EDM medical solutions

Keep Ultrasound a Safe Modality

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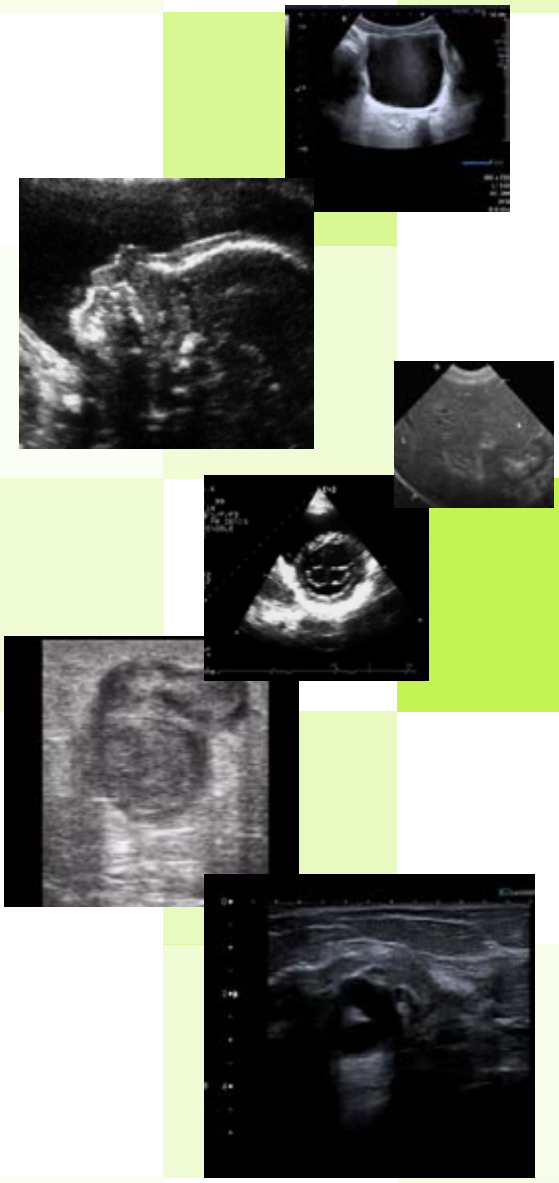
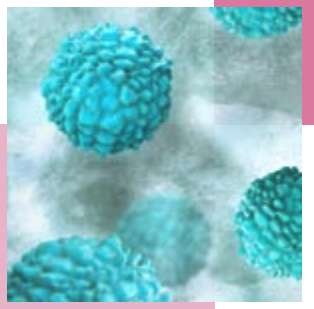
Ultrasound use today

For over seventy years, ultrasound imaging has been used by medical professionals to evaluate, diagnose, and treat a variety of conditions. The use of the modality is wide-ranging and can be found in radiology departments, OB/GYN practices, emergency medicine, and more. Since the founding of the American Institute of Ultrasound in Medicine (AIUM) in 1952, ultrasound use has continued to grow at a steady pace and much of its popularity can be accredited to its reputation of safety.

Ultrasound is the primary imaging technology used in a variety of specialties which comprise diagnostic medical sonography. Correspondingly, this includes clinical areas such as abdominal, breast, cardiac, obstetrics, gynecology, pediatrics, and phlebology. In addition to its diagnostic uses, ultrasound is increasingly becoming one of the modalities of choice in interventional settings. This encompasses a wide range of clinical areas and specialties, such as radiology, pain management, anesthesia, and urology. The versatility of ultrasound has caused it to become a more popular choice for certain applications, such as vascular access or biopsies. As a result, ultrasound-guided biopsies have become more common, particularly prostate and breast biopsies. By permitting the operator to see the target area with greater clarity, the risk of hitting unwanted structures is reduced and thus improves patient comfort and safety.

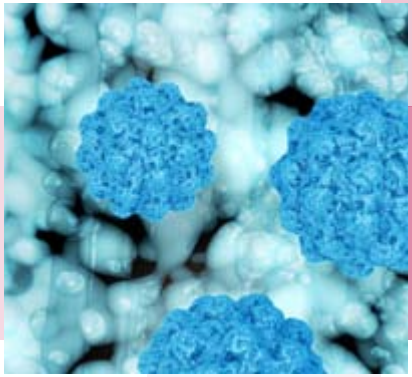
In addition to its ease of use, ultrasound offers other benefits to clinicians. Unlike some common imaging modalities, such as computed tomography (CT) scans, ultrasound does not expose patients to radiation. It can also be performed on patients who have pacemakers or other metal implants, in contrast to magnetic resonance imaging (MRI). The design of the ultrasound transducer means that it can be easily used outside of the imaging suite; thereby, eliminating the need to move patients. Point-of-care ultrasound (POCUS) provides a convenient way for practitioners to diagnose and evaluate patients, especially in emergency cases which involve critically ill or injured patients. By providing clinicians with real-time information, POCUS has played a significant role in accelerating the speed of diagnosis and treatment of certain cases. Its rise is augmented by new technologies that allow practitioners to use a tablet or phone to perform the scan. The American Society of Radiologic Technologists (ASRT) notes how the increased use of POCUS is also tied to the modality's aforementioned lack of radiation exposure and has been bolstered by radiation protection concerns on the part of clinicians (Buerger and Clark, 2017).





