FDA shares data on events related to the reuse of single-use devices

Is reuse of single-use devices (SUDs) a safe practice? Recent headlines have raised doubts. The Associated Press (AP) ran an article July 30 headlined “Recycling medical devices raises concerns.” The article reported that since 2004, the FDA had received 13 reports of patient deaths and 130 reports of serious patient harm related to reprocessed SUDs, noting that some reports could be duplicates.

Questioning the data, OR Manager asked the FDA for details so it could report what these incidents entailed.

On Aug 11, the AP ran a correction, saying the report was based on “erroneous information” from the FDA.

A month later, on Sept 12, the FDA responded to OR Manager’s request with a detailed analysis of 434 reports from its MedWatch database covering the period from Oct 22, 2003, to July 21, 2006.

The analysis found no deaths related to commercially reprocessed SUDs. The 1 report of a death was associated with a tracheostomy tube intended for reuse in the same patient. The FDA found 46 other reports of injury and 18 reports of malfunctions clearly associated with SUDs, but reprocessing was only one of several possible causes, the FDA notes (chart).

Apparently, the FDA ran a computer search for the AP reporter, but neither the reporter nor the FDA reviewed the individual reports to see if they were relevant to reprocessing of SUDs. Reports in the FDA’s MedWatch database are often difficult to interpret. The FDA’s form for submitting a report asks, among other things: “Is this a single-use device that was reprocessed and reused on a patient?” People often check the box in error, the FDA says. Each report must be examined to see if a reprocessed SUD actually was involved. Even then, the cause of an event often cannot be identified.

The database is part of a debate about whether FDA oversight of reprocessing is adequate. Third-party reprocessing companies say the process is safe and well regulated. But original device manufacturers, which stand to lose business if their products are reused, say their devices aren’t designed to be reprocessed and doing so is a risk to patients. They are calling for Congress and state legislatures to take action.

The US House Committee on Government Reform held a hearing on reuse Sept 26. The chair, Rep Tom Davis (R-Va), says the panel plans to look into whether the FDA reporting system is adequate and whether the FDA’s new requirement to label reprocessed SUDs, which took effect Aug 1, will aid reporting. The panel also has asked the Government Accountability Office (GAO) to update its June 2000 report, looking at the safety of SUD reprocessing, FDA oversight, and how SUDs compare with new devices. A date for release has not been announced.

Safety or economics?

Much of the battle over reuse of SUDs is economics rather than safety, some observers say.

Reprocessed SUDs cost about half what new devices cost. Third-party reprocessing has grown into a $100 million a year industry.

Exactly how many hospitals use reprocessed SUDs is unknown. The Association of Medical Device Reprocessors (AMDR) says its members, Ascent Healthcare Solutions (formed by the merger of Alliance and Vanguard) and SterilMed, do 95% of the nation’s SUD reprocessing and have 3,000 accounts, but some may be part of the same organization.
The battle is being fought on a legal and legislative front. In 2005, Johnson & Johnson and its Ethicon Endo-Surgery unit sued Ascent’s predecessors over trademark infringement. “Ethicon believes we should remove their mark in device reprocessing and put our own on. We contend that to remove the trademark is contrary to federal law, so this needs to be resolved in litigation or a negotiated settlement,” says Don Selvey, Ascent’s vice president for regulatory affairs and quality assurance.

Ethicon Endo-Surgery acknowledged the suit but would not comment further.

**Battle in the states**

Device manufacturers have taken the battle to the states. Bills to regulate reprocessing have been introduced in Utah, Massachusetts, Rhode Island, and Virginia, and are expected to be introduced in Ohio and New Jersey, according to AMDR. The bills address liability and informed consent for patients if SUDs are reused.

Utah is the only state to have passed a law that requires reproprocessors of critical SUDs to assume the liability related both to the original manufacturing and reprocessing of the device.

“That means should a reprocessed device fail, it’s the reprocessor’s fault, even if it is an original manufacturer’s defect. We oppose that, but that’s what we see the original manufacturers pushing,” says Dan Vukelich of AMDR.

Original manufacturers counter that customers sometimes return failed devices saying they are defective when they were actually damaged by reprocessing.

New Jersey, as part of its state Patient Safety Act, will require hospitals to fill out a separate form on SUDs when they submit a report on an adverse event at their facility.

A newly formed New Jersey coalition named PatientGUARD has been advocating legislation. The coalition is joined by the HealthCare Institute of New Jersey, a trade association of major pharmaceutical and medical device companies.

