



SAME-DAY SURGERY

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AHC Media

Outpatient programs expand and provide more than just surgery

By **Joy Daughtery Dickinson**, Executive Editor

Decades ago, the idea of having surgery and going home the same day was considered radical. Now, outpatient surgery facilities are expanding their services beyond surgery to include rehab and other areas. Some unusual new services, such as cadaver labs, can help build revenue.

One surgery center in Arizona has offered an after-hours cadaver lab for surgeons to practice new procedures and/or implants. "Since we are an orthopedic center, it is perfect for cadaver labs, although a cadaver lab can be applied to most specialties," says **Karen Knowlton** regarding Summit Recovery Care Center, inside Summit

Center in Flagstaff, where she formerly worked as administrator. If needed, surgery patients stay overnight in the recovery center, where 24/7 care is offered.

"...THE ASC DOES HAVE TO BE A DISTINCT ENTITY, CLEARLY DISTINGUISHABLE FROM ANY FACILITY OR OFFICE-BASED PRACTICE."

The cadaver labs were held after the center closed, because state law won't allow them to conduct any other business when the facility is functioning as a surgery center. To avoid any problems with Medicare, designate your hours of operation, and hold the labs outside of those hours, Knowlton

emphasizes.

Companies sponsored the labs, sent cadavers, and conducted the labs. "An example would be DePuy Synthes [Companies based in West Chester,

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EDITORIAL QUESTIONS
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PA] sending in a torso to sponsor a lab on artificial disc replacement,” Knowlton says. The fees for the labs, which have run from \$1,200 to \$4,000, were negotiated.

The labs were held over 2-4 hours with one staff person. Weekends work best for labs, and Knowlton used contracts so the time of the event was clear.

The center held three labs, Knowlton says. She allowed members of her staff to watch, “which is a good staff motivator and retention tool.” Also, the labs potentially can be used to introduce other surgeons in that specialty to the surgery center while they attend the labs.

OA – Centers for Orthopaedics in Portland, ME, is offering physical therapy in four locations, including one that is in the same building as a surgery center.

“The patients are able to meet the therapist before they have surgery,” says **Linda Ruterbories**, adult nurse practitioner and director. The physical therapist gives the patients instructions on exercises to do immediately postoperatively. “It’s one-stop shopping,” Ruterbories says. However, patients can go elsewhere for physical therapy, she says.

The center also offers scanning, including MRIs and a smaller extremity scanner for orthopedic patients. “We know the pricing is less than the hospital by hundreds of dollars,” Ruterbories says.

In addition, some outpatient surgery providers are working with their local pharmacies to have postop pain medications delivered to patients before they are discharged. Some facilities are adding in-house pharmacies. However, physicians can’t order medications and have them fulfilled from a pharmacy they have ownership in, says **Andrew B. Wachler, JD**, managing partner at Wachler & Associates, Royal Oak, MI, and Detroit.

“When there’s no financial relationship, and it’s done for the convenience of the patient, having the service available so they can walk out of surgery with their medications, I don’t see that as problematic,” Wachler says.

Adding services such as therapy to a licensed ambulatory surgery center (ASC) can be done if the services are offered in areas that are separate from the areas designated for the ASC, he says.

However, there might be issues of common space between the ASC and the added service, he warns. The Centers for Medicare and Medicaid Services (CMS) allows reception rooms and bathrooms to be shared, as long as they’re not used for the ASC and the added service at the same time, Wachler says. Thus, you might need to build separate waiting rooms and bathrooms if both services will be open at the same time. “Sometimes state law may allow it,”

EXECUTIVE SUMMARY

Outpatient surgery providers are expanding their services outside of surgery.

- Some providers are offering imaging, rehab, pharmacy delivery, and even cadaver labs.
- There are potential legal issues, such as restrictions on using in-house pharmacies owned by physicians and having common space with unrelated services.

Wachler says. “But the ASC does have to be a distinct entity, clearly distinguishable from any facility or office-based practice. It doesn’t have to be in a separate building.”

When expanding your services, have your plans reviewed by your

legal representative, he recommends. “You don’t want to be building out and inure expense and maybe license the entire area, then have it preclude you from having a separate physician office, so to speak,” Wachler says. Plan upfront by talking to someone who is

knowledgeable about the rules.

“If you’re going to look at this as having other services available, then you have to make sure you understand what you can do within an ASC and what you can’t,” Wachler says. ■

Morphine following common surgery may be life-threatening, but ibuprofen is safe alternative

(We tweeted about this news on Jan. 26. To keep up with breaking news as it happens, you can follow us on Twitter @SameDaySurgery.)

Treating postoperative pain with morphine can cause life-threatening respiratory problems in some children who have had their tonsils and/or adenoids removed, new research has found.

The study has identified a significant risk for potentially fatal breathing disruption when morphine is administered at home after surgery to treat pain in children who undergo tonsillectomy with or without adenoidectomy. The study also showed ibuprofen is a safe and effective alternative. The study was published in the Jan. 26 online edition of *Pediatrics*. The study was co-conducted by the Motherisk Program at The Hospital for Sick Children (SickKids) in Toronto, Ontario, Canada, and by McMaster University and McMaster Children’s Hospital, both in Hamilton, Ontario.

The research builds on a 2009 Motherisk study and a 2012 study by the two groups that found codeine administered for postoperative pain in the same population of children could cause respiratory problems and fatal outcomes for children who are genetically ultra-rapid metabolizers of codeine. Previously, codeine had

been the standard treatment for postoperative pain in this population across North America.

As a result of the 2009 paper, Health Canada and the U.S. Food and Drug Administration (FDA) issued warnings about the risks associated with giving codeine to this population of children. The FDA gave pediatric codeine a boxed warning as well as a contraindication. *(For more information, see “FDA adds boxed warning on codeine after surgery,” Same-Day Surgery, April 2013, p. 46.)*

While no official recommendation of a safe and effective alternative had been made in response to these warnings, many centers prescribed morphine to these children and clinicians thought that the response to the drug would be more predictable.

This new study is a prospective, randomized clinical trial in which 91 children between the ages of 1 and 10 were randomly assigned to receive postoperative painkillers at home following their outpatient tonsillectomy surgery to treat obstructive sleep apnea. Parents were given a prescription to fill and were instructed about the use of a home pulse oximeter to measure oxygen saturation and apnea events the night before and the night after surgery. Parents also were taught to use the Objective Pain Scale and Faces Scale

to assess their children’s pain levels on postoperative days one and five.