As mentioned prior, the use of ultrasound outside of diagnostic medical sonography has expanded in recent years. A 2018 survey conducted by the University of Louisville found that ultrasound use was especially high in multiple settings outside of diagnostic medical sonography. The survey included responses from over 300 U.S. infection preventionists. When asked of ultrasound usage in their departments, the following had the highest rates: radiology, OB/GYN, emergency, cardiology, operating room, and ICU. More than 80% of each of the respondents for these departments indicated that ultrasound was being used. The ASRT notes how the expansion of use to other specialties signifies the use of the equipment by “nonimaging healthcare professionals,” and points out how adequate training will need to be provided to these individuals to ensure success.

Although the growth of ultrasound has brought clinical benefits, it has not come without its risks. The research team from the University of Louisville warned that this rapid expansion in use may pose a hazard to patient safety in the form of “preventable infection risk” (Carrico et al, 2018). To maximize infection prevention, medical staff are expected to clean and disinfect transducers used for the scan or procedure along with ensuring that any additional supplies, such as gels and covers, are also adapted to the nature of the scan. In 2016, The Joint Commission found that 74% of all immediate threats to life declarations were associated with the improper sterilization of high-level disinfected equipment. The researchers from Louisville wrote, “These outbreaks demonstrate the risks associated with surface ultrasound–guided procedures and suggest the probe and gel can contaminate the puncture site during imaging” (Carrico et al, 2018). Therefore, the use of appropriate ultrasound supplies, particularly in environments where the sterile field must be preserved, is crucial to patient safety. It must be understood that, although ultrasound may be considered a generally safe imaging modality, it can still be a vector of healthcare-associated infections. Previously conducted studies have proven that contaminated probes, especially in interventional settings, can pose a significant danger to patients.



As a result of these concerns, healthcare facilities around the world have moved to develop infection control guidelines for ultrasound. Practitioners in the United States can find ultrasound-specific infection control recommendations from the Centers for Disease Control and Prevention (CDC) and the American Institute of Ultrasound in Medicine (AIUM). In a 2018 survey conducted by the World Federation for Ultrasound in Medicine and Biology (WFUMB), which included over a thousand ultrasound users from 60 countries, sixty percent of respondents indicated that their department had infection control guidelines in place specifically for ultrasound machines and transducers (Abramowicz et al., 2018). Moreover, the survey found that the primary guidelines used by respondents were those from the Australasian Society for Ultrasound in Medicine (ASUM) and AIUM. Respondents also consulted the ultrasound manufacturer-provided cleaning instructions, their facility's infection control protocols, and the recommendations of cleaning product manufacturers.

Although the majority of WFUMB respondents indicated that their departments had these guidelines in place, significant segments of respondents did not seem to prioritize the cleaning and disinfection of transducers. For example, respondents levied multiple concerns in regard to cleaning: 17% said the products were too expensive, 15% said that disinfection methods lacked efficacy, and 32% found the cleaning process too time consuming. The latter issue is particularly aggravated when clinicians are pressed for time and may be tempted to think that the entire process of cleaning and disinfection does not have to be carried out. Some respondents, for example, reported only wiping the transducer with a towel or paper after use, including endocavity use. The consequences of such practices were visible in a 2017 study conducted by NHS Health Scotland. Researchers found that patients undergoing a transvaginal scan and a transrectal scan were 41% and 75 % more likely to have positive bacterial cultures, respectively (Carrico et al, 2018).

Furthermore, it is important to note how the sterilization techniques used on other equipment in interventional settings cannot be applied to ultrasound. In its guidelines for infection control in sonography, the Society of Diagnostic Medical Sonography (SDMS) noted how ultrasound requires sterilization techniques tailored to the unique needs of the modality ("Guidelines for Infection Prevention and Control," 2019). Due to the sensitivity of these instruments, they cannot undergo sterilization in an autoclave or be exposed to heat.

Thus, it is necessary for this understanding of transducer-specific requirements to be integrated into the protocol and that an appropriate alternative be provided. Instead of sterilization techniques such as these, practitioners can rely on high-level disinfection (HLD) processes designed for transducers. In a highlight of the importance of proper HLD knowledge, the Association for the Advancement of Medical Instrumentation (AAMI) developed an American National Standard ST58 on HLD for reusable medical devices.

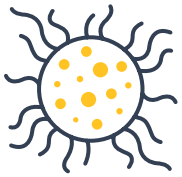
Being cognizant of these differences and ensuring that ultrasound-specific needs are present in the protocol ensures that the facility will not experience gaps in the reprocessing of its transducers, notes the SDMS. Failing to adhere to proper HLD practices can have a significant impact on patient safety. This was recently exemplified in highly publicized outbreaks tied to contaminated flexible endoscopes and endoscopic retrograde cholangiopancreatography and illustrates the consequences of reprocessing failures (Carrico et al, 2018).

In summary, ultrasound is an evolving modality. Its expanded use across specialties also brings new treatment areas. In recent years, researchers have been studying and developing new ways in which ultrasound can be used as a therapeutic tool for diseases, such as Alzheimer's and diabetes. The SDMS emphasizes that practitioners must be aware that "technological advances and new research" signify the need for evolving infection control practices ("Guidelines for Infection Prevention and Control," 2019). To keep ultrasound a safe modality, healthcare professionals across specialties will need to look at how ultrasound can be a vector of infection in their facility and subsequently work to fill any gaps in their protocols. This paper will give an overview of current issues in ultrasound infection control while providing clinicians with insights to keep patients safe.

