

A Goal for all California Hospitals: Zoom In on Zero Retained Surgical Items

In May 2009, the California Department of Public Health (CDPH) issued administrative penalties to 13 hospitals for medical misconduct (1). Three of these penalties were assessed for the failure of the facility to follow its surgical policies and procedures resulting in a patient having to undergo a second operation to remove a retained surgical item (RSI). Undoubtedly, in the wake of the citations, these hospitals revisited their preventive efforts, massaged their surgical count policies and looked at technological adjuncts for surgical sponge management. In early November of this year, the CDPH issued 14 penalties, nine of which were related to retained medical or surgical matériel (2). The penalties did not involve the same hospitals but the same problems were cited. Three of the nine items left in patients were either surgical gauze sponges or a towel. Even though an RSI is an infrequent event, it is a persistent and difficult problem to eradicate. These events invite us to ask why do RSI occur with such regularity and what can hospitals and health care providers do to ensure that this will be a true “never” event?

The new terminology — retained surgical item — distinguishes these events from retained foreign bodies or objects (RFO). RFO has been the classic reference to anything left or found inside a patient such as bullets, shrapnel, bottles or ingested objects and has included sponges, needles and surgical

Editor’s Note: Retained Surgical Items Series

I am pleased to introduce a new series by Verna C. Gibbs, MD. Dr. Gibbs is Staff Surgeon at the San Francisco VA Medical Center, Professor of Clinical Surgery at UCSF, and Director, NoThing Left Behind®. Her research interest is in health services, quality improvement and patient safety, and she introduced the NoThing Left Behind initiative in 2005. The goal is to develop and disseminate evidence and experience-based best practices that will prevent retained sponges, needles and instruments.

Future article topics include

- new AORN Recommended practices for prevention of retained surgical items,
- new perspectives on prevention of retained device fragments and small miscellaneous items, and
- updates on new technological adjuncts for the management of surgical sponges.

Dr. Gibbs is eager to address your questions and comments.

instruments. RSI in distinction refers specifically to the tools, supplies and equipment used by medical practitioners in the course of their work that are inadvertently left inside of patients and are usually a result of medical or surgical practice errors (3). An RSI is a surgical patient safety problem.

Like the other surgical patient safety problems, “the wrongs”: wrong side, wrong site or wrong patient surgery and surgical fires, RSI occur because of problems with multi-stakeholder operating room practices and problems in communication. Early reports on the problem focused on the epidemiology of retained item cases and the identification of patient risk factors for retention (4). It is now recognized that retention has very little to do with specific patient characteristics and everything to do with operating room culture. OR culture is the constellation of shared beliefs and ways of interaction within the surgical workspace, so next steps are to focus on the OR personnel and cultural risk

factors for retention (5). These observations must extend beyond the surgeon and nurse to all stakeholders involved in the surgical care of the patient. This includes the surgical technologists, the anesthesia personnel, radiologists and radiology technologists, administrators and risk managers. In the OR it is not just the performance of surgical item counts by the circulating nurse that is required to prevent RSI, so actions beyond revision of the surgical count policy must take place (6). A retained surgical item case is not a result of individual negligence but reflects system problems in the OR, and system problems require system solutions. The prevention of retained surgical items will therefore require practice change, knowledge and shared information between all perioperative personnel (7). Each member of the surgical team has to become a “content expert” in their domain, do their part and collaborate to ensure there is “NoThing Left Behind.”

— Verna C. Gibbs MD, [NoThing Left Behind®](#), dr gibbs@nothingsleftbehind.org

References:

- 1) California Department of Public Health Issues Administrative Penalties to 13 Hospital — 5/20/2009. Available at: goo.gl/ISHoF.
- 2) CDPH Issues Administrative Penalties to 12 Hospitals — 11/12/2010. Available at: goo.gl/QUwIS.
- 3) Gibbs VC, Coakley FD, Reines HD. Preventable errors in the operating room: retained foreign bodies after surgery — Part I. *Current problems in surgery*. 2007;44(5):281-337.
- 4) Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *The New England journal of medicine*. 2003;348(3):229-35.
- 5) Cima RR, Kollengode A, Storsveen AS, et al. A multidisciplinary team approach to retained foreign objects. *Joint Commission journal on quality and patient safety / Joint Commission Resources*. 2009;35(3):123-32.
- 6) McIntyre LK, Jurkovich GJ, Gunn MLD, Maier RV. Gossypiboma: tales of lost sponges and lessons learned. *Archives of surgery (Chicago, Ill. : 1960)*. 2010;145(8):770-5.
- 7) Gibbs VC. NoThing Left Behind®: A National Surgical Patient Safety Project to Prevent Retained Surgical Items. Available at: www.nothingleftbehind.org.