From September 2012 to January 2014, one group of children was given postoperative standard doses of oral morphine (0.2 to 0.5 mg/kg) and acetaminophen (10-15 mg/kg) every four hours to treat their pain, while the other group was prescribed standard doses of oral ibuprofen (10 mg/kg) every six hours and acetaminophen (10-15 mg/kg) every four hours. Pain was effectively managed and comparable in both groups. On the first postoperative night, 68% of children in the ibuprofen group showed improvement in oxygen desaturation incidents. On the same night, only 14% of children in the morphine group improved. In fact, in the short term, the condition of these children worsened, with substantially more desaturation events in the morphine group: roughly 11-15 events per hour. Both groups had similar minimal levels of other adverse drug reactions and bleeding.

Last year, midway through the planned study period, an interim analysis was conducted by the study’s Drug Safety Monitoring Board. In addition to the general findings, which strongly demonstrated serious respiratory risk associated with morphine, one child suffered a life-threatening adverse drug reaction

including oxygen desaturation after being treated with morphine. These severe outcomes prompted the board to halt the study period early, and the research team notified both hospitals' research ethics boards, as well as Health Canada.

"The evidence here clearly suggests children with obstructive sleep apnea should not be given morphine for postoperative pain. We already know that they should not get codeine either," said **Gideon Koren**, MD, FRCPC, corresponding author of the study, director of the Motherisk program and senior scientist at SickKids. "The good news is that

we now have evidence that indicates ibuprofen is safe for these kids and is just as effective in controlling their pain, so there's a good alternative available for clinicians to prescribe." Koren is also professor of paediatrics, pharmacology, and toxicology, Pharmacy and Molecular Genetics, University of Toronto.

Clinicians should re-think the routine use of morphine for postoperative pain in children with sleep apnea, says study co-author **Doron Sommer**, MD, FRSC(C), a clinical professor of surgery at McMaster's Michael G. DeGroot School of Medicine and a surgeon for

McMaster Children's Hospital.

"These results should prompt clinicians to re-evaluate their post-tonsillectomy pain treatment regimen. Due to the unpredictable respiratory side effects of morphine, its use as a first-line treatment with current dosage ranges should be discontinued for outpatient tonsillectomy," says Sommer.

At SickKids and McMaster Children's Hospital, the use of morphine for postoperative pain from pediatric tonsillectomy is reserved for exceptional cases where it is deemed necessary and safe with appropriate monitoring. ■

GUEST COLUMN

Botched cataract surgery yields \$1.5M verdict

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In this case, the patient was an adult man who suffered from a cataract on his left eye and scheduled surgery to fix the problem in 2008. During the procedure, the ophthalmologist ordered a dye named VisionBlue that is used to stain the cataract in the eye so that it can be more easily visualized and removed during the procedure. The nurse who received the order from the ophthalmologist, however, fulfilled the request as methylene blue

rather than VisionBlue.

Methylene blue, a completely different chemical compound, is extremely toxic to human eyes and can cause severe damage. The nurse who filled the order then passed the methylene blue to the surgical technician and announced that it was methylene blue. After this step, the surgical technician handed the methylene blue to the ophthalmologist, again stating that the solution was methylene blue. Neither the nurse nor surgical technician stated that the solution

was VisionBlue. The ophthalmologist claimed that he did not hear the nurse or the surgical technician state the solution was methylene blue, and thus he believed it to be the correct VisionBlue dye.

After applying the methylene blue to the patient's eye, the ophthalmologist became aware that it was the incorrect solution, and the patient's eye became severely damaged. Corrective surgery was attempted at the same hospital, but the damage from the methylene blue was too serious. A full corneal

EXECUTIVE SUMMARY

A man had standard cataract surgery in 2008 on his left eye. The ophthalmologist ordered a dye named VisionBlue. The nurse instead brought methylene blue. The nurse told the surgical tech that she was handing him methylene blue, and the surgical tech relayed this information to the ophthalmologist. The ophthalmologist claimed that he did not hear this information, and he applied it to the patient's eye.

- The dye caused serious permanent damage, including blindness in the eye.
- The patient sued the ophthalmologist and hospital. The jury found them liable and awarded \$1.5 million in damages.

transplant also was attempted, but the patient's body rejected it. As a result, the patient became blind in his left eye and suffers from glaucoma due to the multiple corrective surgeries.

The patient subsequently brought suit against the ophthalmologist and hospital, and he alleged that both were negligent during the procedure that resulted in the patient's injuries.¹ According to the plaintiff, the ophthalmologist's use of the incorrect solution constituted negligence because the ophthalmologist had a duty to the patient, and by administering the incorrect drug to the patient, he breached that duty. Similarly, the hospital was liable on the basis of *respondeat superior*, which is a legal theory in which an employer is legally responsible for the actions of its employees. It was unclear whether the ophthalmologist was considered an employee, but the nurse and surgical technician were employees for which the hospital was responsible. Ultimately, the jury found the defendant ophthalmologist and defendant hospital jointly and severally liable, and it awarded \$1.5 million in damages.

What this means to you

In this case, the primary issue was to what degree, if any, the ophthalmologist was negligent for administering the incorrect drug to the patient, and whether the hospital was liable for the ophthalmologist, nurse, and/or technician, who all played a role in the incident.

As the primary physician in charge of the procedure, the ophthalmologist owed the patient a duty to perform in accordance with the appropriate standard of care. There are many different ways medication errors can occur, as there are many steps between the initial prescription or order and the administration of the

drug. A physician who prescribes the wrong medication to a patient can be liable for medical malpractice, but there are many other situations that might give rise to a medical malpractice claim as related to a medication error.

For example, look-alike, sound-alike (LASA) medication errors are common. The hospital pharmacy has the responsibility to put caution labels on LASA drugs such as methylene blue and VisionBlue. In addition, the pharmacy stocks medications in the operating suites and should take steps to separate LASA medications from each other to prevent staff from inadvertently choosing the wrong one.

All regulatory and accreditation organizations require staff members and physicians to read medication labels before administration of any drug, even in the operating room. If medication is removed from the original container and not used immediately, a new label must be made and placed on the syringe or other delivery device. Physicians and facility leaders must exercise caution throughout the entire process to ensure that there are no mistakes. In this case, the ophthalmologist ordered the correct drug to be used, so the error originated after this initial involvement. Because the physician holds ultimate responsibility for the patient's medical care, the physician should be cautious when other individuals act as intermediaries or are required to perform duties delegated by the physician.

