

# The Q-Net™ Monthly

Volume 4, Numbers 5,6

May, June 1998

## What's News -

This month's double issue includes a survey. Your anonymous response to each question is greatly appreciated. Surveys yield essential data, yet are rarely conducted. Now is your opportunity to participate and contribute to its success.

## Q-Net '97



'Q-Net-97,' a bound collection of all of 1997's newsletters, is now available. Order your copy today for \$9.95 (includes S&H).

## 'ER' (Essential Reading)

An article entitled, "Are all sterilization processes alike?" appears in the May (1998) issue of *The Association of Operating Room Nurses Journal*.

## What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities not only to ask good questions but also to 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

### ~ POSITION STATEMENTS ~

Several organizations have published guidelines to clarify their respective positions on different clinical practices. No practice is as controversial as the reuse of disposable devices. (Refer to this newsletter's March 1997 issue.)



The *Society of Gastroenterology Nurses and Associates (SGNA)* supports the position that, "In the absence of clear regulatory guidelines for reuse of single-use devices, ... critical medical devices labeled for single-use should not be reused." Cardiac catheters, implants, and biopsy forceps are examples of critical devices. (See Internet site: [www.sgna.org/statement11.html](http://www.sgna.org/statement11.html).)

The *Association of Operating Room Nurses (AORN)* recommends that the benefits and risks associated with the sterilization and reuse of disposable devices be determined for each type of device.

In general, AORN opposes the reuse of a single-use device unless the device's manufacturer - or the hospital - has used a validated testing protocol to determine that the device will be safe and effective during reuse. Because the manufacturer is unlikely to have these data, the onus of quality assurance and validation firmly rests on the hospital's already

overburdened shoulders. (See Internet site: [www.aorn.org/clinical/resource/Reproc.htm](http://www.aorn.org/clinical/resource/Reproc.htm).)

In 1986 the Centers for Disease Control and Prevention (CDC) revoked its opposition to the reuse of single-use devices. While not endorsing this practice, the CDC concluded that data demonstrating that the reuse of all single-use items poses a serious risk of patient injury are lacking and therefore its

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## Survey says ...

The *Q-Net™ Monthly* is read by several thousand health care professionals around the world. Many unique opportunities are provided by such a diverse readership. To assess changing trends in infection control and endoscopy, a survey is included in this double issue. Your **anonymous or confidential** response to each question is greatly appreciated!

The survey's results will be published in this newsletter later this year. For each question, please circle the most appropriate answer(s). *Once completed, please return the survey via mail, fax, or e-mail.*

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continued objection to this practice no longer seemed justifiable (CDC Guidelines. *Am J Infect Control* 1986 June ;14:110-129.)

Realizing that the reuse of disposable devices could jeopardize patient safety, the *Food and Drug Administration (FDA)* maintains that, "there is a lack of data to support the general reuse of disposable medical devices, including disposable guidewires and catheters." (Refer to the *FDA's Compliance Policy Guides, Chapter 3, Sub-Chapter 300, Sec. 300.500; formerly known as CPG 7124.16.*)

☞ A device is usually labeled as *single-use* if its manufacturer has not submitted data to the FDA that support the device's safety and effectiveness during reuse. In contrast, the manufacturer of a device labeled as *reusable* has provided data to the FDA that show the device can be safely and effectively reused.

The FDA asserts that health care facilities (and possibly third party reprocessing companies) that reprocess and/or reuse disposable medical devices will likely have to assume full responsibility and liability were a patient injured during their reuse. (Refer to the *January and February 1998 issues of this newsletter.*)

Hospitals that reuse disposable devices appear to be in compliance with *The Joint Commission on the Accreditation of Healthcare Organizations' (JCAHO)* guidelines, provided the hospital has on file (and strictly adheres to) "written guidelines for the selection, storage, handling, use and disposition of disposable items." Like the CDC and AORN, JCAHO neither favors nor discourages the reuse of single-use devices.

After conducting an informal survey of government and health care professionals in 1994, the *Canadian Hospital Association (CHA)* found that, while the reuse of disposable devices is rare in Canada, an official position sanctioning or rejecting this practice is lacking.

In 1995 England's *Medical Devices Agency* issued a bulletin that discussed the potential risks associated with reusing single-use devices. This agency wrote that reuse of a disposable device may be warranted under "some circumstances" (Medical Devices Agency 1995).

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## Conclusion

Although the reuse of single-use devices is not endorsed by health care organizations or regulatory agencies, most published guidelines or recommendations do not overtly oppose this practice. Several factors, from the device's physical design to legal concerns of liability, may affect whether a manufacturer labels a device *single-use* or *reusable*. For example, a few devices are labeled *single-use* — not because their reuse may jeopardize patient safety — but because their manufacturers have concluded that reuse may adversely affect profits and increase liability.

