



Responding to Adverse Events

In Pennsylvania, one of the first ways healthcare facilities respond to an adverse event is by submitting a report through the PA-PSRS system. However, we not only want you to submit a report, but to learn from your experiences and from others' best practices. That's why we designed PA-PSRS to help promote a culture of safety by facilitating report analysis and internal quality improvement. These *Advisories* also serve that purpose. In our recent User Survey, 74.5% of hospitals reported having made changes within their facilities as a result of articles in the *Advisories*.

Under Act 13, facilities are also required to respond to adverse events by notifying a patient about a Serious Event. While several studies validate the importance of acknowledging, as well as apologizing for, adverse events, providers and managers con-

tinue to wrestle with how they should implement this disclosure requirement.

In a previous column, I wrote about the disclosure requirements of the U.S. Department of Veterans Affairs for all federal Veterans healthcare facilities. I also cited a recent article by Dr. Lucian Leape specifically addressing physicians on this important issue (Vol.2, No.4—Dec. 2005).

Earlier this month, Harvard-affiliated hospitals released a "Consensus Statement" entitled *When Things Go Wrong: Responding to Adverse Events*. This statement is likely to influence health policy makers around the country and is now established in the 16 Harvard teaching hospitals, including such renowned institutions as the Brigham and Women's, Dana-Farber Cancer Institute, Joslin Diabetes Cen-

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Who Administers Propofol in Your Organization?

What are the necessary credentials for administering propofol (DIPRIVAN) for moderate and deep sedation? Healthcare facilities in Pennsylvania and across the country are asking this question. The American College of Gastroenterology and others contend that the safety profile of propofol is such that a gastroenterologist, registered nurse under their supervision, and other "qualified medical professionals" can safely and effectively administer the drug without specific training in the administration of general anesthesia.¹

However, drug manufacturers and several anesthesiology professional organizations believe this may place patients at undue risk.²⁻⁶ What constitutes safe practice for this high-alert medication?

At Issue

The use of propofol during endoscopic, radiologic, and other procedures is growing in hospitals, ambulatory surgical facilities, and physician offices across the country.⁷ Propofol offers certain advantages over other drugs used for sedation when used by trained and credentialed practitioners because it:

- Has a rapid onset and a short duration of action.
- Allows patients to wake up, recover, and return to baseline activities and diet sooner than some other sedation agents.
- Reduces the need for opioids, resulting in less nausea and vomiting.⁸

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Letters to the Editor

Patient Safety Hotlines

Patient Safety Officers are always looking for new ways to encourage reporting within their facilities, and we wanted to share our hospital's experience implementing a patient safety hotline.

We implemented a patient safety hotline in September 2002 as part of the requirement under Act 13 of 2002 to "establish a system for health care workers to report serious events and incidents which shall be accessible 24 hours a day, seven days a week" (Section 307, (b)(3)). This dedicated phone line for our staff to report patient safety events they believed to be serious was in addition to reporting to our Risk Managers, who were already on-call 24 hours a day, seven days a week.

Staff can report events through the hotline anonymously, if they choose. We educate our staff to use the hotline through information in our Patient Safety Plan, via advertisement on our Hospital Intranet page and quarterly Patient Safety newsletter, as part of our new hire education sessions, and as a reminder message in our web-based on-line patient safety reporting system.

We have also recently implemented web-based on-line event reporting within our facility (rL Solutions, Risk MonitorPro), which gives our staff another mechanism for reporting 24 hours a day, seven days a week. On-line event reporting has afforded us the opportunity to receive reports in real-time. After receiving a hotline call, we can immediately pull up the report if it has already been submitted.

The hotline has been very successful and averages approximately 60 calls per quarter. It allows for timely notification of events/incidents, allowing us to meet the timeliness requirements for patient notification and submission to PA-PSRS, should the event be determined to be serious.

These tips may help other facilities considering a hotline or implementation of an electronic patient safety event reporting system.

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Lost Surgical Specimens

I want to take this opportunity to thank you for the great article about lost surgical specimens from the September 2005 edition of the *PA-PSRS Patient Safety Advisory*.

The article gave Berks Center for Digestive Health a good start to doing a CQI project on our specimen errors. Being a busy ambulatory GI center with several employees, it is difficult to eliminate human error completely. With your strategies for reducing these errors, we hope to strive for excellence by reducing the number of errors.

I utilized the eight steps outlined for getting the specimens to the laboratory correctly by creating a colorful board that all employees can review periodically to stay refreshed. This will also aid in the teaching of new employees joining our healthcare team. Also, all of our procedure rooms will have a smaller copy attached to the wall for all assistants to view prior to completing each patient's specimen(s).

Berks Center for Digestive Health is proud of its winning healthcare team. With your eight-step outline, we are able to assure our patients that they are getting exceptional care. Thank you again for your outstanding article.

Sherry Degler, MA
Berks Center for Digestive Health, Wyomissing

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ter, Beth Israel Deaconess Hospital and Massachusetts General. You can access this document at the website of the Massachusetts Coalition for the Prevention of Medical Errors at www.macoalition.org/index.shtml.

In the same vein, I encourage you to consider the “Sorry Works!” initiative, which is being adopted by an increasingly large group of hospitals and systems around the country. See www.sorryworks.net for more information about this successful initiative.

While the action of *reporting* an adverse event involves only staff and administrators at a particular facility, the process of *disclosure* engages the patient and his family as well. Establishing a “Just Culture Community” expands the entities involved to include organizations and agencies external to the healthcare institution.

At the recent 2006 Patient Safety Symposium sponsored by HAP (Hospital and Healthsystem Association of Pennsylvania), the Authority was pleased to underwrite David Marx’s keynote address on “Patient Safety and the ‘Just Culture’.” An engineer and attorney with experience in aviation safety as well as healthcare, Marx expands the traditional definition of patient safety to mean not only freedom from injury or harm, but freedom from the *risk* of injury or harm.

During his talk, he challenged the audience of almost 400 to encourage traditionally competing groups to agree on a common response to adverse events. Marx noted that, in Minnesota and several other states, the hospital association, state health department, and the nursing and medical boards are striving to establish a “Just Culture Community” by agreeing that, in exchange for full and open disclosure by providers, the regulatory agencies would refrain from disciplinary action following an unintended adverse event not caused by reckless or risky behavior.

What makes this process work—requiring provider disclosure in exchange for regulatory restraint—is a commitment by providers to individual and institutional accountability. This innovative, if nontraditional, approach is built upon Marx’s concept of a “just culture,” which blends accountability with system reliability. To learn more about the concept of “just culture,” go to www.justculture.org.

How you respond to an adverse event defines how willing you and your facility are to adopting a culture of safety. Full disclosure, open dialogue, accountability, learning-- these are the components of patient-centered care. And that’s the bottom line for all of us, providing safe, effective and quality healthcare for patients and their loved ones.

Alan B.K. Rabinowitz
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American College of Surgeons Advocates Blunt Needles for Fascial Closures

The American College of Surgeons has issued a statement supporting the universal adoption of blunt needles as the first choice for fascial suturing.¹ The statement cites evidence that puncture wounds of personnel occur in 1-15% of operations,² with 59% of all needlestick injuries occurring during the suturing of the fascia during closure.

Blunt suture needles have been estimated to decrease injuries by 30%.³ Puncture wounds of the surgeon during an operation present a risk of transmitting blood-borne pathogens either from the patient to the surgeon or from the surgeon to the patient. Blunt needles can be used for suturing fascia,

muscle, fat, and organ tissue, but they are not appropriate for vessels or skin.

Reports of needlestick injuries to patients and healthcare workers have been submitted to PA-PSRS, including injury to the surgeon or resident during closure of a fascia incision.

Notes

1. Committee on Perioperative Care. Statement on blunt suture needles. Bulletin of the American College of Surgeons. 2005 (Nov); 90(11):24.
2. Centers for Disease Control and Prevention (CDC). Evaluation of blunt suture needles in preventing percutaneous injuries among health-care workers during gynecologic surgical procedures--New York City, March 1993-June 1994. MMWR. 1997 Jan 17;46(2):25-9.
3. Jagger J, Bentley M, Tereskerz P. A study of patterns and prevention of blood exposures in OR personnel. AORN J. 1998 (May);67(5):979-87.

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However, practitioners may develop a false sense of security, allowing the perceived safety profile of propofol to influence their belief that the drug poses minimal risk. In untrained hands, propofol can be deadly. Administration to a non-ventilator-assisted patient by a practitioner who is not trained to administer drugs that cause deep sedation and general anesthesia is not safe, even if the drug is given under the supervision of a physician performing the procedure.⁸

Further complicating the situation is that several insurance companies have decided that propofol administration in the office setting by gastroenterologists or their assistants is acceptable and safe for some procedures.⁸ Therefore, these insurers will no longer reimburse for anesthesiology services performed for some procedures in office settings. In the article "RNs Pushing Propofol," Meltzer states that this unwillingness to reimburse anesthesia care for procedures in which propofol is used, such as diagnostic endoscopy, has increased the use of nurse-administered propofol. As a result, untrained practitioners may be caught in the middle of the debate and feel pressured to administer propofol.⁸

Medication Errors

The Pennsylvania Patient Safety Reporting System (PA-PSRS) has received over 100 medical and medication error reports in which the use of propofol has been cited. Sixteen percent (16%) of these reports have been classified as Serious Events, including four patient deaths in which propofol may have played a role. Here is one example:

A 40-year-old patient was admitted with injuries to the face and subarachnoid hemorrhaging. The patient received propofol but was not intubated. The patient was then taken to radiology for a CT scan. While in radiology, the patient became bradycardic and suffered a cardiac arrest. The patient was resuscitated but died two days later.

Another example was reported by the Institute for Safe Medication Practices (ISMP) in November 2005. A gastroenterologist who thought propofol was "used all the time in ICU" asked a nurse to prepare "10 mL" (10 mg/mL) of propofol for a patient undergoing endoscopy.⁹ The nurse retrieved the drug from an automated dispensing cabinet via the

override function. Another nurse who was trained in the use of moderate sedation, but not deep sedation or anesthesia, assisted the gastroenterologist. She questioned the physician regarding the dose but began administering the propofol via an infusion pump. The patient experienced respiratory arrest. Fortunately, other ICU staff members were able to help with the emergency and quickly intubated and ventilated the patient.

Another case involved a physician who thought he could safely administer propofol while performing breast augmentation.¹⁰ However, he and his surgical assistant, neither of whom were able and/or qualified to monitor patients under deep sedation or anesthesia, failed to recognize the patient's rapidly deteriorating respiratory status. The patient, a young woman, died of hypoxic encephalopathy.

In another example, nurses in one particular facility have reported being asked to administer "a little more" propofol if the patient moved after the anesthesiologist left the room.⁸ In these cases, the anesthesiologist would leave the propofol syringe attached to the IV port after placing the block and leave the nurses in the room to monitor the patient. The nurses reluctantly complied initially. Later, they brought the issue to the attention of hospital leaders, citing that they were worried about the safety of this practice.³

Professional Society Viewpoints

There is a difference in opinion among professional societies about the necessary credentials for individuals administering propofol for sedation. In brief, the American Society of Anesthesiologists (ASA), American Association of Nurse Anesthetists, and American Association for Accreditation of Ambulatory Surgery Facilities believe that safe administration of propofol to non-ventilator-assisted patients is limited to individuals trained in the administration of general anesthesia who are not simultaneously involved in the procedure.²⁻⁴ The ASA also suggests that, if this is not possible, non-anesthesia staff who administer propofol be qualified to rescue patients whose level of sedation becomes deeper than intended and who enter, if briefly, a state of general anesthesia. The ASA's "Practice Guidelines for Sedation and Analgesia by Non-anesthesiologists" is available on their website.⁹

In contrast, the American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, and Society of Gastroenterology Nurses and Associates endorse nurse-administered propofol under

Physicians can receive continuing medical education (CME) credits for completing the self-assessment questions related to this article. See page 35 for details.

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the direction of a physician if state regulations allow it, if the nurse is trained in the use of drugs causing deep sedation, and if the nurse is capable of rescuing patients from general anesthesia or severe respiratory depression.^{12,13}

Joint Commission on Accreditation of Healthcare Facilities (JCAHO) Standard

JCAHO Standard PC.13.20 requires, for the administration of moderate or deep sedation, that a sufficient number of staff, in addition to the person performing the procedure, be present to perform the procedure, monitor and recover the patient. The person administering the sedative agent must be qualified to manage the patient at whatever level of sedation or anesthesia is achieved, either intentionally or unintentionally. While there may be a need for additional monitoring personnel for the procedure, the person administering the sedation must be qualified to monitor the patient.¹⁴

Product Labeling

Manufacturers of propofol state in the product labeling that:^{5,6}

- The drug should be administered only by persons trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure.
- Monitored anesthesia care (MAC) patients should be continuously monitored by persons not involved in the conduct of the surgical or diagnostic procedure; oxygen supplementation should be immediately available and provided where clinically indicated; and oxygen saturation should be monitored in all patients. Patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.

The official labeling also indicates that propofol should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management when sedating intubated, mechanically ventilated adult patients in the ICU.

The American College of Gastroenterology has petitioned the FDA to remove the following text from the DIPRIVAN (propofol) product label: "For general anesthesia or MAC sedation, DIPRIVAN Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure."¹ However, the FDA has not

made a final ruling on this petition, and as of March 2006 the labeling as presented above continues to be the official and approved labeling for propofol products.

Variable Effects

Propofol dosing and titration is variable, as it is based on the patient's response and tolerance to the drug. Profound changes in respiratory status can occur rapidly. A patient can go from breathing normally to a full respiratory arrest in seconds, even at low doses, without warning from typical assessment parameters.⁸

No Reversal Agent

Unlike other agents used for sedation (e.g., midazolam, morphine), propofol has no reversal agent.

State Boards

More than a dozen states specifically consider nurse-administered propofol beyond the scope of nursing practice according to their Nurse Practice Acts.⁸ Pennsylvania does not have an official advisory opinion or declaratory statement regarding the administration of propofol by nurses.

The Pennsylvania Code stipulates that the administration of anesthesia is a proper function of a registered nurse who has successfully completed an accredited education program for nurse anesthetists and who works in cooperation with a surgeon or dentist.¹⁵ The code also specifies that a registered nurse who is not a certified registered nurse anesthetist may administer intravenous conscious sedation medications during minor therapeutic and diagnostic procedures.¹⁶

Safe Practice Strategies

Unfortunately, there is no easy answer to the question of who to allow to administer propofol in your organization. The process requires input from many parties. A good first step may be to convene a multidisciplinary team consisting of administration, nurses, pharmacists, and physicians (including representatives from anesthesia, gastroenterology, radiology, surgery, and other physicians from areas that may administer or monitor propofol) to:

- Review state regulations to ascertain which practitioners may or may not be able to administer propofol within their respective scope of practice.
- Evaluate the literature and various position statements available from professional societies such as the ASA, American Association of

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Nurse Anesthetists, and others. See the Resources section below for selected societies and web addresses.

