

## Complexity and Infections

*CHPSO reports suggest increased risk of infection with complex devices*

*Initial reports suggest that, as medical devices become more complex, the risk of infection and intraoperative problems rise. This month's article focuses on infections. Future issues of CHPSO Patient Safety News will report on intraoperative risks.*

Preliminary reports from member hospitals raise the possibility of increased infection risk with the use of complex medical equipment (e.g., robotic surgery devices). While the reports do not provide sufficient information to draw conclusions, there are enough concerns related to reprocessing challenges to merit further investigation.

Nationally, there is growing awareness that device complexity has brought new risks both during and after procedures — during because of the number of instruments (and associated opportunities for mechanical failure) and the need for extensive training and experience to develop competency, and after due to the

complexity of preparing devices for their next use.

The Federal Drug Administration (FDA) is currently working with manufacturers to improve device design and instructions specifically to improve reprocessing reliability. Device reprocessing, which several decades ago was fairly simple, has become highly technical and varied — device manufacturers often have different and sometimes contradictory requirements for disassembly and cleaning. Further complicating matters, manufacturers often use different names for common device parts. Instructions may be difficult to understand, remember and follow.

Last October the FDA and Association for the Advancement of Medical Instrumentation (AAMI) held a summit on medical device reprocessing. AAMI issued a comprehensive follow-up report, which contained seven primary recommendations. The full report is available at [www.aami.org/htsi/reprocessing/pdfs/2011\\_Reprocessing\\_Summit\\_publication.pdf](http://www.aami.org/htsi/reprocessing/pdfs/2011_Reprocessing_Summit_publication.pdf).

*AAMI's seven primary recommendations on medical device reprocessing*

1. Gain consensus on adequate cleaning validation protocols.
2. Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.
3. Pay attention to reprocessing requirements throughout the device design process.
4. Make human factors and work environment factors priorities when developing reprocessing requirements.
5. Broaden the use of best practices in reprocessing.
6. Improve end user reprocessing competencies.
7. Create a greater sense of urgency and understanding throughout the health care community about the consequences of inadequate reprocessing.

*FDA's view of the reprocessing challenge*

The FDA has identified safety concerns based on its evaluation of reports received and on available literature. A summary of FDA concerns can be found at [www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252913.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252913.htm).

The FDA presents several examples of device design and reprocessing methodology challenges.

---

Right now, it is impossible to follow manufacturers' instructions for use... There are like instruments with different instructions, processes, and tools. There are complicated instructions with too many steps that are unreasonable, with too many variables. There is minimal repetition of tasks. Device IFU (Instructions For Use) do not specify the brush size needed to clean specific devices. Staff have to work from memory or 'hearsay.' IFU expect people to read an awful lot, in an environment that is not conducive to do such.

— Linda Condon, educator, Central Sterile Processing Department, The Johns Hopkins Hospital

## Device design

The designs of some types of reusable medical devices, endoscopes in particular, have become more complex. This can make optimal cleaning, high-level disinfection or sterilization more complicated.

The FDA's evaluation of adverse event reports and other information identified design features that are prone to retaining debris and biological materials, including:

- Long, narrow interior channels (lumens), including those with internal surfaces that are not smooth, have ridges or sharp angles, or are too small to permit a brush to pass through;
- Hinges;
- Sleeves surrounding rods, blades, activators, inserters, etc.;
- Adjacent device surfaces between which debris can be forced or caught during use;
- O-rings;
- Valves that regulate the flow of fluid through a device (stopcocks); and
- Devices with these or other design features that cannot be disassembled for reprocessing.

### Other device-design-related concerns:

- Post-market design changes that do not take into account how the changes impact the ability to properly clean and disinfect the device.
- Lack of communication between manufacturers and/or between manufacturers and device users when

medical devices used for reprocessing are modified and instructions are revised.

## Reprocessing methodology

Reprocessing is detailed, labor intensive, time-consuming, and can be prone to errors.

Each reusable medical device requires specific reprocessing steps or techniques appropriate for that device. Many variables impact the effectiveness of reprocessing reusable medical devices:

- Reprocessing challenges at individual facilities, such as:

Staff responsible for steps in the process

Training available to the staff

Equipment (e.g. appropriately sized brushes) available for use

- Quality and completeness of the reprocessing instructions provided by the manufacturer.
- Access to the manufacturers' instructions.

These variables are always changing because medical device technology is constantly evolving and reprocessing requires precision, as well as periodic retraining to assure staff competence.