Ultrasound as a vector of infections

Although ultrasound is considered a generally safe imaging modality, clinicians cannot overlook its role as a vector of infections. As ultrasound use has expanded to interventions and surgical use, so has the increased risk of cross-contamination. In their 2017 recommendations for ultrasound infection control, the European Society of Radiology Ultrasound (ESR) working group noted how previous studies revealed that bacterial contamination of ultrasound transducers was significantly higher than that of public toilet seats and bus poles (Nyhsen et al., 2017). Findings such as these have resulted in the issuance of infection control guidelines from regulatory bodies and ultrasound imaging associations on an international scale. Clinicians using ultrasound must note how once a surface is contaminated, pathogens may survive for an extended period of time, and this applies to transducers. Even though it may be difficult to determine the path of infection, the ESR working group encouraged practitioners to consider the risk involved in their scans, including those not in interventional settings such as postprocedure follow-up ultrasound scans.

Survival of Pathogens



Type of Pathogen	Duration of Persistence
Bacteria:	
Campylobacter jejuni	Up to 6 days
Clostridium difficile (spores)	5 months
Escherichia coli	1.5 h - 16 months
Haemophilus influenzae	12 days
Mycobacterium tuberculosis	1 days - 4 months
Neisseria gonorrhoeae	1 - 3 days
Pseudomonas aeruginosa	6 h - 16 months (dry floor up to 5 weeks)
Staphylococcus aureus, including MRSA	7 days - 7 months
Fungi:	
Candida albicans	1 - 120 days
Viruses:	
SARS associated virus	72 - 96 h
HAV	2 h - 60 days
HBV	> 1 week
HIV	> 7 days
Herpes simplex virus 1 & 2	4.5 h - 8 weeks
Papillomavirus	16 > 7 days
Rotavirus	6 - 60 days

Source: World Federation for Ultrasound in Medicine and Biology

Researchers have found that the synthetic materials present on the ultrasound transducers and other portions of the equipment, including the cable, are susceptible to colonization by pathogens (Nyhsen et al., 2017). Not all types of ultrasound-guided procedures pose the same risk to patients. Depending on the type of scan, patients may be exposed to potential infection at varying levels. The ESR working group noted that practitioners should consider likelihood of exposure to the normal bacterial flora of patients, contact with body fluids, and the degree of invasiveness when evaluating risk (Nyhsen et al., 2017). Thus, today's broad use of ultrasound across multiple specialties and clinical areas signifies that clinicians must consider the infection control implications of the procedure.

In principle, if ultrasound transducers are not reprocessed correctly then they may pose a significant risk to patient health. On any given day, the Centers for Disease Control and Prevention (CDC) estimates that 1 in 31 hospital patients will contract a healthcare-associated infection or HAI (CDC, n.d.). Multiple studies, including that of the ESR working group, have found that a variety of bacteria and viruses can be transmitted via ultrasound. As facilities actively combat HAIs, it is important for infection preventionists and clinicians to take into account those infections being spread through the modality. As previously mentioned, pathogens can form colonies on ultrasound transducers and other portions of the machine. Practitioners should note how long these pathogens can survive on dry inert surfaces. Bacteria such as Escherichia coli, Pseudomonas aeruginosa, and Staphylococcus aureus can have survival times of up to several months or longer on dry inert surfaces. Viruses such as hepatitis A, herpes simplex virus (HSV), and rotaviruses can last several weeks. Fungi such as Candida albicans can survive for up to 120 days. In addition to their long survival time, bacteria such as Pseudomonas aeruginosa are constantly finding new ways to combat the effects of antibiotics. If pathogens are able to form antibiotic resistance, then they may also become multi-drug resistant, thereby impeding treatment efforts via antibiotics (CDC, n.d.).

Moreover, some of these bacteria may already be carried by patients themselves. For example, staphylococcus aureus, also known as staph, is carried by 30% of people in their noses. Although many times staph does not cause harm, staph infections in healthcare settings pose a life-threatening risk to patients, even if the infection is not antibiotic-resistant. They can cause serious and sometimes fatal conditions such as bacteremia, pneumonia, endocartis, and osteomyelitis. Overall, more than 119,000 people contracted bloodstream staph infections in 2017 and 22,000 died from them that same year (CDC, 2019). The threat posed by these pathogens to patient health is only augmented during interventional use. The ESR researchers noted how post-contamination survival of the pathogens can be strengthened "by co-existent organic material such as skin cells or body fluids" as they can permit for the formation of a protective nidus for microbes (Brady et al., 2017). If this occurs, even disinfectants may not be able to fully penetrate and remove the pathogens, say the authors. It is important to note that healthcare-associated infections not only threaten patient safety, but also result in higher costs as noted by a study which estimated that the overall direct cost to hospitals in the United States ranged from $28 billion to $45 billion (Stone, 2009). Thus, protecting ultrasound transducers from cross-contamination not only improves patient care but also reduces the costs associated with HAIs.

Body sites and their physiological flora and potential pathogens

-	Normal flora	Potential pathogens	Pathogens
Skin	Coagulase-negative Staphylococcus spp. (S. epidermis etc.), diphtheroids, Gram-positive and Gram-negative anaerobes	*S. aureus*	
Throat and upper airways	Viridians streptococci, Neisseria spp., Gram-positive and Gram-negative anaerobes	*S. aureus, S. pyogenes, Haemophilus. Influenzae, N. menigitidis*	*Mycobacterium tuberculosis*
Gastrointestinal tract	Escherichia coli and related Gram-negative bacilli, Pseudomonas aeruginosa, Enterococcus faecalis and other Enterococcus spp., Clostridium perfringens, C. difficile, and other Clostridium spp., Gram-positive and Gram-negative anaerobes	Salmonella typhi and other Salmonella spp., Campylobacter spp., Shigella spp., pathogenic strains of E. coli such as E. coli O157, C. difficile	
Male perineum and external genitalia	Faecal and skin flora as outlined above, Candia spp.	S. aureus, E. coli	Sexually transmitted pathogens such as N. gonorrhoeae, Chlamydia trachomatis and other Chlamydia spp., Mycoplasma genitalis, HSV I + II
Female perineum, external genitalia, and vagina	Faecal and skin flora as outlined above, Candia spp., Lactobacillus spp.	S. aureus, E. coli	Sexually transmitted pathogens such as N. gonorrhoeae, Treponema pallidum, Chlamydia trachomatis and other Chlamydia spp., Mycoplasma genitalis, HPV, HSV I + II
Body fluids including blood			Blood borne viruses, i.e. hepatitis B virus, HCV, human immunodeficiency virus

Please note: These are examples. This is not an exhaustive list.