- Establish policies and practice guidelines for the administration of propofol (or other agents such as thiopental, methohexital, or etomidate) to non-ventilator-assisted patients undergoing minor surgical or diagnostic procedures.
- Define qualifications of professionals who can administer propofol to non-ventilator-assisted patients during procedures.
- If nurse-administered propofol is agreed upon as acceptable, specify the circumstances and required education and mentorship to be accomplished beforehand and competencies to be evaluated and met periodically. Keep in mind that ACLS certification alone may not be sufficient for this purpose.⁸
- Evaluate locations where propofol administration is appropriate, and ensure that those areas are able to follow the developed criteria for administration, including expertise and availability of equipment to intubate patients.
- Define and document the intended level of sedation that patients should receive. Ensure that all patients, even if moderate sedation is intended, are able to be monitored and rescued from deep sedation.
- Establish a continuous monitoring process and assessment criteria (e.g., vital signs, oxygen saturation, capnography) for non-ventilator-assisted patients who are receiving propofol.
- Ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.

Conclusion

Propofol, an injectable emulsion, is a high-alert medication according to ISMP.^{17,18} Based on the action and nature of the medication and the number of error reports submitted to PA-PSRS and other organizations, the safest strategy is to limit propofol use to healthcare professionals with specialized training in administering, monitoring, and treating its untoward effects. However, errors can still occur despite the presence of a trained healthcare professional. The largest number of events involving propofol received by PA-PSRS occurred in the ICU and OR—practice settings designed with constant supervision in place.

While the debate will continue over the appropriate credentials for administering and monitoring propofol, one thing is clear: whenever propofol is used for sedation/anesthesia, it should be administered only by persons who are capable of recognizing and treating any untoward effects with this largely beneficial, but potentially deadly, agent.

Resources

American Society of Anesthesiologists
(www.asahq.org)

American Association of Nurse Anesthetists
(www.aana.com)

American Association for Accreditation of Ambulatory Surgery Facilities (www.aaaasf.org)

American College of Gastroenterology
(www.acg.gi.org)

American Gastroenterological Association
(www.gastro.org)

American Society for Gastrointestinal Endoscopy
(www.asge.org)

Society of Gastroenterology Nurses and Associates
(www.sгна.org)

Notes

1. FDA Docket 2005P-0267. Remove from the Labeling for Propofol (Diprivan) the Warning that Propofol should be Administered Only by Persons Trained in the Administration of General Anesthesia, Rather than by Other Qualified Medical Professionals. FDA Dockets Management. [online]. [cited 2006 Feb 22]. Available from internet: <http://www.fda.gov/ohrms/dockets/dockets/05p0267/05p-0267-cp00001-01-vol1.pdf>.
2. American Society of Anesthesiologists. GI Physicians Endorse Propofol Use; ASA to Issue Statement [online]. 30 Mar 2004 . [cited 22 Feb 2006]. Available from Internet: <http://www.asahq.org/news/propofoluse.htm>.
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4. American Association for Accreditation of Ambulatory Surgery Facilities. For Surgery Facilities. [online]. 2006. [cited 22 Feb 2006]. Available from Internet: <http://www.aaaasf.org/surgicenters.php>.
5. Diprivan® (propofol) injectable emulsion US prescribing information. AstraZeneca Pharmaceuticals LP. [online]. Aug 2005. [cited 22 Feb 2006]. Available from Internet: <http://www.astrazeneca-us.com/pi/diprivan.pdf>.
6. Propofol injectable emulsion US prescribing information. Bedford Laboratories. [online]. Apr 2005. [cited 22 Feb 2006]. Available from Internet: <http://www.bedfordlabs.com/products/inserts/PPFI00.pdf>.
7. Marshall S. Pleasant dreams: office surgeries fuel demand for anesthesiologists. Crain's New York Business. 10 Jan 2005.
8. Meltzer B. RNs pushing propofol. *Outpatient Surgery*. 2003;4(7).
9. Institute for Safe Medication Practices. Propofol sedation: Who should administer? ISMP Medication Safety Alert! Acute Care Edition. 2005 Nov 3;10(22):1-3.

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10. WFTS ABC Action News. Doctor still on the hook for 'accidental' surgery death. ABC Action News Tampa-St. Petersburg. 18 Mar 2004.

11. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guideline for sedation and analgesia by non-anesthesiologists. 17 Oct 2001. Available from Internet: <http://www.asahq.org/publicationsAndServices/sedation1017.pdf>.

12. American College of Gastroenterology. Three Gastroenterology Specialty Groups Issue Joint Statement on Sedation in Endoscopy: Gastroenterology Societies Reach Consensus on Recommendations for Sedation During Endoscopic Procedures. [online]. 8 Mar 2004. [cited 22 Feb 2006]. Available from Internet: <http://www.acg.gi.org/physicians/nataffairs/trisociety.asp>.

13. Society of Gastroenterology Nurses and Associates. Statement of the Use of Sedation and Analgesia in the Gastrointestinal Endoscopy Setting. [online]. 2004. [cited 22 Feb 2006]. Available from Internet: <http://www.sgna.org/Resources/statements/statement2.cfm>.

14. Joint Commission on Accreditation of Healthcare Organizations. Moderate Sedation Medication and Patient Monitoring.

[online]. 1 Jan 2006. [cited 22 Feb 2006]. Available from Internet: http://www.jcaho.org/accredited+organizations/hospitals/standards/hospital+faqs/provision+of+care/operative_hrp_sed_anesth/sed+med_pat+med.htm.

15. The Pennsylvania Code. Chapter 21: State Board of Nursing. Subchapter A. Registered Nurses. Section 21.17. Anesthesia. [online]. [cited 22 Feb 2006]. Available from Internet: <http://www.pacode.com/secure/data/049/chapter21/chap21toc.html>.

16. The Pennsylvania Code. Chapter 21: State Board of Nursing. Subchapter A. Registered Nurses. Section 21.413. Interpretations regarding the administration of drugs – statement of policy. Subsection d. [online]. [cited 22 Feb 2006]. Available from Internet: <http://www.pacode.com/secure/data/049/chapter21/chap21toc.html>.

17. Institute for Safe Medication Practices. FAQ 7. What is a "high alert" medication? [online]. 2006. [cited 22 Feb 2006]. Available from Internet: http://www.ismp.org/faq.asp#Question_7.

18. Institute for Safe Medication Practices. ISMP's list of high-alert medications. [online]. 2005. [cited 22 Feb 2006]. Available from Internet: <http://www.ismp.org/Tools/highalertmedications.pdf>.

The Changing Faces of Unit-Dose Tylenol Packets

In the Fall of 2005, McNeil Consumer and Specialty Pharmaceuticals changed the packaging of its unit-dose TYLENOL (acetaminophen) 500 mg caplets for hospital use. The caplets, previously packaged in bright yellow packets, were switched to white packets to maximize accurate readability of the newly added bar code by scanning devices. Unfortunately, the new 500 mg packet looks virtually identical to the Tylenol 325 mg unit-dose packet (Figure 1).

Pennsylvania healthcare facilities have reported multiple mix-ups involving these products to PA-PSRS. Practitioners have reported to ISMP and the manufacturer that the striking pack-

age similarities can lead to confusion and may result in excessive doses in facilities that do not use point-of-care bar coding.¹ As a result of all the reports received, the manufacturer will be returning to the familiar yellow packet reportedly in March 2006 that includes a bar code (Figure 2) and will continue to explore ways to improve scanning reliability while maintaining visually differentiated packaging.²



Figure 1. "New" white 500 mg unit-dose packet (left) and 325 mg unit-dose packet (right) look-alike. Image provided courtesy of ISMP.



Figure 2. Yellow Tylenol packet to return with barcode. Image provided courtesy of ISMP.

Notes

1. ISMP Medication Safety Alert! Acute Care Edition. Look-alike Tylenol packets. 17 November 2005.
2. ISMP Medication Safety Alert! Acute Care Edition. Your reports at work: Tylenol packaging returns to yellow. 26 January 2006.

Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery

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PA-PSRS has received reports of complications from the placement of temporary epicardial pacing wires during open heart surgery. One report was of bleeding from the insertion site, leading to pericardial tamponade post-operatively. The tamponade was treated with pericardiocentesis, and the patient was returned to the OR for correction of the underlying leak. The other report was of a fatal, exsanguinating hemorrhage into the chest upon post-operative removal of an atrial pacing wire, because the removal of the wire tore the child's atrium. These two reports represent the Scylla and Charybdis of temporary epicardial pacing wire placement, leaking and binding. PA-PSRS asked Dr. James McClurken, a cardio-thoracic surgeon with expertise on this topic, to comment. John R. Clarke, M.D., Editor

For years, virtually all patients at most cardiac surgical centers received temporary epicardial pacing wires (TEPW). Although the incidence of complications from placement or removal of TEPW has been low, the adverse events can cause major morbidity and even mortality. In addition to inadequate lead function, the majority of serious morbidity reported relates to lead removal. Complications reported have included bleeding from ventricular or atrial laceration, tamponade, side branch or graft avulsion, superior epigastric artery laceration and or retention.^{1,2} Transmigration of a retained TEPW endobronchially has also been reported.³

Recently, the evolution of indications has shown a more defined pathway for TEPW use in coronary artery bypass grafting (CABG) patients.^{4,5} In fact, less than 10% of CABG patients may require post-operative use of TEPW. Predictors of necessity for TEPW on multivariate analysis of CABG patients include diabetes, preoperative arrhythmia, and pacing required to separate from bypass.⁴ Added to that list on univariate analysis were advanced age, cardiomegaly, preoperative antiarrhythmic therapy, and inotropic agents upon leaving the operating room. The need for TEPW may be greater for complex and valvular cardiac surgery,⁶ especially where decalcification of the aortic annulus may risk dysfunction of proximate conduction system fibers. Key but subtle features of the dynamics of myocardial functional recovery after cardiac surgery frequently are the indications also cited by many surgeons for use of TEPW.

Complications of TEPW can be reduced by attention to certain details involved in both technical aspects of placement of wires and in considerations for removal. These considerations are presented in list form.

Placement of TEPW:

1. Keep electrodes at least 1.5 – 2.0 cm apart on the epicardium to maximize efficacy.
 - a) Electively, test and record threshold function for wires.
 - b) Secure the TEPW at the exit site with a suture.
2. Carefully select locations.
 - a) Avoid arterioles/venules on the right ventricle.
 - b) Pick 'thicker' spots on the right atrium on the mid and lower right atrial wall; consider Waterston's groove, left atrium.
 - c) If right atrial appendage used, be certain bare wire does not inadvertently also contact right ventricle, as simultaneous atrial and ventricular contraction could occur with resultant hemodynamic compromise.
 - d) Be ever mindful of the exit course of the wire and its relationship to nearby graft(s) – avoid "clotheslining."
 - e) Keep exit direction of pacing wire from epicardium in as straight a line as possible to epigastric exit site, to avoid Gigli saw effect or tearing upon removal.
3. If repair suture for bleeding required, use smallest suture possible (e.g. 4-0, 5-0, or even 6-0).
 - a) Consider mattress suture with or without pledgets rather than figure-of-8 sutures, in order to facilitate removal.
 - b) Don't over tighten/strangulate the hemostatic suture, as the TEPW needs to be removed.
4. Avoid long, redundant loops of wire; prevent conduit ensnaring or lassoing which could occur at removal.
 - a) Be especially cognizant of conduit side branch clips and their relationship to the TEPW course to avoid avulsion of clip at removal.
 - b) Be certain both ventricular and/or both atrial wires are on the same side of a graft to prevent constriction at removal.

Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery (Continued)

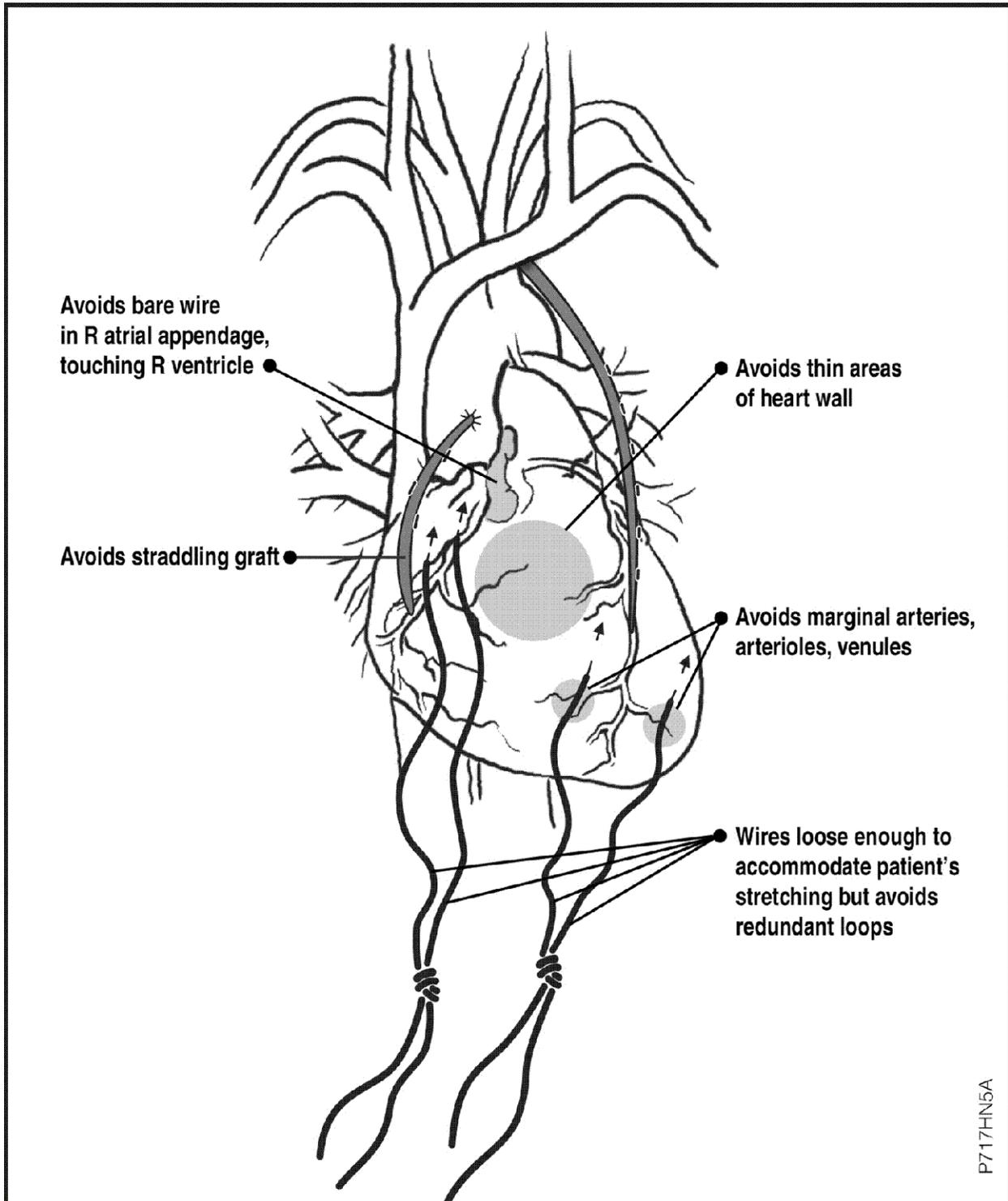


Figure 1. Correct Placement of Pacing Wires (Heart Only)

Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery (Continued)

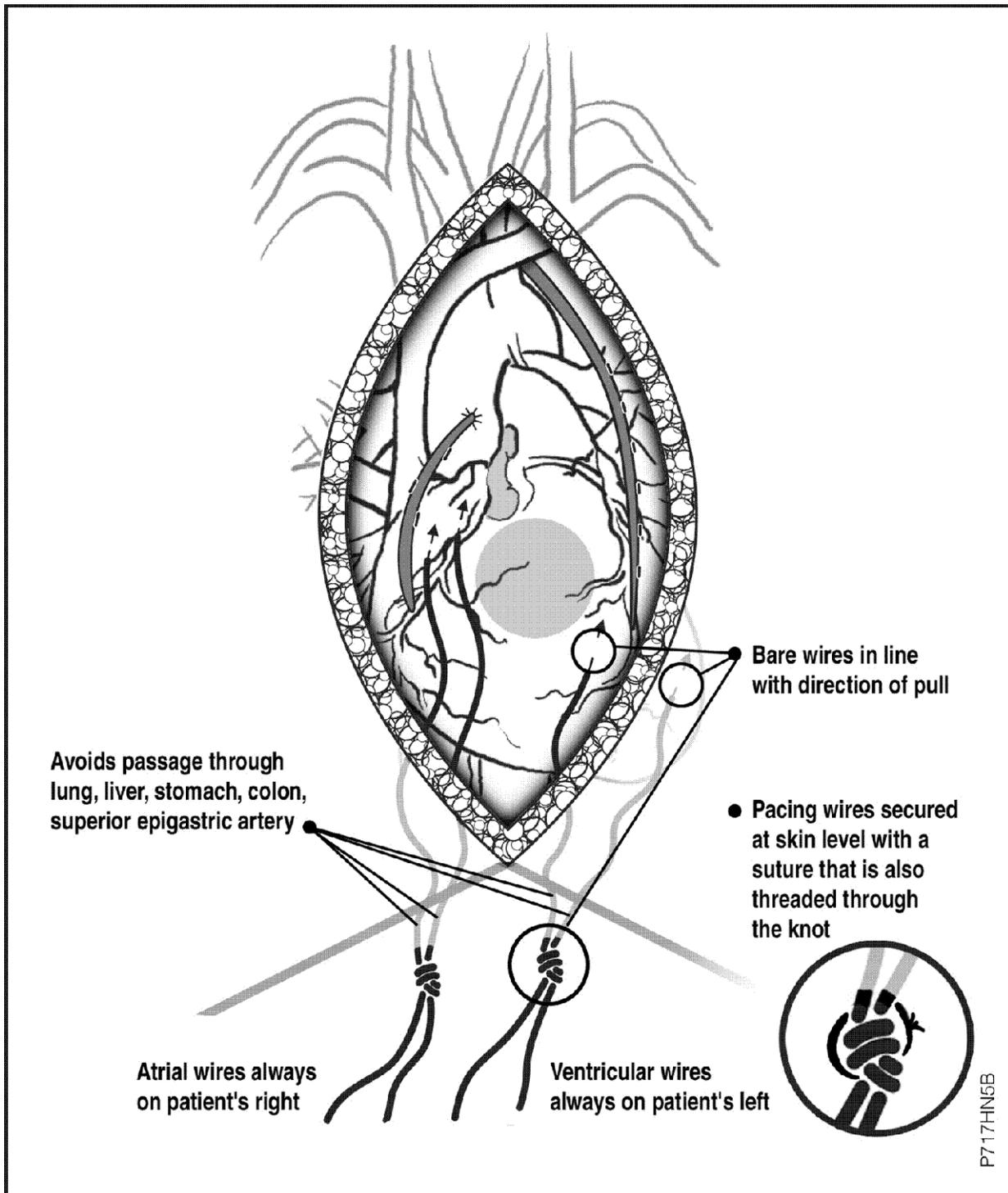


Figure 2. Correct Placement of Pacing Wires (In Situ)

Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery (Continued)

5. Keep epigastric exit sites near the midline on each side with intra-institutional standardization for ventricular wires to the left of midline and atrial to the right. This avoids confusion for critical care/nursing staffs.

- a) Check intrathoracic epigastric exit site carefully to avoid exit of the needle through the colon, stomach, liver or lung.
- b) Check for epigastric artery and rectus muscle bleeding after TEPW needles passage.

6. Keep electrode ends of TEPW electrically isolated in some fashion.

Removal of TEPW:

1. Be certain TEPW is no longer needed (especially if removal is driven by a clinical pathway protocol.)
2. Be aware of coagulation status and medications.
 - a) If the patient is on intravenous heparin, discontinue temporarily.
 - b) If the patient is on warfarin, allow INR to drift down to <1.5.
 - c) If the platelet count is low, understand the reason and correct if necessary.
 - d) It is probably acceptable to continue aspirin and clopidogrel as long as no subcutaneous heparin is being given and there is no abnormal aPTT, INR, or platelet count.
3. Pull one wire out at a time, using gentle traction.
 - a) If undue 'cardiac tugging' is encountered while trying to remove, consider transecting the wire after sterile prepping of skin and external wire. Then, with as much gentle traction as possible cut with sterile scissors flush with skin level. Notify the patient and family

that some TEPW necessarily remains. Subsequent removal of remnant wire is infrequently required.

4. Keep the patient in hospital ~ 24 hours after TEPW removal to watch for signs of delayed tamponade or rhythm disturbances with one hour of bed rest immediately after removal.

- a) Keep on telemetry.
- b) Periodic vital signs.
- c) Consider ECG, CXR to assess voltage and mediastinal silhouette stability prior to discharge.
- d) For any serious concerns, rapid patient evaluation and treatment must occur with possible emergent return to the OR.

5. Avoid TEPW removal late in day or if there is concern about coverage team.

Considerations should be given to having emergency sternotomy trays stored on the unit where pacing wires are removed.

These considerations are indicative of a strategy for safety as regards TEPW. There are many ways to achieve similar results, and these considerations are by no means immutable.

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Minimizing Complications from Temporary Epicardial Pacing Wires after Cardiac Surgery (Continued)

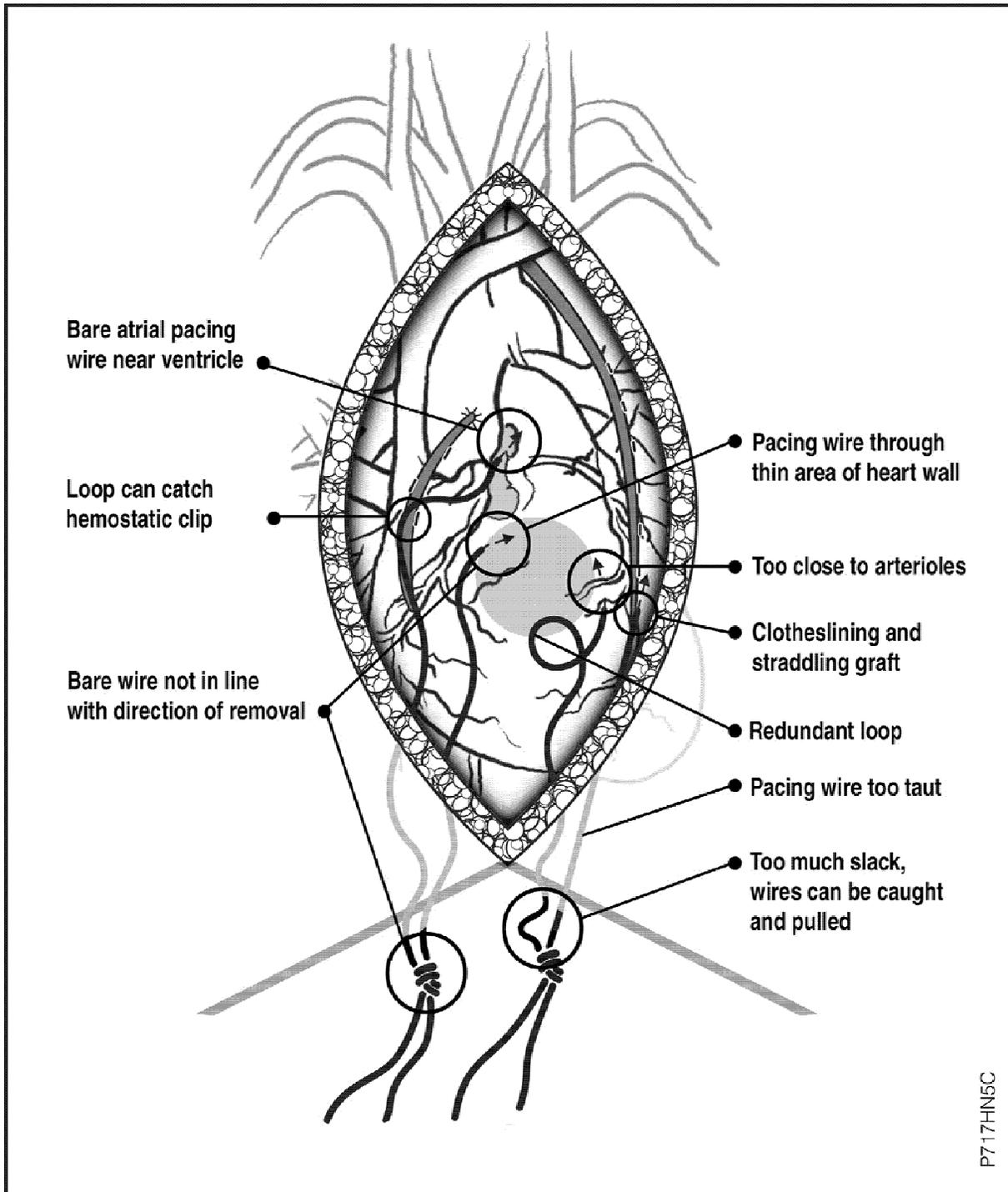


Figure 3. Potential Failure Modes—Incorrect Placement of Pacing Wires

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks

Several reports submitted to PA-PSRS describe problematic actions by or reliance on healthcare industry representatives:

A procedure was delayed while a surgeon was on the telephone with a sales representative, trying to learn how to use a new image-guided surgery system. This significantly lengthened the patient's time under anesthesia.

A company representative photographed a patient's x-rays with his cell phone without the patient's permission.

A sales representative incorrectly advised a surgical services team that a drill being used on trial should be gravity flash sterilized at 270° for 10 minutes. After the procedure, the manufacturer's literature was found to indicate that the drill should be gravity flashed at 270° for 15 minutes.

A sales representative removed a plate press from the shelf and opened the instrument for the sterile field. The circulating nurse, preoccupied with checking blood transfusion information, later found holes in the outer wrap indicating a break in sterile technique.

What is wrong with these pictures? This article provides information about the role of healthcare industry representatives (HCIRs) and strategies to reduce patient safety risks.

Definition

HCIRs are individuals who sell, promote, and give training and advice concerning medical devices, systems, and procedures.¹

Benefits

Physicians, nurses, and technicians have a responsibility to obtain education and training about new technology, products, and equipment for use on patients.² HCIRs can help the surgical staff stay current on rapidly changing surgical technology.³⁻⁵ HCIRs can provide cutting edge knowledge to the perioperative team concerning drugs, research being developed, and new products, so that a facility and team may remain competitive in the healthcare market.⁶

There is a need for technical support in the OR due to the proliferation of new products, increasingly complex instrumentation, sophisticated equipment,

and new procedures.⁷ Most medical schools do not teach students about the machines and equipment used in everyday practice.^{4,5} Because of their knowledge and expertise about their products, HCIRs can provide technical support in the OR as well as in other settings, such as cardiac catheterization labs or special procedure rooms.¹ Their expertise and presence may be welcome, especially during use of complex technology such as cardiac pacemakers or orthopedic equipment.^{4,5} HCIRs may be more familiar with their own devices, systems, or procedures than the multifaceted physician or healthcare team¹ and can enhance safe product use through verbal assistance, if called upon.

Risks

As the above-mentioned PA-PSRS reports indicate, healthcare industry representatives can be inappropriately involved in patient care in several ways:

- A surgeon may inappropriately rely upon the expertise of an HCIR, rather than directly acquiring the training/skills necessary to use a technology.
- An HCIR may deviate from established professional standards of conduct (for example, invasion of privacy).

Highlights

1. Healthcare industry representatives (HCIRs) can provide technical support for new products within the healthcare setting.
2. Their presence in the operative setting can provide an extra layer of safety, but cannot substitute for proper training and credentialing of healthcare providers.
3. The presence of the HCIR, like any other visitor, is a privilege, not a right.
4. The role, conduct, and confirmation of credentials (including credentials reflecting an adequate standard of training) of the HCIR is the responsibility not only of the representative and/or company, but also of the healthcare facility.
5. It is important for the role, responsibilities, and behavior of the HCIR to be clearly defined, documented, and apparent to the patient (such as through informed consent).
6. Most facilities have policies that prohibit HCIRs from touching a patient directly or indirectly and from acting beyond the scope of providing verbal technical support concerning the use of their product.
7. In 2005, the American College of Surgeons (ACS) and the Association of Perioperative Registered Nurses (AORN) each issued position statements concerning HCIRs.