—Rory Jaffe, MD, MBA, [rjaffe@chpso.org](mailto:rjaffe@chpso.org)

## More member data reports needed

Infections typically are not entered into an incident reporting system, but CHPSO encourages members to submit reports to the CHPSO/ECRI database that indicate issues with reprocessing procedures for reusable medical devices. We also are looking for reports indicating intraoperative issues (complications, retained surgical items, etc.) with complex devices such as surgical robots.

## Berwick Commends Patient Safety Leaders

Renowned health care visionary Don Berwick, MD, MPP, urged 450 California hospital leaders May 17 to accelerate their work in improving the quality and safety of care delivered to patients. The former administrator of the Centers for Medicare and Medicaid Services and founder of the Institute for Health Improvement spoke to leaders at quality improvement forums held in Walnut Creek and Newport Beach.

Berwick commended California hospitals for their work and said America will look to California for ways to change health care for the better. "Leadership has never been more important to show how quality improvement and patient safety at full scale is within reach and how this improvement is key to health care affordability.

"Politics and policy matter, but can't alone bring a ship into port." Providers and

Subscription service: [www.chpso.org/lists/](http://www.chpso.org/lists/)

Questions or comments: Rory Jaffe, MD MBA [rjaffe@chpso.org](mailto:rjaffe@chpso.org)

Copyright © 2012 [California Hospital Patient Safety Organization](http://CaliforniaHospitalPatientSafetyOrganization.org)

This newsletter may be freely distributed in its original form.

Opinions expressed by the authors are their own and not necessarily CHPSO's.

leaders at the community level have the power to effect change, he emphasized.

“Leaders can either nurture or extinguish efforts,” particularly in the area of creating a safe culture in which to share and learn from what went wrong and why. Accelerating change, he said, requires unprecedented teamwork and the belief that improvement is an ethical duty. “It’s not enough to just do no harm. We must accomplish contributions to the greater good,” that achieve safety, effectiveness, patient-centeredness, timeliness, efficiency and equity.

CHPSO was one of the co-sponsors of the forums along with the California Hospital Association, the Hospital Council of Northern & Central California, the Hospital Association of Southern California, and the Hospital Association of San Diego & Imperial Counties. John Muir Health in Walnut Creek and the UCLA Health System in Los Angeles provided substantial support for the events.

— Frances Sutz Brown, [fsutzbrown@chpso.org](mailto:fsutzbrown@chpso.org)

## CHPSO Redesigning Website: Seeks Input

The California Hospital Patient Safety Organization (CHPSO) is redesigning its website. The new site will be easier to navigate and will include new member-only features. We are looking for volunteers to provide input and test usability. If you’re interested in participating, please contact Frances Sutz Brown, director, Operations and Communications, [fsutzbrown@chpso.org](mailto:fsutzbrown@chpso.org) or 916.552.7598.

## The Meaningful Use of Safety Data

### Quantros perspective

The recent January 2012 report by the Office of the Inspector General (OIG), [Hospital Incident Reporting Systems Do Not Capture Most Patient Harm](#), states that incident reporting systems detected only 14 percent of independently verified safety events. Clearly, more effort and resources are needed to close this gap.

Study interviewers asked hospital administrators about responses to reported events, and their perceptions of the causes for underreporting. The most commonly cited cause was failure to recognize an event as reportable (that is, not caused by a perceptible error and so on). The study results seem to bear this out. Some form of investigation (ranging from informal review to formal root cause analysis) following the incident report occurred in about 70 percent of the events reviewed in the study. However, only 13 percent of these investigations led to a safety performance policy change.

As limited as they may be today, automated incident reporting systems are the driver for the meaningful use of safety data, as well as a first line of defense against preventable medical errors. Incident reporting systems enable hospitals to capture near-miss information and unsafe conditions they may otherwise miss. The reporting and analysis of near-miss events increase the collective knowledge about what leads to safety incidents and promotes planning that factors in predictable human error. The overwhelming majority of this highly useful information resides outside of the electronic health record — and would be forever lost if not for the incident reporting system.

### *People, processes and technology: A three-Lane highway to safer care*

But the incident reporting system itself is just one component of an effective patient safety management program. To bridge the gap between reported events and the delivery of safer, higher quality care, hospitals should have the appropriate people and processes in place to establish a supportive, action-oriented environment and culture of transparency.



### *Program components*

An effective safety management program should be multifaceted: It should not only improve event-capture rates, but also directly point out trends and seamlessly engage evaluation and intervention. Surveillance tools that detect both high-risk situations as well as safety events that have already occurred can be a potent addition to the technology platform. With a sufficient body of internally captured event information and external comparative data available, automated surveillance can identify patterns and actionable items difficult to detect with human eyes alone.

For many hospitals, the data to drive this surveillance already exists. Structured clinical data sources (diagnoses, problem lists, lab, radiology results, and treatment orders) can be used to detect safety events, and even possibly identify unsafe conditions.

