Best practice guidelines for ultrasound reprocessing

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Introduction
Ultrasound usage in the UK has increased steadily in recent years, with diagnostic ultrasound procedures in the English NHS rising from seven million in 2013 to 8.3 million in 2017; an increase of over 17%.1

While use of ultrasound in diagnostic imaging has grown, there has also been extensive growth in ultrasound-guided invasive procedures such as central and peripheral line placements, biopsies, drainages and others. Indeed the use of ultrasound has become so widespread that most hospital departments utilise ultrasound to some degree.2

While ultrasound continues to bring great clinical benefit, there are also risks associated with its use. As with all reusable medical devices, there is a risk that the ultrasound transducer or associated equipment can transmit pathogens from patient to patient if proper infection control measures are not observed. Healthcare associated infections are a major issue for anyone receiving care as well as being a significant burden on the economy, with an estimated impact of £1 billion per year in England alone.3

For the most part, ultrasound-associated infections have resulted where best practice guidelines have not been followed. In particular, these cases have occurred where ultrasound transducers have not been adequately cleaned and disinfected and where use of non-sterile ultrasound coupling gel in invasive procedures has led to the introduction of pathogens. These infections, as well as the implementation of a pragmatic, risk-based approach to management of reusable medical devices, have led to a global shift towards reducing risk through improved practice.

In recent years, specific reprocessing guidelines for ultrasound transducers have been introduced in the UK and Europe following existing guidelines in the USA, Canada and Australia.4-7

Most recently the Society and College of Radiographers (SCoR) and the British Medical Ultrasound Society (BMUS) have updated their Guidelines for Professional Practice to reflect the need for appropriate cleaning and disinfection of ultrasound transducers.8 These guidelines recommend that all semi-critical transducers (contacting mucous membranes or non-intact skin) undergo high level disinfection even if a sheath is used and that all non-critical transducers (contacting only intact skin) undergo low-level disinfection between patients.

Risk
There have been a number of infections resulting from improper infection control measures in relation to the use of ultrasound. In 2012, a patient in Wales contracted hepatitis B, with the infection being attributed to an improperly reprocessed transoesophageal ultrasound transducer. The infection was fatal and led to the issue of an alert by the Medicines and Healthcare Products Regulatory Agency (MHRA) requiring users to ensure appropriate decontamination of all endocavitary ultrasound transducers.8

In 2017, NHS Scotland and Health Protection Scotland published a population-level study assessing linkage between infection risk and endocavitary ultrasound procedures. During the study period only 9.5% of sites were performing high level disinfection for endocavitary transducers. At this time there was no specific guidance in Scotland requiring high level disinfection.9

The researchers found that there was an increased hazard ratio (HR) for positive microbiological reports for patients who had undergone transoesophageal (HR: 4.92), transvaginal (HR: 1.41) and transrectal ultrasound (HR: 3.40).

For transvaginal procedures, the analysis showed greater significance when interventional transvaginal procedures were removed, addressing any concern that ultrasound may simply be associated with procedures with higher infection risk.10 Health Protection Scotland and Health Facilities Scotland have also released guidance recommending high level disinfection for all endocavitary probes.11

While the need to perform high level disinfection of endocavitary transducers is now better understood and adhered to in clinical practice, the use of surface ultrasound transducers to guide invasive procedures could also represent significant risks to patients.

In 2017, two outbreaks occurred involving contaminated ultrasound gel. In Australia, Burkholderia cenocepacia was detected in blood cultures of nine patients from intensive care units across two Australian states.

Patients contracted the infection after having central lines placed under ultrasound guidance using an ultrasound transducer cover and gel where the gel was contaminated with the pathogen.12

There was a further 2017 outbreak in Saudi Arabia, where patients across three ICUs were infected following ultrasound-guided CVC placements with contaminated gel.13 In total 14 patients were found to have positive blood cultures and two died as a result of septic shock. These outbreaks highlight the care that needs to be taken with the ultrasound transducer, gel and any covers, particularly where these items may contact the vascular system.

