Analysis of Development in Patient Safety Over the Last 15 Years

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Patient safety is a significant healthcare issue with substantial clinical and economic consequences. The extensive research in 1999 on patient safety stated that preventable medical errors in US were killing as many as 99,000 people per year. The aim of this paper is through the analysis of patient safety management development to identify main obstacles and success factors for its improvement, coming from global literature review combined with a case study. The literature review was a qualitative meta-analysis from which identified barriers and critical success factors for improvement. This research is underlined by a case study which also shows clear adoption barriers. In the result of analysis of literature review and secondary statistical data, main conclusions can be stated such as: (1) The scope of improving patient safety has not made significant progress and further efforts are rare and not centred; (2) Several macroeconomic obstacles are still observable end especially in the field of commitment, funding, and education, but main attention paid by author of this paper is the analysis of managerial aspects of patient safety at micro-level which is creating the third group of conclusions.

Keywords: patient safety, hospital management, medical error

Patient safety is a significant healthcare issue with substantial clinical and economic consequences. What is patient safety? According to AHRQ (Agency for Healthcare Research and Quality), "patient safety refers to freedom from accidental or preventable injuries produced by medical care. Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events" (AHRQ Patient Safety Network, 2016; Sherman et al., 2009).

The patient safety movement was brought to the medical mainstream by a report of the Institute of Medicine (IOM)—"To Err Is Human" (Kohn, Corrigan, & Donaldson, 1999), with the goal to eliminate preventable patient harm through improved systems and find solutions to previously "unpreventable" errors (Wachter, 2012). Improvement in patient safety is also a major aim of hospital management these days. Five years after "To Err Is Human", two authors Leape and Berwick (2005) stated, "The groundwork for improving safety has been laid in these past five years but progress is frustratingly low". Nearly 10 years later, RAND Europe estimated that in the 27 European Union member states, between 8% and 12% of patients admitted to hospital suffer from adverse effects while receiving healthcare (Conklin, Vilamovska, de Vries, & Hatziandreu, 2008). A report from the National Patient Safety Foundation stated that 15 years after the IOM released "To Err Is Human", the work to make care safer for patients has progressed at a rate much slower than anticipated.

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They further stated that safety issues are far more complex and pervasive than initially appreciated (National Patient Safety Foundation, 2015).

The two key underlying questions of this research are:

(1) Why is the patient safety progress over the last 15 years slower than anticipated?

(2) What are the key drivers to improve patient safety?

This research is fully based on literature research. The literature is used to analyze both kinds of case studies, successful and not successful studies in improving patient safety. Based on the literature findings, the author analyzes factors which are influencing the adoption of patient safety initiatives in hospitals to help management to overcome these barriers.

Theoretical Background

Even after 15 years of patient safety initiatives, recent research has found that roughly one in two surgeries had a medication error and/or an adverse drug event (Nanji, Patel, Shaikh, Seger, & Bates, 2016) and more than 12 million patients each year experience a diagnostic error in outpatient care, half of which are estimated to have the potential to cause harm (Singh, Meyer, & Thomas, 2014). On the other side, there is 1.3 million estimated reduction in hospital-acquired conditions (2011-2013) as a result of the federal Partnership for Patients initiative (Agency for Healthcare Research and Quality, 2015).

Although the current evidence regarding overall improvement in patient safety in the US and world is mixed (Baines et al., 2013; Baines, Langelaan, de Bruijne, Spreeuwenberg, & Wagner, 2015; Landrigan et al., 2010; Shojania & Marang-van de Mheen, 2015), the majority of the panel in "Free from Harm" and management felt that overall health care is safer than that in the past (National Patient Safety Foundation, 2015).

