Beyond Traditional Patient Safety Tools and Techniques

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ABOUT FORUM

Forum provides in-depth analyses of specific medical malpractice cases and issues along with practical loss prevention advice and case abstracts.

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Over the past decade, the patient safety movement has made progress. But false starts, failed initiatives, and lingering problems (e.g., wrong medications, missed MI, retained foreign objects) tend to get more media coverage than the successes achieved by those working to “fix” this aspect of health care delivery. Impatience for faster and more dramatic results may lack appreciation for the Herculean task at hand.

“Health care” encompasses an enormous spectrum: from a dose of kaopectate to bariatric surgery, from preconception counseling to end-of-life decisions. There is, quite frankly, a lot of room for error and fixing everything that can go wrong in a solitary physician’s office, on a Labor and Delivery Unit, in the OR, in a skilled nursing facility—and everywhere in between—is a monumental task. It is also a task that can only be approached incrementally, will require time to sort the solutions that work from those that don’t, and competes for limited resources with other aspects of health care on the agenda. Even Hercules might think twice before accepting this challenge.

One of the many dilemmas faced by health care professionals working to reduce errors and improve patient safety is whether to:

A. try to use existing tools and techniques more effectively,

B. develop better tools and techniques from scratch, or

C. look for appropriate tools and techniques elsewhere and apply them to health care?

In this issue of Forum, we explore option C; several experts from within and outside of health care comment on what models and techniques hospitals and practices and individual providers can employ as they move into the more difficult stages of patient safety improvement.
What Can Health Care Learn from Sophisticated Industries?

by Steven J. Spear

Steven Spear is a Senior Lecturer at MIT and a Senior Fellow at the Institute for Healthcare Improvement.

American health care offers painful contrasts. Well-trained people, inspired by altruistic motivations, use advanced science and technology to reduce the pain and suffering of others. We should expect the absolute best. Yet, there are terrible shortfalls in quality, affordability, and access. What we actually receive is far from what we expect or require. The gap cannot be explained away by the complexity of health care. Other industries—those which have had relentless complication of products, services, and the organizations required to bring offerings to market—have experiences converse of health care’s. For them, even with rising complexity, quality gets ever better, abundance increases dramatically, and unit costs fall to a fraction of their original.

There are stark differences between typical health care organizations and the most successful organizations in the most successful industries. Reflecting historical antecedents, most health care providers are organized around disciplines and specialties—departments of orthopedics, anesthesiology, physical therapy, nursing, and pharmacy. This might have been adequate when specialties were few and organizing around each fostered discipline-specific research and training. Short attention to integrating the individual pieces into well-harmonized systems was less consequential when care delivery was simpler.

Other industries—for instance, automobile, jet engine, and integrated chip design and manufacturing—and other service examples—e.g., financial, transportation, entertainment, and hospitality—have seen an explosion in the number of technological disciplines they have to master and the depth of knowledge required in each. The most successful companies have learned that it is inadequate to manage each independently. Rather, each discipline has to be managed in service to the larger system to which it contributes. Within these organizations, there are distinct roles for those whose responsibility is ensuring that specialty pieces come together well.

Were such the case in health care, we would see more than departments of specialists. We would also have “service lines,” organized around knee repair as distinct from hips, shoulders, and ankles and certainly distinct from thoracic and vascular service lines. On the diagnostic side, we would expect centers focusing on respiratory problems, bringing a cross-functional approach to diagnosing and treating patients, rather than the specialist-by-specialist search for a solution. (The son of a friend saw a pulmonologist who was certain the child had asthma, an allergist who found reactions to several foods, but no ENT to reveal his obstructing adenoids. Without an integrated picture, the boy had multiple medicines, not well reconciled, and collectively ineffective).

Aside from this structural problem, there is a dynamic issue: organizational learning. Successful organizations are exceptionally disciplined in designing systems to incorporate their best knowledge on how to succeed. And, they are relentlessly rigorous in identifying when their designs are inadequate. They constantly look out for contradictions to what they expected—someone’s time being demanded when it wasn’t planned, micro fluctuations in process parameters that hadn’t been anticipated. Each of these signals something is going on which they don’t understand. Once aware, they pounce on the aberration with tenacity until they understand why it had occurred. Then, they still don’t rest. They build that newfound understanding into their approaches going forward, until they discover another inadequacy to be resolved and converted into expertise.

What a far cry this is from what so many healthcare organizations do. Not only is there little discipline in designing end-to-end service lines over which patients will be treated. Nurses, especially, are expected to constantly make do, work around, and otherwise be heroic to “get the job done.” People repeatedly fight the same battles, achieve little headway in making things better from a quality, affordability, or capacity angle. Even worse, sometimes several “small” problems occur in just the right combination to cause a serious harm to a patient.

There is some small cause for optimism, though. A few health care providers have looked to other industries and copied their more sophisticated approaches to managing complex systems. The results are staggering. Complications like central line and surgical site infections, patient falls, and mismedications? Eliminated. Readmissions—after patients destabilize—eradicated, the attendant costs of “rework” removed, and capacity freed for staff to care for far more people more effectively.

For all the internal differences between the management of the typical health care provider and the best non-healthcare organizations, there is another factor worth considering. Normally, people buying a product or service can make informed choices. Knowing where they will find more value, they steer business to better competitors, depriving worse ones of traffic they have not earned, providing incentive and reward to innovators to do even better. Everyone benefits.

