# A Culture of Safety: A Business Strategy for Medical Practices

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Physician practices can enhance their economics by taking patient safety to a new level within their practices. Patient safety has a lot to do with systems and processes that occur not only at the hospital but also within a physician's practice. Historically, patient safety measures have been hospital-focused and -driven, largely due to available resources; however, physician practices can impact patient safety, efficiently and effectively, with a methodical plan involving assessment, prioritization, and compliance. With the ever-increasing focus of reimbursement on quality and patient safety, physician practices that implement a true culture of safety now could see future economic benefits using this business strategy.

**KEY WORDS:** Culture of safety; medical practice; physician; patient safety; healthcare environment; culture change; economics; Paul Gluck, MD; Neil Hutcher, MD; Institute of Medicine; PPACA; compliance; assessment.

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Today's healthcare environment makes clinical outcomes and patient safety more important than perhaps ever before to medical practices and physicians. Physicians have always wanted to provide good, safe care to their patients. The 1999 wake-up call, widely-known as the Institute of Medicine (IOM) Report, brought to the forefront that the main causes of the approximately 98,000 preventable deaths per year are systems and process issues. It is clear that the healthcare industry remains aware of and focused on patient safety improvement in iterations spanning the spectrum of related entities. Despite the many steps taken in the right direction, commentators have stated that "these efforts have been insufficient," and patient safety requires major culture change.[1]

Nationally, many organizations and groups have been working to take patient safety to another level. They include the National Patient Safety Foundation, federal government, health insurers, and organized healthcare professionals (medical societies and professional liability insurers, for example). What has become clearer recently is that patient safety can lead to:

- Enhanced outcomes for patients and their families;
- Decreased healthcare costs for patients and payers;
- Increased patient satisfaction;
- Increased employee satisfaction; and
- Decreased liability risk for healthcare professionals.

And in today's healthcare environment, all of the above have an impact on economics.

An opportunity exists for physicians to address patient safety directly in their own practices as well. It is a challenge. Culture change requires impacting healthcare systems and processes; front-line staff, behaviors, and policies and procedures; and your physician colleagues—all on a daily and consistent basis. It requires incremental but consistent change.

This article provides a unique look at the patient safety movement with interviews of two outstanding patient safety experts. One, Paul Gluck, MD, has been at the forefront of patient safety since its inception. He is a past chairman of the National Patient Safety Foundation and one of its founding members. The other, Neil Hutcher, MD, has been a participant and leader in dramatic patient safety changes in the bariatric surgery field. He is the Chairman of the Board of Surgical Review Corporation and its Chief Medical Officer.

## 1999 TO PRESENT: A SLOW START

In 1999, the IOM issued its groundbreaking report *To Err Is Human*, which suggested that most medical errors are a result of a complicated healthcare system, the culture of which lends itself to human error. In complex systems, like

healthcare, where 24-hour/day operations, team coordination, long hours, and other factors exist, the industry inherently possesses a high potential for error.[2] Its authors called for a national focus on medical errors with a five-year goal to reduce such errors by 50%.[2]

The IOM Report prompted significant activity in the following years, and patient safety made some strides forward. They included the creation of the Agency for Healthcare Research and Quality (AHRQ, 2001) and a Center for Quality Improvement and Safety;[3] the National Quality Forum's serious adverse event list (2002);[4] JCAHO's national patient safety goals (2003);[5] and the creation of the National Patient Safety Foundation.[6]

Despite these and similar activities and initiatives, progress was reported as slow, with one prominent report giving overall efforts in the five years following the IOM Report a "C+."[7] Another article stated, "[T]he groundwork for improving safety has been laid in these past five years but progress is frustratingly slow."[8]

Slow progress continued to the 10-year mark. What was previously a "C+" was upgraded to a "B-," citing "striking improvements in reporting and leadership" but deficiency in utilization of health information technology and accountability.[9] During this time Congress passed the Patient Safety and Quality Improvement Act of 2005.

