Enabling Practice Leaders to Reduce Patient Harm through “System-Base Practice and Practice-Based Learning and Improvement”

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Abstract

Background: Healthcare organizations regularly face new challenges. Their leaders must be adaptive through systematic approaches. These approaches must meet three basic needs: 1) facilitation of workflow/task assessment and improvement; 2) creation of high reliability organization; and 3) respect of each practice as a special part of the total healthcare system. The US Institute of Medicine has called for higher quality at lower cost through “leadership that fosters continuous learning”. Retrospective methods are currently the most commonly used. These reveal only the tip of the iceberg of the total harm. The US Inspector General takes the view that the “current methods of detection of adverse events are inadequate”. Recommended Approach: An innovative prospective process is put forward. It fosters empowerment and ownership, eventually leading to high reliability practices. Conclusion: This approach is shown to be effective in measuring safety state in a practice and reducing patient harm. Could this be the “better way” that the Inspector General is seeking? Our experience with this approach in the domains of medication safety, falls safety, postoperative pain, and assessment of effects of HIT introduction has demonstrated that it also promotes core competencies of “system-based practice and practice-based learning and improvement” in staff.

Keywords

Harm, Leadership, Practice, Reliability, Safety, System

Subject Areas: Health Policy, Internal Medicine

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1. Introduction

“First do no harm” call from Hippocrates (5th century BC), call for hygiene from Nightingale (1820-1910), preceed the modern thrusts in this mission that include US Institute of Medicine (IOM) Report “to err is human” [1] and Donaldson’s report “An Organization with a Memory” [2]. In 2004 WHO formed World Alliance for Patient Safety. The progress towards improvement has been very unsatisfactory. This calls for systems approach and practice-based management. Various accreditation authorities have started paying attention to this. For example, ACGME has recently called for implementation of “Next GME Accreditation System” [3], paying due attention to “System-Based Practice and Practice-Based Learning and Improvement”. In the outpatient settings alone, up to two hundred thousand preventable deaths occur per year [4] [5]. According to the Institute for Health Improvement (IHI), in the US healthcare eleven million patients are harmed every year. Primary care has a critical role in providing the health and well-being of communities across the nation. Reduction of harm is an ethical, societal and fiscal imperative. “Progress in 12 years after the Institute of Medicine’s (IOM) calls for listening to patients and 50% reduction of harm by 2005 has been disappointing” [6]. The US Inspector General of Health Human Services (HHS) has stated: “Current methods of detection of adverse events are inadequate and risk misdirection of present efforts to improve safety based quality”. Annual economic impact of harm to patients is estimated to be more than $1 trillion. Literature on patient safety is relatively scarce [6]. Healthcare non-system needs major overhaul. A large proportion of US adults have had experience of harm caused by medical treatment. In the US consumer Union’s view preventable adverse events are kept secret from them [7]. The WHO regards patient safety to be a Basic Human Right. It takes the view that healthcare should be a balm for human suffering and not a contributor to it [8]. Practice leaders must, therefore, play the appropriate role.

2. Quality and Safety: Their Commonalities and Differences

2.1. Quality

The quality of any health care practice/setting is its total system characteristic. It has seven dimensions and can be defined as the degree to which health services for individuals and populations deliver better health, better care, and better value, consistent with current professional knowledge. The seven dimensions are 1) Safety, 2) Timeliness, 3) Effectiveness, 4) Equity, 5) Efficiency, 6) Patient Centered, and 7) Continuity of care. The first six were adopted in the IOM 2001 report [9]. The needs expressed in the Patient Protection and Affordable Care Act must be addressed systematically so as to develop and assess innovative methods for inviting/engaging/enabling all stakeholders, particularly patients.

2.2. Safety

It is one of the world’s most pressing health care challenges. It can be defined as freedom from avoidable injuries. Its goal is to avoid, prevent and ameliorate adverse outcomes emanating from the care processes. It is important to state that “a safe organization is a cost-effective quality organization” (Ex-Secretary of the Treasury, Ex-CEO of ALCOA and RAND, Paul O’Neill) [10]. “Partnership for Patients: Better Care Low Costs” and “Meaningful Use of Health Information Technology” are initiatives from the Department of Health and Human Services (HHS) designed to make care truly “patient-centered” [11].

