CONSENSUS STATEMENT

ISUOG Consensus Statement on rationalization of gynecological ultrasound services in context of SARS-CoV-2

INTRODUCTION

Given the challenges of the current coronavirus (SARS-CoV-2) 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 rationalization of ultrasound investigations for gynecological indications.

While the provision of ultrasound is an essential service and all individuals with gynecological complaints deserve high-quality investigation, the current coronavirus disease 2019 (COVID-19) pandemic warrants triaging of referrals for gynecological ultrasound assessment. This is based on the following principles related to a pandemic:

1. Medical resources should be spared and prioritized.
2. Maximum care should be taken to avoid unnecessary contact between (potentially infected) medical personnel and (potentially infected) patients. The risk of transmission is particularly high during ultrasound investigations as neither the medical personnel nor the patient can abide by the social distancing recommendations.
3. Visits should be limited to those strictly necessary to avoid spread of the virus.

Therefore, ultrasound appointments for gynecological indications should be triaged based on the clinical scenario, as follows:

1. Ultrasound assessments that should be performed without delay (**NOW**);
2. Ultrasound assessments that can be delayed for a few weeks (**SOON**);
3. Ultrasound assessments that can be delayed for the duration of the pandemic (**LATER**).

This guideline focuses on patients with gynecological complaints. Recommendations for each triage category are summarized in Table 1 and justification is provided within the document.

Table 1 Recommended rationalization of ultrasound scans for gynecological indications in context of COVID-19 pandemic

Priority	Action/allocation	Clinical scenario
NOW	Patient should present without delay to emergency department for immediate investigation.	• Acute persistent pelvic pain – differential diagnoses: - Ovarian torsion; - Ruptured hemorrhagic ovarian cyst; - Pelvic inflammatory disease and/or tubo-ovarian abscess. • Postoperative/post-procedure complications. • Ovarian hyperstimulation syndrome. • Abdominopelvic 'mass' with symptoms (e.g. distension secondary to ascites). • Abnormal uterine bleeding: - Menorrhagia with severe anemia or hemodynamic instability.
SOON	Ultrasound can be delayed for 2–4 weeks.	• Abnormal uterine bleeding: - Postmenopausal bleeding.. • Abdominopelvic 'mass': - High risk of malignancy as per IOTA-ADNEX model (≥ 10%) • Ultrasound staging for biopsy-proven or incidentally diagnosed (during unrelated imaging testing) gynecological malignancy, if useful for management. • Postcoital bleeding. • Signs of recurrent gynecological malignancy. • Family history of gynecological malignancy with genetic predisposition (e.g. BRCA positive).
LATER	Ultrasound evaluation should be postponed for duration of pandemic. Patients may still be referred for ultrasound assessment, but appointments will not be given until pandemic is over. Appropriate systems should be put in place to ensure appointments take place at a later date.	• Abnormal uterine bleeding, non-severe, in non-postmenopausal patients: - Breakthrough bleeding while on hormonal medication; - Heavy menstrual bleeding/menorrhagia (heavy menstrual bleeding) without associated anemia; - Infrequent menstrual bleeding (oligomenorrhea), PCOS; - Intermenstrual/irregular bleeding; - Perimenopausal abnormal uterine bleeding. • Non-acute pelvic pain: - Chronic pelvic pain; - Cyclical dyschezia; - Dysmenorrhea; - Dyspareunia. • Family history of gynecological malignancy (no genetic predisposition know/identified). • Incontinence. • Infertility and recurrent pregnancy loss. • Prolapse. • Review of previously noted "likely benign" adnexal pathology: - Unilocular cyst; - Endometrioma; - Dermoid/Mature cystic teratoma; - Hemorrhagic ovarian cyst (including corpus luteal cysts);

		- Hydrosalpinx; - Low risk of malignancy as per IOTA-ADNEX model (< 10%). • Review of previously noted pelvic pathology: - Uterine polyp(s); - Leiomyoma(s); - Adenomyosis; - Endometriosis. • Review of intrauterine contraceptive device. • Postmanagement of gynecological malignancy without signs or symptoms of recurrence.

