Changing the State of Today’s Health Care Quality and Safety

Six experts shared their lessons learned and addressed the state of patient safety. On November 9th, 2006 they discussed safety initiatives, operational improvements, pay for performance and professional liability issues. The speakers shared some practical approaches to reform health care.

The Business of Patient Safety

“All men make mistakes, but only wise men learn from their mistakes.” —Winston Churchill.

When it comes to handling mistakes, health care should take a lesson from the highest performing organizations in the industrial sector, according to Steven J. Spear of Massachusetts Institute of Technology.

Companies like Alcoa, the world’s largest aluminum producer, and Toyota, the world’s second largest automaker, make developing a culture of superlative safety a priority. They learn from mistakes and take action against repeating them. “Alcoa experienced a sea change in attitude, recognizing that the industry was not inherently dangerous,” said Dr. Spear. “It was how complex processes were being run that made them a threat to human life. In the same way, health care seems to have a vast gap between the breakthroughs in medical science and the overall quality of health care system performance.”

Alcoa, Toyota and others learned the importance of quickly analyzing why glitches occurred and implementing corrective measures. “Their approach is to see the problem as it happens, solve the problem, broadcast their findings and ensure company-wide follow-through,” said Dr. Spear.

Dr. Mark Chassin, Executive Vice President for Excellence in Patient Care, at Mount Sinai Medical Center agreed that health care safety ratings pale in comparison with most other complex, high-risk industries. But he adds that attitude and approach are a large part of the problem too. There’s an unrealistic expectation of perfection. According to Dr. Chassin, “When we look at adverse events, we find that there really is no smoking gun. It’s more like the domino effect where multiple individuals make multiple errors, challenge multiple defenses and ultimately cause harm to patients.”

This domino effect is compounded by tendencies for the health care community to ignore or work around problems, rather than address them head on. Dr. Spear stressed the necessity for health care organizations to change this mindset and, “…make it easier to get it right and excruciatingly difficult to get it wrong.” By analyzing the what, who and when of each process, organizations can redesign problematic patient/procedural flows to improve safety and efficiency.

Dr. Spear illustrated these points with several examples. By analyzing and changing their pre-op patient flow, the staff in preambulatory surgical nursing was able to cut processing time for registration and chart work by 80–85% and completely eliminate redundant blood bank and lab reporting. Allegheny General Hospital experienced similar success with central line associated blood stream infections (CLABs). In one year, by changing day/night shift procedures and processes for line placement and maintenance, infections dropped 84%; and associated deaths dropped from 19 to 1. Following similar approaches of rapid problem solving and process redesign the Pittsburgh health care community as a whole had a 68% reduction in CLABs.

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Enacting Quality Initiatives

"Unless there is a crisis, efforts to change are painfully slow as health care leaders typically respond to regulations, then economics and lastly professional standards," said Dr. David Shulkin, CEO of Beth Israel Medical Center. But he sees another impediment — consumers not demanding better care, primarily because it is still difficult for them to assess institutional quality.

Dr. Shulkin advocated publishing quality measurements and granting public recognition as dynamic motivators for organizational improvement. He observed a trend of consumers evaluating quality treatment alternatives on a global scale. Web sites such as Planet Hospital promote medical tourism and Hospital Survival Guides increase consumer awareness. To address quality and safety issues at Beth Israel, Dr. Shulkin courts meaningful patient/family involvement through shared care plans. For example, "power boards" are available in each room to post a patient’s personal preferences for care.

Another safety issue Dr. Shulkin addressed at Beth Israel is improving physician behavior. He sees Pay for Performance (P4P) as a solid motivator. "Doctors are competitive, they want to be on the ‘good’ list and earn money for it," said Dr. Shulkin. "But for P4P to be 100% effective, it must represent at least 18% of a doctor’s income; anything less is meaningless. We also have introduced formal gain sharing with physicians as a means for rewarding high performance."

The leadership at Beth Israel implemented several changes in the area of safe best practices. "Our 225 plus rapid response teams for handling codes and cardiac arrests have managed to cut codes in half. And while it may be controversial, we’re giving patients the ability to call for a team," said Dr. Shulkin. "With our innovative Red Rules (see Red Rules at left), anyone can stop an unsafe process in its tracks. We’ve also conducted extensive teamwork training to get personnel working together and address our 43% rate of closed cases involving teamwork errors."

Dr. Chassin also targeted staff mentality at Mt. Sinai. He addressed health care quality by expecting every-
one at the hospital to observe three imperatives: trust, report and improve. “These goals are interdependent; you must be able to trust to report. When you report, you expect to see action taken. And when you see things change and improve, it reinforces your trust in the system,” said Dr. Chassin.

