are meaningfully involved in care design and safety and quality initiatives.	Patient engagement must occur at all levels of the health care system.	Health Care Organizations Health Care Workforce HHS ONC Patients/Families
7.4	Actively engage patients in care (e.g., shared decision making, playing an active role in bedside rounding, removing limits on family visiting hours, and making available patient-activated rapid response teams) and in root cause analyses.		Health Care Organizations Health Care Workforce Patients/Families
7.5	Develop meaningful measures of patient engagement, patient-reported outcomes related to safety, and develop systems for capturing patient reports of safety incidents.	Patient engagement is a key priority, and we cannot improve what we do not measure.	HHS (AHRQ) NQF Patients/Families

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Recommendation 8: Ensure That Technology Is Safe and Optimized to Improve Patient Safety

Technology has proven potential to improve patient safety, but only if we can minimize the risks. Health IT, which includes EHRs, patient portals, health information exchanges, and software for "smart" medical devices, has been touted as a powerful lever in health care reform. When designed and implemented well, health IT can facilitate patient engagement and care coordination. Since the IOM report was issued 15 years ago, health care organizations have increasingly adopted these new technologies, and this development has implications for patient safety.

The widespread use of health IT has led to demonstrable reductions in medical errors. Computerized physician order entry (CPOE) has been shown to decrease medication errors by about 50% in acute care settings (Bates et al. 1998, Radley et al. 2013). Because CPOE virtually eliminates handwritten orders, it removes illegible handwriting as a source of errors and delays in care. More importantly, computerized ordering can drastically reduce dosing errors and known medication allergy errors. Electronic medication-administration systems with barcode verification have been shown to reduce medication errors by more than 50% and to eliminate transcription errors (Poon et al. 2010). Technology has also reduced errors directly related to clinical care, for example with smart pumps and barcoding for transfusion (Fanikos et al. 2007, Askeland et al. 2009). Health IT can also improve patient outcomes; for example, implementation of advanced EHRs has been associated with reductions in mortality among hospitalized patients (Amarasignham et al. 2009, Parente and McCullough 2009, Banger and Graber 2015).

Technology has proven potential to improve patient safety, but only if we can minimize the risks.

Health IT is not, however, a panacea for errors in health care. Implementation of health IT has downstream effects on patient flow, quality of communication between patients and health care professionals, care professionals' time, and direct contact with patients. Health IT can also potentially introduce new adverse events, such as errors from alarm fatigue, patient misidentification, copy and paste, or software malfunction. A recent study confirmed the existence of adverse events related to the use of electronic medical systems occurring across the care continuum and found such events to be associated with "an appreciable incidence of severe harm and death" (Graber 2015). In addition, some systems may be faulty. A simulation study of a CPOE system at 62 hospitals found that the system failed to identify 52% of potentially fatal errors (Metzger et al. 2010). Another study analyzed thousands of incidents involving CPOE, classified the errors, created sample erroneous orders involving identified themes, and observed users attempting to enter those orders at 16 study sites (Schiff et al. 2015). Overall, 79.5% of the erroneous orders were entered with 28% being easily placed, another 28.3% placed with only minor workarounds and no warnings.

Poor interoperability between systems yields lack of integration of data across the care continuum. A survey of 63 accountable care organizations found that more than 95% cited lack of health IT interoperability as a significant issue (Premier 2014). Some systems also have poor usability, which can induce new errors (Harrington 2013, Kellermann and Jones 2013). Health IT has been shown to contribute to clinician burnout; primary care physicians using EHR systems with more complex functions had higher burnout rates than those using systems with fewer complex functions (Babbott et al. 2014).

Underlying these issues is the lack of clear, enforceable standards for the development and use of health IT and other forms of technology, including patient portals and applications, telemedicine, and new testing or diagnostic tools. Even when regulations do exist, they may not be adhered to. A recent research letter documents the almost complete failure of many of the top 50 vendors (vendors with the highest number of provider customers and all certified by the ONC) to engage in basic usability testing (Ratwani et al. 2015).

