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Don't be one of the horror stories — Learn proper use of flash sterilization

'The rules have changed,' says author of updated practice

The stories abound:

- A hospital that routinely flash sterilize implants.
- Facilities where staff don't understand the difference between different types of flash sterilization or between indicators and integrators.
- An instrument falls in the field, and a staff person puts it under tap water in the scrub sink, then places it in the sterilizer without using any detergent and without making sure all gross soils are removed from the lumens.

With all of these problems, should you flash sterilize at all? "They should do it when they have no other choice," says **Ramona Conner**, RN, MSN, CNOR, perioperative nursing specialist at the Center for Nursing Practice at the Association of periOperative Registered Nurses (AORN). "It should not be routine."

That position is supported by AORN's *Recommended Practices for Sterilization in the Perioperative Practice Setting*, which has been updated this year. The recommended practice now states: "Flash sterilization should not be used as a substitute for insufficient instrument inventory."

EXECUTIVE SUMMARY

Flash sterilization experts suggest that the practice is widespread and is being overused due to poor planning. Also, they suggest that it frequently is being done improperly.

- An updated recommended practice from the Association of periOperative Registered Nurses says, "Flash sterilization should not be used as a substitute for insufficient instrument inventory."
- It is critical to follow proper decontamination steps before flash sterilization.
- Documentation is essential. (*Editor's note: We offer four forms with the on-line version of this story.*)

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Don't flash sterilize because of poor planning, says **Stephen M. Kovach**, director of education at Saint Claire Shore, MI-based Healthmark Industries, which features products for sterilization, decontamination, storage, and security of medical equipment and supplies. "It shouldn't be because you don't have enough instruments, or you scheduled cases incorrectly, or you have to turn cases around quickly," he says.

However, many outpatient surgery providers report that flashing is routine, often due to a lack

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Editorial Questions

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at (229) 551-9195.

of instrumentation, with seriously lacking documentation. The issue seems to be particularly problematic with ophthalmic centers, Conner says. "Often they don't want to invest in the appropriate number of instruments so they won't be flash sterilizing between every case," she says.

You need a policy, says **Nancy Chobin**, RN, CSPDM, primary author of the AORN sterilization recommended practice, and corporate consultant and educator with Saint Barnabas Health Care System in West Orange, NJ. The policy at Saint Barnabas, which follows New Jersey state law, says flash sterilization is used only in an emergency.

[**Editor's note:** A copy of this policy is available with the on-line version of *Same-Day Surgery*. If you're accessing your on-line account for the first time, go to www.ahcpub.com. Click on the "Activate Your Subscription" tab in the left-hand column. Then follow the easy steps under "Account Activation." If you already have an on-line subscription, go to www.ahcpub.com. Select the tab labeled "Subscriber Direct Connect to Online Newsletters. Please select an archive." Choose "Same-Day Surgery," and then click "Sign on" from the left-hand column to log in. Once you're signed in, select "2006" and then select the August 2006 issue. For assistance, call Customer Service at (800) 688-2421.]

Keep in mind that many manufacturers no longer provide instructions for flash sterilization, Chobin says. "That means that if I do it, and the manufacturer did not give me instructions, I, as a practitioner, assume full liability for it," she says. Few nurses understand this liability, she says. "In the old days, you put it in and flashed it, but that's not the world we live in anymore."

Joint Commission weighs in

Accreditation groups also are following this issue, Chobin says.

"Frankly, when the Joint Commission [on Accreditation of Healthcare Organizations] comes in and sees abuses, they're going to come down on you, too," she warns.

Standards from the Joint Commission do not address flash sterilization specifically, says spokeswoman **Charlene Hill**. However, some standards apply indirectly, including IC.3.10, EP 5 and IC.4.10, and EP 1.

"While we do not survey for [Centers for Disease Control and Prevention, Healthcare Infection Control Practices Advisory Committee] guidelines, we expect organizations' processes to

be based on them and, if not, why not?" Hill says. The guidelines recommend a minimization of the use of flash sterilization, she says. "It should not be used as a convenience, to avoid the purchase of additional instrument sets, or to save time," Hill says.

Are you flashing correctly?

The issue with flash sterilization is how you do it, Chobin emphasizes.

"Often it's done under terrible conditions, in a substerile room," she says. "They're washing the item, which is not appropriate." Staff usually aren't wearing protective equipment, Chobin adds. Nurses aren't aware of these problems, she says. "The rules have changed."

The Association for the Advancement of Medical Instrumentation (AAMI) and American National Standards Institute (ANSI) have a consolidated and updated steam sterilization standard, expected at press time to be approved in early July. *ANSI/AAMI ST-79:2006* says four conditions should be met for flash sterilization:

- Before sterilization, providers must ensure that cleaning and decontaminating, inspecting, and arrangement of instruments is being done properly in the recommended sterilizing trays or containers.
- The department must be laid out in a way that ensures sterilized items are delivered directly to the area where they are being used. For example, the sterilizer may open into an area within the procedure room or directly next to the room.
- Providers develop, follow, and audit procedures to be certain there is aseptic handling and staff safety while sterilized items are transferred from the sterilizer to the area where they are being used.
- The devices should be needed immediately following the sterilization.

Implantables should not be flash sterilized, according to AAMI. (**For more on AAMI's new sterilization standard, see story, p. 88.**)

To be in line with recommended practices from AAMI and AORN, consider these suggestions:

- Properly decontaminate before flash sterilization.**

When someone needs an instrument right away, staff often cut corners on cleaning, "and that is the last place you want to cut corners," Chobin says.

The No. 1 precaution for flash sterilization is that the instrument must be properly decontaminated,

Conner emphasizes. "They often abbreviate or entirely skip what is a critical factor in flash sterilization," she says.

Instruments should go through the same decontamination process regardless of how they are sterilized, Kovach says. "Is the staff [members] who are cleaning trained, and are they taking shortcuts?" he asks. Doing the cleaning over a sink is not correct, Kovach maintains.

- Develop a safe procedure and mechanism for transporting the sterilized instrument from the sterilizer to the point of use.**

AORN staff often suggest that providers use sterilization containers that are designed for flash sterilization, Connor says. "They can be enclosed and help facility transporting sterilized items to the point of use and protect it from contamination," she says.