Not so in healthcare. By and large, patients have only rudimentary and unreliable information when choosing therapies and therapists. Lack of competition can only impede progress, as it slows the accrual of benefits to patients, payers, and providers alike from the work the pioneers have done to match the sophistication of healthcare technology and science with an equally sophisticated approach to managing its delivery.
What Can Health Learn from Other Industries of High Intrinsic Hazard?

by David M. Gaba, MD

Dr David M. Gaba is Associate Dean for Immersive and Simulation-based Learning, and Professor of Anesthesia; Stanford University School of Medicine.

Health care is but one of many intrinsically hazardous endeavors in society where human lives are at risk on a daily basis and are in the hands of trained professionals working as individuals and teams. Other such arenas include aviation, power production, and the military. Especially in the branches of health care that deal with highly dynamic situations (e.g., anesthesia, intensive care, surgery, emergency medicine) there are marked parallels between the industries at the level of the “sharp end” work.

The rate of fatal accidents in these industries is markedly disparate. Take commercial aviation. Between 2002 and 2008 there were on the order of 10.2 to 10.9 million departures on major airlines with between 0 to 3 fatal accidents killing 0-50 people.1 Taking only the most optimistic health care estimates—say the rate of fatal accidents due only to anesthesia care for healthy patients having routine surgery—one death per 200,000 cases, health care is still 25 times more dangerous than flying and the “accident rate” for health care as a whole is probably 200 times worse.

Patients Are Not Airplanes

Certainly, some aspects of health care safety are intrinsically different from the other high-hazard industries; after all, “patients are not airplanes.” Infinitely diverse human beings are not instrumented by nature to provide critical information about their physiology. At best, clinicians obtain a smattering of data from non-invasive external sources. Airplanes, on the other hand, are (usually) in good shape when we fly them (and there isn’t a mechanic working on the aircraft during a flight at risk of severing a hydraulic line or the like).

Organizational Differences Between Health Care and Other Industries.

But still other aspects of health care safety suffer because of differences in the organizational structure of health care versus that of “safer” industries. This means that health care has much to learn from how these other endeavors operate. It does not mean health care has to achieve the same level of proceduralization and control that mark these industries, but the pendulum in health care is quite far to the other extreme. Getting to a happy medium is an important goal on the road to improving safety and quality.

Integration and Economics of Scale

In the United States, both aviation and health care are decentralized. But, whereas only about 10-12 airlines are responsible for most of the 11 million flights per year, invasive health care is conducted at 4,000-6,000 hospitals and a similar number of standalone surgicenters (all owned by thousands of firms). Thus, health care doesn’t have the economy of scale that aviation has (or even more so, the nuclear power industry). A good aviation safety idea, even if not an official “de jure” regulation, can be adopted by the industry nationwide if 10 firms think it is worth doing. In health care, one would have to convince each one of the many thousands of firms.

Regulation

In the US a single federal agency regulates air transport, and comprehensively oversees nearly every level of equipment, personnel, and detailed work processes. A national independent agency (the National Transportation Safety Board) investigates accidents and makes safety recommendations. The airlines themselves exert firm control over the pilots with standard operating procedures and policies that are strongly adhered to.

In health care, one federal agency regulates drugs and devices, but does not regulate the practice of medicine. The level of government regulatory control is variable and, in general, limited or non-existent at the level of actual physician/crew practices. Individual firms impose only modest practice controls over individual clinicians and there is no independent official safety organization for health care.

Thus, finding the optimal balance between centralized and local control remains a future goal for the health care industry. Work systems in health care should seek to implement standard operating procedures (based on global evidence or, at least, on local consensus) while retaining the flexibility to handle the vagaries of caring for human patients.

Education and Training

Differences between the industries on the structure and organization of education and training are also profound. Selection of personnel in aviation is focused less on knowledge-based tests and more on actual job skill and performance. Airlines have highly-focused training programs to teach and assess performance according to their own strictures and requirements. Regular training (mandated by the firm and by the government) can be done either in a real plane or a simulator. On top of this, is a regimen of yearly performance assessment of pilots (by the government regulator) both during simulated flights and actual “line” flights.

Health care, on the other hand, uses intense selection at the level of professional school entry, followed by a long period of “book learning” (mostly of concepts and basic skills), then followed by an intense but haphazard apprenticeship taking

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ince the patient safety movement gained momentum with the publication of *To Err is Human*, health care practitioners have been urged to learn from safety practices in other industries. The aviation industry has been very influential and vocal in exhorting health care to adopt practices such as safety checklists, simulator-based training, and crew resource management training. Other safety critical industries, such as mining, nuclear energy, and the petrochemical industry have also provided lessons.

Reviewing the range of patient safety interventions and practices and parallels in other industries provides compelling evidence that health care has been particularly receptive to learning from experiences elsewhere. Table 1 contains a summary of a range of interventions to improve quality and safety and their links to practices in other industries.

Clearly safety and quality improvement in health care has been influenced by safety practices in other industries. Nevertheless, health care is not as advanced on the safety improvement journey as some other industries and this may be partly attributed to difficulties in successfully implementing the solutions and practices that work in other industries.

To make these practices work in health care, we need to go beyond simply introducing techniques and develop a deep understanding of what is required to make these practices work in practice. Efforts to make these techniques effective are currently hampered by a tendency to only partially implement solutions, a lack of knowledge, and inadequate resourcing. Below, are examples of the challenges of gaining maximum benefit from:

- incident reporting,
- prospective risk analysis methods,
- incident investigation, and
- safety culture assessment.