## THE STRIDES SEEN IN THE DATA

According to the most recent data, the annual cost attributable to medical errors is estimated at $19.5 billion, or about $13,000 per error.[10] However, there are signs of gradual improvement. The overall improvement rate in healthcare quality is about 2.3% per year.[11] Data released in 2010 and 2011, for instance, are as follows:

- The percentage of adult surgery patients who received appropriate timing of antibiotics improved from 74.9% to 91.4% between 2005 and 2008.[10]
- From 2004 to 2007, the rate of deaths following complications of care declined from 128.9 to 105.7 per 1000 admissions of adults ages 18 to 74.[10]
- From 2004 to 2007, the inpatient pneumonia mortality rate decreased overall from 55.2 to 40.8 per 1000 admissions.[10]
- From 2005 to 2008, the proportion of heart attack patients who underwent procedures to unblock coronary arteries improved from 42% to 81%.[12]
- Average patient safety culture composite scores on the AHRQ 2011 Hospital Survey on Patient Safety Culture increased by 2 percentage points over approximately 20 months.[11]

Unfortunately, troubling trends continue as well:

- From 2004 to 2007, the overall rate of postoperative sepsis increased from 13.2 per 1000 discharges to 15.8.[10]
- From 2005 to 2007, there was no statistically significant change in medical adverse events associated with central venous catheter placement.[10]

We know that systems issues continue with handoffs, test tracking and notification of abnormal test results, and so on.[10]

## AND THEN CAME PPACA

The recent inertia began around 2008, when the Centers for Medicare & Medicaid Services (CMS) stopped paying for care required as the result of "serious preventable events" occurring in the hospital setting under Medicare.* Then, in 2010, came the big push. Congress enacted The Patient Protection and Affordable Care Act (PPACA); and soon thereafter, Accountable Care Organization (ACO) regulations were promulgated.

PPACA contains myriad provisions aimed at improving the quality of healthcare, reducing errors, and improving patient safety that include mandated data-driven testing of performance, new centers, demonstration projects, and funding.[14] For example:

- Creation of the Center for Quality Improvement and Patient Safety to "identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in healthcare quality, safety, and value";
- The publication of patient safety ratings related to certain quality data points. Pursuant to this mandate, beginning in October 2011, CMS officials began publishing patient safety ratings for U.S. hospitals on its Hospital Compare Web site; and
- Creation of the Medicare Shared Savings Program, which "promotes accountability for a patient population," coordinates care, and maximizes quality and efficiency through ACOs. ACOs can share in Medicare savings achieved through attainment of metrics associated with those goals, which include 33 quality measures broken into four domains: Patient/caregiver experience; care coordination/patient safety; preventative health; and at-risk population. Simply stated, the ACO program uses financial incentives to improve patient safety.

Whether PPACA remains or not, the impact of it will be a continued trend of tying outcomes to reimbursements, rather than volumes to reimbursements. Commercial insurers, self-funded employers, and others have accelerated in this area already.

*At least 23 states have now adopted similar policies as well.[13] And on June 30, 2011, CMS published a final rule requiring that states implement nonpayment polices for provider-preventable conditions including healthcare-acquired conditions and other provider-preventable conditions, pursuant to the requirements of PPACA Section 2702. As such, beginning in 2012 it would no longer reimburse hospitals for care associated with "provider-preventable events" rendered to Medicaid patients.

### A Call to Action

With this background, it is more important than ever for physicians to collaborate and to create processes and systems to enhance patient care and outcomes. However, even with the 1999 Institute of Medicine Report and its call to action, progress has been slow. In looking back at all the great work done to date, why hasn't there been significant change? The authors believe it is due to a lack of a true safety culture within organizations, from the start. While various initiatives and changes here and there can have an impact on certain areas of care, the missing piece for the long-term success in patient safety change and outcomes is a *safety culture.*

## MAKING IT WORK IN PRACTICE

What is a *safety culture?* It is the overall attitude, beliefs, perceptions, and values that not only an organization exhibits but also that the organization's employees exhibit in relation to safety on a consistent basis. It permeates throughout every part of the organizational structure and services.