The final imperative — to improve — entails acting on reported incidents, pinpointing causes and tailoring and sustaining specific interventions. Mt. Sinai uses the Six Sigma Quality Improvement program to teach and deploy tools for enacting these changes. Despite their progress, Dr. Chassin said, “When it comes to safety, the health care industry still has a long way to go in terms of grasping the magnitude of the challenge, agreeing on the need for change and identifying role models and tools to carry out the effort.”

Echoing Dr. Chassin’s approach, Dr. Shulkin said enacting sweeping reforms in health care quality and safety usually requires changing an organization’s culture and structure. “It’s essential to develop a healthy culture with open communication, a sense of ownership and a policy of no secrets/no excuses.”

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Trust is an expectation of professionalism. There must be clear, enforced standards with a no-blame policy for most situations and discipline for egregious errors and intimidating behaviors. Mt. Sinai encourages reporting anything that compromises patient care, including malfunctioning equipment; poorly-designed or implemented processes and protocols; adverse events; and near misses. “Learning begins with reporting,” said Dr. Chassin. “A high-reliability organization focuses on near misses and close calls because they are often the early warning signs that a process is ‘broken.’ To show you how far we’ve come, we hold very popular weekly M, M and M sessions (Morbidity, Mortality and Misses).”

The Health Care Dichotomy

“Modern health care is a victim of its own success. We have amazing technological potential with scientific advances that can improve care quality, access, ease and safety; balanced against actual performance that is marred by errors, delays, injuries and even deaths. Some of the highest performing organizations in health care as well as other industries across the country have successfully reduced rates of error and injury by 90% and more, while cutting costs and burdens on staff. They have done so by adopting a process-based approach.”

—Steven Spear
Consequences of the Quality and Information Technology Revolutions

A noted physician, teacher and author sounds off on the current state of Quality Measurement and Pay for Performance but expresses confidence in the future of these patient safety trends.

Medicine is not the only industry that gets it wrong. Dr. Robert Wachter, the conference’s first keynote speaker, recounted a BBC broadcast intended to be a live interview with a leading IT expert, Guy Kewney, to discuss a trademark dispute involving Apple computers. The interview is well underway before the journalist realizes he’s interviewing the wrong Guy, literally. The producers mistook Guy Goma — a man waiting for a job interview at the television station — for Guy Kewney and put him on-air. Dr. Wachter’s point? “Glitches happen everywhere, the difference is that the BBC ends up with egg on its face, and we kill people,” said Dr. Wachter. “Our stakes are higher. But this particular example, with its breakdown in communication and verification, resembles situations we see in health care every day.”

“Most providers want to do well, which can often be enough to catalyze action.”

Robert Wachter

Mega-Trends for Patient Safety and Quality

The health care community is experiencing two mega-trends that dovetail with patient safety, namely, the push for Quality Improvement (QI)/Pay for Performance (P4P) and the implementation of Health Care Information Technology (HIT). Although these trends are generally positive, Dr. Wachter argued they can have unforeseen consequences that may actually harm the quality of patient care. “Many view P4P as inevitable; I think it’s more like the flavor of the month,” said Dr. Wachter. “Change is possible without P4P. Once we begin to measure quality and science gets better, we can do a lot of things with the data; P4P is only one example. Other alternatives to achieving quality include relying on a sense of physician/institutional professionalism and motivation to do well, using reputation and shaming, and even channeling patients to higher quality providers.” He questioned the incremental value of paying differentially over simple transparency. “Most providers want to do well, which can often be enough to catalyze action,” said Dr. Wachter.

Dr. Wachter illustrated his point with a 2002–2004 study of US hospitals that found simple public reporting, without P4P, doubled performance measurements for pneumonia management techniques such as the pneumococcal vaccine (pneumovax) and smoking cessation counseling. It also shows similar quality improvements for acute myocardial infarction measurements. “The point is, if this had been started as a P4P experiment, we’d be touting that as evidence of proof of concept,” said Dr. Wachter. “Yet, comparative data suggests that simple transparency and other strategies can work with much less hassle and administrative costs.”

Even if P4P doesn’t last, quality measurements are here to stay and will transform health care institutions in some profound ways. “We are entering a new era where reputation will be forged through publicly reported data about quality,” said Dr. Wachter. “Case in point is the annual release of U.S. News & World Report’s Best Hospitals. While the methodology is light and mostly reputational, institutions are quick to flaunt their good rankings on the list. They also want to protect that image and will work hard to dispel any negative quality indicators. When my hospital, the UCSF Medical Center — one of “America’s best hospitals” — ranked in the lowest percentile for pneumovax administration, we rallied the troops by appealing to their pride and competitive spirit, and raised our rate to 90% by the next year.”
It’s important to be mindful of the consequences of these quality measures. If we “play for the test,” what happens to things that are not measured? Clearly, for patients with complex illnesses, the standard approach to treatment and related quality measures may need to be tweaked to improve safety. Dr. Wachter pointed out, to sustain value, the quality model must constantly adapt to new information.

