



### **SAFETY STATEMENT**

# ISUOG Safety Committee Position Statement on use of personal protective equipment and hazard mitigation in relation to SARS-CoV-2 for practitioners undertaking obstetric and gynecological ultrasound

Endorsed by the Australasian Society for Ultrasound in Medicine (ASUM), the British Medical Ultrasound Society (BMUS), the Society and College of Radiographers (SCoR), Sociedad Española de Ginecología y Obstetricia (SEGO) and Società Italiana di Ecografia Ostetrica e Ginecologica e Metodologie Biofisiche (SIEOG).

In view of the challenges of the current coronavirus (SARS-CoV-2) pandemic, the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) has compiled the following expert-opinion-based guidance on safe use of personal protective equipment (PPE) and how to reduce the hazard of SARS-CoV-2 infection for clinicians undertaking ultrasound examinations (physicians, sonographers and allied professionals). The European Centre for Disease Prevention and Control (ECDC) has released a technical report for wearing and removing PPE in healthcare settings managing patients with suspected or confirmed coronavirus disease 2019 (COVID-19)<sup>1</sup>, as have the Centres for Disease Control and Prevention (CDC)<sup>2</sup>, World Health Organization (WHO)<sup>3</sup> and, in the UK, Public Health England (PHE)<sup>4</sup>. At the time of writing, none of these recommendations has addressed the safe use of PPE when performing ultrasound examinations specifically. As guidance in relation to PPE differs from country to country and region to region, we recommend that local guidance is followed when this is available; if no guidance specific to ultrasound examinations exists, this document may be referenced.

This guidance describes steps that may be taken to minimize the risk of SARS-CoV-2 transmission between the patient and the practitioner during ultrasound examinations. It is important to note that many of the measures discussed in this document are supported by limited research-based evidence. This may explain why advice varies widely between different parts of the world (Appendix S1). Nevertheless, the authors, several of whom work in some of the areas first affected by the virus, including China (Appendix S2), Singapore, Hong Kong and Italy, have been able to synthesize what are believed to be the most effective interventions for reducing the transmission of SARS-CoV-2 between patients and healthcare providers.

# BACKGROUND: RISK OF INFECTION DURING ULTRASOUND ASSESSMENT

An ultrasound examination has several unique attributes that are likely to increase the risk of transmission between patients and ultrasound operators (and potentially vice versa). These include, but are not limited to, the following:

- Physical proximity to the patient is less than 2 m or 6 feet, and may be as little as 30–50 cm;
- The ultrasound rooms or enclosed areas are typically small:
- The ultrasound rooms often have restricted ventilation, as the air-conditioning systems are in some cases closed loop and/or there are no windows;
- The examination time may last between 10 and 60 min;
- Invasive or transvaginal procedures may need to be carried out:
- The woman may be asked to inhale or exhale deeply, and hold her breath;
- Therapeutic and interventional procedures may increase the risk of exposure to bodily fluids;
- There is a risk of the patient coughing, sneezing or exhaling heavily;
- The surfaces of the ultrasound machine, especially the keyboard, touch screen and trackball, are touched frequently.

These attributes have not been formally studied in relation to the risk of transmission of viral infection during ultrasound examination. A recent study on the ability of an exhaled turbulent gas cloud to carry respiratory pathogens a long distance, suggests that appropriate PPE should be considered for all healthcare workers, even if they remain further than 2 m away from a symptomatic patient<sup>5</sup>.

#### NON-PPE RISK MITIGATION

Given that the undertaking of an ultrasound examination inevitably prevents distancing and requires that a doctor or sonographer remains in close contact with a patient for a long period of time, mitigation measures should be considered to reduce the risk of SARS-CoV-2 transmission.

#### Triage ultrasound scans

During the COVID-19 pandemic, depending on local disease prevalence and staff shortage, high-risk patients should be prioritized for ultrasound assessment, while prioritization by type of scan should be considered, with the second-trimester anatomy scan taking precedence over the first-trimester scan, and growth scans performed based on coexisting and emerging comorbidities. Further details are provided in the ISUOG Consensus Statement on organization of routine and specialist obstetric ultrasound services in the context of COVID-19<sup>6</sup>.

