Journal of Healthcare Management Standards
Volume 3 • Issue 1

What Will It Take to Make Healthcare Safer?
Learning From the Past and Accelerating Improvement

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ABSTRACT

Patients are harmed too often by the care they receive today. The authors discuss a recent large study of harm, its results in terms of harm incidence, and distribution, and compare these with prior studies of harm in hospitals. The authors suggest what these results imply in terms of improving the safety of care, and how to accelerate it. They go over the roles of boards, and leadership including the c-suite. They discuss metrics and achieving sustainable results. They also evaluate the role of culture, and the future potential of artificial intelligence to improve safety. Overall, there is great room for improvement, but achieving it will require addressing all these areas.

KEYWORDS

Costs of Care, Harm, Improvement, Leadership, Measurement, Patient Safety, Prevention, Quality of Care

WHAT DO WE KNOW ABOUT PATIENT SAFETY IN US HEALTH CARE?

Healthcare is not as safe as it should be. The problem of patient safety in the U.S. became a major priority following the publication of the Institute of Medicine's "To Err Is Human Report" in 1999 (Institute of Medicine, 1999). That report relied heavily on the findings of the 1991 Harvard Medical Practice Study (HMPS), (Brennan, 2004; Brennan, 2004) which identified an adverse event rate of 3.7 events per admission in a random sample of patients from New York cared for in 1984.

"To Err Is Human" resulted in substantial funding, and major growth in publications in this area. However, several recent studies suggest that nearly one in four admissions includes some type of harm event. These included a report from the Office of the Inspector General (OIG) published in 2022 (Grimm, 2022) on 2018 data and done in Medicare patients, which found that about a quarter of these patients suffered harm during their admission, 43% of which were preventable. It also included the SafeCare study (Bates, 2020), done in a sample of 11 hospitals from Massachusetts, using methods like the original Harvard Medical Practice Study, which similarly found a harm rate of 23.6%, of which 38% were judged preventable (Bates, 2020).

DOI: 10.4018/JHMS.329200 *Corresponding Author

So why are these rates still so high—and why are they nearly ten times as high as the original estimates from the Harvard Medical Practice Study? Differences in study methods and changes in health care make comparisons between the HPMS study and recent reports challenging. During the original study, paper records were the norm, and they were often hard to find and not always legible. Today, they are electronic, and adverse events are likely easier to detect. Second, the adverse event definition used in the more recent studies are broader than in the original study, which required death or disability at discharge, or prolongation of length of stay by two days. Third, the detection approaches today are better; triggers are used, and nurse reviewers are assessing cases with specific triggers in mind, such as unexpected transfer to the intensive care unit. Globally health care diagnostics and therapeutics have advanced, and the site of care has changed with more services being delivered in the ambulatory setting. In many ways, the health care we are evaluating in 2018 bears little resemblance to health care evaluated in 1984.

Nonetheless, harm rates measured before the pandemic have gone up, not down, even though we are 25 years out from "To Err Is Human." Much has changed on the safety front. Nearly all hospitals have spontaneous reporting of error systems in place, and safety groups which review these reports. Many root cause analyses are performed, and mid-course corrections are made. The "blame and shame" approaches in dealing with those who made errors are much less frequent, and many institutions have "just culture" programs, which are focused on changing the way that errors and accidents are perceived. This kind of approach helped aviation become safer, and indeed the U.S. aviation industry has gone years between fatal crashes.

WHAT IMPACT DID THE PANDEMIC HAVE ON PATIENT SAFETY?

While the pre-pandemic 2018 reports on performance were alarming, performance during the pandemic published by CMS and CDC leaders in February 2022, (Fleisher, 2022) showed slippage in common safety indicators in hospitals and nursing homes. For example, rates of central line associated blood stream infections which had decreased by 31% in the preceding five, was essentially reversed and there was a 28% increase early in the pandemic in 2020. As we move ahead to develop more pandemic-resistance approaches to delivering safe care, it is important to reflect on the learnings. What did we learn? The workforce was fearful for their safety and believed that workforce safety is foundational for patient safety. We should ensure that the lens on safety includes the caregivers as we go forward. Today's workforce safety issues include violence, burnout, and others, but the lessons from the pandemic are transferable. The explosion in virtual care for ambulatory visits and to augment inpatient care both at the bedside and to provide support across acute facilities was felt to be beneficial by most during the emergency and remains a mainstay of care. Guidance on using these tech-enabled approaches, safely, should be developed to ensure we train the workforce appropriately, enhance the platforms, set patient expectations appropriately and monitor results. Most organizations used emergency preparedness structures to manage their patient surge and goals, clear communication, and rapid cycle improvements were used to meet that challenge. As organizations revert to their routine management procedures, they should reflect on the benefits of aligned purpose and clear communications, accountability, and rapid decision making. Post-pandemic we may well be starting at a lower level of performance than pre-pandemic years, but we have new platforms and learnings that can be and should be used to accelerate recovery and set a higher bar. Establishing safety in high-risk industries such as aviation and nuclear power has been a preoccupation for scaling and sustaining these industries. Injuries in health care are rarely as devastating as a fatal plane crash or nuclear power plant accident, however, there are injuries everyday across thousands of hospitals in the US and many are preventable. Clearly, we know that safety reporting and many other investments in roles, infrastructure, technologies, and practice changes, which have been made across the health care industry have not been sufficient to achieve a safe health care delivery system.

