



Supporting Documentation
On Reuse Practices

Ethical Questions Linger About Reuse Practice

- Jim Rohrlack

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CHICAGO — With no solid answers to the ethical questions about the practice of reusing single-use devices, hospitals are wondering if the potential pitfalls are worth treading the path.

On one hand, hospitals tacitly favor the controversial practice because it can reduce consumption and therefore cut costs. On the other, hospitals wonder whether the reused devices compromise the quality of patient care, particularly if the devices are not reprocessed properly. Another key question involves the integrity of a device designed for one use after it's been reprocessed.

"When we reprocess, we aren't always too sure of what we are going to be getting back," Janet Schultz, R.N., an Allison Park, PA-based consultant told operating room professionals attending the

10th Annual "Managing Today's OR Suite" conference. "We began using single-use devices because it was an easier, more efficient and worry-free way to do a procedure. [With] managed care, we find ourselves cutting costs everywhere we can."

Schultz indicated that reusing single-use devices is beginning to make its way into the mainstream media because of the potential infection risks the practice poses. And the providers are attracting much of the criticism. That's because since 1987, hospitals and other health care facilities in the United States have had to bear the responsibility for making sure that the devices they use are clean and sterile, according to the Food and Drug Administration.

Other countries have washed their hands of the subject. For example, Australia and France have prohibited the reuse of single-use medical devices, according to Schultz. In Canada, the practice continues with little formal reporting, save for the Quebec province, which forbids it.

Today, there are no laws or provisions in the U.S. that would lift the burden of self regulation from the hospital or the doctor. (See August 1997 *Healthcare Purchasing News*, p. 17.)

Schultz stressed that the liability issue should be of the utmost concern to both the doctor and the hospital until there is some sort of regulation.

If a patient contracts an infection during a surgical procedure where a single-use device was reused, the provider most likely will not be alone in assuming responsibility, Schultz noted.

The device manufacturer probably could be named in any lawsuit, she said. Because the third-party reprocessor typically does not assume ownership of such devices, it avoids facing any legal danger, according to Schultz.

While the hospital or third-party reprocessing company must comply with the FDA's good manufacturing practices policy, it still may leave the physician stuck in the middle.

"The hospital usually owns the equipment," Schultz said. "But it is the doctor who is supposed to be in control at all times during any and all procedures."

With hospitals and doctors expected to assume the liability if something goes wrong, they should consider a number of factors before making the decision to reuse single-use devices.

"The safety and effectiveness of the devices are the first two things that obviously come to mind," Schultz said.

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Hospitals and doctors will have to determine whether they know enough about the cleaning and sterilization process and whether they have the necessary resources to sterilize and clean the instruments.

This is where central service becomes an important part in making sure hospitals toe the line.

Facilities must establish protocols in cleaning and sterilization and be able to validate them if asked.

They also must evaluate the design of each device, and its composition to see if it can withstand sterilization under intense heat. (Some device material may break down from exposure to certain sterilization methods.)

"Unless it is a simple device, assume that you can't use it again," Schultz advised. "Some of the machines have a difficult time as it is penetrating protein materials."

Another factor involves biofilms, Schultz said. Biofilms are bugs that lay down a slime shielding them from being killed off during a sterilization process that doesn't use steam.

This usually occurs in lumens, she added, and it doesn't happen immediately — but it can over time.

If a hospital does choose to reuse single-use devices, Schultz strongly recommended they keep track of their devices being used and what criteria are in place for testing cleanliness.

"All of these factors are going to determine your cost effectiveness," Schultz said. ■