#### Ventilation of ultrasound room

Very few studies have assessed environmental contamination as a route of transmission of SARS-CoV-2 in the healthcare setting<sup>7</sup>. Infection control advice is based on the reasonable assumption that the transmission characteristics of COVID-19 are similar to those of the 2003 SARS-CoV outbreak.

Adequate ventilation is the main way to reduce air environmental contamination and exposure to SARS-CoV-2 infection. The WHO divides environmental ventilation methods into three types: mechanical, natural and mixed-mode<sup>8</sup>. Good ventilation of rooms to clear aerosols is recommended by several organizations<sup>9-11</sup>. Although most guidelines refer to conditions in which aerosol-generating procedures (AGP) are performed, AGPs are rare in routine ultrasound practice. The rate of clearance of aerosols in an enclosed space depends on the number of air changes per hour. A single air change is estimated to remove 63% of airborne contaminants and after five air changes less than 1% of airborne contamination is thought to remain<sup>9</sup>. After an AGP, a minimum of 20 min of ventilation is considered pragmatic, which can be reduced to 5 min if ultraclean ventilation is used (e.g. in some operating theaters). This situation is very unlikely to pertain to obstetric and gynecological ultrasound.

Air-conditioning systems equipped with high-efficiency particulate air (HEPA) filters provide adequate protection especially if combined with the use of PPE and facemasks. Most hospital systems are not equipped with HEPA filters, hence, turning off air conditioning and, where there are windows, opening them for good ventilation if an independent air supply is not feasible, has been recommended by WHO for rooms hosting patients with suspected SARS infection<sup>12</sup>. As every ultrasound environment is different and there are no

consistent regulations or advice regarding ventilation, we recommend that consideration is given to ventilation in ultrasound rooms in individual workplaces.

#### ADVICE TO PATIENTS

First point of contact: should temperature be taken and history of travel, occupation, contact and cluster (TOCC) be asked before or on arrival at the ultrasound department?

According to the Royal College of Obstetricians and Gynaecologists, maternity departments with direct entry for patients and the public should put in place a system for identification of potential cases of COVID-19 as soon as possible, to prevent potential transmission to other patients and staff<sup>13</sup>. This system should be set up at the first point of contact (either near the entrance or at reception) to ensure early recognition and infection control. This should be employed before a patient sits in the maternity waiting area<sup>13</sup>.

From an epidemiological point of view, the SARS-CoV-2 virus first emerged in the Hubei province in China. Therefore, in the early phase of the epidemic, history of travel to the Hubei province, as well as contact with people known to have been infected by SARS-CoV-2, obtained via TOCC assessment, was advocated as the first measure to identify potential carriers of the SARS-CoV-2 virus 14,15. Nonetheless, the rapid spread of the disease across countries and continents, as well as the evidence of existence of asymptomatic carriers 16, has led to circumstances in which all patients are to be considered at risk of infection and hence potential carriers of the SARS-CoV-2 virus.

On this basis, and following the available recommendations<sup>2,9,15</sup>, in the most affected areas, such as northern Italy, several maternity units have implemented strict protocols for the triage of women accessing the unit. Such measures include the arrangement of 'check point' triage areas in which dedicated medical personnel equipped with PPE take the temperature and assess the medical history, in terms of symptoms and contact, of women attending the maternity units and the ultrasound departments.

Women should be advised that triage of their symptoms and contact represents the first-line assessment in order to allow the identification of contacts should they develop symptoms at a later stage. According to ISUOG's Interim Guidance, patients identified to be at risk for SARS-CoV-2 infection should delay their antenatal visit and routine ultrasound assessment by 14 days<sup>15</sup>. We recommend that this advice is considered on a local basis after taking into account the potential implications of a delayed ultrasound examination in the context of local/national regulations. This advice applies only to routine ultrasound examinations; clearly, pregnancies requiring time-critical examinations should be considered on a case-by-case basis.