“Many consequences of the IT and quality revolutions are actually foreseeable and should not be used as an impediment to change.”

Robert Wachter

The Tipping Point for HIT

Dr. Wachter also tackled HIT and Electronic Health Records (EHRs), the key focus of last year’s annual conference. He noted that this trend has reached the “tipping point,” where institutions can no longer resist the need for computerization. However, he does warn that electronic health care systems, in particular Computerized Prescription Order Entry (CPOE), should never be viewed as a safety cure-all. In fact, after implementing HIT, many institutions have reported a whole new set of patient safety consequences and errors. In one famous case, Cedars-Sinai Medical Center in Los Angeles, California, the system was shut down shortly after its launch, at a cost of tens of millions of dollars. According to Dr. Wachter, there are only a few published HIT success stories, mainly because of a shortage of well-designed off-the-shelf systems, little opportunity for organizational customization, a lack of process integration and cultural buy-in, poor training and support, and the perceived threat to clinical control.

The biggest is the “shift in the locus of clinical control from individual physicians to central entities,” that HIT will bring, particularly as decision support is implemented. “It will be critical to find the ‘sweet spot’, balancing the value of guidelines and mandates to hardwire evidence-based practice with physicians’ individual practice styles and desire for autonomy,” said Dr. Wachter. He predicted that few institutions will repeat Cedars-Sinai’s mistake of building in lots of alerts and guidelines at first. “Computer systems will start out as user friendly as possible and gradually build-in added controls and guidelines, but do so in a way that doesn’t instigate a doctors’ revolt.”

In closing, Dr. Wachter conceded, “Many consequences of the IT and quality revolutions are actually foreseeable and should not be used as an impediment to change; with change comes opportunity and in the end, patients are likely to benefit from the improvements.”

In September 2006, Dr. Wachter interviewed Dr. James Bagian, (see page 6) about his views on a number of patient safety issues. For more on this insightful conversation, visit In Conversation with…James P. Bagian, MD on the WebM&M AHRQ Web site at: http://www.webmm.ahrq.gov/perspective.aspx.

For more from Dr. Bagian see the story, Structure Is Key To Safety on page 6.
Patient safety is not a new issue. Dr. Bagian, the second keynote speaker at the conference, looked at studies and reports from the past 40 years, and questioned the concept of preventable injuries. “Shouldn’t all patient injuries be preventable?” he asked. “Perhaps we aren’t trying hard enough.”

Looking at health care, many problems stem from its cottage industry mentality with total reliance on individual responsibility, perfection and the tendency to “train and blame.” “Health care is culturally different from other industries,” said Dr. Bagian. “No one has had systems engineering training, so there’s little understanding of systems relative to people and processes.”

To provide a framework for understanding, Dr. Bagian outlined the significant studies that have been conducted, particularly highlighting the landmark Institute of Medicine (IOM) report in 1999. This report identified six key patient safety and quality of care goals for health care providers: Safe, Timely, Effective, Efficient, Equitable and Patient-centered. (See Sidebar for more information on STEEEP.)

A common approach to these goals has been to react with a slew of new policies, regulations and reporting systems. But, Dr. Bagian believes too often these goals are unclear, lack relevance to stakeholders or do not have leadership backing. As a result, goals are lost during implementation and follow-up, making it difficult for institutions to support and sustain these safety initiatives. In contrast, successful safety systems value the role of reporting, focus on systems-based solutions and emphasize the importance of learning from close calls.

To illustrate, Dr. Bagian drew parallels between early aviation and health care today. “Initially, the aviation industry lost more planes to training accidents than flew on regular missions,” said Dr. Bagian. “The life expectancy of an airmail pilot was just three years. Today’s aviation is a high-reliability industry that values reporting and communications debriefing. It requires a complete safety check process before every flight. Think of the possible improvements if health care consistently applied a similar approach in the OR, with pre-operative checklists, candid team communication, and post-surgical debriefings on a procedure.”

Fault is the ‘F’ Word

According to Dr. Bagian, the guiding principles for a successful patient safety system must focus on learning not accountability. Lack of awareness and shame are the biggest hurdles. Corrective action should focus on what and why, not on who’s at fault. He said, “Fault is the ‘F’ word in medicine. People don’t come to work to hurt someone or make a mistake. Typically it’s about judgment calls and the options that were available at the time.”

“We need to identify vulnerabilities not statistics. In health care, no one seems to take notice unless someone dies, but close calls offer a better environment for learning as people are more willing to talk about what happened.”

James Bagian

“Experience may be the best teacher, but it is also the most expensive teacher,” said Dr. Bagian. By reviewing close calls, encouraging interdisciplinary involvement, and culling prompt feedback with no blame attached, institutions can establish an atmosphere that promotes changes in quality and safety. “There’s a big gap between the incidents that happen and what’s reported,” said Dr. Bagian. “We need to identify
vulnerabilities not statistics. In health care, no one seems to take notice unless someone dies, but close calls offer a better environment for learning as people are more willing to talk about what happened.”

