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Major Article

Ultrasound probe use and reprocessing: Results from a national survey among U.S. infection preventionists

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Background: Improper infection prevention practice associated with ultrasound probe use has been linked to increased infection risk, outbreaks, and death. Although guidelines for reprocessing and use of probes exist, it is unclear how extensively these have been adopted in practice.

Methods: Infection preventionists from U.S. health care facilities were surveyed (N = 358). The anonymous survey had 31 multiple choice, sliding scale, and text response questions. The survey was developed and deployed and the data were stored in the REDCap system.

Results: A high degree of noncompliance with U.S. guidelines was identified. Surface probes used in invasive procedures were not high-level disinfected or sterilized 15% (intraoperative) to 78% (peripheral line placements) of the time. Of invasive procedures, 5%-47% did not use sterile gel (same procedures, respectively). Of the participants, 20% were aware of instances where an ultrasound probe was used but was not correctly reprocessed. Extensive breaches of infection control guidelines were reported. The rapid expansion in use of ultrasound has brought clinical benefit but may be exposing patients to preventable infection risk.

Conclusions: Infection preventionists are well placed to act as major drivers of change based on their expertise and experience in the management of infection risk across facilities and health systems. They, along with clinicians responsible for probe use and reprocessing, should review practices relating to ultrasound in their facilities. Where practice does not comply with guidelines, policy and training should be updated to ensure patient safety.

In recent years, ultrasound procedures have seen a rapid expansion throughout U.S. hospitals, outpatient ambulatory settings, and medical offices. This expansion carries with it documented infection risks that have been recognized worldwide. In 2016, The Joint Commission found that 74% of all immediate threats to life declarations were related to improperly sterilized or high-level disinfected equipment.[1] In 2017, the first study to investigate the risk of improper reprocessing at an epidemiologic level was published.[2] The retrospective study, undertaken by a department of the NHS Health Scotland, showed that patients undergoing a transvaginal scan were 41% more likely (hazard ratio [HR], 1.41) to have positive bacterial cultures and 26% (HR, 1.26) more likely to be prescribed antibiotics in the 30 days after ultrasound versus matched controls ($P < .001$). Similarly, patients undergoing transrectal scans were 3.4 times (HR, 3.4) and 75% (HR, 1.75) more likely to have positive cultures and be prescribed antibiotics, respectively. Compounding these findings are recent studies demonstrating glutaraldehyde and *ortho*-phthalaldehyde (OPA) are ineffective in inactivating human papillomavirus (HPV).[3,4] It has also been reported that >80% of probe handles are contaminated with pathogens, including methicillin-resistant *Staphylococcus aureus*, supporting the call for inclusion of the handle in reprocessing along with the probe body.[5,6]

Patient deaths have also been reported as a result of ultrasound probe contamination. In 2012, a patient death because of hepatitis B after an endocavitary examination with an improperly

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reprocessed transesophageal ultrasound probe was reported.[7] Numerous outbreaks implicating contaminated ultrasound gel have also occurred, including cases where bacteremia and death resulted.[8,9] These outbreaks demonstrate the risks associated with surface ultrasound–guided procedures and suggest the probe and gel can contaminate the puncture site during imaging. Appropriate use of sterile gel and adequate ultrasound probe reprocessing play key roles in preventing these adverse events.

Globally, there has been a movement toward ultrasound-specific guidelines from Europe, the United Kingdom, and Australia in response to these recent findings and outbreaks.[10-14] In November 2017, in response to results from a practice survey, the European Society of Radiology Ultrasound Working Group published best practice recommendations regarding infection control in ultrasound use. These recommendations include a minimum of high-level disinfection (HLD) and use of a sterile sheath and gel for interventional ultrasound (eg, biopsies, injections, or any procedure where the skin is breached). In addition to HLD for endocavitary procedures, they strongly recommend the use of sterile gel inside and outside the cover.[15]

The United States has ultrasound-specific guidance from the Centers for Disease Control and Prevention (CDC) and the American Institute of Ultrasound in Medicine (AIUM), and the Association for the Advancement of Medical Instrumentation (AAMI) has developed an American National Standard ST58 on the HLD and sterilization of reusable medical devices.[16-18] The recent highly publicized outbreaks associated with flexible endoscopes and endoscopic retrograde cholangiopancreatography are timely examples of the consequences of reprocessing failures.[19-22] It is important to investigate and understand ultrasound use practices, associated patient safety risks, and the gap that is present between existing practice and best practice, as defined in U.S. guidelines and standards.

