

The Q-Net™ Monthly

Volume 8, Number 6, 7

June, July 2002

What's News

► This month's double issue is the second of two articles that discuss the recent recall of Olympus bronchoscopes.

The May (2002) issue of *Infection Control and Hospital Epidemiology* published an article, written by this newsletter's editor, that recommends monitoring the rinse water used during endoscope reprocessing. This same journal's July (2002) issue will publish an article, also written by this newsletter's editor, that asks whether crucial lessons in outbreak investigations are being learned.

Editor-in-Chief

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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 healthcare.

Device recall revisited

The second of two articles that discuss the recent recall of Olympus bronchoscopes

Background: Last month's double issue of this newsletter discussed the recent recall of several Olympus bronchoscope models. This voluntary recall was apparently in response to the findings of investigators researching the cause of a potential bacterial outbreak at Skyline Medical Center ("SMC") in Nashville (TN).² A chronological presentation of the events prior to and after the issuance of this recall is displayed in **Figure 2**, p. 12. (Figure 1 is presented in last month's double issue of this newsletter.)

Briefly, this past September physicians at SMC noticed that an unusually high number of bronchoalveolar lavage (BAL) samples were contaminated with *Pseudomonas aeruginosa*. After conducting a thorough investigation into the cause of this potential outbreak, officials concluded that the biopsy channel port housing of the bronchoscopes used to collect these BAL samples was the source of the bacteria.^{2,4,6,9}

On November 30, 2001, Olympus recalled 15 of its bronchoscope models, stating that their biopsy channel port housing could become loose and trap bacteria inaccessible to cleaning, disinfection and drying (see **Figure 1**, p. 7).^{2,6}

One month later, at the end of December, physicians at Johns Hopkins

Hospital ("JHH"), unaware of Olympus' recall or SMC's findings, noticed that the *P aeruginosa* infection rate for its hospitalized patients who had recently undergone BAL was significantly higher than expected. An investigation was conducted to determine the source of this bacterium. Several weeks later in early February (2002), investigators at JHH concluded, just as SMC had several months earlier, that the bronchoscope's loose biopsy channel port housing was the source of the *P aeruginosa*.^{10,12}

Are crucial lessons being learned?

This bronchoscope recall raises as many questions as lessons it teaches and recommendations it provides. **Table 1** (p. 13) presents several questions, the answers to which are not entirely clear. It is recommended that these questions be reviewed and their answers researched and published, to prevent future infections following endoscopy.

Recommendations: The study of this recent Olympus bronchoscope recall reveals several deficiencies, including an apparent lack of communication during the recall process between a medical device manufacturer/distributor, medical facilities, and the Food and Drug Administration (FDA). It is therefore recommended that all measures be explored to improve the exchange of information between these three parties, not only before, during and after a device recall, but also whenever a new series of flexible endoscopes (or other device type), with unique design features and special reprocessing demands, is introduced into the marketplace.

Several additional recommendations

(Continued on page 12)

are provided to optimize the medical device recall process and minimize the risk of patient injury. Although these recommendations are provided in the context of the Olympus bronchoscope recall, some may also apply to other devices.

Manufacturer: Once a design or manufacturing defect is detected, it is recommended that the medical device's manufacturer (or distributor):

1. Develop and test a modified (upgrade) design, to ensure it is safe, effective, and overcomes the original design's flaw. Also, ensure the modified design allows for all of the device's potentially contaminated surfaces to be easily cleaned and disinfected or sterilized (and dried) after each use.

2. Promptly, urgently and without equivocation initiate a recall and notify each facility that purchased the defective device of the recall. (Waiting until a patient is injured before initiating a recall is problematic.) In the recall letter/notification, provide the specific details of the recall, including why the recall is being initiated, which specific device

models (and serial numbers, if necessary) are affected, whether the device should be returned for modification or discarded for a replacement, and what other specific steps must be taken by the facility to comply with all of the recall's requirements.