Analysis

Patient safety improvements demand a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety, and risk management, including infection control, safe use of medicines, equipment safety, safe clinical practice, and safe environment of care (Hughes & Clancy, 2005; Reid, Compton, Grossman, & Fanjiang, 2005; Smits, Christiaans-Dingelhoff, Wagner, van der Wal, & Groenewegen, 2008). Further, advancing patient safety requires an overarching shift from reactive, piecemeal interventions to a total systems approach to safety in which safety is systematic and is uniformly applied across the total process and also includes management commitment (Pronovost, Ravitz, Stoll, & Kennedy, 2015). According to Ball, Kaminski, and Webb (2016), patient safety depends on the actions and beliefs of the person highest on the health care ladder (as health care has a long tradition of being hierarchical). The understanding of errors is linked to the ability to maintain a "fair and just culture" in which errors are quickly reported and addressed rather than hidden. However, such a culture is often difficult to construct, modify, and maintain (Ball et al., 2016). Patient safety culture, which is also called patient safety climate, is an overall behaviour of individuals and organizations, based on common beliefs and values which should be supported by hospital management (Nieva & Sorra, 2003).

Already in 2005, two authors of "To Err Is Human", Leape and Berwick, stated that the main reason for no measurable improvement is due to culture of medicine. Creating a culture of safety requires changes that physicians may perceive as threats to their autonomy and authority. Fear of malpractice liability, moreover,

may create an unwillingness to discuss or even admit to errors. Other issues include a lack of leadership from management at the hospital and health plan level; and a scarcity of measures with which to gauge progress (Leape & Berwick, 2005). All these articles are showing that patient safety depends on the culture. Consequently, improvement fully depends on the culture. There is a growing change trend in the number of articles on patient safety culture research; however, there has been no objective and quantitative evaluation of the quality of these researches so far (Xuanyue, Yanli, Hao, Pengli, & Mingming, 2013). A project-by-project approach did not lead to widespread, holistic change. To generate holistic change, we need to embrace a wider approach to safety rather than focusing on specific, circumscribed safety initiatives—meaning culture. This requires clear guidance and support from management in hospital with priority to patient safety and clear role modelling that reporting mistakes is something that no one is blamed for.

After understanding that the major barrier for slower improvement in patient safety is culture, the author further analyzes what drives patient safety culture. The following explains which factors are influencing culture while aiming to improve patient safety and what can help management with regard to improving the safety of patients.

An essential part of culture, and one key strategy to improve patient safety is enhancing transparency of performance on safety, clinical and service quality (Ball et al., 2016). This is of course not an easy goal since no one wants to actively show mistakes. Already, the IOM report in 1999 stated that if there is a safety culture where adverse events can be reported without people being blamed, they have the opportunity to learn from their mistakes and it is possible to make improvements in order to prevent future human and system errors, and thus promoting patient safety (Kohn et al., 1999). Actively showing mistakes has to be supported by management. Being transparent is part of the successful patient safety culture.

By embracing safety as a core value, other industries have moved beyond competition to a stage of cooperation. Health care organizations should also make this shift. While some health care organizations have begun to work cooperatively with each other to advance patient safety, a commitment to share safety data and best practices is most evident among paediatric hospitals. For example, the Children's Hospitals' Solutions for Patient Safety (SPS) network has seen significant improvements in patient safety metrics as a result of collaboration (Lyren, Brilli, Bird, Lashutka, & Muething, 2013). Unfortunately, many other health care organizations and their respective management seem to believe that they must differentiate themselves based on their safety record. Organizations should not compete on safety; such competition slows progress of inpatient safety by blocking the free flow of information crucial to preventing harm.

