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Society for Maternal-Fetal Medicine Special Statement: Reducing the risk of transmitting infection by transvaginal ultrasound examination

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Recent surveys have shown widespread lapses in the procedures used to reduce the risk of transmitting infection via medical devices. Transvaginal ultrasound examination has the potential to transmit vaginal infections, including human papillomavirus. Areas of particular concern are the use of probe covers with high rates of leakage, disinfectants that are not effective against human papillomavirus, and coupling gel from multiple-use containers. We reviewed these issues, and we recommend 4 steps to reduce the risk of transmitting infection. First, during every transvaginal ultrasound exam, the probe should be covered with a sterile, single-use "viral barrier" cover or a condom. Second, sterile, single-use ultrasound gel packets should be used. Third, after every examination, the probe should be cleaned to remove any visible gel or debris. Finally, after cleaning, the probe should undergo high-level disinfection using an agent with proven efficacy against the human papillomavirus, including hydrogen peroxide, hypochlorite, or peracetic acid. Glutaraldehyde, orthophthalaldehyde, phenols, and isopropyl alcohol have virtually no efficacy against the human papillomavirus.

Key words: Glutaraldehyde, hydrogen peroxide, infection prevention, orthophthalaldehyde, ultrasound gel, ultrasound safety

Introduction

Transvaginal ultrasound examination has the potential to transmit vaginal infections between patients unless certain well-described procedures are followed to clean and disinfect the intravaginal ultrasound probe between examinations.[1] Two recent surveys have found widespread and extensive lapses in infection prevention practices related to ultrasound probes and other medical devices.[2,3] The incidence of such lapses has been increasing in recent years.[2]

The purpose of this document is to review the recommended procedures to minimize the risk of transmitting infection via transvaginal ultrasound examination, with emphasis on recent data demonstrating that some disinfectants do not neutralize human papillomavirus (HPV).

Why is the disinfection of transvaginal probes an important issue?

Transvaginal ultrasound has become a routine part of obstetrical care. In the first trimester, transvaginal imaging is a key adjunct to transabdominal imaging for evaluating threatened pregnancy loss, ectopic pregnancy, and fetal anomalies.[4,5] In second-trimester screening for the risk of preterm birth, transvaginal measurement of cervical length is superior to transabdominal measurement.[6,7] Some experts have advocated for universal transvaginal cervical length screening for all singleton pregnancies,[8–11] although universal screening has not been mandated by the Society for Maternal-Fetal Medicine.[12]

Clinically significant pathogenic bacteria and viruses can survive on transvaginal probes. These include strains of *Staphylococcus, Bacillus, Pseudomonas, Enterococcus, Clostridium*, *Chlamydia,* and HPV.[13–15] Of particular concern, HPV types 16 and 18 can withstand harsh conditions, including several widely used disinfectant methods.[16,17] These high-risk HPV strains are the most common causes of cervical cancer.[18,19]

Improper cleaning and disinfection of ultrasound probes are clear problems that require urgent attention in the United States. In a 2016 survey by The Joint Commission, 74% of all discovered immediate threats to life were related to improperly sterilized or disinfected equipment.[2] The rate of noncompliance with The Joint Commission infection prevention standards was 60% in hospitals, 57% in office-based settings, and 53% in ambulatory healthcare

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BOX
Reasons for noncompliance with infection prevention standards in surveys by The Joint Commission

Mistaken belief that the risk of transmitting pathogens to patients is low or nonexistent.
Staff lacks the knowledge or training required to disinfect equipment properly.
Staff does not have access to or lacks knowledge of evidence-based guidelines.
Leadership oversight is lacking.
Disinfection of equipment is a low priority within the organization.
There is a lack of a culture of safety that supports the reporting of safety risks.
Processes for disinfection are not followed (ie, staff take shortcuts).
The time frames for proper disinfection of equipment are not followed.
There is no dedicated staff member to oversee the proper disinfection of equipment.
Facility design or space issues prevent proper disinfection of equipment (eg, processing takes place in a small room that is also used for storage).
There is a lack of monitoring or documentation of disinfection of equipment, which makes it difficult to track the use of equipment on a specific patient, complicating the patient notification process when an outbreak occurs.
Equipment is spread throughout the facility and may be processed or stored in numerous locations, making it difficult to track the equipment for documentation purposes.

Adapted from The Joint Commission.[2]
Hamm et al. Reducing the risk of transmitting infection by transvaginal ultrasound examination. Am J Obstet Gynecol 2020.

facilities—rates that have steadily increased since 2009. Several contributory factors were identified, including lack of appreciation for the risk of transmission, lack of staff knowledge or training, and lack of priority given by leadership to infection prevention (Box). In a 2018 survey of 358 US healthcare facilities, 20% reported incorrect processing of ultrasound probes, with most of those cases in obstetrics and gynecology and emergency departments.[3]

Are sterile probe covers sufficient to prevent transmission of infection?