- Take steps to avoid injury from hot instruments.**

Use trays designed to facilitate handling of hot instruments, Conner suggests.

Also, "I am aware of incidents when patients have been injured by hot instruments taken straight from the autoclave and used in patients," she says.

- Maintain proper documentation.**

The AORN recommended practice states that "a sterilization log or database should include information on each load, including the device(s) processed, the patient receiving the item(s), and the reason for flash sterilization."

Those records need to be maintained for about three years, Connor says.

Staff often forget to document everything, Kovach says. "The [AAMI] guideline is very specific: Write down the item, monitor the cycle, sign off, document in the patient record what was flashed, so you have all that."

Saint Barnabas maintains a flash sterilization

SOURCE/RESOURCE

For more information on flash sterilization, contact:

- Stephen M. Kovach**, Director of Education, Healthmark Industries, Saint Clair Shores, MI. Phone: (800) 521-6224, ext.6621. E-mail: cpdguy@healthmark.info.

Kovach maintains a web site at www.healthmark.info/CPDGuy/InfoOnFlash.htm. It includes articles and case studies on flash sterilization, a step-by-step explanation of the technique, and a sample policy.

log, to meet state requirements. (**The log is available with on-line edition of SDS.**) "Our health department wants to see the reason you did flash sterilization as part of the [quality assurance] process," Chopin says. "You have to record why, and you'd better not show it was because the doctor didn't have the instrument."

Chobin suggests that surgery managers can develop a quality assurance (QA) project that documents the flash sterilization and uses that documentation to help prioritize the purchase of instruments. Saint Barnabas conducts a quarterly audit of the flash sterilization records in the operating room that includes a review of sterilization logs to ensure they include signature, chemical indicators, doctor's name, etc. If flash sterilization is known to be excessive (after QA data collection), then QA monitoring should be performed monthly with process improvement implemented until the instances of flash sterilization are according to national standards, Chobin says. (**A copy of the audit form is available with the on-line version of SDS.**)

- **Match technology to the device.**

Not all medical devices can withstand steam sterilization, Connor emphasizes. "There is not one sterilization technology that fits every device and every need," she says. While steam sterilization is the most common and fits most devices in the OR, "it doesn't meet all needs," she says. (**Education also is a critical step. See story, below.**) ■

Educating staff is critical piece

Staff need a thorough understanding of the principles of decontamination and sterilization to perform flash sterilization properly, says **Ramona Conner, RN, MSN, CNOR**, perioperative nursing specialist at the Center for Nursing Practice at the Association of periOperative Registered Nurses (AORN).

"Every person who has anything to do with any portion of the sterilization process should be educated or trained at hire and periodically to validate competency in operating specific equipment and sterilizing instruments used in that facility," she says.

In addition to the basic principles, staff members need to understand how the equipment operates and which parameters are standard.

They need to know when to use different parameters than the routine, so they also need to understand the requirements of sterilization for the specific devices, Conner says. One example is orthopedic powered instruments, she says.

"Sometimes they need extended cycle times or dry times even if they're flash sterilized."

Sterilization is much more complicated than 20 years ago, when shorter cycle times were used, reports **Stephen M. Kovach**, director of education at Saint Claire Shore, MI-based Healthmark Industries, which offers products for sterilization, decontamination, storage, and security of medical equipment and supplies. "Now with the complexity of instruments, those cycle times might not be adequate," Kovach says.

Staff need to be educated by the instrument manufacturers and the sterilizer manufacturers, he emphasizes. "It's not just flipping a button," he says. There should be an annual orientation and annual competency on how to work the flash sterilizer, Kovach says. "Anyone who can use it should have a competency," he says. (**An example of a competency form is available with the on-line version of SDS.**) ■

AAMI incorporates several practices into one

The Association for the Advancement of Medical Instrumentation (AAMI) and American National Standards Institute (ANSI) are combining the recommended practice on flash sterilization with other standards into a single document on steam sterilization.

ANSI/AAMI ST79:2006, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities incorporates the recommendations of

RESOURCE

At press time, the Association for the Advancement of Medical Instrumentation (AAMI) expected to have ANSI/AAMI ST79:2006 available for purchase by early August. The order code for the print edition is to be ST79 and ST79-PDF for a PDF downloaded version. The price is \$100 for AAMI members and \$200 for nonmembers. To order, go to the web site, marketplace.aami.org.

ANSI/AAMI ST37, Flash sterilization: Steam Sterilization of Patient Care Items for Immediate Use. The new document addresses steam sterilization in all health care facilities. It covers steam sterilization by the wrapped and flash methods and provides detailed guidance on decontamination and packaging, with special reference to rigid sterilization container systems.

At press time, the nearly 200-page document was expected to be approved in early July and released in August. (See resource box, p. 88.) The new document will be the first AAMI recommended practice to be annually reviewed and updated. ■

New Patient Safety Goals added for next year

Medication list required

Medication lists for patients, development of a process for patients to express concern, and identification of patients at risk for suicide are the main changes and additions to requirements of the Joint Commission on Accreditation of Healthcare Organizations' 2007 National Patient Safety Goals for ambulatory and hospital-based outpatient surgery programs.

Goal 8B was included in the 2006 safety goals and required organizations "to communicate a complete list of medications to the next provider of service when a patient is referred or transferred to another setting, service, practitioner, or level of care." This goal has been amended to say

EXECUTIVE SUMMARY

The 2007 National Patient Safety Goals have been announced.

- Ambulatory organizations focus on reducing medication errors and improving communication between patients and providers. In addition to providing a complete list of medications to providers to whom patients are referred, an organization also must provide the list to all patients. Patients must be informed of the process to report concerns about patient care or safety.
- Hospital-based programs must develop a process to identify patients at risk for suicide and implement a program to refer these patients to appropriate health providers.

"the complete list of medications is also provided to the patient on discharge from the facility."