Reason’s trajectory of errors [12] aids understanding of the causes of failures in the form of situational (e.g. very unusual work load, power supply failure at critical juncture), latent (e.g. deficiencies in design, operation, maintenance, organisation and management) and active failures (e.g. human fallibility) that can result in adverse events, in the absence of appropriate technical (e.g. use of informatics, safe dosage packaging) and administrative (e.g. standard protocols, non-hierarchical team culture [13] [14]) barriers to this trajectory. The overall purpose is to create high reliability organization (HRO) [15].

2.3. Commonalities

Any quality health care setting has dimensions/components housed in a protective Donabedian “house of quality triad” of: “structure, process and outcome” [16] portrayed in Figure 1.

Structural quality expresses healthcare system capacities, how the system is configured, description of its
components, and their inter-relationships are expressed. Organisational culture [13] [14] and stakeholder’s satisfaction through their empowerment (with bottom-up approaches) are important elements.

Interactions between patients and clinicians as well as how care is delivered are through well designed work process [17] [18]. The best process measures should be based on evidence relating better process to better outcome (e.g. reliable testing processes reduce misdiagnosis-related harm).

Changes in health status of the patients and patient satisfaction are outcomes. Any safe health care setting, whilst being an indispensable and vital dimension of quality, has to be designed to face following systemic threats:

- Variability from patient to patient.
- Use of inappropriate time constraints.
- Lack of initiative to handle the unforeseen.
- Complexity of the process of care.
- Poor interfacing (e.g. transition between settings).
- Lack of error-preventing barriers.
- Inconsistency in the standards of care.
- Human fallibility—to err is human.
- Use of hierarchical in the system.

3. Basic Approaches to Practice-Based Learning and Improvement for Harm Reduction

Because healthcare organisations regularly face new challenges they must be adaptive to improve quality continually. Quality improvement in any setting has to be a systematic approach driven by experience and memory of all stakeholders and has to be data-informed. All improvement approaches must meet three basic needs: 1) treatment of each setting as a unique micro-system, 2) creation of high reliability organisation (HRO) [13]-[15], and 3) facilitation of workflow/process/task improvement [17] [18].

Apart from financial incentives (e.g. salary, capitation, fee for service, and pay for performance) that are fraught with shortcomings [19] [20] there are two basic approaches that have been used to reduce the burden of unsafe care. These are retrospective and prospective methods of safety assessment for management of improvement.

3.1. Retrospective

These include trigger tools, quality and safety indicators, internal and external audits, and error reports. Each
one of these reveals only a tip of iceberg of quality gap and different perspectives of the same reality. These methods tend to be top-down and do not fully meet needs expressed earlier. Generalisations of the results from retrospective methods lead to dissatisfaction in stakeholders.

Even after the advent of PSOs, error reporting leads to both under-reporting (due to continued fear of repercussions) and abuse (examples of abuse include reports filed and counter-filed as a means of retaliation against colleagues). The culture of blame has been slow to change. As stated earlier, the Department of Health and Human Services’ Inspector General (IG) has stated: “Current methods of detection of adverse events are inadequate and risk misdirection of present efforts to improve safety based quality” [21]. The IG has called for better ways of monitoring safety.

One of the main flaws in current methods is that they fail to incorporate the patient perspectives. There is worldwide awareness that patients are a primary source of information about these avoidable AEs [22]. We need to develop methods of inviting, engaging and enabling patients by creating a shared vision [23]-[25]. The Assistant Secretary for Health at Department of HHS (Koh et al. [26]) draws attention to the fact that patient engagement is the “blockbuster drug of the century” [24]. Reform has to happen at the point of delivery of healthcare [25]-[29]. Advantage should be taken of the AHRQ Guide to Patient and Family engagement and the Patient-reported outcome measures (PROMs) Report [30].

3.2. Prospective

This is designed to capture the memory [2] of all stakeholders so as to anticipate adverse events. Failure modes and effects analysis (FMEA) is the main method used in this category. It is recommended by IOM and the Joint Commission, recommending a series of steps based on FMEA [31] [32]. In ambulatory practices, however, this methodology is not feasible, particularly in underdeveloped countries [33].

