

Patient Safety in the Commonwealth of Massachusetts

Current Status and Opportunities for Improvement

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Acknowledgments

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Abbreviations

| | |
|-----------|-----------------------------------------------------------------------------------------------|
| ACO | accountable care organization |
| CAUTI | catheter-associated urinary tract infection |
| CDS | clinical decision support |
| CLABSI | central line-associated bloodstream infection |
| CMS | Centers for Medicare and Medicaid Services |
| CPOE | computerized provider order entry |
| DPH | Department of Public Health |
| DVT | deep vein thrombosis |
| EMR | electronic medical record |
| FMEA | failure mode and effects analysis |
| HAI | health care–associated infection |
| Health IT | health information technology |
| IHI | Institute for Healthcare Improvement |
| IOM | Institute of Medicine |
| MOLST | Massachusetts Medical Orders for Life-Sustaining Treatment |
| PROMISES | Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and Satisfaction |
| RCA | root cause analysis |
| SRE | serious reportable event |
| SSI | surgical site infection |
| STAAR | STate Action on Avoidable Rehospitalizations |
| VAP | ventilator-associated pneumonia |

Introduction

Twenty years ago, Betsy Lehman, an award-winning health columnist for the *Boston Globe*, received a massive overdose of chemotherapy at the Dana-Farber Cancer Institute, one of the nation's most prestigious cancer hospitals. Tragically, the error that led to her untimely death went unnoticed until several months later, when it was discovered at the time of a review of clinical trial data (Altman, 1995). Otherwise, it might never have come to light. At about the same time, a group of investigators at Harvard Medical School documented that errors like the one that took Betsy Lehman's life were far from unique in Massachusetts and other states (Brennan et al., 2004). Preventable adverse events were occurring every day. More often than not, the adverse events and errors that caused them went undocumented or unnoticed. Hospital leaders and clinicians seemed unaware of the scope of the problem and unsure that it could be remedied. Many dismissed adverse events as inherent to the complexity of modern health care.

The discovery of these avoidable errors and adverse events was a wake-up call. During the 1990s, health care leaders and researchers began studying and documenting the scale of the safety problem in health care. They gathered insights from other industries about methods that could make health care safer. The Institute of Medicine (IOM) convened a panel to examine the problem. Building on this research, the IOM 1999 report, *To Err Is Human*, estimated that up to 98,000 deaths occur annually in hospitals as a result of medical error. Many experts have concluded that the actual numbers are much higher than this (OIG, 2010). Nevertheless, for the first time, the public learned that adverse events related to medical error were among the leading preventable causes of death and disability in the United States and a major contributor to health care spending (Wachter, 2004).

In memory of Betsy Lehman, the Betsy Lehman Center for Patient Safety and Medical Error Reduction was launched in 2004 with a mandate to improve patient safety in the Commonwealth. During the past 20 years, Massachusetts has served as an intellectual incubator and catalyst for several patient safety initiatives. Research led by Massachusetts scientists has defined dimensions of risk, developed innovative approaches and tools, and tested their efficacy. Massachusetts has been home to 117 patient safety research projects (including 104 federally funded projects), accounting for more than \$41 million in federal spending on patient safety research.

Researchers have discovered that patients in Massachusetts experience adverse events in all health care settings. As many as one in four Massachusetts *hospital patients* report experiencing an adverse event, one third of which are thought to be preventable (Forster et al., 2003; Weingart et al., 2005; Fowler et al., 2008; Weissman et al., 2008). One in five patients receiving *intensive care* experienced an adverse event with 45 percent of those considered preventable (Rothschild

et al., 2005). Among more than 500 patients in an *emergency department* in 2004, 8.6 percent experienced a preventable medical error (Epstein et al., 2012). There were 6.5 adverse drug events and 5.5 potential adverse drug events per 100 non-obstetrical hospital admissions. One in four of these adverse drug events were judged to be preventable (Bates et al., 1995). In the *ambulatory setting*, 25 percent of patients reported an adverse drug event and 11 percent of these events were considered preventable (Gandhi et al., 2003).

In the past 20 years, Massachusetts has relied upon two adverse event reporting systems to collect retrospective information on serious incidents in health care. One system is administered by the Department of Public Health (DPH), the licensing authority for hospitals, and the other is administered by the Board of Registration in Medicine (“Board”), the licensing authority for physicians (Sheedy et al., 2014). While reports submitted to the Board are confidential, redacted versions of reports submitted to DPH are public records under Massachusetts law and subject to release in response to a specific request. DPH receives reports on the 29 “serious reportable events” (SREs) in health care defined by the National Quality Forum (NQF, 2011). The number of reported events has been relatively small (although it has increased in recent years). In 2013, 753 SREs were reported by acute care hospitals to DPH and 206 were reported by non-acute hospitals. The majority of reported events involved injuries after falls, pressure ulcers, and surgical mishaps (wrong-site surgeries or retained foreign objects after surgery). Neither system is considered exemplary in terms of public transparency. A comparison with other research findings suggests that the true rate of SREs is much higher, indicating widespread underreporting.

Massachusetts has been home to several high-profile efforts to study and document the safety of care and to intervene to make care safer, however urgent questions remain unanswered. 20 years after the death of Betsy Lehman, we still do not know precisely how safe health care is in Massachusetts. Researchers have developed measurement tools and tested several methods for producing safer care, but these are not yet routinely used in the delivery of care (Parry et al., 2012). Several new safety programs and policies have been introduced—not just in Massachusetts, but nationwide. Yet an appraisal on the tenth anniversary of the IOM report gives them barely passing grades (Wachter, 2010). Has progress been made in reducing the risks of injury and death? Which areas of risk have improved and which have not? Are organizations and their current efforts well positioned to reduce patient safety risks? How should the list of potential future initiatives be prioritized?

To begin to answer these questions, the Betsy Lehman Center for Patient Safety and Medical Error Reduction commissioned a RAND research team to conduct a set of interviews with more than 40 expert observers (including patients and caregivers, leaders of health care delivery

organizations, academic experts, advocates, and payers and purchasers) about progress to date and opportunities to produce safer patient care in the future.

Methods Used to Develop This Report

RAND conducted a set of interviews with expert observers having relevant expertise in health care safety. Appendix B contains details of our approach to data collection and analysis. Before conducting the interviews, RAND reviewed published literature, websites, newspaper articles, and other documents relevant to patient safety in Massachusetts. The purpose was to identify quantitative estimates about the safety of care; review the status of Massachusetts' adverse event reporting systems; and identify potential expert observers for interview. Individuals approached for interview included representative patients and caregivers, academic experts, leaders of health care delivery organizations, independent safety and quality advocacy organizations, and payers and purchasers. RAND researchers conducted confidential interviews with 41 individuals at 35 organizations. The interviews were based on a semi-structured interview guide drafted and refined by RAND researchers with input from Lehman Center staff. The interview guide was designed to ask fairly open-ended questions and allow the participants, as much as possible, to focus on those topics and issues that they found most important. The interviews were transcribed and anonymized for a thematic analysis using Dedoose, a secure online software platform for coding and analyzing large volumes of qualitative data. This report offers a summary of the key themes that emerged from that analysis. Appendix A contains an expanded description of the thematic results with illustrative quotations.

What Kinds of Patient Safety Risks Did Expert Observers Identify?

We asked expert observers to reflect on the changing profile of patient safety risks over time. We asked them about the safety risks known 20 years ago that have been addressed and in some cases reduced over time, persistent risks that have been identified and addressed, but are still important concerns, and newly apparent risks that have become more visible in recent years as patient safety research and practice have advanced.

In general, the Massachusetts expert observers responding to a general question about safety risks spoke about *patient-specific safety risks* (errors and adverse events in the care of individual patients) and also *systemic risks* that increase the probability of an error or adverse event. The systemic risks described by observers are often identified as *contributing factors* in the chain of causation that leads to a medical error or an adverse event. Expert observers recognize that modifying these systemic risks can prevent patient-specific errors and adverse events.

Examples of *patient-specific safety risks* include medication-prescribing errors, health care-associated infections, and treatment-related mishaps. They include errors and near misses, whether or not they progress to the point of causing an adverse health outcome.

The systemic risks occur at two levels, the level of the individual organizations that deliver care and the policy level. *Organizational characteristics and capabilities* include staff awareness, culture, leadership, and team functioning and also tangible capabilities such as the use of standardized protocols to identify and mitigate risks (such as functioning adverse event reporting systems), or the availability of electronic medical records (EMRs) with safety features such as computerized order entry. *Policy influences* create the context in which organizations and individuals may be at greater or lesser risk of patient safety problems. These include accreditation and regulatory monitoring, public awareness of the safety of health care, payment policy, and public reporting. The policy influences affect how organizations and professionals carry out their work and how they respond to patient safety risks. For example, duty hour limits imposed through regulation are intended to ensure that clinicians are awake and alert in order to prevent errors, but this policy may have other effects as well.

Based on this logic, we organized the risks expert observers described to us into three categories: (1) *patient-specific safety risks*; (2) risks associated with *organizational capabilities*; and (3) risks associated with *policy influences*. While the latter two categories of risk may not be obvious at the time an individual patient experiences an error or an adverse event, changing these organizational and policy factors may provide significant leverage in making care safer.

Universally, the expert observers made two general points. First, *awareness of patient safety among providers is higher than at any time in the past*. 20 years ago, one of the pressing patient safety problems was lack of awareness among providers. Few understood the magnitude of errors and adverse events or the opportunities to prevent them. Several expert observers recalled that most health care administrators and clinicians believed that adverse events and errors were isolated incidents or inevitable—part of the “cost of doing business” or a necessary risk to receive the benefits of the modern hospital. This change of awareness was considered to be an important step forward.

Their second point was that *nearly all of the advances in patient safety have taken place in hospitals*. Given the expense and risk associated with hospitalization, technology, and the significant management infrastructure in most hospitals, this was a natural place to begin. But 20 years later, the hospital is no longer the only or even the primary place that patients receive complex, acute care. Diagnostic procedures, chemotherapy, surgery, and complex medication regimens that once were delivered in the hospital are now delivered in outpatient clinics or at home. This shift has profound implications for future efforts to deliver safer care.

Patient-Specific Safety Risks

Expert observers highlighted several types of risks that occur during interactions between clinicians and patients (sometimes called the “sharp end of care”), mentioning both adverse events and categories of error. In general, most expert observers held the view that progress had been made but that it had been slower than expected in most areas. None of the patient safety risks had been eliminated entirely and in most organizations they remain important targets for improvement work. One expert observer said,

The big three things are falls, infections, and med errors. Those are the three horses of the apocalypse, and they have always been. That’s where most of the morbidity comes from.

Health care–associated infections. Health care–associated infections (HAIs) are a widely recognized threat. Many expert observers believe that HAIs in hospitals have decreased in Massachusetts, although there are limited data to document this trend. The focus on reducing HAIs has been on hospitals and “most hospitals have come on board,” according to one expert observer. Initiatives that have disseminated best practices for HAI prevention and an approach for hospital reporting on HAI measures include the 2006 Statewide Infection Prevention and Control Program of the Department of Public Health (Betsy Lehman Center, 2008), and the Institute for Healthcare Improvement (IHI) quality improvement “bundles” (sets of evidence-based practices focused on a condition or procedure). These initiatives have targeted central line–associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), surgical site infections (SSIs) and catheter-associated urinary tract infections (CAUTI). In the view of expert observers, the risk of CLABSI had been reduced the most and CAUTI had seen the least progress. Despite progress, expert observers cautioned that HAIs are a serious, persistent challenge that warrants ongoing attention.

Medication error. In the wake of Betsy Lehman’s death, a substantial amount of effort has focused on medication error. Expert observers believe that health information technology (health IT), computerized provider order entry (CPOE), clinical decision support (CDS) for prescribing, barcoding, medication reconciliation protocols, and pharmacist screening for potential drug-drug interactions and drug allergies have made a difference in the hospital and increasingly in the ambulatory setting. However, expert observers were quick to point out that medication error is a persistent and challenging problem, particularly in ambulatory and pediatric care settings, and among elderly patients with complex medication regimens. Medication reconciliation across settings during care transitions remains difficult. As one expert observer commented, “It’s a heterogeneous problem that’s sort of ‘trench warfare’—one drug and one system at a time.”

