The importance of infection prevention and control in medical ultrasound

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Abstract

Infection control and prevention is critical to delivering safe and high-quality care to patients undergoing sonographic procedures. In Australia comprehensive standards for reprocessing of ultrasound probes are based on the AS/NZS, TGA and ASUM recommendations. These standards align with the US Centers for Disease Control and Prevention recommendations. However compliance to these guidelines is not ideal and there exists an unmet need for refinement of the guidelines relating to specific factors in clinical sonography. Significant microbiological evidence exists reflecting the increased risk of infection transmission specifically through inadequately reprocessed ultrasound probes. Studies have reported > 80% of transvaginal ultrasound probe handles are contaminated with disease causing pathogens since handle disinfection is omitted from standard reprocessing protocols. Significantly, it was recently discovered that widely-used high level disinfectants referred to in guidelines are unable to kill HPV while it is becoming increasingly apparent that attention must be paid to the clinical sonography environment as a potential source of nosocomial pathogens.

Ultrasound probe reprocessing guidelines and standards are comprehensive however the challenge is in general awareness and effective implementation into practice. As future research in this area is performed, guidelines will need to be amenable to revision to provide patients with the best standard of care.

Keywords: Australian guidelines, disinfection, handles, HPV, infection control, ultrasound.

The need for infection prevention and control

Infection control and prevention is critical to delivering safe and high-quality care to patients undergoing sonographic procedures. Ultrasound is generally considered a relatively safe procedure when compared with radiation-based imaging techniques, however poor ultrasound probe reprocessing protocols and environmental disinfection methods may result in a risk of patient cross-infection.

In particular, endocavitary ultrasound and ultrasound procedures that involve contact with sterile tissues represent an opportunity for transmission of epidemiologically relevant pathogens with potentially severe consequences. While guidelines currently exist regarding ultrasound probe reprocessing, compliance varies and guidelines need to be updated to reflect the latest research in the area. In particular, human papillomaviruses have been shown to be resistant to some disinfectants, and there is an increasing awareness of the role that probe handles and the general ultrasound environment can play in increasing infection risk. It is anticipated that guidelines will need to be continually reviewed and updated as new research comes to light.

Australian guidelines for ultrasound probe reprocessing

Standards for reprocessing of ultrasound probes in Australia and New Zealand are based on AS/NZS 4187:2014 and AS/NZS 4815:2006.[1,2] These standards detail how medical devices are to be disinfected and sterilised in general with specific mention of ultrasound probes in AS/NZS 4815:2006. In Australia, the Therapeutic Goods Administration (TGA) regulates the use of disinfectants for the reprocessing of medical devices.[3,4] The TGA sets requirements for the clearance of disinfectants such as high level disinfectants (HLDs) in terms of efficacy, material compatibility and performance. Additionally, organisations such as the Australian Society of Ultrasound in Medicine (ASUM) publish guidelines to assist their members in complying with the above standards and regulations.[5] Organisations such as the US Centers for Disease Control and Prevention (CDC) also have guidelines for the reprocessing of ultrasound probes.[6]

The reprocessing of medical devices including ultrasound probes is based on the Spaulding classification system which categorises medical devices depending on their intended use. These classifications and the level of disinfection required are summarised in Table 1 with reference to the AS/NZS, TGA, ASUM and CDC standards and guidelines.

Under the Spaulding classification system, medical devices are classed as either critical, semi-critical or non-critical. Critical devices (e.g. probes used in surgery) contact sterile tissues and require sterilisation to kill all microorganisms within the recommended contact time. Intracavity ultrasound probes are

Table 1: The Spaulding Classification applied to the disinfection of ultrasound probes.

Designation	Example Procedures	Level of Disinfection	Standards Recommendations for Ultrasound Probes
Critical Contacts sterile body cavity or tissue including the vasculature.[2,3]	Use of ultrasound probes in surgery; biopsies, punctures and drainages; vascular ablation; intraoperative procedures; venous catheter placement; transvaginal oocyte retrieval; needle guidance.	**Sterilisation** A sterilant is an agent that destroys all viable microorganisms.[1,2,4]	Critical ultrasound probes should be sterilised between patients. If this is not possible, then the probe should undergo a minimum of HLD and be covered with a sterile probe cover.[6]
Semi-Critical Contacts intact nonsterile mucosa or non-intact skin.[2,5]	Transvaginal, transrectal, transoesophageal ultrasound and any surface ultrasound procedure that involves broken skin such as wound scanning and burn graft evaluation.	**High Level Disinfection (HLD)** HLD kills all microorganisms except bacterial spores.[1] HLD is the minimum requirement for reprocessing a semi-critical device.[4] High level disinfectants must act as sterilants under prolonged exposure.[1]	Semi-critical probes should be sterilised or minimally high level disinfected even if a sheath is used.[5] TGA approved HLDs referred to in the ASUM guidelines include glutaraldehyde, *ortho*-phthalaldehyde and hydrogen peroxide.[5] Intracavity probes should be used with a sheath.
Non-Critical Contacts healthy intact skin.[2,4]	Surface ultrasound procedures that involve intact skin such as transabdominal pelvic ultrasound.	**Low Level Disinfection (LLD)** Low level disinfectants rapidly kill most vegetative bacteria and medium sized lipid containing viruses; not effective against bacterial endospores, mycobacteria, fungi, or all small non-lipid viruses.[3,4]	Non-critical ultrasound probes should undergo cleaning and LLD.[2] Low level disinfectants are also appropriate for environmental surfaces in the sonography clinic (e.g. probe cable, keyboard, and patient bed) however there are no specific standards on environmental disinfection for sonography.

