Safe Injection Practices for Administration of Propofol

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ABSTRACT

Sepsis and postoperative infection can occur as a result of unsafe practices in the administration of propofol and other injectable medications. Investigations of infection outbreaks have revealed the causes to be related to bacterial growth in or contamination of propofol and unsafe medication practices, including reuse of syringes on multiple patients, use of single-use medication vials for multiple patients, and failure to practice aseptic technique and adhere to infection control practices. Surveys conducted by AORN and other researchers have provided additional information on perioperative practices related to injectable medications. In 2009, the US Food and Drug Administration and the Centers for Disease Control and Prevention convened a group of clinicians to gain a better understanding of the issues related to infection outbreaks and injectable medications. The meeting participants proposed collecting data to persuade clinicians to adopt new practices, developing guiding principles for propofol use, and describing propofol-specific, site-specific, and practitioner-specific injection techniques. AORN provides resources to help perioperative nurses reduce the incidence of postoperative infection related to medication administration. AORN J 95 (March 2012) 365-372. © AORN, Inc, 2012. doi: 10.1016/j.aorn.2011.06.009

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identified as risk factors in two of the infected patients.4

These outbreaks of infection prompted the pharmaceutical company that manufactures propofol to add language to the product circular stating that “strict aseptic technique must always be maintained during handling . . .”5 and preparation of propofol for injection. The FDA issued propofol administration guidelines based on recommendations from the CDC,4 the American Society of Anesthesiologists,6 and the Anesthesia Patient Safety Foundation7 that are similar to the manufacturer’s recommendations summarized in Table 1. All recommendations were based on the following facts:

- Propofol is a lipid-based emulsion that supports bacterial growth.8
- Bacterial contamination increases rapidly over time.9
- Disinfection of propofol ampules or vials before opening considerably reduces the risk of bacterial contamination of the medication.8

Disodium edetate, which inhibits bacterial growth, was added to propofol in 1996; as a result, the incidence of propofol injection infections was reduced but not eliminated.10

During a 10-year period from 1998 to 2008, 35 documented outbreaks of hepatitis occurred in nonhospital health care facilities (e.g., pain clinics, endoscopy clinics, hemodialysis centers), which put more than 60,000 patients at risk for developing bloodborne pathogen infections.11 These outbreaks were traced to

- reuse of syringes on multiple patients,
- single-use medication vials used for multiple patients,
- failure to practice aseptic technique, and
- failure to follow fundamentals of infection control practices.11

In 2002, the Oklahoma State Department of Health investigated an unexplained outbreak of hepatitis C (HCV).12 All the infected patients had been treated for pain at the same outpatient clinic. The Oklahoma health department was able to test 795 (88%) of the patients who had been treated since the clinic opened and found that 71 patients had contracted HCV and 31 had contracted hepatitis B during 2002. Interviews with staff members regarding injection practices revealed that care providers used a single needle and syringe to administer three different sedation medications. In addition, these providers used the

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**TABLE 1. Propofol Handling Guidelines**

<table>
<thead>
<tr>
<th>US Food and Drug Administration recommendations</th>
<th>General product insert guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Vials of propofol and prefilled syringes are intended for single (i.e., one patient) use.</td>
<td>■ Strict aseptic technique must always be used when handling sterile injectable medications.</td>
</tr>
<tr>
<td>■ Begin infusion immediately after drawing up or opening the vial of medication.</td>
<td>■ Propofol should be inspected before use for particulate matter, discoloration, or evidence of separation of the emulsion.</td>
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<tr>
<td>■ Infusion from prefilled syringes or vials must begin within 6 hours of opening/filling the syringe.</td>
<td>■ Do not use if contaminated.</td>
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<tr>
<td>■ Propofol that is infused directly from a large volume (e.g., 100 mL) vial is to be limited to one patient and must be infused within 12 hours of opening the vial or spiking the stopper.</td>
<td>■ Fill syringes or spike the vial immediately before administration to each patient.</td>
</tr>
</tbody>
</table>

same needle and syringe to administer these medications to all of the patients treated that day. Results of the investigation suggest that the infections were transmitted from patient to patient after a provider used a syringe and needle on a patient positive for hepatitis and then used the same syringe and needle to administer medication to subsequent patients. The outbreak stopped when the practice of reusing syringes and needles stopped.12