Surgical risks. As noted above, the frequency of surgical serious reportable events (wrong-site surgery and retained objects after surgery) continues to be unacceptably high. The Massachusetts expert observers believe there has been significant improvement in recent years, crediting the introduction of “checklists” used by the surgical team before, during, and after surgery. They believe also that the Joint Commission’s National Patient Safety Goals have contributed to safer surgery. However, some expert observers believe that a zero rate of surgical serious reportable events is achievable and that surgical safety must remain a high priority in the Commonwealth.

Patient falls. Falling is a frequent cause of morbidity and mortality (particularly among the elderly). Despite statewide initiatives such as the Massachusetts Falls Prevention Coalition and some amount of progress by inpatient, skilled nursing, and home health in implementing protocols for fall prevention, some expert observers remain pessimistic about the potential to reduce falls. They worry that factors leading to falls are outside the control of hospitals and doctors’ offices. Others point to innovations such as “comfort rounds,” in which providers check on patients regularly to minimize risk factors for falls, and the establishment of hospital-level fall committees as limited, but important steps.

Pressure ulcers. Some expert observers report that rates of pressure ulcers have gone down in hospitals while others view pressure ulcers as a persistent patient safety issue. One expert observer, reflecting on the network’s monthly review of serious reportable events remarked that falls and pressure ulcers were consistently at the “top of the list.” The collaboration among state agencies to disseminate pressure ulcer prevention practices in both long-term care facilities and hospitals has been fruitful in the eyes of one expert observer. Interventions to prevent and detect pressure ulcers may be helping, but hard data are not available.

Risks Related to Organizational Capabilities

When asked about patient safety risks, expert observers often identified ***organizational capabilities***. This category of risks includes staff awareness, culture, leadership and team functioning as well as standardized processes to identify and mitigate risks (functioning adverse event reporting systems or staff trained in root cause analysis), and the availability of EMRs with safety features such as computerized order entry. Risks associated with organizational capabilities are ***systemic*** in the sense that they may not be immediately apparent when an individual patient experiences a safety event, but may be identified as *contributing factors* in a root cause analysis.

Lack of a patient safety culture. According to several expert observers, the most profound change over the past 20 years is the growing recognition of the need to promote a “just culture” in which adverse events and errors are investigated openly without blame in order to understand the factors that contribute to errors. This process of learning can lead to the redesign of care

protocols, staff training, information technology changes, and other actions that will prevent future errors and adverse events. Ideally, this replaces the traditional “punitive culture” that views adverse events and errors as opportunities to blame, punish, or fire individuals for errors in care in hopes of motivating everyone to “be more careful.” In spite of the promotion of this new culture, expert observers were split on the extent to which this cultural shift had occurred and whether it would be durable. Some pointed to the legitimacy conferred by the development and use of measures of patient safety culture and the strides made within some organizations:

Some organizations have done a terrific job on this, where clinicians and care delivery members of the team feel comfortable speaking up about patient safety.

Others thought the shift might not be so widespread yet or sustainable even in organizations that have made progress:

I would say that effort to change the punitive environment has completely gone now. We are right back towards an incredibly vicious environment in which it's not just punitive, it's actually looking for a scapegoat.

Failure to provide patient-centered care and engage patients and caregivers in care. Expert observers viewed the movement toward patient-centered health care and patient engagement as seismic. Expert observers described many new opportunities to engage patients in ways that make care safer: the introduction of patient-family advisory committees at hospitals, tools that foster effective dialogue between patients and professionals, social media and mobile technologies, the increasing involvement of case managers and patient navigators, and new disclosure and apology approaches. The impact of these initiatives is not yet well studied, but the expert observers were cautiously optimistic:

I think [that in] 20 years we have really changed that understanding that as consumers of health care, as patients, we have a whole set of rights and obligations and responsibilities in our own health care and decisions . . . That's . . . a sea change.

I think we're still mostly talking about it and not necessarily doing it, but...at least it's on our radar.

Expert observers described barriers to progress such as a lack of time to redesign traditional office workflow, continuing pressure to see many patients quickly, and a concern that inclusion of communities marginalized by poverty, language barriers, and cultural differences will require resources that most health care organizations will choose not to spend.

Risks related to health information technology. Published studies of health IT have demonstrated its efficacy in reducing errors and communication failures (Bates et al., 1998; Bates et al., 1999; Hug et al., 2010; Poon et al., 2010). If health IT is well implemented, expert observers noted, it can reduce some patient safety risks dramatically. For example, clinicians can be alerted about risky prescribing at the point of order entry (reducing drug-drug interactions and dosing errors) or barcoding of medications can assure that the correct medication is administered. Since 1994, health IT implementation has become more widespread, although the level of health IT adoption is not yet ideal. Some care settings (such as long-term care) have low rates of IT adoption and limited interoperability, which means that patient data may not be available to emergency room physicians or primary care physicians in usable forms.

Even where health IT is implemented, expert observers referred to health IT as a “two-edged sword” highlighting several increasingly apparent challenges. For example, poor implementation of notes and reports may be leading to information overload. Clinicians are paging through so much data that they can miss critically important information, like abnormal laboratory test results in a way that can delay diagnosis or lead to poor treatment choices. Erroneous data (like incorrect weight entries) can cause inappropriate medication dosing. In the words of one clinician:

We get a lot of information electronically. There are times when it’s just plain demoralizing because you can’t meaningfully assimilate all that information. You’re sifting through to figure out, ‘do I care that the ear, nose, and throat doctor removed wax from his patient’s ear, or is this a very important ear, nose, and throat work up with action items for me . . .’

Some experts questioned the responsiveness of health IT vendors when health care providers identify patient safety problems that might be related to software design or health IT system implementation. They noted that solving such problems can require significant joint work by leaders, vendors, and users of health IT systems.

Risks related to non-standardized care. Adherence to standardized protocols is widely known to reduce risks in many high-risk industries. Standardization is important in front line practice, but also provides the basis for detection, measurement, analysis, and monitoring of adverse events and errors. In the past 20 years, the potential to use risk mitigation tools, human factors thinking and safety design principles to create safer health care has become much more widely known. However, observers note that Massachusetts institutions vary widely in assuring that those principles are “in the minds of both people in quality and safety, but also the people on the front lines.” Risk mitigation tools such as root cause analysis (RCA) and failure mode and effects

analysis (FMEA) have gradually been adopted in many hospitals, but not yet extended to other settings. (RCA is now required in hospitals, although its application may vary.) Hospitals are beginning efforts to enhance staff reporting of errors and adverse events, but their use is still uneven.

Even when standard protocols are in place, too many clinicians resist adherence, according to some expert observers. For example, adherence to hand hygiene, correct labeling of specimens, isolation precautions, checklists, and even annual influenza vaccination of staff are incomplete despite well-documented evidence of effectiveness. Expert observers notice variation in practice across units and between day, night, and weekend shifts. One expert observer pointed to a health system that had appointed a “diffusionist”—an expert clinician who is responsible for monitoring and ensuring the consistent use of safe practices throughout the hospitals and clinical practices of the health system.

Lack of leadership focus on patient safety. Several expert observers had a bleak view of the current leadership of health care organizations. They noted that safety was not an institutional priority and that insufficient attention is paid to safety culture, patient engagement, and health IT.

I think a vacuum in leadership—and vacuum is not too strong a word—is really a very major obstacle in making progress in safety. None of us has come up with very good ideas about what to do for that.

Patient safety culture cannot compete in an environment in which “finances rule,” said one expert observer—that is, when the CEO and board are rewarded primarily for financial rather than clinical outcomes. Some were concerned that patient safety has become a “silo” activity in some organizations, poorly coordinated with activities of other departments like information technology, quality improvement, and staff training and not considered a responsibility of every staff member. As one expert observer put it, “It’s an elegant silo, but it’s a silo. As so many other things move in, this silo is at risk of not being reinforced or emphasized.”

Limited workforce availability and capability. Expert observers highlighted three safety challenges related to workforce. First, workforce shortages (especially in the area of behavioral health) are leading some institutions to use “floaters” rather than full-time staff, especially within facilities that disproportionately rely on Medicaid. A second challenge is related to hiring skilled staff; although the patient population is becoming more acute and complex, financial pressures may be driving facilities to hire staff who lack the skills and experience to manage complex patients. A third challenge is spotty compliance with policies and procedures, which was viewed by some as a training problem. One expert observer said, “the single most compelling problem in

my view is the reluctance of doctors and hospitals to actually [do] some of the things that they're organized to do, or are committed to doing, or have policies to do.”

Policy Influences

The expert observers we interviewed identified three areas (payment policy, public reporting, and government oversight) that influence how organizations invest in detecting and addressing risks to patient safety.

Risks related to payment policy. Federal and state payment policy is viewed by expert observers as a key influence on hospitals. Traditionally, if patients acquired complications as a result of treatment, hospitals or surgeons could submit additional bills for the cost of treating these complications—a perverse financial incentive inconsistent with the notion of motivating hospitals to invest in system changes to prevent such complications. Reversing this incentive led to the idea of a “warranty” for care. For example, the policy of non-payment for the treatment of HAIs or other acquired complications represents a relatively small change in revenue for most organizations, but has been resisted by many health care leaders.

Expert observers view modification of financial incentives as well intentioned, but they saw little evidence to date that they are generating meaningful pressure on hospital leaders to invest in avoiding complications. Some speculated that hospitals would simply manipulate coding practices to avoid incurring the penalty. Some expert observers worried that these incentives for safer care were far outweighed by incentives tied to greater care volume or those tied to patient experience scores that—an expert observer asserted—lead to investment in marketing and amenities rather than safer clinical care. As payment policy evolves, there will be ongoing opportunity to try to design more effective incentives to promote safe care.

Lack of a coherent reporting program. Statewide performance reports on hospitals, surgical procedures, and doctor’s offices are publicly available in Massachusetts, but such reports have limited systematic information on patient safety (<http://healthcarecompassma.org>; <http://patientcarelink.org>). Expert observers had mixed views about the need for public reporting on safety:

[W]e want to be transparent but we also want people to feel comfortable talking about errors. And they can be at odds with each other.

On one hand, consumer advocates and public officials ask why the delivery system is not more publicly accountable for the safety of care it provides. DPH has operated a reporting system for serious reportable events for nearly two decades. While the redacted reports can be read by the public (and often by reporters from the media), the number of reports is small. Reporting by

facilities is uneven, with some reporting no events at all, so it would be difficult for the public to use the data to select a hospital or doctor. On the other hand, most health care organizations resist making such data available to the public because of fear of liability and threat to reputation. They sense that conscientious hospitals and doctors dedicated to detecting and analyzing safety issues will be unfairly tarred while those that fail to report face no such penalty. Public reporting may also drive a “blame and shame” response, undermining the internal reporting and analysis of serious reportable events by staff.

Risks related to poorly implemented regulatory oversight and accreditation programs. Some expert observers believe that the Joint Commission National Patient Safety Goals program has focused hospital leaders’ attention on patient safety and that unannounced visits and an emphasis on process have motivated hospitals. Some viewed DPH as having made progress on setting a less punitive tone and focusing more effort on providing services that support organizational improvement while still assuring accountability to the public. Notable examples were the participation of DPH in voluntary collaborative efforts like the Massachusetts Medical Orders for Life Sustaining Treatment (MOLST) initiative and the Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and Satisfaction (PROMISES) initiative. Expert observers tended to be in agreement that insufficient staffing and budget had made it difficult for DPH to pursue additional initiatives although some expressed the idea that DPH needed to stick to its accountability mission and allow the improvement work to be pursued by other organizations. The Board of Registration in Medicine uses licensure and disciplinary procedures when safety problems are reported to it but in the view of expert observers, it has used a limited set of tools to pursue the safety agenda and its initiatives have not been proactive. The overlapping safety reporting systems operated by DPH and by the Board were viewed by expert observers as relatively ineffective because their investigations tend to occur after the fact and the public is generally not aware of these reporting programs except when an exceptionally tragic adverse event is described in the media.

Frontiers in Patient Safety

The attention to patient safety over the past two decades has surfaced some ***newly apparent risks***—that is, patient safety risks that were not previously fully appreciated. These include patient safety risks that had not received much attention in any setting (such as diagnostic error) and risks that have been described in some settings (e.g., hospitals) but are now being recognized in other settings, such as ambulatory physician offices, skilled nursing facilities, or home care.

