Judy Thompson, MSN, RN, VA-BC™, Director of Clinical Education, Association for Vascular Access
J. Hudson Garrett Jr., PhD, FNP-BC, IP-BC™, VA-BC™, Assistant Professor of Medicine, Division of Infectious Diseases, University of Louisville School of Medicine, President, Board of Directors, Vascular Access Certification Corporation, Co-Founder, Infection Prevention Institute

Transducer Disinfection for Evaluation and Insertion of Peripheral and Central Catheters for Vascular Access Teams and Clinicians

Introduction / Summary

Use of real-time ultrasound guidance for vascular access (USGVA) procedures is recommended by multiple organizations, associations, guidelines and standards [1-13]. When performed by trained, competent clinicians, USGVA has been shown to decrease complications and reduce multiple attempts to gain vascular access [1-8,10-26].

Use of ultrasound for vascular access, particularly peripheral access, presents distinct challenges to existing recommendations. Healthcare professionals responsible for vascular access also have a responsibility to ensure patient safety during those procedures, therefore, they also must address inconsistent practice with respect to cleaning and disinfection practices involving USGVA.

There are conflicting published guidelines regarding the level of disinfection a transducer must undergo between patients/procedures [22,27-37]. The Association for Vascular Access (AVA), in conjunction with experts in infectious disease and infection prevention, have developed this professional guidance document which serves as a basis for evidence-based decision making. Additionally, this document identifies areas of practice that require continued monitoring and clinical research.

Background / Problem

Greater than ninety percent (90%) of hospitalized patients have a Vascular Access Device (VAD) inserted, making VAD insertion the most common invasive procedure patients experience ([38-40]) Use of ultrasound in VAD insertion also has a strong and increasing presence in outpatient settings making consistent practice across the care continuum an essential yet complex goal. Use of ultrasound for vessel assessment and real-time guidance is strongly recommended by many professional clinical societies and organizations, is widely practiced, and has shown to decrease complications, reduce multiple access attempts and, as a result, has improved patient safety and satisfaction ([1-14,16-21,23-25]). Use of ultrasound for the placement of VADs is directly aligned with the Institute for Healthcare Improvement Triple Aim philosophy of improved population health, improved patient satisfaction with care, and cost reduction [41].

As identified previously, conflicting guidance documents have been published regarding the most appropriate level of disinfection for ultrasound transducers. As defined by the Spaulding Classification, global recommendations range from High-Level Disinfection (HLD) to Low-Level Disinfection (LLD) [22,27-36,42-47]. AVA's collaborative document will guide safe practice for the disinfection of ultrasound transducers used in access procedures providing a consistent approach to the application of the Spaulding classification scheme. Adhering to recommendations of HLD or sterilization for ultrasound transducers used during peripheral and central intravenous catheter insertion may have unacceptable repercussions resulting in adverse patient outcomes.

This guidance document examines existing practice with respect to ultrasound transducer disinfection as it is currently performed. Furthermore, this document evaluates how the current evidence supports existing best practice and meets the evidence-based criteria. Recommendations and guidelines must be able to be reasonably operationalized if we expect compliance. That is not to say that patient safety is ever negotiated, but we must address risk versus benefit. Complexities layer this issue and require insights of front line specialists with respect to practice and areas where there is a need for process and outcomes research[15].

Use of ultrasound has been demonstrated to improve clinical outcomes through the:

1. Reduction of:
   a. Multiple needle sticks
   b. Pneumothorax/Hemothorax
   c. Inadvertent arterial access

Disclaimer: This document is meant to serve as a basis for evidence-based decision making. Nothing contained within this guidance document should take the place of following a medical device's approved instructions for use provided by the manufacturer. This document should also be used in conjunction with a facility-specific infection control risk assessment to create institutional procedures for the proper use and cleaning/disinfection of these ultrasound devices.