*Incident reporting* is now firmly established in health care, but recent work has suggested that learning from retrospective incident data to improve safety has been less effective. Many hospitals are overwhelmed by the sheer number of incidents reported and many practitioners feel that learning from incidents is not effective. Implementing improvements and evaluating the effectiveness of interventions are particular problems. These problems highlight the pitfalls of introducing practices from other industries without considering how they would work in healthcare. There is a need for systems and processes that will allow healthcare practitioners to maximize the learning from the incidents they report.

Similarly, *prospective methods* of analysing risk such as Failure Modes and Effects Analysis (FMEA) are commonly used in other industries and are now familiar in health care, especially in the United States. These methods enable practitioners to analyse processes to identify risks and pre-emptively implement changes to prevent harm from occurring. However, many prospective analyses in health care are not systematically conducted and although analyses are conducted sporadically by in house practitioners there are few attempts to conduct the ongoing analyses that could generate deep knowledge about the system. In other high-risk industries, such analyses are maintained as living documents that provide a knowledge base of the system which is updated as the system changes. It is rare to find these methods being used in such a way in health care.

Another example can be found in the use of *accident investigation* and analysis techniques. In health care, root cause analysis is almost exclusively used. But other effective methods, such as MORT (Management Oversight and Risk Tree) and barrier analysis, are rarely used in health care. In other industries, accident investigators call upon a toolbox of methods to find the best method for a given situation. Health care accident investigations are often conducted by staff with limited inves-

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**Table 1**

<table>
<thead>
<tr>
<th>Type of intervention</th>
<th>Examples</th>
<th>Other industries</th>
</tr>
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<tbody>
<tr>
<td>Patient safety culture assessment</td>
<td>Tool for measuring culture—Hospital Survey on Patient Safety Culture (HSPC), Tool for improving culture—Manchester Patient Safety Assessment Framework (MaPSaf)</td>
<td>Nuclear, Offshore oil</td>
</tr>
<tr>
<td>Quality improvement methods</td>
<td>Lean, Six Sigma, Rapid cycle change (PDSA)</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>Skills training</td>
<td>Crew resource management, Simulation, Non technical skills training</td>
<td>Aviation, Offshore oil, Rail industry</td>
</tr>
<tr>
<td>Risk management systems</td>
<td>Incident reporting, Prospective analyses such as FMEA, Root cause analysis</td>
<td>Aviation, Chemical, Nuclear, Rail industry</td>
</tr>
<tr>
<td>Error prevention techniques</td>
<td>Surgical safety checklist, Clinical guidelines, Engineering solutions (connectors, interlocks)</td>
<td>Aviation, Process industries</td>
</tr>
<tr>
<td>Monitoring normal operations</td>
<td>Clinical audit, Trigger tools</td>
<td>Aviation, Petrochemical, Process industries</td>
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tigation training who are not always aware of other approaches to investigation that might be beneficial. Other high-risk industries typically devote more resources to accident investigation because it is viewed as a specialized, complex task requiring a high degree of skill.

Although safety culture in health care is now receiving increasing attention from researchers, ongoing measurement of an organization's safety culture is less common. Safety culture is a crucial factor in determining the success of safety improvements and needs to be explicitly addressed in ongoing improvement efforts. In the offshore oil and nuclear industries, baseline measures of safety culture are used as a foundation for ongoing assessment of how the culture is developing. This allows organizations to monitor responses to events and initiatives. Such approaches have the potential to deepen understanding of safety improvement efforts and how to increase their impact.

In conclusion, in health care there is a tendency to implement initiatives without a deep understanding of how to make these practices work and deliver real safety improvements. Learning from safety professionals and human factors practitioners is the key to developing effective practices that are implemented in depth. Adequate resourcing of safety initiatives and an examination of how to gain maximum benefit from the procedures already in place are now required.

References


Care of patients under (variable levels of) supervision. There is little systematic performance assessment. Training mostly ends with completion of residency and/or fellowship period, with a minimal (and variable) state-based requirement of “continuing education.”

To follow the lead of other industries health care should seek to adopt a system of comprehensive integrated continuous and career-long selection, training, and performance assessment of individuals and teams using many different modalities of education, but especially applying the many different techniques of simulation that have proven so important to make high-hazard undertakings safe.

Restructuring Healthcare?

Thus, many of the differences we find between health care and other industries, are not intrinsic to the fact that patient care is different. Health care can, in fact, adopt and adapt very similar kinds of structures and methods to achieve better results. The status quo is a result of historical, political, and economic forces, not the analytical or experience-based consideration of how best to achieve the desired results.

We are currently witnessing the debate over the restructuring of the system of insurance coverage for health care. Perhaps this will provide both the impetus and the mechanisms to tackle reformation of the organizational aspects of clinical quality and patient safety using lessons from other industries whose safe performance we take for granted.

Reference


Suggested Reading

Gaba DM. Out of this nettle, danger, we pluck this flower, safety: Health care vs. aviation and other high hazard industries (editorial). Simul Healthc. 2007; 2:213–217.
What Can Health Care Learn from the Nuclear Power Industry?

by Craig S. Webster, BSc, MSc, PhD

Dr. Craig S. Webster is a Senior Research Fellow at the University of Auckland, in New Zealand.

Modern health care involves the use of some of the most complex and advanced technologies in existence, however, safety practices in medicine have not kept pace with this increasing complexity. Anesthesia is generally considered to be a leader in the improvement of patient safety, yet even here more powerful safety strategies must be found and employed to achieve the threshold improvement in safety recently called for throughout the world.