Source: European Society of Radiology

To better understand the types of infection which can be borne out of a contaminated ultrasound transducer, it is important to highlight the difference between endogenous and exogenous infections. Endogenous infections occur when microbes from a patient's natural flora enter previously sterile areas of the body. This stands in contrast to exogenous infections which bring in pathogens from outside of the patient via a contaminated surface, such as the transducer. Clinicians should note that during certain procedures probes may push microbes from the natural flora into sterile areas, thus increasing the risk of an endogenous infection. To minimize the risk of infection, physicians may decide to perform antimicrobial prophylaxis prior to a procedure, such as a prostate biopsy. This practice consists of giving antibiotics to the patient, especially to those who have certain risk factors for microbial infection. However, there are cases in which the clinician will not be able to eliminate the risk of an endogenous infection. Such is the case in transrectal ultrasound-guided biopsies where the very nature of the procedure means that the needle used may introduce microbes into sterile areas. On the other hand, practitioners have greater control in fighting exogenous infections. For example, a patient who previously had hepatitis C virus (HCV) negative who then proceeds to present acute viral hepatitis following an ultrasound-guided procedure is an example of an exogenous infection as it is most likely that it was contracted from another patient, note the authors (Nyhsen et al., 2017). Proper reprocessing is crucial in minimizing the risk of this occurring.

Furthermore, the risk of infection is amplified by asymptomatic carriers who've developed a degree of immunity. These patients may be less susceptible to an endogenous infection from their flora; however, they may pass the pathogens onto another patient if the same probe is used and not properly reprocessed. Thus, the ESR states pathogens from these patients should be characterized as "potential pathogens" as they are a threat to other patients, even if the carriers themselves do not acquire an endogenous infection from them (Nyhsen et al., 2017). For example, healthy individuals may carry S. Aureus in their nose, but the organism can cause post-surgical wound site infections if a susceptible patient contracts it. As a vector of infections, a contaminated ultrasound probe can have deadly consequences for patients. In 2012, a patient death was reported from a hepatitis B infection contracted from an improperly reprocessed transesophageal ultrasound probe (Carrico et al., 2018). Additionally, practitioners must take into account how the transducer itself is not the only possible vector of infection. Ultrasound gels, covers, and cables can all be vectors of infection. The WFUMB authors called ultrasound gel a "proven vector for pathogenic contamination" and noted how it had been the cause of patient deaths and multiple infections (Abramowicz et al., 2018). Thus, it is important that the selection of ultrasound gels and probe covers be done with the procedure in mind. Multiple surveys found alarming amounts of respondents failing to use sterile gel or sterile covers in settings where it was required. It is important that practitioners do not allow all of the focus to shift to disinfecting and protecting the ultrasound probe while disregarding the other supplies involved in the scan.

Frequency of cleaning the ultrasound machine keyboard and cords

Cleaning frequency	Machine keyboard	Machine cord
After each patient	19.47% (198)	*30.00% (388)*
Once a day	49.46% (503)	*29.58% (302)*
Once a week	18.09% (184)	14.99% (153)
Once a month	6.19% (63)	7.05% (72)
Once every 6 months	1.87% (19)	3.04% (31)
Never	4.92% (50)	7.35% (75)
Total	1,017*	1,021†

*Of a total of 1,017 respondents, 12 skipped questions

†Of a total of 395 respondents, 8 skipped questions

Source: World Federation for Ultrasound in Medicine and Biology

As previously mentioned, ultrasound gel itself can be contaminated and transfer pathogens to the patient. For example, numerous outbreaks from central line insertions have been caused by contaminated gel and many of these cases resulted in bacteremia and death. Therefore, it is essential that professionals adhere to the use of sterile supplies depending on whether the procedure is classified as critical or semi-critical. We will explain these ratings further in future sections. It is also important to note how sterile probe covers should be used in interventional settings. Although they provide a physical barrier to infection, a non-sterile cover is not a replacement for a sterile one as it can become a vector of infection if it is contaminated by the provider, blood, or other bodily fluids. Additionally, clinicians should avoid making the mistake of believing that a multiuse gel, rather than a sterile one, that is inside of a probe cover cannot be contaminated. The authors of the Louisville study noted that these gels can be contaminated even within a cover, thereby becoming vehicles for pathogen transmission (Carrico et al., 2018). It is important to note that 5-liter packs of ultrasound gel are banned in some European countries, such as France, because of the infection control risk they pose. The gel from these packs is typically poured into smaller bottles; however, if the ultrasound gel in these bottles becomes infected then the entire pack may be comprised. Thus, clinicians must exercise caution with these packs as their shared use poses an increased risk of pathogen transmission.

