Web-Based Meaningful Reporting of Patient Harm: Proposal of a Prototype for Creating High Reliability Hospitals

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Abstract

Background: Healthcare settings require a system that detects errors and near misses and learns from them to prevent their reoccurrence. Development of such a system requires engagement of all stakeholders. Retrospective reporting, analyzing and preventing future errors is currently the most prevalent approach to reducing harm to patients. It is important to point out that a recent report regarding reporting by the US Department of Health and Human Services Office of the Inspector General to Congress suggests that "current methods of detection of adverse events are far from adequate and risk misdirection of present efforts to improve safety based quality". **Recommended Approach:** In an approach to overcome numerous limitations of current reporting methods, the authors propose a web-based user-friendly method that helps engagement of all stakeholders. Whilst invoking "improvement science" with "design science" it applies safety principles. It enables meaningful reporting that applies concepts from organizational models of accidents (based on Reason's Trajectory). The design and use features are described in detail. **Conclusion:** Pilot tests with this reporting tool have been very encouraging. This trajectory model appears to help reporters to detect and understand that most accidents can be attributed to one or more of three weaknesses: *situational*, *latent*, and *active*.

Keywords

Barriers to Reporting, Reliability, Safety, System, Trajectory

Subject Areas: Health Policy, Public Health

1. Introduction

Ethical and fiscal imperatives of "First Do No Harm" are well captured by the WHO's declaration that patient safety is a basic human right. Healthcare errors harm one in 10 patients in industrially advanced world [1]. In the US alone about nine million patients are harmed in hospitals [2]. Disability associated with hospitalization occurs in nearly a third of patients older than 70 years. According to the Centers for Disease Control (US CDC), the third leading cause of mortality, after heart disease and cancer, is harm to patients [2]. The US Consumers Union takes the view that preventable adverse events are kept secret from consumers. Minorities of low income seem to be at higher risk. According to the Office of the Inspector General of the US Department of Health and Human Services [3], one in seven Medicare beneficiaries was harmed in 2010. The value of lost lives and disabilities caused by harm in 2006 was estimated to range from 18% - 45% of total US healthcare spending [4]. Data on adverse events have been very hard to get because only about 4% - 5% of known errors are reported [5]. Opportunist of understanding their causes and design for preventing them are lost [6]. It is not surprising that 13 years after "To Err Is Human" for all practical purposes we have not reduced this huge "iceberg" of harm to patients [7].

What healthcare settings require is a system that detects errors and near misses and learns from them to prevent their reoccurrence. Development of such a system requires engagement of all stakeholders. The Institute of Medicine (IOM), very rightly, asserts that there can be no quality without safety. A 2012 IOM report recommends continuous learning [8]. An August 2013 report to the British Prime Minister by Britain's National Advisory Group on the Safety of Patients in England calls for a promise to learn and a commitment to act to improve safety of patients [9]. These should help fulfill the mission of the US Patient Protection and Affordable Care Act.

Retrospective reporting, analyzing and preventing future errors is currently the most prevalent approach to reducing harm to patients. It is important to point out that a recent report [3] regarding reporting by the US Department of Health and Human Services Office of the Inspector General to Congress suggests that "current methods of detection of adverse events (AEs) are far from adequate and risk misdirection of present efforts to improve safety based quality".

In an approach to overcome numerous limitations of current reporting methods, the authors propose a web-based user-friendly method that helps engagement of all stakeholders. It applies safety principles, whilst invoking "improvement science" with "design science". It enables meaningful reporting that applies concepts from organizational models of accidents (based on Reason's Trajectory) and from high reliability organizations (HRO's) to healthcare. The main research question is: can the proposed web-based method improve the quality and quantity of error (and close call) reports by *all stakeholders at the points of care as well as help develop HRO's*?