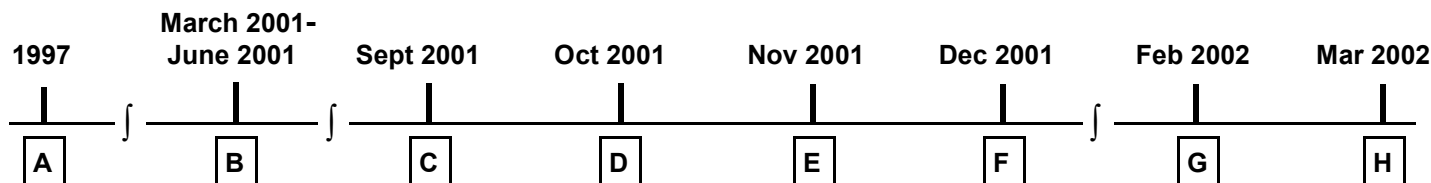
3. If feasible, deliver the recall letter not just to a department or an administrator at the facility known to have purchased the defective device but also to all health care practitioners who may use the defective device.

4. In addition to having it confirm receipt of the recall letter, request that the facility acknowledge understanding its details. Ask the facility to provide a contact name (which can be generic, such as "CEO," or "Risk Manager") and department, its address, telephone and facsimile numbers, and an e-mail address, for recall updates and future correspondence.

5. Instruct the facility to remove from service all recalled device models, even if upon inspection by the facility the device does not appear to be defective or malfunctioning.

(Continued on page 13, column 2)

FIGURE 2. A chronological presentation of events prior to and after the recall of Olympus bronchoscopes



- A:** On June 5, 1997¹⁸, Olympus introduces the flawed biopsy channel port housing design that was recalled in 2001.
- B:** A hospital in Lyon, France, reportedly notices a high number of contaminated bronchoalveolar lavage (BAL) samples. It conducts an investigation that links the contamination to two bronchoscope models. This hospital notifies Olympus' French division that it suspects the design of these two bronchoscope models may be defective.
- C:** Skyline Medical Center (SMC) notices that an unusually high number of BAL samples are contaminated with *P aeruginosa*. SMC suspects patient infection and notifies Olympus and government agencies of its concerns. SMC conducts an investigation into the cause of this potential outbreak. Olympus performs its own testing and concludes that patients are not at risk of bacterial infection, provided the bronchoscope is properly reprocessed.⁸
- D:** SMC concludes that the biopsy channel port housing of some of its Olympus bronchoscopes had become loose and was the source of the *P aeruginosa*.^{2,4} SMC informs Olympus and the FDA of its findings.⁵
- E:** On November 30, 2001, Olympus mails out its first of two recall letters to purchasers of 15 of its bronchoscope models.⁶ Olympus modifies the recalled bronchoscope models, replacing a plastic cap with a stainless steel cap.
- F:** Johns Hopkins Hospital (JHH) notices that an unusually high number of BAL samples are contaminated with *P aeruginosa*.¹⁰ Unaware of the recall, JHH conducts an investigation into the cause of this potential outbreak.
- G:** JHH completes its investigation and concludes, as did SMC, that the biopsy channel port housing of some of its Olympus bronchoscopes had become loose and was the source of the *P aeruginosa*.^{10,12} JHH informs Olympus of its findings only to discover for the first time that three of its contaminated bronchoscopes were models subject to Olympus' recall issued more than two months earlier ('E', above).^{3,10,13} On February 27, 2002, Olympus issues a second recall notification letter.¹⁵
- H:** On March 4, 2002, JHH holds a news conference and notifies the public of its findings.^{10,28} Several news sources immediately report the details of JHH's potential outbreak.^{2,3,5,8,13,17,21} On March 20, 2002, the FDA posts Olympus' recall on the agency's website.¹⁸ The hospital in France ('B' above) learns of Olympus' recall via the Internet.

