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Letter to the Editor

Updates to our web-based infection prevention data toolkits

Dear Editor:

We would like to thank the readership for their interest in 2 of our recent manuscripts, each outlining free, open-source, web-based tools to support data needs of infection preventionists and health care epidemiologists.[1,2] Recently, 2 changes have been made to the applications that may impact individuals who use these tools. First, all of our applications have been merged into 1 toolkit, now called "IPStat." We hope this will facilitate ease of use of each application, and will simplify future additions. Second, and more important, owing to constraints on the prior server, the web address of the tool has moved. Those interested can now access IPStat at the following web address: http://capo.ctrsu.org:3838/shiny/ipstat/.

As always, no data are saved, stored, or otherwise eavesdropped upon by these applications or anyone on our study team. We feel strongly that the intense data needs of the practitioner can be simplified so everyone can get back to their critical patient safety efforts. We hope these free tools can help.

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Response to the letter to the editor regarding "Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists"

To the Editor:

Thank you for the opportunity to comment on and discuss some of the questions posed by Gase et al[1] regarding the ultrasound use survey. Ultrasound use is 1 of the fastest growing procedures in health care, across virtually all settings and departments, so continued dialogue and practice investigation are important parts of our shared patient safety priorities.

This response will lay out in logical detail the application of the Spaulding Classification to ultrasound guided procedures, as well as address other questions from Gase et al.[1]

Gase et al[1] then requested clarification on the guidelines used to categorize ultrasound procedures under the Spaulding Classification and Figure 2[2] from the survey report. The authors write, "The figure cites CDC, AIUM and AAMI recommendations as the source [the figures provide algorithms for decision-making]. However, it is not clear that those three organizations intended to support this level of processing for these low risk uses of ultrasound probes."[1] The assertion that these probes are low risk is not supported by any specific evidence, and, as described below, they are likely to be considered high-risk items by Spaulding. Although we do not know the intent of those organizations (Centers for Disease Control and Prevention, American Institute of Ultrasound in Medicine [AIUM], and Association for the Advancement of Medical Instrumentation [AAMI]), relevant statements from those guidelines and recommendations shown below cannot be discounted. In these guidelines, critical medical devices are those that "are introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body";[3] "enter sterile tissue or the vascular system" and "contact sterile body sites";[4] and "during use contact normally sterile tissue or body spaces."[5]

When applied to ultrasound, the consensus of these definitions is that an ultrasound probe that contacts sterile tissue (eg, the puncture site) during a guided procedure would be considered critical by Spaulding. The Spaulding Classification is a rational approach to reusable medical device processing that has been used for decades. By necessity, in many procedures, ultrasound probes must be in very

close proximity to the needle and puncture site so that the needle can be visualized. This is demonstrated in figures from a number of publications showing typical needle guidance technique in which there is direct contact between the probe and puncture site.[6-8]

The authors point out that the "CDC guideline does not list venous or arterial catheter placement procedures, or needle biopsies, as examples for semicritical or critical items."[1] This is true; however, guidelines based on Spaulding do not exhaustively list all examples of semicritical or critical items or procedures. New procedures and new devices continue to enter clinical use, so enabling and using a standard set of criteria are vital if we are to ensure consistent, reliable, and reproducible approaches to disinfection. As reported by the respondents to the survey, ultrasound use is pervasive and without a framework to follow; therefore, it is reasonable to anticipate decision errors and inconsistent practice.

It is also noteworthy to mention that US Food and Drug Administration guidelines specifically address biopsy probes as either semicritical or critical and also indicate that use of a sheath does not replace sterilization or high-level disinfection of the probe: "For clinical applications of a semi-critical or critical nature (e.g., intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally marketed probe sheaths. Note that the use of sheaths does not change the type of reprocessing that is recommended after each use."[4] Likewise, probes "used in semi-critical applications should be sterilized between uses whenever feasible, but high level disinfection is minimally acceptable. In addition, the use of a sheath is recommended for every semi-critical use of the probe. Critical devices should be sterilized and the use of a sterile sheath is recommended. Please note that the use of sheaths does not change the type of processing that is recommended for the transducer . . . Sheaths can fail during use and the level of resulting contamination may not be easily visible."[4]

Similarly, the CDC states that sheaths cannot replace sterilization or high-level disinfection of ultrasound probes: "Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail."[3]

> Although federal agencies and national standards provide detailed recommendations, user groups such as the AIUM also offer their perspective. Gase et al[1] rightly point out that the AIUM guidelines currently recommend low-level disinfection with the use of a sheath for percutaneous procedures. However at the time of submission and acceptance of the survey manuscript, the AIUM recommended high-level disinfection of these probes as follows: "Although internal ultrasound probes are routinely protected by single-use disposable probe covers, leakage rates of 0.9% to 2% for condoms and 8% to 81% for commercial probe covers have been observed in recent studies . . . These probes are therefore classified as semi-critical devices . . . For maximum safety, one should therefore perform high-level disinfection of the probe between each use and use a probe cover or condom as an aid to keep the probe clean. For the purpose of this document, 'internal probes' refers to all vaginal, rectal, and transesophageal probes, as well as intraoperative probes and all probes that are in contact with bodily fluids/blood or have a remote chance to be in contact with dry/cracked skin and body fluids, including blood."[9]