Risks related to poor coordination of care. Many expert observers considered lack of coordination of care to be among the most pressing patient safety risks. There has been considerable investment in improving care transitions between levels of care within hospitals, between institutions, and to and from outpatient and home care. However, as one expert observer

said, “We don’t have any clear understanding of what the harm is that goes on between the silos.” Some risks are intensified during transitions (e.g., medication errors, risks of falls), and—as one expert observer put it—clinicians in all settings need to take responsibility for transitions and “not just safety to the doorstep.” Lack of coordination between emergency departments and other settings (hospitals, primary care, specialists, home, long-term care, etc.) was seen as an area of excess risk, particularly during peak demand. For example, patients are frequently left in emergency room hallways while awaiting a hospital bed or experience long waits after being sent from physician offices to the emergency department. These transition problems are especially problematic for patients with behavioral health needs or limited language or cultural proficiency.

Coordination among providers seems unpredictable to patients and their caregivers with much of the responsibility for communication (i.e., keeping track of medication lists) delegated to people who are poorly equipped to manage such complexity. One expert observer noted that there are “pockets of excellence,” but that “it’s not a reliable process yet.”

Risks related to diagnostic error. Several expert observers identified diagnostic errors as a major, complex risk in both inpatient and ambulatory settings. One expert observer told us that diagnostic risks are “the next frontier.” This broad category includes several types of mishaps such as failure to follow up on abnormal laboratory test results, incorrect interpretation of an imaging test, or failure to order the tests that would identify colon cancer as the cause of a patient’s anemia and weight loss. Expert observers commonly suggested that diagnostic errors have been a pressing risk for years but that their scope and impact are only recently being described. According to one observer, diagnostic errors are responsible for more than two-thirds of malpractice claims and are associated with the largest malpractice claim payouts.

Expert observers pointed to multiple contributors to diagnostic errors. Incomplete data, “cognitive biases” in decision-making under time pressure, poor physician-patient communication, and stereotyping of patients were identified as important contributors to diagnostic error. One suggested opportunity to reduce the risk of diagnostic error included the use of “duplicate readers” to improve detection of abnormalities in imaging studies, but the area was viewed as ripe for further research and likely to gain increasing attention:

I would say diagnosis risk was there . . . 15 years ago, but because of ACOs [accountable care organizations] and accountable care, there’s been a lot more attention being paid to it.

Risks related to limited data on the safety of settings outside the hospital. Several expert observers emphasized the significant risks outside of the hospital, such as doctors’ offices, community health centers, outpatient surgical facilities, and long-term care facilities. As one

succinctly put it: “On the outpatient side it’s a whole different ball [game] and I think patient safety is really in its infancy.” The main concern outside of the hospital setting is that so little is known about the magnitude of the problem. Most expert observers emphasized that the current lack of knowledge about errors and adverse events outside the hospital is itself a major risk to patients.

In addition, sicker patients with more complex care needs and more acute illness are increasingly receiving care outside of hospitals—a trend that is likely to continue as cost containment efforts accelerate. The settings are diverse. Several stakeholders pointed to the risks specifically in assisted living, noting:

There’s a lot of concern about assisted living because many people prefer to live there, as opposed to living in a nursing home. So people who are much more frail and much more sick are currently living in assisted living with a lot less regulatory oversight and a lot less support. So things like falls and medication problems and infections are happening in assisted living as well.

As one expert observer put it, the safety risks outside of the hospital present a “huge challenge” because it took so many years to make progress in hospitals. Regulatory and oversight attention needs to be split between continuing vigilance about hospitals and this new focus on the safety of care outside the hospital, where safety management expertise may be in short supply.

Looking Ahead: Opportunities to Advance the Safety Agenda in Massachusetts

Our study was commissioned to obtain confidential and anonymous input from a cross-section of expert observers about potential opportunities for an organization like the Betsy Lehman Center for Patient Safety and Medical Error Reduction to pursue initiatives that can advance patient safety in Massachusetts. As the results suggest, expert observers identified several opportunities. Some identified areas that need more focus, such as nonhospital settings, while others suggested programmatic actions, such as convening expert observers or disseminating evidence-based information. A few expert observers sounded a cautionary note. The unmet needs in patient safety are substantial, but the “niche” for new initiatives may not be immediately apparent. Expert observers pointed to significant “change fatigue”—the difficulty of continually altering daily work patterns. Learning new protocols and habits takes significant concentration, focus, and energy with “staff burnout” as a significant potential problem. As health reform unfolds, providers are facing many new requirements from federal and state programs that could distract them from the patient safety agenda. Expert observers believe action on safety is needed but

hope for a careful and judicious approach to new initiatives with a focus on those that will truly reduce risk for patients.

Areas of Opportunity: Initiatives and Programmatic Roles

The most frequently mentioned areas of opportunity to improve safe care pertained to newly apparent risks. They included reducing diagnostic errors, extending work on safety of care in nonhospital settings, extending work to support safe care transitions, and engaging patients and caregivers in the safety of their care. Potential programmatic roles included convening expert observers, identifying priorities for statewide action, engaging leaders of health care organizations, disseminating evidence-based safety practices, supporting advocacy and activism, providing technical assistance, and supporting research.

Many of the suggested initiatives involved research and measurement. On diagnostic errors, expert observers were calling for better knowledge: “How many diagnostic errors are there of a certain type and then how could you intervene to either decrease their frequency or reduce the delays in diagnosis?” For nonhospital settings, expert observers suggested analysis and monitoring of setting-specific patient safety risks, particularly risks in ambulatory settings (physician office practices, ambulatory surgical centers, home health care) and skilled nursing facilities.

Expert observers recommended convening experts and providers to set priorities for patient safety work. Several expert observers suggested that a neutral convener was needed to “bring the different parties together”—a role that few organizations are able to perform. They pointed to a number of different methods that might be used, including conferences, newsletters, and an online forum where people can post their accomplishments. One purpose would be to identify patient safety priorities and develop an explicit patient safety agenda for the Commonwealth.

Establishing clearer standards and providing new tools to assist the care coordination challenge were also suggested areas for action. To improve care coordination, several expert observers noted the need for “leveraging the implementation of electronic health records and computerized prescribing and to ensure that people are using that well.”

Other suggestions from one or more expert observers included the following:

- Consider creating an organization that could disseminate evidence-based recommendations about patient safety that would serve as a repository and clearinghouse of best practices, facilitating communication about patient safety.

- Consider creating an extension center that could offer technical assistance on safety improvement: “What we need desperately is more expertise in industrial engineering and ways to bring in those kinds of skills to solve some of the problems we have.”
- Consider focusing on patient engagement:
Patients can partner . . . in both developing and designing programs, but also . . . using patient portals in a more effective way, creating opportunities for patients, particularly with chronic disease, to take on more responsibility, to do safety reporting.
- Consider a statewide organization that pursues two types of advocacy: serving as an ombudsman to advocate for patients or caregivers (i.e., consumers) and serving as an activist organization, driving change at several levels, including the leadership and the policy level. In the words of one observer, “It needs to be gutsy. It needs to have an in-your-face urgency . . .”
- Consider approaches that can better engage senior leaders of health care organizations in a statewide safety agenda in order to promote culture change within health care organizations. They also saw the need for an effort to keep patient safety on the active agenda of health care CEOs and governing boards across the Commonwealth.
- Pursue research and demonstration projects, rather than—or in addition to—disseminating findings. One expert observer said that “research that would help advance the ball in the state . . . [could] help leverage new opportunities or prevent things that we don’t know so much how to prevent.” Another proposed that an organization was needed to support demonstration projects that once shown to be successful could be taken up by other organizations.

Conclusion: Questions About the Commonwealth’s Future Patient Safety Efforts

In the 20 years since Betsy Lehman’s tragic death from a medical error, Massachusetts has been an intellectual incubator for new knowledge about patient safety, important demonstration projects, and new tools that can mitigate safety risks (Forster et al., 2003; Weissman et al., 2008; Bates et al., 1998). These tools have been taken up in federal legislation and in several organizations. It is less clear whether progress has been made in making care safer for the citizens of the Commonwealth. The challenge of documenting progress on patient safety is not unique to Massachusetts. Several observers have suggested that evidence that care is getting safer care is scant or absent (Landrigan et al., 2010; Wachter et al., 2012). The expert observers

we interviewed asserted that some progress has been made, but that it has mostly set the stage for the vital work that remains. Standardization of care, improvements in communication across settings, reducing diagnostic error and transferring the lessons learned in the hospital to other care settings are just a few of the areas for progress.

The path to safer care is daunting. It involves changing nearly every aspect of health care delivery. No aspect of the delivery system can be ignored and all clinicians and staff must be involved. It is convoluted and technically difficult. Culture is slow to change. Without strong leadership and dedicated, well-organized, collective effort, safer care will be difficult to achieve.

We conclude by suggesting several questions that could guide statewide efforts:

- 1) How should actions that can make care safer be prioritized and coordinated among participating organizations and professionals?

Our expert observers have seen more progress in areas where actions were focused on high-leverage modifications (reducing medication error, reducing the risk of HAIs). A set of shared priorities could enable the development of state-level resources that would support most organizations in Massachusetts. Once the priority areas are identified and agreed upon, the actions of clinicians, patients and caregivers, and leaders of organizations can be selected to tackle safer care.

- 2) How should measurement and reporting be used?

The use of data collection and reporting in safety is complicated because of the reputational impact, legal liability climate, and shame associated with errors and adverse events. Transparency is desirable but difficult. What data should be mandatory? What data should be made public for use by patients and payers and what data should be protected to encourage clinicians and others to report on adverse events, errors, and near misses? What role can patient safety organizations play in measurement and reporting?

- 3) How can alignment be achieved between federal requirements, accreditation standards, state regulations, and organizational policies?

Organizational leaders have finite bandwidth to respond to a large number of mandated activities. When those are misaligned, even high priority actions that can improve safety may have to be sidelined. Alignment is critically important, but no single organization is positioned to create such alignment. Could a convening organization take on the

alignment challenge on behalf of the state's delivery organizations and professionals through an honest broker's role?

4) How should patients, caregivers, and the public be engaged in patient safety?

Several organizations advocate for patients, caregivers, and the public perspective. Politicians, government agencies, institutional boards, advocacy organizations, experts, and the media often have a role in representing the perspectives of citizens of the Commonwealth. Organizing the representation of public perspectives could play an important role in assuring that the safety agenda is sustained rather than driven in fits and starts by a tragic death, an infectious outbreak, or a highly visible lapse in care that is reported by the media.

The expert observers we interviewed spoke passionately about the potential for Massachusetts to leverage its intellectual capital, organizational excellence, and political will to demonstrate that health care can be made safer. Such a demonstration would set a course for action on patient safety, building out from the areas of progress to date. The Commonwealth's voyage would not just save lives, but enhance the health and lives of patients and their caregivers in Massachusetts and also nationwide.

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Appendix A: Qualitative Interview Results

Through semi-structured interviews with a selected sample of expert observers, we aimed to elicit perspectives on the past, present, and future of patient safety in Massachusetts. Specifically, we asked expert observers about the most pressing current risks, the effectiveness of ongoing efforts to reduce these risks, areas in which patient safety has improved demonstrably over the past two decades, opportunities to improve patient safety moving forward, and the extent to which information about medical errors and adverse events should be made public. The interview included open-ended questions to enable exploration of topics that were raised by expert observers but that had not yet been identified as relevant by the research team. This appendix contains a detailed description of the themes that emerged from RAND's analysis of the interviews, including many illustrative quotes from expert observers.

What Kinds of Patient Safety Risks Did Expert Observers Identify?

We asked expert observers to reflect on the changing profile of patient safety risks over time. We asked them about the safety risks known 20 years ago that have been addressed and in some cases reduced over time, persistent risks that have been identified and addressed, but are still important concerns, and newly apparent risks that have become more visible in recent years as patient safety research and practice have advanced.

In general, the Massachusetts expert observers responding to a general question about safety risks spoke about *patient-specific safety risks* (errors and adverse events in the care of individual patients) and also *systemic risks* that increase the probability of an error or adverse event. The systemic risks described by observers are often identified as *contributing factors* in the chain of causation that leads to a medical error or an adverse event. Expert observers recognize that modifying these systemic risks can prevent patient-specific errors and adverse events.

Examples of *patient-specific safety risks* include medication-prescribing errors, health care associated infections, and treatment-related mishaps. They include errors and near misses, whether or not they progress to the point of causing an adverse health outcome.

The systemic risks occur at two levels, the level of the individual organizations that deliver care and the policy level. *Organizational characteristics and capabilities* include staff awareness, culture, leadership, and team functioning and also tangible capabilities such as the use of standardized protocols to identify and mitigate risks (such as functioning adverse event reporting systems), or the availability of EMRs with safety features such as computerized order entry.