CHPSO Hiring

We are pleased to announce that we are seeking a Director Quality and Patient Safety. The Director will foster multi-facility collaboration for patient safety improvement and facilitate patient safety initiatives throughout California. As an expert resource for members, the Director will identify successful patient safety practices and models, and other proven and effective strategies and provide assistance to members seeking to expand their safety efforts; enable peer-to-peer connectivity to facilitate learning and sharing of experiences; and bring practitioners and industry leaders together to share knowledge and foster innovations in quality and patient safety.

Further information is available at www.chpso.org/dirqual.pdf.

What's in a Name?

Once again, the New England Journal of Medicine has published another study validating the benefits of using a surgical safety checklist. In this study, six hospitals implemented the SURPASS checklist, which encompasses the previously discussed WHO checklist, while five control hospitals did not. The hospitals that implemented the checklist experienced a 39 percent reduction in surgical complications as compared with no significant change in the control hospitals. The authors noted the significantly greater reductions in complications experienced by those hospitals that had greater than 80 percent compliance with checklist items versus those with lower compliance. While these results don't surprise my aviation colleagues and me, we're elated

to see the growing awareness of the value of hard-wiring known best practices.

One of the things I find interesting about the checklist is that of the hundreds, perhaps even thousands, of things that must be done for a surgical procedure, the checklist only includes 19 items. The reason for this is that researchers have found that if a checklist is too long it will suffer from non-compliance and it's more likely to have items missed. So these 19 items have been deemed the most important of the hundreds of tasks mentioned above. One item that is noteworthy, because it doesn't have anything to do with the patient or equipment, is the first item on the time-out section. All team members are expected to introduce themselves by name and role. Why on earth was that included?

The answer to this question is discussed in the [WHO's Guidelines for Safe Surgery](#). That document notes that a "safety culture" must reduce hierarchy and tear down barriers to communication. My friend Jane Reed is one of the nurses who were a part of the conference in Geneva where the checklist was created. Her work with the National Health Service in the United Kingdom was consistent with that of her nurse colleagues from other parts of the world. They insisted that these introductions be included in order to reduce the hierarchy and improve communication in the OR. There is the added benefit of more efficient communication facilitated by knowing other people's name. If I make a specific request of someone, I'm far more likely to have it heard, acknowledged and acted upon. Once again, my aviation colleagues and I are in complete agreement.

Subscription service (additions and removals): La Shon Tate ltate@calhospital.org
Questions or comments: Rory Jaffe, MD MBA rjaffe@calhospital.org
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One question remains unanswered for me and my aviation peers. Why do physicians introduce themselves as “Doctor Smith, Attending Surgeon” instead of “Tim Smith, Attending Surgeon?” If titles are critical in an OR, then why “Doctor Smith” and not “Nurse (or Physician Assistant, Nurse Anesthetist, etc.) Smith?” If it’s critical for safety and efficiency that we reduce hierarchy in a clinical setting, then why, besides demonstrating due subservience, isn’t everyone referred to by their first name, as is currently done for everyone but the physician? I understand that this is provocative to some, just as it would have been in commercial aviation in the 70’s. Today’s aviation culture would find it odd for the Captain to identify herself on the intercom with the flight attendants as “Captain Jones,” instead of “Tina.” If it’s any comfort for clinicians, there’s no question that the Captain is still the Captain, but “Tina” is much less intimidating, and far more approachable. This is a safer culture, and I hope it doesn’t take health care 30 years to figure it out like it did for my colleagues and me.

— Steven Montague, Vice President,
[LifeWings, lifewings@verizon.net](mailto:lifewings@verizon.net)

Reference

Vries EN de, Prins HA, Crolla RMPH, et al. Effect of a Comprehensive Surgical Safety System on Patient Outcomes. *The New England journal of medicine*. 2010;363(20):1928-1937.