WHERE DO WE GO FROM HERE? HOW DO WE ACCELERATE IMPROVEMENT?

In July 2023, the Executive Office of the President's Council of Advisors on Science and Technology (PCAST) released their pre-decisional draft for public review (PCAST, 2020). The fact that safety is not where is should be is declared and validated and four areas of recommendations are proposed: measure adverse events in a reliable and efficient way, standardize approaches to identify and focus on preventable adverse events, they note that key organizational elements include safety culture, participation coordination on safety and quality and recommend new practices and mitigations via research and urgent leveraging of technical advances. While this critical PCAST proposal continues to be developed and goes through the approval process, there is much for organizations to consider today. While setting a higher bar and recommitting to zero harm should be a theme throughout our work, it is also critical to acknowledge that patient safety is not the only critical issue and today's health care leaders are understandably focused on urgent operational issues including financing, access, workforce burnout and others. With that said, it is possible to recommit to improvements in patient care, patient safety (Berwick, 2023), quality and equity and bring these issues into the daily conversations, routine meetings, periodic discussions on results, annual goals, and the organization's strategic plan. Lessons learned from our past will continue to come forward, new recommendations from PCAST and others will be forthcoming and, it's worth reviewing recent national action plans that have been prepared by our country's experts in the field (National Steering Committee for Patient Safety, 2020) in the meantime, we all should raise the bar on our performance goals and consider how to hard wire new, more reliable and pandemic proof approaches, into our systems for providing care. For those looking for guidance on how all members of the health care industry can contribute, below we offer both evidence-based solutions and best practice considerations, as well as practical advice for stakeholders to consider All stakeholders have opportunities to act now.

WHAT SHOULD BOARDS BE DOING?

There are multiple challenges for boards and members of senior management teams in health care. Despite this, maintaining a consistent focus on patient safety and quality improvement is essential, and it starts at the top. While the accountability and structures of health care boards vary, the purpose of health care organizations is to provide safe and high-quality care and many boards have both fiduciary responsibilities and accountability for clinical performance including patient safety. Good management principles would suggest that boards should be educated about patient safety, have a dedicated quality committee where strategy and goals are tracked. Boards nominating committees should consider quality experts as members. The boards should work with management leaders to create environments where quality and safety is *the* organization's priority and where every person from the board to the bedside understands his or her role in promoting patient safety. Developing strong board structures that raise the bar on patient safety goals and strengthens the foundations of the organization have been discussed in the literature (Conway, 2008; McGaffigan, 2017), and need a new round of review and refinement. Clearly board education and engagement will be very important as we emerge from the pandemic.

WHAT IS THE ROLE OF MANAGEMENT AND THE C-SUITE?

Hospital and health care presidents and their senior team have responsibility for establishing the institutional goals, including quality and safety, operational and financial plans, and ensuring they are executed successfully. Today's management teams and committee structures have evolved since the 1999 report was published. The industry has invested in infrastructure and developed roles and responsibilities for experts in quality and patient safety. There may be a dedicated quality and safety leader, or Chief Quality Officer (CQO), or in many organizations the safety and quality work

is incorporated into another senior role ranging from Chief Medical or Nursing Officer, or Chief Operating officer. The leader may have a team with expertise in safety reporting, process improvement, data and analytics, clinical compliance risk, management, patient experience, and health equity. These individuals track external requirements and emerging innovations, inform their colleagues about evidence-based opportunities, new technologies and digital solutions, orchestrate required reporting, inspire teamwork, advance safety culture, just culture and typically will be involved in setting and tracking performance on institutional goals. Clearly these investments have not paid off as hoped across the industry. The question for senior teams in health care, now, is why not? We should all reflect on the contributing factors in the category of management and leadership that sheds light our slow progress. There are several hypotheses, including that the accountability for quality and safety has become too siloed and that if we step back and look closely at every leader's portfolio, we might be well served to clarify each leader's responsibility for quality and safety. While the quality officer and quality team have the expertise to advance new ideas, facilitate planning and implementation, for reliable and sustainable implementation coordination with operational leaders and alignment of goals is required. Those who provide direct care with their clinical, administrative, and operational leaders supporting them, constitute the operational teams. They are the front end of care delivery and accountable for their performance. How best to coordinate and partner with quality experts to ensure the operational teams have the knowledge, tools, and time to raise the bar is our challenge. Consider if each C-suite and senior leader had the responsibility for defining their team's contributions to patient safety and starting each year with explicit goals that cascade into their teams and harmonize with others. A simple example would be to consider reviewing all job descriptions and consider starting with a statement that describes how each employee's job advances patient safety and quality. Accordingly, the employee would be oriented to their role with emphasis on that aspect on safety and quality and their performance would be reviewed against those criteria. Thought leaders have proposed that it is the way that organizations manage that can distinguish high performers (Dixon-Woods 2019). This is an opportunity for all of us.