As Gluck explains (see box on page 240), the concept of patient safety over the years has truly taken hold; however, the question remaining with many institutions and physicians is how do we accomplish this? Teamwork, systems and process changes, employee education, and collaboration are key. It is the steps taken (actual actions) after an organization realizes what it must do to enhance safety that are critical to ensuring change.

## BARIATRIC SURGERY: A SUCCESS STORY

The field of bariatric surgery is a testament to the ability to successfully impact patient safety through a comprehensive program of safety. A decade ago, in the midst of a professional liability crisis nationwide and a lack of affordable insurance coverage for bariatric surgeons, severity of claims had risen steeply, and the median verdict for medical malpractice claims exceeded $1 million for the first time. Nationwide trends saw increasing severity and, in some states, a concurrent increase in frequency as well.[15]

Recognizing a crisis and the need to maintain a specialty that is important to a large population of patients, the bariatric surgery field responded. Research revealed that the risks associated with bariatric surgery had been generally misperceived and, more importantly, that the risks that did exist could be affected positively.[16]

In 2004, the American Society for Metabolic and Bariatric Surgery established the Bariatric Surgery Center of Excellence (BSCOE) program to recognize physicians and facilities providing superior care.[17] In conjunction with BSCOE, in 2007 the Surgical Review Corporation created the Bariatric Outcomes Longitudinal Database (BOLD) to ensure ongoing compliance with BSCOE and to develop general knowledge about optimal bariatric surgery practices.[17]

In 2006, CMS issued a National Coverage Determination that expanded coverage for numerous procedures including laparoscopic and Roux-en-Y gastric bypass and restricted reimbursement for bariatric surgery to accredited centers, recognizing that surgeries done in a BSCOE resulted in shorter lengths of stay and lower overall complication rates.[18] Success in patient safety in bariatric surgery continued.

The results have been dramatic. Numerous studies have established mortality rates in bariatric surgery at 0.3 to 0.8%.[19-21] Compare that with BSCOE, where from 2007 to 2009 mortality rates were 0.05% in-hospital, 0.09% after 30 days, and still only 0.11% after 90 days.[22,23] Mortality was reduced by more than half through strong commitment to patient safety.

As Hutcher explains (see box on page 242), the results in bariatric surgery are due to a change in culture.

## OBSTETRICS: AN OPPORTUNITY

The obstetrical field is following a trajectory toward patient safety similar to bariatric surgery. As recently as 2009, obstetric cases were the most expensive claims of all medical specialties, accounting for 14% of claims but 32% of dollars paid.[24] Efforts to improve patient safety and reduce claims began more than a decade ago, but significant recent progress represents a turning point in the industry.

In multiple studies and implementations, comprehensive safety planning has been shown to have a positive and substantial impact on patient safety. In one study between 2004 and 2006, incremental introduction of multiple patient safety interventions including outside expert review, protocol standardization, the creation of a patient safety nurse position and patient safety committee, and training in team skills and fetal heart monitoring interpretation led to a 43% reduction in adverse outcomes based on 10 indicators and improvement in the perception of safety climate.[25] The study's authors argue that a combination of evidence-based standardization, enhancements in communication, and a dedicated patient safety nurse are integral to their success.[25]

In a more recent implementation, multiple safety plans were introduced from 2007 through 2009, including team training, electronic fetal monitoring educational courses, multidisciplinary teaching rounds, obstetrical emergency simulation, and evidence-based protocols.[26] Results included:

- Management of abnormal heart rate tracings increased from 53% to 93%.
- Documentation of obstetric hemorrhage increased from 45% to 100%.

## Paul Gluck, MD

Obstetrician Paul Gluck, MD, is a recognized leader in the patient safety movement who has written and spoken on the topic for more than 15 years. Gluck was a founding member of the National Patient Safety Foundation and is the past Chair of its Board of Directors. Recently, Gluck shared some of his thoughts on the patient safety movement:

**On the current state of patient safety:**
"Despite efforts on many fronts, broadly speaking, there has been no measurable improvement in patient safety since the 1999 report. We have seen pockets of success such as the Keystone Project in Michigan, but recent studies substantiate that widespread improvement in patient safety still requires a great deal of work."