Blame is a hot button issue in the patient safety field. Dr. Bagian believes institutions need to establish a definition of what is blameworthy and stick to it. He advised hospital leaders to reserve blame and punitive consequences for serious offenses such as criminal and purposely unsafe actions, situations involving illicit drugs or drinking, etc. They need to encourage trust with blame-free reporting of all other safety and human errors. He shared the story of how the FAA learned this lesson the hard way.

A Successful Systems Approach

Can institutions sustain a systematic approach to patient safety and is there a business case for doing so? Dr. Bagian believes so. He cited several examples of responsive system-based changes that have resulted in both reduced patient risks and dramatic savings to organizations. For example, the implementation of ventilator humidifiers that were not only safer but that also resulted in recurring savings of over $100,000 per year on disposable costs alone.

A successful systems approach requires organizations to clearly specify all problems and goals, set up an organizational structure, and develop a process to move those goals forward. “It’s vitally important to involve personnel from every sector and obtain management concurrence,” said Dr. Bagian. “Go to your worst critics early on because they’ll be happy to share what’s wrong with the plan. Use volunteers for pilots as they are motivated to make it work and their success shows that the goal is not impossible to achieve. Evaluate and disseminate feedback and results. Encourage teamwork. And above all, create an environment conducive for reporters and participants; one where problem-solving and information sharing, not blame, takes precedence.”

In closing, Dr. Bagian invited leadership to “lead by example, making patient safety a relentless drumbeat that’s part of every agenda.”

Dr. Bagian also emphasized the necessity of culture change. This is accomplished by first prioritizing patient safety risks based on severity and probability in conjunction with what makes sense from a practical business process and regulatory perspective. And it is important to adopt a systematic approach to:

- Pinpoint cause/effect and related human factors engineering issues;
- Identify management involvement and assess the respective actions to take;
- Determine related impacts of different processes; and
- Identify potential outcomes.

“Action assessment is important as so often, a temporary fix or workaround becomes the norm, which is not always the best solution to a particular safety issue,” said Dr. Bagian.
Moving Beyond Pay for Performance

Pay for Performance (P4P) has been touted as a significant health care quality initiative. However, the general consensus among speakers at FOJP’s conference is P4P has fallen far short of expectations. One patient safety expert examines the limitations and makes a case for igniting P4P reform.

Alice Gosfield, JD, is Principal, Gosfield & Associates and Former Chair, National Committee for Quality Assurance (NCQA).

Alice Gosfield believes in P4P — just not as it exists today. “The point of P4P is to propel health care to change to more science, more safety and more patient-centeredness, made known through more transparency,” said Ms. Gosfield. “Thus, by applying purchasing power and paying for results, processes and systems, P4P would bring about change much faster than incremental changes ever could.”

To reward quality performance, P4P has taken on many forms but the basic assumption is providers will earn extra money for doing what they were not doing before. However, the reality is that P4P has inspired some change; but minimal performers have only improved in small increments and those who always did well, are still doing well. Now they are simply getting paid for it.

There also is the issue of sustainability. “You move up to the raised bar and then what?” asked Ms. Gosfield. “P4P is an add-on to existing incentives that simply aren’t working. Fee for Service (FFS), has its perverse incentives that motivate medication/procedural overuse. The more you do, the more you get. Or Diagnosis Related Group (DRG), with its aligned incentives that invite under use—the less you have to do, the more you get.”

Another issue is adverse selection, where a “fabulous reputation” attracts a higher percentage of the very sickest, at-risk patients. And as a P4P-designated provider, physicians may face challenges in disease management when conflicts erupt between P4P expectations, regular coverage guidelines and a patient’s actual needs.

“The idea is to custom craft the art while standardizing to the science,” said Ms. Gosfield. “It is also vital to engage physicians in a way that speaks to how they treat and recognizes their central, plenary role.”

Ms. Gosfield is a member of the PROMETHEUS Payment™ design team. They are developing a new approach that aims to deliver the right combination of services according to science, address some of the “toxicities” of FFS and capitation, and cut administrative burden. As proposed, this program would be voluntary, allowing providers to participate in any combination they choose. It would work with existing payment programs because, at most, it will cover about 65% of what Americans receive in health care. In addition, there would be complete transparency of everything, from guidelines and roles to ratings and scores.

Ms. Gosfield considers P4P to be transitional at best. “It addresses the issue that not all quality is the same in health care as it lifts the little curtain behind which the wizard is operating,” she said. “But it cannot lead to major change.”