Policy influences create the context in which organizations and individuals may be at greater or lesser risk of patient safety problems. These include accreditation and regulatory monitoring, public awareness of the safety of health care, payment policy, and public reporting. The policy influences affect how organizations and professionals carry out their work and how they respond to patient safety risks. For example, duty hour limits imposed through regulation are intended to insure that clinicians are awake and alert in order to prevent errors, but this policy may have other effects as well.

Based on this logic, we organized what the expert observers described to us into three categories: (1) *patient-specific safety risks*; (2) risks associated with *organizational capabilities*; and (3) risks associated with *policy influences*. While the latter two categories of risk may not be obvious at the time an individual patient experiences an error or an adverse event, changing these organizational and policy factors may provide significant leverage in making care safer.

1. The Past Twenty Years: Beginning the Journey

The expert observers we interviewed shared several insights about the origins of patient safety activity in Massachusetts. Over the past 20 years, two events had a galvanizing effect: Betsy Lehman's death due to a chemotherapy dosing error 20 years ago and the publication of the IOM Report *To Err is Human* 15 years ago. The Commonwealth has been home to several research projects and safety initiatives since then. Expert observers confirmed that during the past 20 years, Massachusetts has served as an intellectual incubator for patient safety. Research led by Massachusetts scientists has defined dimensions of risk, developed innovative approaches and tools (especially for use in hospitals), and tested their efficacy.

Most expert observers expressed the belief that progress had been made in reducing some patient-specific safety risks, especially health care–associated infections, medication errors, and surgical risks. However, nearly all expert observers emphasized that on every risk mentioned, significant room for improvement remains, and many expert observers actually identified these patient-specific risks as pressing *current* risks. Furthermore, several expert observers noted that systematic monitoring and tracking of the type and prevalence of medical errors and adverse events has not been established, leaving considerable uncertainty about whether the safety of patient care is improving.

Lack of awareness. 20 years ago, lack of awareness was one of the most pressing patient safety problems. Few providers understood the magnitude of errors and adverse events or the opportunities to prevent them. The public was not aware of how dangerous health care facilities can be for patients. Events like Betsy Lehman's death and the publication of *To Err Is Human*

raised awareness about the frequency of medical errors and adverse events in hospitals. One expert observer described it this way:

Let me say that there's no question in my mind that the cat is out of the bag. People do now know that hospitals are not necessarily safe havens. People do now know that if you can avoid going, that's a good thing. People do now know that you can get an infection in a hospital that you didn't walk in with. Doctors do now know that somebody's watching.

In addition to an increased recognition that health care can pose safety risks to patients, expert observers pointed to a new awareness among the public and providers about specific risks and especially the risk of health care–associated infection. Expert observers noted that even health care providers used to believe that health care–associated infections were inevitable:

The notion [used to be] that [health care–associated infections] were a cost of doing business, that you couldn't avoid central line infections because the minute you put something through somebody's skin . . . and into their vascular system, you're going to get infections. Well, it turns out you take an audacious goal of reducing it and, in fact, you can. . . . It's important to say "keep pushing. There is not necessarily an intrinsic limit there."

Another expert observer pointed to improvements in knowledge of the prevalence of specific types of medical errors and adverse events, as well as research on how to tackle these problems:

We know much more than we did [20 years ago] about the frequency and level of harm associated with adverse drug events, in particular. We also know about some types of hospital-acquired infections, a lot more about surgical errors . . . We've had a pretty good sense for some time about falls and pressure ulcers and to a reasonable extent about DVTs [deep vein thrombosis], too. . . . what we know about prevention is actually pretty radically different.

Focus on the hospital setting: Several expert observers stated that most of the patient safety work in the past two decades has focused on the hospital setting, and that nearly all of the advances in patient safety have taken place in this setting. One expert observer described the key challenges in the ongoing effort to tackle risks in the hospital:

We've gotten a lot of the low-hanging fruit with the hospitals in terms of the problems that can easily be fixed. . . . But it seems to me that there's perplexity

about how to deal with the events that remain, which are more complicated in their causal nature.

2. Progress and Current Status

Patient-Specific Safety Risks

Expert observers highlighted several types of risks that occur during interactions between clinicians and patients (sometimes called the “sharp end of care,”) mentioning both adverse events and categories of error. In general, most expert observers held the view that progress had been made but that it had been slower than expected in most areas. None of the patient safety risks had been eliminated entirely and in most organizations they remain important targets for improvement work. One expert observer said:

The big three things are falls, infections, and med errors. Those are the three horses of the apocalypse, and they have always been. That’s where most of the morbidity comes from.

The discussion that follows addresses the past progress and current status of patient safety in each of the patient-specific risk areas most often mentioned by expert observers.

Health care–associated infections: HAIs are a widely recognized threat. Many expert observers believe that health care–associated infections have decreased in Massachusetts over the past two decades because of hospitals’ focus on this risk area:

The awareness of hospital-acquired complications and hospital-acquired infections has been enormous; most of the hospitals have come on board . . . to eliminating hospital-acquired infections.

Expert observers suggested that hospital-based efforts have been successful in reducing the rates of four of the most studied HAIs: CLABSI, VAP, SSIs, and CAUTI. Several expert observers identified CLABSI as the infection that has been reduced the most and CAUTI as the infection that has been reduced the least. Some expert observers were concerned that HAIs remain a persistent problem.

Expert observers identified a few tools and initiatives that have driven improvement on HAIs in Massachusetts. Multiple expert observers referenced “bundles,” which are sets of evidence-based practices focused on a condition or procedure. Several expert observers asserted that

Massachusetts hospitals have successfully employed bundles to reduce CLABSI, VAP, SSIs, and CAUTI.

Medication errors. Many expert observers indicated that considerable effort has been focused in Massachusetts on reducing medication errors. Some hypothesized that Betsy Lehman’s death was a key impetus to focusing on this issue. Expert observers often emphasized the role that health IT has played in reducing medication errors, particularly through CPOE and barcoding. Expert observers also pointed to medication reconciliation practices and pharmacist review as drivers of improvement. One expert observer asserted that his or her health care organization had employed several of these tools to tackle medication errors, with measurable success:

Medication safety has gotten significantly better. I think about [name of health care organization] where I was and we had order entry and then we added barcoding and other things and . . . I know it made a huge difference because we studied it.

While some expert observers had identified medication error as a risk that had been reduced over the past 20 years, many others emphasized that this remains a pressing risk. As one expert observer explained, “I think the problem with med errors is just it’s a heterogeneous problem and that it’s sort of ‘trench warfare,’ one drug and one system at a time.”

Expert observers also highlighted the challenge of poly-pharmacy, especially with older and medically complex patients. Coordination is a major challenge for patients who typically receive care from multiple providers in different settings:

Our clients . . . if they have less than 10 meds, it’s very unusual. Usual is more like 14, 18, 20 meds. And you wonder. . . is . . . everybody on the same page? The hospital is going to have their own perspective when somebody comes in for a stay and they may be changing meds and because hospital stays are so short, the patient is not even acclimated, potentially, to those meds . . . before they come home.

Medication dosage errors are of particular concern for high-risk medications taken at home. Care transition coaches and home care nurses frequently discover misunderstandings when they review medications in the patient’s home. Pediatricians and oncologists face unique medication-related risks related to weight-based dosing, which creates more opportunities for mistakes. Pharmacists often play a key role in the medication management process, but one expert observer noted that pharmacies can contribute to medication errors as well:

We're finding some pharmacies, like some national pharmacies, are doing automatic refill and calling patients and saying 'okay, your refill is ready,' but they've been prescribed a different dose and now they're getting that dose, too. So it can be really confusing to people.

Surgical risks. Many expert observers identified surgery as a major risk area—specifically wrong-site surgery and retained foreign bodies. Expert observers asserted that efforts to reduce the risk of surgical errors have been successful, especially through the use of checklists—short lists of items that the surgical team reviews and checks off before surgery. One expert observer explained:

I also think there have been a lot of improvements in the operating room based on surgical checklists that have been propagated by Atul Gawande and others. Wrong-site surgery or wrong-patient has decreased tremendously because of that.

They believe also that the Joint Commission's National Patient Safety Goals have contributed to safer surgery. However, some expert observers believe that a zero rate of surgical serious reportable events is achievable and that surgical safety must remain a high priority in the Commonwealth.

Patient falls. Several expert observers highlighted falls as a current safety risk, despite what some described as moderate progress in the inpatient, skilled nursing, and home health settings in implementing plans and protocols for fall prevention. One expert observer asserted that hospitals have a limited ability to predict patients at risk of falling:

It's hard to create a way of identifying patients that are at risk for a fall which doesn't either end up including everybody that's in the hospital or nobody that's in the hospital. There's not a good way of predicting 'these three patients are the ones on your floor that are the most likely to fall next.'

Other expert observers identified effective risk reduction efforts, such as “comfort rounds,” in which providers check on patients regularly to minimize risk factors for falls, and the establishment of hospital-level fall committees. A few expert observers pointed to statewide efforts, such as the Massachusetts Commission on Falls Prevention and the Massachusetts Falls Prevention Coalition, as evidence of progress.

A few expert observers noted that long-term care facilities have reduced the use of physical restraints. These restraints were intended to reduce falls, but evidence has

demonstrated that they are ineffective and actually increase risks to patients (Möhler, 2012).

Pressure ulcers. A few expert observers noted that hospitals and long-term care facilities have initiated efforts to reduce pressure ulcers. One expert observer attributed these efforts to the education of health care organizations on pressure ulcer prevention, as well as to “a real collaboration between the regulatory agencies in long-term care.” Even so, a few expert observers suggested that pressure ulcers are persistent safety risks in hospitals, long-term care facilities, and patient homes. One expert observer explained:

One of the activities that we do on a monthly basis is to review serious reportable events from the hospitals within our network. The two things that are consistently at the top of the list are falls and skin ulcers. So from an inpatient perspective, I would say those are two things that, even though hospitals are trying to address, they still occur with some frequency.

Risks Associated with Organizational Capabilities

Expert observers often pointed to ***organizational characteristics and capabilities*** as pressing patient safety risks. This category of risks includes staff awareness, culture, leadership, and team functioning. More tangible capabilities include standardized processes to identify and mitigate risks (functioning adverse event reporting systems or staff trained in root cause analysis), or the availability of EMRs with safety features such as computerized order entry. Risks associated with these capabilities are ***systemic*** in the sense that they may not be immediately apparent when an individual patient experiences a safety event, but may be identified as *contributing factors* in a root cause analysis.

Lack of a patient safety culture. Expert observers asserted that a profound shift in the past 20 years has been the growing recognition of the need to move away from a “punitive culture” to a “culture of safety” or “just culture” in which errors and adverse events are investigated openly without blame to understand the factors that contribute to errors. They noted that health care organizations are increasingly recognizing the contributing role of systems and are viewing medical errors and adverse events as opportunities for system improvement. An expert observer explained: “I think [safety] is being appreciated more as a system problem rather than just sort of a smart doctor or dumb doctor problem.” Expert observers were split on the extent to which this cultural shift had occurred and whether it would be durable. Some pointed to the legitimacy conferred by the development and use of measures of patient safety culture and the strides made within some organizations. One expert observer asserted:

I think there's a lot of work done on creating culture of safety within organizations. . . . some organizations have done a terrific job on this, where clinicians and care delivery members of the team feel comfortable speaking up about patient safety. . . . I don't think that we're 100 percent there but I think we're moving away from "blame and shame."

While a few expert observers pointed to a shift in patient safety culture as a major area of improvement over the past two decades, several emphasized that significant room for improvement remains. One asserted: "Are we where we need to be? Absolutely not; there's still plenty of issues with the destructive behavior, with people being afraid to speak up." Another expert observer indicated that the state of safety culture is even more dire:

For a little while at the beginning, there really was a push in the institutions to try to set up a culture in which they wouldn't be as punitive. . . . I would say that effort to change the punitive environment has completely gone now. We are right back towards an incredibly vicious environment in which it's not just punitive, it's actually looking for a scapegoat.

A few expert observers suggested that creating a culture of safety begins with the education and training of young clinicians.

I think there needs to be more education at the training level around the importance of the culture of safety and the importance of everyone being an active participant in making patient safety a priority. I think monies toward education [are] critical, so that the next generation of providers that we train understand the priority.