Third Annual Patient Safety Colloquium Set for January 18

Registration is now available for the third annual Southern California Patient Safety Collaborative (SCPSC) Colloquium, set for Tuesday, Jan. 18 at the Hilton Hotel in Long Beach.

The colloquium is the third annual celebration and continued learning opportunity offered by SCPSC. Last year’s colloquium was the largest educational event ever held by the Hospital Association of Southern California, with more than 430 attendees. This year’s agenda features the following keynote speakers: Dr. Michael Leonard of Pascal Metrics, Jim Conway of IHI and the Disney Institute. Twenty-four breakout sessions will be offered in eight tracks.

The colloquium has set forth the following learning objectives:

- Understand how a patient safety culture enhances clinical and financial outcomes and the importance of leadership.
- Learn about patient and family-centered care and how engaging patients can enhance all aspects of patient care.
- Learn how to distinguish your organization through delivery of quality services and create loyalty through outstanding experiences.
- Learn about successful safety and quality strategies that have been implemented in area hospitals.

January 2010 marked the beginning of Patient Safety First ... a California Partnership for Health. California’s three regional hospital associations (Hospital Association of San Diego and Imperial Counties, Hospital

Association of Southern California, and Hospital Council of Northern & Central California), the National Health Foundation and Anthem Blue Cross have joined together in a three-year, \$6 million effort that builds upon the work of established peer-to-peer learning collaboratives like SCPSC. The three initial areas of focus for the collaboratives are:

- Sepsis — reduction of mortality and morbidity
- Hospital Acquired Infections in the ICU Setting — reduction of the incidence of VAP, CLBSI and CAUTI
- Perinatal Care — reduction of elective deliveries prior to 39 weeks

SCPSC participant hospitals and team members include CEOs, COOs, CMOs, CNOs, VPs of Quality, VPs of Risk Management, Directors of Pharmacy and their staff, respiratory therapists, clinical nurse specialists, wound specialists and other clinicians. The colloquium is also open to all who are interested in quality and patient safety.

Registration includes continental breakfast, lunch and handouts and is offered at the following levels:

- \$99 per registrant: Group Discount (three or more from same organization registering at same time)
- \$125 Early Bird per registrant (prior to December 20)
- \$135 per registrant (after December 21)
- \$150 Walk in Registration (January 18)

For a complete brochure of the event, including a list of all breakout sessions and accompanying form for registration, please visit goo.gl/9xNLo. To register online, please visit goo.gl/kqE2d.

— Catherine Carson ccarson@hasc.org

Patient Safety First...
a California Partnership for Health



A Facility-Level Solution for Addressing Medical Device Events

Oversight of the \$60 billion medical device industry in the United States falls to the US Food and Drug Administration (FDA), which manages a broad portfolio. According to the Medical Device Safety Institute, the FDA oversees approximately 23,000 manufacturers who produce over 500,000 models in 1,700 medical device categories.

The FDA does have a surveillance system in place so that the safety and efficacy of marketed devices can be continually assessed. And that system has proven effective — there have been over 500,000 medical device issues reported over the past decade affecting countless individuals. Recalls of faulty pacemakers and defibrillators alone have been a factor for over a million patients since 1990.

However, the FDA's post-market surveillance system may not be sufficient to help health care organizations prevent or reduce medical device events in their own facilities.

From a Passive to a Proactive System

The FDA system was designed to hold manufacturers accountable for tracking their products and reporting issues, which typically become apparent only after they have been implanted in or used on patients. Although this may result in recalls that prevent other patients from being harmed, it places individual hospital systems and facilities in a reactive mode. Health care providers wait until a report is filed by the manufacturer and then respond to it by discontinuing use of the suspect device. A more proactive approach, one that provides decision makers with a view of what is happening

in their own facilities as well as across the industry, is required if health care organizations hope to reduce the number of medical device events.

A Facility-Level Solution

The causes of medical device events can generally be broken down into three categories — user error, maintenance problem and device-related issue (including malfunction or design error). The FDA system is designed specifically to address device-related issues. With two of the three medical device event categories rooted in the facility and a large percentage of medical device events attributed to user error, reporting device-related issues is insufficient to help health care organizations reduce their incidence.

