Using a Patient Safety Organization to Integrate a Statewide Surgical Collaborative and Apply Adverse Event Reporting

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Surgery is an area of health care with great potential for reducing patient safety events. Programs such as the Surgical Care Improvement Project (SCIP) and the National Surgical Quality Improvement Project (NSQIP) have been implemented in recent years to prevent surgical site infections (SSIs). In 2008, the Joint Commission implemented the Universal Protocol to prevent surgical errors.

The World Health Organization’s surgical checklist has been demonstrated to reduce the risk of morbidity and mortality in the perioperative setting.1 Despite these measures, the Joint Commission’s sentinel event reports show that the number of surgical events continues to increase, and SSIs are still one of the most common infections.2,3

Developing an improvement strategy

The Michigan Health & Hospital Association (MHA) has developed a strategy that addresses specific areas of care and patient–provider interactions where improvement is possible. This strategy includes the MHA Keystone Center for Patient Safety & Quality, created in 2003 to provide hospitals with evidence-based interventions and best practices to enhance patient safety and quality.

Another element in this strategy is a federally listed patient safety organization (PSO). MHA’s PSO, formed in 2009, collects and analyzes data submitted by Michigan hospitals on adverse events to identify opportunities to prevent future incidents.

Surgical collaborative focuses on safety

The MHA Keystone Center launched a surgical collaborative in late 2007 with 104 participating hospitals. The effort, funded by a grant from the Centers for Disease Control and Prevention (1H75CI000625-01) and a donation from Blue Cross Blue Shield of Michigan, aims to reduce the risk of surgical harm by implementing pre-operative and post-operative debriefings.

In previous efforts, these interventions have shown improved teamwork and reduced harm.4 The briefings and debriefings, implemented to improve culture using the Comprehensive Unit-based Safety Program (CUSP) developed by Peter Pronovost, MD, PhD, from Johns Hopkins University, target improvement in surgical team communication and reduction of patient risk.5

Pre-op briefings prepare the surgical team

The pre-operative briefing involves the surgeon, anesthesiologist, and surgical nursing staff. Its focus is to ensure that the surgical team has all the information necessary to begin a successful procedure. This briefing facilitates an open environment for the surgical team to be comfortable raising concerns they may have during an operation.

“The briefings and debriefings, implemented to improve culture using the Comprehensive Unit-based Safety Program … target improvement in surgical team communication and reduction of patient risk.”

The pre-operative briefing is most often done using a checklist of key elements:

- Team member introductions
- Critical nursing review
- Surgical and anesthesia information

Some teams have modified the briefing checklists to include items specific to the type of surgery. Because time in the operating room is valuable, it is critical that the briefing process be as efficient as possible. Once implemented, the average briefing takes approximately 3 minutes.6

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Post-op briefings identify safety issues
The post-operative debriefing is conducted before the surgeon leaves the operating room. The team is asked if they experienced any issues, including concerns regarding specimen labeling, diagnosis and procedural information or any other special considerations for post-operative care (eg, intensive care unit bed or ventilator). The team also is asked if anything occurred that would have a negative effect on the patient’s care, including communication issues. The average debriefing lasts approximately 2½ minutes.6

CUSP identifies and addresses errors
The Comprehensive Unit-based Safety Program (CUSP) involves 4 steps:

1. The process begins with a review of the science of improving patient safety, focused on high-reliability organization concepts and why errors occur.

2. The clinical team identifies defects or situations where staff believed that patients were at risk. A defect is defined as a clinical or operational event or situation that one would not want to recur.

3. A senior executive participates in the team meetings, having a presence on the unit and providing administrative support for the team.

4. Teams are asked to learn from one defect per month using the Learning from Defects Tool, a simplified root cause analysis.7

Tracking data to measure progress
Having sound data is critical to provide useful feedback to the teams and to demonstrate effectiveness of the interventions. Each month, the teams use a Web-based system to submit data on the number of briefings and debriefings conducted. They also provide the number of issues identified in communication, equipment, laboratory, pre-operative area, and radiology or supplies.

The teams use the data from briefings and debriefings to identify opportunities to make care safer. Some improvements made include ensuring that the necessary equipment is available and that appropriate antibiotics have been given in a timely manner.