"I don't see that this requirement will be a challenge for most outpatient surgery programs, but it may pose a problem for diagnostic programs such as endoscopy programs," says **Michael Kulczycki**, executive director of the Ambulatory Accreditation Program at the Joint Commission. The difficulty for smaller, more diagnostic-oriented programs is related to the nature of the program, he points out. Goal 8A requires organizations to have a process that enables them to compare a patient's current medications with new medications that are ordered, so an organization will have a list of medications for the patient. But organizations may not have a method to easily provide that list to the patient, he explains.

Lisa Hamilton, practice administrator of Asheboro (NC) Endoscopy Center, says her facility is a little different from many other endoscopy centers. "We are a freestanding center, but we are owned by one group of physicians, and our electronic medical records system interfaces with the physicians' office system," she says.

This connection means that Hamilton's center has access to information on medications that the patient has reported to the physician as well as medications the patient reports to the endoscopy center upon admission for service. "We do have patients that ask us to give them a copy of their medication list, and we can easily do it by pushing one key on the computer," she adds.

The only process change the Asheboro center will need to make to comply with the new goal is to automatically give every patient a copy of the medication list, says Hamilton. "On a personal level, I am glad to see this requirement added to the patient safety goals," she says.

With an elderly father who has multiple medical conditions, Hamilton points out that it is difficult for her father and mother to keep up with everything that he is taking. "Endoscopy centers see a lot of elderly patients who are going from provider to provider for care for multiple health conditions," she points out. With several different providers involved, it is likely that a medication will be forgotten when the patient is asked to list medications, she says. "Although we may only see them once every few years, at least we can provide a list that serves as a good starting point, and they can revise it as needed," she adds.

Even without electronic medical records, there are tools that outpatient surgery programs can use to encourage a patient to keep an updated list

of medications, says Kulczycki.

"Joint Commission's Speak Up program offers different tools, including a wallet-sized medication card that organizations can print with their logo and distribute to patients," he says. (See resource box, below.)

Identify patients at risk

One piece added to the hospital patient safety goals is under Goal 15, which requires organizations to "identify safety risks inherent in its population." Goal 15A requires organizations to identify patients at risk for suicide, says Kulczycki.

Implementing a risk assessment in the admission or pre-op process, and having a process to refer the patient to a crisis hotline or counseling, would meet this goal, he says.

The new goal added for ambulatory organizations is Goal 13, which requires them to encourage patients' involvement in their care. Goal 13A requires organizations to "define and communicate the means for patients and their families to report concerns about safety and encourage them to do so."

One of Joint Commission's accreditation participation requirements (APR 8) already defines an expectation for the organization to notify patients about the process to report concerns about patient care and safety, points out Kulczycki. "The patient

safety goal is meant to reinforce the intent of that requirement for ambulatory organizations," he says. While the Joint Commission does not prescribe the exact manner of meeting this goal, an organization can use its web site, a brochure, posters, or a statement included on the informed consent form to notify a patient of the process for reporting concerns, he says.

"We give a patient survey to all patients upon discharge, with instructions that if they have any concerns, we want to hear about them," she says. "It's important to develop a good rapport with patients so that they will come back, and we want them to know that we are always trying to improve and fill in any gaps in good service that they may see." ■

New JCAHO standard requires flu vaccine

A new infection control standard that will require hospitals to offer influenza vaccinations to staff members, volunteers, and independent licensed practitioners who have close patient contact will take effect Jan. 1, 2007, for organizations accredited by the Joint Commission on Accreditation of Healthcare Organizations. The new requirement does not apply to ambulatory facilities.

The Joint Commission standard was developed in response to recommendations by the Centers for Disease Control and Prevention (CDC) that identified reduction of influenza transmissions from health care professionals to patients as a top priority in the United States.

Influenza causes 36,000 deaths and more than 200,000 hospitalizations annually, and health care-associated transmission of influenza has been documented and infections have been linked epidemiologically to unvaccinated health care workers, according to the CDC. The CDC also reports that fewer than 40% of health care workers are immunized each year.

While the Accreditation Association for Ambulatory Health Care does not have as specific a requirement as the Joint Commission's new standard, Chapter 19 does address health and occupational services offered to employees, says **Stephen Kaufman**, RN, MA, senior director of accreditation. "If an organization chooses to provide health services, an assessment of risk factors for employees and patients must be

SOURCES/RESOURCE

For more information about 2007 National Patient Safety Goals, contact:

- **Lisa Hamilton**, Practice Administrator, Asheboro Endoscopy Center, 700 Sunset Ave., Asheboro, NC 27203. Telephone: (336) 625-0305. E-mail: lhamilton@asheborogi.com.
- **Michael Kulczycki**, Executive Director, Ambulatory Accreditation Program, Joint Commission on the Accreditation of Healthcare Organizations, One Renaissance Blvd., Oakbrook Terrace, IL 60181. Phone: (630) 792-5290. E-mail: mkulczycki@jcaho.org.

To access free artwork for wallet cards for patient medication lists, go to www.jointcommission.org, highlight "patient safety" on the top navigational bar, then click on "Speak Up." Scroll down to "Medication Mistakes." In addition to artwork for wallet cards, organizations can download artwork for patient brochures and posters.

performed and vaccinations that should be offered must be identified," he explains.

The new Joint Commission standard will require organizations to:

- establish an annual influenza vaccination program that includes at least staff and licensed independent practitioners who have close patient contact;
- provide access to influenza vaccinations on-site;
- educate staff and practitioners about flu vaccination, nonvaccine control measures and diagnosis, transmission, and potential impact of influenza;
- annually evaluate vaccination rates and reasons for nonparticipation;
- implement enhancements to the program to increase participation. ■

Hospital, docs responsible in impairment case

Doctor fired, then given glowing recommendations

In a first-of-its-kind court case, a jury held that a Louisiana hospital and two physicians intentionally misrepresented a former anesthesiologist's qualifications to a hospital in Washington state where he later was said to have botched a tubal ligation that left a 31-year-old woman with severe brain damage.^{1,2}

According to court documents:²

- The anesthesiologist didn't monitor the 31-year-old mother of three properly.
- He allowed her blood pressure to drop dangerously low, and then he removed her breathing tube while she still was paralyzed from sedatives.
- The patient had a heart attack.