This situation could have been prevented by having additional measures relating to communication. Oral communications can inherently be unreliable. If the communication is one-way, it is impossible to know whether the other party has heard the message. This situation is exactly

what happened here more than once. The nurse and surgical technician claimed to have announced that the solution was methylene blue, but the ophthalmologist never heard those words.

The situation potentially could have been prevented if the hospital had a policy requiring confirmation in this context. Note also that the surgical technician should not have been involved in the confirmation process, as the technician is not trained to administer medication. Certainly the technician can pass medication from the hand of the nurse into the hand of the physician, but that involvement is the only one that the technician should have. Communications involving medications must be between physicians and staff trained in medication administration unless the physician is directly supervising the untrained individual and not involved in another activity such as performing surgery.

Using 'repeat-backs'

To prevent oral communication errors in operating rooms, emergency departments, and even over the phone, "read-backs" or "repeat-backs" are used in most facilities. When a physician orders a medication verbally, the receiver repeats the name of the drug and the dose to the physician, and the physician confirms it. Had this practice been carried out, the physician would have said, "VisionBlue" and the nurse would have said "methylene blue," which would have given the physician the opportunity to correct the error. Requiring this important oral communication process is a simple solution that provides extra defense for physicians and facilities, and in this case, could have prevented injury and litigation. Written

communications are inherently even clearer than oral communications; however, the realities of an operating room don't allow for everything to be done in writing, so oral

communication is not forbidden. (Editor's note: For more information on *LASA* drug errors, see the SDS Accreditation Update inserted in this issue.)

REFERENCE

1. Superior Court of Durham County, NC. Case No. 11-CVS-1525. Aug. 19, 2014 ■.

No viral load means no HCV restrictions

Hospitals follow SHEA guideline for healthcare workers

Everything seemed in order for the certified surgical first assistant to start a new job. He filled out the human resources paperwork and went through the routine screening in employee health. He was healthy and had been working as a contractor at the hospital for 15 years, so he didn't expect any stumbling blocks. But one question put a temporary hold on his hiring.

The technologist had been treated for hepatitis C, and doctors had told him he was cured. Ribonucleic acid (RNA) testing and routine monitoring by a gastroenterologist confirmed that he had no detectable viral load. But when he revealed his prior infection, the hospital was unsure how to respond. It lacked a system for evaluating the potential risk of employees with hepatitis C or handling the growing number of people who are cured of the disease.

"I have this fear that my whole career is over," the surgical tech said.

Weeks later, the hospital approved his hiring, subject to bi-annual testing to make sure he maintains an undetectable or very low viral load. That approach is in keeping with the guidelines on the management of healthcare workers infected with hepatitis B, hepatitis C, or HIV issued by the Society for Healthcare Epidemiology of America (SHEA). (For coverage of the guidelines, see the June 2010 and July 2010 issues of

Same-Day Surgery.)

The case highlights the continuing need for facilities to update their policies, about five years after those guidelines were released. New treatments for hepatitis C and HIV enable patients to have a very low or undetectable viral load and greatly reduce the risk of transmission, says **David K. Henderson**, MD, deputy director for clinical care at the National Institutes of Health Clinical Center in Bethesda, MD, and lead author of the guidelines.

"The group did not feel that simply having had one of those infections precluded you from doing anything in healthcare," he says. It would be up to an expert review panel to evaluate the healthcare workers' job tasks and viral load, he says.

The certified surgical first assistant reached out to AHC Media, publisher of *SDS*, to share the impact of outdated employee health policies related to HCV. "My hope is that every healthcare institution will now update their HCV policies and stop discriminating and treating HCV as a disease once considered as a 'junkie's' disease," he says. "It is now treatable and curable."

An estimated 3 million Americans have chronic hepatitis C, and many of them don't know it. Because many of those undetected cases are among Baby Boomers, the Centers

for Disease Control and Prevention recommends anyone born between 1945 and 1965 be tested. However, the CDC has no recommendations for testing or management of healthcare workers with HCV.

The SHEA guidelines don't advise mandatory testing, but they state that healthcare workers performing exposure-prone procedures, such as extensive surgeries, are "ethically obligated" to know their status related to hepatitis B, HCV and HIV.¹ An expert review panel evaluates each individual situation and determines if any restrictions are necessary, according to the SHEA guidelines. The panel may be convened at the facility level or by the county or state health department, and typically includes infectious disease experts and other specialists, such as occupational medicine physicians. In North Carolina, for example, the state Department of Public Health convenes a panel that includes the healthcare worker's personal physician. Confidentiality is maintained, says **David J. Weber**, MD, MPH, professor of epidemiology at the University of North Carolina at Chapel Hill and a co-author of the SHEA guideline. "To my knowledge, nobody has been denied the ability to work, although there have occasionally been some restrictions," Weber says.

Healthcare workers should feel that they can seek advice from an expert review panel without fear of discrimination, says Henderson. "It's an advocate for the provider and will help the provider provide safe healthcare," he says.

Marshfield (WI) Clinic tests new employees for hepatitis C as a way to avoid future workers' compensation claims of occupationally acquired infection. Since 1996, nine new

employees have tested positive. None of them had been aware of their HCV status, says **Bruce Cunha**, RN, MS, COHN-S, who recently retired as the manager of employee health and safety. Those employees did not work in a high-risk job, he says. If they had, the clinic would have sought guidance from an expert review panel. But the employees still would have a job.

"It is not a condition of employment to have a negative

hepatitis C [test]," Cunha says.

REFERENCE

1. Henderson DK, Dembry L, Fishman NO, et al. SHEA guideline for management of healthcare workers who are infected with hepatitis B virus, hepatitis C virus, and/or human immunodeficiency virus. *Infect Control Hosp Epidemiol* 2010; 31:203-232. ■

SDS Manager

Answers to some of your most pressing questions

By Stephen W. Earnhart, MS
CEO
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Austin, TX

Here are some enlightening questions from readers over the past couple of months that others might find helpful:

• **Question: Pain management.**

You mentioned a couple of months ago in your article about an opportunity with pain management procedures in the OR. Can you share that in more detail? I spoke with a couple of pain physicians in our area, and they said they did not have an interest in doing procedures at our hospital. What's the deal?

