PROBE DISINFECTION DIRECTIVES

On October 2, 2015, The Center for Disease Control (CDC) issued a Health Alert Network advisory regarding disinfection of medical devices. That alert is of concern to PMCs providing sonograms. In keeping with nationally recognized guidelines from AIUM and sonography experts, NIFLA encourages the use of the transvaginal ultrasound probe to obtain superior images in the first trimester of pregnancy. Proper probe disinfection is always necessary for patient safety. The American Institute of Ultrasound in Medicine (AIUM) has also developed official statements on probe disinfection.

CDC Advisory Statement

1) Background - Recent media reports describe instances of patients being notified that they may be at increased risk for infection due to lapses in basic cleaning, disinfection, and sterilization of medical devices. These events involved failures to follow manufacturers' reprocessing instructions for critical and semi-critical items and highlight the need for healthcare facilities to review policies and procedures that protect patients. Of note, a vaginal ultrasound probe, though covered by a probe cover is classified as a semi-critical device as it comes in contact with mucous membranes. However, these devices should be reprocessed to be free from all microorganisms. Users should be instructed to thoroughly clean these devices and high level disinfection should be used.

2) Recommendations - Healthcare facilities should have a healthcare professional assess their reprocessing procedures. This assessment should ensure that reprocessing is done correctly, including allowing enough time for reprocessing personnel to follow all steps recommended by the device manufacturer. CDC recommends three areas where healthcare facilities should take action which include personnel training and competency for disinfection, audit and feedback from practices, and policies and procedures in place for disinfection. Those recommendations can be found in full in the CDC Health Update on their website listed in the references of this Clinic Tips.

AIUM’s Official Statements

“Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Probes Between Patients,” approved April 2, 2014, available at www.aium.org, is referenced below. These Guidelines should be reviewed for step-by-step directives for disinfecting both abdominal and vaginal ultrasound probes. AIUM also describes the various high level disinfectants which should be used on vaginal probes. NIFLA is aware of this concern, and urges PMCs who perform vaginal scans to always use a high level disinfectant product to soak vaginal probes, as approved by the manufacturer.

In the last two or three years, there has been much discussion in OB/GYN sonography circles about the necessity of purchasing an automated vaginal probe disinfection system, Trophon EPR, utilizing vaporized hydrogen peroxide. Such systems cost $10,000 - 12,000 and require monthly cartridges replacements each costing around $200 plus. It is claimed by some that this is the only system which is effective at destroying all virus and microorganisms. Yet, AIUM has not made any official statements stating such a need for this system. Further, reports from sonographers around the country report on a sonographer’s Facebook group report that
this system is damaging their probes, resulting in tips coming off with leakage.

Simply washing the probe and/or using a disinfectant wipe is not sufficient for high level disinfection, soaking is necessary. Safety Data Sheets (SDS) should be obtained for the high level disinfectant products from the manufacturer and kept on file for reference. A soak method must be used after initial washing with soap and water to remove all gel and residue which can contaminate any disinfectant and reduce its effectiveness.

Most PMCs have opted to use the high level disinfectants Ortho-Phthalaldehyde product such as Cidex-OPA or a hydrogen peroxide disinfectant such as Revital-Ox™ RESERT® High Level Disinfectant. Both would satisfy AIUM Guideline and are FDA approved high level disinfectants. In past years, one machine manufacturer (which no longer makes ultrasound equipment) approved a bleach solution (1:100 bleach to water dilution for soaking probes), which the AIUM still references in its disinfection documents, though no companies approve such a method.

PMCs must be aware that if they use methods of high level disinfection NOT approved by their ultrasound equipment manufacturer, any probe damage is not likely to be under warranty. For those without a warranty or maintenance agreement, the probe replacement costs can run $5,000 or more.

For all high level disinfection products, there is concern for vapors that could cause health concerns. The peroxide based products, upon exposure to air, become water and oxygen.

Rooms where probes are disinfected should have adequate ventilation and air exchanges to prevent exposure to chemicals. One system many PMCs have purchased -- the GUS system -- is a closed system with fan and air filtration.

Ultrasound probes should also be disinfected between patients with a disinfectant compatible with the probe as per the manufacturer. Protex is a quaternary ammonium product which has been used for years, and disinfectant wipes developed for delicate probes may be appropriate as well if your manufacturer approves.

Remember -- keep all probe cords off the floor where they can become dirty and stepped upon. Each probe cord has approximately 128 fine wires carrying information to the machine. Due to the fine gauge wires used, these can be easily broken and begin to degrade ultrasound images.

In review, make sure to access the AIUM Official Statements on probe disinfection., PMCs should begin every scan with an abdominal probe for a global view of the pelvis, then utilize transvaginal scanning as needed to obtain superior imaging in the first trimester, followed with appropriate cleaning methods.

Years of training in sonography have proven that early pregnancy vaginal scanning is often the only means to obtain diagnostic quality images to rule out ectopic pregnancy, document fetal cardiac activity and accurate measurements. Numerous factors contribute to the need for vaginal scanning. Because of this, PMCs must be vigilant to appropriately clean the ultrasound probes first and then disinfect it with a high level disinfectant. The women we serve not only need accurate information from sonograms but also protection from infection.

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