

The Q-Net™ Monthly

Volume 13, Number 12

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What's News

Happy Holidays! ● Last November *ASP* issued three voluntary corrective actions, one of which provides a product correction regarding the processing of Olympus flexible surgical endoscopes in the STERRAD® NX™ Sterilization System. Visit *ASP*'s website for more information: www.sterrad.com. ● Although a single issue, this month's newsletter features 4 pages. ● This newsletter's articles published between 1996 and 2007 are available at: ► <http://www.myendosite.com>

Editor-in-Chief

All of the articles published in this newsletter are written by **Lawrence F. Muscarella, Ph.D.**, Chief, Infection Control at Custom Ultrasonics, Inc. Ivyland, PA

What is 'Q-Net'?

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

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and OR communities not only to ask good questions but also to demand 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.

HCV transmission in NY

The reuse of syringes (not needles) is blamed for at least one case of patient-to-patient transmission of the hepatitis C virus.

BACKGROUND: A recent breach of infection-control protocol demonstrates the contribution of the improper use of syringes and multi-dose medicine vials to disease transmission. The reader is encouraged to review both the February, 2002, and March, 2002, issues of this newsletter. The former discusses aseptic technique, and the latter provides recommendations in response to a question about whether filling syringes with a medication in the morning for use throughout the day or the next day poses an increased risk of healthcare-acquired infections. Although their focus is the gastrointestinal (GI) endoscopic setting, the latter's recommendations are applicable to any healthcare setting where surgical, endoscopic, and/or pain management procedures are performed.

The reader is also encouraged to review the recommendations provided in this newsletter's July, 2001, issue, which discusses an outbreak of the hepatitis C virus (HCV) associated with GI endoscopy performed in a clinic in 2001. These three articles previously published in this newsletter provide important and timely infection-control recommendations. (All of this newsletter's articles

can be read at: www.myendosite.com.)

Patient-to-patient transmission of HCV: On November 10, 2007, health officials in New York advised 628 patients by certified mail to be tested for infection with HCV, the hepatitis B virus (HBV), and HIV.¹⁻³ These patients were deemed to be at risk of infection because records indicate that each had received an injection from an anesthesiologist between January 1, 2000, and January 15, 2005. Health officials concluded that during this five year period this anesthesiologist—who is referred to in this article as "Doctor A"—injected these patients with medicines in stark violation of infection-control standards.¹⁻⁶ (Refer to Figure 1, "Timeline of events," on p. 24.)

Health officials reportedly knew since January, 2005, that Doctor A's penchant for the verboten practice of reusing syringes between 2000 and 2005 was "likely" responsible for at least one case of patient-to-patient transmission of HCV.¹⁻⁸ Nevertheless, it was not until last month (November, 2007)—34 months later—that health officials overcame obstacles and notified these 628 patients of the risk of their exposure to HCV and other blood-borne pathogens.

And, just this month (December, 2007), health officials decided to inform 8,500 additional patients of Doctor A's that they too may be at risk of HCV infection.⁹ To date, no cases of HIV transmission have been linked to Doctor