PRIORITIZATION OF SCANS BASED ON CLINICAL SCENARIO

Acute pelvic pain (NOW)

Acute and non-resolving pelvic pain should continue to be considered a gynecological emergency until proven otherwise. When pregnancy has been ruled out based on a negative urinary pregnancy test, the following scenarios should be considered as a possible etiology:

- Ovarian torsion: in the majority of cases (other than transient states of ovarian torsion), emergency surgical intervention is warranted. Though ovarian torsion remains a clinical diagnosis, ultrasound is critical in the evaluation of patients with acute pelvic pain.
- Ruptured hemorrhagic ovarian cyst: while this is often very painful, outpatient medical management with analgesia is generally sufficient. Ultrasound assessment is necessary to rule out ovarian torsion.
- Pelvic inflammatory disease (PID) and/or tubo-ovarian abscess (TOA): symptoms may overlap with those related to SARS-CoV-2 infection (e.g. fever). As with ovarian torsion, diagnosis and treatment can be guided by ultrasound findings when TOA is present. Ruling out TOA is a critical component of the management of patients with PID.

Non-acute pelvic pain (LATER)

For the purposes of this guideline, we have grouped together all forms of non-acute pelvic pain, including the following:

- Chronic pelvic pain;
- Cyclical dyschezia;
- Dysmenorrhea;
- Dyspareunia.

Endometriosis and adenomyosis are amongst the most common conditions leading to any of these pain complaints. In many cases, a number of symptoms are present. While these are extremely troublesome conditions, patients and healthcare providers should consider delaying ultrasound evaluation until resolution of the COVID-19 pandemic. Acute episodes of pelvic pain in the presence of persistent non-acute pelvic pain should continue to be evaluated as outlined above.

Postoperative/procedure complications (NOW)

Although some centers have suspended elective gynecological surgery, most centers continue to perform urgent gynecological oncology procedures. In all centers, emergency procedures (e.g. Cesarean section, ectopic pregnancy, ovarian torsion) will still need to be performed during the pandemic and postoperative complications (e.g. hemorrhage, abscess, collections, hydronephrosis) should be considered. If there is suspicion of a procedure-related complication (e.g. perforation) or the patient experiences an adverse event post-procedure, such as after placement of an intrauterine contraceptive device (IUCD) (e.g. severe pain, bleeding, infection), gynecological ultrasound should be offered immediately. Ultrasound assessment should also be offered after major oncological procedures if required (see also 'gynecological malignancy' section below).

Infertility

Many centers have suspended elective assisted reproductive technology (ART) procedures during the pandemic. Scientific societies are cautioning against undergoing ART at this time[1,2]. However, ART in the setting of fertility preservation due to malignancy is expected to continue.

- Ovarian hyperstimulation syndrome (**NOW**): whether in the setting of ongoing ART for typical infertility or ART for fertility preservation, ovarian hyperstimulation syndrome remains a serious and acute gynecological problem that warrants immediate ultrasound evaluation.
- Infertility and recurrent pregnancy loss (**LATER**): ultrasound evaluation for infertility and recurrent pregnancy loss should be postponed until physical distancing recommendations are lifted and fertility centers can resume offering patient care.

Abnormal uterine bleeding

Generally, abnormal uterine bleeding (AUB) in premenopausal patients represents a non-life-threatening benign condition. Ultrasound evaluation of the following forms of AUB can be postponed until a later date (once physical distancing recommendations are lifted). If patients are troubled by their symptoms during this time, they should consider arranging a telephone/video consultation with their family physician or gynecologist to help them manage their symptoms empirically.

- Breakthrough bleeding while taking hormonal medication (**LATER**).
- Heavy menstrual bleeding (HMB) without anemia (**LATER**).
- Infrequent menstrual bleeding (oligomenorrhea) (**LATER**). If possible, pregnancy should be ruled out.
- Intermenstrual bleeding (**LATER**).
- Perimenopausal AUB (**LATER**).
- Postcoital bleeding (**SOON**):
    a) Speculum examination and/or cervical smear should be considered;
    b) The possibility of cervical cancer should be considered and necessary steps taken to ensure this is not missed.

