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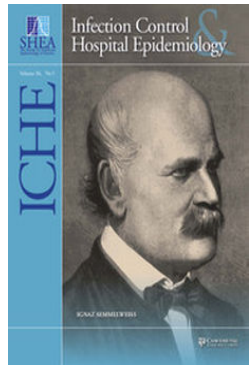

Intra-cavitary Ultrasound Probes: Cleaning and High-Level Disinfection Are Necessary for Both the Probe Head and Handle to Reduce the Risk of Infection Transmission

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COMMENTARY

Intra-cavitary Ultrasound Probes: Cleaning and High-Level Disinfection Are Necessary for Both the Probe Head and Handle to Reduce the Risk of Infection Transmission

Michelle J. Alfa, PhD, FCCM

(See the article by Ngu et al, on pages 581–584.)

Ultrasound devices are frequently used imaging tools that facilitate diagnosis of various abnormal conditions. Some ultrasound probes are used only on intact skin (requiring only cleaning and low-level disinfection) and some are designed to be introduced during surgery into sterile body sites (requiring cleaning and sterilization), whereas intra-cavitary ultrasound devices (ICUDs) are introduced into a variety of body orifices including vagina, rectum, trachea, etc. Because ICUDs contact mucosal surfaces, they are classified by North American guidance documents[1,2] as "semi-critical" devices requiring cleaning and a minimum of high-level disinfection (HLD). All of these ICUDs have 3 basic components: (1) the ultrasound transducer "head," which is the portion that generates the ultrasound signal; (2) the "handle," which is the portion that is used to position the device; and (3) the electrical cord, which attaches to a power source for generation of the ultrasound signal. The head portion of an ICUD contacts the patient's mucous membranes. The handle portion does not directly contact the patient but does contact the gloved hands of the technician during positioning of the probe. The handle portion of the ICUD is somewhat controversial because technically it should not have direct contact with the cavity mucous membrane (ie, noncritical component), but functionally it can get spattered with mucous membrane secretions so should be considered a semicritical component. The electrical cord does not directly touch the patient nor is it used for positioning the probe head. The cord is non-immersible and would be considered a noncritical component that should receive at least low-level disinfection. To further compound this issue, some ICUD manufacturers state that the handle portion is non-immersible. Because the ICUD is not entirely immersible, there is confusion about how to properly reprocess these devices.

The study by Ngu et al[3] in this issue of the journal reported that after patient use as well as cleaning and HLD there were 80.5% and 5.3% of vaginal ultrasound device (VUD) handles that were contaminated with microorganisms when the handle did not or did receive HLD, respectively. Although this study considered only nonfastidious bacterial organisms and did not assess viral contaminants, it does raise an important issue regarding the need to clean and decontaminate the handle and not just the probe head of VUDs. This is particularly relevant when one considers the recent review and meta-analysis by Leroy[4] indicating that the pooled prevalence of contamination on reprocessed endovaginal/rectal ultrasound probes (with or without use of sheaths) was 12.9% for bacteria and 1.0% for viruses. The study by M'Zali et al[5] documented that despite use of a protective sheath on the VUD head and quaternary ammonium compound for disinfection of the probe, VUDs remain heavily contaminated because 86% of 100 probes evaluated had bacteria. Furthermore, 7% and 2% of the probes had nuclease-resistant human papillomavirus (HPV) and *Chlamydia trachomatis* genetic material, respectively (nuclease-resistant genetic material suggests it is from intact virus and not just noninfectious genetic material alone). The potential role of VUDs as possible vectors of infection transmission despite the use of sheath covers has been raised by a number of researchers. [5–8]

In Canada and the United States the current reprocessing guidelines[1,2] indicate that reusable ICUDs that contact mucosal surfaces (with or without a sheath cover) should minimally receive HLD and those that contact sterile body sites (with or without a sterile sheath cover) should be sterilized. Despite these guidelines, there are often no formal protocols in place in healthcare facilities to ensure proper cleaning and disinfection of ICUDs.[7,8] Indeed, the study by Sanz et al[7] documented that there was visible blood on 1 of 10 VUDs that were ready for next patient use in the emergency department.

The concern about residual contaminants on ICUDs and in particular HPV residuals on VUDs is further compounded by the recent data reported by Meyers et al.[9] They were the first to report that HPV type 16 was resistant to commonly used HLDs such as glutaraldehyde and *ortho*-phthalaldehyde. Indeed, they recommended that policy changes are needed concerning the disinfectant used for VUDs. So what exactly should be done considering the issues raised by Ngu et al,[3] Meyers et al,[9] M'Zali et al,[5] and Leroy[4] ?

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It is clear from the Canadian Standards Association[1] and Centers for Disease Control and Prevention[2] guidelines that ICUDs should receive cleaning followed by a minimum of HLD. Furthermore, the data provided by Ngu et al[3] supports the need for the handle of VUDs to be cleaned and disinfected in the same manner as the VUD head. This approach for the handle also makes sense from an infection prevention and control perspective because any microbial contaminants on the ICUD handle would act as a reservoir that could easily be transmitted to the probe head (directly if unsheathed), to the protective sheath during positioning, or directly to the patient via caregivers' gloved hands that grasp the handle during the procedure.

The dilemma then becomes this: "What HLD process should be used to ensure both the VUD head and handle are high-level disinfected?" If the manufacturer's instructions for use do not allow for immersion of the handle portion of the VUD, then one can use ultraviolet C light[6] or nebulized hydrogen peroxide vapor,[3,10] which both have been reported as effective for VUD disinfection. However, in some countries ultraviolet C light may not yet be approved as a means of HLD for VUDs. If the manufacturer's instructions allow for immersion of the handle as well as the probe, then use of long soak containers (or some automated probe disinfection systems) allows for immersion of the handle as well as the probe and use of traditional chemicals approved for HLD (providing the disinfectant manufacturer has validated that there is materials compatibility with the VUD). The liquid chemical immersion approach requires access to tap water to rinse off the residual HLD chemical as well as workplace safety measures to protect workers from fumes (where applicable). Furthermore, the choice of chemical for HLD of VUDs needs to reflect the recent data showing that neither glutaraldehyde nor *ortho*-phthalaldehyde can effectively kill HPV16.[9]

In summary, Ngu et al's publication[3] raises important issues related to current guidelines and healthcare practices for the reprocessing of VUDs as well as other ICUDs. In light of recent publications showing microbial survival on VUDs when non-HLD methods are used, as well as the inadequacy of HPV killing by some chemicals commonly used for VUD HLD, it is imperative that guidelines and healthcare policies are updated to ensure that the VUD handle as well as the probe head are adequately cleaned and disinfected after every patient-use. Although Ngu et al's article[3] is directed at vaginal ultrasound probes, the concepts are also relevant to other types of intra-cavitary ultrasound probes.

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