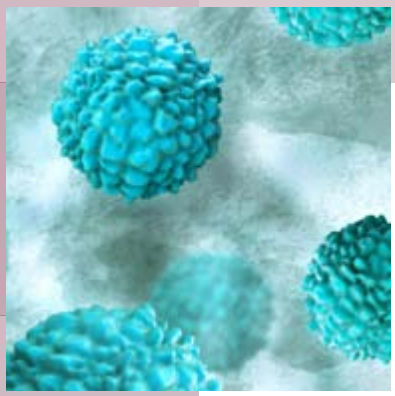
When measuring vectors of infection in ultrasound-guided procedures or scans, healthcare professionals should take a holistic view of each piece of equipment and the supplies involved. Transducers are a primary vector of infection and clinicians should be concerned about their proper reprocessing; however, a clean probe alone does not guarantee patient safety. Clinicians should also monitor the cleanliness of the transducer's cable, the keyboard and interface of the machine, and any other piece of equipment that may come into indirect or direct contact with patients. The ESR recommends that these surfaces be thoroughly cleaned and disinfected due to the risk they pose to patient health (Nyhsen et al., 2017). Additionally, probe covers and ultrasound gels are also potential vectors of infection. Utilizing sterile supplies can reduce the risk of infection and cross-contamination. It is important to note, however, that not all procedures or scans will require sterile supplies. In certain cases, non-sterile multiuse gel can be used as well as non-sterile covers. Thus, clinicians should seek to evaluate the need for such supplies based on the nature of the procedure and risk level. To more clearly define which supplies should be used and when, various organizations have issued recommendations on how to properly categorize each procedure.

Guidelines for keeping ultrasound safe

To achieve a greater understanding of ultrasound as a vector of infection, we must examine the risk level associated with the modality. As we touched upon earlier, ultrasound is not confined to a few clinical areas, but rather its expanded use signifies that the risk level of each procedure is far more diverse. To aid in properly assessing risk, practitioners can turn to the Spaulding classification. This classification consists of three distinct levels of risk: non-critical, semi-critical, and critical — ordered from lowest to highest risk, respectively. However, in its recent guidelines for infection control, the ESR released a modified Spaulding classification. This classification eliminates the second level – semi-critical – and simplifies the process of determining the proper infection control measures. The reasoning behind this is intrinsically tied to developments in infection control. The original semi-critical rating referred to procedures where the device would come into contact with intact mucous membranes of non-sterile body sites, but the ESR noted how this was insufficient. Due to the fact that procedure-associated microtrauma of these membranes cannot be excluded, the ESR has decided to join it with the critical rating to maximize patient safety. Additionally, the semi-critical rating shared similar disinfection recommendations to the critical rating, such as requiring high-level disinfection (HLD) for transducers. Thus, joining both works to simplify the Spaulding classification and can facilitate greater adherence to the protocol. The ESR defines non-critical and critical as follows: “Non-critical: non-invasive, contact of US transducer with intact skin only, requiring low level disinfection. Critical: invasive, such as US-guided punctures or injections, contact of the US transducer with mucous membranes and body fluids or a combination of both” (Nyhsen et al., 2017).

Developments in ultrasound infection control have revealed that proper classification is a crucial component of patient safety. Ultrasound-guided invasive procedures can range from minimally invasive fine needle aspirations (FNA) to intraoperative use. Regardless of how invasive the procedure may be, practitioners must note that all of them will involve the breaking of intact skin or mucous membranes. Considering this aspect of the procedure is paramount to properly evaluating the risk of pathogen transmission. The ESR noted how needles used in a minimally invasive procedure such as acupuncture have been shown to carry viral material following the treatment of hepatitis C-positive patients (Nyhsen et al., 2017). As a result, practitioners using ultrasound in procedures such as these must keep in mind that the risk of pathogen transmission remains high, even in minimally invasive procedures. Due to the risk involved when intact skin or mucous membranes are broken, the ESR emphasized how ultrasound users should seek to classify all of these procedures as critical and follow the appropriate guidelines to minimize any impact on patient safety.

To this end, both the ESR and the Society of Diagnostic Medical Sonography (SDMS) have issued guidelines aimed at improving infection control for ultrasound-guided procedures. These recommendations can be divided between critical and non-critical procedures in accordance with the modified Spaulding classification.



Non-critical procedures

Non-critical ultrasound procedures are defined as non-invasive and involve placing the transducer on intact skin only. In addition, it includes procedures in which the transducer will not come into contact with bodily fluids and where no skin diseases or known transmissible infections are present (Nyhsen et al., 2017). In these cases, practitioners need only perform low-level disinfection (LLD). The SDMS defines LLD as the inactivation of vegetative bacteria, enveloped viruses, some non-enveloped viruses, and most fungi in a period of 10 minutes or less (Carrico et al., 2019). LLD is commonly available as sprays and wipes and is typically made of quaternary ammonium compounds, phenols, and alcohols.

Clinicians should heed manufacturer disinfection recommendations and ensure that the chosen LLD method will not damage the transducer. According to a 2016 survey conducted by the World Federation for Ultrasound in Medicine and Biology (WFUMB) on ultrasound usage, 47% of respondents stated that they had received cleaning recommendations from the manufacturer upon purchasing the machine. Alcohol-based wipes are a particularly popular option for cleaning — nearly half of the WFUMB respondents used them after patient use for both critical and non-critical procedures. However, users should note that some disinfectants, particularly alcohol, may be ineffective in eliminating HPV type 16, and may actually cause surface damage to the transducer (Nyhsen et al., 2017). We recommend practitioners refer to manufacturer guidelines and avoid using alcohol wipes and sprays on transducers as they may damage the probe's crystals.