#### Should the patient wear a mask?

Surgical masks, also referred to as medical masks, facemasks or simply masks, provide only a barrier protection against droplets, including large respiratory particles, while they do not effectively filter small particles from the air and do not prevent leakage around the edge of the mask when the user inhales<sup>2</sup>. The rationale for the use of surgical masks is two-fold: to protect the wearer from sources of infection, such as splashing or spraying of blood, hand-to-face contact and large droplets and sprays, and to protect others from the wearer in case they are a source of infection<sup>17</sup>. If no mask is used, the mucosal surfaces of the nose and mouth are exposed, providing an easy route of entry to the body for pathogenic microorganisms. There is no standard definition of a surgical mask, and there is a wide variation in the design and quality of the masks currently in use. In terms of the design, it is recommended that masks should fully cover the nose and mouth of the wearer. Two randomized controlled trials support the use of surgical masks in a community setting 18,19 and the use of masks is recommended in cases of suspected or confirmed SARS-CoV-2 carriers in order to prevent spread of the infection 1-3,20.

N95 and FFP2 respirators filter out particles, including bacteria and viruses<sup>2</sup>. Statements from leading health organizations (ECDC, WHO and CDC)<sup>1-3</sup> provide different recommendations for the use of respirators in a healthcare setting. However, respirators are recommended for use only by healthcare professionals requiring protection from both airborne and fluid hazards (e.g. splashes, sprays), while no indication exists outside of the healthcare setting<sup>2</sup>. There is little or no evidence supporting the use of N95 or FFP2 masks by patients.

The rapid increase of the epidemic curve of the SARS-CoV-2 virus, together with evidence that carriers of the disease can be asymptomatic <sup>16</sup>, has led to a situation in which all individuals, including the medical staff and patients, represent potential carriers of the infection. On this basis, and despite the lack of evidence as to whether asymptomatic carriers contribute to the spread of the SARS-CoV-2 virus, in certain countries both the health-care staff and patients, as well as other hospital attendants, have been advised to don surgical masks in a healthcare setting in order to minimize the dispersal of respiratory secretions and reduce environmental contamination.

We consider that, currently, there is too little evidence to recommend the routine use of patient masks by asymptomatic low-risk patients. We do, however, recommend that local protocols should advise that patients with symptoms of COVID-19, or those judged to have suspected or probable infection, should wear a surgical mask when undergoing imaging.

#### PERSONAL PROTECTIVE EQUIPMENT

The SARS-CoV-2 virus is spread mainly by close contact and respiratory droplets, with airborne transmission being likely in specific circumstances<sup>21</sup>. In general, respirators,

as opposed to surgical masks, are recommended for healthcare personnel who come in contact with patients with strongly suspected or confirmed COVID-19, however, surgical masks are an acceptable substitute when supply of respirators is limited<sup>22</sup>. A detailed description of available surgical masks and respirators is provided in Appendix S3.

#### Staff age and comorbidities

- Ultrasound providers of advanced age or with health conditions that predispose them to infection and severe disease should avoid scanning patients with suspected or confirmed COVID-19, and should consider wearing appropriate PPE when working in a region affected by the COVID-19 pandemic, even if they are examining an asymptomatic and TOCC-negative patient.
- Individuals at highest risk for severe COVID-19 and death include those aged over 60 years and those with underlying conditions, such as hypertension, diabetes, cardiovascular disease, chronic respiratory disease and cancer.
- Individuals who have a comorbidity should ensure that their occupational health departments are aware of their underlying condition, age and area of deployment.

#### General considerations

- Attention should be paid to train ultrasound providers on safe donning, doffing and disposal of PPE<sup>23,24</sup>.
- Proper functioning of respirators requires that an
  effective seal is created between the mask and the face
  of the wearer. Variation in face size and shape, and
  availability of different respirator designs, mean that a
  proper fit is only possible for a minority of healthcare
  workers for any particular mask. All healthcare workers
  should therefore undergo a fitting test for respirators
  and should continue to wear the type of respirator for
  which they have been fit-tested.
- Hand hygiene should be performed before and after patient contact, contact with potentially infectious material, and before putting on and after removing PPE, including gloves. Hand hygiene after removing PPE is particularly important to remove pathogens that might have been transferred to bare hands during the removal process. Hand hygiene should include use of 60–95% alcohol or washing hands with soap and water for at least 20 s.