Two days after the surgery, the anesthesiologist admitted to hospital officials that he diverted narcotics meant for patients to his personal use for back pain following a car accident.¹ He then immediately entered a physicians' drug treatment program, according to court testimony. The anesthesiologist no longer practices medicine.¹

Court testimony indicates that the anesthesiologist's partners fired him in 2001 for working in an "impaired physical, mental, and emotional state."¹ About two months later, two partners praised him as an excellent clinician in letters given to the Washington hospital before it hired him. Also, the Louisiana hospital did not disclose

EXECUTIVE SUMMARY

For the first time, a hospital has held another hospital responsible for not disclosing information about a physician. The jury ordered the hospital and anesthesiologists to pay \$4.1 million after the drug-impaired physician reportedly botched a tubal ligation and left the patient with severe brain damage.

- Perform due diligence on an applicant's qualifications and background.
- Attempt to obtain a signed release from a problem physician saying they release you from any liability for providing true information about their time practicing at your facility.

that a 2000 audit of his narcotic medication records raised concerns that he'd withdrawn a large amount of a drug from the pharmacy without proper documentation.

The jury ordered the hospital and anesthesiologists to pay \$4.1 million. According to one of the lawyers, this is the first time that one hospital has held another one responsible for not disclosing information about a doctor.¹ Also, the anesthesiologist's insurer paid \$7.5 million to settle a malpractice claim bought on behalf of the disabled patient.

Fear of litigation is driving factor

Everyone has become terribly cautious in giving *any* recommendation for ex-employees, says **Waldene K. Drake, RN, MBA**, vice president of risk management and patient safety at Cooperative of American Physicians in Los Angeles.

"This is largely due to the fear of litigation alleging defamation of character, libel, or slander," she says. Many employers merely release dates of employment, title, and salary, says Drake, who expresses surprise that "glowing" letters of recommendations were sent in this case.

This verdict reinforces to everyone in the health care community that withholding information that might compromise a patient's safety is unacceptable, Drake points out. "The truth is that [the anesthesiologist] may have filed suit against the Louisiana group for defamation of character, libel, or slander had they told the truth as they knew it without proof to back it up," she says, "and, they might have won." Consider these lessons learned from the case:

- **Don't rely solely on references.**

When it comes to who is and who is not hired by or credentialed to practice in your facility, it

generally is your facility's responsibility to perform due diligence on the person's qualifications and background and not simply rely upon the person's references, advises **Edward J. Carbone**, JD, shareholder with Buchanan Ingersoll in Tampa, FL. "In practical terms, most people do not use or name a reference that they believe would give anything less than a glowing report," he says.

Most jurisdictions have special programs for drug and alcohol abusing physicians and health care workers, Carbone points out. "Oftentimes, the specifics of those records are confidential, but it would behoove a potential employer to check the records from any jurisdiction where the practitioner was licensed or at a minimum point-blank ask the practitioner if there are issues that would interfere with their ability to perform," he says.

- **Get a signed release from any problem physicians.**

When you have a problem with a physician on your staff, obtain a signed release from that physician releasing you from any liability for providing true information about their time practicing at your facility, suggests **Margaret Bastow**, in charge of education matters for Hortsy Springer, a Pittsburgh law firm that counsels hospitals.¹ If a physician doesn't provide such a release, a prospective employer can refuse to process the physician's application, she says.

The best time to get this signed release is at the time of initial appointment and every reappointment, some outpatient surgery experts maintain. If the release is not obtained then, the second best time is when the problem is being addressed, as part of the resolution agreement, they say.

Health care providers hurt their own interests when they seek to protect another provider by hiding damaging information about that provider from credentialing reviewers, Carbone says. "The providers' patients suffer in the short term, but the entire system suffers in the long term," he says. (For information on addressing drug-impaired staff, see *Same-Day Surgery* coverage: "Take action now before drugs cause a tragedy at your facility," June 2003, p. 61; and "How do employees act when drug-impaired?" July 2003, p. 80. Also, see our award-winning coverage of this topic in the October 2001 and November 2001 SDS.)

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Center given moratorium after abuse allegations

State: Some complaints weren't investigated

Outpatient surgery managers, take note: A Florida ambulatory surgery center (ASC) was banned from admitting new patients for 18 days following a determination by the state that the administrator/risk manager failed to prevent a male staff member from sexually abusing a patient after complaints from other staff members.

"An ASC is going to have liability issues if it allows this to happen," says **Brian A. Lapps Jr.**, JD, attorney with Waller Lansden in Nashville, TN. The more it happens, the more allegations there are, the more they are likely to have significant legal problems."

At Oakridge Ambulatory Surgery in Fort Lauderdale, the complaints about the male staff person included:

- A female patient reported that the male employee touched her breast and placed his finger on her sexual organ. The administrator/risk manager documented that the staffer touched her breasts and "belly button."
- Nurses reported to the administrator/risk manager that they saw the male employee inappropriately touch the pubic area of a sedated

EXECUTIVE SUMMARY

According to a Florida state agency, a risk manager failed to investigate allegations of sexual abuse of a patient by an employee and thus failed to comply with her facility's policies and state laws. The center was given a moratorium from admitting new patients for 18 days.

- Build trust with your employees so that they can come forward will allegations of misconduct.
- Familiarize yourself with your state's requirements for background checks.
- If you have a risk management program, train your staff, follow it, and take action when allegations arise. Consult with an attorney to determine whether legal authorities should be contacted.

female patient. There was no incident report or investigation, and the police were not informed. "The staff was generally afraid to make any complaints to the facility," according to the State of Florida Agency for Health Care Administration.¹ "Those who did were reprimanded."

- Four RNs and one tech stated that the same male employee isolated female patients in the bathroom and assisted them as they changed into their clothes, even after being instructed to stop that practice.

- A plastic surgeon complained about the same male employee staring at the breasts of female patients. These incidents were not investigated or documented on incidence reports.

- A nurse complained that when standing preps were done on female patients, the same male employee would stop doing work, turn and face the back of the patient, and watch the procedure. The nurse told the risk manager.

The male employee was terminated Aug. 15, 2005; however, there were at least four incidents before September 2004 before any action was taken to remove this staff member. Three of those incidents were never investigated by the risk manager or anyone else at the facility.

