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Guide to Consent and Chaperones for Intimate Medical Ultrasound Examinations

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I Introduction

Purpose of the guide

The purpose of this document is to provide a consent and use of chaperone guide for medical sonographers who perform intimate ultrasound examinations. It outlines principles and best practices that can be applied during examinations that patients may perceive as intimate. By adhering to this guide, sonographers can enhance patient safety, reduce medico-legal risks, and improve overall patient outcomes.¹ This document is relevant not only to sonographers but also to all health professionals involved in intimate ultrasound examinations.

Scope and applicability

This guide is intended for members of the Australasian Sonographers Association (ASA) irrespective of gender, who conduct or assist with intimate ultrasound examinations across various clinical settings. It should be read in conjunction with other relevant documents, including the <u>ASA Sonographer Code of Conduct</u>, <u>NZ Code of Ethical</u> <u>Conduct</u>, <u>ASA Guide to Consent for Medical Ultrasound Examinations</u>, and documents related to ASA membership, workplace protocols and relevant regulations. This guide does not provide advice on how to perform, or the technical requirements of intimate ultrasound examinations.

Disclaimer

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Date, review date

This guide was produced in May 2024 by the ASA's Research and Standards team after consultation with ASA's Sonographer Policy and Advisory Committee and members. Feedback was obtained from key stakeholders. ASA Board approval September 2024. This guide will be reviewed September 2027.

II General principles

What are intimate ultrasound examinations?

An intimate examination typically involves the breasts, genitalia, or internal structures (such as vaginal or rectal regions). Individual patients may also consider that for them, other examinations such as of the groin, upper hip or thigh regions or transthoracic echocardiograms, are intimate. For the purpose of this guide, 'intimate examinations' do not include ultrasound examinations where incidental or accidental contact of intimate structures may occur.

The concept of an intimate examination varies among patients because of religious, cultural, experiential, gender, sexual orientation, and age-related factors. Sonographers must approach each individual with sensitivity and avoid making assumptions about their personal boundaries regarding what they consider intimate.¹ Intimate examinations require sensitivity, respect, and adherence to ethical and professional standards. Workplaces may provide guidance on what constitutes an intimate examination, and it is essential to follow workplace guidelines.

What information should be provided to the patient?

Patients undergoing intimate examinations may experience uncertainty and vulnerability. These feelings can intensify when the examination involves partial undressing or takes place in dimly lit conditions.² Prior to any examination commencing, including asking for clothing to be moved or removed, all components of the examination must be fully explained including an explanation of which part of their body will be touched, by what (such as ultrasound gel or the gloved hand of a sonographer), and why the examination is necessary.^{1,3} Clear communication ensures patient understanding and comfort. The sonographer should:

- **Explain the purpose and consent process**: Clearly communicate to the patient the reason for the examination in a way that they can understand. Emphasise that having the ultrasound examination is voluntary, that they have the right to decline without any negative repercussions. Explain that even after consenting to the examination, consent can be withdrawn at any time during the examination, without repercussions.
- **Explain the right for a chaperone**: The patient may ask to have a person provided by the department to act as a chaperone. It is also important to explain if it is departmental/personal policy to have a chaperone for intimate examinations. The patient also has the right to have a support person present during the examination.
- **Describe the examination**: Provide details about what the examination involves using layperson terminology, including how long it will take, equipment used, what areas of the body will be exposed and touched, what measures will be taken to respect their privacy, the offer of a chaperone, and the associated risks and benefits. The sonographer may consider offering the patient the transducer for self-insertion for a transvaginal examination, considering both the clinical environment and the patient's preferences.¹Ensure the patient is provided with privacy to change and supply a modesty sheet.
- **Discuss potential discomfort**: Inform the patient about any transducer movement they may feel (including the need to test organ mobility if applicable), sensations they may experience and ask them to advise you during the examination if they feel pain, discomfort or if they wish you to stop. Communicate to the patient that the examination may be stopped at any stage if they wish. i.e., they may withdraw their consent at any time during the examination.
- Address questions: Encourage the patient to ask questions and seek clarification prior to commencing. Open communication helps alleviate anxiety and ensures a more comfortable experience for the patient.