Some commercially produced ultrasound probe covers have unacceptably high rates of leakage (8% to 81%)[20,21] and cannot realistically be considered to offer an effective barrier against transmission of infection, particularly viruses. There are at least 2 commercial probe covers that are considered to be "viral barriers" and have demonstrated a low failure rate for leakage of particles as small as 20 nm in laboratory tests.

Alternatives to commercial probe covers include condoms and surgical gloves. These items are manufactured to meet strict Acceptable Quality Limit (AQL) standards that reflect the percentage of items in a sample that are free from holes. The AQL is 0.25% for condoms, 1.5% for surgical gloves, and 2.5% for standard examination gloves.[1,22,23] Leakage rates of 1% to 2% have been reported when condoms are used to cover endovaginal ultrasound probes.[20,24] In a study of 500 commercially produced probe covers of 10 brands, leakage rates ranged from 0% to 5%.[25]

Recommendations: Disposable, single-use "viral barrier" probe covers or condoms are recommended for transvaginal ultrasound examination because of their relatively low failure rate. Standard examination gloves and commercially produced probe covers without proven viral protection are not recommended. However, all probe covers have a finite failure rate and cannot be relied on as the sole method of infection prevention. Thus, the ultrasound probe itself must be cleaned and disinfected after each transvaginal ultrasound examination.

Is it sufficient to wipe down the probe and spray it with a disinfectant after each use?

Wiping the probe to remove ultrasound coupling gel and other visible debris is a component of cleaning, as defined in Table 1. Additional cleaning may include rinsing the probe under running water and then drying thoroughly with a soft, clean towel. Disinfectant sprays such as phenolics or

TABLE 1
Levels of cleaning, disinfection, and sterilization

Level	Definition
Cleaning	Removal of visible material from objects and surfaces, usually accomplished manually or mechanically using water with detergents or enzymatic products
Low-level disinfection	Destruction of most bacteria, some viruses, and some fungi, but does not necessarily inactivate *Mycobacterium tuberculosis*
Mid-level disinfection	Inactivation of *M. tuberculosis*, bacteria, most viruses, most fungi, and some bacterial spores
High-level disinfection	Destruction and/or removal of all microorganisms except bacterial spores
Sterilization	Destruction and/or elimination of all forms of microbial life

Adapted from Rutala et al.[26]
Hamm et al. Reducing the risk of transmitting infection by transvaginal ultrasound examination. Am J Obstet Gynecol 2020.

TABLE 2
Recommended disinfection levels for medical devices

Type of device	Definition	Examples used in obstetrics and gynecology	Minimum processing recommended after each use
Critical	Objects that enter sterile tissues or the vascular system, resulting in a high risk for infection if contaminated with any microorganism	Surgical instruments, laparoscopes, implants, intraoperative ultrasound probes	Cleaning, then sterilization
Semicritical	Items that contact mucus membranes or nonintact skin	Vaginal ultrasound probes, abdominal ultrasound probes used on nonintact skin, vaginal speculums, diaphragm fitting rings	Cleaning, then high-level disinfection
Noncritical	Items that only contact intact skin	Abdominal ultrasound probes, stethoscopes	Cleaning as needed, then low-level disinfection

Adapted from Rutala et al.[26]

Hamm et al. Reducing the risk of transmitting infection by transvaginal ultrasound examination. Am J Obstet Gynecol 2020.

quaternary ammonium are low-level disinfectants.[26] These are generally acceptable for transabdominal ultrasound probes and other external-use devices, which are classified as "noncritical" devices, as shown in Table 2. However, low-level disinfection is insufficient for transvaginal ultrasound probes and other internal-use devices because methicillin-resistant *Staphylococcus* and other pathogenic organisms can survive such treatment.[13,14,27] Transvaginal ultrasound probes are considered "semicritical" devices and are recommended to undergo high-level disinfection after each use.[26]

Recommendation: After each use, transvaginal ultrasound probes should be cleaned and then treated with high-level disinfection. Wipe down and spray are low-level disinfection procedures and are not sufficient for transvaginal probes.

Are glutaraldehyde and orthophthalaldehyde adequate for high-level disinfection of vaginal ultrasound probes?