Failure to provide patient-centered care and engage patients and caregivers in care. Expert observers saw considerable improvement in patient-centered care and patient engagement over the past 20 years, perhaps because this topic was rarely discussed prior to the IOM reports. Expert observers who pointed to progress were quick to emphasize several opportunities to advance patient centeredness and patient engagement. With regard to patient-centeredness, one expert observer said:

You know, I think it's really nice that we are now at least talking about making the patient the center of the care plan and we have moved away from the paternalistic approach to medicine that still characterizes our work.

Another expert observer noted that failure to listen to the patient was part of Betsy Lehman's story. After the chemotherapy overdose, Ms. Lehman raised a concern that something was wrong, but her symptoms apparently did not prompt further investigation by the clinicians involved in her care (Altman, 1995).

Expert observers sense a growing awareness among patients and family members of their role in assuring that they receive safe care:

I don't think it was on people's horizons 20 years ago—the issues of patient safety and medical errors—as much as it is today . . . either [due to] tragedies or growing health care consumer awareness of one's rights to question doctors and our health care providers and to be much more self-advocates for our care and to ask questions. . . . I think [that in] 20 years we have really changed that understanding that as consumers of health care, as patients, we have a whole set of rights and obligations and responsibilities in our own health care and decisions . . . That's . . . a sea change.

Some expert observers characterized a persistent lack of patient engagement as a major safety risk. They pointed to the absence of a comprehensive approach to patient engagement and suggested that patient engagement should be a new priority area for patient safety. In speaking about the contributors to this lack of patient engagement, they identified the difficulty of promoting physician engagement with patients. One expert observer pointed to time constraints:

I think it's important for doctors to have [meaningful] relationships with their patients... If I have four minutes to see somebody or I'm supervising 20 other people, then I'm not going to get to know those patients supposedly under my care.

Another pointed to additional barriers:

. . . there's also, on the patient side, sometimes fear [that] if they ask a lot of questions are they going to be labeled as difficult. Lack of tools . . . are there appropriate tools that you can use to help explain things better and so on. . . . There's fear from the provider's side—if I round at the bedside, it's going to add all this time to my day and patients may not understand what we're talking about . . .

A few expert observers highlighted the lack of shared terminology between doctors and patients that can make communication difficult:

We don't get taught as a patient or a family member how to speak in doctor's terms, so when they want to do a handoff to a resident in the middle of the night, they use certain language. It's 'tribal language'; they should teach us the same language . . .

Expert observers emphasized the need to better engage patients in communities marginalized by poverty, language barriers, or cultural differences, and were concerned that their inclusion will require resources that most health care organizations will choose not to spend. One observer noted that patients and caregivers in these communities may be at greater risk of medical errors and adverse events.

Another expert observer noted that distinct patient populations—specifically younger patients and the elderly—rely on different media channels to obtain information. Particularly as meaningful use standards begin to promote the use of electronic communication with patients through secure email and web portals, younger patients may be more receptive because they are more tech savvy in their use of social media and mobile device applications. In contrast, vulnerable populations, such as the elderly, those with language barriers, and those marginalized by poverty, may not be in a position to benefit.

[U]nless they have someone helping them navigate . . . they can't do it or they're not adept at it. We're going to have a population of patients that we're not going to be able to engage and we don't meet them where they are. I do worry that as everybody moves to the electronic age, that population will be at risk because we haven't addressed them before. . . .

At least two expert observers attested to the value of recently instituted patient-family advisory councils, which provide input to hospitals on opportunities for improvement, including safety. Massachusetts hospitals are now required to have patient and family advisory councils. However, some expert observers suggested that these councils have not always had a meaningful impact on hospital practices.

A few expert observers noted an increase in some settings of disclosure and apology to patients and family members about errors and adverse events.

I think there is a growing awareness in the health care industry that things such as apologies and acknowledgement of mistakes [are] a good thing, [are] more acceptable. But I think it still feels as if it's nascent to me, you know, still in the early days.

Some expert observers pointed to the Massachusetts Alliance for Communication and Resolution following Medical Injury health care alliance as an important effort in implementing the Communication, Apology, and Resolution model throughout the state. Even so, disclosure and apology programs are relatively new and some expert observers are still trying to sort out how best to engage patients and caregivers:

. . . the very specific issue of how you partner with patients and families in the aftermath of serious adverse events, particularly root cause analysis, people are just absolutely continuing to struggle with that.

Risks related to health information technology. Many expert observers believed that EMRs and other forms of health IT, such as health information exchange, have great potential to reduce patient safety risks, and have already done so in areas such as bar coding of medications. However, expert observers also described the implementation of health IT as having a number of unintended consequences. One said:

I think the adoption of health IT can create super systems but I think we also need to be aware of some of the unintended consequences and [the need to] really do due diligence and . . . making sure, both from a workflow perspective and from a patient receiving perspective, that they're safe.

Some expert observers referred to health IT as a “two-edged sword,” with some health IT features that were designed to improve safety also introducing new patient safety risks. For example:

You can't order medication without a patient weight being recorded in the [EMR], which sounds like a nice safety feature. But in an emergency department, you may not know, the patient may not know, and somebody made a guess [about the patient's weight] just so that they could order some medications. And it turns out that they were off by quite a bit. That was the weight that was included, and the patient received a significant overdose of Heparin because they were off by quite a bit. . . . The evidence, in my opinion, that [EMR] has substantially improved patient safety is not as robust as people believe.

Expert observers expressed some frustration with the usability of health IT software products, which some attributed to an emphasis in the product designs on facilitating billing and coding instead of clinical purposes, such as organizing and prioritizing information in clinical notes.

These design and usability problems have the potential to create hazardous situations. One expert observer explained:

We get a lot of information electronically. There are times when it's just plain demoralizing because you can't meaningfully assimilate all that information. You're sifting through to figure out, 'do I care that the ear, nose, and throat doctor removed wax from his patient's ear, or is this a very important ear, nose, and throat work up with action items for me in it?' You're having to sift through really crushing amounts of data to find the pieces that are meaningful to you. . . . [Y]ou're going to make mistakes if you have too much coming at you. This is part of the increasing provider burden . . . if you read a note that was written in an EMR, almost any EMR, there is so much busy stuff on the page that is not the fundamental points that you need to know. You have to ignore them as you're trying to look for meaningful information. You will miss important things because there is so much garbage, really garbage, filled in electronically, automatically. I think that's a safety issue because I have missed things. I've seen other people miss things.

Clinicians are paging through so much data that they can miss critically important information like abnormal laboratory test results in a way that can delay diagnosis or lead to poor treatment choices. Expert observers suggested that poor usability can lead to risky workarounds such as using “free text” instead of “structured” fields. For example,

If I try to order insulin a certain way in a computer, and the computer is just too unfriendly or it's too difficult or too complicated or I can't find the kind of insulin I want, then I just do a lot of this in the free text ordering part. A number of studies have shown that's more of a risk for errors if you start doing things in free text in the comments field.

Expert observers also noted the major challenges with getting “point of care” information using current health IT platforms:

We can get [all kinds of sensitive] information . . . on our phones, but we cannot access . . . timely medical information without going to a desktop computer and going through [several] levels of log-in. And from a workflow standpoint, [that] is a barrier to care. . . . We have put time and logistical barriers in front of people getting the information they need. An example of that is I [have to] go through three password-protected log in screens to get into patient information as an attending [physician].

The other thing is . . . I have to go find a desktop . . . we're literally competing for desktop computers. . . . And so the first barrier is not using hand-held and lightweight tablets and smart phones as virtual workstations. Because when we are forced to go to landed desktops, there are just too many workers [physicians, nurses, residents, interns, pharmacists]. We're not pushed information. We have to go seek and . . . find information.

Expert observers recognized issues related to interoperability of health IT systems as the source of potential safety risks. For example, during mergers and acquisitions of health care organizations, merging entities are often unable to effectively harmonize their health IT systems. Interoperability issues are arguably even more problematic when different providers caring for the same patient need to exchange information and use completely separate health IT systems. Said one expert observer:

I think the biggest issue is the lack of integration of systems and the disparateness of the transfer of information. Having patients see providers at multiple different locations . . . and the lack of availability of the information because there's no way to access the information at the point of care. If you go from one place to another that's not part of a health care system, it's a significant risk. If everything is going to electronic, then we need to make sure that there's a mechanism—and money needs to be put into the mechanism—[for] information [to] be accessed at those critical points in time.

One expert observer pointed out that other states are substantially ahead of Massachusetts in terms of interoperability and information sharing among providers

Health IT has also created a new “actor” in the field of patient safety: health IT system vendors, who, according to our expert observers, are not always responsive to the issues that health care providers discover in the course of using their products. Some of these problems are endangering patients. An expert observer posed the following questions:

Can you get our vendors to listen to us when we say there's a problem with the software that's endangering the patients? They say 'we'll put it on the list and you can buy it in the next upgrade.' Why is that acceptable?

Expert observers noted that solving such problems can require significant joint work by leaders, vendors, and users of health IT systems.

While many expert observers pointed to the risks introduced by health IT, a few believe that the health IT products available today are “rudimentary” and that development and implementation of more-advanced technology has the potential to further reduce safety risks. One expert observer explained:

There was some nice work done in the earlier rollouts of CPOE to make it smarter than just electronic order entry. . . . Order sets in my observation have kind of stagnated. . . . There are some standard orders for pneumonia testing and a handful of high-frequency conditions, but why in 2014 are we not up to 30 and 50 of those instead of like three to five? And there’s no funding for it.

Risks related to non-standardized care. The introduction of standard procedures and protocols—including the use of tools such as RCA for identifying and mitigating safety risks—was viewed as an important step forward. One expert observer noted that human factors thinking and safety design principles have become much more widely known, whereas 15 years ago there was a “lack of any concept of a systems approach.” Now these are increasingly “in the minds of both people in quality and safety, but also the people on the front lines.”

Risk mitigation tools, such as RCA and FMEA, have gradually been adopted in many hospitals, but not yet extended to other settings. (RCA is now required in hospitals, although its application may vary.) Hospitals are beginning efforts to enhance staff reporting of errors and adverse events, but their use is still uneven. “Proactive assessments” were cited by one expert observer as an area of improvement; this observer suggested that hospitals are “trying to change from just reacting when bad things happen to trying to identify proactively where the risks are and changing processes.” Another expert observer suspected that health care organizations still have a long way to go in this area—that for the most part they are still “waiting until they’ve harmed someone, and then doing a root cause analysis.”

Detection strategies seem inadequate. As one expert observer said:

If I look at serious reportable events in my hospital, I know medication-related events must be significant from everything I read, but they’re not significant from what I see and the events that we’re reporting. I don’t think still that our error detection skills are strong, particularly in the area of medication safety.

Even when standard protocols are in place, non-adherence is a problem. For example, adherence to hand hygiene, correct labeling of specimens, isolation precautions, checklists, and even annual influenza vaccination of staff are incomplete despite well-documented evidence of effectiveness.

Within organizations, there is variability in the use of safety practices depending on the unit and the time of day:

The way we deliver care is different evenings, nights and weekends. . . . And I worry that we're really not getting 'below the covers' to understand what that means . . .

One expert observer pointed to the value of having a single person in an organization responsible for the diffusion of best practices across the organization:

[The] Mayo Clinic [has] created a new role called the 'diffusionist' and that role is about assuring spread [within the organization]. The [diffusionists] are kind of the agricultural extension agent, but they are predominantly nurses who are making sure that everybody is practicing to the best of the safe practices that they know. . . . [By contrast], we tolerate variation and I think that's a leadership challenge.

Lack of leadership focus on patient safety. Expert observers expressed that health care organization leadership is insufficiently engaged in reducing specific areas of risk—like safety culture, patient engagement, and health IT—as well as in establishing safety as an institutional priority. One expert observer explained:

We really have to figure out how to motivate the leaders of the hospitals to take responsibility for safety. That means they have to change their culture. They have to lead. They have to motivate their second rank, department chairmen, and so forth, into buying into getting serious about safety. And something as simple as effective methods for dealing with disruptive behavior. That's all known, we know how to do all that, but it's pretty discouraging to me that there's so many hospitals in our commonwealth that just aren't touching that issue. That's a leadership issue and it's a critical issue, a whole challenge of creating a culture of safety. Cultures are created from the top down. The top has to help envision and motivate people. . . . I think a vacuum in leadership—and vacuum is not too strong of a word—is really a very major obstacle in making progress in safety.