An annual assessment of the safety culture is conducted by administering a safety culture questionnaire to all surgical staff, including physicians. The data are presented in 6 domains: teamwork, safety, perceptions of management, stress recognition, working conditions, and job satisfaction.

The recently formed MHA PSO offers new measurement methods for hospital teams. Data collection for the PSO, a process which began in summer 2009, will allow for longitudinal monitoring of adverse events.

Collaborative effort can improve patient safety
Communication among team members is at the core of preventing surgical harm. The information collected early in the surgical project shows significant opportunities to improve communication, and one important element is familiarity among the surgical team.

While often not an issue in smaller facilities, large or teaching hospitals may have staffs with fewer opportunities to interact; this may inhibit open communication. Combining a collaborative improvement project with adverse-event data from PSOs will likely cause an improved reaction to events identified in the context of better surgical team communication.

The merging of active adverse event data collection with a collaborative focus on cultural improvement using communication interventions is new and evolving. There are significant opportunities to study results and outcomes, and to improve healthcare delivery to provide patients with highest-quality and safest care. NPSF

References


Dangers to patients from medical devices lurk in large numbers. These dangers are present in many devices, such as:

- MRI equipment
- CT scanners
- Nuclear medicine equipment
- Defibrillators
- Infusion pumps
- Ventilators
- Patient monitoring systems
- Electronic Health Record computers

There are also dangers in medical accessories such as:

- Interface connectors
- Surgical trays
- Syringes and valves
- IV tubes that transport blood
- Catheters

While medical devices are obviously designed to benefit patients, they can also cause harm. Healthcare professionals at all levels must be made aware of these high risks. In 2008, the US Food and Drug Administration (FDA) recalled 845 medical devices—the highest number ever recalled in a single year.1 From 1999 to 2005, one in three FDA device recalls were due to software errors.2 This article addresses some examples of hidden dangers in medical devices and offers several suggestions for how hospitals can work to reduce these dangers.

What are the dangers?
The hidden dangers in medical devices and accessories come from a number of sources:

- **Inherent technology.** Radiation from CT scans performed in 2007 was estimated to cause 29,000 cases of cancer and kill nearly 15,000 Americans, according to findings published in the *Archives of Internal Medicine* and reported in the *New York Times*.3,4 Cardiologist Rita Redberg, an *Archives* editor, states, “What we learned is there is a significant amount of radiation with these CT scans, more than what we thought.”

- **Equipment software.** In 2005, a Florida hospital disclosed that 77 brain cancer patients had received 50% more radiation than prescribed because one of the most powerful—and supposedly precise—linear accelerators had been programmed incorrectly for nearly a year.5 Software usage failures have resulted in delays or interruptions in the operation of infusion pumps, interfering with intervention and causing serious harm.6

- **User interface.** The computerized physician order entry (CPOE) interface has resulted in prescribing errors, improper dosage or quantity, wrong dosage form, extra doses, omission errors, unauthorized or wrong drugs, and drugs administered to the wrong patient.7 In one emergency department’s color-coded screen, a colorblind nurse had problems interpreting priorities.

- **Device reliability.** Medical devices are designed and assembled by humans. Because of variability in human factors as well as in the manufacturing process, the devices can fail at any time during normal use. In some portable ventricular assist devices (VADs), the drivers stopped when the compressor motor wore out much sooner than after the expected 3,000 hours of use. A compressor motor can stop without warning. When the motor fails, there is a loss of VAD support for the patient, causing inadequate blood flow to and from the heart.8

“While medical devices are obviously designed to benefit patients, they can also cause harm.”

- **Defective components.** Some pacemakers were recalled when defective leads caused serious injuries. Pinholes and exposed wire braids were found in some catheters, which could result in a brain clot or a blood vessel puncture. The catheters were recalled.