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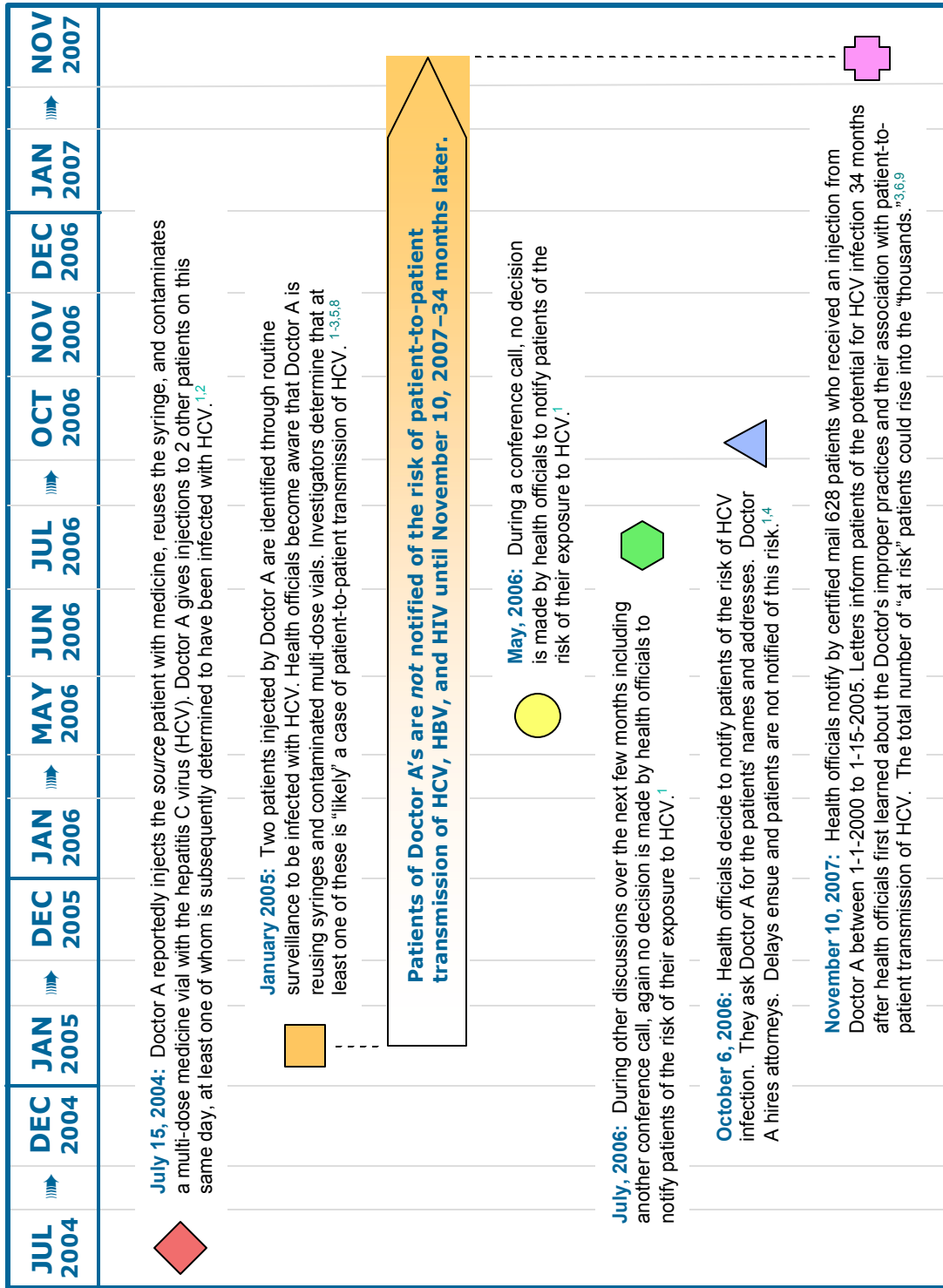


Figure 1. A Timeline of events: The reuse of syringes. This figure displays the sequence of events associated with Doctor A's reported reuse of syringes. On July 15, 2004 (diamond), the source patient transmits HCV to another of Doctor A's patients, known as the index patient. This case of patient-to-patient transmission of HCV was confirmed January, 2005 (square). But, it was not until November 10, 2007 ("plus" sign)—34 months later—that health officials notified patients of the risk of infection from HCV, HBV, and HIV. ©

A's infection-control breaches, although at least one case of HBV transmission is suspected.⁹ (Doctor A is reported to be currently practicing medicine in New York.⁷)

HCV is the causative agent of a potentially fatal liver disease, and contact with the blood of an infected person, which can occur during the reuse of a syringe (or needle) and/or a contaminated multi-dose medicine vial, is ordinarily required for its transmission. Other practices associated with the transmission of HCV include tattooing and unprotected sex. Prompt identification of all patients who may have been nosocomially infected with HCV is important to control and prevent its spread.

The reuse of syringes: This reported case of transmission of HCV demonstrates that the pernicious practice of reusing syringes is not limited to underdeveloped countries, but can occur anywhere in the world, including the U.S. This case also underscores the importance of healthcare facilities ensuring that medical personnel fully understand that reusing syringes (and contaminated multi-dose medicine vials) is a risk factor for the transmission of HCV and other blood-borne pathogens.