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

- The surgical team may rely on the HCIR's incorrect advice rather than reviewing manufacturer's documents about the technology.
- The HCIR may become inappropriately involved as a member of or replacement for a member of the surgical team.

In most states, only a physician is authorized to perform surgery. While the law may provide that a physician may use assistants, HCIRs are not considered appropriate assistants, as they lack facility credentialing.^{4,5} Therefore, an HCIR operating surgical equipment during a procedure may be considered practicing medicine without a license.⁸ The presence of an HCIR in the OR/special procedures room may also be considered a tort/wrongdoing of an invasion of privacy – allowing a non-medical person to intrude in private matters.^{9,10} Touching a patient without specific consent may also constitute a battery.^{4,5,8-10}

Healthcare equipment and supply companies frequently have policies prohibiting their HCIRs from touching patients or instruments in contact with patients, helping nurses, or participating in extraneous conversations in the OR. These companies may also require their HCIRs to maintain technical expertise concerning the products for which they provide technical support and to be knowledgeable about infection control and sterility. However, these policies may not be consistent among the various healthcare companies.

It is incumbent upon the surgical services team and facility leadership to closely monitor and regulate the actions of all persons in the OR, including HCIRs.⁶ Risks can be reduced and patient safety enhanced by written policies and procedures^{1,4,5,11} that clearly define the role of HCIRs in the facility, how their presence is authorized, what they are and are not allowed to do, and how their activities are monitored.¹² This uses the knowledge and expertise of HCIRs to best advantage, ensuring safe use of their products, while reducing the risks of having these “outsiders” in the OR.

Policy Formulation

The challenge in developing your facility's policy on HCIRs is to strike a balance between the benefits of an HCIR's technical support and the facility's need to ensure patient safety and privacy.¹² A periodic review of standards from government, accreditation, and professional organizations will determine

whether revision is required.^{1,11,13,14} The 2005 position statements of the American College of Surgeons¹¹ and The Association of Perioperative Registered Nurses are helpful in policy formulation.^{13,14}

Multidisciplinary input in policy development and revision promotes “buy-in” to the policy from the perioperative staff, surgeons, anesthesia, risk management, general counsel, and administration.¹³

For clarity and consistency, a policy on HCIRs should be consistent with related policies on credentialing/privileging, materials management, biomedical engineering, and surgical services.¹ Such policies may be integrated into protocols relating to all outsiders in the OR, such as visiting surgeons. The need for an HCIR policy applies not only to hospital ORs, but also ambulatory surgery centers and special procedure rooms – in fact, wherever HCIRs are admitted to witness procedures.^{9,10} The protocols may specify appropriate HCIR behavior within and beyond the OR, in other areas of the facility.^{9,10} Consider how best to communicate the policy to surgical team members, patients, the general public, manufacturers, and HCIRs.¹³

Education, Training, Competency

HCIRs

The education and experience of HCIRs varies considerably.^{3,15} Some companies prepare their HCIRs to be present in the OR, with or without demonstrations/return demonstrations. Others rely on the facilities to provide such training. There is no universally accepted set of competencies for HCIRs.⁷ Each company determines how intensive or structured the training will be, and OR staff do not control the training that companies provide their HCIRs.³ A company may have a certification program requiring an HCIR to successfully complete several hundred hours of laboratory and classroom instruction as a condition of employment.¹⁵ Alternatively, the company may simply distribute written guidelines that inform an HCIR of simple OR protocols such as wearing surgical masks, donning OR attire, covering hair and shoes, and not touching tables with sterile materials.¹⁵

The Credentialing Resource Center outlines the following basic education for HCIRs: a baccalaureate degree with basic science courses in human anatomy and physiology, biology, chemistry, and physics.¹ In addition, the HCIR must know the medical system, device, or procedure (generically referred to as product). This can be shown by proof

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

of experience in the OR with that product or proof of being successfully supervised by an experienced HCIR through a mentorship program^{1,3,15} (such as providing technical support on at least five occasions in the past 12 months for that product).¹

The HCIR also must understand the standards and policies that pertain to the OR, including:

- The concept of a sterile field^{1,8,12,14-17}
- Aseptic technique^{11,18}
- Handwashing¹⁶
- Proper use of surgical attire^{8,16-18} and when to use it^{9,10,14,15}
- Universal precautions^{8,14,16-18}
- Protection from bloodborne pathogens^{1,12,14,16}
- OR traffic patterns^{8-10,14-16,18}
- Infection control practices^{1,11,12,14,18}
- Tuberculosis¹⁶
- Back safety¹⁶
- Radiation safety^{16,17}
- Fire and electrical safety^{1,8,11,12,14,16-18} (including use of fire extinguishers and fire alarms, location of fire exits, overhead call codes)^{2,7}
- Patient rights and confidentiality,^{11,12,14-16} including HIPAA compliance^{1,12}
- Appropriate conduct in the OR environment^{1,8,11,14,15}
- Other applicable protocols such as authorization for product use, patient consent, business procedures^{1,3,11} and the role of various staff.¹⁸

Safe presence in the OR is promoted when HCIRs understand concepts such as sterility, asepsis, anti-septic, microorganisms, bacteria, sterilization, and the responsibilities of perioperative personnel.³ A lack of such basic information can jeopardize the patient and expose a facility to potential liability.^{3,9,10} Yet, in a 1996 survey conducted by ECRI^{9,10} few respondents indicated that such training and education was incorporated into their policies.^{9,10}

Facilities can provide this education in different ways. Some have developed self-learning modules with written quizzes the HCIR must complete after

each section. The quizzes are graded, and individualized educational plans are developed to address deficiencies. The HCIR also signs a statement confirming that he/she has read the module, understands the information and agrees to abide by it.¹⁶

Continuing education companies offer live seminars.⁷ The AORN has partnered with an on-line training company to provide an OR Protocol Course for HCIRs.^{7,19,20} The manufacturer may also provide such information.^{2,12} In the United Kingdom (UK), HCIRs of many medical device manufacturers are required to attend a hands-on course. The course is successfully completed by passing a final examination. The HCIR receives a certificate that confirms competency. This card has become recognized as the “gold standard” in the UK.⁷ In the United States, most education programs provide a certificate of completion or wallet card that can be presented upon request.⁷

The AORN suggests that facilities develop a system to document that HCIRs have completed education in those areas required by the facility.¹²

If facility-specific education is provided, test/quiz results can be filed. If a letter, card, or certificate of attendance/completion is accepted from an outside organization, an outline of the curriculum can be requested and reviewed to assure that the education is consistent with facility requirements/policies.^{2,7} Such information could be maintained in a file for each HCIR.^{1,6} Other documentation to consider may include:

- Signed attestations that the HCIR understands and will abide by the facility policies/requirements.¹⁶
- Review sheets provided to the HCIR.¹²
- Verification of HCIR’s competency with the product for which technical assistance is to be provided.¹
- Documentation that competency with the product is maintained by providing technical support for that product at least five times over the past 12 months.¹
- Proof of continuing education pertaining to the product.¹
- Letter of sponsorship from an active member of the medical staff who has privileges compatible with privileges requested by the HCIR.¹

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

- Any recredentialing information for new products.
- Documentation of specialized training of HCIRs who may perform remote calibrations to adjust devices to surgeons' specifications (such as pacemakers).^{1,14}
- Results of background checks.^{1,11}

Some facilities institute an annual process of reapproval of HCIRs to help ensure competencies when HCIRs return to the facility to train a second generation of personnel on a given product.¹ Proof of education, training, and competency can all be procured prior to the HCIR entering the OR,^{3,16} and an HCIR may be prohibited from entering the OR without successful completion of this facility-defined credentialing process.¹

Surgical Services Team

While a surgeon would generally be trained and credentialed well in advance of using a new product on a patient, other members of the surgical team may also need training in how a product will be used, closer to the time of a procedure. Also at the time of a procedure, the HCIR may be helpful when recent product changes have been introduced, to confirm that the entire team is aware of such changes.

Just as HCIRs must be trained in advance of their presence in the ORs, surgical teams must also be trained about the product prior to the day of the surgical procedure.^{2,21} If situations arise in which training needs cannot be anticipated, the surgical team would at least expect training immediately prior to the surgical procedure.^{2,21} The HCIR meets with the surgeon and other appropriate members of the surgical team to review the mechanism and proper function of the product, as well as its risks and benefits.⁶ This may help to avoid a scenario in which the surgical team must learn a new product "on the fly" during a procedure.

Many facilities maintain a record of all training provided in the form of attendance sign-in sheets and/or competency/skills checklists.^{1,2,14}

Training by an HCIR does not abrogate the responsibility of professionals to seek specialized training. Facilities may encourage staff training by offering educational time off or travel expenses. Physicians can also attend continuing education to learn the new technology, followed by obtaining additional privileges at the facility at which the new technology will be used.^{4,5}

An HCIR's intra-operative technical support is no substitute for staff or the physician instruction before using the new product in the OR.¹³ However, even with fully trained staff and physicians, an HCIR's presence in the OR may be beneficial when a new equipment model is used or during the first few times that a new prosthesis is implanted.^{4,5}

Approvals/Authorizations

A facility-defined approval process in advance of HCIRs entering the OR/surgical suite^{1,11} allows department managers and staff to prepare for HCIR visits.² Such preparations may include obtaining patient consent, providing an adequate work space for the HCIR and equipment, confirming that documentation of HCIR competencies exists.² A standard protocol could include:

- Which authorities must give permission for an HCIR to be present^{1,8,11,14} for what specific purpose.¹² Ordinarily, physician approval of the visit would be required prior to the procedure.^{1,8,11,14,15}
- A timeframe for securing such approval.^{1,11,14,21}
- Biomedical Department review and approval of the new equipment/device for use in the OR,^{1,13,18,21} even if use is on a trial basis,¹³ and confirmation that it is approved by the FDA for the intended use.⁶
- Documenting and forwarding to Surgical Services all written authorizations and approvals.

Moreover, a standard protocol can include a requirement for all HCIRs, sales calls/visitors or observers in the OR to make an advance appointment with facility leadership^{1,8,15,17} to facilitate procedure preparations. Such persons would provide the following information when establishing the appointment whether in the OR or anywhere else in the facility: name, supplier, address, phone number, product and sales information, department/personnel to be visited.^{9,10}

References

As part of the HCIR approval process, Surgical Services may require letters of reference.¹ References considered may include:

- The director of the HCIR's program of OR protocol training.
- The director of the training program pertaining to the product.

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

- The chief of surgery at the facility at which the HCIR most recently provided technical support for the product.
- A letter of sponsorship from the active medical staff member with privileges consistent with the services requested by the HCIR.¹ This letter could also indicate that the physician is responsible for the HCIR's involvement in the case.¹

Patient Consent

The risk of invasion of privacy or battery claims may be reduced if the surgeon obtains written, informed consent from the patient concerning the HCIR's presence in the OR.^{9,10} Such consent may involve the following concepts.^{1,8,11,12,14}

- The presence and the purpose of the HCIR's presence in the OR.^{1,8}
- The HCIR's limited role and level of involvement.^{1,6}
- The benefits and risks of the new product.⁶
- Clearly specifying in the informed consent if an HCIR will be touching a piece of equipment directly attached to the patient.⁶

The patient has the right to refuse the HCIR's presence and the use of the new product for the particular procedure.⁶

Some facilities document this consent on a form that is separate from the surgical consent,⁶ and it is placed in the permanent part of the patient's medical record.^{8,12} This consent can be signed by the patient and physician and even the HCIR before the HCIR is present in the OR.¹²

Health Status

The facility may require the HCIR to provide written evidence of good health prior to initial entry in the OR, as follows:

- Immunity to hepatitis B, rubella, rubeola, varicella, mumps, diphtheria, tetanus.^{1,6}
- Proof of not having tuberculosis as confirmed by annual purified protein derivative PPDs skin tests or chest x-rays.¹

Concerning *Mycobacterium tuberculosis*, the CDC has specified, "Administrators of healthcare facilities should ensure that physicians and other personnel not paid, but working in the facility, receive skin testing at appropriate intervals for their occupa-

tional group and work location."³ Such requirements would be similar to those required for facility health-care workers or volunteers.^{7,9,10}

The facility may also require the HCIR to agree, in writing, not to enter the OR if symptoms of a contagious disease exist.^{1,6} A policy could also give the OR manager the authority to prevent an HCIR's entry to the OR if such symptoms are evident. This health-related documentation could be maintained in a file for each HCIR.

Security/Identification

The facility can signify approval of the HCIR's presence by implementing several security measures. The OR manager can formally introduce the HCIR to all members of the surgical team. The HCIR can be required to wear standard, facility-generated identification when in the OR or in any other part of the facility.^{1,11,14,21} Such identification could include the HCIR's name, company affiliation, destination within the facility, and date of approved presence.¹²

As with any other visitor, HCIRs can also be required to document in a sign-in log at the time of entering the facility/OR. The information provided can include name, company, sponsor, purpose of visit, department/contact person to be visited.^{15,21} When the HCIR's pre-approved business is completed, the HCIR can be escorted from the facility.¹⁷

Such practices are consistent with currently existing security practices of many facilities.