For a non-critical procedure, clinicians should begin by performing a thorough cleaning of the transducer. Cleaning, as defined by the SDMS, consists of removing all visible gel, soil, and bioburden on all surfaces of the transducer as well as any ancillary equipment (Carrico et al., 2019). Practitioners have various potential cleaning agents at their disposal for transducers, such as a neutral pH cleaner, wipes, soap and running water, and enzyme soaks. As with LLD, clinicians should ensure that the selected cleaning method is in line with the ultrasound manufacturer's recommendations. However, transducer compatibility is not the only factor which facilities should consider. The WFUMB survey reported that ultrasound users presented several objections or obstacles regarding cleaning – 32% believed it was too time consuming while 17% found cleaning products to be too expensive (Abramowicz et al., 2018). Thus, facilities should also take time, efficacy, and cost into account, as noted by the SDMS.

Practitioners must begin by removing all gel on the transducer with soap and running water or detergent wipes before using disinfectants. Using detergents is also recommended as it can remove invisible gel remnants which disinfectants cannot penetrate. It should be noted that gel remnants such as these may contain pathogens, and as a result, they pose a risk to patient safety. Clinicians should avoid using dry paper to wipe transducers as it is less effective than wipes and soap and may scratch the device. After allowing the transducer to dry, users should visually inspect the device to ensure that all soil has been removed. Following the inspection, they should proceed to perform LLD. Never apply disinfectants on a wet transducer as it can reduce or eliminate their efficacy. It is crucial that practitioners allow enough time for the transducer to dry as this permits the disinfectant to reach its maximum effect. During the procedure, the SDMS recommends using techniques that minimize the transfer of pathogens from potentially contaminated surfaces, such as clothing, non-sterile gloves, other equipment, and the environment (Carrico et al., 2019).

Critical procedures

As previously noted, critical procedures are categorized as those in which the transducer will have contact with mucous membranes, any bodily fluids, or infected skin and wounds. Thus, all endocavity procedures as well as ultrasound-guided interventional procedures, such as tissue sampling, vascular access procedures, and injections, are considered critical procedures. Following the procedure, the SDMS recommends that users immediately clean the transducer by removing any leftover gel or bioburden as they can interfere with the disinfection process, place it in a transport container (i.e. container with lid), label the container as dirty, and deliver it to the reprocessing area for disinfection and sterilization (in cases where the disinfection is performed in another room). Per the modified Spaulding classification, procedures which may have been classified as semi-critical in the original version should now be considered critical. Therefore, the following recommendations are suitable for both.

Overall, the general consensus is that critical procedures require high-level disinfection (HLD) of ultrasound transducers, including the handle (Nyhsen et al., 2017). The SDMS describes HLD as “the removal of all microorganisms except bacterial endospores, of which small numbers are permitted to remain” (Carrico et al., 2019). In the event that a transducer cannot be sterilized, HLD is considered a suitable alternative so long as the transducer was used with a sterile probe cover. Unlike sterilization, disinfection is not sporicidal, and it should be noted that only a handful of disinfectants – chemical sterilants – will kill spores with prolonged exposure times (3-12 hours). Although a high number of respondents to the WFUMB survey used HLD in critical procedures – 84% after endocavity use and 80% when in contact with blood and bodily fluids – it must be noted that these numbers are not high enough to keep ultrasound safe (Abramowicz et al., 2018). We believe that time may be a significant factor as to whether HLD is employed. If clinicians feel the process is too time consuming, or if their department is moving at such a rapid pace that it does not accommodate for HLD, then this step may be eliminated or not executed properly. Adherence to HLD after critical procedures must be viewed as an essential step if patient safety is to be maximized.

Following the recommendations of the ultrasound manufacturer, clinicians may choose from three HLD methods per the ESR: approved manual multistep disinfectant wipes and sprays which are validated for HLD, standardized automated validated systems, and other approved HLD procedures such as an immersion bath (Nyhsen et al., 2017). Companies, such as Tristel in the United Kingdom, have been developing high-level disinfectants in spray and wipe form. For example, Tristel’s Duo ULT delivers chlorine dioxide as a foam and has been designed for use on endocavity ultrasound probes. These manual multistep disinfectants are not yet available in the United States as they are not FDA approved. Various standardized automated validated systems, such as hydrogen peroxide mist devices and UV light devices, are available to stateside physicians. Notably, UV light for infection control has grown in popularity in recent years, and some companies, such as Germitec in France, have been developing systems for ultrasound transducers. Other noteworthy automated validated systems include the Trophon system from Australia-based Nanosonics which provides clinicians with a compact and safe-to-use HLD method while also facilitating a simplified workflow. In addition, manual HLD, such as soaking stations, are also an effective option. Practitioners should use approved liquid chemicals in the immersion bath such as glutaraldehyde, ortho-phthalaldehyde, peracetic acid, hydrogen peroxide, and accelerated hydrogen peroxide. In its recommendations, the SDMS noted that automated processes are preferable due to the minimized risk of operator error. Additionally, automated HLD is much faster than its manual counterparts — usually taking less than 10 minutes to disinfect in contrast with the average manual soaking time of 20-30 minutes. However, manual HLD is significantly less expensive than automated processes and may be more suitable and cost-effective for practices with a lower volume of critical procedures, such as OB/GYN offices.

Moreover, facilities should seek to choose HLD methods that are efficient, effective, reliable, and safe for the user, transducer, patient, and environment. With critical procedures, practitioners should combine LLD and HLD to ensure that the entirety of the ultrasound machine is properly disinfected, thereby leaving no room for pathogen spread. While HLD is performed to disinfect the head and handle of the transducer, clinicians can utilize LLD methods to disinfect cables and connectors. As was noted prior, studies have shown that these components of the ultrasound machine can harbor pathogens and become vectors of infection. Before performing HLD, thoroughly clean the transducer per the same guidelines for non-critical procedures. It is essential that any gel, bodily fluids, or bioburden is removed from the transducer with soap and running water, cleaning sprays, or detergent wipes. Drying time is equally important, since applying HLD to a wet transducer can minimize its efficacy. After performing HLD, allow for the transducer to dry. Similarly to LLD, this is necessary for the disinfectant to reach its maximum potential.

