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Guidelines

Recommendations for the Cleaning of Endocavity Ultrasound Transducers Between Patients

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ABSTRACT

The COVID-19 pandemic highlighted the importance of infection prevention and control measures for all medical procedures, including ultrasound examinations. As the use of ultrasound increases across more medical modalities, including point-of-care ultrasound, so does the risk of possible transmission from equipment to patients and patients to patients. This is particularly relevant for endocavity transducers, such as trans-vaginal, trans-rectal and trans-oesophageal, which could be contaminated with organisms from blood, mucosal, genital or rectal secretions.

This article proports to update the WFUMB 2017 guidelines which focussed on the cleaning and disinfection of trans-vaginal ultrasound transducers between patients.

Introduction

This article proports to update the WFUMB 2017 guidelines which focussed on the cleaning and disinfection of trans-vaginal ultrasound transducers between patients [1]. Endocavity ultrasound transducers (also known as probes) are used to perform trans-vaginal (TV), trans-rectal (TR) and trans-oesophageal echocardiography. In all of these procedures, the transducer has the potential to come into contact with mucous membranes from the vagina, anal canal or oral cavity and so correct reprocessing/decontamination is essential to ensure the removal of microbial load and to prevent the transmission of pathogenic organisms between patients. Endocavity transducers with working channels or gas/water channels like those used for gastro-intestinal and endobronchial ultrasound are not specifically covered in these recommendations. They require machine cleaning and disinfection like endoscopes.

Pathogens of concern include human immunodeficiency virus, *cytomegalovirus*, human papillomavirus, enteric gram-negative pathogens such as *Escherichia coli* and *Klebsiella* sp, methicillin-resistant *Staphylococcus aureus* (one of the five most common causes of health care-acquired infections), *Pseudomonas aeruginosa* (common component of biofilms, highly resistant to antibiotics), *Mycobacterium avium* (opportunistic pathogen affecting immune compromised patients), *Clostridium difficile,* vancomycin-resistant *Enterococcus* in addition to gonorrhoea and syphilis.

Classification of medical devices according to infection risk

Reusable medical devices are classified according to the potential infection risk they present. Systems used for this purpose include the original 1957 Spaulding classification: non-critical, semi-critical and critical, also referred to as low risk, medium risk and high risk [2,3]. Accordingly, cleaning of these instruments between uses depends on the aforementioned classification status and ranges from wiping to ‘sterilisation’.

Non-critical devices, such as abdominal transducers, pose the lowest risk to patients, as the only contact is usually with intact skin. Low-level disinfection is recommended. Most bacteria (but not bacterial spores) and fungi, as well as certain types of viruses, including human immunodeficiency virus, will be eradicated.

Semi-critical devices are those that pose a higher risk because of contact with non-intact skin or mucous membranes. All endocavity transducers are classified as semi-critical or medium risk devices requiring high-level disinfection (HLD) which should eliminate all microorganisms except for high numbers of bacterial endospores [4]. Joint

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Commission International and other equivalent organisations mandated the use of HLD of endocavity ultrasound transducers during their accreditation reviews.

Critical devices pose the highest infection risk as they are used in sterile body areas, such as the intravascular space. As the majority of ultrasound transducers cannot undergo traditional 'sterilisation', it is imperative that correct HLD is undertaken.

Transducer cover use

The risk of infection associated with endocavity transducers used without a protective covering or incorrect level of decontamination was examined by Westerway and Basseal [5]. Specific cases were discussed which highlighted that ultrasound transducers can become contaminated with bacterial pathogens and, hence, are a potential vector for transfer of microorganisms from patient to patient. The presence of human papillomavirus has been reported after low-level disinfection [6]. Given that endocavity transducers should routinely be encased in a disposable probe cover, the risk may be considered less critical. The quality of these covers, whether they be condoms or dedicated transducer covers varies significantly between countries, with a 2019 study by Basseal et al. [7] demonstrating a leakage rate for condoms from 0.4% to 13% and for commercial covers from 0% to 5%. A 2007 publication by Masood et al. [8] indicated a 9% risk of condom perforation in patients undergoing trans-rectal biopsy under ultrasound guidance. Therefore, high-level disinfection of the transducer used for endocavity procedures is required. Covers with pore sizes of less than 30 nm are recommended and a new probe cover should be applied prior to scanning each patient. Condoms are not sterile, nor are the majority of dedicated probe covers used for TV and TR examinations. To reduce the risk of contamination, it is recommended to use covers that are individually wrapped. Sterile covers should be used for all sterile ultrasound procedures.