Documentation of HCIR's Presence

The circulating nurse and/or the physician should specifically document the HCIR's presence in the OR in the intraoperative record.^{9,10,12}

HCIR Role/Conduct

Policies can do more than describe the limited roles of the HCIR. Written protocols can be used to restrict specific HCIR behaviors, as well.^{1,11} These restrictions may apply not only to the OR, but throughout the entire facility.^{9,10,15} For example, HCIRs may not be permitted to participate directly in patient care, touching the patient,^{3,8,15} or any procedures on the patient.^{1,11,14} HCIRs may be prohibited from scrubbing,^{1,11,14,15} performing circulating duties,¹⁵ and serving as an extra body for opening sterile or unsterile supplies or tying gowns.^{1,13} Some facilities prohibit them from troubleshooting equipment made by another vendor.¹² While many facilities also restrict HCIRs from manipulating equipment while in use/connected to a patient,^{8,13,15,21} HCIRs with specialized training may, under the sur-

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

geon's direction, adjust remote calibrations of devices such as pacemakers.¹²

Other HCIR requirements often include:

- Maintaining privacy and confidentiality at all times – of patients, staff, employees, physicians.^{9,10} This could include a prohibition of taking photographs/digital images in the OR without prior knowledge and consent of the patient and surgical team.⁶
- Contacting only those personnel or departments for which prior authorization was given.^{9,10} Attempting to circumvent the department's contact would be prohibited^{9,10} and considered grounds for removal from the facility.
- Unless prior arrangements were made to meet with a specific physician, not permitting HCIRs in physician's lounges.^{9,10,15,17}
- Prohibiting personal or sales/marketing calls on department telephones.^{9,10,15}
- Keeping conversation/noise level to a minimum.¹⁵
- Prohibiting aggressiveness, harassing, abusive, vulgar behavior or language,^{9,10,15} as well as behavior deemed disruptive or distracting by the surgeon, staff, or awake patients.³
- Negative comments about competitors, previous HCIRs or competitors' products could be deemed unacceptable.^{9,10,15}
- Prohibiting wandering throughout the department, or from room to room, or throughout the facility.^{8,15}
- Removing from the OR anyone conducting unauthorized selling, marketing, or lobbying.^{15,21}
- Requiring HCIRs to present at in-services only information previously approved by the OR manager/designee.⁵
- Requiring the HCIR to use a disinfectant to wipe any equipment not requiring sterilization that an HCIR brings into the OR.^{5,15}
- The HCIR could be required to leave the area immediately when told to do so – with or without cause.^{9,10} Some reasons may include: upsetting a member of the OR team, interference with the procedure, or

not complying with instructions.¹⁷ Finally, HCIRs could be denied access to specific or aggregate patient information beyond that of the case for which the patient has consented. Such information is limited to a need-to-know clinical level.¹

Policy Deviations

Departures from policies place the facility, perioperative team, HCIRs, and their companies at increased risk for litigation and compromise patient safety. Policy breaches are less likely to occur, however, if the facility's HCIR protocols are known and understood by the healthcare team.² A clearly defined policy can support the staff in addressing such departures, refusing to proceed with surgery, and reporting the issue through an established chain of command.^{1,14,18}

Some facilities report breaches (including accidental) to the immediate supervisor for action^{1,14,17} and file a risk management report.² Corrective actions may begin with informing/educating the party. For repeated violations, the facility may contact the company and/or prohibit the HCIR from entering the facility.¹² If a physician repeatedly brings in HCIRs without following authorization/credentialing policies, Surgical Services could refer the issue to the medical staff executive process for resolution.¹²

If HCIR behavior is beyond the scope of policy boundaries, the circulating nurse can use the established chain of command. First, the HCIR can be asked to stop the behavior. If the behavior continues, the circulating nurse can notify the surgeon. If this does not resolve the issue, the nurse can contact the manager/charge nurse for administrative assistance to address the behavior.²¹

The facility's HCIR deviation policy can be integrated into the system improvement and peer review activities established throughout the healthcare institution.

The Credentialing Resource Center suggests that HCIRs go through a credentialing and privileging process that is incorporated into the facility's medical staff/allied health professional credentialing process. HCIR noncompliance with facility policies may result not only in removal from the OR^{15,21} but also in termination of privileges without right to appeal.^{4,9,10} The facility board might consider granting HCIRs privileges which, on behalf of the board, the CEO may rescind at any time for noncompliance.¹

Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks (Continued)

There is no requirement that HCIRs be allowed in the OR.¹³ "Admission to the operating room is a privilege, not a right."¹⁵ The privilege should be granted or maintained when the benefits to the patient and providers are clear and are agreed upon.⁶

Benefits of an HCIR Policy

A comprehensive policy encourages consistency in how HCIRs are approved and function within the facility/OR suite. Healthcare workers will have the protection and support of the policy to: act upon policy deviations, use the chain of command, protect patient safety and privacy, and institute corrections if necessary. HCIRs will have clear expectations concerning OR access and appropriate conduct/behavior. Finally, a policy allows patients and healthcare providers to receive the benefit of the HCIR's technical expertise, while reducing the risks.

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19. Guidelines for health care industry representatives in the operating room. [cited 2005 Apr 1]. Available from Internet: <http://www.ormanager.com/PDF/rep>.
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Root Cause Analysis Training (May 31 - June 1, 2006)

The Patient Safety Authority is offering a two-day, hands-on workshop on Root Cause Analysis (RCA). The curriculum, under a faculty headed by internationally recognized safety expert Dr. James Bagian, is based on investigation practices that have been successful in aviation, spaceflight and medicine.

More information and registration forms are accessible on the Authority website at www.state.pa.us under "In the News", see Brochures. You can also contact the Authority directly.

Bioburden on Surgical Instruments

Pennsylvania hospitals have submitted a number of reports to PA-PSRS describing cases in which sterilized surgical instruments have been contaminated with organic material from a prior procedure—something healthcare workers call “bioburden.” While most of these cases are recognized before the devices reach the patient, in some instances these soiled instruments have contaminated the sterile field.

These occurrences put patients at risk of surgical site infection (SSI), even if the instrument never touches the patient, because of the potential for contaminating the surgical field. Additionally, when contaminated equipment is recognized after a procedure has begun, precious operating time is lost, and the patient experiences prolonged anesthesia while properly sterilized equipment is obtained.¹

Background

Despite modern infection control practices, the incidence of SSIs remains high. SSIs have been estimated as the third most frequently reported type of healthcare-associated infection.² Despite advances in asepsis, environmental controls, and antimicrobial prophylaxis, SSIs continue to cause morbidity and mortality among surgical patients. Various explanations include an increase in the number of frail patients with chronic debilitating diseases who undergo surgery, increased utilization of implants and organ transplants, and the presence of antibiotic-resistant organisms.²

In July 2005, the Pennsylvania Health Care Cost Containment Council (PHC4) reported on hospital-acquired infections in the state, estimating that patients with SSIs had a mortality rate of 3.1%.³

Reports to PA-PSRS

Following are excerpts from reports submitted to PA-PSRS in which sutures, bone, or tissue have been discovered when instruments were unwrapped in the surgical field:

When placing the tissue protector on the drill, old dried blood and tissue came out.

Triple trocar was full of dried blood and smelled foul. Removed from sterile field.

Bone found in reamer prior to using it on patient. Bone was removed and reamer autoclaved. Equipment was not used on patient.

Suture remained on tunneler.

Particles of tissue were found in cannulated instrumentation.

These cases indicate problems of quality control in the form of failure to adequately clean and inspect instruments before sterilization.⁴⁻⁷

Adequate cleaning requires removal of all residue remaining on the instrument from previous use. Failure to remove debris interferes with disinfection and prevents sterilization.⁸⁻¹¹ Even sterilized foreign material left behind from a previous surgery becomes a foreign body inside the patient and will stimulate the patient’s defense mechanisms to reject or wall off this alien substance. Additionally, damage to instruments, such as corrosion, rust, or pitting, can occur from prolonged contact with organic material when cleaning is not thorough.^{1,12,13}

The level of disinfection or sterilization depends on the intended use of the instruments. The accepted gold standard is the Spaulding method (see Exhibit 1), by which medical instruments are categorized as critical, semicritical, or noncritical according to their intended use. This method has been in use for more than 35 years and guides decisions related to levels of disinfection and sterilization.^{9,11} However, all instruments, regardless of the category of use, require appropriate cleaning.

Surgical Instrument Preparation

Surgical instruments are processed in a multistep, prescriptive fashion.¹ Initially, instruments are cleaned either manually or with equipment, depending on the manufacturer’s recommendations. Instruments then undergo disinfection, removing most disease-causing organisms. Sterilization is the final step to kill all organisms, including pathogens. Sterilization is effective only if all residual debris has been removed in the preceding steps.^{5,8-10}

Cleaning instruments, like cleaning dishes, is more difficult when material has dried. The objective is to remove debris before it has a chance to dry. Pre-cleaning may be done during the surgery or as soon as possible after the procedure.^{6,10,12,13} Methods include:

- Wiping the instrument with a lap or gauze sponge wet with sterile water during or after the procedure.
- Soaking the instrument in an enzymatic solution according to manufacturer recommendations after the procedure.⁸

Bioburden from Surgical Instruments (Continued)

Exhibit 1. Rational Approach to Disinfection and Sterilization

More than 35 years ago, Earl Spaulding developed a method to categorize medical instruments according to the amount of contact the instrument has with the body to determine the level or degree of disinfection and sterilization required.¹ There are three categories: critical, semicritical, and noncritical.

- **Critical objects** are items that penetrate soft tissue, bone, or the vascular system or through which blood flows, such as implanted medical devices, and should be sterile when used.
- **Semicritical items** are objects that touch mucous membranes or nonintact skin, such as endoscopes and respiratory therapy equipment, and require high-level disinfection (elimination of all microorganisms except high numbers of bacterial spores).
- **Noncritical items** are objects that contact intact skin, such as bedpans, blood pressure cuffs, and bedside tables. Low-level disinfection is required.^{2,3}

Notes

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2. Rutala WA, Weber DJ. New disinfection and sterilization methods [online]. *Emerg Infect Dis* 2001 Dec [cited 2005 Jul 7]. Available from Internet: <http://www.cdc.gov/ncidod/eid/vol7no2/pdfs/rutala.pdf>.

3. Association for Professionals in Infection Control and Epidemiology. APIC guideline for selection and use of disinfectants. *Am J Infect Control* 1996 Aug;24(4):313-42.

- Flushing the instrument lumens with sterile water during or after the procedure.
- Using a nonfibrous sponge to wipe delicate microsurgical and ophthalmic instrument tips.¹³

The Association of periOperative Registered Nurses (AORN) suggests that sterile water be maintained in a sterile ring stand to separate it from sterile saline on the operating room back table. Sterile saline should not be used to clean instruments, as saline causes pitting and damage.^{1,12}

Instruments should be prepared for cleaning by separating all detachable parts. Complete disassembly is necessary to expose all surfaces during the mechanical action of cleaning, whether automated or manual. All movable parts should be disassembled. Instrument box locks, hinges, and joints should be opened.^{7,10} The lumens of cannulated instruments must be flushed with the cleaning solution and checked for soilage.

Manual and Mechanical Cleaning/Decontamination

The goal of cleaning is threefold: remove visible debris, remove invisible soilage, and eliminate as many microorganisms as possible.¹⁰ These tasks are completed in central supply by technicians who are often trained by the institution. Education is important to help ensure that the technician recognizes the significance of his/her contribution to an infection-free surgical outcome.^{8,14}

Meticulous cleaning is a prerequisite for disinfection and is essential to the integrity of sterilization.⁴⁻⁷ Cleaning begins with decontamination and removal of obvious debris. Typically, instruments are arranged in trays. Hard-to-clean equipment may be soaked in an enzymatic solution or covered with spray, gel, or foam to initiate the decontamination process.

Various methods exist to ensure that instruments are decontaminated in readiness for sterilization.¹ Automated methods include washer/sterilizers, ultrasonic cleaners, and washer/decontaminators; as a last resort, devices may be cleaned manually. Manual cleaning using brushes is effective for instruments with lumens. The amount of friction or the number of brush strokes used during cleaning affects consistency of instrument cleanliness.⁸ In manual washing, the instruments are cleaned underwater to reduce the risk of employee exposure to potentially contaminated aerosols. Advantages of automated cleaning include decontamination consistency and protection of staff from exposure to organisms.

Mechanical cleaning is performed using several different types of equipment. Washer-sterilizers use mechanical action and detergent to remove residue. If instruments have crevices or are cannulated, preliminary irrigation and cleaning are necessary to ensure that all residue is removed before decontamination in the washer-sterilizer.

Automated cleaning with heat will bake any residual gross organic material onto the instruments, rendering them a challenge to sterilize.¹⁰ A washer-decontaminator can remove excess debris and eliminate the need for manual cleaning of instruments, but automation does not eliminate the need for inspection after they have been cleaned.

Ultrasonic cleaning uses high-frequency sound waves to penetrate and remove debris after the visible or gross residue has been rinsed off the instrument.¹⁰ It is most effective once the overt resi-

Bioburden on Surgical Instruments (Continued)

due is removed, and it is effective on instruments with lumens or joints.⁸

Vigilance in verifying the removal of bioburden is of utmost importance to ensure sterilization. The term "bioburden" is often used to describe organic material on instruments^{15,16} but actually refers to the number of microorganisms contaminating an object.¹⁷ Properly cleaned nonlumen instruments have been demonstrated to contain a minimal number of organisms, which are not pathogenic.¹⁸

Inspection

Inspection is important to ensure that instruments are clean and disinfected, with no residue. Whenever any resistance or stiffness is noted in the movement of a part, the presence of residual debris should be suspected, and the instrument should be inspected accordingly.^{1,7} During inspection, staff should verify that teeth mesh, that equipment demonstrates proper tension, that ratchets work correctly, and that parts designed to move freely do so.⁷

In January 2002, AORN revised its "Recommended Practices for Cleaning and Caring for Surgical Instruments and Powered Equipment." The goal of these practices is "to assist perioperative nurses in decontaminating, cleaning, maintaining, handling, storing, and/or sterilizing surgical instruments and powered equipment."¹ Acknowledgment is given in the guideline to the innumerable specialized instruments and powered equipment that necessitate manufacturers' guidance for cleaning.

AORN presents eight detailed recommended practices, which provide generalized direction for cleaning instruments.¹ The following is a synopsis of these practices:

1. Surgical instruments and powered equipment should be cleaned, handled, and used according to manufacturers' instructions.
2. Instruments should be kept free of gross soilage during surgical procedures.
 - a) Instruments should be wiped with sponges moistened with sterile water to prevent corrosion, rusting, and pitting from dried blood and debris.
 - b) Lumened or cannulated instruments should be irrigated with sterile water. Saline causes instrument deterioration and should not be used.
3. Effective and timely decontamination of instruments should be performed in a manner that minimizes risk to those performing the task.
4. Surgical instruments with moving parts should be checked for function after cleaning. Lubrication may be indicated.
5. Instruments that have come in contact with prions (resilient protein substances) should be treated according to a specific prion deactivation protocol. When changing policies the most recent updates related to prion deactivation should be obtained from the Centers for Disease Control and Prevention (CDC), the World Health Organization, and experts publishing new findings. Creutzfeldt-Jakob disease (CJD) is caused by a prion (see Exhibit 2). The following is a condensed version of the recommended practices for cleaning instruments when prion exposure is suspected:
 - a) Keep instruments moist before treating.
 - b) Clean instruments as soon as possible.
 - c) Keep instruments of similar tissue infectivity levels together.
 - d) Decontaminate instruments before processing:
 - Dispose of instruments that are impossible to clean or when cleaning is difficult and disposal is not cost-prohibitive.
 - When indicated, soak instruments for one hour in normal sodium hydroxide before cleaning and sterilizing.
 - Steam autoclave instruments at 132° to 134°C for 18 minutes in a prevacuum sterilizer or at 121°C for 60 minutes in a gravity displacement sterilizer.
 - e) Avoid using power drills or saws on highly infective tissue.
 - f) Note that disposable equipment is preferred and should be incinerated.
6. Surgical instruments should be visually inspected and prepared for storage or sterilization after decontamination; specifically, staff should consider:
 - a) Keep instruments moist before treating.
 - b) Clean instruments as soon as possible.
 - c) Keep instruments of similar tissue infectivity levels together.
 - d) Decontaminate instruments before processing:
 - Dispose of instruments that are impossible to clean or when cleaning is difficult and disposal is not cost-prohibitive.
 - When indicated, soak instruments for one hour in normal sodium hydroxide before cleaning and sterilizing.
 - Steam autoclave instruments at 132° to 134°C for 18 minutes in a prevacuum sterilizer or at 121°C for 60 minutes in a gravity displacement sterilizer.
 - e) Avoid using power drills or saws on highly infective tissue.
 - f) Note that disposable equipment is preferred and should be incinerated.

