SAFETY STATEMENT

ISUOG Safety Committee Position Statement on safe performance of obstetric and gynecological scans and equipment cleaning in context of COVID-19

In view of the challenges of the current coronavirus (COVID-19) pandemic and to protect both patients and ultrasound providers (physicians, sonographers, allied professionals), the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) has compiled the following expert-opinion-based guidance for the performance of ultrasound investigations in pregnancy and for gynecological indications. The guidance assumes that robust local processes are in place for cleaning ultrasound equipment after each patient routinely, and gives specific recommendations for ultrasound examinations in suspected or confirmed cases of COVID-19.

BACKGROUND

The novel coronavirus infection spreads very easily and even asymptomatic patients or caregivers can be a route of transmission. The two main principles of undertaking safe ultrasound examinations during the COVID-19 pandemic are (1) prevention of the spread of the virus and (2) protection of the healthcare workers.

Ultrasound is an essential part of obstetric and gynecological care, but exposes the patient and the caregiver to high risks, given the impossibility of keeping the recommended distance between them during the ultrasound scan. It is therefore essential to take all possible precautions when undertaking routine clinical activity.

Every country follows national and international guidelines for the performance of routine or targeted ultrasound investigations during the COVID-19 pandemic. The decision as to what constitutes an elective or an emergency examination is to be decided locally and will not be addressed in this document. This document is intended to serve as an adjunct in the context of the current COVID-19 pandemic and should be considered in conjunction with relevant advice from other organizations (Appendix S1).

The aspects that should be considered when planning an ultrasound examination in an obstetric or gynecological care setting in the context of the COVID-19 pandemic are: (1) how to prepare and clean the ultrasound room and equipment and (2) how to protect the patient and ultrasound providers (physicians, sonographers, allied professionals).

PREPARATION AND CLEANING OF ULTRASOUND ROOM

(Advice appropriate for all routine ultrasound services during the COVID-19 pandemic)

- The survival of severe acute respiratory syndrome (SARS)-associated viruses (including SARS-CoV-2) on dry inanimate surfaces, such as ultrasound systems, is between 48 and 96 h\(^5,6\). The ultrasound room should be cleaned thoroughly each morning and all contents should be wiped with a compatible low-level disinfectant (LLD), including the ultrasound monitor, computer keyboard and mouse, stretcher rails, transducer holder, gel container, door handles, cabinet knobs, light switches, chairs and counter tops.
- The number of transducers connected to the ultrasound machine should be reduced to a minimum, usually one transabdominal and one transvaginal, and all other transducers should be stored safely in a clean closed cabinet and brought out as needed.
- All unnecessary accessories in the room should be removed and, where possible, stored in cabinets.
- Fabric-covered chairs should be replaced with hard-surface chairs that can be wiped.
- Where possible, all washable linen, such as towels, pillow covers and sheets, should be replaced with disposable covers.
- Ultrasound transducers and cables should be cleaned (as recommended below) every morning and this should also be performed after each scan.
- The patient bed or couch should be wiped with a LLD prior to replacing the disposable paper cover.
- The disposable paper cover should be removed with gloved hands and folded and disposed of immediately at the end of each examination.
- Ensure that the highly touched surfaces (e.g. keyboard, cord and screen) of the ultrasound machine are thoroughly cleaned after each examination.
PREPARATION AND CLEANING OF ULTRASOUND EQUIPMENT AND ULTRASOUND TRANSDUCER

(Advice appropriate for all routine ultrasound services during the COVID-19 pandemic)

The transducer and ultrasound equipment should be cleaned with a compatible LLD after each patient, in accordance with local guidelines.

PREPARATION AND CLEANING OF ULTRASOUND EQUIPMENT

(Advice appropriate after performing an examination in a suspected or confirmed COVID-19 case)

• SARS coronavirus, Middle East respiratory syndrome (MERS) coronavirus and endemic human coronaviruses (HCoV) can persist on inanimate surfaces, such as metal, glass or plastic, for up to 9 days, but can be efficiently inactivated by surface disinfection procedures with 62–71% ethanol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 min. Other biocidal agents often used include 0.05–0.2% benzalkonium chloride (Clinell™) or 0.02% chlorhexidine digluconate.

• Check the required contact time for each product.