WHAT METRICS AND REPORTING DO WE NEED?

We all know the adage; you can't manage what you don't measure. The industry is woefully behind in its ability to measure and trend patient harm. At this point in time most hospitals are collecting some patient safety metrics yet there is little consistency in how the information is communicated to all staff members and is how the information is aggregated and prioritized for display on hospital dashboards. In an earlier study comparing hospital safety dashboards across ten hospitals there was wide variation in the number of indicators per dashboard, color schemes used to assess progress, and use of benchmarks (Kuznetsova, 2021). Standardized these presentations across units within hospitals and across hospitals could also help to drive awareness and improvement. The Office of the Inspector General study on Medicare patients, (Grimm, 2022; Bates, 2023), and The SafeCare study (Bates, 2023) collected safety events using modified chart reviews of 'triggers', or clues that may represent patient harms and that can be identified electronically. Nurse reviewers were then involved in investigating the triggers and physicians were then asked to validate nurse reviews and judge whether the harm was preventable. This method of identifying patient harms is expensive, retrospective, not easy to scale and not able to prevent harm in real-time. There are methods, advancing rapidly as artificial intelligence (AI) tools emerge to improve the sensitivity and specificity of adverse events identified in EHRs. Soon, with the explosion of new large language models, it will likely be possible to identify other types of harms that today are simply not identified unless they are submitted through safety reports. These include delays, misdiagnoses, overtreatment, bias and psychological harm, intraoperative errors, more. Building a robust set of valid and reproducible metrics that can be used to track improvement, compare sites and drive learning should accelerate our improvement in patient safety. As part of the SafeCare study we held a world café session to develop consensus on

the most important metrics to use in safety monitoring across a wide range of clinical areas. Groups of content experts worked through five hundred metrics most of which are not routinely collected but have been proposed by national organizations and prioritized what they feel we should focus on for the future, demonstrating an opportunity gap that could be explored further (Logan et al., 2021). In addition to continuing to develop new measures of safety, in parallel we should advance tools to identify of pending harms with opportunities to intervene and prevent harm should be priority for those exploring how to deploy generative AI in health care. Our current measures of safety lag other areas of health care quality measurement. Voluntary reporting of adverse events, a current mainstay, is simply insufficient to support improvement.

HOW CAN WE IMPROVE IMPLEMENTATION TO ACHIEVE HIGHLY RELIABLE AND SUSTAINABLE RESULTS?

Since 1999, the research community has identified many strong interventions and effective technologies have emerged when can reduce the risk of patient harm. These point solutions are available, they are found in the literature, and many are listed on government websites, with AHRQ being the principal example. Their on-line resource, Patient Safety Network, (PS Net)(Agency for Healthcare Research and Quality Patient Safety New) houses research results and tools. World class performance improvement organizations such as the Institute of health Care Improvement (IHI), and others, use their influence to convene stakeholders, and encourage improvement from the podium to share known solutions and inspire sharing of best practice and advancing learning systems across the industry. Despite this wealth of information hospitals and national action plans recently published (National Steering Committee for Patient Safety, 2023; IHI, 2020), hospitals lag in their ability to implement and sustain performance reliably. Learning from this experiencing and understanding the barriers to implementation, is key as we ask our colleagues recommit to improvement. In the SafeCare Study, Patient Care Events such as falls, and hospital acquired pressure injuries were the most likely to be preventable (Bates, 2023). Patient falls have been a consistent focus for patient safety for many years, yet the implementation of evidence based preventative strategies has been very slow. In 2007 an intervention called the Fall Tips for Tailoring Interventions for Patient Safety demonstrated significant reduction in falls with injury and total number of falls which is now implemented in over 100 hospitals (Carter, 2020). Other technologies such as bed alarms, sensors, remote monitoring and rounding protocols, have been advanced and yet preventable falls still occur. Additionally, the high instance of adverse drug events (39%) in the SafeCare Study is an example of how significantly medicine has changed over the past few decades as well as our ability to identify patient harm. While bar coding, electronic medical record alerts, pharmacy review processes, and safety features of automated dispensing cabinets in place, widely, should be reducing the risk of medication errors, clearly we still have opportunity for improvement and understanding the failure modes and barriers to full adoption and proper use of all available tools is an important step before layering on more solutions or simply returning to the workforce, reeducate and implore them to 'work harder'. There may well be other enhancements such as surveillance systems that could detect earlier signals of adverse drug effects in patients which would further reduce harm. The use of medical record surveillance systems with associated algorithms to look for triggers that require response and can notify clinicians in real time have potential for decreasing adverse events. Given the high stakes, it is important to prioritize the development of innovations that reduce risk, particularly with improved EHR functionality, selective decision support and AI tools, which may be more successful that past interventions that require a significant amount of behavior change, ongoing training and that are prone to drift. Improved decision support that is more selective and tailored warnings to present to clinicians prescribing medications could also decrease medication events. While hypotheses that explain implementation failures can be generated it would be fruitful to take examples like patient falls, medication administration, and