A cursory review of practice among a small group of U.S. infection preventionists (IPs) was done in late 2016, and concerns were identified regarding the increasing use of ultrasound technology and the associated practices that ensure their safe use for patient care.[23] To better understand existing practices and the gaps that may exist, a larger survey was undertaken. The objectives of the larger survey were (1) to define the current state of ultrasound use in U.S. health care facilities, (2) to identify existing practices regarding decontamination and disinfection of the ultrasound probes, and (3) to identify practices that serve to prevent infection transmission to patients across the spectrum of procedures that depend on the use of ultrasound probes.

METHODS

A survey was developed, pilot tested, and revised with the intent to deploy in an electronic format to U.S. IPs practicing in a variety of health care settings. The project was reviewed by the University of Louisville Institutional Review Board and was deemed exempt. A standardized e-mail message was crafted containing a link to the survey and a short video describing the intent of the survey and a brief background of the problem. The survey consisted of 31 questions and was deployed using a Web-based e-mail service. The REDCap system was selected as the survey development, deployment, and data storage platform.[24] Survey questions included multiple choice response options and sliding scale response options for questions involving perceptions and confidence. Anonymity was ensured by procedures that prevented retention or tracking of any e-mail address or respondent information. Within the survey, there was a link to a Portable Document Format file containing all survey questions and response options. This was provided so respondents could observe and investigate existing practices prior to completing the survey. E-mails were sent in August 2017 with the survey link and a video link along with information about the intent of the survey. Three additional e-mail reminders were sent at regular intervals. The survey closed 8 weeks after the initial deployment in October 2017.

Data analysis was performed by personnel in the University of Louisville Data Coordinating Center. Descriptive statistics were reported with frequency and percentage for categorical data. Medians and interquartile ranges (IQRs) were reported for continuous data.

RESULTS

Respondent demographics

A total of 12,937 IPs were sent the survey link with 358 surveys completed for a response rate of 2.8%. The response rate and sample size are similar to ultrasound surveys from Australia/New Zealand and Europe.[25,26] Most IPs worked in a hospital setting (59.5%). The remaining respondents were from long-term care, long-term acute care, outpatient clinics, or ambulatory surgery centers (<10% each). Each facility had a median of 1 (IQR, 2; minimum, 0; maximum, 34) full- or part-time IP and a median of 1 (IQR, 2; minimum, 0; maximum, 31) full- or part-time certified IP.

Ultrasound and Doppler probe use throughout health care facilities

Figure 1 shows the wide range of ultrasound use in the respondents' facilities.

Radiology, obstetrics/gynecology/maternal fetal medicine, the emergency department, and the operating room had the highest rates of ultrasound usage. The departments where there was highest uncertainty about ultrasound usage were physical therapy, neurology, oncology, and anesthesiology.

Use of ultrasound probes, probe covers, and ultrasound gel in procedures

Respondents were asked about ultrasound use and reprocessing in specific procedures. If the procedure was performed, the respondent was asked about ultrasound probe reprocessing (Fig 2 and Table 1), use of sheaths or covers (Table 1), and type of ultrasound gel used (Table 2). Current ultrasound use and reprocessing guidelines have been published by both the CDC and the AIUM.[16,17] Additionally, AAMI has developed an American National Standard on the requirements for sterilization and HLD of reusable medical devices in health care facilities.[18] These recommendations are summarized in Figure 2A. Answers compliant with the recommendations appear in Figure 2B (probe reprocessing) and are indicated in Table 1 (probe reprocessing and sheath use) and Table 2 (gel use). Respondents who did not have the procedure at their facility or were unsure were excluded from subsequent reprocessing and use questions. Of respondents, 37% were unsure about injections (ultrasound-guided delivery of drugs/therapeutics to tissue or bloodstream, such as nerve blocks and intra-articular injections), 29% were unsure about scans across nonintact skin (ultrasound probe across nonintact skin, such as burn, skin breakdown, and partially healed wound), 22% were unsure about intraoperative scans (eg, surgical procedure, contact with sterile body cavity or sterile tissue), 20% were unsure about tissue sampling (ultrasound-guided tissue sampling procedure, such as biopsies), 7% were unsure about peripherally inserted lines (ultrasound-guided peripheral line placement), 2% were unsure about central venous catheter (CVC) placement (ultrasound-guided central line placement), 2% were unsure about intact skin (ultrasound probe across intact skin, such as fetal heart tone, pulse check, and transabdominal scan), and 1% were unsure about endocavitary scans (eg, contact with mucous membranes; rectal, vaginal, or esophageal use).