# When managing patients with confirmed or suspected COVID-19 infection, or if there is widespread community transmission<sup>22</sup>

 To avoid infection through respiratory droplets, practitioners should don appropriate PPE, including a surgical mask, upon entering the ultrasound room.

- To avoid infection through contact, all patients with suspected or confirmed COVID-19 should preferably be scanned in a single dedicated room. The practitioner should don appropriate PPE, including gloves and gown, upon entering the ultrasound room, and use of disposable equipment should be preferred, where possible.
- To avoid airborne transmission, the patient should be asked to wear a surgical mask if they are symptomatic or have confirmed COVID-19. The healthcare worker should wear appropriate PPE, including a fit-test approved respirator or surgical mask, depending on the level of infection risk, gloves, gown, face and eye protection, upon entering the room. High-risk healthcare workers should be restricted from entering the ultrasound room and disposable equipment should be used where possible.

## PPE in obstetric, gynecological and early-pregnancy scans (Appendices S4 and S5)

Guidance is provided in Table 1 according to patient symptoms and infection status, considering three groups of patients:

- 1. Asymptomatic and TOCC-negative patients in a region in which there is no widespread community transmission.
- 2. Asymptomatic and TOCC-positive patients in a region in which there is no widespread community transmission.
- 3. Patients with suspected/probable/confirmed COVID-19 or in a region in which there is widespread community transmission.

Table 1 Personal protective equipment (PPE) recommended for use by ultrasound providers based on risk assessment of patient for COVID-19

PPE	Asymptomatic and TOCC negative	Asymptomatic and TOCC positive	Suspected*/probable/confirmed COVID-19 or where there is widespread community transmission
Clothing	Dedicated work clothes	Dedicated work clothes	Dedicated work clothes
Hand hygiene	Yes	Yes	Yes
Surgical facemask	Yes†	Respirator (N95, FFP2/3)‡	Respirator (N95, FFP2/3)‡
Respirator	No	Yes (N95, FFP2/3)‡	Yes (N95, FFP2/3)‡
Isolation gown	No	Disposable fluid-resistant and impermeable protective gown (e.g. AAMI level 3)	Disposable fluid-resistant and impermeable protective gown (e.g. AAMI level 3)
Disposable gloves	Yes	Yes (two pairs)	Yes (two pairs)
Eye protection	No	Goggles or face shield	Goggles or face shield
Hair cover	No	Yes	Yes
Additional consideration for transvaginal scan or invasive procedures	Standard condom or commercial transducer cover <sup>25</sup>	Standard condom or commercial transducer cover; cover for cable if available <sup>25</sup>	Standard condom or commercial transducer cover; cover for cable if available <sup>25</sup>
Staffing/environment	_	_	Ideally scan at bedside rather than in a clinic; minimize number of staff in room and ensure that most senior person is undertaking scan
Disinfection/cleaning <sup>26</sup>	Low-level disinfection for external probes; high-level disinfection for internal probes	Low-level disinfection for external probes; high-level disinfection for internal probes; additional low-level disinfection for ultrasound machine and cables	Low-level disinfection for external probes; high-level disinfection for internal probes; additional low-level disinfection for ultrasound machine and cables

<sup>\*</sup>Symptomatic patient with or without travel, occupation, contact and cluster (TOCC) risk factors, in area in which there is widespread community transmission. †Extended use of surgical facemasks is practice of wearing same surgical facemask for repeat close-contact encounters with several different patients, without removing facemask between patients. In most cases, one facemask can be safely used for a typical clinic of 3-4 h. Surgical facemask should be removed and discarded if it is soiled, damaged or hard to breathe through. Healthcare workers should take care not to touch their surgical facemask; if they touch or adjust their surgical facemask, they should immediately perform hand hygiene. Healthcare workers should leave patient care area if they need to remove their surgical facemask. Re-use should be implemented according to CDC guidance<sup>27</sup>. ‡All healthcare workers should undergo training on appropriate use of and fit testing for respirators. Alternatives to respirators: filtering facepiece respirator, elastomeric half-mask and full facepiece air purifying respirator, if available; all these alternatives provide equivalent or higher protection than N95 respirators when worn properly. Extended use refers to practice of wearing same N95 respirator for repeat close-contact encounters with several different patients, without removing respirator between patient encounters. Extended use of respirators is well-suited to situations in which multiple patients with COVID-19, whose care requires use of respirator, are cohorted (e.g. housed in same hospital unit). Limited re-use of N95 respirators when caring for patients with COVID-19 might become necessary. However, it is unknown what is the potential contribution of contact transmission for SARS-CoV-2, therefore, caution should be exercised. Re-use should be implemented according to CDC guidance<sup>28</sup>. Recommendation: When putting on new mask/respirator, even if it is type, size and shape that fitted last time, recheck sealability, not only in neutral head position, but also in positions taken when actually scanning a patient, for example, by turning head to side or tilting chin up to face monitor, or during use of two hands to hold transducer or other device.