Bedrock of the PROMETHEUS

Evidence-based Case Rates, or ECRs, form the bedrock of the PROMETHEUS Payment™ approach, a model Gosfield believes has relevance for the future. ECRs define the total cost to deliver clinically appropriate care during a patient’s entire episode of treatment. These ECRs encompass all providers who are involved in treating a patient’s condition. As the basis for ECR development, the PROMETHEUS design team and ECR working groups are currently evaluating recognized Clinical Practice Guidelines (CPGs) in the clinical areas of cancer care, chronic care, interventional cardiology, orthopedic care and routine and preventive care.

These evaluations are used to determine:

- Level of services;
- Clinical variation of services above guidelines and related unit price; and
- Adjustments for illness severity, regional variations and profit margins for each CPG.

The PROMETHEUS design team looks forward to the medical industry developing additional CPGs that can form the basis for developing ECRs for most other medical conditions and procedures.

For more information, visit www.prometheuspayment.org.
More than 15 years ago, the United States Pharmacopeia (USP) and Institute for Safe Medication Practice (ISMP) began identifying “look-alike/sound-alike” (LASA) drugs through the USP-ISMP Medication Error Reporting Program. However, the LASA problem is still prevalent today. Each year, approximately 1.5 million people are injured by medication errors, resulting in increased health care costs.

In response, the Institute of Medicine (IOM) of the National Academies conducted a study at the request of the federal government. The resultant IOM report, “Preventing Medication Errors: Quality Chasm Series” published in July 2006, found some of these errors were inevitable due to inherent drug-related risks, but 25% of incidents were attributed to similar drug names and 33% related to labeling and packaging issues.

The Joint Commission on Accreditation of Health care Organizations (JCAHO), in an organized effort to reduce these incidents, made LASA drug errors one of the National Patient Safety Goals for 2006 and 2007. Patient Safety Goal #3, requirement #3C requires health care providers to identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used by the organization, and take action to prevent errors involving the interchange of these drugs. In tandem with the ISMP, JCAHO issued a list of LASA drugs with recommendations for preventing drug mix-ups. Organizations must identify at least 10 LASA drugs used in their care-settings and develop and implement measures to reduce errors related to these drugs. See the LASA Drugs and Consequences of Drug Interchange table on page 10 for examples of the drugs JCAHO added to the list.

In addition to provider responsibility, educating the consumer public is a powerful method for reinforcing patient safety. To this end, the IOM created a fact sheet, What You Can Do to Avoid Medication Errors. Practitioners can access the sheet at www.iom.edu and distribute to their patients. The fact sheet encourages patients to actively seek information about the drugs they take and to avoid taking any medication without first knowing the reason for doing so. By promoting awareness of LASA drugs among health care professionals and educating consumers on medication safety, potentially dangerous or fatal medication errors will be minimized.

LASA Drugs and Consequences of Drug Interchange

*(Information compiled from Physicians’ Drug Reference and on-line pharmaceutical resources.)*

<table>
<thead>
<tr>
<th>DRUG BRAND NAME</th>
<th>DRUG BRAND NAME</th>
<th>ADVERSE CONSEQUENCES OF DRUG INTERCHANGE</th>
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<tbody>
<tr>
<td>Cardura</td>
<td>Coumadin</td>
<td>Since both drugs are available in similar dosed tablets, accidental interchange can lead to complications related to blood pressure control, heart disease or bleeding and clotting.</td>
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<tr>
<td><strong>Indications:</strong> Hypertension, benign prostatic hypertrophy, congestive heart failure</td>
<td><strong>Indications:</strong> Anti-coagulation</td>
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<tr>
<td><strong>Dosing:</strong> Available in 1 mg., 2 mg. and 4 mg. tablets</td>
<td><strong>Dosing:</strong> Available in 1 mg., 2 mg., 2.5 mg, 3 mg., 4 mg., 5 mg, 6 mg., 7.5 mg. and 10 mg. tablets</td>
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<tr>
<td>Zestril</td>
<td>Zyprexa</td>
<td>Interchanging Zyprexa could result in agitation, possible fainting, stroke in elderly patients and, when indicated, should be used with caution in patients with heart disease. Unintentional use of Zestril could lead to low blood pressure, fainting and exacerbation of psychotic symptoms if Zyprexa levels drop.</td>
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<tr>
<td><strong>Indications:</strong> Hypertension</td>
<td><strong>Indications:</strong> Psychosis</td>
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<tr>
<td><strong>Dosing:</strong> Available in 2.5 mg., 5 mg., 7.5 mg., 10 mg., 15 mg. and 20 mg. tablets</td>
<td><strong>Dosing:</strong> Available in 2.5 mg., 5 mg., 7.5 mg., 10 mg., 15 mg. and 20 mg. tablets</td>
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<tr>
<td>Mucinex</td>
<td>Mucomyst</td>
<td>Interchanging these drugs could have serious consequences when Mucomyst is missed in patients with severe obstructive respiratory disease or when indicated for acetaminophen overdose or prevention of renal complications. Unintended use of Mucomyst could cause complications in patients with angina, chronic liver disease, peptic ulcer disease and history of kidney stones.</td>
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<tr>
<td><strong>Indications:</strong> Cough, congestion</td>
<td><strong>Indications:</strong> Respiratory inhaler for chronic severe broncho-pulmonary disease. Can also be used orally as antidote for acetaminophen overdose or to prevent renal complications from contrast dye</td>
<td></td>
</tr>
<tr>
<td><strong>Dosing:</strong> Available in 600 mg. tablets</td>
<td><strong>Dosing:</strong> Available in 10% and 20% solution and in 500 mg., 600 mg. and 750 mg. tablets or capsules</td>
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Overlooking Risk Factors
Post-operative Patient Develops a Large Sacral Pressure Ulcer