Bioburden on Surgical Instruments (Continued)

Exhibit 2. Prion Concerns

Effective reprocessing of surgical instruments is essential in the prevention of Creutzfeldt-Jakob disease (CJD), a prion disease that is a transmissible spongiform encephalopathy.^{1,2} CJD is a fatal disorder that more commonly occurs in older people, although vCJD (new variant Creutzfeldt-Jakob disease) occurs in younger people. Classic CJD is described as “insidious, taking up to 20 or more years for symptoms to appear, with death occurring within 5 to 14 months after symptoms present.”¹

While developing a test for assessing removal of protein from surgical instruments after cleaning, researchers in England discovered that alcohol strongly binds blood to stainless steel. Reports related to transmission of CJD between humans and chimpanzees indicate that the instruments were cleaned with alcohol-formaldehyde solutions.³ Therefore, when CJD is suspected, alcohol and formaldehyde should not be used to decontaminate surgical instruments used in neurosurgical cases.

The following strategies can help to reduce the risk of CJD transmission:

- Use disposable instruments in known CJD cases or in brain biopsy procedures if possible.^{1,4}
- Quarantine instruments used in neurosurgery until a diagnosis is available.¹
- Incinerate instruments that cannot be cleaned.¹
- Do not use flash sterilization.⁴
- Keep instruments moist to prevent drying of organic material.⁴

Notes

1. Exposure to Creutzfeldt-Jakob disease. *Jt Comm Perspect* 2001 Aug;21(8):10-1.
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4. Rutala WA, Weber DJ. Creutzfeldt-Jakob disease: Recommendations for disinfection and sterilization. *Clin Infect Dis* 2001 May 1;32(9):1348-56.

- a) cleanliness and proper functioning
- b) the presence of cracks, corrosion, pitting, burs, and nicks
- c) sharpness of cutting edges
- d) loose pins
- e) wear and chipping of inserts and plated surfaces
- f) any other defects.

7. Powered equipment and any attachments should be disassembled, decontaminated after use, lubricated, assembled, tested, and sterilized according to manufacturer instructions.

8. Policies and procedures regarding the care and cleaning of surgical instruments and powered equipment should be developed, reviewed at regular intervals, and made readily available in the practice setting.

See the published recommendations for details related to instrument and powered equipment cleaning and care when developing and/or revising policies.¹

Considerations for ensuring that surgical instruments remain free of debris include the following:

- Create an environment in which a team spirit is encouraged and infection prevention is a shared duty and begins with the responsibility of ongoing monitoring of the care of surgical equipment.^{7,8,10}
- Implement routine proactive efforts during and immediately after surgery to prevent soilage from drying on surgical instruments.
- Educate central supply staff on the principles of decontamination, disinfection, and sterilization.^{8,14}
- Maintain quality control by reviewing instrument management practices and reinforcing routine inspection of cleaned surgical instruments, especially those likely to have retained soilage.^{4,16}

To minimize the risk associated with a breakdown in sterility, consider the following practices:

- Open sterile instruments on a separate stand, such as the ring stand, and inspect

Bioburden on Surgical Instruments (Continued)

the contents to avoid the risk of contaminating other equipment or the surgical field. If contaminated instruments are found, the scrub nurse's gown and gloves can be changed without contaminating the supplies and other items in the sterile field.⁴

- If a soiled instrument is noted during the procedure, pass the instrument off the table and inform the surgeon so that prophylaxis can be provided.⁴

Look for new guidelines on processing practices to be released some time in the future. This will be the first revision since the 1985 release of CDC's "Guideline for Handwashing and Hospital Environmental Control." The new guidelines, which are in draft form as of February 2006, are intended to replace the section on sterilization and disinfection in the original guideline. The June 2002 issue of *OR Manager* contains highlights of the draft, which covers inactivation of pathogens such as those causing CJD, disinfection of equipment, decontamination of bone, endoscope disinfection, and new sterilization processes.¹⁹ The draft is no longer available on CDC's Web site and is in the process of comment review.²⁰

Notes

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3. Pennsylvania Health Care Cost Containment Council. Hospital acquired infections in Pennsylvania [online]. Research Briefs. 2005 Jul [cited 2006 Jan 30]. Available from Internet: <http://www.phc4.org>.
4. Petersen C. Surgical-grade stainless steel; when to administer antibiotics; medication labels; mixing medications; bioburden [online]. *AORN J* 2002 Dec [cited 2005 May 20]. Available from Internet: <http://www.aorn.org/journal/2002/decci.htm>.
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12. Petersen C. Compressed medical gases; preparing IV fluids in advance; *Clostridium difficile*; sterile water on back tables; closing OR doors [online]. *AORN J* 2004 Dec [cited 2005 Jul 7]. Available from Internet: <http://www.aorn.org/journal/2004/decci.htm>.
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New Guidance on Preventing Anesthesia Awareness

Since the publication of our article on Anesthesia Awareness in the September 2005 issue of the *PA-PSRS Patient Safety Advisory*, the American Society of Anesthesiologists (ASA) Task Force on Intraoperative Awareness released a Practice Advisory for Intraoperative Awareness and Brain Function Monitoring.

The Practice Advisory:

- Identifies risk factors associated with intraoperative awareness.
- Provides decision tools to assist the clinician in reducing intraoperative awareness.
- Encourages assessment of prevention/reduction strategies related to intraoperative awareness.
- Provides guidance concerning use of brain function monitors as they pertain to intraoperative awareness.

The ASA indicates that practice advisories are not founded on scientific literature to the same extent as standards or guidelines because there are too few controlled studies on a topic. Practice advisories provide a review of the literature and consensus based on opinions of task force members, expert consultants, public commentary, and open forums. Practice advisories are revised as indicated by changes in technology, medical practice, and knowledge.

The ASA advises the following interventions to reduce the risk and impact of intraoperative awareness:

Preoperative Evaluation

Identification of Risk Factors

- Patient Condition: Reviewing the medical record to identify risk factors in the patient's history:
 - Previous episode of intraoperative awareness
 - History of anticipated difficult intubation
 - Receiving high doses of opioids for chronic pain
 - Substance use/abuse
 - ASA status 5-4
 - Limited hemodynamic reserve
- Surgical Procedures: Determining potential risk of intraoperative awareness associated with the type of surgery:
 - Cardiac
 - Trauma
 - Emergency
 - Cesarean section
- Anesthesia Plan: Determining potential risk factors associated with planned anesthesia:
 - Nitrous oxide – opioid anesthesia
 - Use of muscle relaxants during maintenance phase of general anesthesia
 - Reduced doses of anesthesia in the presence of paralysis

Interview/Discussion

- Interviewing patients preoperatively to:
 - Gather information about previous anesthesia experiences
 - Assess anxiety level
- For those determined to be at substantially increased risk of intraoperative awareness, the clinician informs the patient of the risk, if possible.

Preinduction Phase of Anesthesia

- Using a checklist protocol for anesthesia machines and equipment to ensure the delivery of proper doses of anesthetic agents.
- Verifying proper function of other equipment: intravenous access, infusion pumps, connections, appropriate back-flow check valves.
- On a case-by-case basis in selected patients, determining whether prophylactic benzodiazepine is appropriate (such as for patients requiring smaller doses of anesthetics).

Intraoperative Monitoring

Monitoring anesthesia depth with multiple approaches:

- Conventional monitoring systems: BP, HR, ECG, end-tidal anesthetic analyzer, capnography.
- Clinical observations: checking reflexes or purposeful movement. (But, neuromuscular blocking agents may mask such movement).
- Brain function monitoring: The practitioner decides to use such a monitor on a case-by-case basis for selected patients (such as those receiving light anesthesia). The ASA does not recommend routine use of such monitors for general anesthesia patients at this time.

Intraoperative and Postoperative Management

- On a case-by-case basis, deciding whether to administer intraoperatively a benzodiazepine after a patient unexpectedly becomes conscious.
- Speaking with patients who recall intraoperative events to discuss possible reasons for the occurrence and to obtain the patient's perspective of the details of the event.
- Using a structured interview or questionnaire to capture the details of what the patient experienced.
- Completing a report about the event for quality management purposes.
- Offering counseling/psychological support to those reporting intraoperative awareness.

Source

Excerpted from Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, Copyright 2005, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

Glacial Acetic Acid: Doing More Harm than Good?

A facility recently submitted the following report to PA-PSRS:

A patient was to receive iontophoresis with acetic acid in a hospital-affiliated, off-site Physical Therapy department. Prior to the treatment, the therapist applied an acetic acid-soaked patch to the patient's skin. The patient immediately complained of burning, in response to which the therapist immediately removed the patch. Underneath, the patient had a reddened, raised skin area that was exactly the size of the iontophoresis patch. The therapist washed the area and notified Pharmacy. At the pharmacist's recommendation, the therapist applied sodium bicarbonate to the affected area. The patient sustained a first degree burn with skin discoloration and minor scarring. Glacial acetic acid had been dispensed by the hospital pharmacy instead of a 10% solution. The bottle sent to the Therapy Department was labeled as a 10% concentration.

What is Glacial Acetic Acid?

Glacial acetic acid is a 99.5-100% concentration of acetic acid. The term "glacial" refers to its property of forming crystals at 17 degrees Celsius (62.6 degrees Fahrenheit)—giving it the appearance of being frozen, like a glacier.¹ Glacial acetic acid is a poisonous and corrosive liquid that may cause severe burns to tissue. If swallowed, it can result in perforation of the esophagus or death. Lung and tooth damage can occur if the product is inhaled. Eye contact may result in severe eye damage, including loss of sight.²

Medical Uses of Glacial Acetic Acid

Undiluted glacial acetic acid has **no** medical use, but diluted formulations of acetic acid are used for treatments such as iontophoresis, bladder and wound irrigations, treatment of ear canal/outer ear infections, and during colposcopy to identify cervical dysplasia.¹

Investigation

The facility's investigation uncovered many factors that may have contributed to this error. Ordinarily, the facility uses dexamethasone for iontophoresis procedures. Following this typical practice, a pharmacy student compounded dexamethasone for iontophoresis on the Friday before the patient's Monday treatment. However, because this patient was allergic to steroids, the physician ordered acetic acid instead.

The Physical Therapy department sent a request (not the physician's order) to pharmacy for "acetic acid for iontophoresis" with no concentration specified. On Monday, a pharmacist discovered that the acetic acid solution had not been prepared. A recently graduated pharmacist rushed to get the acetic acid ready in time for a courier to pick up and transport it to the off-site therapy department. He poured some glacial acetic acid from a larger bottle, located in the compounding area, into a smaller brown bottle and labeled it 10%. While the Pharmacy has a compounding book which contains a description of how to perform the dilution, the pharmacist did not refer to it. At the time, there was no double check system for preparing and dispensing acetic acid.

The label on the larger glacial acetic acid bottle clearly indicated both the concentration and the deleterious health effects of exposure to the product (see Figure 1). While the pharmacist is aware of the poisonous, corrosive nature of glacial acetic acid, he does not know why he dispensed undiluted glacial acetic acid. The pharmacy director indicated that the facility does not use glacial acetic acid for any purpose other than for diluting it for medical treatments.

Another Example

The Institute for Safe Medication Practices has also reported patient injuries associated with undiluted glacial acetic acid being mistakenly dispensed for a medical purpose. For example, wound irrigations were ordered for a paraplegic with bilateral greater trochanter wounds. The nurse called the Pharmacy and requested "acetic acid for irrigation." The phar-



Figure 1. Label on Undiluted Bottle of Glacial Acetic Acid Showing Warnings. Image provided by reporting facility. Used with permission.

Glacial Acetic Acid: Doing More Harm than Good? (Continued)

macist dispensed glacial acetic acid, which was used for two days. As a result, the patient sustained burns of the irrigated wounds. The wounds never healed, and the patient ultimately underwent disarticulation of both hips.¹

Patient Safety Strategies

As seen in the examples above, errors involving glacial acetic acid can cause serious patient harm. Since this chemical serves no medical purpose in its undiluted form, the most effective strategy to prevent error is to remove glacial acetic acid from your facility altogether, making it available only in diluted forms. Other strategies include:

- Determining and standardizing on only the acetic acid concentrations your facility requires for medical purposes.
- Purchasing commercially available, pre-mixed acetic acid solutions for medical purposes.¹
- Conferring with medical staff to determine the lowest acetic acid concentrations required to be medically effective.
- Determining to what extent table vinegar (5% acetic acid) could be used for medical purposes, rather than pharmacy compounding this concentration from glacial acetic acid.
- Outsourcing dilution of acetic acid to a trusted pharmacy service so that glacial acetic acid is no longer needed in house.³
- Requiring prescribers to:
 - Specify the exact strength of acetic acid required
 - Not use “glacial” in the order (such as, “dilute glacial acetic acid”)¹
- Educating all staff that glacial acetic acid is never used for medical purposes, and that glacial acetic acid is the most concentrated form of acetic acid.¹ The Material Safety Data Sheet and container label can be used to emphasize the dangers of this chemical.
- Placing the glacial acetic acid in a separate, locked area¹ away from the compounding area in pharmacy, so that it does not become confused with diluted acetic acid.
- Posting a written alert where glacial acetic acid is stored, indicating that it must be diluted for medical purposes.
- Placing a brightly colored label on the glacial acetic acid to differentiate it from other concentrations.¹
- Placing diluted acetic acid in visibly different containers than those used for glacial acetic acid.
- Requiring that orders for compounding glacial acetic acid be forwarded to pharmacy at least one business day before the product is to be used – to allow adequate time for compounding the solution.
- Prohibiting interruptions when compounding glacial acetic acid.