**Has anything changed?**
"When we used to talk about patient safety, people would say, 'What's that?' Now the question is, 'How do we do it?'"

**So, how do we do it?**
"The concepts of patient safety are things such as teamwork, communication, standardization, and hand washing, simple especially when compared with clinical work. To achieve implementation and sustainability of patient safety, the key is a culture change. And culture change requires strong leadership both administratively and clinically."

**What are the barriers to widespread adoption of patient safety principles?**
"Four main hurdles make culture change difficult:

1. Lack of leadership within the institution or practice;
2. Hesitation to understanding the economic benefits such as reduced litigation and increased efficiency, even when taking costs (e.g., electronic medical records) into account;
3. Culture change requires not just individuals, but fixes to systemic defects with negative effects on patient safety; and
4. Practitioners are not taught interdisciplinary teamwork. Physicians need to learn to work with nurses, and nurses with pharmacists, and so on."

**Where have these barriers been overcome?**
"Examples of great work can be found where great leaders drive culture change. These include places like Cornell University, Columbia University, University of Michigan, and Johns Hopkins University. Another example was the MedTeam study, in which team skills were implemented in labor and delivery departments in a number of very different hospitals. Training in leadership, communication, situational awareness, and mutual support (asking for and offering help) led to reduced risk, better outcomes, and improved satisfaction for both patients and staff. Yet another was the standardization of the use of oxytocin in the labor and delivery departments of a large hospital group. This simple step dramatically improved their outcomes."

**What can I do if I'm not a leader in my organization?**
"Whether you are a designated leader such as a chief medical officer, chief nursing officer, department chair, or not, in a clinical sense all physicians are leaders. I am very fond of a quote from Krause and Hidley's *Taking the Lead in Patient Safety* [John Wiley & Sons, 2009], which states, 'The doctor who doesn't think that his or her professional identity encompasses a leadership role in patient safety is part of the problem.'"

**What does such a leadership role entail?**
"A physician's leadership, whether explicit or implicit, means we all have a responsibility to work toward improving patient safety. It means holding people accountable for adherence to safety practices even if the outcome isn't bad but remembering that a bad outcome does not make someone a bad person. It means allowing yourself to be open to changing your habits to allow for broad cultural change in your organization and modeling that change to improve patient safety.

"Widespread improvements in patient safety can only come when designated and clinical leadership come together to change the culture. We haven't done as well as we'd like to do, but with simple steps and a collaborative spirit, we can make dramatic progress."

- The number of deliveries with adverse outcomes decreased by more than 50%, from 104 in 2007 to 59 in 2008 to 41 in 2009.
- Staff perception of safety improved from 55% positive to 77% positive.
- Patients' perception of whether staff worked together improved from 80% to 90%.

Other comprehensive patient safety initiatives have produced similar results.[27,28] Most recently, the department of obstetrics and gynecology at the New York Weill Cornell Medical Center published results of its implementation of a comprehensive obstetrics safety program from 2003 to 2009. For the first time, a comprehensive obstetrics safety program was tied to economic savings. Its initiatives included electronic medical record charting and templates for high-risk events, chain of communication policies for labor and delivery, standardizations and use of checklists, and performance of obstetrical emergency drills, among others.[29]

The patient safety program produced dramatic results. Sentinel events and adverse outcomes steadily declined from 1.04 per 1000 deliveries in 2000 to no sentinel events at all in both 2008 and 2009; and over the final six years of the study, there were no maternal deaths on labor and delivery.[29] Another significant consequence of the program was that yearly obstetric patient payments in 2009 represented a 99% decrease from the 2003 to 2006 average (from $27,591,610 to $250,000). In fact, for the first time in a decade there was no professional liability suit initiated involving a possibly brain-damaged infant in either 2008 or 2009.[29]

Obstetrics is poised to make a leap in patient safety outcomes. The data exist. The hard part is making it happen, and making it happen for the long-term. The obstetrical field and medical practices can learn from the past to understand how to most effectively achieve a rooted patient safety culture.

