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● *Technical Note*

GUIDELINES FOR CLEANING TRANSVAGINAL ULTRASOUND TRANSDUCERS BETWEEN PATIENTS

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Abstract—The purpose of this article is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes. These recommendations are also applicable to transrectal probes. (E-mail: Jabramowicz@bsd.uchicago.edu) © 2017 World Federation for Ultrasound in Medicine & Biology.

Key Words: Infection control, Ultrasound, Transducer cleaning.

INTRODUCTION

Transvaginal ultrasound (TVUS) transducers (also designated as *endovaginal probes* in some countries) are routinely used in clinical obstetrics and gynecology. Strict decontamination is essential between patients because these transducers may come into contact with mucous membranes. The main pathogens of concern are human immunodeficiency virus (HIV), cytomegalovirus (CMV), human papillomavirus (HPV), enteric gram-negative pathogens (*e.g.*, *Escherichia coli*, *Klebsiella* spp.), for both transvaginal and transrectal ultrasound examinations. In addition, specific concerns include gonorrhea and syphilis for TVUS and *Clostridium difficile* for transrectal ultrasound (Leroy 2013).

CLASSIFICATION OF MEDICAL DEVICES ACCORDING TO INFECTION RISK

Medical devices may be classified according to the infection risk they present. Systems used for this purpose include the original 1957 classification: non-critical, semi-critical and critical (Spaulding 1957), also referred to as low risk, medium risk and high risk (McDonnell and Burke 2011). Accordingly, cleaning of these instruments

between uses depends on the aforementioned classification status and ranges from simple wiping to sterilization.

Non-critical devices pose the lowest risk to patients, because the only contact is with intact skin (such as abdominal probes). Low- or intermediate-level disinfection is recommended. Most bacteria (but not bacterial spores) and fungi, as well as certain types of viruses, including human immunodeficiency virus (HIV), will be eradicated. If added decontamination is desired (for a wider range of viruses and mycobacteria), additional use of disinfectants, such as alcohol, aldehyde, phenolic and quaternary ammonium compound-based disinfectants, is recommended (McDonnell and Burke 2011). This represents mid-level disinfection (inactivation of bacteria, most viruses, most fungi, *Mycobacterium tuberculosis* and some bacterial spores).

Semi-critical devices are those that pose a higher risk because of contact with non-intact skin or mucous membranes (as is the case with TVUS probes). High-level disinfection with destruction/removal of all microorganisms except bacterial spores is recommended using various chemical components (see details below).

“*Critical devices*” pose the highest risk. They are used in sterile body areas, such as the intravascular space. Sterilization of these devices is imperative.

Transvaginal ultrasound transducers are categorized as semi-critical or medium risk (Leroy 2013). The real risk of infection associated with TVUS transducers

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used without a protective covering or decontamination is unknown. No case of related specific infection (cross-contamination between patients) has been reported in the literature, but ultrasound transducers can become contaminated with bacterial pathogens and, hence, are a potential vector for transfer of microorganisms (Fowler and McCracken 1999; Ohara et al. 1998). It is the recommendation of experts that specific measures be taken to avoid such an occurrence (Westerway et al. 2014). Given the fact that transducers should routinely be encased in a disposable probe cover, the risk may be considered less critical. However, leakage rates of 0.9%–2% for condoms and 8%–81% for commercial probe covers have been reported (Chalouhi et al. 2009; Rooks et al. 1996). These are relatively old studies and numbers may be different today, but the only more recent publication indicated a 9% risk of condom perforation in patients undergoing transrectal biopsy under ultrasound guidance (Masood et al. 2007), and recent data comparing the two types of covers are not available. The presence of human papillomavirus has been reported after low-level disinfection (Casalegno et al. 2012). Therefore, high-level disinfection of the transducer between uses is required. A new condom or probe cover should be applied after each use of the instrument, for a new patient (American Institute of Ultrasound in Medicine [AIUM] 2009). Review of clinical practices reveals various protocols, many of which are considered inadequate (Gray et al. 2012). Often, failures in eradication of microorganisms result from poor education and non-optimal adherence to reprocessing guidelines or protocols (Ofstead et al. 2010). An additional consideration is the fact that the transducer handle and cable can also become contaminated and may also require disinfection (Alfa 2015) (see below).

RECOMMENDATIONS

After a patient has been examined, and before the TVUS transducer is used in the next patient, the following procedures should be performed: (i) removal of the transducer cover, (ii) transducer cleaning, (iii) transducer disinfection, and (iv) application of new transducer cover.

After removal of the transducer cover, the transducer is cleaned. Running water is usually sufficient to remove any residual gel or debris from the transducer. Additionally, a damp soft cloth with a small amount of mild non-abrasive liquid soap (such as household dishwashing liquid) may be used, followed by running water. A paper towel or soft cloth should be used to dry the transducer. The additional use of a high-level disinfectant will ensure further reduction in microbial load, and because of potential leakage of the protective sheath (see above), high-level disinfection is recommended. The disinfection

method may need to be adapted to local conditions, with the assistance from infection control authorities. High level disinfectants recommended by various ultrasound manufacturers include:

- Glutaraldehyde 2.4%–3.2% products, such as Cidex (Advanced Sterilization Products, ASP, a division of Cilag International, a Johnson & Johnson company, New Brunswick, NJ, USA), Metricide (Metrex Research, Orange, CA, USA) and Procide (Medline Industries, Mundelein, IL, USA). Mode of action is powerful binding of the aldehyde to the outer cell wall of the organism. These products are sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal and has been found to achieve high-level disinfection in 20 min at 20°C and to be long-lasting and reusable for up to 14 days when monitored with CIDEX Solution Test Strips. These products have mostly been replaced by the next type of product.
- Non-glutaraldehyde agents such as Cidex OPA (*o*-phthalaldehyde). The mechanism of action of *o*-phthalaldehyde is similar to that of glutaraldehyde. It achieves high-level disinfection in 5 min at 20°C and has long-lasting efficacy (reusable for up to 14 days when monitored with CIDEX OPA Test Strips). The Advantages over the glutaraldehyde agents are its mild odor and its lack of a requirement for activation or mixing, thus reducing handling. Furthermore, it has low vapor pressure for minimal inhalation exposure risk.
- Chlorine dioxide, used extensively in the United Kingdom and Australia (Tristel Trio and Duo, Tristel Solutions Unit 1B, Snailwell, UK), acts as an oxidizing agent. It reacts with several cellular constituents, including the cell membrane of microorganisms and has sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal efficacy. Chlorine dioxide has been proven effective against microorganisms of concern in ultrasound, such as hepatitis B and C, HIV, human herpesvirus, simian virus 40 (surrogate of human papillomavirus), *Candida albicans*, *Aspergillus* spp., *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Bacillus* spp., *Clostridium difficile*, *Mycobacterium tuberculosis*, *Mycobacterium avium*, *Neisseria gonorrhoeae*, *Gardnerella vaginalis*, *Streptococcus agalactiae* and *Acanthamoeba castellanii* (one of the causative organisms of *Acanthamoeba* keratitis). The use is relatively simple with (i) a pre-decontamination wipe for gross contamination with a tissue impregnated with an enzymatic detergent; then (ii) use of another wipe which is effective in 30 s against all organisms mentioned above; and (iii) a rinse wipe that is a sterile packed, non-woven tissue impregnated with de-ionized water. It has been reported to be very effective in high-level disinfection of flexible endoscopes (Coates 2001) and

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