Case Details
A 34 year-old female weighing 435 lbs had a gastric bypass and was transferred to the Surgical Intensive Care Unit (SICU). While hospital policy required an evaluation of the patient's risk factors for a pressure ulcer, the clinician did not document that the patient was turned every two hours or the type of bed or mattress in use. The patient was on a ventilator and sedated. On Day 2, nursing noted a reddened sacral area (by definition, a stage I pressure ulcer, also known as a decubitus ulcer) on the back.

The patient developed Acute Respiratory Distress Syndrome (ARDS) and did not tolerate weaning from the ventilator or sedation. She had persistent fevers, but clinicians could not identify the source of infection. Nursing documentation regarding skin care, turning or other pressure ulcer prevention measures was inconsistent or missing. On Day 4, nursing noted the sacral area had broken down and notified two physician assistants on Day 5. The patient was given a pressure reduction mattress. However, there was no physician documentation acknowledging the pressure ulcer until Day 7, when the intensivist noted the skin was breaking down. But again, no exam was documented and no pressure ulcer interventions or consultations were ordered. The physicians’ notes were silent about the pressure ulcer until Day 11 when the intensivist noted a stage II pressure ulcer, and on Day 12 noted a necrotic sacral area of 10 x 50 cm and questioned if it was the source of the persistent fevers.

The patient returned to the OR for an exploratory laparoscopy to determine a source of the persistent fevers, but none was found. By Day 16, the patient’s physician described the sacral breakdown as a large stage III pressure ulcer requiring operative debridement and concluded it likely was the source of the infection. At this point, consultations with a skin care nurse and plastic surgeon were planned. The pressure ulcer elevated to stage IV. On Day 18, debridement down to the spine was done. The patient markedly improved and on Day 37 was transferred to rehabilitation. The pressure ulcer ultimately healed. However, despite months of physical therapy, the patient never regained her preoperative functional status. She has right leg weakness and paresthesia and left hand neuropathy.

Allegations
The allegations include failures to properly turn and position the patient, and utilize the appropriate pressure reduction mattress post-operatively. As a result of these failures, the patient developed a stage IV sacral pressure ulcer requiring multiple debridements and caused permanent neurological damage.

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Risk Reduction Strategies

Although pressure ulcer prevention traditionally is the responsibility of nursing, as this case illustrates, it requires a team approach. The clinician must be alert to the risk factors for pressure ulcers — immobility, sedation, obesity, poor nutritional status, underlying debilitating illness — for any patient with an acute illness, change in mobility, or level of consciousness. An evaluation for risk factors of pressure ulcers should be made at the onset of treatment.

The nurse who initially cared for the patient did not follow policy and turn the patient every two hours. She did not discuss her decision with a more senior staff member nor document her actions and rationale. A patient’s condition may necessitate a variance from written policy. However, before diverging from policy, have a discussion with a senior clinician. The rational for the decision, discussion with other staff, alternative treatment implementation and the patient’s response should be documented.

The physician’s assistants were notified about the pressure ulcer, but there was no physician acknowledgement of the problem until several days later. A clinician’s timely response to input from a team member not only improves the patient’s care, it also demonstrates all input is received and valued. This fosters good team communication, a key component of patient safety.

The intensivist’s initial note about the pressure ulcer did not include a documented exam of the site or a plan of care. The size, location, appearance and stage should be documented. Serial photographs — if permitted — are an adjunct for documenting progression of the pressure ulcer, but do not replace a written one. Standardized criteria for staging pressure ulcers should be used by all clinicians so the stage appropriate interventions are done and everyone is on the same page for evaluating response to treatment.

Consultations with skin care/wound care specialist, plastic surgeons, nutritionists, dieticians and rehabilitation specialists should be considered.

