

Patient Safety

Where should patient safety be installed?

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The structure of an organization is important, and structure has a profound influence on the way people work and what gets done.¹ Where work units and individuals in an organization are placed, to whom they report, and with whom they are grouped signals power, prestige, and privilege. It also divides workers into groups with common interests and motivations. The question is, where should patient safety be placed in a health care organization? Such a question can be answered only within a framework of understanding that gives a clear definition to patient safety. We define safety, as do safety professionals from other industries, as the reduction of risk. This definition is also in concert with the risk management model that identifies claims management, risk financing, and loss control as its foundational triad.²

BACKGROUND

It should not come as a surprise to the reader that no “perfect” model for safety organizations exists in health care or elsewhere. Noticeably missing from the patient safety literature are models to guide studies to empirically examine system design in relation to patient safety and medical errors. The model described by Reason,³ often referred to as the “Swiss cheese” model, is probably the most well-known system model used within the patient safety community.⁴ Another framework familiar to the reader should be Donabedian’s quality framework of structure, process, and outcomes measurement in which *structure* includes the *organizational structure*. Yet even these two models do little to expand upon Petersen’s initial recommendations regarding organization, and neither expresses a preference for a reporting structure in a health care setting.⁵ While the Institute of Medicine (IOM) has stated that it considers patient safety “indistinguishable from the delivery of quality health care,” it remains relatively mute on the more vexing challenge of where it (or quality) should be placed organizationally.⁶ Therefore, to answer the question of where to place patient safety organizationally, we turned to models for safety employed in other high-

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reliability organizations (HROs) such as the aviation, transportation, chemical processing, and food production industries.

MODELS FROM OTHER INDUSTRIES

- In discussion of where the safety function is best placed, Petersen⁷ and others recommend that: Safety report directly to a leader with influence.
- Safety has a *direct* channel to the top of the organization.
- Safety has the ability to influence activities across the entire organization.

A survey conducted by Andersen Consulting⁷ of 7 leading non-health care organizations found that all 7 had safety programs led by a VP of Safety, and the position was of sufficient organizational stature to participate in strategic planning and operations management. *The International Encyclopedia of Ergonomics and Human Factors*, a common desk reference among safety professionals, notes that most companies and large governmental research and development organizations have a corporate or executive safety office that reports to the organization director.⁸

RELATIONSHIP TO QUALITY AND COMPLIANCE

The concept of quality in health care and its relationship to patient safety has become a source of confusion. In practice, quality usually means adherence to evidence-based guidelines.⁹ We observed that the studied non-health care models took effort to clarify the different roles of quality and safety. Most notable were safety models from the food industry that equated safety functions with risk reduction and quality with compliance to known standards. Safety was found to be the reduction of relative risk levels of illness or death and not the relationship of an outcome to a mean or expected outcome. This is not dissimilar to the description by the Institute of Medicine's (IOM) of safe care as "avoiding injuries to patients" found in the 2001 *Crossing the Quality Chasm* report. Our conclusion was that patient safety has a near-term focus that uses a systems approach to limit the risk of patient harm due to substandard performance. Quality takes the long view in seeking both compliance and overall improvement in patient-relevant outcomes and process measures that are expressions of standards. Quality management is thus linked to scientific evidence related to clinical interventions and programs through measurement.

Neither did we find support for the notion that quality is either an assurance of safety or that safety is a component that falls under an overarching quality umbrella. A study by the Conference Board found that Baxter International, upon recognizing that their organization-wide compliance and quality improvement focus did not ensure safety, moved the safety program into a channel that reported directly to top management. The Baxter experience demonstrates that safety cannot be assumed to be a product of even a robust of quality improvement effort. In fact, perfectly functioning, reliable, and fully compliant independent operational system elements, when combined, can still produce poor and sometimes even unsafe outcomes. In the

complex sociotechnical systems of health care, accidents often result from integration of perfectly functioning systems where “operators tend to be inheritors of system defects created by poor design, incorrect installation, faulty maintenance, and bad management decisions.”^{10,11}

Even the best compliance and quality improvement program is no guarantee of safety. The literature and press are rife with examples of health care organizations that were in full compliance with national quality standards (and often accredited by the Joint Commission) and simultaneously engaged in unsafe acts—all too often with multiple patients and over a span of time. Traditional approaches to quality often rely on the Donabedian model, which examines structures, processes, and outcomes of clinical care. In this model, poor quality is presumed to be the result of not following the correct means of performing a task to reach a measurable production goal. However, this model is limited in its recognition of the interactions of and interdependencies among system components.

In addition, in a study of hospital work process failures, Tucker and Edmonson found that rather than process improvements, the failures elicited workarounds by nurses 93% of the time. Furthermore, reporting the failure to someone who might be able to do something about it occurred only 7% of the time. Patient safety places a much greater emphasis on the system in which care is provided and less on individual performance, and thus encourages improvements to systems through hazard elimination and forcing functions rather than workarounds.^{1,3}

POTENTIAL CONFLICTS WITH MISSION AND GOALS

High-level organizational placement of safety is necessary because safety goals may be in conflict with production goals—for example, in the marine transportation industry (eg, tonnage delivered). Clearly, during inclement weather, ship direction should be altered and speed checked to preserve safety of crew and cargo. Similarly, the overtly stated mission of rapid, reliable EMS response (ie, less than a 7-minute arrival time) may be in conflict with safety during night operations. Obviously, there are times when safety absolutely trumps mission or operational goals such as the absolute prohibition by the California Highway Patrol on night pursuits by motorcycle officers. In health care, this direct, high-level reporting relationship of safety to the C suite is necessary because, unlike other attributes of an ideal health care system identified by the Institute of Medicine (safe, effective, timely, efficient, equitable, and patient centered), **[AU: Please insert previously cited reference number here or add new reference and renumber remaining references. In other words, this should be 6 now based on refs list at end of article, correct?]** only being too safe (risk adverse) can be in direct conflict with operational goals assuming that one can rarely be too equitable, too effective, or too patient centered.