What type of consent is suitable for intimate examinations?

The consent process upholds the ethical principles of autonomy and freedom of choice by allowing patients to make well-informed decisions. Consent from the patient must be obtained before initiating an intimate examination and ensuring consent is obtained for each component of the examination.¹ Consent requires that the patient fully understands and voluntarily agrees to the examination. Consent should encompass situations in which a reasonable person would anticipate giving consent including the presence of students/trainees during the examination.^{1,4}

The sonographer may supply written material, diagrams, or further explanation to ensure that the patient has sufficient understanding to provide consent.^{1,4} An example of a patient information sheet for a transvaginal examination is provided in <u>Appendix I</u>. An example of a consent for transvaginal examination is provided in <u>Appendix I</u>. An example of a consent for transvaginal examination is provided in <u>Appendix I</u>.

All local protocols regarding requirements for different types of consent should be adhered to.

In cases where the patient cannot provide consent due to factors like incapacity or being underage, a legal representative or surrogate decision-maker may give consent on their behalf, following established legal and ethical guidelines. If a patient lacks capacity, you should follow the guidance in <u>ASA Guide to Consent for Medical Ultrasound Examinations</u>.

- **Verbal Consent**: Verbal consent involves a full and open discussion, including general requirements of examination consent, followed by clear verbal agreement from the patient. It is suitable for routine examinations^{4,5} including low-risk breast, genitalia, transvaginal and transrectal ultrasound examinations.^{5,6} This is consistent with an advisory statement issued in 2021, by the Diagnostic Imaging Accreditation Scheme (DIAS).⁵
- Written Consent: Written consent involves a full and open discussion, including general requirements of examination consent, followed by obtaining the patient's signature on a consent form. Written consent is required for all high-risk examinations.⁶ High risk examinations include those that have an interventional component (e.g. injections or biopsies), when the examination is being performed for non-diagnostic reasons (e.g. research and teaching/demonstration) or any other examinations is deemed high risk for individual patients by the local department or its jurisdictions.⁵
- Implied consent does not meet minimum requirements for intimate examinations.

The detailed and ongoing dialogue between the sonographer and patient during an ultrasound examination is a fundamental aspect of the consent process. It is also essential to document the discussions and the consent process.

When should a chaperone be used?

Chaperones serve as partners in maintaining a professional and patient-focused approach during intimate examinations. In intimate examinations both the patient and the sonographer have the right to request a chaperone be present.

All patients having an intimate examination, should have the examination explained to them, together with their right to request a chaperone.¹ This information can be provided through prominently placed posters, practice leaflets and verbally, prior to the examination.¹

If the sonographer requests a chaperone, or if it is departmental policy to provide a chaperone, then this information should be provided in the consent process. It is essential to inform the patient why a chaperone is required, that having a chaperone present is a standard practice, and the patient's right to refuse.⁷ During the consent process, it is important to clearly communicate the name and role of the chaperone to the patient. This ensures transparency and allows the patient to make an informed decision regarding their care.³

• Considering sonographers' needs:

- Sonographers should consider their own comfort and safety during intimate examinations.
- Regardless of patient gender, sonographers have the right to request a chaperone if they deem it necessary.
- Particular care should be given regarding the use of chaperones when there are concerns related to mental health, cognitive abilities, or emotional state of patients or their parents/guardians.
- Patient preferences and autonomy:
 - Patient preferences vary according to age, cultural background, and personal experiences.

• Irrespective of the sonographer's gender, patients retain the right to request or deny a chaperone. Their autonomy should be respected.

What is the role of the chaperone?