In 2007, investigation of an outbreak of HCV at an endoscopy center revealed that five of the six infected patients had undergone procedures on the same day.13 Direct observation of the center’s personnel demonstrated that they inappropriately reused syringes and used single-dose medication vials on multiple patients. Clean needles and syringes were used to withdraw medication from a single-use bottle of propofol. The medication was injected through the patient’s IV. If more propofol was needed, then the same syringe with a clean needle was used to withdraw more medication. Investigators theorized that backflow from the patient’s IV or the needle may have contaminated the syringe with HCV, thereby contaminating the vial. The remaining medication was used on subsequent patients.13,14

The findings of the investigations into these various outbreaks of postoperative infections may be summarized into four major points that relate to safe injection practices.

- Propofol is a lipophilic IV injection that is known to support the growth of microorganisms.
- The addition of a preservative to propofol only inhibits microbial growth, it will not prevent it.
- There is quantitative evidence that extrinsic microbial contamination and cross contamination has led to outbreaks of serious postoperative health care-associated infections.
- It is essential to use strict aseptic technique when handling propofol, as mandated by the manufacturer’s written instructions.

MEDICATION PRACTICES SURVEYS

In July 2009, AORN conducted a random electronic survey of 500 of its 40,000 members to determine their current practice for handling propofol. A total of 410 members completed the survey for a response rate of 82%. Seventy-two percent of the respondents practiced in a hospital setting (ie, academic, community, rural), and 28% of the respondents practiced in ambulatory surgery centers or endoscopy units. The highest percentage of respondents (ie, 36%) worked in facilities with five to 10 ORs (Figure 1), and most respondents worked in ORs in which an average of 51 to 100 surgical procedures were performed per week (25%) (Figure 2). The majority of the respondents (87%) reported that, in their facilities, anesthesia providers (eg, physicians, certified RN anesthetists) draw up propofol medication products for administration (Figure 3). When asked how often the vial of propofol was typically accessed, 50% reported once, whereas 44% reported witnessing the same vial being accessed two to three times. Six percent of respondents reported seeing the same vial of propofol being accessed more than four times (Figure 4). When asked if

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there were multiple accesses to a vial of propofol for the same patient, 68% answered “yes” and 32% answered “no.” The majority of respondents (82%) reported that multiple accesses to the vial of propofol for different patients did not occur. Most facilities routinely stock 20 mL (44%) and 50 mL (39%) vials of propofol, and the majority of respondents (70%) reported that different volumes of propofol were not being used outside of the OR. When asked the number of steps involved from initially accessing the propofol container to administering the medication to the patient, 62% noted that one to three steps were involved in this process (Figure 5). Fifty-eight percent of respondents reported that their facility had a policy or procedure in place to prevent contamination of propofol medication products.

Pugliese et al15 conducted an online survey of multidisciplinary clinicians in 2010 at different types of health care organizations. A total of 8,035 clinicians (eg, nurses, physicians, anesthesia professionals, dentists, surgical technologists) responded. The researchers included 5,446 respondents who administered parental

Figure 1. The number of ORs.

Figure 2. The average number of cases per week.
medications in the final analysis and excluded clinicians who do not prepare or administer parenteral medications. The survey contained questions about injection safety, frequency of performing injections, and how the respondents obtained injection safety information. In this survey, 30% of respondents reported accessing a single-dose vial more than once, in contrast to the 50% of the AORN survey respondents who had witnessed this practice in perioperative settings. The majority of respondents (ie, 66%) reported using a multidose vial for more than one patient. Researchers calculated the practice of reusing a syringe but changing the needle for more than one patient to be 1% and the practice of reusing the syringe for additional doses from the same multidose vial to be 15%.