The analogy of the anesthetist as “pilot” of his or her patient is well established. However, the fact remains that the pathophysiology of a patient connected to a large amount of high-technology equipment and undergoing an anesthetic and surgery, comprises a system that is considerably more complex than an aircraft. From an analysis of such complexity and other system characteristics, I propose an alternative analogy for safety in anesthesia—that of the nuclear power industry.

As with an anesthetized patient, nuclear power plants are highly complex, and their components can rapidly interact in ways that can produce unexpected and dangerous crises. Such events can bewilder the operator, who must deal with crises quickly and under conditions where model-based diagnosis (reasoning from first principles) is often not possible. Such systems are considered functionally opaque because of an inability to understand the system’s behavior despite a detailed knowledge of its components. Confirmation bias often hinders diagnoses of problems for anesthetists and plant operators alike, where an early but wrong interpretation of events leads to further misinterpretation of subsequent information and inappropriate corrective action. In such circumstances “fresh eyes” entering the room can often be immediately beneficial in identifying the true source of the problem. Furthermore, the nuclear power industry can provide useful safety lessons for anesthesia due to the industry having spent vastly more time and money than has health care on the development of safety.

Safety strategies developed in the nuclear power industry since its conception can be broadly summarized into five phases, all of which have relevance to the analogy with safety in anesthesia and each adding more sophisticated and robust safety approaches:

1. *a priori* design of purportedly fail-safe facilities;
2. accident reporting leading to relatively minor equipment and procedure improvement;
3. simulator training to improve operator performance;
4. major system redesign based on in-depth analysis of previous failures (e.g., the design of inherently safer, new generation reactors); and
5. the lowering of the threshold for the reporting of incidents to include many events, other than accidents, that may adversely affect the safe operation of the reactor.

Each phase also indicates changes in the underlying presumptions about the nature of the technology involved. Presumptions underlying Phase 1 were that nuclear reactors were inherently predictable, controllable and therefore safe. Data collected in Phase 2 did not necessarily contradict the presumptions of Phase 1—it probably indicated only that refinements on the Phase-1 designs were required. However, by Phase 4, the *a priori* designs from Phase 1 were viewed as inherently unsafe—thus prompting the design of a new generation of inherently safer reactors.

By Phase 5, however, reactors were considered inherently unpredictable due to their complexity, making them more akin to living things (the antithesis of Phase 1). This means that even the experts’ understanding of the system is incomplete. Therefore, long-term safety improvement at Phase 5 cannot be achieved entirely *a priori*, but can be achieved only through treating the operation of the reactor as an ongoing experiment in which the collection of data allows better understanding and prediction of the system’s behavior in the future.

In its pursuit of safety, the discipline of anesthesia has progressed through Phases 1 and 2 above, and has recently begun widespread employment of Phase 3. However, despite anesthesia being generally considered one of the most safety conscious branches of medicine, it has progressed through these phases considerably more slowly than the nuclear power industry—anesthesia has been in use for over 150 years, while nuclear power generation has existed for approximately 50 years. However, evidence-based system redesign does work—by employing the last two phases, our group has recently demonstrated a 40 percent reduction in drug administration error in anesthesia.

The slower safety progress in anesthesia almost certainly reflects the persistent blame-centered approach in medicine and the fact that disaster in anesthesia, although no less tragic, generally kills individuals one at a time, rather than en masse. Greater emphasis is needed on the cost savings associated with the reduction of iatrogenic harm in order to motivate greater spending on health care safety.

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3. Webster CS. The nuclear power industry as an alternative analogy for safety in anaesthesia and a novel approach for the conceptualisation of safety goals. *Anaesthesia*. 2005;60:1115–1122.
Are Lean and Six Sigma Good Tools for Improving Quality and Patient Safety?

by Susan McGann and Walter Ettinger, MD

Susan McGann is President and CEO of Pivotal Healthcare Solutions, LLC. Dr. Walter Ettinger is President of UMass Memorial Medical Center.

Health systems and hospitals have made significant progress over the past decade towards improving the quality and safety of the care they provide. Nonetheless, there are still disparities in performance and even the best organizations are not consistently excellent. One of the major causes of this inconsistency is variability. Variability is present in practice, equipment, people, and especially processes.

Because the improvement methods used by most organizations have not consistently achieved nor sustained outstanding performance, a few health care organizations have embarked on the use of industrial tools such as Lean and Six Sigma, and have made significant strides in improving quality and patient safety. These tools can be utilized in different combinations, but ultimately attack variation and sustainability.

**Lean**

There are a series of tools under the umbrella of “Lean” that are applicable to the improvement of patient care. The purpose of Lean is to eliminate forms of waste and to constantly pursue perfection while creating continuous flow through a process. Lean strives to decrease or eliminate bottlenecks in processes, many of which can lead to variability and errors, and adversely affect quality and safety. According to Lean methodology, the forms of waste that need to be addressed are:

- **defects**: anything that does not meet a customer’s specification or need;
- **overproduction**: creating too much of anything that is not used efficiently;
- **waiting**: by either patients or staff;
- **not using talent**: putting the wrong people in the wrong jobs;
- **transportation**: when something or someone has to be moved for the next step in the process to take place;
- **inventory**: overstocking of equipment or supplies;
- **motion**: supplies or people not where they are needed resulting in having to go looking; and
- **extra processing or rework**: an activity that takes place as a work around for something else that is broken in the process.