When the risk manager was interviewed, "the risk manager did not feel, even up to the current time, that there was any problem with the risk management function," according to the state Agency for Health Care Administration. "The risk manager was not knowledgeable of the facility's policies and procedures or of state risk management requirements."¹ Those requirements include investigating and analyzing adverse incidents to patients and developing measures to minimize the risk of adverse incidents through prevention.

According to the agency, staff did not think their observations were treated seriously, "and even worse, staff was reprimanded for coming forward with these complaints. This fostered an atmosphere in which observed incidents would not be reported and therefore the protection of the patients was compromised."¹

The moratorium was lifted by the Florida agency when officials determined the surgery center was in compliance with state regulations.

This allegation of misconduct is one of the more blatant ones that Lapps has seen. "If you nip it in the bud and fire someone who does this right away, report it to the appropriate authorities timely, and take appropriate action, that is best chance or avoiding or minimizing liability."

In fact, the key reason the center was banned

from admitting patients for 18 days was that its risk management didn't respond appropriately and timely, he says. "It's almost as if the risk manager tried to cover it up," Lapps says. "It's the cover-up that gets you in trouble."

Build trust with your employees so that they can come forward, Lapps advises. "Develop credibility, and take these types of allegations seriously," he says.

Also, familiarize yourself with your state requirements for background checks, Lapps adds.

When an incident is reported, consult with an attorney to determine whether legal authorities should be contacted, he suggests.

"The big lesson is don't stick your head in the sand," Lapps says. "If you have a risk management program, train your people on it, follow it, and do something."

If you have a cancer in your body, you don't cover it up and hope it goes away, he points out. "The same principle applies to dealing with a bad employee." (For more information on how to address sexual abuse of patients by staff, see these stories in the January 2006 issue of *Same-Day Surgery*: "In light of 2 criminal cases, how do you ensure employees don't abuse patients?" p. 1; and "Take these steps to cut liability risk," p. 4.) ■

ISMP warning: Providers confuse Carpuject syringes

Follow 5 tips to avoid drug mix-up

In an ambulatory surgery center that was busy recently handling several patients, two patients received two doses of fentanyl instead of one dose each of fentanyl and midazolam, according to the Institute for Safe Medication Practices (ISMP) in Huntingdon Valley, PA.¹

The errors were found when counting narcotics, according to the ISMP. No patient harm occurred, but this is one of many reports that ISMP has received regarding errors with look-alike Carpuject syringes from Hospira in Lake Forest, IL.

All of the Carpuject syringes now have green caps, says Michael Cohen, RPh, ScD, ISMP president. "At one time, they were color-differentiated," Cohen says. The company has retained color differentiation for the drug name on the syringe. Additionally, the midazolam information is boxed to differentiate the products.

EXECUTIVE SUMMARY

The Institute for Safe Medication Practices continues to hear reports of errors with look-alike Carpuject syringes. They offer these suggestions:

- Store items separately that look alike and are prone to mix-ups. Don't store Carpuject products together in automated dispensing units.
- Use auxiliary labels on outer cartons, or circle the name of the drug to call attention to it. If they are stored in the carton, leave the flap so the drug name is visible.
- Consider requiring an independent double-check of selected Carpuject narcotics that can be confused.

Hospira uses its enhanced product labeling to distinguish each medication, not the green caps which only indicate that the product has a luer tip, says **Shannon Gore**, a spokeswoman for Hospira. Hospira encourages clinicians to take advantage of differentiating features on the product labeling when selecting drugs, she says. For example, Gore adds, key differences in the fentanyl and midazolam product labels include:

- **color:** Fentanyl has a red label and midazolam has an orange label;
- **capitalization:** The name "midazolam" contains all capitalization and has a box around the name and dosage;
- **units of measure:** Fentanyl is dosed in micrograms, and midazolam is dosed in milligrams;
- **classification:** Fentanyl is labeled as a Class C-II controlled substance, and midazolam is labeled as a C-IV controlled substance;
- **bar code:** Fentanyl and Midazolam have unique bar codes to differentiate the products.

ISMP offers five tips to reduce the risk of errors with Carpuject syringes:

- Identify Carpuject products that are prone to mix-ups, and separate the storage of these products.
- Place Carpuject products in automated dispensing cabinets in discrete pockets, never together.
- Ask pharmacy staff to apply auxiliary labels to the outer cartons.

Outpatient surgery providers who don't have pharmacy staff could circle the name of the drug to call attention to it, Cohen says.

- If the syringes are stored in the carton, leave the carton flap that lists the drug name and strength intact.
- Consider requiring an independent double check of selected Carpuject narcotics prone to mix-ups.

This step is especially needed if the drugs are being given intravenously, Cohen says. "With opiates, all of these, there can be such a potency difference in the drugs," he says. When given intravenously, the patients would be immediately affected if there is an overdose, Cohen says. "It's always better where possible to have a second individual look at the label to make sure you have the correct drug and dose," he says.

(Editor's note: Five tips are reprinted with permission from June 2006 issue of ISMP Medication Safety Alert Nurse Advise-Err newsletter. For more information, see www.ismp.org.) ■

Blue Cross sued over payment policy

Payments to increase for nonhospital endoscopies

The California Hospital Association has sued Blue Cross of California to stop a new payment policy that decreases reimbursement for endoscopic procedures that are performed in hospital outpatient departments and boosts payment when the procedures are performed in physician offices and freestanding surgery centers.

The lawsuit claims that Blue Cross is violating state law by giving incentives to physicians to make medical decisions based on financial considerations. The new policy will penalize physicians who perform colonoscopies in a hospital outpatient facility by cutting their payment by 20%, according to the hospital association. If the same procedure is performed in a physician's office or freestanding surgery center, Blue Cross will give the physician a 5% bonus, in addition to the full fee.

The suit claims that Blue Cross also is violating provisions of the state's insurance code and the Knox-Keene Act. These provisions, which regulate health plans and insurance companies, not only require doctors to make medication decisions unhindered by financial concerns, but also make it unlawful to provide financial incentives to reduce, deny, or limit services, the association says.