## HOW YOU CAN DO IT TOO

Undoubtedly, the resources and infrastructure of a hospital or health system are different than those of a medical practice. This does not mean, however, that medical practices can't incorporate a patient safety infrastructure and also receive the same advantages that inure to hospitals that have a patient safety culture. It just means that the process and plan for achieving the same need to be different.

Your process should include:

1. Realistically assess your safety culture.
2. Create a prioritization plan with incremental goals and metrics.
3. Seek compliance.

### Assessment: What Is Your Patient Safety Culture Level?

The authors are aware of a simple tool that you can use to get an initial baseline understanding of your safety culture status. The brief quiz will help with your discussions with leadership and others that must be on-board with the concept and to gain funding needed to execute on your new safety culture. For example, the quiz may ask:

- Do you have a designated patient safety professional in your medical practice?
- Do you have an annual in-service on patient safety?
- Do you use a test-tracking tool that ensures timely receipt of patient test results and timely notification to patients of abnormal test results?
- Does your practice have a three-year patient safety plan that includes patient safety goals?
- Does your practice use e-prescribing?

In short, the survey provides a vehicle for you to bring the concept of patient safety culture to the forefront of your medical practice. There are also many organizations that provide on-site patient safety culture evaluations in an objective fashion. Only through objective reviews can you truly drill down on your medical practice. Obtaining an outside review also mitigates the amount of personnel and internal resources that your practice would otherwise have to devote to this process.

### Implementation Plan: Incremental, with Prioritization and Metrics

The implementation piece is the one often missing from the patient safety story, and one of the hardest things to do. Implementation is strategic and methodical. It will not happen overnight, nor should it. The greatest successes occur with medical practices that implement gradual change as different components of the implementation plan take root and become part of the norm.

*To be effective, change needs to be incremental.*

However, in this step of the process, we must continue to recognize the resource limitations of a medical practice, although the same recommendation for incremental change is what hospitals and healthcare systems use as well. To be effective, change needs to be incremental.

By *incremental*, we mean establishing long- and short-term plans for pursuing changes in care and processes/systems that relate to the areas identified from the assessment. What will you do in year 1? What will you do in year 2? And then how will you implement those changes in year 1? Stay focused on the discreet two or three items that are part of your year 1 plan. Often, outside consultants conducting the assessment will provide you with some thoughts on prioritization. You must make sure this advice fits with your organizational needs, resources, and priorities.

Importantly, the initiatives pursued and put into place must include metrics. Otherwise, it is the definition of insanity: doing the same things over and over again either for no reason or without the needed and anticipated results. You have to be willing and able to make changes if the metrics tell you that something is not working.

### Compliance: Require It

Certainly the patient safety culture is a team concept; one person cannot make it happen. The oft-asked question following almost any assessment review is, "How do we make sure that our colleagues are committed and do this?" It's a good question, with the corollary issue being that many groups have one or two "naysayers" who at the outset the organization is concerned will not participate; without them on-board, the success of the whole group is impacted.

## Neil Hutcher, MD

Neil Hutcher, MD, is a world-renowned leader in the advancement of bariatric surgery and Centers of Excellence (COE). He is the current Chairman of the Board of Directors and Chief Medical Officer of the Surgical Review Corporation, the global leader in designating bariatric surgery COE. Below is an interview with Hutcher on the topic of patient safety.

**What is your impression of the current state of the patient safety movement?**
"There has been a significant focus on patient safety since the 1999 Institute of Medicine report. Things have improved, but they are still not where they should be. It's one thing to develop guidelines, processes, and best practices, but it's another to build a patient safety culture. We still have a long way to go."