WHO DIRECTS THE SAFETY PROGRAM IS IMPORTANT, TOO

Non-health care organizations have been quicker to recognize the advantage of recruiting and hiring credentialed, degreed safety professionals. In the late 1970s Alcoa, under the leadership of Paul O’Neill, began hiring degreed safety professionals to give safety a stronger voice. **[AU: Please insert previously cited**

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In health care, however, safety is often a “tacked-on” responsibility or the result of a departure from a career trajectory in health care quality. There is a belief in health care that a clinical credential is an absolute necessity in technical but non-patient care professions such as risk management or safety, and health care organizations have generally failed to effectively recruit from the safety profession, often choosing instead to divert or recycle nurses trained and experienced in quality. Fully 90% of the employment opportunities posted on the American Society of Healthcare Risk Management (ASHRM) website require the applicant to possess an RN degree, yet a significant number of the past 14 presidents of that organization did not have a clinical credential. In most non-health care industries, safety is recognized as a degreed and credentialed profession unto itself requiring no further credential.

While the nonclinician safety professional may not have the same clinical know-how as “sharp end” personnel, they certainly should and must have the authority to involve those with clinical expertise in needed safety improvements.¹² Thus, a new role for health care safety that is modeled after other HRO industries is envisioned, placing a high value on understanding system complexity and focusing on component interdependencies ... not just standards compliance.¹³ This “big picture” characteristic is echoed when the term *competent person* is used in many Occupational Safety and Health Administration (OSHA) standards and documents such as 29 CFR 1926.32(f) to describe a person who is “capable of identifying existing and predictable hazards in the surroundings or working conditions which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.”¹⁴ By way of training and/or experience, a competent person is knowledgeable of applicable standards, is capable of identifying workplace hazards relating to the specific operation, and has the authority to correct them.

There is recognition in health care that organizational, managerial, and human factors rather than purely technical failures and noncompliance are the prime causes of incidents. While there has been a greater emphasis placed on probing leading safety indicators such as attitude, culture, and safety climate, this has yet to produce a corresponding shift in health care safety focus from compliance and an organizational placement that ensures direct access for safety to top management as it has in other high-reliability organizations. There is and should be an overlap between quality and safety, as both endeavor to narrow the range of clinical outcomes by raising the overall quality and safety of care. However, safety accomplishes this by addressing the physical environment (including attitudinal states such as alertness, fatigue, and motivation), organizational culture and climate, error reporting and analysis, and work design as elements of the work system writ large to identify and “trap” active and latent errors. The core tools of the safety profession, with its emphasis on human factors engineering, forcing functions, team situational awareness, Healthcare Failure Mode and Effect Analysis (HFMEA) and root cause analysis are best targeted at the rare outliers in need of major improvements than the Six Sigma, reliability, LEAN, ISO9000, and compliance tools directed by quality at the middle of the normal distribution. And while the nonclinician safety professional may not have the same clinical know-how as other “sharp end” personnel, they certainly have the corporate authority to involve those with clinical expertise in needed change efforts. Thus, a new role for health care leaders and managers is envisioned, placing a high value on understanding system complexity and focusing on the interdependencies ... not just the components.¹³

CONCLUSIONS

- We found support in the literature for an amalgam of the proposed organizational schemes: Safety should report to a leader with influence.
- Safety should have a direct channel to the top of the organization.
 - Safety should be led by a VP of safety or a title with sufficient stature to participate in strategic planning and operations management.
 - Even the best compliance and quality programs are no guarantee of safety (make safety its own executive office).
 - Failure must be reported to someone who can do something to correct the problem.
 - Safety may find itself in conflict with production goals.

Where should safety be installed? Petersen's assertion that safety should report directly to a leader with influence at the top of the organization and have the ability to influence activities across the entire organization rings true. But also consider what safety credentials, abilities, and previous experience that person should have no matter where they are placed organizationally.

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Doug Paull, MD, MS, graduated from Duke University with degrees in zoology and medicine. He underwent general surgical training at the New York Hospital Cornell Medical Center and cardiothoracic surgical training at the University of North Carolina in Chapel Hill. He received his master's degree in patient safety leadership from the University of Illinois at Chicago. He is a veteran of the US Air Force. He served as an Assistant Professor of Surgery at Wright State University School of Medicine and the VA Medical Center in his hometown of Dayton, Ohio. Since 2008, he has worked at the VA National Center for Patient Safety, sequentially as Co-Director of Medical Team Training, Director of Patient Safety Curriculum, Director of Medical Simulation, and, most recently, as Senior Medical Officer/Deputy Director. He is the author of articles, chapters, and a book on the topics of surgery, patient safety, team training, simulation, and high-reliability health care organizations. He is an Adjunct Clinical Professor of Surgery and Medicine at the University of Michigan and Georgetown University Schools of Medicine, respectively.