Investigation and Case Development

The nursing and surgery experts agreed obesity, sedation and immobility placed the patient at high risk. However, the medical record and the recall of the involved staff demonstrate an absence of treatment for this patient. On admission to the SICU, an evaluation of pressure ulcer risk factors was warranted, but not done. The nurse who cared for the patient in the immediate post-operative period admitted she did not turn the patient every two hours as required by policy. She said the patient was too unstable, but, the records do not evidence a fragile status of desaturations with movement or care. Once the skin breakdown began, the documentation about the skin and preventative measures remained inconsistent or absent. A jury could easily conclude pressure ulcer prevention and care measures were not done. This immobile, obese patient required a large bed with a pressure reduction mattress. Yet, the record is silent about the bed and mattress until Day 5 when nursing noted the patient was switched to a pressure reduction mattress and large bed. The lack of earlier or more frequent documented sacral exams by the physicians troubled the defense attorneys.

Resolution

The hospital wanted to settle the case, but the plaintiff’s demand was too high. The case went to trial, but then settled for $525,000.

Conclusion

Traditionally, only the elderly, chronically ill or non-functional patients were thought to be at risk for a pressure ulcer and were not expected to resume a high level of functioning. As this case illustrates, young, functional patients can quickly develop a life threatening pressure ulcer. The illness may resolve, but the aftermath of a pressure ulcer can interfere with full return to their expected productive and active life. Although pressure ulcers may occur with the best of care, the documentation is the only irrefutable proof the appropriate and timely care was given. The inconsistent and scanty documentation about pressure ulcer prevention and treatment made this case difficult to defend. Recall of events diminish over time but the medical records are permanent. Accurate, thorough and timely documentation will always help in the defense of a lawsuit.
Expensive Complications
How Leadership-Supported Multidisciplinary Prevention Strategies Reduce the Cost of Pressure Ulcers

Do you consider pressure ulcers an accepted risk of care? Weigh the preventative measures against the toll complications take — both physically and financially.

Red creases in the skin from pillows and sheets are harmless, temporary marks. However, for people unable to reposition themselves, prolonged external pressure leads to impaired circulation and decreased oxygenation of cells resulting in cell death and tissue damage. In as little as three hours unrelieved pressure could cause significant tissue damage. Pressure ulcers begin as minor skin irritations that progress to openings in the skin and worsen into deep wounds and tissue necrosis. They result from immobility and continuous unrelieved external pressure. People who are bed-bound or wheelchair-bound due to critical or chronic illness, obesity, paralysis or other neurological impairment are at risk for tissue damage, infection, sepsis and death.

Prevention Today
Care providers and hospitals are hard-pressed to prevent the occurrence of pressure ulcers. The cost to treat pressure ulcers in the United States is estimated at $11 billion annually. Regulatory health care agencies like the Centers for Medicare and Medicaid (CMS) and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are promoting prevention actively. In 2006, JCAHO added Goal 14, pressure ulcer prevention for long-term care (LTC) facilities to the National Patient Safety Goals. The new goal requires that LTC facilities “assess and periodically reassess each resident’s risk for developing pressure ulcers and take action to address any identified risks.” LTC facilities with greater populations of immobile clients tend to have a higher incidence of pressure ulcers, ranging from 2.2% to 23.9%. Acute care and home care settings are plagued by high incident rates.

In hospitals, home care and LTC facilities, the nursing profession generally assumes responsibility for pressure ulcer prevention. Nursing assessment tools, such as the Braden and Norton Scales, help identify patients at risk for skin breakdown. The Norton Scale rates five areas of risk: 1) physical condition; 2) mental condition; 3) activity; 4) mobility; and 5) incontinence. The Braden Scale focuses on: 1) the patient’s level of sensory perception; 2) nutrition; 3) moisture; 4) activity; 5) mobility; and 6) friction/shear.

By using these tools, nursing staff can identify appropriate strategies such as mobilizing patients by assisting them out of bed or turning them every two hours. Other strategies include avoiding compromised circulation to bony or prominent areas such as heels and elbows. Pulling or sliding bed-bound patients against rough surfaces also should be avoided to reduce friction or shear that might irritate or tear the skin. Moisturize excessively dry skin; dry moisture from perspiration and eliminate hindering

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How One Health Care Community Fights Pressure Ulcers

In 2003 Sutter Health, a not-for-profit network of health care providers in Northern California, rolled out an aggressive initiative to fight pressure ulcers. They took a comprehensive approach and targeted most patients — not just patients at the highest risk — at the organization’s 27 hospitals. The approach reduced incidents of pressure ulcers from 12% to 4%.

“With different interventions we can often prevent incidents,” says Nancy Posey, Vice President and Chief Risk Officer of Sutter Health.

The first phase of the project involved installing new, pressure relieving mattresses for 5,000 in-patient beds. “Our clinicians told us that anybody at risk should be on pressure relief modality,” says Ms. Posey. “When you look at who is hospitalized, everybody is at risk. Instead of saying, if you are at this much risk, you get an inflatable mattress pad; if you are at a higher risk you get a pressure relieving mattress, and if you are at an even higher risk get a different bed, we decided to make it easy for all our staff. Every in-patient bed is outfitted with a pressure relieving mattress that was selected by our staff.”