The first author has already published [8] evidence of successful use of paper version of this trajectory model that has helped reporters to understand that most accidents can be attributed to one or more of three factors/weaknesses: *situational*, *latent*, and *active*. The error reporters began to understand that the system as a whole produced failures when all individual barriers/weaknesses aligned, permitting "a trajectory of accident opportunity", so that a hazard passed through all of the holes in all of the defenses, leading to a failure/harm. This trajectory has also been used successfully for simulation training. This paper will describe:

- What are the critical factors that are barriers to collection of hospital related errors?
- How do errors propagate in a health care system?
- How can IT systems be designed to make such error reporting easy, highly available, anonymous, and devoid of any attribution of blame?
- How can these errors be classified in a way that provides a deeper understanding of the processes that lead to such errors?

The design and use features are *visually* described in detail so as to reduce verbosity.

2. Reporting: Retrospective Approach to Reduction of the Tip of "Iceberg" of Harm

Retrospective reporting, analyzing and preventing future errors is currently the most prevalent approach to re-

ducing harm to patients. The overall objective is to reduce the size of the "iceberg", particularly its tip that is revealed (4% - 5%) by reporting [10]. This approach has led to development of multitude of reporting methods and development of error taxonomies, at various national and international levels [11]. It is vital that reporting system be perceived by all to be safe (free from blame and shame), easy, and worthwhile [12].

Lately, the profession has realized:

1) the importance of creating a common vision to inculcate team spirit between *all* stakeholders [13]; this, in turn, demands that we help the *teams* to overcome current barriers to reporting.

2) the importance of making safety information useful at the point of care to patients and healthcare providers [14]; similarly, the United Kingdom's House of Commons Committee of Public Accounts, in its report calls for a unified and convenient form for reporting that encourages feedback on solutions to specific patient safety incidents. Therefore, in addition to the "macro-system level" data, individual practices/healthcare-sites and organizations need local information that is directly relevant to them and can be used internally to drive safety improvement in each *unique* site. Such information, reported internally for quality and safety improvement purposes, potentially has more legitimacy in the eyes of local staff and clinicians in any health care setting.

In the US, 2005 Patient Safety and Quality Improvement Act established a federal voluntary database [15]. Federal government is expected to coordinate data collected from Patient Safety Organizations (PSOs) that collect data from hospitals under contract. These PSOs (current total number is about 78) are expected to analyze errors and recommend improvements. The reports are confidential and cannot be used in liability cases. This establishment has six very serious flaws as described below.

1) It is a top-down approach wherein the front line workers and their patient loose the opportunity of understanding of the causes of errors and near misses in their *unique* setting, and of devising prevention strategies with the resources available to the stakeholders: a bottom-up approach.

2) It lacks transparency to consumer groups.

3) It fails to engage patients. This engagement is the "blockbuster drug of the century" [16].

4) It fails to promote and to enable communication with patients or their families when disclosing adverse events [17] [18]. Disclosure has been shown to decrease lawsuits and average litigation costs [4].

5) It does not help inculcate systems thinking that shuns culture of blame and shame.

6) Most importantly, the reporters face a number of challenges and barriers. This is illustrated in **Figure 1**.
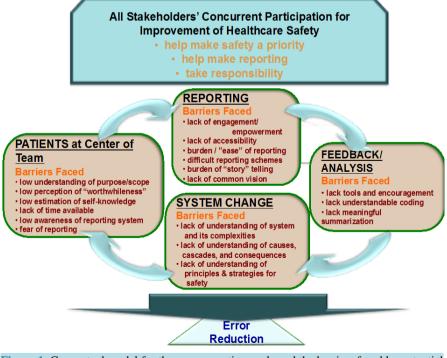

Figure 1. Conceptual model for the error reporting cycle and the barriers faced by potential reporters [9].

It is important to point out that a recent report [3] by the US Department of Health and Human Services Office of the Inspector General to Congress on methods for identifying adverse events in hospitals shows concern that incident reporting systems (five different screening methods) are missing the majority of events, and are unreliable. The report suggests that "current methods of detection of AEs are far from adequate and risk misdirection of present efforts to improve safety based quality" [3].

3. Development of a Concept for Web-Based Meaningful Reporting of Patient Harm

As stated earlier, what healthcare settings require is a system that detects errors and near misses and learns from them to prevent their reoccurrence. Development of such a system requires, engagement of all stakeholders.