Breaches in IPC measures are a result of poor education, lack of training and non-optimal adherence to reprocessing guidelines or protocols. Medical ultrasound societies and the Healthcare Infection Society are a good source for protocols for reprocessing of ultrasound transducers [9–11].

Recommendations

After a patient has been examined, and before the endocavity transducer is used on the next patient, the following procedures should be performed:

1. Removal and safe disposal of the used transducer cover.
2. Transducer cleaning to remove gross contaminants such as gel.
3. High level disinfection of the transducer and storage with a cover.
4. Application of appropriate new transducer cover prior to use.

After removal of the transducer cover, the transducer should be wiped with a tissue/cloth or placed under running water to remove any gross contamination, such as gel, that may prevent the disinfectant from contacting all surfaces of the transducer. Cleaning should be performed with an approved medical grade cleaning agent/product, ensuring all grooves and crevices are cleaned as any organic residue may bind and inactivate chemical disinfectants. A paper towel or soft cloth should be used to dry the transducer prior to the use of disinfectants which will ensure further reduction in microbial load.

There are several options for disinfecting an ultrasound transducer, which will need to conform with local regulations, with the assistance from infection control authorities. Globally, different markets have different regulatory bodies and approvals for various products; however, they share the same standards for compliance. It is essential that the manufacturers' instructions for use are followed, and that the disinfection product chosen is compatible with the transducer and is approved for use by relevant national regulatory authorities. There are many authorities with product recommendations. A list of approved disinfectants for reusable medical devices was issued by the International Organization for Standardization, the Centers for Disease Control and Prevention [12–14]. The labels on these various chemicals and the manufacturer's recommendations for cleaning endocavity probes should be consulted.

High-level disinfectants approved by ultrasound transducer manufacturers include

Glutaraldehyde 2.4%–3.2% products have a mode of action which is a powerful binding of the aldehyde to the outer cell wall of the organism. These products are sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal and have 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 solution test strips or similar. A 2016 update of the Centers for Disease Control and Prevention raised concerns of the occupational exposure risks associated with the use of glutaraldehyde products. Due to the potential toxicity, precautions are necessary when handling glutaraldehyde. These include adequate ventilation, personal protective wear (gloves, face/eye) and thorough rinsing before re-use of the transducer (see label for specific instructions). As a result of the possible risks, glutaraldehyde products have mostly been replaced.

Non-glutaraldehyde agents, such as peracetic acid/peroxyacetic acid and ortho-phthalaldehyde, are available as wet soaks and achieves high-level disinfection in 5–10 min (depending on manufacturer) at 20°C, has long-lasting efficacy and is reusable for up to 28 d when monitored with ortho-phthalaldehyde test strips. Care should be taken that the container used to soak the transducers is placed in a safe and stable position to avoid accidental spillage.

Chlorine dioxide is a highly effective biocide with well-documented sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal efficacy. Microbiocidal activity has been demonstrated in accordance with internationally recognised standards (EN, American Society for Testing and Materials [ASTM] and Association of Official Analytical Chemists [AOAC]). Literature indicates that chlorine dioxide causes the chemical disruption of cell walls and damage to inner cell membranes, the denaturing of proteins and the impairment of genetic material [15–19]. Chlorine dioxide has demonstrated efficacy against pathogens relevant to ultrasound examinations including hepatitis B virus, human papillomavirus type 16 and 18, *Candida albicans, Aspergillus brasiliensis, S. aureus* (including methicillin-resistant *S. aureus*), *P. aeruginosa, Bacillus* spp., *Clostridioides difficile* (formerly *Clostridium difficile*) and *Mycobacterium terrae* (surrogate for *M. tuberculosis*).

Chlorine dioxide acts as an oxidising agent and is used in ultrasound, ophthalmology, otorhinolaryngology (Ear, Nose, and Throat [ENT]), endoscopy, urology, women's health and cardiology. Chlorine dioxide is utilised in established products such as the Tristel Duo range that includes HLD and intermediate-level disinfectant foams, and the Tristel Trio Wipes System for HLD, some of which achieve sporicidal efficiency in as little as 30 seconds (Tristel, UK). This technology is compatible with the materials used for the production of endocavity ultrasound probes, and many probe manufacturers have validated the efficacy of the product on their medical devices according to ISO EN ISO 17664-1:2021, and included its use in their device's user guide or cleaning instructions.