**What positive steps have been taken?**
"The medical community is aware of hot-button issues such as medication administration, patient identification, blood transfusions, wrong-side surgery, the use of electronic medical records, etc. Actions related to those issues have been undertaken to develop specific processes and procedures, utilize checklists, and improve the use of technology. Those actions have had a positive impact and some represent major culture changes."

**Why hasn't there been more improvement?**
"It is important to remember that culture change takes time. Physicians must embrace knowing what they don't know, and people need to be taught not to be afraid to report errors. 'Upward escalation' is key; nurses and other staff cannot be intimidated about reporting up."

**How do you do that?**
"All people who impact patients must be involved and invested in patient safety, from the department chair to the housekeeper. Clinical transformation requires utilization of everyone to improve patient safety."

**That seems so simple . . .**
"Of course it is not as simple as it seems. However, there are simple steps that can be taken that have a significant impact on patient safety. For example, in a surgical setting everyone is wearing gowns and masks, so they get hot and want the air conditioning turned up. However, we know that if a patient's temperature drops during surgery that there is a greater likelihood of infection. Providers' interests must be aligned to focus on the patient's interests first, and the tension between provider comfort and patient safety eliminated. The outcomes will speak for themselves."

**Can you provide another example?**
"Standardization has been a key contributor to safety in bariatric surgery. Using the data collected, bariatric surgery standardized patient clinical guidelines and processes and procedures, and based those standards on evidence-based data. Organizations like Surgical Excellence, LLC, are helping bariatric programs throughout the country to incorporate these proven guidelines that enhance patient safety and outcomes."

**How has patient safety improved in the field of bariatric surgery?**
"The processes developed by bariatric leaders and the requirements subsequently set for Bariatric Surgery Center of Excellence (BSCOE) resulted in practitioners providing bariatric surgeries that are committed to excellence and on-going maintenance of quality of care, resulting in an incredibly safe set of outcomes."

**Have the successes in bariatric surgery provided broadly applicable lessons?**
"Absolutely. In fact, 8 of the 10 principles developed for BSCOE are applicable to all medical work. They have already begun to be implemented in minimally invasive gynecologic surgery as well as other disciplines."

**What key points should be kept in mind when considering patient safety improvement?**

1. "People at all levels must be involved from the beginning and feel invested—change cannot be simply mandated from above.
2. Using data is crucial. Standards without monitoring are ineffective, but when data are recorded, analyzed, and used to make changes, outcomes improve in every instance.
3. Be open to knowing what you don't know. Admit to problems, address the problems, and then deal with the outliers."

One strategy hospitals have used, which medical groups are now also beginning to use, is the concept of a "compact"—an agreement between leadership and physicians that sets aside past issues, concerns, and disputes and starts a new journey with a group committed to patients and patient safety. The compact is customized to address key factors of a particular institution. For example, areas of importance may include respect, excellence, and integrity, among others. Medical practices have reported a true change in culture with the use of these compacts.

The authors recommend taking the compact a step further by adding the staff of the medical practice to the compact. It will then truly be a team effort. If a team member is unwilling to do so, you are able to deal with that at the

front-end of your process rather than finding out when it is too late that certain professionals are not on-board with the safety culture. Hospitals are beginning to incorporate the compact into physician recredentialing and reviews.

Beyond the initial expectation-setting process, you do need to ensure that the changes that were put into place are being done on a consistent and regular basis. Larger practices can handle this auditing task internally; however, some practices hire outside consultants to conduct regular audits (yearly). In addition, there are new electronic means for ensuring compliance that take the administrative piece of this process off the practice's plate. It also requires participation by the practice members and can act as a good educational tool to reinforce the safety measures and need to be complying with those measures.

## CONCLUSION

Practices find that with a rooted patient safety culture and ongoing commitment, they achieve many of the benefits noted earlier in this article. It is anticipated that these same practices will be a step ahead of their colleagues who have not rooted such a culture, as the healthcare environment continues to evolve into a pay-for-performance reimbursement model from the old volume-based reimbursement model.

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