Although the reuse of most disposable devices has the potential to cause patient injury, published reports suggest that a few may be safely reused (refer to this newsletter's *March 1997 issue*). But determining which disposable items may be safe for reuse is an arduous task and may require extensive testing and investigation. In general, hospitals are not equipped to perform these onerous tests, leaving the health care professional stuck between a cost-conscious rock and a patient-oriented hard place.

A disposable device may be a candidate for reuse if several criteria, including the following, are satisfied:

- ✓ the risks associated with this practice are understood;
- ✓ the device can be thoroughly cleaned and re-sterilized;
- ✓ validated tests that demonstrate the device's safety and effectiveness during reuse have been performed; and
- ✓ the reused device satisfies the same regulatory standards (e.g., Quality System regulation, 510(k) notification, premarket approval) as required of the disposable device's original manufacturer (see Internet site: [www.himanet.com/library/petition.pdf](http://www.himanet.com/library/petition.pdf)).

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD. Please return completed survey to:*

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Return completed survey, via Fax, mail or e-mail, by June 30, 1998



- ✓ If **Yes**, following what type(s) of endoscopic procedure(s)? (Circle all that apply): (A) bronchoscopy (B) ERCP  
(C) colonoscopy (D) sigmoidoscopy (E) urology (F) other \_\_\_\_\_.

- Please specify type/name of infection(s): \_\_\_\_\_.
- Please specify microorganism(s): \_\_\_\_\_.

- 8 What sterilizing agent do you usually use to process your flexible **biopsy forceps**? (A) steam autoclave (B) ethylene oxide  
(C) 2% glutaraldehyde (D) peracetic acid (E) hydrogen peroxide (F) other \_\_\_\_\_.

### PART 3: Rigid endoscope reprocessing

- 1 What chemical agent do you use most of the time for processing **rigid endoscopes**? (A) 2% glutaraldehyde (B) heat/steam  
(C) ethylene oxide (D) peracetic acid (E) hydrogen peroxide (F) other (specify) \_\_\_\_\_

- Please specify the chemical agent's trade name: \_\_\_\_\_
- If the chemical agent is a liquid sterilant, please specify its soaking time and temperature: \_\_\_\_\_ mins; \_\_\_\_\_ oC

- 2 How does your facility process most of its rigid endoscopes? (A) manually (B) with an automated system

- ✓ If you answered "B," please specify the automated device's trade name: \_\_\_\_\_

- 3 Where does your facility process rigid endoscopes: (A) in the OR (B) near the OR (C) in CS (D) in GI (E) other: \_\_\_\_\_

- 4 Have any cross-infections occurred in your facility following a rigid endoscopic procedure? (A) Yes (B) No

- ✓ If **Yes**, following what type(s) of procedure(s)? (Circle all that apply): (A) arthroscopy (B) laparoscopy  
(C) other \_\_\_\_\_.

- Please specify type/name of infection(s) (if known): \_\_\_\_\_.
- Please specify microorganism(s) (if known): \_\_\_\_\_.

### PART 4: Outsourcing/Reuse of single-use devices

- 1 Does your hospital "outsource" instruments to a commercial company for reprocessing? (A) Yes (B) No (C) Not sure

- ✓ If **Yes**, please list the outsourced instruments: \_\_\_\_\_.

- 2 Does your hospital reuse 'single-use' devices? (A) Yes (B) No (C) Not sure (D) Maybe

- ✓ If **No**, you have completed this survey. Thank you!

- ✓ If **Yes**, please continue with this survey and specify the disposable device(s) your hospital reuses:

\_\_\_\_\_.

- 3 Our hospital occasionally: (A) reuses disposable items on more than one patient (B) reuses disposable items that have been opened, but have not been previously used (C) both A and B (D) other \_\_\_\_\_

- Please specify the method most often used to sterilize these reused items: \_\_\_\_\_

- 4 When your facility reuses a disposable item:

- Is the patient usually informed? (A) always (B) sometimes (C) never (D) not sure

- Is the patient usually charged the price of a new item? (A) always (B) sometimes (C) never (D) not sure

- 5 Has a patient ever been injured in your hospital as a result of reusing a disposable item? (A) Yes (B) No (C) Not sure

- ✓ If **YES**, please describe the injury: \_\_\_\_\_.

\*\* END OF SURVEY.

YOUR PARTICIPATION IS APPRECIATED! \*\*