- **Sneaky conditions.** Sometimes devices deliver unexpected behavior due to so-called sneak circuits—especially electronic devices, which are subject to uncontrolled interactions among circuits, software, and components. The devices can fail to deliver required functions, deliver wrong functions, deliver unexpected outputs, fail to deliver a function when they should, or deliver too much or too little treatment.
There are many instances of such failures in ventilators, defibrillators, and infusion pumps. A hospital reported a fatal central venous air embolism caused by the separation of a specific manufacturer’s side port/hemostasis valve catheter-to-sheath adapter from the same manufacturer’s percutaneous sheath hub. The accident occurred when the standard Luer-lock fitting disconnected as a patient was moved from a bed to a chair. The hospital could have bought a one-piece device interface instead of a 2-piece interface from the same manufacturer to avoid the mishap.9

- **Expired sterility.** Infections can result from surgical devices with an expired sterility date, or those packaged in unsterilized or improperly sanitized bags.
- **Accessories.** The FDA has warned that the plastic material in IV tubes used in cardiac surgery may contain BPA, a highly toxic chemical. BPA can combine with warm blood in the tubes.
- **Incorrect labeling information or instructions.** The label insert for a video-guided catheter contained inappropriate information on use with an energy-delivering instrumentation. Instructions for an implantable ventricular assist device (IVAD) stated it could be implanted or placed in the external position. If the IVAD is placed externally, air leaks might develop in the pneumatic driveline.10
- **Incorrect servicing.** Accidents from inaccurate settings of MRI machines or improper calibrations of other devices are not uncommon. FDA recall Z-0165-2008, *Class 2 Recall ONCOR Expression*, suggests that the miscalibration can affect the beam profile of the radiation therapy system.11

These are only some of the dangers inherent in medical devices. For a listing of medical device recalls, visit the FDA’s web site, [www.fda.gov](http://www.fda.gov).

**How can hospitals protect patients from these dangers?**

Once a device has been approved by the FDA, current law protects medical device companies from failure-to-warn and design-defect lawsuits on defects designed into that device.

To help protect patients from potential dangers in medical devices and accessories, hospitals can:

- Use FDA recall information to strengthen the current device use procedures and develop safeguards and checklists.
- Conduct a hazard analysis such as the Failure Mode and Effects Analysis for dangers on new technologies and devices. Some hazards will not be on the FDA recall list, as the dangers have not shown up yet.
- Discuss the results of the hazard analysis with suppliers so they can design the equipment to include safeguards, alerts, monitoring software for inaccurate performance, and built-in self-checks. An example of a built-in check is a car’s software that makes sure the air bag is in good working condition every time the ignition key is turned.
- Create the healthcare equivalent of the Commercial Aviation Safety Team (CAST), a public–private partnership to reduce hazards in aviation. Peter Pronovost and colleagues are exploring a healthcare version of CAST with an ad hoc group whose stakeholders include the Agency for Healthcare Research and Quality (AHRQ), the FDA, the Joint Commission, ECRI Institute, and more than 15 large health systems. This approach has been named the Public Private Partnership to Promote Patient Safety (P5S).12
- Use knowledge of inherent medical device and accessory dangers in bedside intelligence systems.

**Use a team approach to risk reduction**

Patient safety safeguards and barriers should be in place in every area, including medical device use, where a possibility of harm exists. The caregivers may have to exercise due diligence. Considering that many patients are exposed to nearly all the medical device dangers discussed above, the probabilities can add up, resulting in highly significant risks. Risk managers and patient safety officers should work together to reduce these risks. **NPSF**

**References**


Collaborating to Promote Learning Focuses Organizations on National Patient Safety Goals

BY CHRISTINE CHASTAIN-WARHEIT, MLS, AHIP, LEWIS B. FLINN MEDICAL LIBRARY, CHRISTIANA HOSPITAL

To work toward achieving the Joint Commission’s National Patient Safety Goals (NPSGs), healthcare organizations need to develop effective ways to provide staff with patient safety alerts. It is important for organizations to establish and maintain a system for ongoing learning in patient safety. The Medical Library Association encourages librarians to become partners in the patient safety activities of their organizations. This article describes one method for librarians to apply their expertise to learning efforts.

Librarians can help keep clinicians informed

Zipperer and colleagues contend that librarians are ideally positioned to create resource maps of external knowledge sources. The patient safety team or department members and hospital librarians can work together effectively; medical librarians’ systematic reviews of new literature can be vetted by the quality/patient safety staff in monthly committee meetings. The resulting information can be shared on the hospital’s patient safety web site and medical library web site should those information sharing tools be in place.