Another expert observer described the risks of leadership investment in a specific patient safety topic, rather than prioritizing patient safety generally:

Frankly, we need more leadership engagement and ongoing organizational recognition as a priority of patient safety and following up on that in operations,

as opposed to [focusing on] a specific topic. . . . It doesn't help to solve CLABSI if [. . .] your staff in their daily work don't recognize all of the other hazards and continually look for risks to patients and work on reducing those risks, and if your leadership hasn't made that a priority so that they're providing the resources and training and skills and supporting that across all of the organization's efforts. . . .

Some expert observers were concerned that patient safety has become a “silo” activity in some organizations—that it is poorly coordinated with activities of other departments like information technology, quality improvement, and staff training, and is not considered a responsibility of every staff member.

[I]n many organizations right now, safety's a silo. It's an elegant silo but it's a silo. And so as other things move in, this silo is at risk of not being reinforced or emphasized.

Other expert observers focused on competing objectives that interfere with health care organization leadership's prioritization of patient safety, noting, for instance, that patient safety cannot compete if financial outcomes are prioritized “above all else.” In the words of one expert observer:

[When] CEOs are rewarded for the financial outcomes of their institutions more than anything . . . that then is the culture and the environment.

Limited workforce availability and capability. Some expert observers were concerned about staff shortages and the impact they have on patient safety, especially in the area of behavioral health. One expert observer described causes of staff shortages in the area of behavioral health:

Medicaid is a disproportionate payer for behavioral health services in the Commonwealth of Massachusetts and nationally. And Medicaid rates are the lowest of any of the rates in the Commonwealth of Massachusetts and pay about 55-60 cents on the dollar for the cost of care. So hospitals . . . don't staff to their physical capacity. . . . So instead of having a cadre of trained staff who know how to work on that unit and know how to work with behavioral health patients, they sort of minimally staff the unit and then add staff based upon the acuity of patients and pulling from per diems and staffing agencies and the like. This is a significant issue around managing people.

Multiple expert observers suggested that the workforce may lack the skills necessary to care for patients who are older and have more complex conditions and are taking multiple medications prescribed by several providers and receiving care in different care settings:

We have a lot of primary care physicians who aren't skilled at managing older patients. So to use medication as an example of this theme: There's certain medication you shouldn't prescribe to older adults, the so-called Beers criteria . . . and the familiarity of our physicians in our network across the state remains less than it could be. . . . Primary care physicians are being asked to manage a lot of patients now with behavioral health problems who also have physical health comorbidities. They don't feel comfortable managing those behavioral health problems. . . . And we don't have access to the behavioral health specialists we need because of the way that they get paid—or don't get paid, depending on how you look at it—so there's, again, challenges and knowledge gaps. Even if the care is coordinated, if you're prescribing medications that put patients at higher risk, and they're not doing it in a thoughtful way, that's a potential problem from a safety perspective.

This expert observer also suggested that specialists have become too narrowly focused, which introduces risks:

They may be only focusing on their particular organ system, to the detriment of the patient on the whole. And this is how you end up seeing people who are on 10 or 15 medications prescribed by three or four different prescribers. And those medications may potentially be interacting or counteracting each other. Or maybe one was started to treat the side effects.

Expert observers also expressed a concern about provider and staff compliance with safety policies and procedures. Explained one expert observer:

A lot of the [patient safety] procedures that have been implemented have been widely accepted, but there remains the single most compelling problem in my view . . . the reluctance of doctors and hospitals to actually [do] some of the things that they're organized to do, or are committed to doing, or have policies to do—or to stop doing, as the case may be—but where compliance is spotty.”

This expert observer argued that poor compliance could be attributed to how medical schools train doctors:

Medical school training and post-medical school—internships and residencies—spend a lot of energy, effort—and teaching, if you will—of young physicians that they are responsible. The corollary of that is autonomy, and autonomy is a dearly held cultural value in the medical profession. . . . So I have some sympathy because you say to people, ‘You are responsible, you better make the right decision or you’re gonna be in trouble,’ and then say, ‘Oh, by the way, [so and so], who never went to medical school, is telling people that you’re not very good or that you’re not careful enough or that you don’t do things the right way.’ That’s tough to swallow. And I think the statements that hospitals and doctors make about their understanding these problems and their understanding the need to improve hides—probably even from themselves—how hard that cultural shift is to put into day-in-and-day-out practice.

Policy Influences

Expert observers pointed to several **policy influences** that can lead to the conditions within and between organizations that create safety risks for patients. These have to do with how organizations and professionals carry out their work and how they respond to patient safety risks.

Risks related to payment policy. Several expert observers discussed the safety risks that payment policies introduce. A few expert observers commented specifically on the impact that federal programs have had on both treatment and billing. Traditionally, if patients acquired complications as a result of treatment, hospitals or surgeons could submit additional bills for the cost of treating these complications—a perverse financial incentive inconsistent with the notion of motivating hospitals to invest in system changes to prevent such complications. Reversing this incentive led to the idea of a “warranty” for care. For example, the policy of non-payment for the treatment of HAIs or other acquired complications represents a relatively small change in revenue for most organizations, but has been resisted by many health care leaders. One expert observer explained that the policy “gives hospitals a very strong financial incentive to either prevent the complication or at least not code it.”

Another expert observer agreed that reimbursement policy around readmissions is leading to gaming of the system, rather than actual improvements in care:

Dinging people for readmissions, you know, it’s a good thing, a good idea because the idea is you don’t want people . . . sent home too quickly. . . . But there’s such a rush to get everybody in and out. . . . So now what the hospitals are doing is they’re creating entire units that are created as observation units, so a whole floor has now been called an observation floor. And what you do is you send that person to the floor and technically they’re just being observed. They’re

not actually technically admitted to the hospital. So in that way, they won't count towards your readmission. . . . I mean they spent inordinate amounts of time and money and energy figuring out how to end-run the system over reimbursement as opposed to go to the whole point of it which is 'we think maybe you're discharging people too quickly.'

Some expert observers argued that incentives tied to patient experience scores have led hospitals to care more about these scores than about quality and safety:

Because CMS [Centers for Medicare and Medicaid Services] reimburses based on patient satisfaction . . . patient satisfaction surveys have become key. The hospital spends millions of dollars on consultants from Disney and hotel industry to teach staff how to interact with the patients, not clinically, but using code words and asking the right questions based on a marketing perspective. . . . And so you're not getting an accurate reflection of what's happening with patients.

Another expert observer warned against underestimating the degree to which financial outcomes drive health care organization behavior:

[S]ome of the bad things that happen in hospitals make money for hospitals. . . . If you keep people from getting an infection or some other medical error that keeps them in the hospital for more days, you get more revenue. If you keep them out of the hospital altogether, you lose revenue. So, again, I don't think anybody deliberately does bad things so as to keep the hospital's revenue up, but it certainly is not part of the incentives to improve. It's a disincentive.

Lack of a coherent reporting program. Several expert observers told us that publicly available data on safety events in Massachusetts is lacking. One expert observer explained:

There has been a lack of transparent data that's easily consumer-understood around health risks and injuries that happen to patients while in hospital settings. Now that's improving in Massachusetts, but I think that is one of those gaps that the public has the right to know—what kind of errors have been in hospitals and what kind of patient injuries have been in hospitals. . . .

Some expert observers commented on the reluctance to make such patient safety data public, especially in behavioral health settings:

I think health care in general is reluctant to have that data made public. Either out of fear of liability—I don't know what the fear is. If I think on specifically, for example, on behavioral health seclusion and restraint information, incidents within a hospital involving behavioral health patients or harm to a patient, harm to staff is never made public. So if I think of it specifically around behavioral health and with the exception of seclusion and restraint, there's not even agreement on what should be reported to the Commonwealth of Massachusetts for behavioral health other than, you know, death.

Some expert observers expressed the concern that current federal and state reporting requirements drive organizations to conceptualize safety more narrowly than they should:

Sometimes I worry, even in the discussion of the hospital-acquired conditions or the metrics, does it have this unfortunate impact that it makes people think: 'Those are the things that are safety, and then all these other ways that patients get hurt. But since we're not reporting those to DPH, that's not patient safety.'

Risks related to poorly implemented regulatory oversight and accreditation programs. A few expert observers asserted that Joint Commission accreditation has helped to focus hospitals' attention on patient safety. The Joint Commission has employed multiple tactics for improving safety, including unannounced visits, an emphasis on process, and the development of the National Patient Safety Goals. An expert observer emphasized the importance of the latter:

[A] huge priority over the last ten to fifteen years has been compliance with the Joint Commission National Patient Safety Goals. Now I know there's other accreditors than the Joint Commission in the space, but the amount of work and effort that went towards the National Patient Safety Goals by hospitals in this country in the last ten years is huge. So I don't think you can leave that out in terms of a major driver of where the attention on safety has been.

Expert observers also discussed the role of regulatory oversight—particularly by the Massachusetts DPH—in reducing safety risks. A few expert observers asserted that DPH can be overly punitive; however, some felt that DPH has transitioned toward using “carrots” rather than “sticks.” One expert observer explained:

So I think [DPH] has been key in setting the tone of improving patient safety and moving away from a punitive culture and 'walking the walk' and 'talking the talk' over the last probably 5 or 10 years. So I think that they have been critically

important in terms of changing our language, changing our culture, and pointing us in the right direction.

A few complained that DPH acts reactively to events like the Framingham compounding pharmacy fungal meningitis outbreak (“the only time DPH gets involved is if something horrible happens”). Other expert observers, though, suggested that DPH is increasingly acting as a collaborative partner; they cite its support for efforts like the MOLST initiative and the PROMISES initiative.

Expert observers tended to be in agreement that insufficient staffing and budget had made it difficult for DPH to pursue additional initiatives although some expressed the idea that DPH needed to stick to its accountability mission and allow the improvement work to be pursued by other organizations. The Board of Registration in Medicine uses licensure and disciplinary procedures when safety problems are reported to it but in the view of expert observers, it has used a limited set of tools to pursue the safety agenda and its initiatives have not been proactive. The overlapping safety reporting systems operated by DPH and by the Board were viewed by expert observers as relatively ineffective because their investigations tend to occur after the fact and the public is generally not aware of these reporting programs except when an exceptionally tragic adverse event is described in the media.

Frontiers in Patient Safety

The attention to patient safety over the past two decades has surfaced some ***newly apparent risks***—that is, patient safety risks that were not previously fully appreciated. These include patient safety risks that had not received much attention in any setting (such as diagnostic error) and risks that have been described in some settings (e.g., hospitals), but are now being recognized more fully in other settings, such as ambulatory physician offices, skilled nursing facilities, or home care.

Risks related to poor coordination of care. Poor care coordination is widely understood to be a significant problem in the current health care system and it may contribute to substantial patient safety risk as well. In fact, many expert observers considered poor care transitions and the lack of coordination of care to be more pressing than any other current patient safety risk. Care transitions can occur when patients are moving from one level of care to another within the hospital (such as from the emergency department to the intensive care unit or other units) or at admission or discharge from the hospital (such as from hospital to home with home health support or readmission to the hospital from a long-term care facility). One expert observer asserted: “we don't have any clear understanding of what the harm is that goes on between the silos.”

A few expert observers described poor coordination of care as a risk that has been present for many years, but has been made worse by growing health care fragmentation:

I think that care is changing rapidly. I think coordination of care and the introduction of places providing more episodic care and patients seeing multiple different providers now creates new sets of patient safety risks that maybe weren't prominent ten years ago.

One expert observer noted that providers often are not aware of the information that is lost as multiple providers attempt to communicate with each other, especially using health IT:

I think probably the most pressing [risk] is the changing health care climate with respect to care being extended further out, beyond our institutional walls, and the lack of systems to support that coordination of care across the full continuum. I think we have discovered systems—particularly in the IT space—that are setting us up for potential problems with loss of critical information and at various points in transition and I don't think that—I'm afraid there's not enough attention to that. Because I think that things are falling through the cracks and I think we only know a small percentage of the times that happens.

Care transitions were perceived as especially risky for patients with chronic conditions who see different providers (typically a primary care physician and numerous specialists):

Each provider is focusing on their own little 'silo,' adding medications that they think are important. The communication [of that prescription] is not necessarily getting back to the other providers. . . . The same goes for diagnostic testing, where the tests will be done and perhaps even redundant tests, because the providers are unaware of the testing which has been already done. So the patients are in the middle of all of this.