Answer. The operative word here is "hospital." The reason many pain management practices wish to do procedures in a *freestanding* ASC is because they might have a partnership with or have a future opportunity to partner with the surgery center and, therefore, have a secondary income stream from the ownership in that facility. Their opportunity to generate that income would be based only upon their ownership interest in the center, however, so many of these physicians would rather develop and

own the surgery centers on their own.

• **Question: Policy and procedure (P&P) responsibility.** You spoke at a lecture I attended last year where you stressed the importance of staff understanding the facility policies and procedures as many of those have changed over the years, even months! What is the easiest way to make this happen? I have over 60 people in my department, and I bet half of them have no idea of the changes we make routinely to our P&Ps.

Answer: I did a "mock" survey for a new facility last week, and I asked one of the staff members the procedure for transporting a patient to a hospital for an emergency. He made up a bunch of stuff, but it was clear he did not know the procedure, and as a result, the facility was marked with a deficiency.

The best way is to give all employees the opportunity to read the policies and procedures and then have them sign a dated letter (which goes into their personnel files) that states that they have read and understand all the P&Ps. Often, signing their names to a letter helps convey a sense of importance and responsibility to it. As policies are amended, provide staff members with a "redlined" version so

they can read the changes and sign on an inservice sheet that they have done so.

• **Question: Supply cost for cataract surgery.** I was working in a local for-profit surgery center in town and wanted to get back into the hospital for more challenging cases. I was floored when I saw that one of the surgeons at the surgery center I worked at had supply cost of over \$800 for his cataract cases that he did at the hospital. What got me was that at the surgery center, it was only \$350! I know because I did his cases.

Answer: It is not at all uncommon for supply costs to vary greatly from a for-profit facility, such as an ambulatory surgery center (ASC), and a not-for-profit hospital. Some of the reasons include:

1. ASCs typically pay less for the same item, even by the same vendor, because they often negotiate each item.
2. Surgeons are motivated to conserve supplies in an ASC because they know someone is watching those expenses and it will increase the profits of the ASC that they might pocket.
3. The surgeon might not know what the supply cost is in a hospital

because often the staff members in the operating room don't know themselves. She/he may assume it is the same as the ASC where they also work.

You might suggest your findings to the appropriate person at the hospital

and recommend they make the surgeon aware of the costs variance.

By the way, the steps above are exactly what happens when people focus on cost control and ways to improve it! [Earnhart & Associates is a consulting firm specializing

in all aspects of outpatient surgery development and management.

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EHR failures can be dangerous without having a contingency plan

Electronic health records (EHRs) can be a boon to clinical care, until the system goes down or the power goes off. Then the clinicians might be flummoxed by how to do things “the old-fashioned way” with paper and pen, or they might not have the resources necessary.

For that reason, managers should ensure their facilities have contingency plans for an EHR failure, says **Dean Sittig**, PhD, faculty member at the University of Texas Health Science Center at Houston, who specializes in clinical information systems and clinical decision support. He was the lead author of a recent paper that quantified how often EHRs go down and how healthcare facilities are prepared to respond. (*An abstract of the study is available online at <http://tinyurl.com/kfm8z43>.*)

The numbers were not good. Sittig and his colleagues surveyed 50 U.S.-based healthcare institutions that were members of a professional organization that focused on collaboration and sharing of best practices related to health information technology (HIT) among its members. All members were large integrated health systems.

Nearly all (96%) institutions reported at least one unplanned downtime (of any length) in the last three years, and 70% had at least one

unplanned downtime greater than eight hours in the last three years. Three institutions reported that one or more patients were injured as a result of either a planned or unplanned downtime.

“It was a little shocking to me how many of these organizations had these large downtimes. Most people would say that can't happen to us,” Sittig says. “If you asked them what they do if the computer were down for eight hours, they would be hard-pressed to imagine how they would carry on. The point of our paper is that you have a very good chance of being in that situation.”

The survey also revealed that most institutions had only partially implemented comprehensive contingency plans to maintain safe and effective healthcare during unexpected EHR downtimes.

Managers can take the lead in ensuring that contingency plans are in place, possibly acting as a liaison between clinicians and the IT staff, Sittig suggests. Even highly skilled and motivated IT professionals might not fully understand the ramifications of even a brief EHR failure, he says. Managers, especially those with clinical backgrounds, will be able to explain.

IT professionals and clinicians can assume that a brief EHR failure will be easily handled with a temporary

return to the pre-EHR work flow, he says. However, they often find that going back is not so easy.

“We were able to afford those nice EHR systems by eliminating the runners we used to employ for taking medication orders to the pharmacy, and we got rid of all the fax machines,” Sittig says. “Plus, there will be some employees who never worked under that system and don't have any idea how to manually accomplish these tasks. In our hospital, at least a third or maybe half of the nurses have never worked in an environment where they didn't have a computer system.”

Sittig suggests these strategies for EHR downtime contingencies:

- Have a binder in each room with the forms necessary for ordering medications and recording treatment notes that normally would be handled in the EHR.
- Ensure that each unit has at least one computer plugged into the emergency generator supply (usually the red plug) so that it will continue functioning in a power outage. Healthcare facilities often have elaborate plans to keep their servers and the network operational in a power outage, but units still are helpless if they don't have a computer on the dedicated power supply.
- A “read-only” computer terminal in each unit can serve as a

backup for all current patient data in the event of an EHR crash. When the EHR goes down, clinicians still can access this computer terminal for patients' medications, lab values, and treatment notes.

Sittig cautions that the risks

from EHR downtimes are easily overlooked. Managers are not worrying about the computers much because they have to worry about falls, medication errors, and those types of risk management issues.

"But it's getting to be so that the

computer is driving a lot of what we do in healthcare, and if the computer isn't working, that can open all kinds of potential for patient harm. And one of the things that can happen is the computer doesn't work at all. No screen. No data. Nothing." ■

Simulated IV fluids were shipped to surgery centers

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are investigating multiple instances of Wallcur's simulated intravenous (IV) saline products being administered to patients. These products are not sterile and should not be injected in humans or animals, the CDC says.