The overarching goal of the authors' interdisciplinary research team is to provide value through quality-improvement and waste-reduction by applying safety principles and invoking "improvement science" with "design science" portrayed in **Figure 2** [19]. In the work presented here, we propose a meaningful reporting methodology that applies concepts from organizational models of accidents [Reason] and from high reliability organizations (HRO's) to healthcare settings.

3.1. Models of Accident Causation

Following the spate of disasters occurring in the late 1970s and 1980s, such as Flixborough, Challenger, Three Mile Island, Bhopal, and Chernobyl, James Reason [20] hypothesized that most accidents can be attributed to one or more of three factors/weaknesses: *situational*, *latent*, and *active*. The system as a whole produces failures when all individual barrier weaknesses align, permitting "a trajectory of accident opportunity", so that a hazard passes through all of the holes in all of the defenses, leading to a failure [21]. Singh *et al.* have successfully used this trajectory model for simulation training in safety.

Figure 3 illustrates Reason's concept of trajectory of errors (accidents).

Figure 4, on the other hand, shows the model that we have adapted to enable its use in reporting and simulation in our past work.

3.2. Prototype Design

As a primary requirement the security framework of this prototype complies with Health Insurance Portability
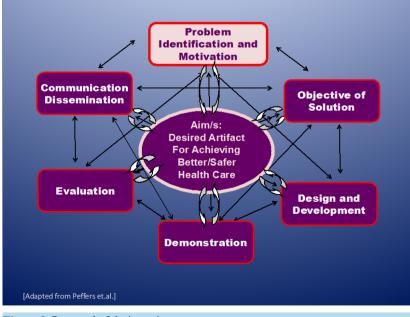

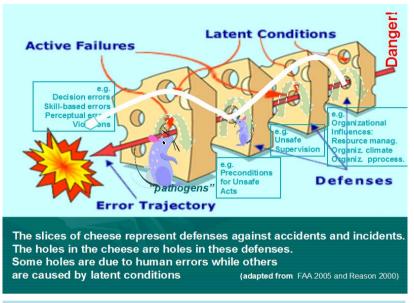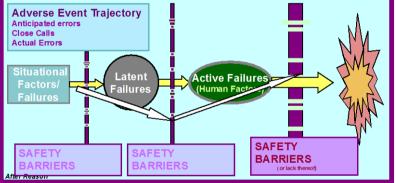**Figure 2.** Portrayal of design science.

Figure 3. Reason's trajectory of errors model [20].

Figure 4. Adapted trajectory of error.

and Accountability Act (HIPAA) regulations. It provides secure login, audit logs, user/reporter privacy, and role-based views of reports.

Contents of **Figure 5** are incorporated in this design to reduce cognitive and emotive biases. This can be seen in the top left hand corner of **Figure 6**.

Figure 6 shows some of the screen shots of this interactive and user friendly prototype.

4. Discussion

During the 1990's researchers in organizational behavior began to understand the cultural factors at the core of the success of organizations and recognized that these factors could have applicability in whole variety of complex, risk-prone enterprises such as healthcare. The core concepts that are thought to underlie the excellence in high reliability organizations, first described by Weick and colleagues in 1999 are: 1) sensitivity to operations; 2) reluctance to simplify interpretations; 3) pre-occupation with failure; 4) deference to expertise; and 5) resilience.