4. Proposed Model for Bottom-Up Humanistic Methodology

Introduction

The reliability and sustainability of a FMEA lies in the fact that it is a bottom-up humanistic approach that reveals the rest of the iceberg [33]. As illustrated in Figure 2, it has to be built on five principles and three important considerations. This methodology contributes to building the structure-process-outcome triad (Figure 1).

This bottom-up systems approach [33]-[38], though based on FMEA, avoids the burden of resource requirements. It is designed to motivate and empower teams in any setting to assess quality baseline, identify most significant problems, devise and implement informed feasible solutions to prioritised issues, track changes and repeat the cycle continually. This 4-stage cyclic method is reproduced in Figure 3 from the author’s earlier publication [13].

Stage (1) Measure current safety status with a confidential and anonymous on-line survey: An Instrument termed “Safety Enhancement and Monitoring Instrument-patient centered” (SEMI-P) is used for this. It is essential for all to understand the system of care in the setting. This is done by first identifying all the components and interlinks between them. This best done with a clear portrait of the practice [39] [40].

The survey includes a total of 140 different failure modes. These were listed after consultation with staff and patient advocates and review of literature [41]-[48]. This survey can be adapted to incorporate uniqueness of any practice.
Figure 3. Bottom-up Error Reduction Intervention Cycle (ERIC) for system-based continuous learning [13].

Stage (2) Rank failure modes according to product of respective severity and frequency: In the survey, each respondent rates the frequency and severity of each error according to the categorical scales. Hazard results are made available in visual format to help formation of consensus regarding prioritization.

Stage (3) Choose solutions to prioritized hazards: The solutions proposed are based on reliability and safety principles.

Stage (4) Implement interventions and monitor their effects: This is done with clear allocation of roles, responsibilities and time limits.

5. Experience with Bottom-Up Methodology

Supported by two AHRQ grants we have shown that all practice staff is able to collaborate fruitfully [33]-[38]. The methodology fosters culture of safety not only in the domains of primary care settings but also in hospital settings (post operative pain management [49] and falls reduction).

6. Discussion

The prevalent approaches are influenced by the 1911 book “The Principles of Scientific Management” [53] whereby only management is empowered to make decisions while workers are expected to follow unquestioningly.

The Error Reduction Intervention Cycle (ERIC) process illustrated in Figure 3 helps in forming shared goals [50]. Ownership and empowerment lead to worker and patient satisfaction and formation of reliable organizations [14] [15] [50]-[52].

Recent recommendations by international opinion leaders support and synergize with the author’s approach as elaborated below.

In September 2012, IOM [54] called for higher quality at lower cost through “leadership that fosters continuous learning”. This report asserts that there can be no quality without safety. An August 2013 report [55] by Britain’s National Advisory Group on the Safety of Patients in England to the British Prime Minister drew attention to the fact that the current state of patient safety is in “Crisis”. It called for a “promise to learn and a commitment to act”, reducing harm to patients by embracing wholeheartedly an ethic of learning. Both reports make the vital statement that the power of bottom-up commitment for continuous learning for quality improvement is, by far, much greater than that of the top-down efforts that are based on rules, standards and enforcement. Bottom-up initiatives and acts will help fulfill the mission of the US Patient Protection and Affordable Care Act (PPACA). We need to develop facilities that enable and help implementation of “A promise to learn—a commitment to act” [55]. Providers are generally frustrated with the top-down management methods that are by their
very nature mechanistic (Taylorism) [53], as against humanistic (bottom-up) methods. Top-down methods include: practice profiles, quality and safety indicators, external audits, and trigger tools. These tools do not recognize the problems involved with defining and quantifying harm at the points of care.

7. Conclusions

Our very positive experience with the proposed approach in the domains of medication safety, falls safety, postoperative pain, and assessment of EMR introduction has demonstrated that it also promotes ACGME’s core competencies [3] [57] [58] of “system-based practice and practice-based learning and improvement”. Our objective is to prepare the minds [56] of teams and the individuals forming them, through our prospective methodology that invokes “Improvement Science” and refrains from reductionism.

The author’s approach is supported by and synergizes with recent recommendations by international opinion leaders [54] [55].

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References