Several expert observers noted that care coordination risks are often greatest during care transitions, and urged that providers accept responsibility for transitions, “not just safety to the doorstep.” An expert observer described how frightening the lack of coordination during transitions can be for patients:

There is no overarching continuity or methodology for continuity from doctor to doctor, from organization to organization. Even if you manage to get your paperwork from one doc to the other, it still doesn't mean that there's any continuity of care. So that's just totally scary. It just kind of seems very random

and there's an awful lot of waste, like it's that connecting-the-dot thing. I haven't seen the dots ever get connected.

Unfortunately, when providers do not coordinate care among themselves, the role of coordinator often falls to the patient and her family. An expert observer explained:

Patients assume that everything is flowing as it should and that information gets to where it needs to get to. They don't realize the danger that we don't have end-to-end systems in health care and that there is a risk of a loss of critical information that will impact their care delivery, if it's not received and consumed by the providers who have to care for them.

Several expert observers focused specifically on the risks associated with transitions between specific settings. Expert observers most often pointed to the transitions between the hospital and skilled nursing facility. One vividly described the risks of these transitions—in both directions:

You send somebody to the hospital from the nursing home; you might have a detailed and pretty extensive fall prevention plan in place in the nursing home. The person gets to the hospital and they [staff at the hospital] don't have that information. Or, they get the information, but they don't read the information. So all of those preventive strategies are not there and the person falls in the hospital and gets a fracture. Or the person in the hospital is put on medication that makes them dizzy or confused. They go back to the nursing home. The nursing home doesn't recognize that and they fall in the nursing home.

Other expert observers argued that the transition from skilled nursing facility to home is associated with even greater risks than the transition from hospital to skilled nursing facility:

The handoff from the hospital to the nursing home is generally good with medication reconciliations and care plans. The handoff from the nursing home to home is dangerous. They [nursing home staff] do not communicate with the primary care doctors. I cannot remember the last time I received a nursing home discharge summary. Especially if you're on Coumadin—good luck. That's when we've seen a number of readmissions because patients are discharged home and there's not a proper handoff. Terrible things happen, especially if they go home on the weekend.

Expert observers noted that transition to the home often carries risks because family members are inadequately prepared to be caregivers. One expert observer noted that health care organizations

do not always evaluate what a patient's home situation is like, including whether there are family members or others who are prepared to take care of the patient after discharge. This expert observer explained a colleague's experience:

His uncle had a brain aneurysm repaired and was still quite dependent on the care that he was receiving in the hospital. . . . [My colleague] asked the staff about what kind of support he was going to have at home. They were assuming that his wife was going to take care of him, but his wife has been in a wheelchair for most of her adult life and he is her caretaker. So the staff really didn't understand that he wasn't going to have any access to someone necessarily to get him out of bed, to ensure that he was fed, and it's that kind of a deficit in understanding the situation that the patient is going to or coming from. And in some cases . . . we have got pockets of excellence where that wouldn't happen—where the care team would do an in-depth interview; perhaps a social worker, a home health person would perhaps even assess the home before the patient is discharged, but it's not a reliable process yet.

Two expert observers were particularly concerned about the emergency department, in particular the ability of emergency departments to assess, triage, stabilize, and transport to the next level of care within the hospital. As one expert observer put it:

The major threats to patient safety are the effects of crowding, which is when the emergency departments are overloaded and caring for people who are admitted to the hospital but boarded for an extended period of time. . . . I think that the major issue is that the hospital is not designed to efficiently move patients from the emergency department through areas. Sometimes it may be a resource access issue (like [a lack of] intensive care unit docs). . . . But I think that the largest concern is that you are caring for more people for a longer time at the same time the floodgates are still open. And so I think that can be, and it has been measured and absolutely is, a direct risk to safety.

Another expert observer expressed concern about the ability of emergency departments to manage patients with behavioral health conditions:

There are a number of individuals with behavioral health conditions who are sort of spending a lot of time in emergency rooms. . . . We know that we have a crisis in terms of patients with behavioral health conditions not being triaged as well as possible to the next level of care that they need. So they're stuck in emergency rooms or they're discharged from emergency rooms and the lack of services to

them and to me that's a real patient safety issue...[Emergency rooms are] not meant to be a treatment center, per se. And for behavioral health patients regardless of age, it's often become [that] patients are there for hours, if not days, waiting for a disposition.

Despite all of these risk associated with care transitions, several expert observers were hopeful that recent care-delivery innovations, such as the patient-centered medical home, would be able to improve care coordination:

I can give you a perfect example of how [the medical home] works well in my personal life because my primary care doctor is National Committee on Quality Assurance certified—NCQA certified—as a medical home practitioner and has been for years. When I need anything, she knows my community and my surrounding area and my options so well that she gives me specific advice, she doesn't let things fall through the cracks. If I don't follow up on a referral, she does. She follows up to see if I didn't pick up a prescription or if I stopped something or it ran out—she's on every element of my care.

Expert observers also indicated that Massachusetts' initiatives like the State Action on Avoidable Rehospitalizations (STAAR) project have effectively contributed to the effort to improve care coordination across settings. In 2009, STAAR was launched by IHI in Massachusetts and other states with the goal of reducing avoidable rehospitalizations, primarily by engaging cross-continuum teams in care transition process improvement activities (Boutwell et al., 2011).

Risks related to diagnostic error. Several expert observers identified diagnostic errors as a major, complex risk in both inpatient and ambulatory settings. Expert observers commonly suggested that diagnostic errors have been a pressing risk for years, but the scope and impact is only recently being described. One expert observer told us that diagnostic risks are “the next frontier.” Another expert observer asserted that diagnostic errors are responsible for more than two-thirds of malpractice claims and are associated with the greatest malpractice losses. Diagnostic errors in the ambulatory setting are especially concerning, as one expert observer explained:

Primary care ambulatory risk is particularly vulnerable to what we see as missed and delayed diagnosis. It's usually cancer cases. It's usually breast, colorectal, prostate, and lung. Those are the top four of the types of cancers that we see usually missed. If it's noncancerous acute issues, it's usually MIs or strokes. So those are things that I would say the clinicians, particularly primary care clinicians, are struggling with to either identify and to really act on.

Expert observers pointed to multiple contributors to diagnostic errors. One expert observer asserted: “Medicine is not a precise science. A lot of it is predicated upon data gathering, interpretation, and availability.” Another expert observer pointed to the role of “cognitive biases” in driving diagnostic errors, saying: “[Clinicians] are not thinking, and . . . they’re anchoring on certain diagnosis and not thinking about others broadly. . . . And the cognitive components often lead to whether they order the right tests or not.”

Still another expert observer blamed poor physician-patient communication and physician stereotyping of patients (“the patient is a drama queen”) that affect the diligence of follow-up on patient-reported symptoms and potential diagnostic errors.

A few expert observers identified opportunities to reduce the risk of diagnostic error. For example, one expert observer described the value of “duplicate readers” for decreasing false negatives in imaging:

Some of the simple recommendations might be to have ‘duplicate readers.’ And some have implemented—for example with mammography—that you have a mandatory second read. And then if there is discordance, you’d have to resolve that. So that might reduce the potential of having a false negative mammogram and then, first of all, the patient having a delayed diagnosis of cancer, but secondly, someone being sued for failure to recognize an abnormal test.

Finally, one expert observer offered an explanation for why attention is increasingly being paid to diagnostic errors, despite the fact that this risk is not new:

I would say diagnosis risk was there . . . 15 years ago, but because of ACOs [accountable care organizations] and accountable care, there’s been a lot more attention being paid to it. So although the problem existed 10, 15 years ago, there hasn’t been an interest at the organizational level to figure out what to do about it.

Risks related to limited data on the safety of settings outside the hospital. Several expert observers focused on significant risks in nonhospital settings, such as ambulatory practices, ambulatory surgical centers, post-acute care, long-term care, and home care. As one succinctly put it: “On the outpatient side it’s a whole different ball [game] and I think patient safety is really in its infancy.” Most expert observers emphasized that the current lack of knowledge about errors and adverse events outside the hospital is itself a major risk. Explained one expert observer:

It seems to me that problems related to errors in the ambulatory setting have not received enough focus. We know relatively little about their prevalence and causes. And compared with the progress we've made in some of the inpatient settings, I suspect there's a lot to be done. In particular, figuring out how to prevent errors and harm in office settings that are not well resourced. They're small, isolated, and not tied into a lot of resources for analysis and making improvement.

Another expert observer noted a lack of research on the risks in these settings: “We haven’t had the depth of studies or experience or analysis to really understand. We’re just still defining the risk, I’d say, in the outpatient and in the post-acute care setting and in long-term care as well.”

Some expert observers felt that the problem was becoming more apparent because the increased acuity of patients being seen in ambulatory settings introduces safety risks. As one explained:

Sicker patients are now getting care in ambulatory settings and we don't hospitalize people for a lot of things that we used to in the past. So higher acuity, more procedures happening, more complexity occurring outside of hospitals, I think that's another factor that's certainly contributing, as well as sicker patients getting discharged from hospitals going to rehabs and other places that now have to handle that acuity.

Some expert observers noted that some risks in the long-term care setting have been reduced, especially falls and pressure ulcers, but emphasized that significant risk remains. Several expert observers pointed to the risks in assisted living, specifically:

People have not even begun to scratch the surface of the adverse events in assisted living. There's a lot of concern about assisted living because many people prefer to live there, as opposed to living in a nursing home. So people who are much more frail and much more sick are currently living in assisted living with a lot less regulatory oversight and a lot less support. So things like falls and medication problems and infections are happening in assisted living as well.

Expert observer also emphasized the risks encountered by people who have been discharged to home. One explained:

People who are living at home with home care—that's only intermittent. . . . there are people living at home who are no longer receiving any sort of home care. So

they're receiving maybe care episodically through organizations that we call 'long-term services and support.' So these are people that are not getting any services under Medicare. So they have potential safety issues and are in a pretty unmonitored environment with family caregivers.

Additionally, multiple expert observers raised concerns about failure to “close the loop” after a test or referral is ordered. Failure to follow up on clinically significant test results is a major risk in ambulatory practices, which receive results from outside laboratories and do not always have systems to ensure that the results are communicated to the clinician and the patient.

Finally, while expert observers pointed to many risks in nonhospital settings, one expert observer reminded us of the risks that would emerge from shifting all focus to nonhospital settings:

All that being said, it doesn't mean that we can stop working in hospitals because I don't think we can check the box and say: Yes, now we have a culture of safety in all our hospitals or we have incredibly safe medications processes or we have incredibly safe surgical processes. And I think all of those things are still areas that need work in the hospital setting.

Expert Observers' Opinions About Publicly Available Data

When asked about their views on making data on adverse events public, expert observers generally acknowledged the value of transparency in driving change by means of accountability and the facilitation of shared learning. However, many noted the value of a safe space in which providers can honestly discuss safety events as part of quality improvement efforts. One expert observer explained:

So after all the work we've done on culture, and the fact that we want to have people report and talk about errors and so on, total transparency can have a chilling effect on that. And that's, I think, a real challenge because we want to be transparent but we also want people to feel comfortable talking about errors. And they can be at odds with each other.

Multiple expert observers referred to the aviation model as an ideal for achieving this balance and improving safety. Some suggested starting with less transparency for the purposes of gaining trust and then gradually increasing transparency.

Expert observers also pointed to the challenge of making data interpretable and useful to patients, as well as the risks of gaming and underreporting by providers. One expert observer explained:

It's sort of like stock listing, I guess, for the lay person—you'd say if you're reviewing funds for investments in the stock market and you just listed everyone's fees, right, it would give you one sense of things. But at the same token, you want it to list the quality side, you want to show the outcomes.

Another asserted: “I think our measures and our tools are very early and very blunt and don’t tell people what they need to know.” Because of these challenges, some expert observers were pessimistic that transparency would ever be effective and suggested that effort would be better invested in other approaches to improving safety, such as working to change the culture of safety.

3. Looking Ahead: Opportunities to Advance the Safety Agenda in Massachusetts

Expert observers described several opportunities to advance patient safety in Massachusetts. Some identified specific areas in need of focus such as nonhospital settings, while others suggested programmatic actions, such as convening expert observers or disseminating evidence-based information.

A few expert observers sounded a cautionary note. While the unmet needs in patient safety are substantial, the “niche” for new initiatives may not be immediately apparent. Expert observers pointed to the potential for “change fatigue”—the difficulty of continually altering daily work patterns. Learning new protocols and habits takes significant concentration, focus, and energy with “staff burnout” as a significant potential problem. As health reform unfolds, providers are facing many new requirements from federal and state programs that could distract them from the patient safety agenda. These expert observers were arguing not for inaction but for a careful and judicious approach to launching new initiatives:

What I see within the landscape [is] . . . a lot of redundancy and confusion. . . . How is [a new program] complementary and not confused and redundant?. . . . I think we're going to need to establish a 'niche' that's really focusing on improvement work that others are not doing or they're not getting from somewhere else.