TABLE 1. Questions to be answered

1. How many of the patient infections at SMC and JHH were due to underlying diseases and not a recalled bronchoscope? How many of the BAL samples contaminated with *P aeruginosa* represented a pseudo-infection?
2. How many of the patient infections at SMC and JHH were due to a recalled bronchoscope? How many of the contaminated BAL samples represented true-infections?
3. What was the original source of the *P aeruginosa*—the environment or an infected patient?
4. If the Olympus recall had been more prompt following the infections at SMC, might the infections at JHH have been prevented? If Olympus' first recall letter had conveyed a greater sense of urgency, might the resulting response rate have been significantly higher?
5. Are the design modifications prescribed by the Olympus recall sufficient to prevent further BAL contamination? Was the biopsy channel port's loose housing the sole design factor responsible for the apparent *P aeruginosa* infections? Or, might another bronchoscope component have also been contaminated with *P aeruginosa*?
6. Did Olympus know that some of its bronchoscopes models were potentially defective in design prior to the infections at SMC? Was the one reported patient infection at SMC solely responsible for Olympus initiating the recall?
7. How many of the reports of patient infection listed in the FDA's databases¹⁹ between June 5, 1997, when the recalled bronchoscope design was introduced¹⁸, and November 30, 2001⁶, when Olympus issued its recall notification, were due to the bronchoscope's flawed design?
8. When JHH sampled its bronchoscopes to determine the source of the *P aeruginosa*, why did the reverse-flushing method yield positive cultures while the forward-flushing method yielded negative cultures? Why were the results dependant on the direction of the flushing method?
9. Where did JHH collect its samples during BAL and the reverse-flushing method—at the bronchoscope's control head or biopsy channel port? (If the BALs were sampled via the control head, one would not expect to collect bacteria from the defective housing's plastic cap [Fig. 1, p. 7], which is external to the sampled channel.)
10. Why were only patients who underwent BAL at SMC and JHH considered to have been potentially infected? Why weren't patients who underwent other procedures using a recalled bronchoscope also included in the studied patient population? Specifically, if the biopsy channel port housing were contaminated, why couldn't biopsy forceps or cytology brushes — devices that presumably would have been inserted through this contaminated housing and into the patient's lungs — also have become contaminated and acted as a vehicle for bacterial transmission?
11. Why did some hospitals in Maryland, Virginia and Washington, DC receive Olympus' first recall letter shortly after its mailing, while others in the same area did not?
12. As part of its recall action plan, did Olympus, in addition to mailing the recall letter to purchasers of each recalled bronchoscope model, notify its sales representatives of the recall and instruct them to inform physicians immediately of the recall, its urgency, and its significance?
13. Should the FDA model its medical device recall requirements after its drug recall requirements? That is, when a medical device is recalled, should the FDA require the manufacturer to notify all users of the recalled device — not just the medical facility or department that purchased the device? And if such a FDA policy had been in effect, might the patient injuries at JHH have been prevented?
14. If the intent of the housing's plastic cap (Fig. 1, p.7) was originally to facilitate instrument repair, how will the replacement of this cap with a more secure stainless steel cap affect the instrument's repair and maintenance?

(Recommendations: Continued from page 12)

6. Develop a program that monitors the recall process, to ensure that each facility that purchased a defective device has been notified of the recall.
7. Track each recalled device and determine the response rate by comparing the number of returned or accounted for recalled devices to the total number of outstanding recalled devices (e.g., defective devices that may still be in use). If the response rate is deemed inadequate, determine what follow-up measures, such as a telephone call, facility visit, or issuance of a second recall notice, may be necessary to improve the recall's response rate.
8. Develop a program that provides for the rapid and efficient posting of the recall and its details on the manufacturer's Internet website. Ensure the posted recall notice is linked to crucial index terms, so that it can be quickly and easily located using most Internet search engines.
9. Educate the sales representatives of the importance of conveying the details of the recall to each potential user of the defective device.²⁸ Prompt and aggressive action by the manufacturer can minimize its liability as well as any risks to the patient population.