Hospital medical librarians conduct patient safety literature searches for clinician groups on NPSG-related topics in many instances, such as when:

- New nurses are assigned to units
- Potential for harm occurs
- A medical error occurs
- A medical error is in the news

Putting the NPSGs into practice

Medical librarians’ efficiency increases when they don’t need to repeat nearly identical searches for each individual. At Christiana Hospital in Newark, Delaware, the reference librarians and library director are collaborating with the director and managers of the patient safety department. Together, they have crafted an initiative to help the patient safety department explain and integrate the Joint Commission’s NPSGs into daily practice.

“It is important for organizations to establish and maintain a system for ongoing learning in patient safety.”

Librarians have prepared “gold-standard,” evidence-based searches on each of the Joint Commission’s NPSGs for hospitals. The Christiana patient safety specialists and librarians decided to address 3 topics first: falls, pressure ulcers and ventilator-associated pneumonia. These three areas were chosen based on their resonance with the Patient Safety team and library reference service usage statistics documenting the interest in the topics by nurses in the hospital.

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The author would like to thank Loretta Consiglio-Ward, MSN, RN, Patient Safety & Accreditation, Christiana Hospital, Christiana Care Health System, Newark, DE, for her review of the publication and commitment to this project.

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No Hospital Librarian?  
Check Out These 5 Patient Safety Resources


2. The Institute for Healthcare Improvement (IHI) Open School for health professions, available at http://www.ihi.org/IHI/Programs/IHIOpenSchool/, offers excellent free online courses in quality, patient safety, and leadership with credits toward IHI certification. Courses are free to students in nursing, health administration, medicine, pharmacy, dentistry, policy and other health professions. This is an effective way to improve patient safety knowledge and skills.

3. The Joint Commission Web Site offers a free archive of patient safety articles selected by its expert team (http://www.jcrinc.com/Patient-Safety-Articles/). This archive is now under development, but promises to be updated monthly.

4. The National Patient Safety Foundation’s Current Awareness Patient Safety Literature Alert, available at http://www.npsf.org/rc/pubs/ca/, identifies articles of interest to the patient safety community twice a month. The NPSF web site has many resources culled from the plethora of patient safety information on the Internet. Patientsafety-L, the foundation’s longstanding email-based discussion forum, provides insights and access to resources of interest to the field as they emerge in the course of doing safety work. It is available at: http://www.npsf.org/pssf/. The NPSF is also on Twitter at http://twitter.com/theNPSF and on Facebook at http://www.facebook.com/pages/National-Patient-Safety-Foundation/19773144333?ref=ts.

5. The Patient Safety Resource Seminar: Librarians on the Front Line, available at http://nnlm.gov/training/patientsafety/, is an interactive seminar with worthwhile information that underscores the need for librarian involvement in patient safety processes and activities.

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PubMed and choose evidence-based articles, including clinical trials, systematic reviews, and meta-analyses, available in full text. It is best for copyright reasons that any full-text articles posted to a hospital intranet site be from sources to which the hospital subscribes. If no evidence-based articles are found, robust journal articles and/or reviews can be selected.

A hospital clinical content expert should decide what represents core, foundational articles for each goal in that hospital context. For institutions without a hospital librarian, the patient safety team can review published literature for the medical errors most common in their environment. (See the sidebar on page 6 for suggested tools to monitor the literature.)

Keeping up with patient safety literature

Staying current on patient safety includes systematically reviewing the literature on:

- Hospital-acquired infections (MRSA, *C. difficile*, VRE)
- Hand hygiene
- Patient identification
- Medication safety
- Retained foreign objects
- Human factors
- Teamwork
- “Present on admission” issues

The goal is to focus on performance improvement in areas that will reduce harm, mitigate risk for patient harm, and be linked to the NPSGs.

Current awareness literature searches should be established for each goal to maintain currency. Christiana Hospital’s process improvement/patient safety department has designated a staff nurse to review and vet the results of the quarterly current awareness searches. This nurse determines what should be added to web page updates and which information is most critical for the organization’s objectives.