Since information about SARS-CoV-2 is incomplete, additional use of high-level disinfectants is recommended; however, this advice is manufacturer-specific. High-level disinfectants include ethanol 80–95% (exposure time 30 s), 2-propanol 75–100% (exposure time 30 s), 2-propanol and 1-propanol 45% and 30% (exposure time 30 s), sodium hypochlorite 0.21% (Antisapril Blu 2%, exposure time 30 s), glutaraldehyde 2.5% (exposure time 5 min) and 0.5% (CIDEX OPA, exposure time 2 min), hydrogen peroxide 0.5% (REVITAL-OX RESERT, exposure time 1 min)⁹. Protective eyewear and gloves should be used when cleaning, disinfecting or sterilizing any equipment.

PREPARATION AND CLEANING OF ULTRASOUND TRANSDUCER

(Advice appropriate after performing an examination in a suspected or confirmed COVID-19 case)

Guidelines regarding cleaning of ultrasound transducers between patients are available⁷–¹⁰. Coronaviruses are enveloped viruses, which are the least resistant to inactivation by disinfection. The structure of these viruses includes a lipid envelope, which is easily disrupted by most disinfectants suitable for use on ultrasound systems and transducers.

According to the Spaulding classification system, medical devices are classified according to the infection risk they present as non-critical, semi-critical and critical (also referred to as low-risk, medium-risk and high-risk). Non-critical devices present the lowest risk for infection as they come in contact with intact skin, such as transabdominal transducers. Low- or intermediate-level disinfection is recommended, which will eradicate most bacteria (but not bacterial spores) and fungi, as well as certain types of viruses, including human immunodeficiency virus (HIV). Semi-critical devices are those that present a higher risk for infection because of contact with non-intact skin or mucous membranes. Transvaginal transducers belong to this category. High-level disinfection for destruction of all microorganisms, including SARS-CoV-2, is recommended and can be performed by means of solutions containing sodium hypochlorite or other disinfectants as detailed above. Critical devices, such as transducers used in invasive procedures, should undergo sterilization as per medical facility guidelines irrespective of whether a probe cover is used.

Preparation of the ultrasound transducer consists of two steps: cleaning and disinfection. Any products used for cleaning or disinfection should be compatible with the ultrasound equipment, as determined by the ultrasound equipment manufacturer¹⁰. Certain products may damage ultrasound equipment or transducers and invalidate warranties.

1. Cleaning

This is an important first step since any remaining gel can act as a barrier to the disinfectant thus diminishing its efficacy. The USA Centers for Disease Control and Prevention (CDC) defines cleaning as ‘the removal of foreign material (e.g. soil and organic material) from objects and is normally accomplished using water with detergents or enzymatic products’. Ineffective cleaning prior to disinfection can limit the effectiveness of chemical disinfection.

Current guidelines for cleaning transvaginal transducers ⁸,¹⁰ recommend using running water to remove any residual gel or debris from the probe before cleaning thoroughly the transducer using a damp gauze pad, or other soft cloth, and a small amount of mild non-abrasive liquid soap (approved for use on medical instruments). The use of a small brush especially for the crevices and areas of angulation should be considered, depending on the design of the particular transducer. The transducer should then be rinsed thoroughly with running water and dried with a soft cloth or paper towel.

Based on the above guidelines, the following steps are recommended for cleaning the transducer, which should be performed wearing disposable gloves:

a. Disconnect the transducer.
b. Clean the transducer with a soft brush and dispose of in clinical waste.
c. Rinse the operative end of the transducer with running tap water (NOT the electronic contact end).
d. Clean the transducer with a soft brush and non-abrasive detergent.
e. Rinse the transducer with tap water.
f. Clean the transducer cable with a LLD wipe.
g. Dry with a cloth or towel (residual water can dilute chemical disinfectants, if this is the preferred method).

2. Disinfection

Always refer to your facility’s infection control policies and protocols, as well as the transducer manufacturer’s instruction for use and labels for use. Disinfection practices are evolving constantly, and this is the most current to date. As mentioned above, high-level disinfection is recommended for transvaginal but not transabdominal transducers. Specific product instructions should be consulted. Available methods (current at the time of publication) include:

Chemical ‘wet’ disinfection:
• 2.4–3.2% glutaraldehyde products (such as Cidex, Metricide and Procidex).
• Non-glutaraldehyde agents (such as Cidex OPA (o-phthalaldehyde) and Cidex PA (hydrogen peroxide and peroxyacetic acid).
• Approved multistep disinfectant wipes containing chlorine dioxide, which are used extensively in the UK and Australia (Tristel Duo®).
• 7.5% hydrogen peroxide solution, which works by producing destructive hydroxyl free radicals.
• Sodium hypochlorite 0.21% (Antisapril Blu 2%).