Unlike single-dose medicine vials, which are labeled for use on *one* patient, multi-dose medicine vials are labeled for *multiple* uses on different patients. Consequently, if single-dose medicine vials virtually eliminate any risk of patient-to-patient disease transmission, multi-dose medicine vials can transmit HCV and other blood-borne pathogens from one patient to another if aseptic technique is not employed.

For clarification, this report of patient-to-patient transmission of HCV was not a result of Doctor A reusing syringes (or needles) on *different* patients, as investigators may have initially suspected. Rather, health officials attribute this case to the more subtle practice employed by Doctor A between 2000 and 2005 of reusing a syringe to *re-inject* the same patient with additional doses of medicines drawn from more than one multi-dose vial. (The reuse of a syringe to redose a patient with additional doses of a medicine drawn from the same multi-dose vial would also pose a risk of patient-to-patient transmission of blood-borne pathogens.)

According to health officials, a patient already infected with HCV and referred to as the *source* patient (i.e., the patient from whom the HCV originated³) received an injection from Doctor A on July 15, 2004 (refer to *Figure 1* on p. 24). This syringe was initially new and sterile but became contaminated with HCV when used to inject this (source) patient with a first dose of medicine drawn from a multi-dose vial. Then, breaching infection-control protocol, Doctor A reportedly reused this same HCV-contaminated syringe (but with a new, sterile needle) to *re-inject* this same (*source*) patient with additional doses of different medicines drawn from other multi-dose vials—a practice that reportedly resulted in the inadvertent contamination of these multi-dose vials and their

medicines with the *source* patient's infectious HCV.^{1-6,8,10}

And, it was the reuse of this contaminated multi-dose vial to inject with medicine other patients of Doctor A's that "likely" transmitted the HCV horizontally from the *source* patient to at least one other patient, known as the *index* patient. (The *source* patient's identity is unknown.¹)

Once health officials established in January, 2005, that Doctor A's reuse of syringes to redose patients was likely responsible for an identified case of patient-to-patient transmission of HCV (refer to *Figure 1* on p. 24), any of Doctor A's patients injected between 2000 and 2005 with medicine drawn from a potentially contaminated multi-dose vial would be deemed by health officials to be "at risk" of infection with HCV and other infectious agents including HBV and HIV. (Doctor A reportedly is not the only physician who reuses syringes to redose patients with medicines from multi-dose vials.⁸ Although the use of multi-dose vials can be safe if proper infection-control measures are taken, the reuse of syringes is contraindicated.)

Other cases of patient-to-patient transmission of HCV: Other reports of patient-to-patient transmission of HCV similar in cause to Doctor A's case have been published. For example, a report published by the *Centers for Disease Control and Prevention* (CDC) in 2003 summarizes the investigation of four outbreaks of HCV and HBV in different healthcare settings.¹¹ According to the CDC, each of these outbreaks was likely caused by the reuse of syringes and needles or the contamination of multi-dose medicine vials.¹¹ An investigation of one of these outbreaks (Oklahoma, U.S.) concluded that a medical practitioner's routine reuse of one syringe and needle to administer different intravenous (IV) medications to as many as 24 patients per day at a pain clinic was most likely responsible for the infection of 69 patients with HCV and 31 patients with HBV. (None of these patients were reported to be infected with HIV.^{11,12})

An investigation of another one of these outbreaks (New York City, U.S.) summarized in this CDC report determined that the contamination of multi-dose medicine vials was likely responsible in 2001 for the transmission of HCV to as many as 19 patients during GI endoscopy.¹¹ Readers are encouraged to review the July, 2001, issue of this newsletter for more details about this outbreak of HCV.