However, no electronic system will achieve its potential without human beings leveraging it properly. Data without action is useless — and so a seamless transition to investigation and intervention is an essential part of a safety management platform. The culture of the caregiver must also promote safety improvements — and fix processes that interfere with that goal. The Patient Safety and Quality Improvement Act of 2005 contributes to the free use of data. This legislation provides caregivers and safety management staff with legal protection of their work product through anonymous reporting, investigation and intervention to improve patient safety.

Process details are shown in the diagram below.

## Meaningful Use Future

Automated incident reporting systems make it easier than ever to capture a complete range of safety event data. With the growth of Meaningful Use, Value Based Purchasing (VBP) and other electronic reporting initiatives, the demand for this data will only grow. But patient safety

improvement depends on leveraging these systems to their fullest potential, and clearly that's not happening. But the technology is improving and incident reporting will be augmented with the automated surveillance of actual events, unsafe conditions and near misses. As hospital leadership drives a supportive culture of transparency, the power of safety management programs will only improve.

—Gerard Livaudais, MD, MPH, Quantros chief medical officer, [glivaudais@quantros.com](mailto:glivaudais@quantros.com)

## HASD&IC Appoints VP for Quality and Safety

Alicia A. Muñoz is the new vice president, Quality and Patient Safety, at the Hospital Association of San Diego and Imperial Counties. She will serve as lead issue manager for quality and patient safety programs and other related local initiatives. She can be contacted at [amunoz@hasdic.org](mailto:amunoz@hasdic.org) or 858.614.1541.

## CHPSO Recruiting Director Quality and Patient Safety

The California Hospital Patient Safety Organization (CHPSO) has an immediate need for a director Quality and Patient Safety. Based in Sacramento, the director Quality and Patient Safety will foster multi-facility collaboration for quality improvement and facilitate patient safety initiatives throughout California.

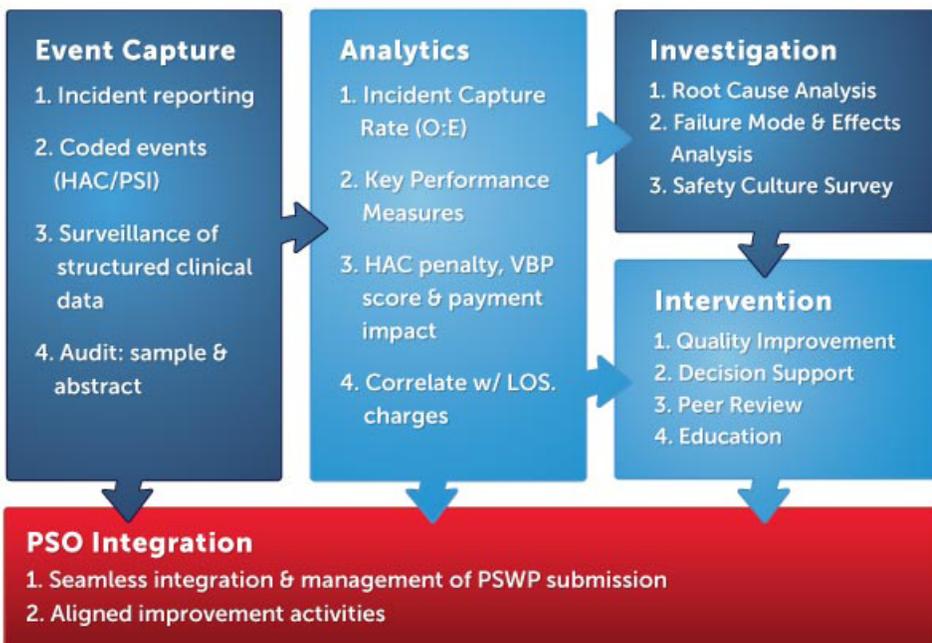
As an expert resource for members, the director will analyze incident reports and root cause analyses; identify patient safety best practices, models, and other proven and effective strategies and provide assistance to members seeking to expand their safety efforts; enable peer-to-peer connectivity to facilitate learning and sharing of experiences; and bring practitioners and industry leaders together to share knowledge and foster innovations in quality and patient safety.

Candidates must have a bachelor's degree in clinical practice and preferably a master's degree in a related health care field. Find more information at [www.calhospital.org/general-information/director-quality-and-patient-safety](http://www.calhospital.org/general-information/director-quality-and-patient-safety). To apply, please forward your resume and cover letter (with salary requirement) to [homeease.adp.com/recruit/?id=689401](mailto:homeease.adp.com/recruit/?id=689401) EOE.