Wallcur's simulated IV saline solution, Practi-0.9% sodium chloride solution, was shipped to surgery centers, medical clinics, and urgent care facilities in numerous states. At press time, more than 40 patients had received infusions of the simulated saline products, and there had been many adverse events associated with these incidents including fever, chills, tremors, and headache. Some patients were hospitalized. There is one death associated with the use of these products, but it is not known if this death is directly related to the use of the product. Adverse events have been reported in Florida, Georgia, Idaho, Louisiana, North Carolina, New York, and Colorado.

Wallcur initiated a voluntary recall of Practi-0.9% sodium chloride IV solutions. (*For more on the recall, go to <http://1.usa.gov/1uDUHZS>.)* Most medical facilities reported that they were unaware that the IV solution bags were simulation products. The FDA is working with distributors who sold the simulated IV products and clinics that purchased and

administered the simulated IV products from Wallcur to determine how these simulation IV solution products entered the supply chain and subsequently were administered to patients.

**THESE
PRODUCTS
ARE NOT
STERILE AND
SHOULD NOT
BE INJECTED
IN HUMANS OR
ANIMALS...**

While sodium chloride 0.9% injection (IV normal saline) has been in tight supply, the FDA has been working with manufacturers to increase supply. In addition, FDA is not objecting to the temporary distribution of additional IV normal saline from alternate sources: Fresenius Kabi USA (<http://1.usa.gov/1D0prn1>), Baxter Healthcare Corp. (<http://1.usa.gov/189bqdl>) or B. Braun Medical Inc. (<http://1.usa.gov/1JiP4TU>).

Staff are encouraged to take these steps to ensure IV solution simulation products are removed from inventory to eliminate the possible injection of simulated products into patients:

- Visually inspect all current IV saline solution bags. Ensure none of the bags are labeled "Wallcur," "Practi-products," "For clinical simulation," or "Not for use in human or animal patients."

- If you have products labeled with any of these words, or you suspect you might have received other products intended for training purposes, separate simulation products from existing inventory and contact your distributor for directions on how to return these products.

- If you have received Wallcur Practi-products by mistake, please contact the distributor or Wallcur of San Diego for return instructions.

- Make sure there are procedures in place to visually inspect all shipments of normal saline products to ensure they are for clinical use.

If you suspect that any Wallcur training IV products might have been administered to a patient, whether or not the incident has resulted in an adverse event:

- Evaluate all potentially exposed patients with new or ongoing symptoms.

- Use appropriate treatment.

- Report suspected cases to the state health department.

- Report any adverse events following use of these products to the FDA's MedWatch program online (<http://www.fda.gov/Safety/MedWatch/default.htm>) or at (800) 332-1088. ■

System settles false claim charges for \$37 million

The healthcare system involved in a false claims investigation prompted by a former employee blowing the whistle has settled the case. Dignity Health hospital system, based in San Francisco, has agreed to pay \$37 million to settle the charges.

The whistleblower in the case, former director of medical management Kathleen Hawkins, had charged that 13 of Dignity Health's hospitals in California, Nevada, and Arizona knowingly submitted false claims to Medicare and TRICARE. She said they admitted patients who could have been treated on a less costly outpatient basis. Dignity

Health said in a statement there is "widespread confusion" about federal standards for approving coverage of patient admissions.

The United States alleged that from 2006 through 2010, 13 Dignity hospitals billed Medicare and TRICARE for inpatient care for certain patients who underwent elective cardiovascular procedures (stents, pacemakers) in scheduled surgeries when the claims should have been billed as outpatient surgeries. In addition, the government alleged that from 2000 through 2008, four of the hospitals billed Medicare for beneficiaries undergoing elective

kyphoplasty procedures, which are minimally invasive and performed to treat certain spinal compression fractures, that should have been billed as less costly outpatient procedures.

Lastly, the government alleged that from 2006 through 2010, 13 hospitals admitted patients for certain common diagnoses for which where admission as an inpatient was medically unnecessary and appropriate care could have been provided in a less costly outpatient or observation setting.

Hawkins will receive about \$6.25 million of the settlement total, the Department of Justice announced. ■

Joint communication addresses challenge of humidity levels, medical equipment in the OR

With more organizations lowering the relative humidity levels in operating rooms (ORs), there are concerns about the impact on sterile supplies and electro-medical equipment. A multi-society communication, organized by the Association for the Advancement of Medical Instrumentation (AAMI), aims to help leaders determine whether a lower humidity level is appropriate.

The statement provides background and presents questions and key points leaders should consider when establishing or adjusting relative humidity levels to below 30%. The statement was developed after a multi-organization meeting at AAMI headquarters in October. The communication was issued by groups including the American Society of Anesthesiologists, the Association of periOperative Registered Nurses,

the Ambulatory Surgery Center Association, and the American Hospital Association.

Last year a hospital was cited by the Centers for Medicare and Medicaid Services (CMS) for setting the humidity level lower than that specified in the instructions for use for certain sterile products in the OR. The citation came despite CMS's categorical waiver of the Life Safety Code in April 2013 that would allow the anesthetizing locations of organizations to operate with a relative humidity of equal to or greater than 20%, rather than the

previous requirement of equal to or greater than 35%.

"Our common goal is to help healthcare delivery organizations understand the challenges and important considerations related to relative humidity levels in the OR," said **Mary Logan**, JD, CAE, president of AAMI. "And we all want to ensure that patients are protected and that resources are utilized effectively. We hope this communication will help achieve these objectives." The joint communication is available at <http://bit.ly/1yoGeiD>. ■

COMING IN FUTURE MONTHS

- Who should provide equipment maintenance?
- Should you offer warranties on surgery?
- What to do when a staffer diverts drugs
- New service adds profits to outpatient surgery

MedPAC finalizes 2016 payment recommendations

The Medicare Payment Advisory Commission (MedPAC) approved a recommendation that ambulatory surgery centers (ASCs) receive a 0% increase in payment rates for 2016. The commission once again approved a recommendation that ASCs be directed to report cost data.

MedPAC recommended a 3.25% increase in payment rates for outpatient and inpatient hospital services in 2016.

ASC Association (ASCA) Chief Executive Officer **Bill Prentice** denounced the ASC recommendation and stated MedPAC's decision not to recommend any payment update for ASCs in 2016 threatens to undermine the ability of thousands of ASCs to

continue saving the Medicare system billions of dollars by their existence as an alternate site for outpatient surgical care.

"Once again, the commissioners suggest that Medicare penalize the most efficient care provider in this market," Prentice continued. "As ASCs strive every day to provide the highest possible levels of quality and patient safety to Medicare beneficiaries, MedPAC seeks to hamstring those efforts with this recommendation, letting ASC rates fall even farther behind those of other sites of service."