In the following cases, AUB may require more timely assessment:

- HMB with severe anemia or hemodynamic instability (**NOW**):
    a) Timely ultrasound evaluation will be required if empirical therapy is unsuccessful and the patient has sequelae due to the anemia. In these cases, the clinician should aim to better understand the etiology of HMB in order to optimize medical therapy. However, the majority of causes of HMB are benign and surgical intervention may not be available due

to the need to redirect hospital resources. As such, healthcare providers should consider whether ultrasound evaluation may alter patient management during the pandemic.

b) Patients with abnormal HMB will require urgent assessment, as some will be likely to have serious pathology, such as cervical malignancy.

- Postmenopausal bleeding (**SOON**):
    a) Endometrial cancer must be ruled out in patients with postmenopausal bleeding. Fortunately, amongst patients with postmenopausal bleeding, cancer is still relatively uncommon, and when present, it is not generally aggressive and fast-developing[3]. In normal circumstances, patients with postmenopausal bleeding are triaged for assessment within 2 weeks of presentation[4]. Considering the present COVID-19 pandemic, we propose delaying this assessment by 4 weeks (i.e. assessment at approximately 6 weeks is recommended).

Abdominopelvic 'mass'

Abdominopelvic masses may be diagnosed incidentally during unrelated imaging. Alternatively, patients may present to a healthcare provider with a self-diagnosed abdominopelvic mass. We propose triaging such patients based on the associated symptomatology.

- Abdominopelvic 'mass' with associated symptoms (**NOW** or **SOON**): depending on the severity of the presenting associating symptoms, the healthcare provider should consider referring the patient to the emergency department for urgent evaluation. This may be necessary if there is a concern for malignancy (signs of bowel obstruction, nausea or vomiting, anorexia, early satiety, unanticipated weight loss, increased abdominal girth). Although associated symptoms (mass effect leading to pressure, bladder/bowel symptoms) are not usually acute or life-threatening, they may signal advanced ovarian cancer, in which case, it may be reasonable to recommend that ultrasound assessment should be carried out by an expert soon and appropriate treatment commenced. A high risk of malignancy would reasonably be defined as ≥ 10% as per the IOTA-ADNEX model[5]. The IOTA ADNEX model can be used online free of charge following this link: https://www.iotagroup.org/research/iota-models-software/adnex-risk-model.
- Abdominopelvic 'mass' without associated symptoms (**SOON** or **LATER**): the healthcare provider may consider delaying the ultrasound evaluation until the resolution of the pandemic if there is a known history of pelvic pathology, such as leiomyoma. Otherwise, a shorter delay of 4 weeks would be acceptable if this is a new incidental finding and the patient is asymptomatic.

Gynecological malignancy (**SOON**)

During the COVID-19 pandemic, consider whether ultrasound imaging by an expert can be fully replaced by computed tomography (CT) or magnetic resonance imaging (MRI) for initial tumor staging, treatment effect evaluation or signs of recurrent disease. Otherwise, ultrasound scanning by an expert should be performed soon in the following situations:

- First diagnosis:
    a) Characterization of abdominopelvic mass using ultrasound.
    b) Ultrasound staging for biopsy-proven or incidentally diagnosed (during unrelated imaging testing) gynecological malignancy, if useful for management.
    c) To rule out postoperative or post-procedure complications, such as collections, hydronephrosis, free fluid and pleural effusions that need drainage.

- Evaluation of treatment effect: although it is beneficial to use the same imaging method that was used at baseline for evaluation of tumor response, CT and/or MRI should be preferred over ultrasound.
- Recurrent disease: in women with signs of recurrent gynecological malignancy (e.g. elevation of tumor markers, new symptoms) in whom ultrasound findings may enable effective oncology treatment, ultrasound assessment should be performed promptly. Balancing the risks and benefits of ultrasound or other imaging methods is important in patients with typical signs of recurrence (e.g. ascites, dyspnea, early satiety) in whom palliative symptomatic care may be the only viable option for care.

