

The Q-Net™ Monthly

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What's News

This month's newsletter addresses a controversial topic: reusing single-use devices. The provided discussion is not designed to resolve all of this complex topic's dilemmas, but rather to introduce the concept to this newsletter's readership and to provide some background information for future discussions.

GI: 'General Interest'

We have received many requests for our book, "Q-Net 96: Questions and Answers in Infection Control and Endoscopy, Part 1," which is a collection of all of Q-Net's 1996 newsletters. We thank you for your orders. To obtain a copy, please fax or call us. The cost is \$19.95. As always, this monthly newsletter is free!



What is 'Q-Net'?

Q-Net is a technology assessment network whose monthly newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Reusing single-use devices

Background

Important factors to consider

While reusing single-use (disposable) devices may seem risky and taboo, its practice is common and not always dangerous.

Past surveys^{1,2} have indicated that more than two thirds of dialysis centers in the United States reused disposable hemodialyzers, apparently without an increase in either the mortality or morbidity rate.³

Other types of disposable devices are also regularly reprocessed. A Canadian survey found 87% of responding hospitals (with more than 200 beds) regularly reused single-use devices.⁴

And for some disposable devices, reuse can generate significant savings.⁵ For example, reuse of disposable hemodialyzers has been estimated to save between \$70 and \$120 million annually.³

✓ Who is responsible if a patient were to be injured by a single-use device that failed mechanically during its reuse?

The institution may be responsible because it has decided, on its own volition, to reuse a device labeled for single-use. The hospital therefore arguably becomes the presumptive manufacturer of the disposable device, re-labeling it for more than one use.

Minimizing risk

Indeed, the risks cannot be ignored. Reprocessing a disposable device can alter its intended function and result in patient injury. Therefore, if its safety is ever in doubt, reuse of a disposable device should not be considered.⁶

However, if a hospital has on file validated test data demonstrating that reuse of a disposable device is safe and effective (i.e., its intended function after reprocessing is the same as a new pristine device's), then its reuse may provide a practical means for cutting costs. And the savings may, in turn, provide funds for patient care that might otherwise have been unavailable.

Before reusing a single-use device, the institution should have in place an effective quality assurance program, which includes the establishment and enforcement of documented guidelines and procedures to ensure the safety of this practice.^{7,8}

Also, the institution should establish a multidisciplinary task force to address such issues as: (a) which disposable devices can be reused without jeopardizing patient safety, (b) the number of times the disposable device can be reprocessed and reused without malfunctioning, (c) which department(s) will perform the validation tests to ensure

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the safety of the disposable device during its reuse, and (d) whether the disposable device can be adequately cleaned, as required to minimize the risk of cross-infection during its reuse.

Members of this task force should include representatives from the institution's administration, its operating room, and departments of risk management, central processing, infection control, (endoscopy, if appropriate), and finance.^{7,9}

Hospitals may also consider minimizing (if not eliminating) this practice's risks by contracting an 'outside' company (also known as 'outsourcing') that complies with all FDA regulations and assumes some or all of the liability associated with reprocessing a single-use device for reuse.

► **FYI:** 2% glutaraldehyde is routinely used contrary to its label. In spite of its label's 45-minute-at-25°C claim, this germicide is typically used for 20 minutes at 20°C. The medical literature is replete with reports that recommend a 20 minute immersion time to achieve high-level disinfection of rigid and flexible endoscopes when preceded by thorough instrument cleaning.¹⁰ (For a detailed discussion of this practice, review this newsletter's November 1995 issue.)

Conclusions

While prohibiting the reuse of single-use devices altogether seems unjustified, so does recommending the reuse of all disposable devices. Rather, the risks associated with reuse should be evaluated for *each* disposable device.¹¹ The reuse of some disposable devices may be cost-effective and not pose a safety risk, but for others, reuse is clearly contraindicated.

Several factors, including initial purchase price, reprocessing costs, and the durability and 'cleanability' of its physical design, will dictate whether a disposable device may be a candidate for reuse. Satisfying at least the following 3 criteria is recommended before considering reuse of a disposable device:

- 1 the disposable device's safety and effectiveness are not adversely affected by the rigors and stresses associated with reprocessing and reuse;^{12,13}
- 2 the disposable device does not contain internal surfaces difficult to clean. (Organic debris remaining on the device after cleaning and sterilization can result in cross-infection, as well as elicit a pyrogenic response);^{14,15} and
- 3 toxic chemical residues used during cleaning and sterilization (or disinfection) do not remain on the disposable device after reprocessing.⁶

In addition to hemodialysis equipment,¹⁶ examples of single-use instruments that appear to satisfy these criteria, and may

therefore have the potential to be reused safely, include certain laparoscopic¹⁴ and flexible endoscopic accessories.¹³

While some types of disposable coronary catheters may also be suitable for reuse,^{8,12} examples of disposable instruments that may jeopardize patient safety when reused include other types of coronary angioplasty equipment,^{6,17} single-use arthroscopic tissue cutters, and single-use flexible biopsy forceps, whose spring-like coiled design does not facilitate cleaning.



Reusing a disposable device used in a patient suspected of having Creutzfeldt-Jakob Disease (CJD) seems unwise. (For a detailed discussion of this disease, review this newsletter's June 1996 issue.)

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Thank you for reading this newsletter. *I have responded to these issues to the best of my ability. Respectfully, the Editor: Lawrence F. Muscarella, PhD.* Please direct all correspondence:

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