As part of ASCA's efforts to educate MedPAC, ASCA staff members met with MedPAC staff members last summer. Although

they continue to disagree on areas such as cost reporting, MedPAC staff members have, in recent years, been more receptive to other issues facing ASCs such as a volume shift back to the hospital outpatient department setting as well as a more streamlined process for moving procedures to the ASC payable list, according to the ASC Association.

MedPAC also recommended that Congress reduce or eliminate payment differences between hospital outpatient departments and physician offices for selected procedures. The commission also voted to approve recommendations that would freeze Medicare payments to physicians in 2016 in place of the sustainable growth rate formula. ■

AAHHC's hospital/health system group accredits its first hospital

The Accreditation Association for Hospitals/Health Systems (AAHHS) in Skokie, IL, recently presented its inaugural accreditation certificate to Sioux Falls Specialty Hospital in South Dakota.

Customized for rural hospitals, critical access hospitals (CAH), and hospitals with fewer than 200 beds, the accreditation program involves a peer-based survey process.

Donald Schellpfeffer, MDA, CEO for Sioux Falls Specialty Hospital, said, "The collaborative nature of the AAHHS survey was a huge differentiating factor for us. We're excited to be the first hospital to earn AAHHS accreditation, and we're confident that, with this accreditation, we are fully prepared for all reviews with the State Department of Health and

well-positioned to continue offering quality healthcare to our patients."

Since announcing its first accreditation certification in October, AAHHS has accredited several other organizations. Through resources, education, and training, AAHHS provides consultation and professional development that helps small and rural hospitals deliver care at nationally recognized standards,

attract staff members, and compete against larger, metro hospitals.

AAHHS was created in 2012 by the Accreditation Association for Ambulatory Health Care (AAAHC). AAHHS and AAAHC have separate governing boards and function independently. AAHHS is working toward receiving deemed status from the Centers for Medicare and Medicaid Services. ■

CNE/CME OBJECTIVES

After reading *Same-Day Surgery*, the participant will be able to:

- identify clinical, managerial, regulatory, or social issues relating to ambulatory surgery care;
- identify how current issues in ambulatory surgery affect clinical and management practices;
- incorporate practical solutions to ambulatory surgery issues and concerns into daily practices.



SAME-DAY SURGERY

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CNE/CME QUESTIONS

1. **If you are offering services that are unrelated to surgery, what should you do to avoid problems with Medicare, according to Karen Knowlton, former administrator of Summit Recovery Care Center?**
 - A. Get something in writing from Medicare first.
 - B. Designate your hours of operation, and offer the service outside of those hours.
 - C. Including wording on all promotional materials that the service is not reimbursed by Medicare.
2. **What procedures were the focus of a \$37 million settlement of false claims charges against Dignity Health hospital system?**
 - A. Elective cardiovascular procedures
 - B. Elective kyphoplasty procedures
 - C. A and B
 - D. Neither A nor B
3. **Treating postoperative pain with what medication can cause life-threatening respiratory problems in some children who have had their tonsils and/or adenoids removed?**
 - A. Morphine
 - B. Ibuprofen
 - C. Morphine and ibuprofen
 - D. Neither morphine nor ibuprofen
4. **Which of the following occurred in a 2008 cataract procedure that resulted in a \$1.5 million verdict?**
 - A. The ophthalmologist ordered a dye named VisionBlue.
 - B. The nurse brought methylene blue.
 - C. The nurse told the surgical tech that she was handing him methylene blue, and the surgical tech relayed this information to the ophthalmologist.
 - D. All of the above.



ACCREDITATION UPDATE

Covering Compliance with TJC, AAAHC, AAAASF, and Medicare Standards

Accreditation organizations point to safety issues with high-alert medications

A patient had standard cataract surgery on his left eye. The ophthalmologist ordered a dye named VisionBlue. The nurse instead brought methylene blue. The nurse told the surgical tech that she was handing him methylene blue, and the surgical tech relayed this information to the ophthalmologist. The ophthalmologist claimed that he didn't hear this information, and he applied it to the patient's eye. The dye caused serious permanent damage, including blindness in the eye.

The patient sued the ophthalmologist and hospital. The jury found them liable and awarded \$1.5 million in damages. *(For a legal analysis of this case, see story in the main issue, p. 28.)*

This case puts a spotlight on problems with high-alert medications, including look-alike, sound-alike (LASA) medications. The Joint Commission (TJC) requires accredited organizations to develop their own list of high-alert medications and to have a process for managing them, but compliance has been spotty for ambulatory and office-based surgery facilities. For the first half of 2014, 32% of ambulatory organizations and 22% of office-based surgery facilities failed to comply with MM.01.01.03, which says "The organization safely manages high-alert and hazardous medications." *(For more information on noncompliance with standards, see story, p. 3.)* The Accreditation Association for Ambulatory Health Care (AAAHC) also has a requirement: "If look-alike or sound-alike medications are present, the organization identifies and maintains a current list of these medications, and actions to prevent errors are evident." (Chapter 11: Pharmaceutical Services. Standard L.)

Even those facilities that technically are in compliance with accreditation standards because they have some type of list and a process might not have a well-thought-out list or a robust system for managing high-

alert medications, according to the Institute for Safe Medication Practices (ISMP).¹ Also, some providers haven't updated their list since the TJC standard was released more than a decade ago. "A list of high-alert medications is relatively useless unless it is up-to-date, known by clinical staff, and accompanied by robust risk-reduction strategies that are more effective than simple awareness, manual double-checks, staff education, and appeals to 'be careful,'" according to ISMP.¹

Consider updating your list with the following: new drugs on your formulary that potentially could cause significant patient harm, drugs added during a drug shortage that are potentially harmful, and medications shown during your own reporting process to be potentially harmful, even if the drug isn't on the ISMP list, ISMP says.¹

"For example, after fatal wrong route errors were identified as a potential threat with the new drug EXPAREL (bupivacaine [liposomal] used for local anesthesia into surgical sites) due to its similar appearance to propofol, hospitals that added this drug to their formulary should have considered it for addition to their high-alert medication list," ISMP says.¹

Both of those medications have a milky white appearance, says **Jeannell Mansur**, RPh, PharmD, FASHP, FMSMO, CJCP, practice leader, medication safety, Joint Commission Resources in Oak Brook, IL. "Our expectation is that all medications are labeled in the operative or procedure suite if they are not given immediately," Mansur says. "When proper labeling

Financial Disclosure:

Executive Editor **Joy Dickinson** and Board Member and Nurse Planner **Kay Ball** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Consulting Editor **Mark Mayo** reports that he is principle in MMC Health Care Consultants, Round Lake, IL. **Robert S. Bray Jr.**, MD, physician reviewer, discloses that he is a stockholder with RSB Spine and with DISC Integrated Medical Group.