Sound familiar? Lean was developed by Toyota Manufacturing and has been adopted by companies all around the world. This concept is taking hold in health care because of easily identified areas of waste. The process starts with a value stream map, different than a typical process map, but very telling and slightly more complicated to execute. The value stream map looks at bottlenecks in the process along with most of the other forms of waste. This activity provides insight as to where to begin the process improvement activities using additional tools such as Kaizen events, 5S-ing, and shadow boarding to name a few.¹

**Six Sigma**

A more quantitative approach to reducing variability is the Six Sigma methodology. Six Sigma is a set of tools adopted from manufacturing for the purpose of eliminating defects. A defect is any activity that does not meet the needs of the customer or their “critical to quality” specifications. Achieving a Six Sigma level of quality means that the defect rate is three per million. Use of Six Sigma requires that one knows the customer(s) of the process and is willing to ask them what their expectations might be. Six Sigma uses advanced statistical techniques to decrease variation and focus on the variables (identified through multivariate analysis) that most greatly impact the process outcomes. This methodology is rigorous and emphasizes a control plan: processes put in place that prevent backsliding once improvements have been made.

Lean and Six Sigma are not mutually exclusive. In fact, they complement each other well and can be used in tandem in what is called Lean Six Sigma. Using them together puts more tools at one’s disposal which eliminates that adage “when all you have is a hammer, everything looks like a nail.” The combination of Lean and Six Sigma allows an organization to address both qualitative and quantitative problems.

Lean Six Sigma is a set of tools, a means to an end. If a health care organization has a strategic goal of improving performance and reducing variability, Lean Six Sigma may be a method to achieve these ends but the use of these tools is not a panacea. Lean Six Sigma requires a substantial investment in personnel who are experts in the methodology and who facilitate and oversee improvement projects. Moreover, staff and physicians must be trained to use these tools.

Organizations must also commit to robust data management systems so that processes and outcomes can be reliably and accurately measured. Most importantly, the leadership of the organization must make a strong commitment to both achieving outstanding performance in quality and safety and to committing resources to implement Lean Six Sigma and be unwavering in that commitment. Many health care organizations have abandoned Lean and/or Six Sigma because the leaders did not have the nerve to make the investment and stay the course when resistance or other priorities occurred.

**References**

Improving patient safety requires attention to behavior and culture as well as a search for technical solutions. The community of patient safety scholars and practitioners would do well to be equally skilled in selecting the one or more approaches that address both the technical and the social dimensions of each specific challenge.

For example, consider how the following two fundamental patient safety risks have been addressed.

**Anesthesia-induced patient injury**

On April 22, 1982, the ABC TV show 20/20 reported that 6,000 patients were dying or suffering serious brain damage due to anesthesia every year.\(^1\)

Armed with malpractice claims data from around the country, the American Society of Anesthesiologists (ASA) found (in 1984) that anesthesia-related deaths were primarily associated with three mechanisms of injury: 1) inadequate ventilation, 2) esophageal intubation and 3) difficult intubation.\(^2\)

The ASA disseminated the information to its members and funded research and the development of technology to make anesthesia safer. The advent of pulse oximetry and capnography largely eliminated inadequate ventilation and esophageal intubation and the associated malpractice claims. The management of difficult intubations has dramatically improved as a result of widely distributed algorithms and videotapes plus the emergence of simulation labs where proper intubation techniques can be practiced under supervision.\(^3\)

**Healthcare Acquired Infections (HAIs)**

Despite the patient safety benefits of infection control precautions having been promoted for more than 150 years,\(^4\) in excess of 18,000 Americans die every year from invasive hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA) infections; 100,000 survivors of these infections suffer illness, prolonged hospitalizations, and repeated and costly interventions.\(^5\) MRSA colonization and infection rates in the US continue to increase on an epidemic scale and have yet to plateau.\(^6\)

**Defining the Problem and Determining the Appropriate Approach(es)**

Anesthesia-related deaths and HAIs belong to a spectrum of health care-related patient harm that ranges from technical problems to those requiring behavior and culture change. Brenda Zimmerman’s method for selecting the appropriate approach and management actions in the complex adaptive systems of health care applies equally well to patient safety. Based on groundwork by Ralph Stacey, she designed a matrix to help identify approaches to decisions on two dimensions:

- the level of agreement among participants on the approach to be taken, and
- the degree of certainty, based on evidence, that the desired outcome can be achieved.\(^6\)

ASA’s 1984 malpractice claims study generated appropriate technical solutions to problems for which there were high degrees of agreement and certainty. These solutions achieved dramatic reductions in the incidence of anesthesia-related adverse respiratory events. ASA’s leadership, and compelling proof of efficacy, led to universal application of these technical solutions.

There is a large area on Figure 1 which lies between the chaos region and regions of the traditional approaches to simple and complicated problems that influence the quality of care (including patient safety.) Zimmerman calls this large center region the zone of complexity. In this zone, the traditional approaches to improving patient safety are not very effective and could actually cause harm. This is an area that requires innovation and breaking with the past to create new modes of operating.