Review of previously noted pathology (**LATER**)

Many patients will have undergone a previous gynecological ultrasound that has called for reassessment, which may be due in the next few months. Below, we highlight a list of possible reasons for reassessment. In all of the following scenarios, we suggest delaying the follow-up ultrasound assessment until resolution of the pandemic. In case of an adnexal mass, the risk of malignancy and acute complication is low if benign morphology was previously noted[6].

- Uterine:
    a) Uterine polyp(s).
    b) Leiomyoma(s).
    c) Adenomyosis.
- Ovarian:
    a) Unilocular cyst measuring < 10 cm in its largest diameter.
    b) Endometrioma.
    c) Dermoid cyst (mature cystic teratoma).
    d) Hemorrhagic cyst (including corpus luteal cyst).
    e) Mass with low-risk of malignancy as per the IOTA-ADNEX model (< 10%)[5].
- Extrauterine and extraovarian:
    a) Endometriosis.
    b) Hydrosalpinx.

Review of intrauterine contraceptive devices (**LATER**)

During the pandemic, there is expected to be a decrease in face-to-face consultations, which will likely mean a reduction in appointments for placement of IUCD. However, contraception is essential and patients should still be offered IUCD as an option. Should a patient choose an IUCD and undergo placement, we recommend postponing any routine evaluation of placement by gynecological ultrasound until the resolution of the pandemic. If IUCD strings cannot be seen on speculum examination, we suggest recommending to the patient back-up contraception and postponing ultrasound evaluation, as it is known that asymptomatic perforation or expulsion is very rare.

Urogynecological complaints (**LATER**)

In the vast majority of cases, urogynecological complaints are not dangerous or life-threatening. Ultrasound evaluation should be delayed until the resolution of the pandemic for cases of:

- Incontinence.
- Prolapse.

Follow-up of gynecological malignancy after completion of oncology treatment (**LATER**)
Patients undergoing active follow-up based on ultrasound should be counseled about the symptoms of recurrent disease and be advised to inform the gynecological oncology team in charge of their care by telephone if they develop any such symptoms.

GENERAL GUIDANCE

Screening for SARS-CoV-2
All women in need of care should be triaged based on their symptoms and infection status. Ideally, this should be carried out by phone with a senior healthcare practitioner prior to an appointment. However, in the event that the patient is first seen in the clinic, the healthcare professional undertaking triage should wear appropriate personal protective equipment (PPE). Triaging for common symptoms, such as cough and fever[7], is critical before a patient gains access to a clinical area for an ultrasound scan or consultation. Screening for travel, occupation, contact and cluster (TOCC) risk factors should also be implemented. If the local prevalence of SARS-CoV-2 increases, a policy of managing all patients as high risk may need to be implemented at some point. We also recommend that senior healthcare practitioners acquire and consider the details of the clinical history of the women to determine whether they need to attend the hospital or clinic.

Policy for patients with suspected or confirmed COVID-19
Any woman with suspected or confirmed COVID-19 should be asked to not attend the unit. If assessment is required, they must be seen in a designated COVID-19 area. Only screen-negative patients or patients with suspected COVID-19 who need to be reviewed without delay should be asked to attend the unit. If an ultrasound scan is required, we recommend that one ultrasound machine and room is designated for patients with suspected or confirmed COVID-19, if possible. It is important to clean the equipment according to safety guidelines[8].
Any patient with a suspicion of possible concomitant SARS-CoV-2 infection must immediately be highlighted to all healthcare team members.

Patients with suspicion of COVID-19 requiring admission
If a patient with suspicion of COVID-19 is stable, they should be sent home to self-isolate for 7 days, if clinically appropriate. Ideally, any patient who is cohabiting with someone who shows possible symptoms of COVID-19 should self-isolate for 14 days; however, in the context of early-pregnancy care this is unlikely to be practical. Any rooms or areas in the department in which the patient was present will require deep cleaning. If the patient requires admission to the hospital, the location will depend on the reason for admission and availability of a side room until SARS-CoV-2 testing confirms their status.
Any patient with a suspicion of possible concomitant SARS-CoV-2 infection must immediately be highlighted to all healthcare team members.

