

The Q-Net™ Monthly

Volume 4, Number 1

January 1998

What's News

This month's newsletter is the first of two articles that addresses outsourcing and instrument reprocessing. While outsourcing may significantly reduce the hospital's instrument reprocessing costs, its effect on the quality of patient care is less clear.

Publisher's note: *The contents of this newsletter should not be interpreted as either an endorsement or disapproval of outsourcing. The intent of this article is simply to bring this topic to the fore for discussion.*

'Q-Net 97'



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

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 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.

Outsourcing

What is it and is it for you?

Introduction

The unrelenting demand to reduce costs continues to force health care facilities to trim fat where only bone is visible. Ironically, as the responsibilities of many of the hospital's departments are increasing, their resources are simultaneously shrinking. This paradoxical trend affords the hospital's instrument reprocessing and materials management departments no deferential treatment.

In response to this trend many hospitals are now considering practices that hitherto were viewed as taboo. For example, hospitals that in the past refused to even consider the reuse of disposable instruments, are now reevaluating this decision, weighing the risks against the potential benefits.

Advocates reference data that suggest some disposable items can be safely reused. Opponents to reusing disposables object on both scientific and ethical grounds, expressing concern that the quality of patient care may suffer.

Contributing to the controversy is the difficulty in discriminating between those disposable items that may be legitimate candidates for safe reuse, and those that are not.

Justification for reusing some disposable

items may be based on the premise that some manufacturers label instruments for single-use, not because their reuse may jeopardize patient safety, but because recommending a new instrument for each procedure is more profitable. Limiting manufacturer liability is also cited as a reason for labeling items for single-use.

Lest there be any doubt, the reuse of disposable items is contraindicated whenever any of the following 3 criteria are satisfied: (1) their safety and effectiveness during reuse cannot be guaranteed, (2) their internal designs do not facilitate cleaning and sterilization, as required to prevent cross-infection, and (3) toxic chemical residues remain on the item after reprocessing.

Refurbish or Reprocess?

The disposal of single-use instruments opened in the sterile field, but not used during the procedure, is frequent and costly. So is discarding disposable items whose sterility has expired (time-related sterility) or whose packaging appears

(Continued on page 2)

In the context of this article two definitions apply:

- ✓ **Refurbishing:** *the re-packaging and re-sterilization of unused disposable instruments for reuse; to recycle.*
- ✓ **Reprocessing:** *the cleaning, inspection, packaging, and sterilization of potentially contaminated reusable instruments.*

violated (event-related sterility).

Refurbishing these unused disposable items will reduce costs. (Refer to the definitions of *refurbish* and *reprocess* on page 1.) *But does refurbishing place the patient at risk?* The reuse of disposables is not recommended unless validated data is available demonstrating that the item's safety and effectiveness during reuse are the same as those of a new pristine item.

Industry has responded, developing reprocessing programs advertised to reduce costs without sacrificing safety, quality or performance. Also known as *contract sterilization*, *third-party reprocessing*, and *off-site sterilization*, 'outsourcing' is a service offered to health care facilities by a commercial company. Outsourcing companies typically offer at least one of the following services:

- Refurbish (i.e., re-package and re-sterilize) the hospital's unused disposable instruments, such as drill bits;
- Reprocess (i.e., clean, inspect, package and sterilize) the hospital's reusable instruments, such as arthroscopic meniscus cutters and burrs; and
- Purchase and loan instruments, such as reusable laparoscopic instruments, to the hospital on a per use basis.

✓ *Outsourcing companies claim that they can refurbish and reprocess instruments for as much as 50% less than the hospital's current cost without compromising patient care.*

Although instrument reprocessing may be the hospital's responsibility, even its deserved rite, an outsourcing company's advertised savings of as much as 50% is bound to attract the attention of many. Outsourcing offers hospitals the opportunity to reduce the rising costs of reprocessing and procuring new and expensive instrumentation.

The reliability and quality of outsourcing, however, has yet to be fully investigated in a controlled setting. *Might this service potentially place the patient at risk for the myopic sake of increasing the bottom line?* As with any new service, proceeding with open, albeit cautious, eyes seems warranted.

Liability and Risk Management

Outsourcing companies may also reprocess used disposable instruments. Because of the greater risks to the patient, this service is more controversial than either refurbishing unused instruments or reprocessing reusable instruments. While reprocessing used disposable items, such as coronary angioplasty catheters and endoscopic biopsy forceps, may reduce costs, the benefits rarely outweigh the risks. (Refer to this newsletter's March and November 1997 issues.)

Before contracting with an outsourcing company, the hospital should obtain the answers to several questions, including who is responsible if a patient were injured by a refurbished (or reprocessed) instrument: The hospital or the outsourcing company? (Next month's issue of this newsletter, entitled "Outsourcing, Part 2," continues this discussion.)

The reprocessing services and indemnity policies of different outsourcing companies vary. To avoid any confusion or misunderstandings, the responsibilities of both the hospital and outsourcing company should be discussed and clearly defined.

Most outsourcing companies will indemnify the hospital if a patient is injured as a result of negligence on the part of the outsourcing company (i.e., the instrument was not properly cleaned or sterilized). Much less clear, however, is whether the outsourcing company will indemnify the hospital if a patient is injured as a result of a refurbished or reprocessed instrument that malfunctioned or broke during reuse.

Unless specifically indemnified by the outsourcing company, the hospital (or physician) is arguably at fault because the decision to reuse the instrument was made by the hospital, not the outsourcing company. Whenever it reuses a disposable item, the hospital may be considered the item's presumptive manufacturer, since the hospital has in effect re-labeled the item for more than one use. But the outsourcing company may still share some culpability, for it refurbished (or reprocessed) the instrument fully aware of the hospital's intent to reuse it contrary to its label's disposable claim.

(To be continued next month ...)

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 direct all correspondence to:

LAWRENCE F MUSCARELLA, PHD
Director, Research and Development
Chief, Infection Control

Custom Ultrasonics, Inc.

144 Railroad Drive
Ivyland, PA 18974

Tele: 215.364.1477; Fax: 215.364.7674

E-mail: q-net@msn.com

<http://www.myendosite.com>



Copyright © 1995-1998. All rights reserved. *It is a violation of federal copyright laws (17 U.S.C. Sec. 101 et seq.) to copy, fax, or reproduce any portion of this newsletter without its publisher's consent. Q-Net is a registered trademark of Custom Ultrasonics, Inc.* (v5_98)