Culture Results of Pre-Spiked IVs and IV Tubing Indicate That USP 797 Regulations for Pre-Spiked IVs Should Be Revised

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Introduction: Emergency OR cases require a rapid response from anesthesiologists. While it is important in an emergency situation to have the OR ready with necessary medications and IVs prepared, regulatory agencies have instituted policies that in essence preclude maintaining setups such as pre-spiked IV solutions. USP 797 regulations, which govern JCAHO, CDC, and OSHA regulations, specifically state that “opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products … shall be used within 1 hour if opened in worse than ISO Class 5 air quality; and any remaining contents must be discarded.” Thus, anesthesiologists are conflicted between being prepared for emergency cases and abiding by regulations requiring that IVs not be pre-spiked for over an hour prior to use. As patients’ lives are at stake, we wanted to determine if there is a scientific basis for this regulatory requirement by culturing IV setups at 24, 48 and 72 hours after initial assembly.

Methods: Two versions of pre-spiked IV setups were assembled in the anesthesia workroom by anesthesiology technicians and flushed so they were ready for immediate use. One setup had a normal infusion set, and the other set had blood transfusion tubing. Both included 1 liter lactated ringer (LR) bags with stopcocks and extension tubing attached. Two sets of each type were made for a total of four IV fluid sets. Our Infection Prevention and Control Division performed both bacterial and fungal cultures of these prepared IV solutions at 24, 48 and 72 hours. Cultures included samples obtained from the IV bag as well as from the IV tubing.

Results: A total of 48 microbiologic cultures were obtained-- one fungal and one bacterial culture from both the IV bag and the IV tubing from the four IV sets at 24, 48 and 72 hours. All cultures were negative.

Conclusion: Current regulations that pre-spiked IVs have to be used within one hour place a significant burden on personnel preparing ORs for emergency procedures, and this places patients at risk as set up time can be better allocated to resuscitating or inducing the patient. Given the fact that all cultures were negative up to three days after preparation, we suggest that regulations be appropriately adjusted to enable anesthesiologists a reasonable time frame for preparing ORs for emergencies.