2. Assessment/identification of:
   a. non-patent vasculature to prevent inappropriate catheterization complications
   b. vessel irritation, thrombosis, and other potentially adverse events
   c. nerve bundles and prevents associated complications
   d. guidewire direction [1-12,14,16-21,23-25,37]

USGVA is transforming practice into the accepted standard of care across the entire healthcare continuum. Ultrasound technology is now being used in Emergency Departments, Intensive Care Units, preoperative units, acute care units, long term care facilities and clinics for peripheral and central access. AVA expects this trend to continue and overall usage of these evidence-based technologies to expand in the coming years. Recent literature from global publications recommend HLD for reprocessing non-invasive ultrasound transducers used for the insertion of VADs.[22,29-36]

Use of HLD for these procedures make reprocessing of these transducers impracticable and problematic for multiple reasons:

1. Reduce throughput by creating delays in transducer availability due to HLD cycle time
2. Increase cost of additional ultrasound probes
3. Increased cost related to HLD products (special facilities, equipment and associated disinfection chemicals)
4. Non-Compliance with HLD policy and procedure
5. Additional HLD training and competency requirements
6. Reduced ultrasound guidance for VAD insertion

Through this guidance document, AVA provides a pragmatic approach to disinfection of the USGVA transducers which promote patient safety, reduce risk for healthcare-associated infections, creates uniformity and consistency to healthcare facilities across the continuum of care and enhances the opportunity to improve patient satisfaction which is so critical to evidence-based care.

Using the Spaulding Classification to Assess Patient Risk and Influence Decision-making

The authors of this guidance document conducted an extensive literature review of relevant published manuscripts to provide background and context on this important clinical issue. In addition, the authors reviewed relevant clinical guidelines and guidance statements from clinical societies and the United Stated Food and Drug Administration and Centers for Disease Control and Prevention. Each guideline cites the Spaulding Classification Scheme [35,37,48,49].

Interpretation of the Spaulding Classification is very specific in some areas and left to interpretation in others. According to the CDC, the Spaulding classification is strategy for determining reprocessing methods for contaminated medical devices based upon the use of that device [50]. The system classifies a medical device as critical, semicritical, or noncritical on the basis of risk to patient safety from contamination of a device. The system also recommends three levels of disinfection activity (Sterilization, HLD, and LLD) for use according to the classification of medical devices (critical, semicritical, and noncritical). By necessity, the Classification must recognize the prior use of the device as well as the intended use in determining the level of disinfection or sterilization. For example, an ultrasound used during a procedure where contamination with purulent tissue or material is present must be cleaned and disinfected using a process that can reliably remove and inactivate the organisms involved. In addition, the user must consider the intended subsequent use of the device, so it is disinfected to meet that purpose. This demonstrates the complexity involved in disinfection of an ultrasound transducer that healthcare personnel may share and use as equipment for more than vascular assessment or VAD insertion.

The intended use of an ultrasound transducer for the purposes of placing peripheral or central vascular access devices is to assess vasculature under intact skin and not come in contact with mucous membranes. However, during insertion, the device comes into contact with the blood of the patient, and *de facto* the bloodstream of the patient. Therefore, cleaning and disinfection practices used within a given facility must assess the risks involved in the ultrasound transducer use and the ability to perform the necessary level of cleaning and disinfection in a manner that is consistent, reliable and reproducible.

The Association for Vascular Access (AVA) recommendations:

Vascular Access Device Low-Level Disinfection

Practice Recommendations

Given the variability of facilities, personnel, organizational capabilities, and practices, AVA recommends the following steps regarding cleaning, disinfection of an ultrasound transducer used for vascular access:

1. Healthcare Facilities should conduct a thorough infection prevention and control risk assessment in collaboration with Vascular Access, Infection Prevention and Control, Environmental Services, and other relevant facility stakeholders to evaluate risks with ultrasound transducers used for vascular access to evaluate risks of healthcare associated infection transmission.
2. Prior to the first episode of ultrasound transducer use, and at least annually, all clinicians involved in USGVA will undergo comprehensive training on proper disinfection of US transducers/probes.
3. Training to include, at a minimum, cleaning and disinfection of all ultrasound transducers used as part of job responsibilities, application and use of sheaths (sterile and unsterile), application and use of gel (single use sterile), process monitoring, and performance improvement.
4. Training should be competency-based with validation.
5. All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low level disinfection using an EPA-registered, hospital-grade germicide with broad spectrum efficacy claims against clinically relevant microorganisms (including enveloped and non-enveloped viruses such as Hepatitis B Virus and HIV,