**THE FDA SAFE USE (PROPOFOL) HEALTH PROFESSIONALS MEETING**

To gain a better understanding of the issues related to the outbreak of infection, the FDA and the CDC convened a group of clinicians on July 29, 2009, to assess the problem. In attendance

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**Figure 3. Health care professionals who administer propofol.**

![Figure 3](image1.png)

**Figure 4. The number of times that the propofol vial is accessed.**

![Figure 4](image2.png)
were FDA and CDC staff members, anesthesiologists, nurse anesthetists, pharmacists, gastroenterologists, and perioperative and gastroenterological nurses. Health care professionals attending the conference identified and prioritized issues related to the safe handling of injectable medications that needed to be addressed, including

- implementation of universal standards of practice as they relate to practice guidelines (eg, collection of evidence-based data, development of practice guidelines for all settings, description or definition of specific administration techniques).
- education across cultures and disciplines as to what are acceptable and unacceptable medication administration practices.
- clearly defined meanings and definitions of practice terminology related to medication administration (eg, product labeling, single use, single access).
- site-specific handling management guidelines that address the issues of cost, pressure for efficacy, and quick turnover times in free-standing ambulatory facilities.
- direct observations that monitor compliance and competency related to following best

practices guidelines (eg, aseptic technique, hand hygiene, standard precautions) and manufacturer’s instructions for preparation and handling of medications.

- resolution of confusion surrounding the manufacturer’s written instructions and information (eg, single access, single use).
- a coordinated policy from professional associations (eg, the American Association of Nurse Anesthetists, AORN, the American Society of Anesthesiologists, the Anesthesia Patient Safety Foundation) regarding practice guidelines.
- practical applications of the US Pharmacopeia that address the use of sterile medications related to anesthesia practice.17

The meeting participants proposed the next steps, which included collecting data to persuade clinicians to adopt new practices; developing guiding principles for propofol use that would be adaptable to any practice setting; and describing injection techniques that would be propofol specific, site specific, and practitioner specific.

As a result of the 2009 meeting, the FDA has taken a broader-based approach to some of the issues that were raised. As a regulatory
agency, the FDA is looking at the language that is used on various products to see how well it communicates to and is understood by the health care professionals who need to read and use it.\textsuperscript{18} In addition, the FDA is looking at the issue of standardization of terms used on manufacturer labels, evaluating which terms are preferable and whether standardizing terms would be beneficial. After completing its analyses, the FDA may provide guidance to industry and to FDA reviewers on additional issues that they should consider when evaluating new medication applications. For example, the FDA has been evaluating fill amounts, closures on liquid injectables, and other factors that could contribute to the way these products are used.\textsuperscript{18}

Shortages of propofol that began in November 2009 have further complicated the situation. Manufacturers have stopped production and recalled several lots. The shortage is a result of quality control issues and decreasing profit margins.\textsuperscript{19} At present, only one manufacturer in the United States is producing propofol. Future regulatory initiatives may develop as a consequence of these issues.

**CONCLUSION**

There is a growing concern about the risks for transmitting infections during routine health care procedures requiring IV medications. Outbreaks of infection have occurred with increasing regularity. The gap between what is recommended and what is actually done clinically regarding safe injection practices must be addressed. Safe medication practices may be summarized as

- performing hand hygiene before preparing medications for administration,
- storing and preparing medications in a clean area,
- using a clean syringe and needle for every patient, and
- implementing aseptic technique when preparing sterile medications and solutions for injection.

Unsafe practices include

- pooling or combining vial contents;
- reusing a syringe or needle to withdraw medication from a multidose vial;
- re-entering a single-use vial, ampule, or solution;
- reusing a syringe or needle on any patient; and
- using the same syringe or needles to administer medications to multiple patients.\textsuperscript{19}

In the 2010 survey by Pugliese et al.\textsuperscript{15} 60% of the respondents selected their professional organization as their most frequent source of practice information. AORN continues to provide educational and evidence-based practice resources to members and the industry related to safe medication practices related to the handling and administration of medications and solutions.

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Resources


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