Optimizing the benefits and minimizing the unintended consequences of health IT is critical. The ONC and other groups are now focused on identifying hazards related to health IT. Guidelines are available to promote safe health IT use, such as the SAFER guides that identify key recommended safety practices for EHR implementation (Sittig et al. 2014). In addition, vendors and implementers should share information about health IT safety hazards and potential best practices. This need was highlighted in a report from the FDA that recommended the creation of a national health IT safety center that would serve this purpose (ONC 2014).

One organization, ECRI Institute, has created a national Partnership for Health IT Patient Safety. This collaborative obtains information and input from health IT developers, PSOs, participant providers, and others, in an effort to reduce risk, promote patient safety, and enhance health IT innovation in a non-punitive environment for sharing and learning (ECRI 2015). More of such collaborative efforts may facilitate transparency along with developing and sharing best practices, in order to optimize the design and implementation of health IT to improve patient safety.

We recommend that stakeholders leverage the following tactics to advance progress in the safe use of technology in health care.

Recommendation 8: Ensure that technology is safe and optimized to improve patient safety

Tactics		Rationale	Audience
8.1	Establish mechanisms for vendors and users to be transparent about health IT safety hazards and best practices.	Transparency about safety issues is the key to improvement.	Health Care Organizations ONC Public/Private Partnerships Safety Organizations Vendors
8.2	Identify and measure the adverse effects and unintended consequences of health IT and implement best practices for risk mitigation.	Health IT has the potential to improve patient safety, but to date poor design and implementation limit that potential.	Health Care Organizations HHS (AHRQ, FDA) NQF ONC Public/Private Partnerships Vendors
8.3	Establish expectations for health IT safety performance, such as routine testing for unsafe orders.	Much work remains to optimize existing systems.	Accreditors Health Care Organizations Researchers Vendors
8.4	Design health IT to facilitate communication and coordination with the patient and family.	Health IT can facilitate patient engagement.	Health Care Organizations Patients/Families Vendors

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Conclusion: A Call to Action

While much has improved since the IOM released *To Err Is Human* in 1999, too much remains the same. We in health care are more aware of the complexity of problems inherent in eliminating patient harm related to care. We have made valuable improvements in specific circumscribed settings. We have seen that progress is possible.

The panel feels strongly that we have failed to make substantial, measureable, system-wide strides in improving patient safety. Other priorities have overshadowed the agenda of keeping patients safe from harm related to care. Insufficient collaboration and perhaps lack of will have stalled progress. We have failed to adopt a total systems approach to safety and a single, coordinated agenda.

Patient safety is a public health issue that requires the full attention of the health care system. We should not compete on safety, but rather work in a coordinated, cohesive way to accelerate progress toward total systems safety.

To drive this acceleration, we have made eight key recommendations:

1. **Ensure that leaders establish and sustain a safety culture**
2. **Create centralized and coordinated oversight of patient safety**
3. **Create a common set of safety metrics that reflect meaningful outcomes**
4. **Increase funding for research in patient safety and implementation science**
5. **Address safety across the entire care continuum**
6. **Support the health care workforce**
7. **Partner with patients and families for the safest care**
8. **Ensure that technology is safe and optimized to improve patient safety**

Specific tactics for action, rationales for the importance of these actions, and the audiences to whom these actions should be addressed are explained in the report and are summarized in the appendix.

Safety must be a top priority, and the eight recommendations outline a framework to move forward from a piecemeal, project-by-project approach to a system that has an overarching safety culture and a rigorous approach to tackling safety. It is no accident that we list leadership and culture first in our recommendations—this was the overwhelming area of challenge and the most critical area to address according to our panelists. Nonetheless, culture is necessary but not sufficient, and this framework also highlights other key priority areas.

In health care, we cannot afford to let these barriers block our success any longer. It is critical that we work together to adopt a systems approach to safety, to create a coordinated agenda, and to ensure strong organizational leadership that prioritizes safety. Patient safety is a relatively new field, and progress has been made, but much more slowly than we would like. We must accelerate our efforts in order to create a world where patients and those who care for them are free from harm.