considered semi-critical devices as they come into contact with non-sterile mucous membranes or broken skin and minimally require high-level disinfection (HLD). Similarly, surface ultrasound probes that come in contact with non-intact skin are considered semi-critical and must also undergo HLD. High level disinfectants kill all microorganisms except bacterial spores and must act as sterilants at extended contact times. Non-critical devices (e.g. surface ultrasound probes used only on intact skin) come in contact with healthy, intact skin and only require low level disinfection. This classification system informs current standards in ultrasound probe reprocessing both internationally and in Australia.[1–6]

Despite comprehensive guidelines being in place for infection prevention and a thorough understanding of disease transmission, compliance is still not ideal. ASUM launched a survey in March 2015 (entitled 'Disinfection and Hygiene Practice in Medical Ultrasound') to gather data on standards knowledge and compliance in clinical sonography. The data, to be presented at the annual ASUM 2015 meeting in September, will be invaluable in identifying areas where guideline refinement and educational initiatives would promote excellence in infection prevention practice. Applying infection prevention practices in different clinical settings can be a challenge where human error, minimal disruption to workflow, meeting daily consult thresholds and other economic burdens are non-trivial obstacles. However the human and financial costs resulting from non-compliance are substantial.

Consequences of non-compliance

Poor compliance with medical device reprocessing standards has recently had fatal consequences. In 2012, the Medicines and Healthcare products Regulatory Agency (MHRA, UK) released a medical safety alert describing a fatal case of hepatitis B transmission from an inadequately decontaminated transoesophageal echocardiography probe.[7] This led to a review of guidelines in the UK, Scotland and Wales to ensure high-level disinfection of semi-critical devices along with an emphasis on education to ensure staff are appropriately trained and aware of their responsibilities. Cases of hepatitis C transmission have also been recorded during prostate biopsy and assisted conception procedures associated with endocavitary ultrasound.[8,9]

In addition to these cases of transmission, there is a large body of evidence to show that improper reprocessing can lead to increased risk of transmission through contamination of ultrasound probes with communicable and epidemiologically relevant pathogens. A meta-analysis examined the routine use of transvaginal and transrectal probes with probe covers, followed by low level disinfection (LLD) with wipes or sprays, a common practice in several countries. The study found the probes were contaminated with bacteria and virus and the pooled prevalence of infected patients after a procedure was estimated to be 3.1%.[10] A German study reported that 21% of ultrasound probe bodies remained contaminated after disinfection with low-level disinfectant wipes containing quaternary ammonium compounds.[11] There have also been reports of Doppler probes contaminated with skin flora, potentially pathogenic coliforms and diphtheroids as well as nosocomial staphylococci (coagulase negative and methicillin sensitive *Staphylococcus aureus* (MSSA)).[12,13] An Australian study earlier this year reported that 57% of transducers were contaminated with blood and 46% with bacteria following probe sampling across five emergency departments and five intensive care units.[14] These probes that had come into contact with blood would be considered semi-critical or critical devices and should minimally be high-level

disinfected. Together these studies underscore the urgency for the rapid adoption and compliance of guidelines for the reprocessing of semi-critical ultrasound probes in the clinical setting to prevent infection transmission and ultimately ensure patient safety.

Transducer handle disinfection guidelines are lacking

Current ultrasound probe reprocessing guidelines do not specify inclusion of the transducer handle in the HLD process. Some probe manufacturers contraindicate immersion of probe handles in liquid disinfectant (since the handle is not fully sealed) while other manufacturers state that this is possible, but that the cable should not be immersed. This often results in confusion and immersion protocols exclusively for the probe body without consideration for handle disinfection.[15,16] A recent study reported 80.5% of vaginal ultrasound device handles were contaminated with clinically relevant bacteria following probe body immersion in glutaraldehyde per normal practice; *S. aureus* was isolated in 15.4% of these samples and one isolate was found to be methicillin-resistant *Staphylococcus aureus* (MRSA). Causative agents of urinary tract infections were also isolated from the handle including *Staphylococcus haemolyticus*, *Staphylococcus saprophyticus* and *Enterococcus faecium*. Handle contamination decreased to background levels after disinfection with an automated system designed for simultaneous disinfection of the probe handle and body.[16] Others have reported similar figures (83% when the handle is not disinfected).[11] The ultrasound transducer handle must therefore be considered a reservoir for microbial contaminants and a potential source of cross-infection. In some instances, patients may come into direct contact with handles or indirect contact may occur via the healthcare worker or probe sheath. Infection prevention and control in clinical sonography could benefit from inclusion of probe handle HLD standards in the current guidelines.