Making safety information easy to access

The patient safety team can use a “dashboard” or summary on the hospital intranet to correlate hospital experiences that show monthly progress on goals.

As partners in the patient safety process, Christiana Hospital’s librarians can refer clinicians to the Hot Topics in Patient Safety page for both core and current articles on the patient safety issues and NPSGs of highest importance to the hospital and the clinician.

As others have observed, it is hard to demonstrate evidence that information gathered in this way is effectively “used [by clinicians] to further enhance an organization’s patient safety strategy,” but it can be a useful and efficient collaborative tool. NPSF

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**NPSF Announces Patient Safety Research Grant Opportunity**

The NPSF Research Grants Program is accepting applications for grant projects beginning in 2011. In this first stage of a two stage application process, Letters of Intent (LOIs) are solicited for research and development that is broadly related to identifying the causes of preventable injuries and errors and/or developing prevention strategies and methods to implement them. Based on these LOIs, a limited number of applicants will be invited to submit a full proposal.

The National Patient Safety Foundation (NPSF) Research Grants Program seeks to stimulate new, innovative projects directed toward enhancing patient safety in the United States. The Program’s objective is to promote studies leading to the prevention of human errors, system errors, patient injuries, and the consequences of such adverse events in the healthcare setting. Since 1998, the Program has supported 34 research projects with a total of nearly $3.4 million in grant funding. Many of these grants have been awarded to interdisciplinary teams to support research on diverse topics in areas such as medication errors, organizational design, and disclosure or communication issues.

The deadline for submission of Letters of Intent is September 10, 2010. For more information and application instructions, go to [http://www.npsf.org/r/](http://www.npsf.org/r/). NPSF
Plan to Attend the Lucian Leape Institute Annual Forum and Gala

Special Guest Speaker: David Blumenthal

Please join us for the Lucian Leape Institute Third Annual Forum and Gala on September 16, 2010, in Boston.

During the afternoon, an interactive discussion at the historic Boston Omni Parker House will be led by the Leape Institute members, who will offer insights into their work and seek attendee reaction and input. Dialogue with attendees will also focus on health information technology (HIT) and its implications for patient safety, in lead-up to the dinner presentation on this topic.

The evening program of networking reception and dinner at the State Room, overlooking Boston’s skyline and harbor, includes our honored speaker, David Blumenthal, MD, MPP, the National Coordinator for Health Information Technology at the Department of Health and Human Services. Dr. Blumenthal will offer his thoughts on HIT as a patient safety lever and the focus placed on its development by the Federal government.

For details and reservations go to [http://www.npsf.org](http://www.npsf.org).

NPSF Honors Achievements in Patient Safety with Annual Awards

The following awards were presented at the 2010 NPSF Patient Safety Congress:

**National Patient Safety Foundation Chairman’s Medal**
Awarded in recognition of emerging leadership in the patient safety field.

*Recipient: Jonathan B. Perlin, MD, PhD, MSHA, FACP, FACMI, President, Clinical Services, and Chief Medical Officer, Hospital Corporation of America*

**National Patient Safety Foundation Socius Award**
Given in recognition of work that promotes positive and effective partnering between patients/families and providers in pursuit of improved patient safety.

*Recipient: Riley Hospital for Children, A Clarian Health Partner*

**National Patient Safety Foundation Stand Up for Patient Safety Management Award**
Granted to a member hospital of the National Patient Safety Foundation’s Stand Up for Patient Safety™ program in recognition of the successful implementation of an outstanding patient safety initiative that was led by, or created by, mid-level management.

*Recipient: Virginia Mason Medical Center*

**Pfizer Health Literacy in Advancing Patient Safety Award**
Recognizes an individual, group, or organization that has made significant strides in improving the health literacy of their constituents or community through research, advocacy, or program implementation in order to improve patient safety and quality of care.

*Recipients: Patricia Donaldson, RN, MSN, CDE, Veterans Health System, Malcolm Randall Veterans Administration Medical Center*

*Jolie Haun, PhD, EdS, Veterans Administration Health Services Research & Development, Rehabilitation Research & Development Research Center of Excellence.*