The case study CLABSI (central line-associated bloodstream infections) from 2005 shows that key success factor for improving patient safety is to create clinical communities in which peer hospitals are learning from each other (Aveling, Martin, Armstrong, Banerjee, & Dixon-Woods, 2012). These hospital communities are powerful vehicles in changing the overall behaviour and beliefs to "I" can do something about it (Pronovost, Cleeman, Wright, & Srinivasan, 2015). The power of peer communities comes from peer learning and tapping into intrinsic motivation among professionals (Dixon-Woods, Leslie, Tarrant, & Bion, 2013; Gould et al., 2015). This concept has not reaped rewards in others (Reames, Krell, Campbell Jr., & Dimick, 2015; Urbach, Govindarajan, Saskin, Wilton, & Baxter, 2014). To achieve success, some project-based initiatives, such as the CLABSI checklist, required major changes in teamwork and culture (Pronovost et al., 2006). It is telling that most initiatives succeed only when they implement tactics using a broader approach. In fact, a fundamental finding from the past 15 years is that patient safety initiatives can advance only by making teamwork, culture,

management, and patient engagement a key focus. By taking into account systems design, human failures, human factors engineering, safety culture, and error reporting and analysis, the systems approach epitomizes a more comprehensive view. Another example from Young-Xu shows that team training in surgery has been shown to reduce mortality by 50% compared with control sites (Young-Xu et al., 2011).

In the decades since the IOM issued its landmark report, "To Err Is Human: Building a Safer Health System", there have been a number of successful efforts undertaken to improve patient safety in the United States (Leape & Berwick, 2005). Nevertheless, the nation remains far from realizing the vision of eliminating harm to patients from care that is meant to help them. The case study from Ball et al. describes the progress that has been achieved by one organization committed to developing a culture of high reliability. ProMedica Health System is a non-profit integrated health care delivery system headquartered in Toledo, Ohio. In 2012, they set out to transform the cultural operating system with the goal of "zero events of harm" (Ball et al., 2016).

A study in 2015 stated that healthcare lacks robust mechanisms to routinely measure the problem and estimates of the magnitude vary widely. Further, this study states that it is hard to gauge safety when healthcare uses multiple different measures for the same harm and provides limited investment in measurement, implementation, and applied sciences. According to Pronovost et al., a valid and reliable measurement system is essential to monitor progress, to do benchmarking, to hold clinicians accountable, and to be able to compare and summarize measurements across different unit types (Pronovost et al., 2015).

Culture is not only determined by the caregivers and the hospital management. The regulatory framework is also part of the overall safety culture and can help to improve patient safety. For example, Leape and Berwick said, the current reimbursement system can also work against safety improvement, and in some cases, may actually reward less-safe care. For instance, some insurance companies will not pay for new practices to reduce errors, while physicians and hospitals can bill for additional services that are needed when patients are injured by mistakes (Leape & Berwick, 2005). The complexity of the health care industry, with its vast array of specialties, subspecialties, and allied health professionals is also mentioned as a reason for slow improvement in patient safety (Leape & Berwick, 2005).

The US Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 earmarked more than $20 billion to foster electronic health records (EHRs) at US hospitals and other medical facilities, and facilities have spent billions of their own to digitize patient records and clinical work flows. What benefits have accrued? Have EHRs lowered the cost and improved the quality of healthcare? In particular, what has been the effect of EHRs on patient safety? There is some evidence that EHRs reduce costs over the long term and under the right conditions (Payne, 2015). But evidence is scant on the effect of EHRs on patient safety (Dranove, Forman, Goldfarb, & Greenstein, 2014). An IOM 2012 study, "Health IT and Patient Safety", concluded, "current literature is inconclusive about the overall impact of health IT on patient safety" (IOM, 2011). This lack of evidence prompted an econometric study of patient safety at Pennsylvania (PA) hospitals. Patient safety improved for Pennsylvania hospitals that adopted EHRs: a 27% decline in overall patient safety events and a 30% decline in medication errors. EHRs were already recommended in the review of five years after "To Err Is Human" as a next step (Leape & Berwick, 2005), however so far not very widely spread. The example of EHR shows that even if a safer system (like EHR) was implemented, it must not be successful. Without having a safe culture and commitment from management, the whole new system will not be successful. In general, electronic support in health care will lead to safer care, e.g. barcoding has been shown to reduce medication administration errors (Poon, Keohane, & Yoon, 2010).