EXECUTIVE SUMMARY

The Joint Commission reports ambulatory and office-based surgery organizations have difficulty complying with requirements to develop their own list of high-alert medications and to have a process for managing them. The Accreditation Association for Ambulatory Health Care requires that organizations identify any look-alike and sound-alike (LASA) medications, maintain a current list, and act to prevent errors.

- In addition to using a nationally available list, develop one specifically for your formulary. Don't forget the crash cart.
- Develop a system to identify LASA medications, such as bright colors on labels or tall man lettering.

does not occur, these medications can be mixed up, and the bupivacaine liposomal can inadvertently be given intravenously.”

Expect surveyors to ask about a high-alert medication list. **Raymond E. Grundman**, MSN, MPA, FNP-BC, CASC, vice president and general manager for ambulatory accreditation operations at AAAHC, says that when he is on site, “Number one, I'm going to ask ‘How did you identify look-alike, sound-alike or high-alert medications?’”

Your ‘go-to’ document

ISMP's list of these medications is your “go-to” document, Grundman says, but don't stop there. Include medications in your own formulary. Cross reference the ISMP list with your own inventory, including the crash cart, he advises. Your consulting pharmacist might be able to assist. Put your list in a sheet protector, and place it in a location where staff have easy reference, Grundman says. “Definitely have a copy on the crash cart,” he says.

Sheldon Sones, RPh, FASCP, a pharmacy and medication safety consultant based in Newington, CT, points to the ISMP lists for “Confused Drug Names” and the “High Alert” list. (*See resources at end of this article.*) “Regarding the former, although there is a list for ambulatory care, the acute care list is more germane to ASC [ambulatory surgery center] practice,” Sones says.

Surveyors often look for a specific list, he says. “In our practice, we have long held that while the list of formulary drugs maintained at a center is important, equally important, if not more so, is awareness of the multitude of other drugs that patients may present on, on admission,” Sones says. Accordingly, he has provided facilities he visits

with the master list and urged highlighting of formulary drugs while, at the same time, allowing easy access to the long list of other drugs.

He is passionate about high-alert drugs. “In our work, we consider all code cart drugs as ‘high alert’ and similarly used this list with annotations of what is actually stocked in the facility,” Sones says.

Develop strategies

A “one-size-fits-all” approach doesn't work for high-alert medications, Mansur says.

“Take the time to understand the specific risks associated with each high-alert medication, and design strategies to mitigate those risks,” she suggests.

Use the buddy system, when possible, to show each other the medications you draw up and the orders, Grundman advises. Have the second person confirm the 7 Rs: right medication, right indication, right dose, right route, right patient, right time, and right documentation.

“That's a double challenge in a very fast-paced environment,” Grundman says. “Surgery centers often are focused on throughput and room turnover; we're focused on efficiencies. But job number one is patient safety.”

When Grundman surveys, he interviews all nurses about whether they do double checks on medications. He also asks how they identify LASA medications, such as with bright colors on labels, tall man lettering, or other methods. For example, drugs can be labeled EPINEPHrine and ePHEDrine. Those two medications often are located in a crash cart in the same drawer, but they have very different indications and elicit different responses from patients who need resuscitation.

“You need an alert sticker to be sure you're giving the right one,” Grundman says.

The important thing is to be consistent, he says, so employees know, for example, if they see a bright orange or green sticker, that the colored sticker means a high-alert medication.

When possible, when choosing medications for your formulary, avoid ones that fall into the LASA category, Grundman advises. Also, use the manufacturer's trade name as opposed to the chemical name when referring to medications, he suggests. Many medications in the same drug “family” have the same prefix, such as “cef,” and are easily confused, Grundman says.

For your strategies to be effective, they must address the underlying causes of errors. To do this, ISMP suggests you do the following:¹

- review data from your internal medication error reporting;
- review the results of any root cause analyses that apply;
- search external literature to uncover reports of errors

elsewhere.

“A failure mode and effects analysis or self-assessment tool also might help identify underlying risks associated with each high-alert medication/class of medications,” ISMP says. “This important first step should not be skipped — if you can’t describe the ways that errors have happened or could happen with the drug, your strategies may not lessen the risk of an error at all.”¹ (*For information on how to manage staff regarding this issue, see story, below.*)

REFERENCE

1. Institute for Safe Medication Practices. High-alert medication list ... Relatively useless without risk-reduction strategies. *ISMP Medication Safety Alert! NurseAdvise-ERR* 2013; 11(4):1-5. Accessed at <http://bit.ly/1JGIBII>.

RESOURCES

- Institute for Safe Medication Practices. Confused Drug Names: <http://www.ismp.org/tools/confuseddrugnames.pdf>. High Alert list: <http://www.ismp.org/tools/highalertmedications.pdf>. ■

Take these steps with your staff

A discussion of high-alert medications should be part of every new employee’s training, says **Raymond E. Grundman**, MSN, MPA, FNP-BC, CASC, vice president and general manager for ambulatory accreditation operations at the Accreditation Association for Ambulatory Health Care in Skokie, IL.

Tell employees your policy on look-alike, sound-alike drugs, and show them your list, Grundman advises. This orientation should be given for any person who has any interaction with medications, including surgeons and anesthesiologists, he says. “That should be done on day one before they handle any medications,” Grundman says. Also, periodically provide inservices on medication safety, he advises.

Tell your staff members to understand that they’ll often catch their own mistakes, and those are called “near misses” or “good catches,” he says. “Make sure staff are comfortable reporting near misses,” Grundman says. “Make sure they understand there’s no retribution or punishment when a potential medication error could have happened or is about to occur, and they caught it.”

The issues that should be explored following a reported near miss are what staff can learn from it and how it can be avoided in the future, he says.