Also, the suit claims that Blue Cross is committing fraud because it tells members they have a choice of health care providers within the plan's network, but that choice is being severely limited, the association says.

The suit is seeking an immediate injunction to prevent Blue Cross from implementing the plan.

At press time, the new policy was scheduled to take effect July 1.

In a letter addressed to Blue Cross of California, **John C. Lewis**, executive vice president/CEO of the California Medical Association, said, "Physicians and their patients, not health plans, are in the best position to make medical decisions, including the most appropriate site of service based on each individual patient's medical circumstances." Additionally, Lewis pointed out that many physicians don't have privileges at the ambulatory surgery centers (ASCs) that Blue Cross has presented as options, and many of those ASCs are not accepting new applications for medical staff membership. "In order to avoid Blue Cross' penalty, physicians will be forced to refer their own patients to a participating physician that has medical staff privileges at one of the Blue Cross designated ASCs," he says. "The patient/physician relationship is disrupted and continuity of care may be adversely impacted." ■

sold it. Ever since XXX Company bought us, we have not received any type of bonus. They tell us we probably will not receive a bonus — that it is not in their budget! We complained to our surgeons, but they just tell us that they have no say in the management of the center any further. How many centers do pay a bonus to the surgery center staff? Is this company just plain cheap?"

Answer: I am sure that XXX paid a handsome price for your surgery center to the owners. They are going to try to recoup as much of that as possible and as quickly as possible! Most centers I am familiar with do pay their staff a bonus or some form of incentive. So yes, I think that company is just plain cheap.

Question: Can a certified registered nurse anesthetist be the chief of anesthesia at a hospital?

Answer: Of course! Many are, and they do a great job.

Question: Our gastrointestinal (GI) surgeon told us that he is going to have to take his cases to the surgery center down the street because Blue Cross/Blue Shield is going to reduce his professional fee if he continues to do it in the hospital. Is he just giving us that excuse, or is this true?

Answer: Actually, he is right. Blue Cross/Blue Shield is reducing the professional fee to surgeons if they do their gastrointestinal cases in the hospital — and will actually pay them more if they are done in a lower-cost facility such as a

Same-Day Surgery Manager



Questions about bonuses, moving GI procedures

CRNA administrators, lap bands are OK?

By **Stephen W. Earnhart, MS**
CEO
Earnhart & Associates
Austin, TX

Question: Our surgery center was bought by a chain surgery center at the end of last year. We received a bonus every quarter for the past 12 years by the surgeons who owned it before they

CE/CME instructions

Physicians and nurses participate in this CE/CME program by reading the issue, using the references for research, and studying the questions. Participants should select what they believe to be the correct answers, then refer to the answers listed in the answer key to test their knowledge. To clarify confusion on any questions answered incorrectly, consult the source material. After completing this semester's activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

COMING IN FUTURE MONTHS

- Should you prepare for the bird flu?
- Healing the wounds of war with outpatient surgery
- Are you getting your share of outpatient surgery growth?
- Drawing the line for ambulatory surgery criteria
- Find out what your competitors charge

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CE/CME questions

- **Identify** clinical, managerial, regulatory, or social issues relating to ambulatory surgery care.
 - **Describe** how current issues in ambulatory surgery affect clinical and management practices.
 - **Incorporate** practical solutions to ambulatory surgery issues and concerns into daily practices.
5. What of the following statements is included in the updated recommended practice on sterilization from the Association of periOperative Registered Nurses?
- A. Flash sterilization is acceptable if the facility documents the lacking instrument inventory.
 - B. Flash sterilization is acceptable on a short-term basis (less than one year) if the facility documents the lacking instrument inventory.
 - C. Flash sterilization should not be used as a substitute for insufficient instrument inventory.
6. Which of the following is true of a new infection control standard from the Joint Commission on Accreditation of Healthcare Organizations?
- A. Hospitals and surgery centers are required to offer influenza vaccinations to staff members, volunteers, and independent licensed practitioners who have close patient contact.
 - B. Hospitals are required to offer influenza vaccinations to staff members, volunteers, and independent licensed practitioners who have close patient contact.
 - C. Hospitals are required to offer influenza vaccinations only to staff members and independent licensed practitioners who have close patient contact.
 - D. Hospitals are required to offer influenza vaccinations only to staff members who have close patient contact.
7. What action does the addition to National Patient Safety Goal 8A require?
- A. Pharmacists must review a patient's list of medications.
 - B. Nurses cannot rely on handwritten lists from patients.
 - C. Insurance companies must receive a copy of medication list.
 - D. Patients must be given a copy of their complete medication list upon discharge.
8. What does the Institute for Safe Medication Practices recommend to avoid errors with look-alike Carpuject syringes?
- A. Store items separately that look alike and are prone to mix-ups. Don't store Carpuject products together in automated dispensing units.
 - B. Stop using Carpuject syringes immediately.
 - C. Suggest an independent double-check of selected narcotics if the staff member is confused.
 - D. Never leave the flap on the carton box.

Answers: 5. C; 6. B; 7. D; 8. A.

REVISED 5/16/03

**APPROVED BY SPD AND PERIOP COUNCILS
TO INFECTION CONTROL**

POLICY #:

TOPIC: FLASH STERILIZATION

EFFECTIVE DATE:

Approved by: _____

Date: _____

Director, PeriOperative Services

Date: _____

Supervisor, Sterile Processing

Date: _____

Infection Control Committee

Date: _____

PURPOSE: To define proper use of flash sterilization and how to perform it correctly.

- POLICY:**
1. Flash sterilization will be restricted to those items needed in an emergency in which the patient will suffer an unfavorable outcome if processed through the usual wrapped cycle.
 2. Flash sterilization will not be used for routine sterilization of devices used on patients or for implantable devices.

QUALIFICATIONS:

1. OR nurses, surgical technicians, and sterile processing personnel who are competent in decontamination, sterilization and asepsis.

EQUIPMENT: As outlined

DOCUMENTATION: System wide Flash Sterilization Log

PROCEDURE

1. In the event of an emergency and a one-of-a-kind item is needed but is not sterile, flash sterilization of the device will be necessary.