Areas of Opportunity: Initiatives and Programmatic Roles

In general, expert observers tended to mention **newly apparent safety risks** as areas of opportunity for new initiatives. The most frequently mentioned were extending efforts to reduce diagnostic errors, extending work on safety of care in nonhospital settings, extending work to

support safe care transitions, and engaging patients and caregivers in the safety of their care. Potential programmatic roles included convening expert observers, identifying priorities for statewide action, engaging leaders of health care organizations, disseminating evidence-based safety practices, advocacy and activism, technical assistance, and supporting research. Each of these is discussed briefly below.

Initiative Areas

Diagnostic errors: Expert observers described diagnostic errors as one area of patient safety that an organization like the Lehman Center may want to consider addressing. One expert observer noted that the following questions remain unanswered: “How many diagnostic errors are there of a certain type and then how could you intervene to either decrease their frequency or reduce the delays in diagnosis?”

Safety of care in nonhospital settings: Some expert observers suggested that analysis and monitoring of setting-specific patient safety risks, particularly risks in ambulatory settings (physician office practices, ambulatory surgical centers, home health care) and skilled nursing facilities, would be valuable. As one expert observer put it:

[It] would be helpful to really get a broader sense of what the risks [are] in these settings . . . kind of taking that step back. . . . I think better understanding the landscape would be a key first step before then going in to try to do some targeted things.

Another expert observer recommended convening a group of experts in patient safety in the types of nonhospital settings used most often by individuals with chronic diseases:

When you get a bunch of doctors together, they tend to start talking about hospitals. Nurses aren't much better. [We need to] make sure that people who are living with chronic disease, particularly dementia and cognitive impairment, throughout the health care system, that someone is paying attention to adverse events that happen in nursing homes, in assisted living, in home and community-based services, and not make this a hospital-centric initiative. I think we need a separate group of people with expertise in those settings to be convened . . . on a regular basis for the purpose of prioritizing projects, getting grants, and ensuring that work is done, and working with our regulators to make sure that they're looking at these things as well, because that will drive practice.

Care transitions: Some expert observers recommended a focus on the topic of care transitions. One explained:

If there were a clear voice coming through, advising people in general how they can improve safety, it would be around handoff. . . . Handoffs are still a big vulnerability. . . . If there were a way to articulate and advise people on what information is really meaningful in a handoff and how to stick just to that and eliminate the noise, that would be . . . establishing a clearer standard, and possibly could move us all in the same direction of being more concise and more mindful in our written communications.

Another expert observer agreed, suggesting that a focus could be:

Working across the continuum of care for those aspects of patient safety that might span across the hospital environment and the long-term care environment or the outpatient environment and the inpatient environment, and taking a more population based look at patient safety.

Such a systems approach to patient safety that looks across the care continuum may depend on the existence of robust and interoperable health IT, which could also improve patient safety. Several expert observers noted the need for “leveraging the implementation of electronic health records and computerized prescribing and to ensure that people are using that well.”

Patient engagement: Expert observers emphasized the importance of patient engagement to improving patient safety, and many suggested that patient engagement would be an especially appropriate focus for a new initiative. One expert observer stated:

Patients can partner . . . in both developing and designing programs, but also . . . using patient portals in a more effective way, creating opportunities for patients, particularly with chronic disease, to take on more responsibility, to do safety reporting.

Programmatic Roles

Expert observers suggested several possible programmatic opportunities.

Convening: Several expert observers suggested the need to “bring the different parties together” as a neutral convener—a role that not many organizations are able to perform, although the Massachusetts Coalition for the Prevention of Medical Error was described as effectively convening safety expert observers on several topics and initiatives. As one expert observer described it, the opportunity remains for different organizations to:

Work together and pull the wisdom out of folks who have done a lot of good work in each of the different environments in which they practice . . . I think being a neutral body and bringing folks together . . . to get a full understanding of where we're at from a patient safety perspective and where we need to focus our efforts would be extremely helpful.

Another expert observer pointed to a number of different methods for convening expert observers:

Cross-pollination in the broadest sense would be a perfect opportunity . . . whether it's at the level of conferences, at the level of newsletters, at the level of an online forum where people can post what they've done. . . .

Identifying priorities: Some expert observers saw a need to identify patient safety priorities and explicitly develop a patient safety agenda for the Commonwealth. Explained one expert observer:

I'm pretty happy that somebody is willing to look at everything that's going on and be willing to say 'these are our safety priorities.' We have heard from everybody, this is what we see that's the same across settings, this is what we see as different and as safety experts, this is what we are putting our dime on, it's our safety agenda.

Engaging leaders of health care organizations: One expert observer suggested a need to engage senior leaders of health care organizations. Engagement of senior organizational leadership was described by many expert observers as crucial to promoting culture change within health care organizations. They also saw the need for an effort to keep patient safety on the active agenda of CEOs and governing boards across the Commonwealth.

Disseminating evidence-based practice: Expert observers identified the need for an organization that could act as a disseminator of evidence-based recommendations about patient safety—having an organization that could serve as a repository of information about patient safety, help to translate evidence-based information into practice, and facilitate communication around the topic of patient safety. Explained one expert observer:

I could see [this organization] as maybe being a place that knows what's going on in all these different aspects [of patient safety] and can be a clearinghouse so that people can easily find out about these initiatives but also play some kind of a coordinating role [across initiatives].

Advocacy. Expert observers saw the need for two different types of advocacy: the role of an ombudsman to advocate for patients or caregivers (i.e., consumers) and the role of an activist, driving change at several levels. The ombudsman role was described:

[An organization] . . . consumers could call to get help with navigating the health care system or if they or someone else has experienced a medical error or something around health care . . . [this organization] could . . . help them navigate or point them in the right direction.

Although many expert observers recommended a convening, disseminating, or advocacy role, a few recommended a much more vocal and active role as a “driver of change.” Explained one expert observer: “It needs to be gutsy. It needs to have an in-your-face urgency role.” Another expert observer said:

I think there’s just plenty of evidence that there are things that we can do that will reduce adverse events. I think the literature on safety culture is pretty good now. I just think we need to move on this. I think we could sit around for another couple of years and have a lot more roundtables. I think we can really take some greater actions sooner.

Providing technical assistance. Some expert observers suggested the need for an organization that could provide educated technical assistance on safety improvement. One expert observer explained:

Many of the folks driving improvement work in the hospitals, including risk managers, are not safety science people. They don’t quite get this whole idea of process mapping. . . . What we need desperately is more expertise in industrial engineering and ways to bring in those kinds of skills to solve some of the problems we have.

Generating research: Some expert observers suggested the need for research, rather than—or in addition to—disseminating findings. One expert observer said that “research that would help advance the ball in the state . . . [could] help leverage new opportunities or prevent things that we don’t know so much how to prevent.” Another expert observer proposed that an organization was needed to support demonstration projects that could then be taken up more broadly.

As the expert observer interviews suggest, Massachusetts is richly endowed with exceptionally thoughtful leaders and experts steeped in many aspects of patient safety. Some Massachusetts

health care organizations have done prominent work to develop new tools, approaches, and practices in patient safety. Nevertheless, expert observers see several unmet needs. Common themes included the sense that at this point in the journey, progress has been made but that much more remains to be done; that complacency and change fatigue are constant threats; and that professionals, care delivery organizations, and oversight agencies need to harmonize their efforts. If these challenges can be overcome, health care can be made safer in the Commonwealth than it is today.

Appendix B. Research Methods

The purpose of this project was to characterize the patient safety landscape in Massachusetts. To do so, we interviewed more than 40 expert observers selected for their expertise, knowledge, or leadership related to patient safety in Massachusetts.

We first reviewed published literature, websites, newspaper articles, and other documents relevant to patient safety in Massachusetts. The purpose was to identify and abstract key quantitative estimates of medical errors, adverse events, and other patient safety issues in Massachusetts; review the status of Massachusetts' adverse event reporting systems; and identify potential expert observers for interviews. RAND research staff conducted searches of published peer-reviewed literature from 1994 to 2014 using PubMed. All searches had Massachusetts or Boston as a MeSH term or in the title or abstract, as well as a safety issue (e.g., adverse events, adverse drug events, falls, patient engagement, safety culture) or the name of a patient safety researcher known to use Massachusetts data. The references of relevant papers were reviewed to identify additional literature. Research staff also conducted Internet searches using the above terms and reviewed the websites of health care organizations and other expert observer groups to identify expert observers. In addition, we retrieved and reviewed documents mentioned during expert observer interviews. Key estimates of safety issues and the current status of Massachusetts' adverse event reporting systems are described in the introduction to the main report.

RAND research staff conducted semi-structured interviews with 41 expert observers at 35 organizations between July and October 2014. The primary goal was to describe the current patient safety landscape in Massachusetts, focusing on the most pressing current risks, the effectiveness of ongoing efforts to reduce these risks, areas in which patient safety has improved demonstrably over the past two decades, opportunities to improve patient safety moving forward, and the extent to which information about medical errors and adverse events should be made public. All interviews were conducted in compliance with requirements of the RAND Institutional Review Board, including giving informed consent to participate in the research.

We reviewed published literature, websites, newspaper articles, and other documents to identify key organizations and individuals with expertise, knowledge, or leadership related to patient safety in Massachusetts. Drawing on the project team's knowledge of patient safety experts and leaders, and with input from Lehman Center staff, we developed a sample of 55 potential expert observers. We aimed to achieve a balance of professional backgrounds, geographic locations, service settings, and expertise with specific patient populations. Of the 55 individuals invited to

participate in interviews, 37 agreed to participate. Some of the expert observers suggested or invited relevant colleagues to join interviews. A total of 41 individuals participated in 33 interviews. Table B.1 describes the final expert observer sample.

Table B.1 Final Expert Observer Sample: Professional Background and Areas of Expertise

| Professional background | Number of expert observers (41 total) |
|-------------------------------------------------------|----------------------------------------------|
| Academic experts | 5 |
| Delivery organization leaders | 18 |
| Independent safety and quality advocacy organizations | 12 |
| Patients and caregivers | 3 |
| Payers and purchasers | 3 |
| Geographic location | |
| Boston and surrounding | 36 |
| Western Massachusetts | 5 |
| Expertise in a specific care setting* | |
| Hospital | 33 |
| Ambulatory | 18 |
| Long-term care | 3 |
| Home care | 2 |
| Expertise in a specific population | |
| Behavioral health | 1 |
| Pediatric | 4 |
| Emergency room | 2 |
| Other perspectives | |
| Nursing | 4 |
| Physician | 14 |

*Several expert observers worked in both hospital and ambulatory care settings, so they were counted in both categories.

We developed a semi-structured interview guide that was used for all interviews. We conducted several group interviews; none included more than three individuals. When interviewing groups, our interviewers elicited comments from each individual. Respondents consented to audio recording so that recordings could be transcribed for qualitative thematic analysis. Interview transcripts were coded by a four-person team trained by an experienced qualitative researcher. To facilitate coding of large amounts of qualitative data, we used Dedoose Version 5.1 (SocioCultural Research Consultants LLC, Los Angeles), a secure online data analysis application. Based on the interview guide questions, we created and entered into Dedoose a

hierarchically organized codebook. This helped us facilitate data coding, ensure coding consistency across interview transcripts and coders, and extract comparable information from all interview transcripts. Analysis of the interview data started after the first three interviews were conducted and transcribed; the codebook was refined by adding new codes or merging existing codes after each subsequent interview to improve the quality of the data coding.

We used both deductive (i.e., based on the interview guide) and inductive (i.e., data-driven) approaches to thematic data coding. After coding 10 percent of the interview transcripts, data coders began to identify unanticipated emerging themes that spanned across interview topics and iterated the codebook inductively. To ensure that the codebook was applied correctly and consistently, all data coders were trained on use of the codebook and practiced coding the same interview transcript independently with discussion of discrepancies, reaching consensus when the coders disagreed, and modifying the codebook based on the feedback from this training session. Once all the interview transcripts were coded, one of the coders reviewed all interview excerpts with a given code as a way to ensure data coding consistency and quality. Finally, we used a version of the constant comparative method of qualitative analysis to identify any differences and similarities between previous and current patient safety risks and to describe risks that were unique to a particular health care setting and those present in multiple care settings.