Another oft-referenced report documents patient-to-patient transmission of HCV during GI endoscopy in Europe,¹³ although the investigation did not determine whether improper administration of IV medications, or the inadequate reprocessing of GI endoscopes or reusable biopsy forceps, was responsible for disease transmission.¹³ Other reports linking patient-to-patient transmission of HCV to contaminated multi-dose medicine vials also have been

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Only use new, sterile syringes (and needles) to draw medicines from multi-dose vials. Reusing a syringe to re-inject a patient with medicine from a multi-dose vial poses a significant risk of disease transmission.

published,¹⁴⁻¹⁶ so, too, have reports of transmission of HCV from physicians and healthcare workers to patients.¹⁷⁻¹⁸

Timeline: Figure 1 (p. 24) displays the sequence of events associated with the investigation of Doctor A's reuse of syringes. The pivotal events displayed in this figure begin on July 15, 2004, when Doctor A reportedly reused a syringe to redose the *source* patient with medicine, and end on November 10, 2007, when health officials notified these 628 patients of their risk of HCV infection. As previously mentioned, however, health officials reportedly first learned that Doctor A's reuse of syringes was likely responsible for patient-to-patient transmission of HCV thirty-four months earlier in January, 2005. Whether this delay of almost 3 years prior to notifying patients of their risk of HCV infection was warranted is a matter of current debate. Responding to public criticism and reproof, health officials state that their thorough investigation of the facts of this case including its cause required almost three years to complete.⁴

Recommendations: As this case of reusing syringes demonstrates, strict adherence to aseptic technique is necessary during the drawing of a medication for an injection. Apropos to this discussion about Doctor A's reported infection-control breaches, this article's author (LFM) wrote in this newsletter's July, 2001, issue that: "Reusing medicine vials, IV tubing lines, and syringes can increase the risk of infection from blood-borne pathogens." In view of Doctor A's reuse of syringes and multi-dose medicine vials, review of the following recommendations, as well as those published in both this newsletter's July, 2001, and March, 2002, issues, some of which are provided below, is strongly encouraged. These recommendations are applicable to GI endoscopy units and other healthcare settings where surgical, endoscopic, and/or pain management procedures are performed. (Specific recommendations to prevent disease transmission during the IV administration of *propofol* are provided in this newsletter's March, 2002, issue and are not repeated below.)

1. Establish a quality assurance program that monitors medical staff members to ensure compliance with aseptic technique when filling syringes, using multi-dose medicine vials, and administering injections (and IV medications).
2. Use a new, sterile syringe and needle (and IV tubing line) for each patient. The reuse of any of these items, including partially-used syringes, is contraindicated. Discard all partially-used (and also emptied) syringes after each injection.
3. Properly label each pre-filled syringe. Include the medication's name and the date and time the syringe was filled.
4. Use single-dose medicine vials whenever possible. These vials are labeled for use on *one* patient. Do not reuse a partially-used single-dose vial to inject multiple patients.

5. Draw medication from multi-dose vials with caution and in strict accordance with their labeling and aseptic technique.

(a) Read the labeling of each multi-dose medicine vial before its use. Discard the vial if contamination is suspected. As Doctor A's infection-control breaches demonstrate, improper use of multi-dose vials (and the reuse of syringes to redose patients; see below) can result in patient-to-patient transmission of blood-borne pathogens.

(b) Do not pool medications from single or multi-dose vials into one vial for use on multiple patients.

6. Never reuse a syringe to redose a patient with (additional) medication from one or more multi-dose vials.

(a) Always use a new, sterile syringe (and needle) to inject a patient with additional doses of medicine ("redosing"), no matter whether drawing these doses of medicine from one multi-dose vial or from different multi-dose vials. *The reuse of syringes is contraindicated.*

7. Ensure that: (a) GI endoscopes, including their valves and internal channels, are properly cleaned, high-level disinfected, and dried after *each* use; and (b) reusable biopsy forceps (and other heat-resistant endoscopic accessories) are properly cleaned and sterilized using pressurized steam. The End ● LFM *Wishing you a very happy New Year!*

The REFERENCES for this article are available at:
www.myendosite.com/refs1207.pdf

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
Please direct all correspondence to:

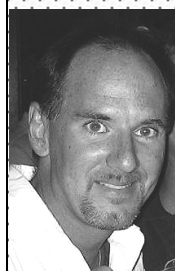
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