Hydrogen peroxide is a widely accepted chemistry for low-temperature sterilisation of heat-sensitive reusable medical devices such as ultrasound transducers [20]. Hydrogen peroxide 7.5% solution works by producing destructive hydroxyl-free radicals. These attack membrane lipids, DNA and other essential cell components. Hydrogen peroxide is active against a wide range of microorganisms, including bacteria, yeasts, fungi, viruses and spores. Trophon technology (Nanosonics, Macquarie Park, Australia) was commercialised in 2009 and generates a fine 'sonically activated' hydrogen peroxide mist which enters the disinfection chamber in an automated and closed system for the HLD of ultrasound probes. The mist particles penetrate to reach areas on the probe

surface ensuring the entire surface has been high-level disinfected. The process is validated, probe compatible, efficient, environmentally friendly, traceable, quality-ensured and has been shown to systematically eliminate probe contamination in the clinical setting [21–23]. Trophon technology is effective against an extensive range of clinically relevant pathogens including multi-drug–resistant bacteria, blood borne viruses, human papillomavirus and bacterial endospores [22–26]. The technology meets acceptance criteria of internationally recognised EN, ASTM and AOAC consensus standards for validation of bactericidal, virucidal (enveloped and non-enveloped), fungicidal, mycobactericidal and sporicidal efficacy of chemical disinfection processes for medical devices [25,26]. The referenced studies (Johnson et al. [20], Ngu et al. [21], Ryndock et al. [23], Vickery et al. [24]; Becker et al. [25]; Buescher et al. [22]) were supported by grants from the manufacturer.

UV-C technology is another approach to disinfecting endocavity transducers. It works by emitting ultraviolet light in the 200–280 nm range, disrupting the DNA and RNA of microorganisms. When microorganisms absorb UV-C light, it forms thymine or uracil dimers, interfering with their ability to replicate. This disruption ultimately leads to the death of the microorganisms, making UV-C light an effective disinfection method for surfaces, air and liquids. It is commonly used in healthcare settings, water treatment, air purification and food processing for its germicidal efficiency.

Various manufacturers offer medical-certified UV-C disinfection devices for the HLD of ultrasound transducers, such as: the UV Smart D45 (the Netherlands), Germitec Chronos (France) and Lumicare One (Australia). After the transducer has been cleaned of visual contamination, it is exposed to UV-C light for between 75 and 180 s. Numerous studies have demonstrated the effectiveness of UV-C disinfection and reaching HLD against a wide range of microorganisms, including bacteria, viruses and spores [27–29]. It has proven to be effective in eliminating pathogens such as *C. difficile*, methicillin-resistant *S. aureus*, vancomycin-resistant *Enterococcus* and human papillomavirus. Ultrasound devices with channels are not suitable for reprocessing with UV-C. The availability of UV-C technology is dependent on individual national regulatory approval. As standardised test methods are developed, UV-C disinfection systems for ultrasound transducers are expected to meet the acceptance criteria of the published standards applicable to its intended application. Human exposure to UV-C light levels above recommended limits may cause erythema and keratoconjunctivitis.

Additional precautions

There may be lapses in training and lack of adherence to protocols regarding recommended methods of transducer cleaning and disinfection. The Centers for Disease Control and Prevention issued an alert regarding this specific issue [30].

1. It is important to remember that regular household detergent wipes and alcohol wipes are used by many practitioners but are not considered high-level disinfectants and may put patients at risk of infection as well as damage transducers.
2. Endocavity transducers should be covered with a barrier before use and latex allergy needs to be considered. The optimal choice is dedicated commercial probe covers that have been individually wrapped with sterile covers used for sterile procedures. If condoms are used for TV and TR ultrasound, they should be non-lubricated and non-medicated.
3. The ultrasound unit keyboard and the transducer handle and cables can become contaminated and also require regular cleaning with detergent wipes or low-level disinfection [30]. In addition, the transducer holder (if used) and the gel container should also be cleaned.

Conclusion

Reprocessing ultrasound transducers according to the manufacturer's instructions for use and in accordance with relevant national regulations is critical for patient safety. In addition to following the steps for reprocessing, users of ultrasound equipment should have access to infection prevention protocols, training in the use of their chosen disinfection methods and a safe working environment for the reprocessing of ultrasound transducers.

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Conflict of interest

The authors declare no competing interests.

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