The relentlessly rising rates of HAIs in the US indicate that traditional approaches to prevention have failed and that these infections are not primarily a technical or knowledge problem, but rather a complex problem requiring social and behavior change. Traditional best practice, industrial (Lean) approaches and regulation and enforcement alone either fail outright or achieve only modest and often transient improvement. The time is ripe for a sociotechnical solution that matches the complexity and nature of the challenge.
Positive Deviance

Positive Deviance (PD) is a liberating behavior and social change strategy. It has been applied with documented success to a variety of complex public health and social problems. PD was first applied in the 1990s in Vietnamese villages by Save the Children’s Southeast Asia Director, the late Jerry Sternin and his wife, Monique. 7

The concept of PD is based on the observations of Tufts University nutrition professor, Marian Zeitlin, that even in impoverished communities, there are families whose uncommon behaviors and strategies enable them to keep their children well-nourished while their neighbors who have access to the same resources do not. The Sternins developed a change process from the theory of Positive Deviance and became its first practitioners and trainers of others. Their approach enabled villagers to reduce childhood malnutrition, which then affected 65 percent of children age five or younger. They approached their work as catalysts with questions rather than experts with solutions. PD’s premise is that solutions to malnutrition already existed among the villagers. Their work began in four communities with a total population of 2,000 children under the age of three, over 65 percent of whom were malnourished.

The Sternins sat at the feet of families to learn from them through discussions and observations. This process enabled the community to define the problem based on their own experience and describe a preferred future that differed from the past. Discussions also uncovered current attitudes and feeding behaviors.

Using existing growth charts created by the villagers themselves, the data were stratified according to economic status. Villagers determined that there were well-nourished children even among the poorest families who had no access to special resources. These were the positive deviant families because they were successful in keeping their kids well-fed by engaging in behaviors that their neighbors did not. Having established that most families fed their children rice two to three times daily, the community with the Sternins discovered that the PD families went out in the rice paddies every morning and gathered fresh water shrimps and crabs and sweet potato greens for their children. These foods were plentiful and readily available to everyone, but conventional wisdom dictated that they were not appropriate for young children. They also fed their children four or five times a day.

Continued on page 10

Which tools should health care leaders consider adopting (or avoid) in their quest to reduce error and improve patient safety?

David M. Gaba, MD

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Simulation: Often portrayed in the media as just the “whiz bang” techno-stuff, simulation is everything from verbal simulation/role playing, to actors, mannequins, and surgical/procedural simulators, including virtual reality and mixed reality. This powerful technique is utilized in almost every human endeavor: rehearsals are simulations; practice games in sports are simulations. Nearly every intrinsically risky endeavor (flying, operating power plants, firefighting) uses simulations extensively. It has many diverse applications in many different parts of health care. I would invite people to become more aware of the many ways it can be used to improve patient care beyond getting novices up the learning curve. See some of the broad scope of how simulation can be used here http://cisl.stanford.edu.

Six Sigma | Lean: Both are highly formal systems of quality management and improvement that are applied throughout work processes. Each has found success in at least some health care settings. The formal infrastructure for these things is very very large, and may possibly outweigh the actual benefit achieved. They are hard to implement incrementally; it seems to be either take the full plunge or stay out of the pool. Six Sigma and Lean require a lot of effort and time of many people in the organization. One might question how much can be gained from adopting some of their principles and activities without adopting the whole package.

Design Thinking: Design trumps training. If a device or a work process is poorly designed, you can try to teach people how to avoid the pitfalls with that device or process, but it will be a losing battle. Bad design is a surefire invitation to make errors and no amount of good intentions or training can guarantee that it won’t happen. So, emphasizing good design—preferably design that is user-centered and proven (e.g., through simulation during the design process)—is a good idea.

Culture Change: Like design, culture usually trumps training and other interventions. You can have evidence-based medicine; you can have exhortations to do things a certain way; you can provide wonderful simulations... but if the prevailing values, norms, and shared practices don’t reinforce those things, then they will never happen. The culture has to value them, make them the norm, and provide subtle incentives to behave “this way” (and subtle disincentives to not behave “that way”). To genuinely change culture, or to create an optimal culture of safety, requires many different techniques from top-down, bottom-up, and sideways-in (so to speak). Frankly, it’s a never-ending activity to try to optimize peoples’ behavior.

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Rather than sharing these local nutritional “secrets” with families who needed help, the Sternins encouraged the villagers to design their own plan for enabling all families with malnourished children to learn these practices on their own. They arranged for the learning families to meet with the resource (PD) families, prepare meals and feed their kids together until the learning families had adopted the successful feeding strategies. Rice was provided. The price of admission for the learning families was that they had to gather and bring shrimps, crabs, and greens. The very people whose behavior needed to change in order to solve the problem acted and became part of the solution. One salient insight of the PD approach is that it is easier to act your way to a new way of thinking than to think your way to a new way of acting.

PD became the preferred approach to preventing childhood malnutrition in Vietnam, where it reduced malnutrition rates by 85 percent. Several other countries in Indonesia followed suit. The newly adapted behaviors were based on proven, successful practices within the community, rather than best practices or theories imported from the outside.

**Positive Deviance and Preventing MRSA and Other Health Care-Acquired Infections**

From 2001–2004, the VA Pittsburgh Healthcare System (VAPHS) adapted the principles of the Toyota Production System (TPS) as a process improvement strategy to reduce the transmission of MRSA infection. This resulted in a dramatic reduction of surgical site infection in two units of the acute care facility over a four-year period.

However, the improvement was difficult to sustain and did not spread beyond these wards. Further, the cost of putting TPS facilitators on the remaining 12 units was prohibitive. Thus, VAPHS sought an innovative approach that could promote and sustain cultural change on a larger scale without requiring a lot more resources. Inspired by reading about PD’s impact in Vietnam, the VAPHS leaders embarked in 2005 on a PD/MRSA prevention initiative to foster support of a staff-owned and operated effort to prevent transmissions hospital wide.