In critical procedures, the role of sterile gel and sterile probe covers is of the utmost importance. Sterile probe covers significantly reduce soiling of the transducer by acting as a physical barrier during contact. Thus, the use of a cover leads to a more effective and efficient post-procedure decontamination. In the WFUMB survey, over 70% of respondents reported covering their transducer during interventional procedures (Abramowicz et al., 2018). It must be noted that a probe cover does not eliminate the need for cleaning and disinfection as the risk of contamination and pathogen transmission is not removed by its use. The results of the WFUMB survey point to the need for an increased emphasis on appropriate probe cover usage, since it cannot be viewed as optional or as an optimal stand-alone solution for critical procedures. Even after LLD, non-negligible contamination levels can be detected when probe covers are used which is why HLD is crucial, warned the ESR (Nyhsen et al., 2017). Although sterile probe covers are not required for non-interventional endocavity procedures, we encourage practitioners to select a sterile option. For all other critical procedures, the use of a sterile probe cover is required. Moreover, clinicians must use FDA-approved probe covers for all procedures, regardless of whether the selected option is sterile or non-sterile. Barriers, such as plastic wraps, condoms, or others, should not be used as the product quality cannot be assured and perforation rates may be high. Although the risk of perforation may vary depending on the chosen probe cover material, developments in the field have led to newer materials which have proven to be safer and more resistant to tearing. Furthermore, probe covers should always be single-use and disposable. When selecting a cover, clinicians should verify whether patients have a latex-allergy, and if so, they should select a latex-free one to avoid triggering a reaction.

Since ultrasound gel can become a vector of infection, the use of sterile gel is essential in a critical procedure. To further understand the threat posed by the gel, we can look to its formulation. Ultrasound gels are typically composed of a polymer to establish viscosity, deionized water, a moisture retaining agent, substances to stabilize the pH, and preservative agents. Thus, the environment of a gel compound has been found to allow bacterial survival and multiplication. Although pathogen transmission via contaminated gels appears to be relatively low, the risk of infection has been highlighted by multiple outbreaks (Nyhsen et al., 2017). Clinicians should not assume that sealed gel bottles are sterile, unless it is clearly stated by the manufacturer. In addition, it is recommended that single-use bottles be used instead of refillable ones as the latter poses a higher risk of contamination. Practitioners should use gel bottle warmers with caution as keeping a gel bottle warm for an extended period of time can significantly increase the risk of pathogen spread. As a result, the gel bottle should only be warmed for immediate use. During critical procedures, the ESR strongly advises clinicians to use sterile gel both inside and outside of the probe cover in case of perforation or porosity.

Lastly, facilities should develop a written policy that highlights the process of documentation and traceability. These measures are necessary for critical transducers requiring sterilization and HLD. The ESR recommends that clinicians document all reprocessing details including the transducer model and serial number, reprocessing personnel identification, validation result, cycle number, date, and patient identification (Nyhsen et al., 2017). It is important that facilities ensure traceability by linking the reprocessing records to the patient on whom the transducer is used. This can be done via both manual or automated processes. Additionally, clinicians should ensure that the reprocessed transducer is properly stored to prevent recontamination before patient use. Facilities have a variety of storage options at their disposal, such as storage covers, boxes, or cabinets. Storing the transducer reduces the risk of re-contamination from environmental contaminants or accidental contamination during storage, noted the ESR researchers. Properly reprocessing and storing transducers will maximize patient safety by significantly reducing the risk of cross-contamination.

New considerations in ultrasound infection control

The most recent infection control challenges faced by the modality are prominent and must be taken into consideration when evaluating next steps. First, the COVID-19 pandemic has undoubtably had a profound effect on ultrasound imaging and the healthcare sector as a whole. On a national scale, US hospitals and clinics have felt the shock caused by the influx of patients. Even in areas where significant COVID-19 spread has not been experienced, healthcare facilities of all kinds have been forced to reevaluate their infection control practices. This undertaking is far from simple, but it can have a significant impact on patient safety and must be embraced by administrators and practitioners alike. Infection control tactics, such as environmental hygiene, screening and cohorting patients, and hand hygiene, must be prioritized as facilities work to reduce the risk of COVID-19 transmission.

Correspondingly, the pandemic has had meaningful implications for ultrasound imaging. The modality's use as a diagnostic tool for the virus has placed it on the front lines of the pandemic. Although it was unclear and contested by some physicians in the early stages of the pandemic, ultrasound has proven to be a valuable tool in the diagnosis and evaluation of COVID-19. Most notably, the use of point-of-care ultrasound (POCUS) has increased physician interest into the modality, and many vouch for its use. The mobility of POCUS and the ability to perform a bedside scan of the patient's chest has made it a solid choice over other imaging modalities which cannot be moved in such a way (i.e. magnetic resonance imaging and computed tomography). Eliminating the need to move patients around the facility permits for better quarantining of those infected or suspected of having the virus. Moreover, it reduces the risk of infecting the imaging suite and minimizes the amount of staff which will come into contact with confirmed or potential cases. However, POCUS does not come without its infection control concerns. During the pandemic, ultrasound equipment's use as a diagnostic tool has further promulgated the risk of it becoming a vector of infection. In a study performed in January, researchers in Germany found that the virus could survive on machines for up to nine days if they were not properly disinfected (Kampf et al., 2020). Such data should serve to increase the urgency of practitioners' adherence to ultrasound infection control guidelines. Furthermore, it is recommended that if ultrasound is being used to diagnose and evaluate suspected or confirmed COVID-19 patients, practitioners set aside a designated machine to minimize the risk of infecting other patients in the facility. As the previous recommendations have shown, transducer reprocessing is essential in high risk situations. Although transducers used for COVID-19 applications may not require the guidelines of a critical procedure, ultrasound operators must weigh the risks presented by its use and determine whether to adopt certain practices which would not be used in a normal diagnostic scan, such as high-level disinfection (HLD). Regardless, it is necessary that ultrasound users properly perform at least low-level disinfection on the transducer after scanning potential or confirmed cases of the virus.