The following points underscore the significance of chaperones:

- Chaperones witness ongoing consent:
 - The chaperone is an impartial observer present during the examination and should be familiar with intimate examinations³ and be aware of their role and responsibilities^{3,8} they are undertaking. Their role is to observe and assist in maintaining appropriate behaviour. The chaperone should act as a witness to verbal consent.⁴ The chaperone stays throughout the examination and is positioned where they can observe the examination⁹ as much as practical without obstructing the examination or interfering with the patient's dignity.⁸ They assess the sonographer's actions and should remain alert to the patient showing signs of distress or comfort.⁸ They should raise concerns if needed.

• Enhancing safety and trust:

- Chaperones contribute to patient safety by providing an additional layer of oversight. All chaperones should be introduced to the patient.⁷
- Patients often experience increased comfort and trust when a chaperone is present, fostering a positive provider-patient relationship.
- Respecting patient dignity:
 - Intimate examinations can be emotionally challenging for patients. Chaperones play a crucial role in maintaining patient dignity by ensuring respectful and compassionate care.
 - By safeguarding privacy and modesty, chaperones create a supportive environment during vulnerable times.

Who can the chaperone be?

- The chaperone should be aware of the role they are undertaking and have an understanding of patient privacy, confidentiality, and professional conduct during examinations. Ensuring chaperones have this understanding is the responsibility of the healthcare provider.³ Specific information for this role may be provided externally or in-house by an experienced staff member and should include:
 - what is meant by the term chaperone.
 - what is an 'intimate examination'.
 - o when and why chaperones need to be present.
 - \circ the rights of the patient.
 - \circ what is the expectation for professional conduct for those performing the examination.
 - the role, responsibilities, and boundaries of a chaperone.
 - o policy and mechanism for raising concerns.

- The chaperone should be prepared to raise concerns³ about the sonographer or patient if misconduct is suspected or occurs, in line with local policy and laws of the relevant jurisdiction(s).
- Chaperones should, where possible, be of a gender approved by the patient or their support person.
- When considering the use of administration staff or students as chaperones during intimate ultrasound examinations, it is essential to weigh their suitability on the basis of their knowledge, training, and independence to fulfil the role. While students can be present for educational purposes, there may be potential liability concerns and students may feel conflicted when observing and reporting a sonographer, especially if they rely on the practice for clinical placement and/or the sonographer is involved in their assessment. ASA does not recommend the use of students as chaperones, but if a student consents to acting as, and is used as a chaperone, it should be documented in the patient's records. It is important to ensure the patient specifically consents to a student being present and acting in the role of chaperone.
- Except in extenuating circumstances and with patient consent, a relative or friend of the patient can act as a comforter, carer, or support person and be present in the examination.³ Their presence should be documented in the patient's records. It is essential to recognise that an attending relative or friend is not regarded as a chaperone and may complicate defending against any allegations. When there is a possibility of misinterpretation, it is advisable to have a chaperone present in addition to the support person.⁸
- Children (i.e. anyone under 18) should not act as chaperones.³

Documentation of chaperone use

- It is recommended that there is documentation of whether a chaperone is used for intimate examinations and the circumstances around the decision.
- When verbal consent is obtained, document the chaperone's presence on the sonographer worksheet/report or in the patient's medical record. Written consent should outline that a chaperone was offered and either accepted or declined. Written consent should be included in medical records.
- Documentation serves several purposes:
 - **Medico-legal considerations**: Proper documentation ensures transparency and accountability. It protects both the patient and the sonographer.
 - **Risk management**: By recording the rationale, sonographers can demonstrate that they acted in the patient's best interest.
 - **Patient-centered approach**: Documenting the reason allows for a patient-centered approach, whereby the patient's preferences and circumstances are considered.
- Chaperone consideration:
 - If a chaperone is required and cannot be arranged, or if the patient is not comfortable with the chosen chaperone, they should be offered the option to reschedule the appointment until an appropriate chaperone becomes available, provided this does not impact patient care.
 - When a sonographer works in settings away from colleagues, such as out-of-hours or regional/remote locations, the same principles regarding the offering and use of chaperones should apply. However, there are situations where this may not be feasible. For instance, urgency or community-based practice might preclude having a chaperone available. In such cases, effective communication and meticulous record keeping become crucial.¹