Decontamination

2. All devices should be decontaminated in accordance with the written instructions from the device manufacturer. **It is preferable that all Decontamination activities be performed in the sterile processing department (SPD).**
3. All devices/instruments will be decontaminated per system-wide Decontamination Policy.
4. If the item(s) will be decontaminated in the OR, the item(s) must first be properly cleaned in the Decontamination or Soiled Utility Room following facility cleaning procedures and the device manufacturer's written instructions (see SPD Decontamination Protocols Policy).

TOPIC: FLASH STERILIZATION**POLICY #:**

5. Soiled devices should be transported to the Decontamination or Soiled Utility Room in such a manner as to prevent contamination of the employee and the environment. Use of an impervious cover (not linen) or rigid instrument container (with filters in place) is recommended.
6. After cleaning, the instruments/device should be wrapped in a surgical towel or placed in a mesh basket or plastic bag and transported to the flash sterilizer located closest to the point-of-use. Contain instruments to prevent dripping water on the floor.

Preparation

7. The sterilization cycle (pre-vacuum or gravity displacement), sterilization time and temperature should be selected from written instructions provided by the device manufacturer.
8. Generally, item(s) should be:
 - a. Opened (not clamped closed)
 - b. Disassembled if possible (or as recommended by the device manufacturer)
 - c. Items with lumens/channels should be flushed with distilled water **immediately before flash sterilization**.
9. Place chemical integrator (CI) inside tray. The integrator should be marked (using a non-toxic marker) with the cycle number for tracking of cycles.

NOTE: The chemical integrator should be a Class V integrator which measures the sterility assurance level (SAL) to 10^{-6} . Chemical integrators measure all the critical parameters for sterilization and the results parallel the results of biological monitoring.

10. Place cleaned item(s) in sterilizer.
 - a. If single item place in wire or mesh basket
 - b. If set, place set basket in sterilizer
 - c. Place baskets flat on sterilizer shelf
 - d. **If using the Riley FlashPak or SPARCO flash pan, see section at end of procedure for proper use of these containers for flash sterilization.**

Sterilization – “Unwrapped” Method – Open Pan

NOTE: The “open pan” method should ONLY be used when the sub-sterile room is immediately adjacent to the flash sterilizer. Otherwise, a closed container should be used for sterilization/transport.

11. Process on “unwrapped” cycle **following the sterilizer manufacturer’s recommended cycle time and temperatures (or the instructions from the device manufacturer, if different).**
 - a) AORN and AAMI recommended exposure times are as follows:

High Speed Gravity Displacement:

Metal instruments, no lumens, no porous material – 3 minutes at 270°F (132°C)

Metal instruments, with lumens and/or porous materials – 10 minutes at 270°F (132°C)

Pre-vacuum Flash Sterilization:

Metal instruments, no lumens, no porous material – 3 minutes at 270°F (132°C)

Metal instruments, with lumens and/or porous materials – 4 minutes at 270°F (132°C)

12. Record device being sterilized and all other required documentation on the Flash Sterilization Log.
13. At the completion of the cycle **and before removing** devices, the sterilizer operator should carefully check the integrator and review the sterilizer chart/printout. If the integrator shows correct color change and if the printout/chart has recorded the correct temperature and exposure time, the items can be removed.
 - a. **The sterilizer operator must sign the printout/chart indicating that all parameters for sterilization were met.**
14. When removing items from the flash sterilizer, care must be taken in removing the item and in the transfer of the device to the room. Use of sterile gloves, mask, and sterile towels to contain the device is recommended.
 - a. The devices can be removed from the sterilizer by the circulating nurse, using some method of protection from the hot tray, and the nurse carries them unprotected to the surgical field
 - b. Devices can be flashed inside a flash container that is brought to the room and can be placed on any unsterile table to facilitate opening by the circulating nurse.

FLASH STERILIZATION USING THE RILEY FLASH PAK CONTAINER

15. If multiple flash containers are in use, each container should be sequentially numbered (base and lid) to track problems.
16. The containers should be washed **daily** with a neutral pH detergent, rinsed with tap water and dried with non-linting towel. The container also can be processed in an automated washer.
17. The container should be visually inspected to ensure there are no cracks or chips. The gasket and silicone vents should be visually inspected to ensure there are no cuts or tears.
18. Check the valves. The valves located in the top and bottom of the container **should be vented at least once a day, when the container is cool.**
 - a. Open the valve vent for 10 seconds.
 - b. **Hold the valve body** and turn the vent knob one turn counterclockwise.
 - c. Close valve vent by turning the vent knob clockwise one turn or until resistance is met.
 - d. **NOTE: Residual vacuum may be retained in the valve bellows. Failure to routinely release the residual vacuum may result in the valve not remaining closed.**
 - e. Verify that the valves in both the lid and bottom are closed and seated.
 - f. Using a dull object (such as the eraser end of a pencil) insert through the perforations and depress the valve.
 - g. Release and visually inspect the contact of the valve to the silicone gasket.
 - h. **Do not use container if there is any area the metal valve cover does not deal securely on the silicone gasket.**
 - i. Document venting of valves on Flash Sterilization Log form daily.
19. Follow the following steps:
 - a. Ensure items have been thoroughly cleaned.
 - b. Place in mesh basket (NOTE: separate instruments to evenly distribute metal mass).
 - c. Verify that valves have been vented (refer to Flash Sterilization Form for documentation of venting). Visually verify the valves in both the lid and bottom of the container are closed and seated.
 - d. Place the mesh basket inside the Flash-Pak.
 - e. Place steam chemical integrators inside pan **in the center of the tray.**Place the lid on the container and secure with latches.
Place container in sterilizer. The container should always be level in the sterilizer.
20. Based upon scientific studies performed, the following parameters for sterilization are recommended:

RILEY FLASH PAK STERILIZATION CYLES:**Hi-Speed Gravity Displacement Flash Cycle:**

- 1) Non-porous, non-lumened devices – **5 minutes sterilization time – no dry time**
- 2) Porous, lumened devices – **10 minutes sterilization time – no dry time**

Pre-Vacuum Flash Cycle: ** See NOTE BELOW

- 1) Non-porous, non-lumened devices – **3 minutes sterilization time – no dry time**
- 2) Porous, lumened devices – **5 minutes sterilization time – no dry time**

NOTE: If your pre-vacuum flash sterilizer has a built-in dry time of 1+ minutes, use of the Riley Flash Pak is not permitted. No dry time can be used; sterility maintenance can be affected.
Instead, use a gravity displacement cycle.