Guidelines
While guidelines for ultrasound reprocessing have been long-standing in the USA, Australia and Canada, it wasn’t until the MHRA alert in 2012 that this issue became more closely scrutinised in the UK. As a result of these alerts and other outbreaks, guidelines have since been introduced by a number of local organisations, as well as European professional societies (table 1). These UK and European guidelines join other guidelines from specific countries as well as the World Federation of Ultrasound in Medicine and Biology (WFUMB).14

Across this broad group of guidelines, all make use of the Spaulding Classification or derivatives thereof. The Spaulding Classification is a widely adopted framework for classifying medical devices based on the degree of infection transmission risk associated with their use.

Devices that only contact intact skin are considered ‘non-critical’, devices that contact broken skin or mucous membranes are considered ‘semi-critical’ and devices that contact or enter sterile tissue or the vascular system are considered ‘critical’. Corresponding levels of disinfection or sterilisation are then assigned, with non-critical devices requiring low level disinfection, semi-critical devices requiring high level disinfection and critical devices requiring sterilisation.15

It is very important that this classification system is applied in advance of the procedure commencing. This means that information about what tissues or body sites may be contacted is required in advance, so that an appropriately disinfected or sterilised transducer can be selected.

While the Spaulding Classification is a good general classification system for devices, ultrasound probes have specific

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**Rad Magazine, 44, 514, 13-14**

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**Table 1**

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<th>Organization</th>
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usage and reprocessing factors that also need to be considered.

Many ultrasound transducers cannot be sterilised and most guidelines permit high level disinfection in lieu of sterilisation for critical probes so long as a sterile sheath is also used. Both endocavitary and surface transducers are often used in conjunction with a sheath or condom. Importantly, guidelines state that use of a sheath (or condom) does not replace the need for disinfection as sheaths (and condoms) can have microscopic tears and can break during use. ¹

All semi-critical transducers therefore require high level disinfection even if a sheath is used. A typical decision tree demonstrating these principles is given in figure 1. Regional guidelines should be consulted to determine what specific requirements exist locally.

In addition to the above points, UK and European guidelines recommend a number of other ancillary measures when implementing ultrasound transducer reprocessing. The 2017 Irish guidelines recommend the use of automation over manual processes stating: “Internationally it is recognised that the use of an automated validated process for decontaminating reusable invasive medical devices will provide enhanced risk reduction of infection transmission.” ¹⁶

A number of guidelines including the Scottish, Irish and ESR guidelines specifically recommend that reprocessing is validated.¹¹,¹⁶,¹⁸

Validation involves demonstrating through on-site testing that reprocessing is occurring according to specification in terms of performance and operation. Validation needs to be performed when reprocessing is initially set-up and at regular intervals thereafter. Additionally, most guidelines require that reprocessing is traceable.

This means that the parameters of the cleaning and disinfection are recorded for each transducer in each reprocessing cycle and that these records are linked to specific patients that the devices are used upon. Traceability allows patient recall in the event of a reprocessing failure and is critically important in managing an infection outbreak.

Finally, some guidelines such as the ESR guideline address the use of ultrasound gel.¹⁹ These guidelines strongly advise that single-use sterile gel be utilised during all major and minor interventional procedures (eg ultrasound-guided injections and tissue sampling), regardless of cover use. In this guideline sterile transducer covers are mandated for invasive procedures, and recommended for endocavitary transducers.

**Conclusion**

The need for standardised infection control procedures is paramount to improving patient outcomes in healthcare settings. With increasing applicability of ultrasound and subsequent increase in ultrasound procedures, infection control becomes increasingly difficult.

As a consequence, UK and European guidelines have formed a consensus that all semi-critical transducers require high level disinfection irrespective of cover use, while all non-critical transducers require low level disinfection. Sonographers should work with their decontamination colleagues to meet these guidelines and evaluate the various options for reprocessing and management of ultrasound transducers.

**References**

Table 1
UK and European ultrasound infection control guidelines.

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<th>ORGANISATION</th>
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Figure 1
Decision tree for ultrasound transducer reprocessing requirements based on the degree of risk associated with contact with specific tissues or body fluids (adapted from Scottish¹¹ and Irish¹⁶ guidelines).