Health care organizations need to track medical device events in their own facilities — even before the FDA reports an issue with a specific device — because the corrective action required for a device-related issue is much different than that required for a user error or maintenance problem.

Organizations can track medical device events by using existing systems and workflows to capture data from their own facilities, comparing themselves to like facilities and using all of this information to develop actions plans.

Capture ...

A facility's existing event reporting and tracking system is the most obvious place to look for medical device events. The system should be configured so that events involving medical devices exist as an independent category. In addition to the information necessary to report an issue to the manufacturer, the system should also capture details about the event that can be used to determine its cause (e.g.,

where the device was retrieved from, label status, involved parties).

This information becomes especially important if the failure was caused by user error or a maintenance lapse. Not only will this prevent non device-related events from being reported to the manufacturer, but will provide a facility with information necessary to prevent recurrence. The manufacturer can investigate and make changes to the design or functionality of the device, but in the vast majority of cases, only the facility can address the processes that lead to user errors and maintenance issues.

Unfortunately, even in the most vigilant organizations self-report systems do not contain all events that occur and may only contain the most severe. Many organizations have a surveillance system already in place and can configure the system to monitor billing data. ICD9 codes relating to devices, using the external cause of injury codes (E-codes), can be flagged and a clinical decision maker can then determine whether an event has occurred and if it should be reported to the manufacturer and/or the event system.

Compare ...

Once an organization has established a baseline and can identify rates for medical device events caused by a problem with the device itself, user errors and maintenance lapses, it can compare and benchmark against like facilities. This provides both a context for performance rates and an achievable goal.

If a facility has a rate for events caused by user error of 57 percent, for example, and the average rate for a group of like facilities is 37 percent, the urgency around staff education will be much higher than if the user error rate were viewed in isolation.

There are a number of ways for facilities to collect data on like facilities and even to exchange information about corrective actions and preventive strategies.

Facilities can subscribe to databases that facilitate comparative reporting and benchmarking such as the Quantros MEDMARX® medication event and adverse drug reaction database. Many of these databases have reporting tools and some even allow access to resolutions reported by members.

Patient Safety Organizations (PSOs) provide another way for facilities to reduce medical device event rates. PSOs, federally recognized entities that collect, analyze and report on relevant patient safety event data on behalf of participating providers, were specifically designed to encourage open and honest communication about patient safety events, including medical device events. PSOs offer a forum in which healthcare professionals can openly discuss safety events and identify a way to prevent them in the future. PSOs also provide a real time database that can be mined to identify issues with medical equipment.

Correct ...

Armed with a view of medical device events in their facilities as well as like organizations, healthcare organizations can assess the situation and develop a corrective action plan based on their findings.

Are a large percentage of the events tied to a department, floor or individual?
Are there a disproportionate number of events for a particular device compared to other facilities? How did a similar facility address the education gaps in their own organization? Is the cause of error related to 'Pump: Improper Use' a case of device design and/or programming or a need for staff education?

This is also a good time to reassess the data being captured by the event reporting system. Facilities may find that they require additional information not currently being collected or that they are collecting data that isn't useful in determining either cause or corrective action.

An Ongoing, Iterative Process

The pace of both medical and technical innovation will remain brisk in the foreseeable future and the number of new and enhanced medical devices introduced to the market will consequently continue to rise. The FDA's surveillance system is sure to keep pace but can't provide the facility-level view so necessary for containing medical device events.

Without in-depth knowledge of the incidence and causes of medical device events in their own facilities and how they compare to others, healthcare organizations will be unable to create effective corrective action plans. Moreover, they will be unable to take proactive steps to prevent medical device events from occurring in the first place.

— Ali Rashidee, MD, MS, arashidee@quantros.com, Juliana K. Hart, BSN, MPH jhart@quantros.com. Reprinted with permission from November edition of DOTmed Business News.

Model Policy for CHPSO Participants

In early February, 2011, CHPSO will release a model policy that participants may use as a basis for their policies and procedures surrounding PSO participation.