- **Respect and document the decision**: Patients have the right to decline a chaperone if they feel comfortable proceeding without one. Clearly document the patient's decision to proceed without a chaperone.
- Seek a collaborative solution: If the sonographer is uncomfortable proceeding without a chaperone, they may consider asking a colleague who is willing to scan without a chaperone as long as the delay would not adversely affect the patient's health.⁸ Collaborating with a colleague ensures patient safety while respecting the patient's autonomy.
- In instances whereby the patient lacks the capacity to make an informed decision or there are other mitigating factors, the sonographer must rely on their professional judgment regarding the use of chaperones. It is crucial to document and justify the chosen course of action.

III Special Considerations

Transvaginal ultrasound in patients who have not had penetrative vaginal sex

When clinically indicated, transvaginal ultrasound(TVUS) should be offered to all consenting patients, regardless of penetrative sexual experience.⁹ It should be acknowledged that for patients that have not had penetrative sex, they may experience greater levels of discomfort, and care should be taken to ensure that full consent has been obtained. The sonographer should be vigilant to maintain patient comfort and inform the patient that the examination can be ceased at any stage before or during the examination.

Patients who experience difficulty with the examination

Some patients may suffer from physical or psychological conditions that make an intimate examination difficult. Conditions such as female genital mutilation, vaginismus, radiation fibrosis, sphincter spasm, or anal fissure may require the examination to be abandoned. Once the patient is dressed and sitting up, discuss options including reattempting the examination at a later date, or an alternate examination can be booked in consultation with the supervising medical practitioner. Document difficulties in patient records.⁴

Transgender patients

Transgender (trans) people should receive equal access to healthcare services.³ However, when undergoing intimate examinations, patients may have additional needs and considerations. Sonographers should be well informed about appropriate terminology to facilitate person-centered communication and care. Key points include:

- **Gender dysphoria awareness.** Be sensitive to language used to avoid distress during examinations. Ask the patient what name they go by and their pronouns. Ask a patient what terms they use for discussing intimate areas of their body e.g. the vagina may be called "front hole", "upper body" instead of breast/chest and "external genitals" instead of testes/penis. It may be preferable to use the term internal scan rather than endovaginal scan. Acknowledge that there may be differences between clinical terms and personally preferred terms. Inform the patient that written reports will use anatomical terms to reduce the chance of misinterpretation and ensure consistency.
- Supportive practice. Many gender diverse and transgender people have had negative experiences affecting their trust in healthcare providers.⁹ Consider the number of people in the room and ensure that the patient feels comfortable with those involved in the examination. All patients should be offered a support person present. Allow time for questions and ensure that the explanation of the examination includes details about touch, movement, pressure, and sounds involved for all intimate examinations. When performing TVUS, check if a transmasculine patient

is experiencing vaginal atrophy due to medical transition, which may affect the tolerance of endovaginal transducer. Ask a patient if they would prefer to insert the transducer themselves.

Religion and culture

Evidence indicates that intimate examinations, when clinically indicated for medical reasons, are generally accepted by people of diverse religious and cultural backgrounds.¹⁰ There are no known reasons why a patient should be denied an examination because of religious mandates. However, cultural and religious factors may influence a patient's consent to intimate examinations. Considerations in gender congruent care, modesty, and use of chaperones should be the same for all patients, regardless of religious or cultural beliefs. Sonographers should be culturally competent and sensitive when performing intimate examinations.