Ultrasound probes used for needle biopsies and venous or arterial catheter placement could contact bodily fluids or blood, which means under the original guideline they would require high-level disinfection. The current version of the AIUM guidelines, released March 25, 2018, now recommend low-level disinfection which is inconsistent with Spaulding and the FDA guideline for biopsies. The current version does include an important caveat, however: *"If there is reason to believe that the probe cover may become compromised, the probe must be high-level disinfected prior to the procedure."*[10]

As mentioned previously, CDC and US Food and Drug Administration guidelines contraindicate the use of a sheath in place of high-level disinfection because of the risks of sheath failure. The risk of accidental sheath puncture is highlighted by the rate of needle stick incidents in radiology: a survey of interventional radiologists found 25.4% sustained a needle stick injury in the previous year, and 75.5% of these were the result of operator error, demonstrating that it is difficult to always control the needle appropriately in these and other similar procedures.[11]

The authors are "concerned at the immense practice change implications that high level disinfection/sterilization for low risk probes would require." According to the manuscript, wide use of high-level disinfection or sterilization for these probes was reported in the study (Fig 2A)[2]. A total of 59% of respondents indicated probes used for biopsies undergo high-level disinfection/sterilization at their facilities; the rate for injections, central line placements, and peripheral line placements was 39%, 33%, and 22%, respectively. Although practice change may be difficult for some settings, the range of respondents stating that they already conduct high-level disinfection or sterilization in line with Spaulding demonstrates that implementation is feasible. Also of note, international guidelines from Europe, the United Kingdom, Canada, and Australia recommend high-level disinfection with the use of a sterile sheath for external probes used in vascular access, biopsies, and other percutaneous interventions.[12-16]

The survey focused on understanding practice and decision-making, and the manuscript pointed out inconsistencies in use of Spaulding criteria as well as application of existing guidelines and recommendations for a variety of ultrasound uses. The authors indicated confidence that outbreaks have not been reported when those guidelines and the Spaulding framework have not been used; therefore, no problem exists. This assertion conflicts with the foundation of infection prevention and control practice, where, in the absence of zero infection, study continues so that undiscovered risk factors may be identified. Many have heard the expression "*the absence of evidence is not evidence of absence.*" The authors continue to have confidence in the need for a process that enables consistent, valid, and reproducible practice. If the Spaulding Classification is not applicable, then an alternative should be proposed and studied.

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Survey responses to policy changes—Overextended consequences

To the Editor:

Carrico et al[1] set out to "define the current state of ultrasound use in United States (US) health care facilities" and to "identify existing practices regarding decontamination and disinfection of the ultrasound probes." However, instead of epidemiologically assessing the current state, the authors essentially measured the knowledge of the participating infection preventionists and their awareness of cleaning, disinfection, and sterilization practices at their individual organization. Although this is valuable information and highlights the need for increased collaboration and education, we are concerned with the assumptions this work is based on and the resulting conclusions and recommendations.

The authors highlight deficiencies in properly adhering to established guidelines and protocols for nondedicated patient care equipment. The flow diagram in Figure 2A indicates the need for high-level disinfection or sterilization for an array of ultrasound probes, including those used for minimal skin punctures (eg, central line insertion or needle biopsies). The figure cites Centers for Disease Control and Prevention (CDC),[2] American Institute of Ultrasound in Medicine,[3] and Association for the Advancement of Medical Instrumentation[4] recommendations as the source. However, it is not clear that those 3 organizations intended to support this level of processing for these low-risk uses of ultrasound probes.

When describing the Spaulding criteria for semicritical items, the CDC Guideline for Disinfection and Sterilization in Healthcare Facilities focuses primarily on endocavitary instruments that contact a mucous membrane. This includes respiratory therapy and anesthesia equipment, some "endoscopes, laryngoscope blades, esophageal manometry probes, cystoscopes, anorectal manometry catheters, and diaphragm fitting rings." The CDC guideline does not list venous or arterial catheter placement procedures, or needle biopsies, as examples for semicritical or critical items.[2]

Further, the American Institute of Ultrasound in Medicine recommendations cited by the authors states specifically that "Interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement, such as vascular access, thoracentesis, paracentesis, arthrocentesis, and pericardiocentesis, lumbar puncture, US [ultrasound]-guided regional/local anesthesia, and other percutaneous procedures should be cleaned using low-level disinfectants and be used in conjunction with a single-use sterile probe cover."[3]

The Association for the Advancement of Medical Instrumentation ST58 does not provide a specific recommendation regarding how to classify ultrasound probes. Rather, it details the safe and effective use of chemical sterilants and high-level disinfectants in health care facilities.[4]

We are concerned at the immense practice change implications that high-level disinfection/sterilization for low-risk probes would require. To our knowledge, there are no examples in the literature implicating external probes (as used with central venous catheter insertion) in outbreaks or transmission of disease when equipment was sheathed with a sterile cover and sterile ultrasound gel utilized. Considering that central line–associated bloodstream infection surveillance is 1 of the highest priorities for most infection prevention departments, we believe that if such outbreaks were happening, it would have been noted by our professional or regulatory/governmental agencies to which the primary outcome (central line–associated bloodstream infections) are routinely reported.

Finally, we would like to call attention to the fact the funding support for the completion of this survey and manuscript preparation was provided by a company actively working to set "the new standard of care globally for ultrasound probe reprocessing."[5] Although this does not discount the work completed by this group, it is another point of caution to ensure that this survey does not become evidence