Topics addressed include:

- What comprises a provider's Patient Safety Evaluation System (PSES)
- What information is to be collected within the PSES and reported to the PSO as Patient Safety Work Product (PSWP)
- How is PSWP is created
- How PSWP is reported to the PSO
- How can decisions be made to not report PSWP to the PSO
- How information designated as PSWP may be de-designated as PSWP and used for other purposes
- How PSWP may be used by the provider
- Maintaining confidentiality of PSWP
- Exceptions to confidentiality
- How to handle state reporting requirements
- Removal of personal identifiers and non-identifiable PSWP
- Root Cause Analyses
- Relationship to Medical Staff peer review
- PSWP and Personnel Actions or Grievances

To accompany this release, CHPSO will be scheduling a teleconference in February. Look for an e-mail announcement later in December. We will also provide support for institutions wishing to use the policy template.

— Rory Jaffe, MD MBA rjaffe@calhospital.org

E-Prescriptions' Unintended Consequence

Many e-prescribing systems allow for both structured and free-text fields in prescriptions, making possible internal discrepancies. This study reviewed 2914 electronic prescriptions that contained free-text fields. Internal discrepancies were found in 16.1% of the prescriptions. Most (83.8%) of the discrepancies could potentially lead to adverse events and many (16.8%) to severe adverse events, involving a hospital admission or death. Discrepancies in doses, routes or complex regimens were most likely to have a potential for a severe event ($p=0.0001$). Discrepancies between structured and free-text fields in electronic prescriptions are common and can cause patient harm. Improvements in electronic medical record design are necessary to minimize the risk of discrepancies and resulting adverse events.

Reference

Palchuk MB, Fang E a, Cygielnik JM, et al. An unintended consequence of electronic prescriptions: prevalence and impact of internal discrepancies. *Journal of the American Medical Informatics Association : JAMIA*. 2010;17(4):472-6.

Calendar Note

CHPSO Just Culture support calls will be moving to a new day of the month in 2011 to avoid conflicting with other California activities. Look for an e-mail announcement later in December.

Calendar

The following upcoming events are still open for enrollment. For more information or to enroll, use the contacts listed below.

December

- 2: SCPC (Southern California Patient Safety Collaborative): Track II: Pressure Ulcers. City of Industry.
- 3: CAPSAC: California Patient Safety Action Coalition Meeting. Torrance.
- 14: HASD&IC (Hospital Association of San Diego and Imperial Counties): Perinatal Collaborative. San Diego.
- 14: SCPC: Track III: Perinatal Safety. City of Industry.
- 15: HASD&IC: San Diego Patient Safety Council; Sepsis. San Diego.
- 15: BEACON: Compass Series 4 of 4. South San Francisco.
- 16: BEACON: Practical Skills for Quality Improvement. Redwood City.
- 21: CHPSO: Just Culture Support Call. 11 AM–noon.

January

- 18: SCPC: Third Annual Patient Safety Colloquium. Long Beach.

For further information on these events:

BEACON: Petrina Aiello paiello@hospitalcouncil.net or www.beaconcollaborative.org

CAPSAC: Theresa Frei FreiTH@sutter-health.org or www.capsac.org

CHPSO: Rory Jaffe rjaffe@calhospital.org

HASD&IC: Lindsey Wade lwade@hasdic.org

SCPC: Catherine Carson ccarson@hasc.org

Free Support for Automated Patient Safety Reporting

Both CHPSO and Quantros, our technology provider, provide free support for member hospitals. Time spent developing the text format for the report may be greatly reduced by using our assistance, as we can provide expertise in data mapping and formatting.

CHPSO can provide expertise on the meaning of the data fields and the correspondence between data in your system and the AHRQ Common Formats.

Quantros provides assistance with understanding the submission XML format and the process of sending in the data to the CHPSO database. They also provide assistance in using the web interface to the CHPSO database, viewing your reports, and conducting secure communications.

As a reminder, there is no need to collect any new data or change the manner in which you currently collect incident reports. We will accommodate any discrepancies between your data and the Common Formats by omitting mismatched fields.

We believe that, over time, the approach to collect incident reports will standardize throughout the country, as hospitals nation-wide will be participating in PSOs. We are aware of the burdens of the various reporting initiatives, and project that this standardization will occur over a significant period of time.

For CHPSO support, contact Rory Jaffe at rjaffe@calhospital.org or 916.552.7568. For Quantros, contact 877.QUANTROS option 2 or support@quantros.com.