Patients under the age of 16

Patients over the age of 16 years with decision making capacity have the right to consent or refuse to consent for medical treatment and/or healthcare.^{11,12} Suitability for consent to an intimate examination is not solely based on age; but must also consider clinical history, maturity, and cognitive capacity.¹³ NZ, ¹⁴ NSW,¹⁵ and SA¹⁶ have documented legislation regarding the age of consent (see <u>ASA Guide to Consent for Medical Ultrasound</u> <u>Examinations</u>), but the presence or absence of legislation in any state, does not preclude a mature minor from providing consent (or refusal) in their own right.

Clinically warranted intimate examinations should be offered to all consenting patients, including those under the age of 16, provided that they can understand the nature, purpose, and potential consequences of having or not having the examination.

Healthcare providers must evaluate each case individually to determine if the minor comprehends the proposed treatment adequately and therefore has the capacity to consent to the procedure.^{10,11} A minor is deemed to have capacity to consent when assessed to have Gillick competency. Gillick competency assesses whether a child has the maturity to make their own decisions and to understand the implications of their decision. The assessment of competency needs to occur by the directing medical practitioner, that is, the specialist or radiologist, but the sonographer has an ethical responsibility to ensure Gillick competence (including state legislation) when providing care to young persons under the age of 16 who wish to receive or decline treatment, without their carers consent or knowledge. Discussions, actions, and outcomes should be documented in the patient's medical records.

If a person lacks this level of competency, they may not be capable of providing consent. Different jurisdictions have specific provisions regarding minors' ability to provide consent. Whenever possible and with consideration of the patient's wishes, the consent of a parent or guardian should be obtained.

For TVUS, special considerations include obtaining parental or guardian written consent in addition to the child's consent for patients under 14 years of age.^{10,11}

Patients that have a history of sexual abuse/assault

Survivors of sexual abuse and/or sexual assault can face significant challenges and potential retraumatisation during intimate examinations.¹⁷ Whilst it may not always be known at presentation, it requires heightened awareness and sensitivity from the sonographer, and it is important to be aware of both the verbal and non-verbal cues to guide practice. Some key considerations include establishing trust and safety, maintaining privacy, and

accommodating the patient's needs (e.g. more time to explain the examination and process of ongoing consent, being open to questions, be aware of using non-judgmental language).

Intimate examination of an anaesthetised patient

This consent is usually given by the patient during the preoperative assessment when they are fully conscious and capable of making informed decisions about their care. Sonographers must adhere to relevant laws and institutional protocols regarding consent in such situations.

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V Appendix I

Example of Patient Information Sheet

Your doctor has requested an ultrasound examination that, in addition to a transabdominal scan (external scan over your abdomen), may also involve an internal transvaginal scan. This safe and typically painless exam provides high quality ultrasound images to aid in diagnosis.

What is ultrasound?

An ultrasound scan utilises a specialised machine that employs high-frequency sound waves to create an image of internal body structures. A small handheld probe, known as a 'transducer,' is gently moved over the skin surface (or inside the vagina for transvaginal scans). The transducer sends sound waves into the body and receives echoes that bounce back, which are then processed by the machine to generate the image that is displayed on a monitor.

What is a transvaginal scan?

Transvaginal scans provide a more detailed view of your vagina, uterus, and ovaries than an external scan. This is because the ultrasound probe is placed inside your vagina and can get very close to these structures. The ultrasound probe is specially designed to fit comfortably within the vagina, and the sonographer may need to use both external and internal gentle pressure to check how your organs move. You may experience some discomfort but please let the sonographer know if you experience pain or wish to stop the examination at any stage. The level of discomfort is usually minimal, similar to what you would experience with an internal examination at a clinic or GP surgery.