REMOVAL FROM THE FLASH STERILIZER:**RILEY FLASH PAK:**

21. When the circulator removes the Flash Pak from the sterilizer::

- a) Open the sterilizer door and remove the container. The container will be warm. Insulating gloves or towels will be needed to hold the container for transportation to the room.
- b) Verify cycle parameters have been met by reviewing and signing the sterilizer printout. If conditions have not been met, re-run the device.
- c) Place container on table at point of use and unlatch lid.
- d) Depress the pressure relief button and remove the lid.
- e) The scrub person will check to ensure the chemical integrator has changed appropriately.
- f) The scrub person may remove the instruments from the basket/tray or remove the instruments and the basket/tray and place them on the sterile field.
- g) **The residual water/condensate should be removed before using the container again.**
- h) Dry the container by blotting with a soft absorbent cloth or towel.

22. When the scrub person removes the Flash Pak from the sterilizer:

- a) The circulator assists the scrub person to the sterilizer.
- b) Cycle parameters are verified and the printout initiated.
- c) Verify the CI response.

SPARCO FLASH PAN SYSTEM:

- i) Place instruments in an open position in bottom of inside container.
- j) Place steam chemical integrator inside tray.
- k) Prop lid of container with the lid prop supplied for this purpose so that the lid is up at the back of the autoclaving pan.
- l) Open porthole in the front of the pan. (**When lid is propped open and porthole is open, steam is able to circulate through the autoclave pan. If this is not done, there will not be adequate circulation of steam through the pan, and sterilization may not take place inside the container.**)

SPARCO FLASH PAN SYSTEM: (Continued)

- m) Place instrument pan into autoclave with the porthole toward the front of the autoclave and the lid open toward the back of the autoclave. (See diagram.)
- n) Close autoclave door.
- o) Activate cycle per the following parameters:

High-Speed Gravity Displacement Flash Cycles:

- 1) Non-porous, non-lumened devices – 3 minutes sterilization time
- 2) Porous, lumened items – 10 minutes sterilization time

Pre-Vacuum Flash Cycles:

NOTE: There have been some reported problems achieving consistent kill in pre-vacuum cycles. Make sure integrators are placed inside the pan for each cycle and the color change verified before using the device.

- 1) Non-porous, non-lumened devices – 3 minutes sterilization time
- 3) Porous, lumened items – 10 minutes sterilization time

23. When the sterilization process has been completed and the pan is ready to be removed, the porthole is closed using the handles supplied with the pan.

- a) The pan lid is slightly lifted in order to allow the prop to drop out from under the lid and the lid to close down on top of the sterilizing container, which makes the container a closed system.
- b) The pan is then carried to the room where needed, and towels are used to prevent burning hands on hot metal.
- c) Verify proper CI response, and initial sterilizer printout if parameters have been met.

Documentation

24. The items flashed in any flash system should be recorded on the Sterilization Log. Note the time/temperature for flash sterilization.
25. All CIs are to be retained for all flash cycles. Place in envelope with Flash Log and printout or chart for all cycles run that day.

Biological Monitoring

26. The process of BI monitoring of flash containers is documented in the Procedure for Biological Monitoring.

Contraindications for Flash Sterilization:

27. **IMPLANTS** — Flash sterilization will not be used for routine sterilization of devices used on patients or for implantable devices.

NOTE: If implants must be flash sterilized in an emergency, the porous, lumened sterilization time MUST be used, unless otherwise recommended by the implant manufacturer (refer to cycle selected), and a biological culture must be included with the device.

28. Batteries should not be flashed if there is any evidence of cracks because the moisture may cause leaking or venting of battery electrolytes.
29. **Power and specialty equipment may require special exposure times. Always consult the device manufacturer for cycle times and temperatures.**

DOCUMENTATION: As outlined in procedure**INFECTION CONTROL:****SAFETY:**

REFERENCES: Association for the Advancement of Medical Instrumentation. *Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use.* ST37, 1996.
Association of periOperative Registered Nurses. *Recommended Practices for Sterilization.*
Riley Flash Pak Instruction Manual.
SPARCO Flash Tray Manual.

ORIGINAL DATE:**REVIEWED: Annually****REVISED:**

FLASH STERILIZATION COMPETENCY TESTING

NAME:			DATE:	
TITLE:			PRECEPTOR:	
COMPETENCY	Return Demo	Date	Initials	COMMENTS
1. Verifies manufacturers' written instructions for processing of device (refers to reference material for times, temperatures, cycles.				
2. Verbalizes the time and temperature profiles for flash sterilization as follows:				
a) High-speed gravity				
1) Non-porous, no lumens				
2) Porous items, lumens				
3) Flash Pak container				
b) Pre-vacuum				
1) Non-porous, no lumens				
2) Porous items, lumens				
3) Flash Pak container				
3. Verifies item(s) properly decontaminated				
4. Documents items on Flash Log				
5. Loads item(s) correctly in sterilizer				
6. Places integrator in proper location in sterilizer				
7. Verifies proper time and temperature setting				
8. Interprets print-out at end of cycle for correct time and temperature profiles				
9. Initials print-out				
10. Interprets integrator at end of cycle				
11. Unloads sterilizer using proper aseptic technique				
12. Transfers device to room without contamination				
Nov.03				

Source: Saint Barnabas Health Care System, West Orange, NJ.

STERILIZER#

FLASH STERILIZATION LOG

DEPARTMENT: _____

Source: Saint Barnabas Health Care System, West Orange, NJ.

MONTHLY FLASH PROCESS IMPROVEMENT MONITORING

MONTH	STER#	# LOADS	# SIGNED	# CYCLES ON PRINTOUT	# LOADS ON FLASH LOG	IMPLANT?	BI RUN?	CI SAVED	Correct Cycle?	MISC.
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Source: Saint Barnabas Health Care System, West Orange, NJ.