The facility that reported the occurrence to PA-PSRS conducted a root cause analysis and implemented several strategies to prevent a recurrence and/or mitigate harm from the error:

- Departments requesting acetic acid must use an order form and specify the concentration and purpose.
- Implementing in Pharmacy a double-check/observation process to confirm that glacial acetic acid is properly diluted.
- Reviewing the compounding log with Pharmacy staff and having it readily available as a reference when performing dilutions.
- Educating the pharmacist and staff concerning the dangers of glacial acetic acid and that it is not used for medical purposes in its concentrated form.
- Educating staff not to use acetic acid if it smells different/stronger than usual.
- Every department that uses acetic acid has baking soda available to neutralize the concentrated acetic acid, should exposure occur.

If glacial acetic acid must be present in the facility:

- Diluting it immediately to standard concentrations and storing the diluted product for medical use.¹

Bottom Line

Glacial acetic acid is just one of many dangerous chemicals that are used in healthcare facilities.

Glacial Acetic Acid: Doing More Harm than Good? (Continued)

Many of the strategies mentioned above are applicable to reducing risks associated with any dangerous chemical. Facilities can begin by taking an inventory of dangerous chemicals in all departments and limiting the number and amount of dangerous chemicals kept in stock by replacing them with safer alternatives when possible. If dangerous chemicals must be used, they can be segregated and secured. A double-check process can be implemented to ensure appropriate use. Clear labeling of dangerous chemical containers (contents, dangers, appropriate use, first aid measures) and readily available chemical information sheets ensure that such chemicals are used properly and with appropriate caution. By implementing system

changes, the facility can build in mechanisms to prevent a dangerous chemical from reaching the patient.

Notes

1. Institute for Safe Medication Practices. End the ice age – is glacial acetic acid really needed? *ISMP Medication Safety Alert*: 2005 May 5;10(9):1-2.
2. Mallinckrodt Baker, Inc. Material Safety Data Sheet. Acetic Acid Glacial [fact sheet]. MSDS Number A0326 [online]. 2005 May 6 [cited 2005 Dec 23]. Available from Internet: <http://www.jtbaker.com/msds/englishhtml/a0326.htm>.
3. Institute for Safe Medication Practices. Messages in our mailbox – in response to our May 5, 2005 article. End the ice age – is glacial acetic acid really needed? *ISMP Medication Safety Alert*: 2005 Jun 30;10(13):3.

An Easy Way to Reduce a Barrier to Reporting

In a recent survey of the attitudes of hospital-based physicians and nurses toward adverse event and near-miss reporting, the single most frequently cited barrier to reporting was a lack of feedback on their reports.¹ If clinicians don't know how their reports are used, they may question the value of reporting and not take the time to submit a report.

An easy way to reduce this potential barrier is to share relevant articles from the *Advisory* with selected groups of clinicians in their own facilities. In this issue:

- The lead clinical article, "Who Administers Propofol in Your Organization?" may be of interest to Pharmacy, Anesthesiology, and your P&T Committee.
- "Healthcare Industry Representatives: Maximizing Benefits and Reducing Risks" may be of interest to your

OR managers, surgical support staff, and risk managers.

- Infection control practitioners may be interested in the article "Bioburden on Surgical Instruments."

In any large healthcare facility, it simply isn't possible to provide feedback on every submitted report. However, redistributing information derived from those reports sends the message that adverse event and near-miss reports are worth the time and effort it takes to submit them and that they are used to improve patient safety.

Notes

1. Attitudes and barriers to incident reporting: a collaborative hospital study. Evans SM, Berry JG, Smith BJ, et al. *Qual Saf Health Care*. 2006;15:39-43.

Eisenberg Award Nominations

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Quality Forum (NQF) are currently accepting nominations for the 2006 John M. Eisenberg Patient Safety and Quality Awards.

These prestigious awards recognize individuals and healthcare organizations that are making significant contributions to improving patient safety and quality.

Past Pennsylvania recipients include University of Pittsburgh Medical Center-McKeesport (2004), Abington Memorial Hospital (2003), and Lehigh Valley Hospital and Health Network (2003).

Nomination forms are available online at www.jcaho.org and www.qualityforum.org. The deadline for nominations is May 1, 2006. The awards will be presented at the NQF Annual Meeting on October 12-13, 2006, in Washington, D.C.

Mix-up Between Skin Prep Solution and Adhesive Remover

PA-PSRS received two reports from one hospital describing a mix-up between skin prep solution and adhesive remover. A hospital staff member mistakenly used an adhesive remover on two patients instead of a skin prep solution prior to applying Holter monitor electrodes. Both events resulted in the patients experiencing erythematous skin reactions at the electrode sites.

The events occurred because the packaging for both the skin prep and adhesive remover are very similar in appearance (see Figure 1). The skin prep

In response to prior reports of the packages looking similar and in response to the events above, Smith & Nephew took steps to redesign the packaging for the skin prep and adhesive remover (see Figure 2). The front of the redesigned skin prep package now contains a green block of color containing the Cat. No. 420400, and the front of the redesigned adhesive remover package contains a maroon color containing the Cat. No. 403100. Both packages use a larger black font to distinguish one from the other. According to Smith & Nephew, the new style packaging has been implemented. However, it may not be available in the market until the second quarter of 2006 due to inventory depletions in the market.

Healthcare facilities that use the above products can alert users to the information in this article, emphasizing the need to carefully scrutinize the packaging when obtaining either the skin prep solution or the adhesive remover. Until the newly designed packaging is available, consider providing signage or other identifiers near the products to alert users to the similar packaging of these products.



Figure 1. Current Style of Packaging for Skin Prep (top) and Adhesive Remover (bottom)

and adhesive remover are manufactured by Smith & Nephew, Inc. (Cat. Nos. 420400 and 403100, respectively) and have the same orange and white pattern with black lettering.

The Smith & Nephew skin prep is a liquid prep solution used to prepare skin for tapes or similar adhesive items and also forms a film on skin to help reduce friction when those items are removed from the patient. The Smith & Nephew adhesive remover is used to soften the adhesives on items such as tapes and to remove adhesive residue.

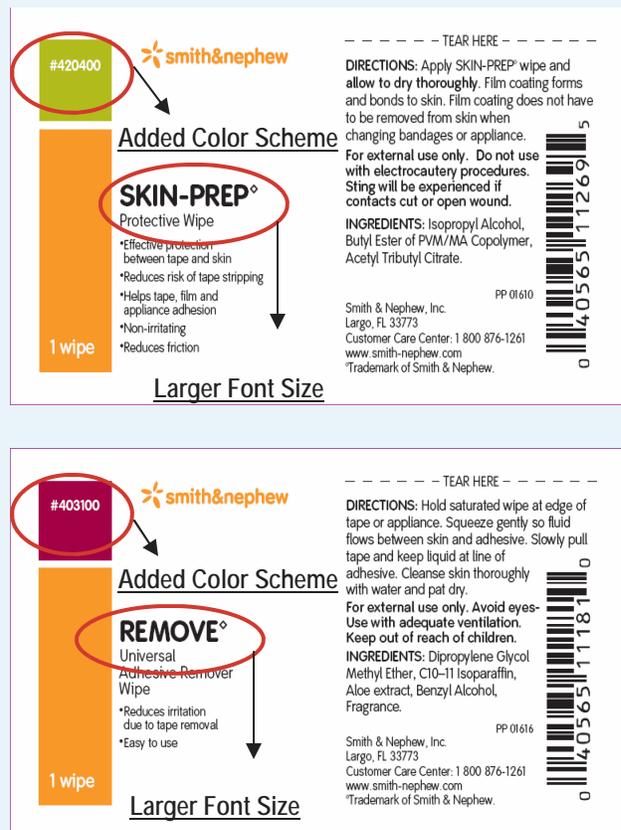


Figure 2. New Style of Packaging for Skin Prep (top) and Adhesive Remover (bottom)

Electrosurgery Safety Issues

An article on electrosurgery and the risk of surgical fires was presented in the September 2004 issue of the *PA-PSRS Patient Safety Advisory*.¹

The article described some of the reasons that surgical fires occur during electrosurgery. This article continues the discussion of surgical fires, but also includes discussions of burns to patients and surgical staff related to the use of electrosurgery. Since the PA-PSRS program began in 2004 we have received approximately 170 reports of surgical fires and burns to patients and staff. In most cases, fires and burns can be significantly reduced or eliminated by instituting and following some basic principles of electrosurgery safety.

Electrosurgery-Related Fires

As stated in the September 2004 *Advisory* article, most surgical fires involve electrosurgery such as an electrosurgical unit (ESU) activated in an oxygen-enriched environment. Fires require three elements:

- An **ignition source** such as an ESU active electrode
- **Oxidizers** such as oxygen, room air (21% O₂), N₂O, or medical compressed air
- **Fuel** such as hair, alcohol, surgical drapes, face masks, and tracheal tubes, and other materials.

Because oxygen is “heavier” than air, it can collect in unexpected places such as under surgical drapes in the head and neck area, creating the potential for fire. Materials that don’t readily burn in room air will easily burn in a slightly oxygen-enriched atmosphere. For example, endotracheal tubes burn in 26% O₂.

An electrosurgical fire can occur under a number of scenarios.

A heat source such as an ESU can easily ignite alcohol vapors from alcohol-based prep solutions resulting in a surgical fire and/or skin burn. PA-PSRS presented on this topic in the June 2005 issue of the *PA-PSRS Patient Safety Advisory*.² A heat source used at the surgical site can ignite alcohol or alcohol-based prep solutions if the solution is allowed to wick into the patient’s hair and linens or pool on the patient’s skin. If the patient is draped before the solution is completely dry, alcohol vapors can be trapped under the surgical drapes and channeled to the surgical site.

Two practices that may reduce the risk of fire or burns are:

- Ensuring that the prep solution does not soak into hair or linens – sterile towels can be used to absorb drips and runs during application.
- Ensuring that the prep solution is completely dry prior to draping, which may take a few minutes depending on the amount and location of the solution.

For a more comprehensive list of mitigation practices, please see the June 2005 issue of the *PA-PSRS Patient Safety Advisory*.

Some dry surgical materials can also readily ignite. PA-PSRS has received four reports of ignition of dry surgical sponges and one report of ignition of a dry graft when in contact with the active electrode of the handpiece during activation of the ESU. According to the reports, none of the events resulted in injury to the patients or staff.

This can happen when dry sponges are used to blot or absorb excess blood. Wet sponges can also absorb blood, and they typically will not ignite when in contact with the active electrode of the ESU handpiece. Wetting grafts prior to contact with an active ESU handpiece also reduces the likelihood of fire during electrosurgery.

We have also received reports in which flames briefly flashed from the tip of active electrosurgical electrodes during electrosurgery procedures. Flames appearing at the tip of an active electrode is usually due to ignition of tissue debris or other flammable material on the electrode tip, which becomes the fuel source in a fire. Ignition is possible, in part, due to locally elevated oxygen concentrations. The active electrode itself will very rarely burn due to its metal and plastic construction. Though some plastics will burn, most of the plastics used in the manufacture of active electrodes have very high ignition temperatures that can only be reached under certain circumstances such as the presence of another fire or possibly laser energy.

Excessive heating of the electrode tip can cause pieces of tissue to adhere to the electrode surface.

Physicians can receive continuing medical education (CME) credits for completing the self-assessment questions related to this article. See page 35 for details.

Electrosurgery Safety Issues (Continued)

Arcing techniques such as “spray” coagulation can generate substantial heat at the tip, leading to tissue sticking to the tip (known as eschar buildup). Eschar buildup can be minimized by choosing the most appropriate ESU mode and by cleaning the tip with an abrasive pad specifically made for that purpose. When possible, avoid using arcing techniques such as spray coagulation during cutting and contact coagulation. Using short ESU activations at minimum power settings to produce the desired tissue effect will minimize excessive heating of the active electrode.³

Surgeons sometimes use coagulation techniques (arcing coagulation) for most or all electrosurgery in place of cutting. The high peak voltage of coagulation will cut tissue; however, the effect is not as clean and the process is not as safe as using a cutting technique. When using arcing coagulation (a non-contact technique) as a contact technique, charring can develop with eschar buildup on the active electrode tip. This buildup can tear the tissue, causing rebleeding, when the electrode is lifted from the tissue. Coagulation should only be used when clinically necessary, such as for true non-contact coagulation.

Although a rare source of surgical fires, PA-PSRS has received two reports of flame or fire from the ignition of bone cement during electrosurgery procedures. Bone cement is primarily composed of methyl methacrylate or polymethylmethacrylate, which are highly flammable substances. Surgical staff need to be aware of the flammability of bone cement in the presence of electrosurgery or other sources of ignition (e.g., laser energy). Bone cement should be used in highly ventilated areas, and methyl methacrylate vapors should be allowed to sufficiently dissipate prior to ESU activation ESU.

Electrosurgery-Related Burns

One of the most common ways for patients and surgical staff to experience skin burns is from inadvertent activation of an ESU (i.e., activated when not in contact with target tissue). Approximately 56% of all ESU-related events reported to PA-PSRS can be attributed to inadvertent ESU activation. Approximately 14% of those events are the result of not placing the active electrode handpiece in a safety holster between intentional activations. The remaining 42% of reports did not provide

enough information to determine the reasons for the inadvertent activations.

A common practice is to place the active electrode handpiece on a flat part of the patient’s body, such as the abdomen, between uses. Inadvertent activation can easily occur if a staff member leans over or on the patient and makes contact with handpiece’s activation switch. The results can include a burn to the patient or the staff member, or ignition of a drape or other flammable material.

More than half of ESU-related burns and fires are attributable to inadvertent ESU activation. Many of these events could be prevented by using a holster for the ESU when it is not in use.

One of the easiest and most effective ways to avoid inadvertent activation is to place the active electrode handpiece in a safety holster that is provided with each new handpiece. For instruments that are too long for a holster (e.g., laparoscopic electrodes), the instrument can be placed on a table such as a Mayo stand that is nearby but away from the patient.

Making contact between an active electrode and another conductive surgical instrument, whether intentionally or unintentionally, can create a burn. For example, PA-PSRS received a report in which a patient experienced a “discoloration” along the vaginal mucosa where a conductive portion of the vaginal speculum was in contact with the vaginal wall. The reporting facility believed that unintentional contact with the speculum during activation of the ESU caused the discoloration. In some cases, intentional contact is made between an active electrode and a conductive instrument such as a hemostat (a technique called “buzzing the hemostat”) in an attempt to control bleeding. In such cases an alternate site burn may occur to the patient if the conductive instrument is also in contact with non-target tissue during ESU activation.