Medical facility: *If a medical facility suspects a bacterial outbreak, it is important to determine whether patients are infected (a true infection), or whether the instrument or environment, but not the patient, is contaminated (a pseudo-infection). If a pseudo-outbreak is confused with a true outbreak, limited resources may be needlessly expended and patients unnecessarily exposed to potentially expensive antibiotic and chemotherapeutic medications.*

During an outbreak investigation, it is also important that the bacterium's strain be sub-typed and the source of the bacterium determined (e.g., the environment or a patient).

(Continued on page 14)

Without these data, speculation will arise as to the exact cause and source of the outbreak.²⁷

To reduce the risk of patient infection, it is recommended that the facility develop a program that monitors virtually every aspect of instrument reprocessing. (Periodically sampling the environment and endoscope may be advantageous, provided the limitations of sampling are clearly understood.) This program should emphasize the importance of strict adherence to published reprocessing guidelines. Healthcare staff responsible for reprocessing complex instruments, such as flexible endoscopes, are encouraged to review these guidelines as well as the instrument's operator's manual, to ensure all of the instrument's internal and external surfaces are cleaned and disinfected (or sterilized) and dried as required after each use. Also, it is necessary to determine whether any of the instrument's internal lumens (e.g., the ERCP channel) or components (e.g., a gastrointestinal endoscope's suction and air/water valves) require specific and unique reprocessing instructions.

The following recommendations are provided for medical facilities during a device recall:

1. Follow the manufacturer's instructions and promptly remove the device from service. Return the defective device to the manufacturer (or discard it, as instructed), even if the manufacturer suggests that the recalled device can continue to be used safely.
2. Consider improving patient surveillance for nosocomial infections following endoscopy, particularly bronchoscopy. It is recommended to determine whether any previous nosocomial infections, the causes of which remain undetermined, can be linked to one of the recalled bronchoscope models. If so, follow FDA guidelines for reporting a patient injury linked to a medical device.

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:

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3. Appoint a department or individual within the facility to whom all recall notices, updates and correspondence are to be addressed. When a recall notice is received, ensure the appropriate department within the facility is notified.
4. Treat all recall notices as urgent. Do not overlook or minimize their importance.²⁸ As prescribed by the recall notification, promptly provide the manufacturer with all of the necessary contact information.

FDA: *Criticizing the FDA's handling and monitoring of the recall, officials at JHH and the CDC voiced concern that the public was not notified of the recall in a timely, clear, or urgent manner, which placed patients at risk.^{3,5,17,28} Whether or not such criticism is justified, the FDA for its part has acknowledged that its monitoring of recalled medical devices could be more effective and efficient.^{17,28}*

Implementation by the FDA of some of the following recommendations during a medical device recall is suggested:

1. Review the agency's internal recall policies and procedures to determine whether improvements are warranted.
2. Assess whether monitoring manufacturers more closely during a device recall would reduce the risk of patient injury. It may be necessary to request more funding from Congress to hire more staff to review a manufacturer's recall notice prior to its issuance, to ensure the notice is thorough, prompt, clear, provides for adequate monitoring during the recall process, and is in all regards in full compliance with the agency's regulations.
3. Determine whether more proactive federal regulatory oversight of endoscope designs is necessary.
4. Consider promptly posting all manufacturer recall letters on the agency's Internet website, making it available to virtually all search engines.
5. Evaluate whether the agency's recall policy that currently applies to drugs—that is, notifying each physician who might prescribe a recalled or (re-labeled) drug—should also be applied to medical devices. For most medical devices, the agency currently requires the manufacturer to send the recall letter only to those facilities that purchased a recalled device.²⁸
6. Finally, encourage the timely sharing of information about recalled or suspect medical devices not only between the agency's own departments, such as the *Office of Device Evaluation* and the *Office of Compliance*, but also with other federal agencies, such as the Centers for Disease Control and Prevention (CDC). ■ *The End*

References

The references to this and last month's double issue of this newsletter are available at:

<http://www.myendosite.com/refs06702.doc>