The key components of the VAPHS MRSA bundle—the “What”—include:

1. an aggressive hand hygiene implementation program;
2. active surveillance (nares swabs) on all patients on admission, transfer, discharge, and death;
3. contact isolation precautions for any patient infected or colonized with MRSA (requiring health care workers to perform hand hygiene, wear gowns, gloves and sometimes masks while providing care);
4. environmental cleaning, and
5. ongoing monitoring of process and outcome measures.

The approach to the “How” developed by the VAPHS in collaboration with Sternins, is an asset-based method of identifying individuals and groups within the system whose strategies and ideas enable them to overcome common barriers to consistent adherence to the MRSA bundle and to devise additional practices to prevent MRSA transmissions. This was accomplished by two facilitators who “sat at the feet” of more than 1,000 front-line staff and—using a series of powerful questions—elicited local behaviors, strategies, and ideas for prevention from people in each unit and support service.

This listening process involved staff who come in direct contact with patients and their immediate surroundings; the “touchers.” It also included those who supply and support them. Not only nurses and physicians were listened to, but housekeepers, respiratory therapists, pastoral care givers, dietary workers, and other ancillary service workers, supply personnel, and administrators.

The most innovative solutions came from people on the front lines, some of whom are unlikely suspects. Discovering that they might be a vector for transmission, ministers, as a group, started using disposable paper operating room caps to cover their Bibles when visiting patients in isolation and then disposing of them along with their gown and gloves before exiting the room. PD enabled those whose behaviors needed to change, to self-discover the behaviors and practices that could eliminate transmissions in their area of work. The approach helped front-line staff discover, analyze, design, and implement newly crafted opportunities to practice known microbial transmission prevention strategies and behaviors. Hundreds of participants from all disciplines created thousands of penny solutions. In the aggregate, their solutions achieved dramatic reductions in MRSA infection rates—in excess of 30 percent system wide—that have continued to the present time. HAIs caused by other resistant bacteria have also yielded to this approach (Figure 2).

In the process, VAPHS has undergone a cultural transformation. The leadership group has evolved from having sole responsibility for infection control to providing support and technical assistance for staff-initiated improvements. MRSA prevention has become the focal point for unlikely partners such as the environmental management staff, multidisciplinary clinical staff, clerical staff, patients, and families. This model has been adopted by all VA acute care hospitals with support from their central office in Washington, DC.
The Robert Wood Johnson Foundation funded PD/ MRSA prevention initiatives in six hospitals, including VPHS from 2006–2008. Results were reported at the annual Society for Healthcare Epidemiology of America (SHEA) meeting in March 2009. The aggregate decline in HA-MRSA infection rates was 72 percent with rate decreases from 53–85 percent.\(^9\)

**Epistemology of Patient Safety Strategies: Embracing the Paradox**

Today’s tough health care challenges have simple, complicated, and complex dimensions and may or may not require behavior or culture change.\(^{10}\) Over the past decade, quality improvement and patient safety scholars and practitioners, looking within and outside the health care industry, have developed a rich repertoire of approaches that address these different dimensions. This has enabled health care professionals to achieve dramatic but isolated improvements in the quality of care and reductions in harm to people receiving care. This repertoire currently includes:

- **Defect-based** system redesign strategies: Team-Based Process Improvement (IHC), Rapid Cycle Improvement (IHI), Lean, Six Sigma, TPS, etc.
- **Asset/Strength-based** approaches: complex adaptive system science, e.g., PD, appreciative inquiry, open space technology, etc.

One of the great opportunities for health care professionals is to embrace the paradox of defect and asset-based patient safety strategies by acknowledging that they are generally complementary, not competing. A reasonable approach would include these components:

1. Develop an epistemology of approaches to improvement that include defect-based and strength-based strategies;
2. Understand the nature of patient safety challenges: problems can have simple and complicated technical aspects as well as complex dimensions that require behavior change; and
3. Educate and train health care professionals to be able to define a problem in all of its dimensions, draw from the rich repertoire of current improvement strategies, and apply the appropriate sociotechnical solution(s).

**References**

7. www.positivedeviance.org
Better design will lead to better implementation. Understanding the obstacles faced by systems used in health care—and how they can be overcome—is an important step. Design thinking helps focus on how people interact with their environment, and can be a useful process in determining which interventions have promise, and how to modify those that—initially, at least—appear untenable. The list below is a good starting point.