Situational Factors	Active Failures
These are unlucky, unusual, or unexpected events or circumstances that put additional stress on the system and can thereby trigger errors. The additional stress placed on the system by situational factors can unmask latent failures (see below) that may have gone unnoticed for prolonged periods of time. **Examples are:** very unusual workload distraction unusual encounter: 2 patients with the same name arriving at the same busy facility requiring blood power supply failure at critical juncture	These sharp-end errors are made by humans/operators in the processes of care. Their effects are felt/observed relatively rapidly or immediately. Numerous human factors bear directly on active errors. **Examples are:** misdiagnosis inappropriate treatment wrong drug prescribed wrong dose or route wrong site procedure picking up wrong bottle from shelf misreading and miswriting
Latent Failures	**Safety Barriers**
These blunt-end failures present the greatest threat to safety. These are errors of design, operation, maintenance, organization, active failures before adverse event can occur. These may facilitate/trigger an error/s or amplify the resulting adversity. Latent errors are built into the system and are difficult for staff to see because they may be hidden or dormant. Fixing of this latent source of errors yields the greatest improvement in safety. **Example are:** disregard of human factors/fallibility poor equipment design poor document control (e.g., laboratory results) bug in the software unclear allocation of responsibility inappropriate scheduling/planning poor interdepartmental coordination poor prescribing protocol inadequate training employment of unsuitable staff poor design/layout of the facility	They hinder humans from committing an active failure or absorb the effects of active failures before adverse event can occur. They can be: Technical (strong) or policies and procedures (week) **Technical** (strong) barrier **examples** are: plug design that prevents erroneous connections equipment failing to safe default state forcing functions informatics safe and distinct storage of drugs safe dosage packaging safety guards intuitive equipment operation **Administrative** (weak) barrier **examples** are: standard protocols and procedures clear clinical pathways adequate credentialing requirements emergency drills, simulations redundancy: double checks, teach-backs smaller number of handoffs smaller number of links in the procedures everything transparent and visible adequate looseness in coupling autonomy to handle the unexpected nonhierarchical team culture

Figure 5. Examples of situational factors, active failures, latent failures and safety barriers.

The essential thrust of these concepts is that all workers should understand: a) the complexity of the systems within which they work and b) the proneness of such systems to fail, leading to adversity/ies. They should develop situational awareness of possibilities for incidents and should report them promptly, even if no adversity occurs. Decision-making should incorporate expertise from whoever has it, regardless of hierarchy, and staff should be prepared to handle adverse outcomes when they occur. The prototype presented here is designed to aid formation of high reliability organizations.

The pilot testers included patients, nurses, auxiliary/support staff, pharmacists and physicians. Conclusions are based on their descriptions of experiences with the new methodology as compared to various currently used methods of reporting. Testers found our method to be easy, safe, and worthwhile [12].

5. Conclusions

The pilot testers of this web-based tool found it to be interactive and user-friendly. These tests have been very encouraging and have demonstrated that the tool aids reporting that is meaningful and useful at the point of care. It also promotes ACGME's core competencies [22]-[24] of "*system-based practice and practice-based learning and improvement*". Our objective is to *prepare* the *minds* of teams, and the individuals forming them, through our methodology that invokes "improvement science" and refrains from reductionism.
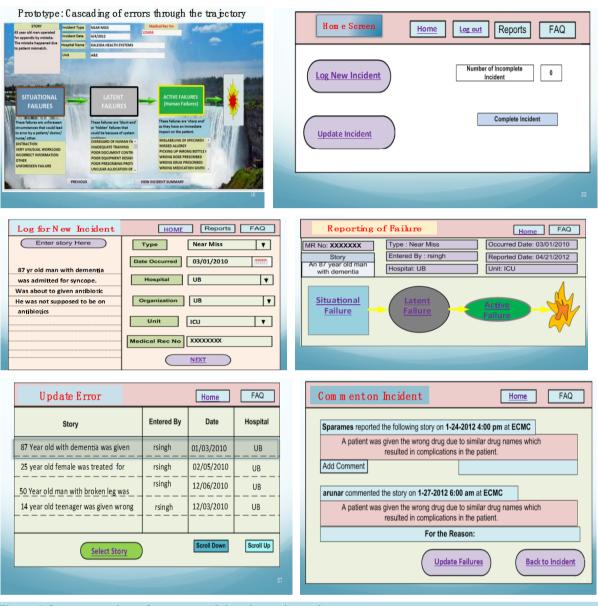
Figure 6. Some screen shots of prototype web-based reporting tool.

The author's approach is supported by and synergizes with recent recommendations by international opinion leaders [25] [26] referred to in Section 1 (paragraph 3).

Our future plans are to make the software adaptable in all healthcare settings (e.g. primary care) as well as package it for general dissemination.

Acknowledgements

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