APPOINTMENT SUPPORT

Precautions that should be taken in the waiting areas and examination rooms

1. Considering the recommendation for social distancing, it is important to respect the time of scheduled visits, to space out the appointment intervals in order to prevent crowding in the waiting room and to space the seats in the waiting areas to at least 2 meters apart.
2. Hand sanitizer should be made available at the entrance to and within the waiting rooms. Pregnant patients and their partners (if present) should be advised to use it immediately upon arrival, and at frequent intervals during their stay in the department and prior to the ultrasound scan. If hand sanitizer is not available due to shortage, then women should be advised to wash their hands for with soap for a minimum of 20 sec prior to the scan.
3. Facemasks must be made available and used according to previously published guidance[9]. Specifically, patients with symptoms or judged to have possible or probable COVID-19 should wear a surgical mask. Sonographers should wear a surgical facemask or respirator (N95, FFP2/3) depending on the risk profile of the patient.
4. Patients should be asked, when arranging their appointment, to either attend on their own or with only one other adult. No children or adults over the age of 60 years should attend the appointment. Women with symptoms suggestive of possible coronavirus infection should avoid visiting the units, unless there is a strong clinical indication for a visit. In such circumstances, the woman should be seen and assessed in a designated 'contaminated' area or SARS-CoV-2 assessment area.

Guidance for staff undertaking routine or specialist ultrasound scans

1. Guidance on cleaning and disinfection of ultrasound transducers and equipment, and how to protect the patients and ultrasound providers during obstetric and gynecological scans, has been provided in a separate document[8].
2. All recommendations from local infection-control departments should be followed, including:
    - The sonographer's arms should be bare below the elbows;
    - The sonographer should not wear a watch or any jewelry.
3. Practitioners should wash their hands or use hand sanitizer both before and after direct patient contact.
4. Practitioners should use latex-free disposable gloves during the ultrasound examination and change after each patient.
5. We recommend the use of a three-ply surgical mask as a minimum when performing ultrasound scans, as sonographers spend a significant time during an examination in close proximity to the patient. When managing patients with suspected/probable/confirmed COVID-19, an appropriate respirator should be used (respirator (N95, FFP2/3)[9].
6. Single-use gel packs are recommended, instead of gel containers, even for transabdominal scans.
7. Non-clinical staff (e.g. receptionists and clerks) are advised to follow local infection-control procedures. If they are able to perform their tasks without being in close proximity to patients, use of a three-ply surgical mask should not be necessary.
8. All personnel working in ultrasound units should be aware of the potential symptoms of SARS-CoV-2 infection, such as new onset of cough, fever and shortness of breath. If they develop any of these symptoms, they should immediately seek medical advice and arrange testing, if allowed by local protocols.

Coordinating your local unit during the COVID-19 pandemic

In addition to the usual day-to-day requirements for running your local unit, we recommend the following:

1. All PPE[9] must be checked daily to ensure your unit is stocked and prepared;
2. All staff must be fit tested for FFP3 masks and records must be kept;
3. Managers should anticipate that staff (or members of their family) may become unwell during the pandemic, and therefore, careful planning of staff and contingency planning should be carried out in accordance with local availability;
4. If patients are tested for SARS-CoV-2, ensure that records of the tests sent are kept and that these results are checked daily. Ensure that the patient is informed of the result, and if they were admitted, the ward staff and team in the hospital are also informed as soon as possible;
5. If multidisciplinary team meetings (MDT) are relevant to practice, we highly encourage units to conduct weekly MDT, which can be arranged using an online meeting platform (e.g. Zoom), to discuss cases;
6. Considering that there is a high risk of SARS-CoV-2 transmission between staff, social distancing with colleagues should be observed where possible and meetings should be kept to the minimum necessary. Meal breaks should be taken in isolation and not as a group.

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