Is It Possible to Follow Regulatory Guidelines and Still Safely Care for Patients in Emergency Settings?

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Date for publication: July 16th

The USP 797 guidelines are applicable to all medications prepared in the operating room, including our arterial line and intravenous line setups. The guidelines state that for all commercial products prepared outside an environment such as a laminar hood (maximum of 100 particles per cubic foot) need to be either utilized or discarded within 1 hour if kept at room temperature.[1] This is contrary to the Healthcare Infection Control Practices Advisory Committee guidelines, allowing the same setup to be utilized for 4 days before it has to be replaced if it is connected to a patient.[2] Naturally, the seeming contradiction in the regulations can lead to frustration for care providers. Is it really safe to continue using intravenous tubing for 4 days if the setup has a high risk for contamination 1 hour after preparation when started at bedside? Is it feasible to start all intravenous setups and arterial setups under a laminar hood for all patients in a large tertiary hospital? Is there any evidence for these guidelines?

In trauma, this brings up another common scenario. The intravenous line is our medium for giving blood and medications to resuscitate and care for our patients. It is impossible to predict when a patient is rolling into the operating room so an intravenous line can be setup in advance but still within the last hour. In the past year, I have asked members of the Trauma Anesthesiology Society and colleagues at other institutions how they met the regulatory guidelines for intravenous setups for the traumatically injured patient crashing back to the operating room. The only solution was to create the setup after the patient was in the operating room, while the anesthesiologist is concurrently managing the airway, assessing the patient's status and injuries, and beginning resuscitation. To make matters worse, patients come in even after "business" hours when staffing is short and some resources may not be as readily available. One individual confided that he had even witnessed an air embolus caused by intravenous tubing not being completely de-aired before the tubing had been connected to the patient.

The solution UF Health implemented was published this past March in *Anesthesia & Analgesia*.[3] For emergency cases, arterial line and intravenous setups are prepared by the pharmacy under a laminar hood. When they are used, a pharmacy technician prepares a replacement so that UF Health can accommodate the next critically ill patient that comes to the operating room. These setups can be kept in the operating room at room temperature for 48 hours before the USP 797 guidelines state that they are at high risk for contamination and should be discarded.[1] Barriers to implementation were training the pharmacy technicians how to prepare the setups and educating anesthesiology providers on reserving the setups for emergency cases.[3]

The questions left unanswered are: "Does it matter what the fluid the setup is created with?" and "How long are the setups really good for?" In response, I took five arterial line setups that had been kept at room

temperature for 8 weeks and I aspirated 30 mL off the tubing and 5 mL from the normal saline bag, and I cultured them. I also took five intravenous line setups that had been kept at room temperature for 8 weeks and I aspirated 30 mL off the tubing and 5 mL from the plasmalyte bag and I cultured them. The intent was to have a pilot study to perform a power analysis for additional studies. We found that even after being kept for 8 weeks (long after the recommended period for discarding), only one of the arterial setup bags grew 1 colony per milliLiter, and all the arterial line tubing was sterile. However, we found that the tubing of one of the plasmalyte intravenous setups had too numerous colonies to count. This is probably because plasmalyte has a pH of about 7.4 and a potential carbon source to promote bacterial growth. Based on this, I would recommend that all emergency setups be created with normal saline to help prevent bacterial colonization and growth.

Acknowledgements

The author would like to thank Nik Gravenstein. Without his mentorship and desire for intellectual scholarship, this article would not be possible.

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