This is further facilitated by the ease of use which POCUS provides, thereby allowing for a wider range of practitioners to undertake the task of scanning the patient. In addition, recent developments in technology now allow for POCUS to be performed via smartphone, tablet, and app-based applications. For example, Butterfly Network's handheld ultrasound scanner is compatible with smartphones, thereby making it easy to use. Originally, this technology was developed with a focus on regions where larger, more expensive ultrasound machines were not always feasible, such as parts of Africa and Latin America. However, the impact of the pandemic has accelerated the adoption of handheld ultrasound devices in the United States and has allowed physicians and medical staff to quickly and efficiently scan patients. The USB-compatibility of these handheld ultrasound probes permits the user to connect it to their smartphone or tablet and use an app to perform the scan. Not only have advances such as these further increased the ease of use and mobility of ultrasound, but it has also made it more cost-effective and has fostered its expansion into new clinical areas.

Furthermore, it is important to note that COVID-19 is not the only threat presented against POCUS. The feasibility of handheld ultrasound combined with mobile applications has allowed more physicians to perform scans during at-home visits. This is particularly prevalent in Europe where physicians commonly visit patients at home. In addition, there are nurses and sonographers in the US who will routinely perform ultrasound scans in a home environment. Thus, we must consider the infection control implications of such use. It should be of no surprise that these settings do not provide the host of disinfection supplies and equipment which clinical settings do; however, this does not mean that ambulatory sonographers and nurses cannot carry LLD sprays and wipes with them. Those using POCUS outside of clinical settings must ensure that they are equipped with the proper infection control supplies. Although at-home scans are not critical procedures, it is essential that practitioners do not eliminate the disinfection and storage recommendations for non-critical procedures. Handheld ultrasound devices can become infected if not properly cleaned, disinfected, and stored, especially during transport. Moreover, practitioners should also take into account how patients are now be able to purchase their own personal ultrasound device over the counter. Of course, these personal devices are most likely only used by the owner; however, ultrasound practitioners should work to inform these patients of the importance of proper ultrasound infection control. Even if the machine is used by one individual, it is not exempt from the risk of pathogen colonization and transmission.

In addition, ultrasound's expanded use has extended to emergency medical services (EMS). Its application in these areas is of benefit to the clinician and the patient as it allows for prehospital imaging to be performed. Unlike decades ago, ultrasound machines are no longer bulky or expensive pieces of equipment which must be confined to a hospital setting. Ultrasound's newfound mobility, cost efficiency, and ease of use have all contributed to its growth in EMS. With the modality in hand, emergency medical technicians, physicians, and field nurses now have the ability to diagnose conditions such as pleural, peritoneal, and pericardial effusion and deep venous thrombosis (Chason et al., 2008). Nonetheless, this new area brings along its own infection control concerns. Ultrasound scanning in a prehospital or ambulatory environment is unique in that it can take place in a variety of settings. However, the mobile nature of the clinical area also signifies that it is a much less controlled and predictable environment than a hospital setting. One study noted how ultrasound was used by EMS in a helicopter as well as a field hospital in Iraq (Chason et al., 2008). Performing diagnostic imaging in both aforementioned situations was only possible because of the nature of the modality. For example, ultrasound does not interfere with avionic equipment. Meanwhile, the field hospital scenario featured tight spaces and high temperatures, conditions which would have been unsuitable for medical imaging in the past. Although it may be challenging to adhere to infection control best practices for ultrasound in emergency or ambulatory settings, it is necessary for practitioners working in this field to develop ways in which they can do so to minimize the risk of pathogen transmission. All ultrasound users must realize that the modality can become a vector of infection, even when used in non-critical procedures.

Healthcare practitioners would be remiss to not acknowledge how this diverse use, although impactful in efforts to improve patient care, brings along new infection control concerns. We must examine the infection control protocols in place for these additional settings. Furthermore, such a wide range of novel use raises the question of whether the recommendations from regulatory bodies are sufficient. It is necessary that for ultrasound to remain a safe modality each specialty and clinical area using it must be considered. Perhaps one of the most prominent challenges faced by infection preventionists focused on ultrasound imaging today is the phenomenal increase in its use. The presence of the modality in so many areas makes it difficult to offer universal guidelines which could satisfy the needs of each clinician. Regardless, this does not indicate that the recommendations should be ignored or tossed aside, but rather that they must be embraced by practitioners themselves. Overall, the primary responsibility of keeping ultrasound safe lies in the practitioner. It is essential that ultrasound users unite to promote proper adherence to infection control guidelines and continue to integrate new ultrasound applications into them. Doing so can lead to a variety of benefits for both patient and provider. Lower rates of infection, lower costs, and better patient care via ultrasound can be achieved through proper adherence. As research continues into new applications for ultrasound, such as therapeutic applications for Alzheimer's and diabetes, it is essential that a culture of infection control be inherently tied to the modality for its continued success and wide-ranging appeal in healthcare.

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