others, and investigate the barriers to full implementation, consider new tactics, such as AI, so that leaders and managers can factor these into solutions.

WHAT IS THE CRITICAL ROLE OF CULTURE AND HOW CAN IT BE STRENGTHENED?

In addition to the suggestions above, it is believed that a strong culture of safety, including just culture and psychological safety, are important for a high performing, highly reliable organization. Hospitals are required to periodically measure their safety culture by regulatory bodies and leaders are working through how best to interpret the results and drive improvement. Tactics such as walk rounds, huddles, communication, celebrations, teamwork are all proposed as solutions. Paul O'Neill emphasized the importance of workforce safety as a pre-condition, for patient safety and as CEO of Alcoa industries, he set a goal of zero harm for his workforce. He shared his approach to advancing workforce safety with attendees at the Lucien Leape forum in Boston in 2014 where advised leaders to ask their workforce three key questions: Am I treated with dignity and respect by everyone, every day, in each encounter, without regard to race, ethnicity, nationality, gender, religious belief, sexual orientation, title, pay grade, or number of degrees? Do I have the resources I need — education, training, tools, financial support, encouragement — so I can make a contribution to this organization that gives meaning to my life? Am I recognized and thanked for what I do (McGaffigan, n.d.). The experience of today's health care workforce includes workforce injury as well as the stress associated with workforce shortages and burnout and now measuring burnout, employee engagement, wellness are all emerging as important tools and tactics to keep our workforce intact, working at the top of their license, engaged and hopefully inspired to embrace the components of a safety culture that keeps them safe and their patients safe too. Leadership attitude, actions listening skills and setting the tone, the climate for the organization is also, many would argue, a precondition for a culture that provides safe care in a highly reliable manner. Board members, C-suite leaders, managers, and supervisors should seek to align in their purpose, plans and actions to ensure that "business as usual" in their organization, achieves the performance they want and that their patients expect and deserve. A compelling study looking at safety culture during the pandemic concludes that teamwork, is foundational and strong teamwork during the pandemic was protective of overall culture and employee engagement (Rehder, 2023).

WHAT IS THE PROMISE OF ARTIFICIAL INTELLIGENCE AS A RESOURCE TO ADVANCE PATIENT SAFETY?

The growing field of AI is already having impact on health care in major ways and promises more advances soon (Bates, 2021). Targets early include adverse drug events, decompensation, and diagnostic error. AI interventions that augment human decision making and eliminate administrative burden are clearly attractive given our crisis in workforce. Addressing the burnout and workforce fatigue with AI applications should be a priority. There are many applications that have promise such as the large language models that can summarize complex data, predict risks of harm, integrate, and streamline suggestions and refine the sensitivity and specificity of our current predictive monitoring and modeling capabilities. The field is growing rapidly (Matheny, n.d.) and knowing what tools to use, completing careful due diligence, and knowing when and where to implement will be important.

CONCLUSION

The evidence that our health care organizations are not as safe as they should be is clear. There is something for all who have been part of the journey to offer as learnings and there are myriad solutions being proposed with hope for a better future. All stake holders have opportunities to act now and align

as we accelerate improvement, embrace new opportunities, and recommit to zero harm care. When organizations commit to a goal, organizational leaders should design their approach carefully to ensure implementation is sufficient to get the desired results and hard-wired enough to stick. The President's Council of Advisor's on Science and Technology in July 2023 proposes a Transformational Effort on Patient Safety. Their set of bold recommendations is about as "from the top", clear, and concise as we can get. Let's move this agenda forward with alacrity. While the news on current performance is sobering, a better future is possible and is in our reach.

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