Table 3 shows the agents considered to be high-level disinfectants by the US Food and Drug Administration (FDA). Over 2 dozen products have aldehydes as an active ingredient. Unfortunately, in bench-testing, these aldehydes have virtually no viricidal activity against HPV.[16,17,28] Phenol and isopropyl alcohol also fail to neutralize HPV.[16] In US women aged 18 to 59 years, the prevalence of genital HPV is 49.9%, and the prevalence of high-risk genital HPV is 20.4%.[18,19] Thus, if the probe cover fails during a transvaginal ultrasound examination, there is a high probability that the probe will become contaminated with HPV. If the disinfectant solution is ineffective against HPV, there is a high probability that the virus will persist on the probe until the next examination. Thus, a transvaginal ultrasound examination may potentially expose an individual to high-risk HPV, the virus that causes most cases of cervical cancer.[18,19]

The high-level disinfection agents that have been shown to be effective against HPV in bench-testing include hydrogen peroxide (sonicated system),[17] hypochlorite,[16,28] and peracetic acid.[16] We are not aware of bench-testing to evaluate whether soaking systems based on hydrogen peroxide, with or without peracetic acid, have anti-HPV viricidal activity.

Ultraviolet C (UVC) radiation is also effective against HPV.[28] A UVC chamber device is approved by the FDA for low-level disinfection.[29,30] Bench-testing of the device showed reasonable efficacy against pathogenic vaginal bacteria but persistent contamination by other bacteria.[31]

TABLE 3
High-level disinfectants and chemical sterilants cleared by the US Food and Drug Administration

Active ingredients	Number of products listed	Efficacy against HPV
Glutaraldehyde	16	No
Glutaraldehyde + isopropanol	3	No
Glutaraldehyde + phenol or phenate	1	No
Hydrogen peroxide	3	Yes
Hydrogen peroxide + peracetic acid	2	?
Hypochlorite + hypochlorous acid	2	Yes
Orthophthalaldehyde	6	No
Peracetic acid	3	Yes

HPV, human papillomavirus.

Adapted from US Food and Drug Association.[29] The source lists 36 specific products, with varying concentrations of ingredients and specific time and temperature requirements for demonstrated efficacy.

Hamm et al. Reducing the risk of transmitting infection by transvaginal ultrasound examination. Am J Obstet Gynecol 2020.

Thus, the UVC chamber alone is not considered sufficient for the disinfection of vaginal ultrasound probes.

Recommendations: After each use, the transvaginal ultrasound probe should undergo high-level disinfection using 1 of the agents with proven efficacy against HPV, such as hydrogen peroxide (sonicated system), hypochlorite, or peracetic acid. Each probe manufacturer has a list of agents compatible with its probes. Disinfection procedures should follow the time and temperature recommendations published by the chemical manufacturer. Because glutaraldehyde, orthophthalaldehyde, phenols, and isopropyl alcohol are ineffective against HPV, if these agents are used for high-level disinfection, the probe should also be treated using a UVC chamber disinfection device with proven efficacy against HPV.

Are precautions needed to prevent transmission of infection via ultrasound coupling gel?

Multiple-use gel containers can potentially harbor pathogenic organisms, especially if they are kept in a warming device.[14,31]

Recommendations: If multiple-use containers are used for transabdominal ultrasound examination, the containers should be discarded when empty and should not be refilled. The use of gel from single-use, sterile, disposable gel packets for both inside and outside the probe cover is recommended to minimize the risk of contamination during transvaginal ultrasound examinations.[1] However, there have been outbreaks of bacterial infection caused by contaminated packets of gel labeled as "sterile" by the manufacturer.[32–35]

Summary and conclusions

The following steps are recommended to minimize the risk of transmitting vaginal infections via transvaginal ultrasound examination:

1. During each examination, the probe should be covered with a sterile, disposable, single-use cover with a documented low rate of leakage—either a "viral barrier" probe cover or a condom.
2. The ultrasound coupling gel should be from sterile, disposable, single-use packets.
3. After each examination, the probe should be cleaned to remove any gel or visible debris.
4. After cleaning, the probe should undergo high-level disinfection using a method with proven efficacy against bacteria and viruses, including HPV, such as hydrogen peroxide (sonicated system), hypochlorite, or peracetic acid. Glutaraldehyde, orthophthalaldehyde, phenol, and isopropyl alcohol are not effective against HPV.

Each step alone is insufficient to prevent transmission of infection. The safest approach is to apply all these steps together.[36]

In light of the reasons for noncompliance with infection prevention standards noted by The Joint Commission and summarized in the Box, an effective program for infection prevention requires a commitment on the part of the leadership of each practice or facility, designation of key personnel who will be responsible for infection prevention, development of written procedures, and training and monitoring of the ultrasonography staff.

Additional information about cleaning and disinfection of ultrasound equipment and other medical devices can be found in excellent overviews by the American Institute of Ultrasound in Medicine[1] and the Centers for Disease Control and Prevention,[26] respectively. The latter document also addresses environmental safety, handling, and disposal of chemical disinfectants—topics that are beyond the scope of this review.

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