Guidelines for cleaning transvaginal ultrasound transducers between patients
WFUMB Safety Committee

Purpose:

The purpose of this document is to provide guidance regarding the cleaning and disinfection of transvaginal ultrasound probes. These recommendations are also applicable to transrectal probes

Introduction:

Transvaginal ultrasound (TVUS) probes (also designed as endovaginal in some countries) are routinely used in clinical obstetrics and gynecology. Strict decontamination is essential between patients since these tranducers may come into contact with mucous membranes.

Medical devices may be classified according to the infection risk they present. Systems used for this include the original 1957 classification: non-critical, semi-critical and critical (1) (also referred to as low-risk, medium-risk and high-risk (2)). Accordingly, cleaning of these instruments between uses depends on the above classification status, and ranges from simple wiping to sterilization.

"Non-critical" devices present the lowest risk to patients, since the only contact is with intact skin (such as abdominal probes). Low- or intermediate level disinfection is recommended (most bacteria [but not bacterial spores] and fungi as well as certain types of viruses, including human immunodeficiency virus [HIV] will be eradicated). If added decontamination is desired (for a wider range of viruses and mycobacteria), additional use of disinfectants is recommended, such as alcohol-, aldehyde-, phenolic- and quaternary ammonium-compound-based disinfectants (2). This represents mid-level disinfection (inactivation of bacteria, most viruses, most fungi, Mycobacterium tuberculosis and some bacterial spores)

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

"Critical devices" present the highest risk. They are used in sterile body areas, such as the intravascular space. Sterilization of these devices is imperative.

TVUS probes are categorized as presenting semi-critical or medium-risk(3). The real risk of infection associated with TVUS probes used without protective coverage or decontamination is unknown. No case of related specific infection has been reported in the literature, but ultrasound probes can become contaminated with bacterial pathogens, and hence are a potential vector for transfer of microorganisms(4, 5). It is the recommendation of experts that specific measures should be taken to avoid such a potential occurrence(6). Providing TVUS probes should routinely be encased in a disposable probe cover, the risk may be considered less critical. However, leakage rates of 0.9% - 2% for condoms and 8%-81% for commercial probe covers have been reported (7, 8) . The presence of Human Papillomavirus has been reported after low level disinfection(9, 9A). Therefore high-level disinfection of the probe between each use is strongly recommended, as is the use of a new condom or probe cover for each new patient (10). Review of clinical practices reveal various protocols, many of which are considered inadequate (11). Often, failures in eradication of microorganisms result from poor education and non-optimal adherence to reprocessing guidelines or protocols (11A).

Recommendations:

After a patient has been examined, and before using the TVUS probe in the next patient, the following procedures should be followed: removal of the probe cover, probe cleaning and disinfection, application of new probe cover.

1. Removal of probe cover

2. Cleaning - After removal of the probe cover, running water is usually sufficient to remove any residual gel or debris from the probe. Additionally a damp soft cloth with a small amount of mild non-abrasive liquid soap (such as household dishwashing liquid) may be used, followed by running water. Use a paper towel or soft cloth to dry the probe.

3. Disinfection - The additional use of a high level liquid disinfectant will ensure further reduction in microbial load, and because of potential leakage of the protective sheath (see above), use of high-level disinfection is necessary. High level disinfectants recommended by various ultrasound manufacturers include:

- 2.4-3.2% glutaraldehyde products (such as "Cidex," "Metricide," or "Procide"). Mode of action is by powerful binding of the aldehyde to the outer cell wall of the organism. It is sporicidal, bactericidal, fungicidal, tuberculocidal and virucidal. This has mostly been replaced by the following product.
- Non-glutaraldehyde agents (such as Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide & peroxyacetic acid). The mechanism of action of o-phthalaldehyde is similar to glutaraldehyde
- chlorine dioxide, used extensively in the UK and Australia, acts as an oxidizing agent. It reacts with several cellular constituents, including the cell membrane of microorganisms and has sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal efficacy.
- 7.5% Hydrogen Peroxide 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.
- Common household bleach (5.25% sodium hypochlorite) diluted to yield 500 parts per million chlorine (10 cc in one liter of tap water), although effective IS NOT recommended by manufacturers because of potential damage to metal and plastic parts.

The labeling of these various chemicals, and manufacturer's recommendations for cleaning TVUS probes should be consulted.

A list of FDA-approved disinfectants for reusable medical devices can be found at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm>

Caution is necessary when handling these chemical disinfectants since they are potentially toxic and many require precautions such as adequate ventilation, personal protective devices (gloves, face/eye protection, etc.) and thorough rinsing before reuse of the probe (see label for specific instructions). Further caution: most systems for chemical disinfection are such that the

probe handle is not in the solution and may remain contaminated, a risk for the end-user, as well as the patient (11*).

Recent studies demonstrate persistence of HPV viruses with the traditionally accepted methods of disinfection described above (11B,11C,11D). The CDC and FDA issued an alert regarding this specific issue in September 2015 (11E). Therefore alternative methods may have to be implemented.

One such method to sterilize the probe is short wave ultraviolet radiation (UVC; 200-280 nm) technology(12). After cleaning the probe with a towel/wipe impregnated with a disinfectant spray, UVC light is applied for 10 minutes. This results in rapid and complete eradication of bacteria and viruses. This technology, however, may not be available in many regions of the world and human exposure to levels above recommended limits may cause erythema and keratoconjunctivitis.

A newly commercialized chemical method for high-level disinfection is based on an automated and closed system. It has been shown to be effective against all microorganisms, including HPV (12A,12B)The process is very rapid (approximately 7 minutes) but cost may be prohibitive for many end-users .

It should be noted that detergent wipes are used by many practitioners but are not considered high-level disinfectants and can cause damage to transducers.

4. Probe cover - The transducer should be covered with a barrier. This can be a commercially-available condom or a dedicated commercial probe cover. Condoms should be non-lubricated and non-medicated. Condoms have been shown to be less prone to leakage than commercial probe covers, are superior to standard examination gloves and equivalent to surgical gloves.

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