Quality and Regulatory Affairs

Pre-Spiking of Intravenous Fluid Bags No Longer Limited by 1-Hour Rule – USP Revises Chapter <797>

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In the face of increasing production pressures seen across the perioperative spectrum, the ability to expand operational efficiency while maintaining patient safety is paramount. One of the most-encountered situations that tests this balance is the need for having supplies ready to go in case of an emergency. I.V. solutions are one of the must-be-ready supplies available in any such situation.

Historically, The Joint Commission mandated that infusion of I.V. fluid bags must begin within one hour of spiking unless the bag is spiked in an ISO Class 5 cleanroom. This stemmed from a recommendation put forth by the Association for Professionals in Infection Control and Epidemiology (APIC), which apparently misinterpreted a United States Pharmacopeia (USP) rule that sets forth regulations concerning compounding of medications (*Am J Infect Control* 2016;44:750-7).

The rule in question is included in USP <797>, which sets the standards for compounding of sterile pharmaceuticals. This document was interpreted to be inclusive of the preparation of sterile I.V. solutions. As part of this interpretation, The Joint Commission mandated that I.V. fluid bags be used within one hour of spiking because of perceived bacterial contamination risks, sparking clinical and economic concerns. For the safety of patients, I.V. bags may need to be pre-spiked more than one hour in advance in order to be readily available for an emergency.

It is hard to comprehend how I.V. solution preparation came to be considered compounding and under the authority of USP <797>. Compounding has a variety of definitions, depending on the source. For example, the U.S. Food and Drug Administration (FDA) definition of compounding states: "Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient" (asamonitor.pub/3ZqFcUD). The USP defines sterile compounding more broadly as, "combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise

altering a drug or bulk drug substance to create a sterile medication" (asamonitor.pub/3aTV3ad). Based on these definitions, ASA has always taken the position that I.V. bag preparation is not compounding.

Because of The Joint Commission's interpretation, multiple studies have been conducted to determine the risk of I.V. fluid bag contamination. The studies that addressed the risk of contamination/infection of pre-spiked I.V. fluid bags and administration sets (generally known as "tubing") did provide evidence-based conclusions supporting the safety of preparing I.V. bags in advance of one hour. Stedman et al. researched the issue in a busy operating suite for five weeks. They collected 125 samples from five once-a-week 37 pre-spiked I.V. bags that yielded 250 specimens. Their results showed there was no culture growth in any of the specimens within 24 hours of I.V. bags being pre-spiked (*Anesth Analg* 2017;124:1564-8). Furthermore, Brock-Utne et al. evaluated pre-spiked normal saline and lactated Ringers solution with dextrose stored in a nonsterile anesthesia workroom and found no bacterial or fungal growth up to nine days after spiking A (*Infect Control Hosp Epidemiol* 2018;39:1029-30). These findings were further confirmed by Haas et al., who found no difference in contamination rates between I.V. fluid bags spiked in a conventional perioperative environment versus under an ISO 5 hood. The Haas study investigated the degree of bacterial growth in which samples were obtained from spiked I.V. fluid bags at the time of spiking and one, two, four, and eight hours after spiking (*Am J Infect Control* 2017;45:448-50). No bacterial growth occurred in any of the 80 bags of lactated Ringers I.V. solutions sampled. This study demonstrated that lactated Ringers I.V. bags do not support any bacterial growth for up to eight hours after spiking.

In order to assist our members with guidelines on timeframes of sterile I.V. administration, ASA released the Statement on Intravenous (IV) Fluid Bag Spiking, approved by the House of Delegates in 2022 (asamonitor.pub/3IwsH2Q). The statement notes that "Based on our understanding of the definitions and guidance put forth by the [Food and Drug Administration] and USP, as well as the available evidence in the published literature to date, not substantiating any risk of infection or contamination, spiking I.V. fluid bags and using them within 24 hours for surgery/procedure appears to be an appropriate and safe practice" and "during the process, aseptic technique should be followed, and appropriately trained anesthesia technicians (or anesthesiologists) should perform the task to ensure sterility."

Despite the scientific evidence, the interpretation of The Joint Commission was unchanged until the USP revised Chapter <797> in November 2022. Through the advocacy of ASA, the USP revised Chapter <797> to exclude the preparation of I.V. solutions from the rules pertaining to compounding, thus eliminating all compounding restrictions, including the "one-hour rule" (asamonitor.pub/3Zlzrat). These revisions include a clear distinction between administration and compounding, and effectively end the one-hour rule for medications and I.V. fluid preparation and administration. Within this revised guidance, the USP made clear that medication administration is officially outside the scope of Chapter <797>.

As of this article, The Joint Commission has no specific requirement regarding pre-spiking of I.V. bags. They now recommend that each accredited organization have guidance within their policies on medication and I.V. fluid preparation and administration. Their new guidance states:

"Organization policies and procedures, staff education/competencies should also consider:

- Product and device manufacturer's instructions for use
- Evidence-based guidelines for safe administration practices
- Applicable law and regulation."

It is crucial that hospitals and other facilities develop a local policy with respect to I.V. solution spiking that The Joint Commission's surveys can address.

The revisions to Chapter <797> as well as the ASA's statement on I.V. fluid bag pre-spiking can help define local policies. The changes also allow for the much needed time to prepare in advance for the safe and appropriate care for patients requiring emergency care, not only in the ORs but in remote anesthetizing locations as well. The changes alleviate the anxiety and confusion that anesthesiologists have faced due to the restrictive one-hour rule and will help increase efficient use of resources while minimizing OR costs and waste. Most importantly, the new regulatory environment on this issue will allow for safe and timely patient care in the face of unexpected emergencies.

Developing clear policies institutionally that support both patient safety and anesthesiologists' workflows will be critical and will need to be produced for review by The Joint Commission during a survey. Educating department members on relevant medication preparation and administration protocols that are evidence-based and manufacturer-guided will provide the basis for a high-quality, safe, and efficient OR (as well as safer remote location environments). These policies are best developed by partnering with hospital administrators and pharmacists and reviewing applicable federal and state regulations to establish the best local organizational policies. ■

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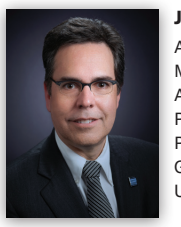

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