**The manufacturer’s view**

Smith & Nephew, a maker of medical devices, including those for single use, has lobbied for the Massachusetts bill. The company says it believes adverse events involving reprocessed SUDs are underreported.

Smith & Nephew opposes reuse of SUDs for several reasons, says Nigel Wilkinson, vice president for regulatory affairs and quality:

- Its single-use devices aren’t designed for reprocessing, and doing so “could pose a risk to patient safety.” The company is particularly concerned about reuse of its arthroscopic shaver blades.
- The company says its own and independent testing of its blades reprocessed by third parties has found contamination, compromised package seals, and damaged cutting edges.
- A survey the company sponsored in 2002 found 82% of nurses and 71% of physicians said they would be uncomfortable if a reprocessed SUD was used on them or their family member.

Wilkinson referred to a study at Loma Linda University that tested 7 new and 16 reprocessed shaver blades and found the reprocessed ones had residual protein and DNA and damage, while no damage or contaminants were found on the new blades. The report, presented as a poster at a 2003 arthroscopy conference, does not describe who reprocessed the blades or how the reprocessing was done. The study was partly funded by an unrestricted educational grant from Smith & Nephew.

In 2003 reports for investors, the company said its sales growth had been affected by reuse of its arthroscopy blade, and it had launched an education campaign on risks of the practice.

**Informed consent for patients?**

One focus of state legislation is whether patients should be informed if a critical type of reprocessed SUD will be used in their care.

Backers of the Massachusetts bill think informed consent is necessary because “there is still some debate about whether [new and reprocessed SUDs] devices are
equivalent,” says Laura Allen of the Massachusetts Medical Device Industry Council. She referred to the Loma Linda study on shaver blades and concerns about the adequacy of FDA oversight. “We think there is still room to discuss whether reprocessed devices are essentially the same as devices coming out of the package new,” she says.

A risk management expert does not agree there is a need to inform patients that a reprocessed SUD will be used in their care. Malcolm S. “Duffy” Parsons, president of RiskOne Consulting Group, Columbus, Ohio, has followed the reprocessing issue for a number of years.

“Are patients told every time we reprocess a surgical instrument or any other device that is reusable even though there is some risk of infection? No,” says Parsons. “The patient assumes the hospital has a process for inactivating microorganisms.”

The same principle applies to reuse of SUDs, he says. The patient assumes the hospital has a process for making decisions about which products it will use, and clinicians have an opportunity to participate in that decision. In so doing, the hospital considers whether a product is manufactured according to good manufacturing practices and, if applicable, is reprocessed according to the appropriate standards. If that is the case, no additional consent is needed, he says.

Parsons says he questions the motives behind the informed consent legislation. “If a patient has the opportunity to say whether a new or reprocessed device should be used in their care, they will opt for the new one every time. If so, the motive seems to be for patients not to tolerate reuse. Then you have to ask, ‘Is the motive also financial?’”

What about charging?

If facilities pay less for reprocessed SUDs, should they charge patients less than for a new device?

“There are many factors that are built into a hospital charge,” says Rick Gundling, vice president of the Healthcare Financial Management Association. “There are all kinds of things to consider besides the direct cost of a particular supply item.” Among these are overhead (including the costs of bad debt and charity care), labor costs, the volume and frequency of the service, and payer policies.

Two readers of OR Manager described their approaches to charging. The OR director at a community hospital says nurses and physicians raised this issue when the hospital embarked on reuse. The director said the hospital would not charge patients less for reused SUDs because the hospital for the most part is not paid according to its charges, and patients don’t pay for all of the costs of a procedure. The second facility, an academic medical center, tracks its use of reprocessed SUDs and uses a weighted average of the cost of new and reused devices in its charges.

Resources

Food and Drug Administration, Center for Devices and Radiological Health. Reuse web site. www.fda.gov/cdrh/reuse

FDA analysis of reports related to reuse of single-use devices

Analysis of 434 reports submitted to the FDA from Oct 22, 2003, to July 21, 2006, in which the reporting form was checked "yes" in response to the question, "Is this a single-use device that was reprocessed and reused on a patient?"

Deaths

Of 14 separate deaths:
5 associated with multi-use items (not single-use device)
5 associated with implantable device (not SUD)
Infections
There were 12 reports of infection (including 1 duplicate). Of the 11 remaining reports, it appears only 1 involved a reprocessed SUD—a trocar. The report noted infection at the port site and the need for additional surgery to retrieve pieces of the broken trocar.