Conclusions

These research findings are showing the picture that there is no clear evidence that patient safety has improved over the last 15 years. Further, different authors explain why patient safety is not improved as expected. Figure 1 shows the flow of the research and also outlines key aspects and key literature of the research. After realizing that there is no clear improvement in patient safety until now, the question is to understand why. In order to help hospital management to improve their patient safety level, they have to understand where the barriers come from.
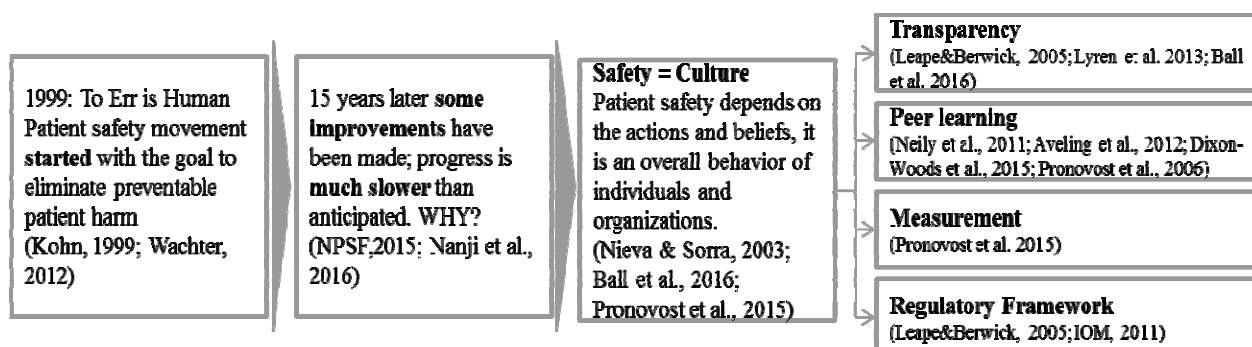

1999: To Err is Human Patient safety movement **started** with the goal to eliminate preventable patient harm (Kohn, 1999; Wachter, 2012)	15 years later **some improvements** have been made; progress is **much slower** than anticipated. WHY? (NPSF,2015; Nanji et al., 2016)	**Safety = Culture** Patient safety depends on the actions and beliefs, it is an overall behavior of individuals and organizations. (Nieva & Sorra, 2003; Ball et al., 2016; Pronovost et al., 2015)

Transparency (Leape&Berwick, 2005; Lyren et al. 2013; Ball et al. 2016)

Peer learning (Neily et al., 2011; Aveling et al., 2012; Dixon-Woods et al., 2015; Pronovost et al., 2006)

Measurement (Pronovost et al. 2015)

Regulatory Framework (Leape&Berwick, 2005; IOM, 2011)

Figure 1. Overview of literature research. Source: Author's illustration.

Progress in patient safety 15 years after "To Err Is Human" is still slower than anticipated—this was analyzed by various authors as described above. This means that even after 15 years and a lot of initiatives, there is still no clear improvement measurable. For hospital management, this means that they have to pay even more attention on patient safety and to analyze it more when they really want to effectuate something.

Safety depends on culture, not only on system improvements—this is the major reason for no incremental improvement of patient safety. Culture is not easy to change and it takes long time and full effort to change cultural behavior. For management, this means that if they want to improve patient safety, they have to be aware of culture and even of cultural change.

Success factors which are determining culture are transparency, peer learning, measurement, and framework. Transparency, peer learning, and measurement are factors which can be influenced and have to be driven by management. However, frameworks or even more implementation of new frameworks are part of decision processes in hospitals.

The analysis of decision making process in the hospitals needs to be taken into account for the system improvements implementation. Hospital management has to understand how decisions are made in order to follow the aim of increasing patient safety by implementing initiatives.

In conclusion, patient safety has made slow improvement over the last 15 years. This analysis showed that the main reason is lack of awareness with regard to culture and therefore lack of frameworks. Hospital management is required to pay attention to culture and to fully understand decision processes in hospitals to overcome the barriers and to overall improve patient safety.

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