## Hospital Council Calendar Notes

June 19 — *BEACON Sacramento Regional Meeting*, Marriott Rancho Cordova, 9:00 AM – 3:30 PM

July 10 — *BEACON San Francisco Regional Meeting*, Marriott San Mateo, 9:00 AM – 3:30 PM



# CHPSO Patient Safety News

June 2012 ≈ Page 5

Join the Hospital Council for a day of networking and learning with peers, as hospitals share their successful efforts in reducing sepsis mortality, hospital acquired infection and perinatal harm. More information on the Sacramento meeting is available at [www.hospitalcouncil.net/post/beacon-sacramento-regional-meeting-0](http://www.hospitalcouncil.net/post/beacon-sacramento-regional-meeting-0), and for the San Francisco meeting at [www.hospitalcouncil.net/post/beacon-san-francisco-regional-meeting-1](http://www.hospitalcouncil.net/post/beacon-san-francisco-regional-meeting-1).

## Hospital Association of Southern California Calendar Notes

June 5 — *Southern California Patient Safety Collaborative Track II Meeting: Care Transitions & Readmissions Reduction*, Pacific Palms Conference Center, 9:00 AM – 3:30 PM.

This HASC-hosted meeting features keynote speakers, Cheri Lattimer, RN, Case Management Society of America (CMSA)/National Transitions of Care Coalition (NTOCC), and Anil Goud, MD, Independent Hospitalists, PLCC / Electronic Health Record Exchange. For more information and to register go to [www.hasc.org/education-event/southern-california-patient-safety-collaborative-track-ii](http://www.hasc.org/education-event/southern-california-patient-safety-collaborative-track-ii).

## CHPSO Calendar Notes

June 21 — *CHPSO/ECRI Web seminar: Best Practices for Managing Medical Product Hazards and Recalls*, 10 – 11 AM.

Learn about recent high profile product recalls and their impact on patient safety. James P. Keller, Jr., vice president, Health Technology Evaluation and Safety, will facilitate discussion on best practices for avoiding patient harm related to product recalls and other reported safety problems. CHPSO members will receive an

invitation in mid-June to participate in the seminar.

## CHPSO Events

Except as noted, these events are for CHPSO members only.

### June

**11:** *CHPSO: Members Call*. 10–11 AM

**21:** *CHPSO/ECRI: Best Practices for Managing Medical Product Hazards and Recalls*. 10–11 AM

### July

**9:** *CHPSO: Members Call*. 10–11 AM

**16:** *CHPSO/ECRI: User Group Meeting, Knowledge Transfer: A Patient Safety Essential: Training as a contributing factor in adverse events*. 11:30 AM–12:30 PM

### August

**13:** *CHPSO: Members Call*. 10–11 AM

**20:** *CHPSO/ECRI: User Group Meeting, Topic Same Name/Look-alike Name Alerts*. 11:30 AM–12:30 PM

### September

**10:** *CHPSO: Members Call*. 10–11 AM

**TBD:** *CHPSO/ECRI: Strategies to Prevent Falls*. Web seminar time TBD.

### October

**8:** *CHPSO: Members Call*. 10–11 AM

**15:** *CHPSO/ECRI: User Group Meeting, Topic TBD*. 11:30 AM–12:30 PM

### November

**12:** *CHPSO: Members Call*. 10–11 AM

**19:** *CHPSO/ECRI: User Group Meeting, Topic TBD*. 11:30 AM–12:30 PM

### December

**10:** *CHPSO: Members Call*. 10–11 AM

**TBD:** *CHPSO/ECRI: Radiology Patient Safety*. Web seminar time TBD.

*For further information on these events:*

Colleen Meacham [cmeacham@chpsso.org](mailto:cmeacham@chpsso.org)  
916.552.7651

## Subscribe Now

Newsletter subscription is free and open to all. If you wish to receive this newsletter and other email updates from CHPSO, sign up at [www.chpsso.org/lists/](http://www.chpsso.org/lists/). This same link may be used to unsubscribe.

## About This Newsletter

*CHPSO Patient Safety News* provides lessons learned from reviews of patient-safety events and news of patient-safety activities in this state. We hope you will find it useful in your efforts to improve patient outcomes. This newsletter may be freely distributed in its original form. Copies of each newsletter are archived on the CHPSO website ([www.chpsso.org](http://www.chpsso.org)).

Prospective authors may submit articles to Frances Sutz Brown: [fsutzbrown@chpsso.org](mailto:fsutzbrown@chpsso.org), 916.552.7598. Typical articles will be brief — between 200 and 600 words. A completed [publication agreement form](#) must be submitted prior to publication.