Note that common household bleach (5.25% sodium hypochlorite) diluted to yield 500 parts per million chlorine (10 mL in one L of tap water), although effective is not recommended by manufacturers because it can potentially cause damage to metal and plastic parts of the transducer. Mention of this disinfectant here does not imply that we consider it to be appropriate, but we are aware that it is used in some settings.

Automated high-level disinfection:
• Antigermix (Germitec, France): the transducer is placed in a closed cabinet and exposed to high-intensity ultraviolet type C radiation.
• Astra VR (CIVCO Medical Solutions, USA): automated disinfection with Cidex OPA and Metricide solutions.
• Trophon (Nanosonics, Australia): sonicated hydrogen peroxide mist.

After cleaning, store transducer in a clean closet or its case with foam inset to prevent damage and protect from contamination with dirt, if it is not going to be used immediately.

PROTECTING THE PATIENT AND ULTRASOUND PROVIDERS

- Screen all patients and visitors using standardized checklists for symptoms of acute respiratory infection and risk factors based on travel history, occupation, contact and cluster (TOCC)11. Ideally, triage should be undertaken before the patient arrives at the ultrasound unit; for this purpose, it may be appropriate to telephone the patient before she arrives in the hospital or clinic.

- Ultrasound providers with specific health problems that place them at greater risk (as detailed by local occupational health guidelines) should be excluded from performing ultrasound examinations.

- In order to reduce the risk of transmission, it is important to respect the time of scheduled visits, to widen the appointment intervals in order to prevent crowding in the waiting room and to space the seats to at least 2 m apart.

- Limit the number of visitors in the examination room to a maximum of one and do not allow the presence of children, trainees or students.

- Use a three-ply surgical mask when performing ultrasound scans as there is direct patient contact. The surgical masks may be reused during the care of multiple patients, if used to protect the healthcare provider from an activity with low transmission risk, such as ultrasonography. Replace the mask as soon as it is damp and do not reuse single-use masks. This will depend on local regulations and the availability of personal protection equipment (PPE).

- Ensure that the ultrasound provider has undergone infection control training and fit test for respirators.

- Hand hygiene is imperative before and after direct patient contact. If it is not possible to wash hands, hand sanitizer can be used.

- Latex-free disposable gloves should be used during the ultrasound examination and changed after each patient.

- Use of single-use gel packs is recommended as opposed to gel containers.

- Consider transducer cover for non-endoluminal probes (this is not a CDC absolute requirement).

- Attempt to shorten the duration of the examination by arranging for the most experienced sonologist/sonographer to perform the examination.

- Inform the patient that a detailed explanation will not be given during the examination.

Ultrasound examination of patients with suspected or confirmed SARS-CoV-2 infection

- All attending medical staff should don PPE (respirator, such as N95 or FFP3, goggles, face protective shield, surgical gown and gloves) prior to entering the examination room. Detailed guidance on the use of PPE in the setting of ultrasound examinations is provided elsewhere12.

- A bedside scan with the patient in situ is strongly recommended.
• If feasible, it is recommended to have one (or more) dedicated ultrasound machine(s) for patients with suspected/probable/confirmed SARS-CoV-2 infection.
• If the patient must be scanned in the clinic, this should be done at the end of the clinic list, as the room and equipment will subsequently require a deep clean.
• It is imperative to perform hand hygiene once the gloves have been removed.

Other considerations, beyond the scope of this document
• Quarantine and isolation of doctors/sonographers may be required after contact with a confirmed COVID-19 case, and should follow facility work schedule arrangements.
• Additional ultrasound capacity may be required for anticipated increase in demand for emergency examinations, thus non-essential examinations should be deferred or cancelled to minimize exposure of an at-risk group of patients to potential COVID-19 contact in the hospital environment.
• The workforce may need to be reduced or divided to keep a non-affected group available, in case some workers get infected.

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SUPPORTING INFORMATION ON THE INTERNET
The following supporting information may be found in the online version of this article:
Appendix S1 National and international society guidance in relation to COVID-19 and ultrasound