### 12 Steps to Better Systems Design

<table>
<thead>
<tr>
<th>Obstacle</th>
<th>Imagine if…</th>
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<tbody>
<tr>
<td>You have an uneasy relationship to failure.</td>
<td>• It was OK to fail, provided that you learned from it, shared it.</td>
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<td></td>
<td>• Failure was celebrated (as a form of risk mitigation and institutional learning).</td>
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<td></td>
<td>• You clearly articulated which kinds of failure were acceptable and which were not.</td>
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<td>Change is a struggle.</td>
<td>• You reframed change as &quot;renewal&quot; or &quot;a fresh start.&quot;</td>
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<td></td>
<td>• The opportunity for change brought with it new energy, passion, and commitment.</td>
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<td></td>
<td>• &quot;Interventions&quot; focused on growing the positive rather than starving the negative.</td>
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<td>You routinely accommodate bad design.</td>
<td>• You didn’t settle for or work around poorly designed products and processes.</td>
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<td></td>
<td>• You issued design guidelines / specs to manufacturers telling them what you needed.</td>
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<td></td>
<td>• You partnered with manufacturers to design better tools.</td>
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<td>You keep adding on, not taking away.</td>
<td>• You held a yearly “purge” to eliminate redundant/inefficient/broken/outdated tools and processes.</td>
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<td></td>
<td>• You could only add a new process or tool if you removed one (or two!).</td>
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<td></td>
<td>• Staff assigned every process and tool a grade to prioritize improvement activities.</td>
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<tr>
<td>[Desirability] and [viability] are still optional in this business.</td>
<td>• You couldn’t “in-source” any task that could be more efficiently outsourced.</td>
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<td></td>
<td>• Customers voted with their feet, and stopped purchasing your least well-designed/most inefficient services.</td>
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<tr>
<td></td>
<td>• All services you offered had to show a profit.</td>
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<tr>
<td>Fundamental system tensions are not being addressed.</td>
<td>• Your strategic planning process actually identified and incorporated these tensions? (e.g., $ for sickness/goal of wellness)</td>
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<tr>
<td></td>
<td>• You connected with community and institutional partners to manage tensions.</td>
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<td>You blame one another rather than the system.</td>
<td>• You had time to walk in the shoes of other disciplines/functions.</td>
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<td></td>
<td>• You developed a spirit of interdependence.</td>
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<tr>
<td>You are skeptical of change methodologies and shed them quickly.</td>
<td>• You could only adopt a new methodology if you committed to it for a period of five years.</td>
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<td></td>
<td>• Leadership created measures and incentives to ensure long-term adoption of a methodology.</td>
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<tr>
<td>You don’t couch change in terms of what people care about.</td>
<td>• Those things to be improved were identified and chosen by the people doing the work.</td>
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<td></td>
<td>• Project teams decided what success looked like and how it was measured.</td>
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<tr>
<td>You wait too long to implement. And when you implement, you do it at too large a scale.</td>
<td>• Continuous experimentation replaced implementation/&quot;roll out.&quot;</td>
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<td></td>
<td>• You had to provide evidence of positive change at a smaller scale in order to get resources for increasing the scale.</td>
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<td>You talk too much.</td>
<td>• You held a moratorium on new technology purchases to encourage non-tech solutions.</td>
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<tr>
<td></td>
<td>• You invested more money on fewer technologies.</td>
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<tr>
<td></td>
<td>• You could stop believing in/wishing for miracles cures.</td>
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<tr>
<td>You look for silver bullets, especially technology ones.</td>
<td>• The five rights of healthcare improvement/innovation:</td>
</tr>
<tr>
<td></td>
<td>• The right stakeholder needs are addressed</td>
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<td></td>
<td>• The right “jobs” are performed</td>
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<td></td>
<td>• The right tools are provided for the job</td>
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<tr>
<td></td>
<td>• The right people are engaged</td>
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<tr>
<td></td>
<td>• The right amount of time is allocated for the activity</td>
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How Do Organizations Reach a Single, Widely-accepted “Way” to Address Patient Safety?

Craig S. Webster, BSc, MSc, PhD

Dr. Craig S. Webster is a Senior Research Fellow at the University of Auckland, in New Zealand.

There is no need to aim for a “single way” in order to remove many of the dangerous alternatives and unnecessary complexity which currently exists in medicine. The system of health care, in which patients and clinicians alike are embedded, is sufficiently complex that attempting to identify problem areas a priori is often not the best approach, or at least is a very blunt approach which may only identify some of the most gross problems.

Good quality incident data is one of the best sources of information with which to identify and understand problem areas. Once understood, such areas can then be targeted for system redesign, and ongoing incident data can be used to identify a reduction in undesirable events due to the redesign...thus demonstrating its efficacy. This is an evolutionary process that can be guided by safe system theory in a top-down way, but also needs to be driven by bottom-up incident data. It also does not require a revolution to a new “single safe standard.”

Sweeping revolutions in highly complex systems are frequently dramatic failures because they often underestimate the complexity of the processes involved and do not anticipate negative consequences of revolutionary change itself. Our hospital recently introduced a paperless patient notes system and simultaneously removed all conventional paper-based patient notes. The new system proved so difficult and time consuming to use that clinicians began printing out their own copies of the entire patient record in order to peruse it, rather than trying to read the notes on the computer.

Thus the electronic paperless notes system, at least initially, massively increased the consumption of paper and reduced efficiency by taking more time to use. An evolutionary approach would have allowed both paper and paperless systems to operate in tandem until the bugs were worked out of the new system and the old one could be phased out.

Evolutionary approaches do not preclude the adoption of new standards, all that they require is that the implementation of new standards should not leave patients or clinicians worse off, at any point, than they were under the old way of doing things.

High-fidelity simulation is a very good way to test new innovations for possible negative consequences, as well as being an excellent method for more conventional training. But good quality incident data will still be needed from clinical practice to determine whether the new innovation is functioning as intended or whether it is leading to unanticipated side effects. Single best ways may emerge from this process over time, but they are likely, at least to begin with, to be restricted to well-defined problem areas. There is much ground to cover in medicine before most single-best ways to do things are discovered.

References

1 Webster C.S. Implementing Safety in Medicine—the Problem, the Pitfalls and a Successful Safety Initiative in Anaesthesia. Saarbrucken, Germany: VDM Verlag. 2008.


Additional Reading

by Judith Jaffe, MLS

Ms. Jaffe is Knowledge Manager for CRICO/RMF.

The following additional resources provide lessons from other industries relevant to risk management and patient safety. This bibliography was compiled from the PubMed (Medline) database of indexed biomedical literature published 2000 through 2009 and select web resources.