The other reports were associated with reusable devices, implantable devices, or initial use of SUDs (including an electrosurgical electrode associated with both an infection and burn to the liver/gallbladder).

Injury and malfunctions without injury
There were 46 additional reports of injury and 18 other reports of malfunctions without injury clearly associated with SUDs for which reprocessing was one of several possible causative factors:

The 46 reports of injury also included reports of:
40 additional procedures to retrieve a broken device
1 bleeding requiring a transfusion
1 skin burn
1 cut finger
1 open-heart surgery with valve replacement
1 prolongation of surgery
1 bone graft.

18 malfunction reports included the following problems:
10 device did not work as intended and was replaced
3 device broke with no mention of intervention
1 normal battery depletion
1 insulation peeled off
1 bent operating tip
1 loose rubber seal
1 broken dialyzer that had to be replaced.

Remaining reports
340 remaining reports do not fall into the previous categories:
300 implantable, multiuse/reusable, or SUDs that were not reprocessed
35 report mislabeling, device mislabeling, out-of-box failures, or events determined to be clearly not device related
5 FDA doing further followup to determine whether reprocessing actually occurred.

Source: Food and Drug Administration, Sept 12, 2006.

Tips for a smooth start on reusing single-use devices
A few years ago, if you asked Michael Frisina whether his OR would reuse single-use devices (SUDs) he would have said, “No way.”

Frisina admits he’s a convert.

Starting in October 2005, his facility signed a contract with a third-party reprocessor to begin reusing a long list of reprocessed items. The facility projected savings of $88,000 in the first year but achieved more than 50% of that by the end of the first 4 months.
“We have not had a single physician complaint about any of the reprocessed items since we started,” says Frisina, who is administrative director for surgical services for the 12 ORs in the Tuomey Healthcare System, Sumter, SC.

“Do your homework” is his advice to OR managers who are considering the reuse of SUDs. Several steps were crucial to getting the project off to a smooth start.

- **Involve the physicians early.** “We got the physicians involved at the beginning and let them know what we were planning,” he says. “We didn’t want to do all of the work up front only to have them say, ‘No, we’re not going to accept these products.’”

- **Have the product standardization committee research third-party reprocessing companies.** Be sure to include surgeons on the committee. See which reprocessing vendors are covered by your group purchasing contract. Examine the list of devices from each company that have received Food and Drug Administration 510(k) clearance. Companies that market reprocessed SUDs must meet the FDA’s regulations, which include 510(k) clearance. To inform yourself about the requirements, go to the FDA’s reuse home page at www.fda.gov/cdrh/reuse.

- **Once you’ve narrowed the list of companies, invite them in for presentations.** Insist that they answer your questions. Plan to visit their plants if possible. Have your risk manager and legal counsel examine their liability insurance coverage.

- **Give surgeons an opportunity for feedback.** At Tuomey, the team organized a blind trial for the surgeons before making its decision to use reprocessed devices. They told the surgeons that during the trial they would be using reprocessed items, but they would not know which instruments were involved. The trial was conducted for about 2 weeks for 40 to 60 cases and used various types of devices in several specialties.

  “We said to the surgeons, ‘If you have problems in any of your cases, let us know,’” he says. There were no complaints about the reprocessed items.

- **Prepare the staff.** “The staff had a lot of concerns initially,” Frisina says. “They knew of hospitals that did it on their own and didn’t do it well. We assured them we weren’t doing it just to save money. But we were considering it because the savings were high enough that, if we could do it safely without sacrificing quality, we had to consider it for the overall health of the organization.”

- **Make it seamless to the staff.** Make it easy for the staff to segregate items for reprocessing. Tuomey has posters to inform the staff which SUDs can be reprocessed. The vendor provides plastic bins placed in each OR, the postanesthesia care unit, and other locations. When full, the bins are removed by the environmental services staff and delivered to a designated area near the loading dock. The bins are then transported in a soiled-materials truck to the materials management department, where the vendor prepares them for shipping to its plant. Frisina says the hospital does not pay shipping charges.

  Frisina says a big concern he had initially was how recalls would be handled. If an original manufacturer issued a recall for SUDs that were being reprocessed, how would the hospital be able to identify them?

  In that case, he says the third-party reprocessor would come to the hospital and remove all items identical to the recalled item, both new and reused. It would replace them at no charge, the same as an original manufacturer would do.