Widely-used high level disinfectants do not kill human papillomavirus

Human papillomavirus (HPV) causes 99.7% of cervical cancers worldwide and is a leading cause of ano-genital and oropharangeal cancer.[17,18] HPV is clinically significant to sonography as there is significant overlap between cancers of HPV aetiology and the body sites where endocavity procedures are performed.

A 2014 study was the first to investigate the resistance of disinfectants to HPV. Surprisingly, the HLDs glutaraldehyde and *ortho*-phthalaldehyde (OPA) were shown to be almost completely ineffective against native HPV16 virions, even with extended contact times up to 24 hours.[18] The continued use of these agents to disinfect endocavitary probes, particularly transvaginal probes needs to be strongly reconsidered.

While some HLDs have now been shown to be ineffective against HPV, further studies have shown residual HPV virus remaining on transvaginal ultrasound probes before and after LLD with wipes impregnated with quaternary ammonium compounds.[19–21] Since HPV is highly stable and has the ability to survive in a dry room environment for several days,[22–25] the risk of using an ineffective disinfectant with each reprocessing protocol amplifies the risk of transmitting cancer causing HPV to the next patient via the ultrasound probe.[26]

A recent study showed that a hydrogen peroxide based disinfection system designed specifically for ultrasound probes (trophon® EPR) was able to completely inactivate native HPV16 and HPV18 virions under FDA and TGA specified test conditions.[27,28] These results are encouraging as they provide the clinical sonographer with a way to manage HPV transmission risk. It is likely that guidelines will be revised to recommend use of HPV-effective disinfectants for semi-critical ultrasound probes.

Ultrasound environment disinfection guidelines are lacking

Current guidelines may need to be revised to extend infection control and prevention practice more generally to the ultrasound environment. If the ultrasound probe can be considered a reservoir of infection causing agents, so too must surfaces and other components in the sonographer's clinic. Some studies have revealed that ultrasound gel can become contaminated and act as a medium for bacterial growth.[29,30] Various other items have been examined for contamination including probes, probe holders, keyboards and gel. One study found that transvaginal ultrasound equipment was contaminated with pathogenic (6.7%) and non-pathogenic bacteria (83.3%).[30] Transrectal ultrasound equipment was contaminated with 3% and 45% pathogenic and non-pathogenic bacteria respectively, while surface ultrasound equipment showed similar contamination rates of 9.4% and 65%. The study recommended revised infection control measures including hand disinfection prior to and following every examination, complete gel removal following every examination, use of a gel with antibacterial properties, probe holder and gel bottle disinfection at the start and end of each day and keyboard disinfection after each patient. The authors also recommended that the whole ultrasound machine should be cleaned with detergent at least once a week and immediately following examination of a patient with a suspected infection.

The safety of both the sonographer and the patient would benefit from a revision of the current guidelines to extend to the sonographer's environment. A more recent study in Australia sampled transabdominal and transvaginal transducers, cords, keyboards and gel confirming the suspicions of earlier studies.[31] Skin and environmental organisms were isolated along with the opportunistic pathogens *Enterococcus sp*, *Brevundimonas sp* (found in reheated gel) and *Acinetobacter sp*. The study recommended a review of current guidelines to include keyboard and cord disinfection and gel handling. Other areas such as the examination bed and rails, door handles and benchtop surfaces may also act as sources of nosocomial infections and these may also need to be addressed in guidelines as research in environmental sources of contamination accelerates.

Conclusion

Infection prevention and control measures are vital for the safety of patients undergoing sonographic examination. Ultrasound probe reprocessing guidelines and standards are comprehensive and clearly define the level of disinfection required based on the intended use of a medical device. The challenge is in general awareness of these guidelines and their effective implementation into practice. In addition revision of guidelines are warranted with regard to transducer handles, HPV and the general

ultrasound environment. As future research in this area is performed, guidelines will need to be amenable to revision to provide patients with the best standard of care.

Conflict of interest

LM is an employee of Nanosonics Ltd, JB is a consultant to Nanosonics Ltd, AN and CM have previously received speaker honoraria from Nanosonics Ltd.

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