Surgical staff must be aware of other instruments in the vicinity of the active electrode to avoid or reduce the potential for burns. Contacting the active electrode with the conductive instrument prior to ESU activation reduces the likelihood of arcing, thereby reducing the likelihood of an alternate site burn.

PA-PSRS has received four reports involving patients wearing jewelry upon entering the OR. In one report the patient refused to remove two nipple rings prior to an appendectomy. In a second report

Electrosurgery Safety Issues (Continued)

two finger rings were removed from the patient while in the OR. The third report described a patient who was unable to remove a wedding band, and in the fourth report the surgeon assured the patient that her belly ring could remain in place during a laparoscopic hysterectomy.

Most healthcare facilities have policies against patients wearing jewelry during surgical procedures, especially those involving electrosurgical instruments. Many institutions developed policies for fear of patients being burned on the part of the body where the conductive jewelry is located if electrosurgery is applied.

Jewelry need not be removed to avoid burns during electrosurgery. The risk of an alternate-site burn (i.e., those away from the return electrode site) from the electrical conductivity of jewelry is extremely low. Alternate-site burns are more closely associated with contact between the patient and a grounded conductive object – jewelry does not greatly contribute to that risk. Nevertheless, some healthcare facilities encourage patients to remove jewelry to avoid the possibility of loss or theft.

There is a different reason to remove jewelry or cover it with tape or gauze during electrosurgery: to help prevent any sharp edges of the jewelry from scratching the insulation layer of active electrodes or cables of the ESU. Damage to the insulation layer can lead to an unintentional burn from electric current passing from the damaged site to the patient or staff. Prior to deciding on leaving jewelry in place, consider any potential for swelling, especially finger rings during surgery or recovery.⁴

The information in this article is not comprehensive with respect to electrosurgery-related fires or burns, but it accurately presents some of the most common problems associated with electrosurgery. Certainly, due diligence and a good understanding of the technical aspects of electrosurgery on the part of surgical staff will greatly reduce or eliminate the risk of electrosurgery-related injuries or fires from occurring.

When performing electrosurgery:

- Use extreme caution in oxygen-rich environments, particularly during head and neck surgery.
- Be mindful of flammable objects near the surgical site.
- Use coagulation techniques only when clinically necessary.
- Keep the ESU handpiece in the safety holster between activations.

Notes

1. Pennsylvania Patient Safety Reporting System. Patient Safety Advisory. Electrosurgical units and the risk of surgical fires [online]. Available from the internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/sept_2004_advisory_v1_n3.pdf.
2. Pennsylvania Patient Safety Reporting System. Patient Safety Advisory. Risk of fire from alcohol-based solutions [online]. Available from Internet: http://www.psa.state.pa.us/psa/lib/psa/advisories/june_2005_advisory_v2_n2.pdf.
3. ECRI. Ignition of debris on active electrodes [Hazard Report]. *Health Devices* 1998 Sep-Oct;(27):9-10:367-70.
4. ECRI. Allowing patients to wear jewelry during surgical (and electrosurgical) procedures {Talk to the Specialist}. *Health Devices* 1997 Nov;26(11):441-2.

Having Problems Receiving E-mail from PA-PSRS?

The primary way PA-PSRS communicates with Pennsylvania healthcare facilities is through e-mail. The *PA-PSRS Patient Safety Advisory* is distributed this way, as are memoranda about technical changes to the PA-PSRS reporting system, user surveys, and other communications.

If you are a PA-PSRS user and think you may not be receiving our correspondence, PA-PSRS may not have your current/correct e-mail address. Your Facility Systems Manager (FSM) is able to verify and update a user's contact information in the PA-PSRS system.

If you verify that your e-mail address in PA-PSRS is correct but you still do not receive our communications electronically, please inform the help desk. Your organization's e-mail system may be unintentionally blocking messages from PAPSRS. If this is the case, we can work with your IT department to resolve these technical difficulties for you.

Please feel free to contact the PA-PSRS help desk by calling toll free 866-316-1070, or send an e-mail to us at support_papsrs@state.pa.us.

Hold on to These Orders

Problem: For years, healthcare practitioners have struggled with what appears to be a fairly simple issue: How do you document and communicate *holding* a single dose or several doses of a medication, whether it is warfarin, insulin, or other medication? Reports from PA-PSRS demonstrate that orders to hold a medication can often result in a variety of missteps in the medication use process.

The classes of medications most frequently involved in breakdowns when communicating hold orders include:

- **Anticoagulants** such as Coumadin (warfarin), heparin, Lovenox (enoxaparin), and Fragmin (dalteparin). These medications were mentioned in one-third of all reports involving hold orders.
- **Antihypertensives** such as Vasotec (enalopril), Norvasc (amlodipine), Tenormen (atenolol) and Lopressor (metoprolol) were involved in over 16% of the reports.
- **Antidiabetic agents** such as insulin, glyburide, and Prandin (repaglinide) were associated with 15% of the reports.

Some examples of breakdowns that occur are simply process issues that occur during the transcription or order entry process, such as:

- Hold orders or the parameters for a hold order were not transferred to the medication administration record (MAR).
- When MARs were recopied, the hold order or corresponding parameters were omitted.
- Hold orders were not “taken off” or transcribed until *after* the dose of medication was administered.
- Hold orders were not sent to the pharmacy.
- Hold orders were missed by the pharmacist and not entered into the computer system.

Issues that arise during the prescribing process include the time when the hold order was written by the prescriber. For example:

Physician wrote a hold order for Coumadin. Order was written after the routine 18:00

administration time. The hold order was not processed prior to administration, and the patient received one additional dose of Coumadin.

Medication orders sometimes are written without specific parameters or indications to specify when medication administration is intended to be restarted or discontinued. This was commonly seen with medications that effect blood pressure or heart rate. A report submitted to PA-PSRS stated:

While checking the MAR, a nurse noted that Norvasc was on hold since the 14th of the month on the old MAR but had not been transcribed onto the new MAR. Consequently, Norvasc 10mg was given at bedtime on the 21st of the month, when it should have been held.

Problems have also been reported in which medications are ordered to be held for upcoming tests or procedures and then restarted once the procedure is completed. ISMP has reported on a case in which an elderly woman had already been hospitalized for several days when the attending physician requested a gastroenterology consult to determine if she was bleeding. He also wrote an order to “Hold Coumadin” with no parameters. Per protocol, the pharmacy interpreted this order as a discontinuation of COUMADIN (warfarin). The gastroenterologist performed an endoscopy, showing benign results. After the procedure, he rewrote orders for all the previous treatments and active medications using the patient’s current 24-hour computer-generated MAR as a reference. However, since the warfarin was no longer an active order, it was not listed on the MAR. Thus, warfarin was not prescribed post-procedure. Six days later, the patient suffered a stroke, which was directly related to inadequate anticoagulation.¹

The opposite type of error can also occur. In one case, a physician wrote an order to hold LOVENOX (enoxaparin) before a patient underwent implantation of a pacemaker, and also wrote to resume the medication 48 hours after the procedure. However, the MAR did not contain the specified timeframe before restarting the drug. Thus, the patient accidentally received a dose of Lovenox as soon as he returned to the ICU following the procedure.

Sometimes a specific hold order has an effect on other medications the patient may be taking as well. One example reported to ISMP includes a diabetic

Hold on to These Orders (Continued)

patient on continuous enteral feedings, who was also receiving 24 units of subcutaneous NPH insulin, twice daily, to control elevated glucose levels. The feedings were held for a CT scan, but no one discontinued the insulin. By the time the blood glucose was checked again, it measured only 26 mg/dL. Dextrose 50% was administered, and enteral feedings were restarted. Fortunately,² the patient recovered with no lasting ill effects.

Solutions

1. If a patient is receiving *daily* medications, such as warfarin, in doses that are based on *daily* lab results, some facilities reflect this on the pharmacy profile and the nursing MAR as an ongoing active order listing just the drug, route, and frequency, with clear annotation on the records to ensure that a dose is prescribed *each day* according to lab values. Each daily prescribed dose is then documented in the pharmacy profile and the nursing MAR. If a dose must be held due to a high INR value, an order for “No warfarin today” is obtained, including the date that the medication is supposed to be held.
2. If medication doses are not guided by daily lab values, hold orders are unsafe unless the prescriber includes specific instructions indicating when to resume the medication, and the specific instructions are clearly noted on the pharmacy profile and nursing MAR. For example, an order to hold furosemide for 48 hours need not result in discontinuation of the drug; rather, clear annotation can appear on the pharmacy profile and the nursing MAR of the conditions for holding and resuming the drug.
3. Orders to hold a medication indefinitely without specific instructions on when to resume the medication can lead to errors. A safer practice is for prescribers to discontinue the medication and rewrite the order when the medication is to be restarted. If an indefinite *hold* order is received, a nurse or pharmacist can clarify the order to learn if specific conditions can be added for resuming administration. If not, the drug can be discontinued.
4. The pharmacy computer can often generate a daily summary of prescribed therapy for each patient (usually prepared during the night) that is placed on the patient’s chart for physician review. These summaries can include, in a discrete section, a list of medications discontinued within the past 48 hours. Physicians can then include this information in their daily review of order interpretation. This method can help to identify and fix any inadvertent discontinuation or continuation of a drug. The summaries would also help physicians when re-prescribing therapy after a procedure (or upon discharge).
5. While orders to hold a medication until after a procedure clearly include instructions on when to resume administration, these orders are unnecessary because, to be consistent with expectations regarding medication reconciliation, all medications are re-prescribed after such a transition in care, and the newly prescribed medications can be reconciled with the previously prescribed medications. If computerized prescriber order entry is available, it may be possible to place pre-procedure orders in a queue and re-prescribe them by releasing each individual drug as appropriate. Applicable post-procedure standardized order sets can also help if they contain prompts to remind prescribers to resume those medications, such as anticoagulants, that were held prior to the procedure.
6. When enteral feedings or total parenteral nutrition (TPN) orders are stopped or held for diabetic patients, any insulin they are receiving may need to be adjusted or discontinued. If enteral feedings or TPNs have the rate of infusion adjusted or held, prescribers need to simultaneously write an order to reflect any needed changes in the dosing of insulin. Directions to adjust or discontinue insulin under these conditions can be done prominently on MARs and on enteral feeding documentation. Pharmacists, working with dieticians or a nutrition team, if available, can improve safety by maintaining awareness of enteral feedings and alerting staff when diabetic patients with insulin orders have their feedings held or discontinued.

Notes

1. ISMP. Medication Safety Alert! Acute Care Edition. 24 March 2005;(10) 6.
2. ISMP. Medication Safety Alert! Acute Care Edition. 4 September 2003;(8) 18.

Physicians can receive continuing medical education (CME) credits for completing the self-assessment questions related to this article. See page 35 for details.

Self-Assessment Questions

Patient Safety Officers told us in a recent PA-PSRS user survey that it would be helpful to have sample questions about selected *Advisory* articles that they could use for internal education and assessment. You may want to use the following examples or come up with your own.

Through a partnership between the Patient Safety Authority and the Pennsylvania Medical Society, physicians may obtain AMA PRA Category 1 Credit(TM) for completing a similar assessment. Visit the Medical Society website at www.pamedsoc.org/cme for more details.

Who Administers Propofol in Your Facility?

- According to the manufacturers' label for propofol, which of the following should be done when administering propofol?
 - Propofol should be administered only by persons trained in the administration of general anesthesia.
 - The practitioner who administers propofol should not be involved in the surgical/diagnostic procedure.
 - Patients should be continuously monitored for early signs of hypotension, apnea, airway obstruction, and/or oxygen desaturation.
 - Propofol should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management when sedating intubated, mechanically ventilated adult patients in the ICU.
 - All of the above.
- Propofol offers certain advantages over other drugs used for sedation. The following are not advantages of propofol compared to other agents used for sedation?
 - Reduces the need for opioids, thus resulting in less nausea and vomiting.
 - Has a rapid onset and a short duration of action.
 - True
 - False
- Which of the following are potential strategies to improve the safe use of propofol?
 - Establish policies and practice guidelines for the administration of propofol to non-ventilated patients undergoing minor surgical or diagnostic procedures.
 - Define qualifications for professionals who can administer propofol to non-ventilated patients during procedures.
 - Evaluate locations where propofol administration is appropriate and ensure that those areas are able to follow the developed criteria for administration, including expertise and availability of equipment to intubate patients.
 - Ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.
 - All of the above.

Electrosurgery Safety Issues

- What are the three elements required for a surgical fire?
 - Electrosurgical unit, oxygen, and air
 - Ignition source, oxidizers, and fuel
 - Oxygen, N₂O, and fuel

- Tissue adhering to the tip of an active electrode can be caused by which of the following?
 - Excessive heating of the electrode tip
 - Spray coagulation
 - Eschar buildup
 - All of the above
- Methyl methacrylate vapors are highly-flammable.
 - True
 - False
- What is the most effective method to avoid inadvertent activation of an ESU?
 - Place the ESU handpiece on the patient's abdomen between intentional activations
 - Clip the ESU handpiece cable to a surgical drape using a hemostat between intentional activations
 - Place the ESU handpiece in a safety holster between intentional activations
- The electrical conductivity of patient-worn jewelry increases the risk of an alternate-site burn during electrosurgery.
 - True
 - False

Hold on to These Orders

- Which of the following choices contains the three drug classes most frequently involved in medication error reports submitted to PA-PSRS?
 - Anticoagulants, benzodiazepines, and NSAIDs
 - Anticoagulants, opioid analgesics, and diuretics
 - Anticoagulants, antihypertensives, and antidiabetic agents
 - Laxatives, anticoagulants, and cardiac/hypertensive medications
- Which of the following types of problems are associated with hold orders?
 - Orders written to hold a medication after the medication has been administered.
 - Orders written without specific parameters or indications to specify when medication administration should be restarted or discontinued.
 - Orders to hold medications for upcoming tests or procedures and *not* restarting the medications once the procedure is completed.
 - Orders to hold enteral feedings or total parenteral nutrition (TPN) therapy without adjusting orders for insulin.
 - All of the above.
- Which of the following are solutions to prevent errors associated with hold orders?
 - Prescribers could provide specific instructions indicating when to resume the medication with the original order.
 - The pharmacy computer can generate a daily summary of prescribed therapy, which includes a list of medications discontinued for each patient, that can be placed on the patient's chart for physician review.
 - Prescribers could discontinue the medication and re-write the order when the medication is to be re-started.
 - All of the above.



An Independent Agency of the Commonwealth of Pennsylvania

The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s website at www.psa.state.pa.us.



ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI’s focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.



The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP’s efforts are built on a non-punitive approach and systems-based solutions.