There is little difference between gynecological, early-pregnancy and obstetric scans from the standpoint of infection, so precautionary measures are applicable to all three fields. Transvaginal ultrasound probes should undergo high-level disinfection as condoms and commercial covers may break<sup>25</sup>. Tracing and record keeping for high-level disinfection is essential. Detailed guidance regarding ultrasound equipment and transducer cleaning in the context of COVID-19 has been provided in a separate document<sup>26</sup>.

#### **AUTHORS**

This document was prepared by and under the auspices of the Safety Committee of ISUOG and members co-opted for the purposes of compiling the document. The authors are:

- **J. S. Abramowicz**, Department of Obstetrics and Gynecology, University of Chicago, Chicago, IL, USA
- J. M. Basseal, Discipline of Infectious Diseases & Immunology, Faculty of Medicine and Health, The University of Sydney; and Australasian Society for Ultrasound in Medicine (ASUM), NSW, Australia
- C. Brezinka, Department of Obstetrics and Gynecology, Medical University of Innsbruck, Innsbruck, Austria
- A. Dall'Asta, Department of Medicine and Surgery, Obstetrics and Gynecology Unit, University of Parma, Parma, Italy
- **J. Deng,** Barts Heart Centre, London; and University College London, London, UK
- **G. Harrison,** Professional Officer (Ultrasound), Society and College of Radiographers (SCoR), UK
- J. C. S. Lee, Department of Urogynaecology, Division of Obstetrics and Gynaecology, KK Women's and Children's Hospital, Singapore
- A. Lim, Imaging Department, Imperial College Healthcare NHS Trust; and Hon Secretary, BMUS, UK
- **K. Maršal**, Department of Obstetrics and Gynecology, Lund University, University Hospital, Lund, Sweden
- **P. Miloro**, Ultrasound and Underwater Acoustics, National Physical Laboratory, Teddington, UK
- L. C. Poon, Department of Obstetrics and Gynaecology, The Chinese University of Hong Kong, Hong Kong SAR
- K. A. Salvesen, Department of Obstetrics and Gynecology, St Olavs hospital, Trondheim, Norway
- **R. Sande**, Department of Obstetrics and Gynecology, Stavanger University Hospital, Stavanger, Norway
- G. ter Haar, Therapy Ultrasound, Division of Radiotherapy & Imaging, Joint Department of Physics, Royal Marsden Hospital, Institute of Cancer Research, Surrey, UK
- S. C. Westerway, School of Dentistry & Health Sciences, Charles Sturt University; and Australasian Society for Ultrasound in Medicine (ASUM), Sydney, NSW, Australia M. X. Xie, Department of Ultrasound, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan, China
- C. Lees (Chair), Department of Metabolism, Digestion and Reproduction, Imperial College London, London, UK

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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 Snapshot of measures taken globally to reduce hazard of SARS-CoV-2 infection, in context of ultrasound examinations (based on feedback from a number of units in each territory but not intended as a comprehensive guide)

Appendix S2 Infection rate of ultrasound providers: experience from Wuhan

**Appendix S3** Comparison of masks and respirators

Appendix S4 Reference chart for selection of personal protective equipment (PPE) before starting or during booking of ultrasound scan

**Appendix S5** Categorization of personal protective equipment (PPE)