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Appendix: Summary of Recommendations and Tactics

Recommendation 1: Ensure that leaders establish and sustain a safety culture

Tactics		Rationale	Audience
1.1	Refocus the boards of organizations to guide and be accountable for patient safety through governance, goal setting, and ensuring that executives and all levels of management value and prioritize safety (e.g., ensure that safety data and stories are presented at every board meeting).	A culture of safety is fundamental to driving improvements in patient safety, and more attention is needed for improvement.	Boards/Governing Bodies Leadership
1.2	Ensure that leadership and governance bodies develop and implement robust processes to initiate and sustain transformation to a culture of safety and respect, specifically one that encourages honesty, fosters learning, and balances individual and organizational accountability.		Boards/Governing Bodies Leadership
1.3	Develop and implement operational culture change "playbooks," based on existing practices and operational experience with successful culture change efforts.	Leaders need practical, tactical strategies to actually change culture.	Boards/Governing Bodies Leadership Safety Organizations
1.4	Create a new norm that every trustee, leader, and regulator completes a foundational program in patient safety science (e.g., just culture, systems).	Boards, leaders, and regulators (e.g., state agencies) need sufficient education in the fundamentals of safety science to foster culture efforts.	Boards/Governing Bodies Educators Leadership Regulators

Recommendation 2: Create centralized and coordinated oversight of patient safety

Tactics		Rationale	Audience
2.1	Align and harmonize national safety activities by designating or creating a central coordinating body.	Lack of coordination between numerous federal agencies and safety organizations leads to a lack of a national strategy and harmonization of efforts on patient safety.	Congress HHS
2.2	Expand and accelerate collaborative improvement efforts (e.g., regional or specialty-specific coalitions) in patient safety across the care continuum.	Lack of sharing data and best practices limits efforts to drive effective improvement.	Health Care Organizations HHS Professional Societies Public-Private Partnerships Safety Organizations

Recommendation 3: Create a common set of safety metrics that reflect meaningful outcomes

Tactics		Rationale	Audience
3.1	Create a portfolio of national standard patient safety process and outcome metrics across the care continuum and retire invalid measures.	Relevant measures of patient safety and harm are lacking, and some current measures are ineffective.	HHS (AHRQ, CDC, CMS) NQF Researchers
3.2	Develop processes and tools to identify and measure risks in real time to proactively manage hazards (e.g., identify the early signs of clinical deterioration).	Much of safety measurement is retrospective rather than prospective.	Researchers Vendors
3.3	Improve safety reporting systems to ensure that appropriate systems improvements are implemented and that timely feedback is provided to all involved.	While significant effort has been spent on reporting systems, often little value is added in terms of actual improvements. More work is needed to identify and better understand what forms of reporting work best to improve safety.	Health Care Organizations HHS Vendors
3.4	Develop measures of safety in settings throughout the care continuum and develop financial and non-financial incentives for innovation and improvement.	Very few measures of patient safety exist for settings outside of the hospital.	HHS (AHRQ, CDC, CMS) NQF Researchers

Recommendation 4: Increase funding for research in patient safety and implementation science

Tactics		Rationale	Audience
4.1	Support collaboration between researchers in patient safety and researchers in safety sciences within other industries and sectors.	A formal method for learning and innovation to occur in health care around patient safety is needed.	HHS (AHRQ) Researchers
4.2	Identify and make available sustainable funding sources for safety and implementation research, including federal funding and public-private partnerships.	Patient safety lacks sufficient funding, relative to its impact on patients.	HHS (NIH, AHRQ) Congress Foundations/Other Funders Safety Organizations
4.3	Expand health care safety scholar programs to train researchers with safety science expertise and to train operational and implementation leaders.	A highly trained workforce is needed to conduct research in patient safety and lead operational improvement efforts.	HHS (AHRQ) Foundations/Other Funders
4.4	Encourage organizations that have successfully implemented safety innovations to establish learning labs and collaboratives to spread them to other organizations.	Spreading and sustaining innovations is critical to meaningful improvement in patient safety.	Foundations/Other Funders Health Care Organizations HHS Public-Private Partnerships Safety Organizations