Beds in obstetrics, pediatrics and psychiatric were not replaced because of the low risk populations in those department. However, Sutter Health did replace operating room table pads and gurney covers to help prevent pressure ulcers. This safety measure reduced the dependence on nurse vigilance to ensure each patient got the right bed. In addition, having appropriate beds in-house eliminated the time wasted waiting for rental beds to be delivered when special needs arose.

The second phase of pressure ulcer prevention program involved instituting enhanced nursing policy and procedures. “First, we assess patients and then apply more aggressive interventions to patients at a lower risk than standard practice calls for,” says Ms. Posey. “That means more aggressive patient education, patient repositioning, moisture and skin protection and so on.”

All patients are assessed at time of admission and given a subsequent skin risk assessment everyday after. The hospitals also conduct quarterly prevalence studies. “We were trying to determine the rate of hospital acquired pressure ulcers and it turned into a nosocomial prevalence study,” says Ms. Posey. “On a particular day every quarter, every inch of patients’ skin is examined. All those found with pressure ulcers require a chart review to determine if that happened on our watch.”

Ms. Posey acknowledges it is often difficult to put a price tag on prevention. “We know that the number of patients who aren’t getting pressure ulcers under our care are also not needing extended lengths of stay, extended treatment, follow-up care, medications or surgery,” says Posey. “We’ve reduced the number of patients with pressure ulcers so there is much less of a chance of a liability claim. Surprisingly, even though it was a dramatic cost to switch out the beds throughout the entire system, we realized that most all of our hospitals were using rental products — either overlays or bed — for high risk patients. The cost of doing that is quite high.” After nearly three years in practice, Ms. Posey can say the increase in quality of patient care is worth much more than the cost of their progressive pressure ulcer prevention program.

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excoriation of the skin from acids in urine and feces in the incontinent patients. Nutritional assessment and support are also important for prevention and healing. Use of highly specialized hospital beds and mattresses for ICU, medical-surgical and bariatric patients provide pressure adjustment or pressure reduction to decrease the likelihood of skin breakdown and allow healing. While they are known to be effective, these specialized beds and mattresses can be costly to rent or purchase, potentially limiting their use.

There was difficulty establishing a clear-cut relationship between staffing and pressure ulcer occurrences.

Regulation Reinforces Prevention

CMS, in collaboration with JCAHO, classified certain costly preventable institution-acquired conditions, including pressure ulcers, as “never events.” Federal reforms are currently in development to allow CMS to deny reimbursement to providers when serious and costly errors or complications occur under their care. Because successful prevention outcomes are not achieved consistently, the initiatives are designed to reduce the incidence of pressure ulcers and other so-called preventable conditions. The reforms will make providers responsible to develop and utilize best practices to demonstrate preventive strategies when qualifying for reimbursement. [Infocus will feature a more detailed look at Medicare reform for “never events” in an upcoming issue.]

A Call for Culture Change

While the Institute of Medicine and the National Quality Forum have established a correlation between pressure ulcers and inadequate nurse staffing, other industry sources disagree. A recent study published in Western Journal of Nursing Research analyzed research to determine if a clear link exists between nurse staffing and the occurrence of pressure ulcers. It referenced a variety of other studies and found inconsistent methodologies were used to evaluate pressure ulcer prevention with regard to staffing. The study found that without adjusting for patient characteristics — not just hos-
pital characteristics — there was difficulty establishing a clear-cut relationship between staffing and pressure ulcer occurrences.\(^1\)

Another study of pressure ulcer prevention research published in a recent issue of *The Journal of the American Medical Association (JAMA)\(^2\)* found insufficient data on evidence-based prevention strategies. Like findings published in the *Western Journal of Nursing Research*, it found most of the randomized non-pharmacological clinical trials performed were limited in their design and did not produce reliable data on the most successful, cost-effective strategies. Preventive measures, treatment modalities and outcomes may vary in their effectiveness because of differences in patient populations. Despite the inconsistent research methods, the *JAMA* article did find improved prevention rates with the use of protective support surfaces, repositioning, optimizing nutritional status and moisturizing sacral skin but it was unclear whether specific turning regimens or specific topical moisturizing agents were more effective than others.

Pressure ulcer prevention presents an institutional and administrative challenge requiring input and participation from leadership as well as a more collaborative, multidisciplinary approach between medicine, nursing, physical therapy, nutrition and ancillary services. Because adequate nutrition increases the potential for tissue generation and healing, frequent nutritional assessment and lab work to assess protein and other markers of nutritional health are important. Providing effective supplies and equipment, albeit expensive, may also make a difference in outcomes. Because pressure ulcers and the associated complications of infection and sepsis are expensive to treat, proper financial planning and allocation of funds for the provision of preventive care and equipment may prove more cost-effective. However, the greatest return on investment is the improved quality of care and level of comfort for patients.\(^7\)


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