A transvaginal scan usually takes about 10-15 minutes. The transvaginal probe is disinfected, covered with a protective cover, and lubricated with gel. You will be lying on your back with your hips and knees bent, with your lower torso and upper legs covered. You may have a cushion placed underneath your lower torso or the end of the bed is lowered. The sonographer will carefully insert the ultrasound probe into your vagina. If you prefer, you may insert the ultrasound probe in the vagina yourself, with guidance from the sonographer. Only a small part of the probe is inserted, and its long handle allows the sonographer to move the probe within your vagina for optimal viewing of your internal structures.

All our staff are fully competent in this examination and the examination may be performed by a female or male sonographer. If you have a preference for a sonographer of a particular gender, please discuss this with the reception staff and this will be arranged if possible.

If a transvaginal scan is required, the individual staff member will discuss the details with you, and you are encouraged to ask questions to assist in making you comfortable during the examination. The sonographer will do their best to maintain your modesty at all times. You will be asked for your consent prior to having the scan.

Please let the sonographer know if you have any allergies to latex or rubber before the examination.

A chaperone can be available if you wish. It may be the policy of the ultrasound department you are attending, or the sonographer may wish to have a chaperone present. Chaperones act as observers during the ultrasound scan, to witness and assist maintaining a professional and patient-focused approach during intimate examinations.

If you do not wish to have this scan, your request will be honoured and an alternative method of obtaining the diagnostic images may be suggested.

VI Appendix II

Example of a consent form for a transvaginal scan

| FOR THE PATIENT | |
|--|---------------|
| In signing this form you are giving written consent to have a transvaginal pelvic ultrasound | 1. |
| Name | |
| Address | |
| Date of birth | |
| Consent | |
| I have been given verbal or written information about what is involved in the | |
| scan and the reason for performing the scan in a format which I understand. | |
| I have been provided the opportunity to have any questions answered to my | |
| satisfaction | |
| I understand I have the right to change my mind at any time after signing this | |
| form, preferably following discussions with the | |
| sonographer/radiologist/referring doctor | |
| Please select one of the following options: | |
| I give my consent to have the transvaginal ultrasound performed | |
| I do not give my consent to have the transvaginal ultrasound performed | |
| I understand what the transvaginal ultrasound scan involves, including why it is necessary, but do not give my consent to have the transvaginal ultrasound to be performed. | |
| Note to patient: if you decline the scan, it is recommended that you talk about this with your referring doctor. | |
| Other information (please talk to your sonographer if you are unsure or have any question | ons about the |
| questions below) | |
| • Do you have an allergy to latex? If so, a non-latex cover to the ultrasound probe | Yes 🗆 |
| will be used. | No 🗆 |
| | Unsure 🗆 |
| • A third person may be present during the scan acting as a chaperone, as | Yes 🗆 |
| requested by your sonographer or yourself. Do you request to have a chaperone present? | No 🗆 |

| Patient name | Signature |
|------------------|-----------|
| Date | |
| | |
| Sonographer name | Signature |
| Date | |

VII Appendix III

Checklist for a sonographer

The sonographer could use this checklist before proceeding with the examination. Documentation is key in cases where complaints are made. Use the 'notes' column to provide documentation about the consent process.

| Checklist item | Notes |
|--|-------|
| Will a student be present during the scan, and what will their role be? (i.e., observer, assisting, conducting examination). Has this been explained to the patient? | |
| If a chaperone is to be present, who are they, have they been trained for the role they are undertaking? Consent to have a chaperone present should be provided by the patient. | |
| Were there any communication barriers prior to the patient providing the information above, and how were they overcome? | |
| Do you have any concerns about the patient's ability or legal right to provide consent? If so, you should not proceed with the examination unless alternate arrangements are made (i.e., alternate decision maker consulted, patient referred back to referring doctor). | |
| Do you have any concerns that the patient is feeling coerced? Do not proceed with the examination if this is the case. | |
| Do you have any concerns that the patient is in a vulnerable situation? If so, further discussion with the patient is required, or an advocate of the patient may be consulted. | |

| Sonographer name_ |
|-------------------|
| Date |

Signature_