“It’s really important in a medication safety program that they not be afraid to step forward and say, ‘I almost made a mistake here,’” Grundman says. “It’s part of the culture of safety that’s really important.” ■

Non-compliance with infection control standards crosses settings for outpatient surgery

The Joint Commission recently identified requirements that were most frequently identified as “not compliant” for the first half of 2014 for accredited organizations and certified programs. One item that showed up on the ambulatory, office-based surgery, and hospital list: “The organization reduces the risk of infections associated with medical equipment, devices, and supplies.” Fifty percent of hospitals, 45% of ambulatory care organizations, and 34% of office-based surgery organizations accredited by The Joint Commission in that time period were noncompliant with the standard.

Compliance with infection control standards can be particularly challenging for ambulatory organizations, such as ambulatory surgery centers (ASCs), says **Kim Delahanty**, BSN, PHN, MBA/HCM, CIC, administrative director of infection prevention and clinical epidemiology at UC San Diego (CA) Health System. Delahanty also is a member of the national board for the Association for Professionals in Infection Control and Epidemiology (APIC) and is a faculty member for APIC’s ASC courses.

Delahanty says that “the outpatient setting sometimes does not have that oversight or resources, authority, or trained staff always available to them for consultation. Usually, in an outpatient, standalone ASCs, the staffing

EXECUTIVE SUMMARY

Hospitals, ambulatory organizations, and office-based surgery programs struggle to reduce infection risks with medical equipment, devices, and supplies.

- Have routine preventative maintenance performed by a certified technician on a regular basis.
- Follow guidelines from the Centers for Disease Control and Prevention and the American Society for Gastrointestinal Endoscopy for cleaning scopes.
- Test the environmental cleaning in your rooms with a liquid that is invisible in natural light but fluoresces under a black light.

forces the surgeon/physician into the role of attempting to write guidelines around disinfecting, high-level disinfecting, and sterilization of medical equipment and devices for which their training is not robust enough.” Also, time constraints don’t allow them to keep up with changes in infection control, she says.

There are national structural guidelines in infection control from the Centers for Medicare and Medicaid Services (CMS), the Association for the Advancement of Medical Instrumentation (AAMI), ASHRE (formerly the American Society of Heating, Refrigerating, and Air-Conditioning Engineers), and the Association for periOperative Registered Nurses (AORN), Delahanty says. Also, The Joint Commission requires organizations to have an infection prevention and control program with someone trained or educated in infection prevention.

“Having dedicated trained competent resources for infection prevention and control available to the outpatient ASCs would help ensure betterment of the patient and avoid organization harm,” Delahanty says. Consider these other suggestions:

- **Ensure you follow manufacturers’ instructions for use (IFU).**

Be sure the equipment is serviced properly, based on manufacturers’ IFUs, says **Marcia Patrick**, MSN, RN, CIC, surveyor for the Accreditation Association for Ambulatory Health Care and consultant in infection prevention, based in Tacoma, WA. Consider sterilizers, for example. “If your sterilizer isn’t working properly, it can put patients at risk,” she says.

Have routine preventative maintenance performed by a certified technician on a regular basis, such as every six months or annually, Patrick says. “Sometimes people forget they can’t just buy it, put in the corner, and use it for 15 years, and not pay attention to its needs” such as gasket replacements, she says. Document the maintenance work that’s done, Patrick adds.

Ensure you have enough medical equipment to perform the disinfecting, high-level disinfection, and sterilization properly, Delahanty says. “This process has required time that it takes to perform it correctly and safely,” she says.

- **Pay special attention to scopes.**

Scopes, especially endoscopes, are fairly intricate, Patrick says.

“Those scopes require attention, specifically in protocols, and when we find problems, such as outbreaks, it’s often a result of poor cleaning, disinfection, and sterilization practices,” she says.

The devices have specific requirements for cleaning and performing leak test procedures, Patrick says.

Ensure you follow guidelines from the Centers for Disease Control and Prevention (CDC) and the American Society for Gastrointestinal Endoscopy (ASGE), she says.

These guidelines include steps such as testing the solution before using it and allowing a set amount of time for how long scopes stay in the solution, Patrick says. “It’s very complex,” she says. *(For more information, on the CDC guidelines, go to <http://www.cdc.gov/hicpac/pubs.html>. For more information on ASGE guidelines, see “Guidelines address safety in GI endoscopy unit,” Same-Day Surgery, April 2014, p. 43. For information about an outbreak tied to duodenoscopes, see “E. coli outbreak at Illinois hospital tied to contaminated specialized GI scopes,” SDS, January 2015, p. 5.)*

- **Ensure environmental cleaning is done properly.**

Managers should ensure environmental cleaning is done appropriately at the appropriate time with appropriate products, Patrick says.

Also, always know what products the environmental cleaning staff use, she suggests. “You have more control if your facility provides them,” Patrick says. If the products require mixing, ensure they’re being mixed correctly. Someone cleaning might mistakenly think that if the instructions call for one ounce of a product, then two ounces is even better, but the chemistry doesn’t work that way, Patrick warns.

She points out that many ambulatory facilities use contracted services after hours. You can stay late to keep an eye on members of the cleaning staff, but they might not do their typical cleaning if they’re being watched, she says.

Another option is to dot 10 surfaces that are heavily touched with a liquid that is invisible in natural light but fluoresces under a black light. The morning after cleaning, you can inspect each of the high-touch objects with a black light to see if the marks were removed, which provides an objective measure of the thoroughness of cleaning. “It’s either there and untouched, which tells you they didn’t do anything, just a ‘lick and a promise,’ not thorough cleaning, or they did,” Patrick says. *(See two products that can be used for this purpose in resources below.)*

Your monitoring can be the basis for a basic quality improvement (QI) study, Patrick says. “The reason we pick 10 surfaces is that you can do a percentage very quickly,” she says.

RESOURCES

- **Glitterbug Potion Handwashing Disclosure Lotion** from Brevis Corp., 225 W. 2855 South, Salt Lake City, UT 84115. Telephone: (800) 383-3377 or (801) 466-6677. E-mail: info@brevis.com Web: <http://www.brevis.com/glitterbug>. Price is \$354 for a case of 24.
- **DAZO Fluorescent Marking Gel** from Ecolab, 370 Wabasha St. N., St. Paul, MN 55102. Telephone: (866) 781-8787. Web: <http://www.ecolab.com/program/encompass-environmental-monitoring-program>. Price varies depending on contract. ■