

July 24, 2018

L. Silvia Muñoz-Price, M.D., Ph.D.
Medical College of Wisconsin
9200 W Wisconsin Ave
Milwaukee, WI 53226
smunozprice@mcw.edu

RE: Request for ASA Support: SHEA Expert Guidance: Infection Prevention in the Operating Room Anesthesia Work Area

Dear Dr. Muñoz-Price:

The American Society of Anesthesiologists (ASA) appreciates the opportunity to work with the Society for Healthcare Epidemiology of America (SHEA) on its *Expert Guidance: Infection Prevention in the Anesthesia Work Area* document. We agree that this guidance has the potential to improve the quality of care delivered by anesthesiologists and other anesthesia personnel and to reduce risks to patients caused by cross-contamination in the anesthesia workspace.

Under its procedures for documents drawn up by external organizations with participation of an ASA representative, ASA offers a statement of support with qualification for this Expert Guidance.

The ASA qualification pertains to the section referencing USP <797>, specifically, the “one-hour rule” for medications not drawn up under conditions specified in ISO Class 5. ASA does not believe, when drafted more than ten years ago, that USP <797> adequately considered acceptable practices that take place in the operating room, namely the need and appropriateness of reconstituting or drawing up into syringes, medications that are essential to the delivery of anesthesia care, especially for medications that may be needed in an emergency. The time urgency of anesthesia care does not permit all medications used in the operating room to be prepared in an on-demand model by the hospital pharmacy under ISO Class 5 conditions.

ASA has worked with USP for the past ten years to modify the requirements of USP <797>. Earlier drafts of revisions to USP <797> have incorporated ASA’s concerns and recommendations. USP <797> is still in revision, with another draft due to be made public in late July 2018. We expect that draft to confirm what we consider acceptable and safe anesthesia practice in the operating room regarding medications. Unfortunately, the finalization of these draft changes will not occur until late 2019, well after publication of this guidance and nearly twelve years after the current USP statement was published.

Therefore, we recommend that Guidance section B9, lines 2-4 include the following statement:

“At the time this manuscript was written, United States Pharmacopeia (USP) Chapter <797>, published in 2008, recommends that the use of provider-prepared sterile injectable drugs commence within 1 hour of preparation. However, the revision of USP Chapter <797> which will go into effect in December 2019 is expected to distinguish between compounding (combining, admixing, repackaging) versus administration (injecting, infusing) of medication, the process

that typically takes place in an operating room. If published as expected, these changes will require modification of this Expert Guidance.”

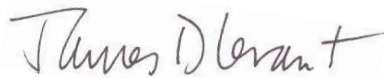
Finally, while not a qualification per se, ASA calls attention to the Guidance’s recommendation for high-level disinfection or sterilization of reusable laryngoscope handles. We recommend that the recommendation in B1 include the statement,

“This recommendation will likely require the use of single-use handles until such time as manufacturers make available reusable handles that have the ability to more easily undergo routine high-level disinfection and sterilization.”

Inclusion of this statement will better assist anesthesiology departments and groups in making needed changes in the facilities where they work.

As it has in the past, ASA stands ready to work with USP, SHEA, and others to improve patient safety, especially regarding infection prevention, while recognizing the practical limits of some recommendations.

Sincerely,

A handwritten signature in cursive script that reads "James D. Grant".

James D. Grant, M.D., M.B.A., FASA
President, American Society of Anesthesiologists

cc: Eve Humphreys, M.B.A., CAE, Chief Executive Officer, SHEA
Valerie Deloney, SHEA Consultant