Recommendation 5: Address safety across the entire care continuum

Tactics		Rationale	Audience
5.1	Increase funding for research to understand the epidemiology of patient safety in settings across the care continuum (e.g., primary care, specialty practices, ambulatory surgical centers, dialysis centers, nursing homes).	Little is known about the epidemiology of patient safety in settings outside of hospitals and about potential strategies for improvement, even though most care is delivered in these settings.	Congress Foundations/Other Funders HHS (AHRQ, NIH)
5.2	Expand infrastructure across the care continuum (e.g., safety expertise, reporting mechanisms, collaboratives) to identify and implement best practices for safety improvement.	Many settings across the care continuum lack the infrastructure for improvement.	Ambulatory Practices and Settings Health Care Organizations Leadership

Recommendation 6: Support the health care workforce

Tactics		Rationale	Audience
6.1	Organizations must adopt modern quality improvement tools and methods and train all professionals in safety culture and implementation science throughout their career trajectory.	Providing the knowledge and skills to improve safety may improve job satisfaction, engagement, resilience, and patient safety.	Accreditors Educators Health Care Organizations Health Care Workforce Health Professional Licensing Bodies Professional Associations Safety Organizations
6.2	Expand or develop resources that support the workforce, including initiatives to improve working conditions and establish an environment of respect; programs to support staff and improve resiliency; fatigue management systems; and communications, apology, and resolution programs.	Workforce safety is a precondition to patient safety; however, physical and psychological harm and burnout are highly prevalent in health care.	Boards/Governing Bodies Educators Health Care Workforce Leadership Professional Associations
6.3	Involve the workforce in identifying domains for measurement and creating workforce safety and wellness dashboards to be reviewed by leadership and boards.	Standardized measures of physical and psychological safety are not available for senior leaders to review.	Boards/Governing Bodies Health Care Workforce HHS (AHRQ) Leadership NQF

Recommendation 7: Partner with patients and families for the safest care

Tactics		Rationale	Audience
7.1	Provide communication training for all health care workers that includes concepts of shared decision making, cultural sensitivity, language literacy, effective listening, and respect in personal interactions.	Patient engagement is critical for patient safety, yet the training and tools for patients, families, and health care workforce are limited.	Educators Health Care Organizations Health Care Workforce Patients/Families
7.2	Ensure that patients and families have timely access to tools, resources, test results, and their full medical records.		Health Care Organizations Health Care Workforce Patients/Families
7.3	Ensure that committees and governing bodies include members of the local patient and family community (representative of the patient population), and these members are meaningfully involved in care design and safety and quality initiatives.	Patient engagement must occur at all levels of the health care system.	Health Care Organizations Health Care Workforce HHS ONC Patients/Families
7.4	Actively engage patients in care (e.g., shared decision making, playing an active role in bedside rounding, removing limits on family visiting hours, and making available patient-activated rapid response teams) and in root cause analyses.		Health Care Organizations Health Care Workforce Patients/Families
7.5	Develop meaningful measures of patient engagement, patient-reported outcomes related to safety, and develop systems for capturing patient reports of safety incidents.	Patient engagement is a key priority, and we cannot improve what we do not measure.	HHS (AHRQ) NQF Patients/Families

Recommendation 8: Ensure that technology is safe and optimized to improve patient safety

Tactics		Rationale	Audience
8.1	Establish mechanisms for vendors and users to be transparent about health IT safety hazards and best practices.	Transparency about safety issues is the key to improvement.	Health Care Organizations ONC Public/Private Partnerships Safety Organizations Vendors
8.2	Identify and measure the adverse effects and unintended consequences of health IT and implement best practices for risk mitigation.	Health IT has the potential to improve patient safety, but to date poor design and implementation limit that potential.	Health Care Organizations HHS (AHRQ, FDA) NQF ONC Public/Private Partnerships Vendors
8.3	Establish expectations for health IT safety performance, such as routine testing for unsafe orders.	Much work remains to optimize existing systems.	Accreditors Health Care Organizations Researchers Vendors
8.4	Design health IT to facilitate communication and coordination with the patient and family.	Health IT can facilitate patient engagement.	Health Care Organizations Patients/Families Vendors

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