

Dangers in the dark: Calling for a safer practice of transvaginal ultrasonography

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Abstract

Background: The intimate examination is an important component of the assessment of a patient presenting with obstetric or gynaecological concerns. Ultrasound practitioners, like any other medical practitioner, are in a unique and privileged position. During the examination, the sonographers engage in a very close and personal interaction with an individual whom they have likely never met. They are also most likely unfamiliar with their social situation, cultural background, previous experiences with the healthcare profession and more importantly, any history of sexual trauma. It is an extremely sensitive area of practice which places a great deal of responsibility on the clinician to ensure that they not only protect their patient from psychological distress, but also themselves, from the threat of litigation arising from such distress.

Aims: This paper highlights the current governance requirements for sonographers and makes suggestions to support them in safeguarding their patients and themselves from allegations of unprofessional conduct, until such a regulatory body exists.

Materials and Methods: A wide-ranging review of the literature exploring the perceptions of female patients regarding intimate sonographic examination was performed using standard search engines. Additionally, grey literature was searched for policy statements and government regulatory documents for guidance on the topic.

Results: Although much research has been undertaken in this field across diverse cultures and knowledge in this area is ever increasing; however, the guidelines for sonographers appear to be site specific and variable. At present, there is no overarching governance for sonographers, as there is with practitioners registered with the Australian Health Practitioner Regulation Agency.

Discussion: While there are practice standards for the purposes of Medicare set out by the Diagnostic Imaging Accreditation Scheme, there is no regulatory professional standard that sonographers are held accountable to. This is problematic and has the potential for inadvertent boundary transgression by the practitioner, as there is also no existing framework for management of such incidents in an equitable manner.

Conclusion: The intimate examination is generally well tolerated; however, there is a subset of the population who are vulnerable to psychological distress arising from the examination. The sonographer must be astute to signs of distress and act in accordance with the intimate examination guidelines set out by AHPRA, for the dual purpose of protecting their patients against harm and also themselves from the threat of litigation.

Keywords: perception, pregnant, sexual, sonography, transvaginal ultrasound, violations.

Introduction

The intimate examination is an issue that is relevant to physicians and sonographers alike. Much attention has been given to professional boundaries for doctors; however, little guidance

exists in the literature regarding these issues for sonographers. According to a statement made by the Australian Health Practitioner Regulation Agency (AHPRA), a sexual boundary violation may involve an inappropriate physical examination, failure to obtain an appropriate informed consent, or asking the patient to undress further than is necessary.¹ For sonographers, who may not be covered by regulations that apply to other

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health practitioners, practice guidance and prohibitions may be ambiguous when it comes to intimate procedures and thus might pose a risk of complaint. In this paper, set in an Australian context, we explore the issues of practice regulation, patient experience and patient and practitioner safety in relation to the transvaginal ultrasound. The authors aim is to discuss legal and ethical issues of practice and highlight risks and protective measures for patients and practitioners alike.

Methodology

A wide-ranging review of the literature was performed utilising standard search engines including Medline, Embase and Pubmed. Additionally, publications in the grey literature including government reports and policy statements were also included. Special emphasis was placed on finding information specific to ultrasonography practice and regulatory issues around transvaginal ultrasound from Australia and overseas. The literature search was limited to articles in English, and only publications pertaining to obstetric and gynaecological ultrasound were included.

Governance and professional regulation

The National Law requires all registered health practitioners, employers and education providers to report any transgression to AHPRA to prevent risk of harm to patients. Hence, all qualified practitioners are legally obliged to report any misconduct to AHPRA, or the appropriate regulatory authority.¹ Under the current law, sonographers are not bound by the requirements of AHPRA Association.² Nevertheless, the expectations set out by AHPRA are the recognised national standard for the provision of safe healthcare in Australia and in the absence of an alternative, could reasonably be regarded as a guide to safe practice for other medical services such as sonography.

The Diagnostic Imaging Accreditation Scheme (DIAS) was developed in 2007 to ensure safety and quality standards for diagnostic imaging practices. DIAS links mandatory accreditation to the payment of Medicare benefits for diagnostic imaging.³ It does set standards for consumer consent; however, it is a service based rather than an individual-based scheme. While DIAS requires each service to have a complaints service in place, in fact, it does not manage complaints as part of its role.

On the matter of therapeutic relationships, the guidelines set out by the Australasian Sonographers Association (ASA) state that 'Professional boundaries are integral to a good sonographer-patient relationship. They promote good care for patients and protect both parties.'² Among other recommendations pertaining to the strict avoidance of sexual relationships with patients, caregivers and previous patients and expression of personal beliefs in a way that exploits vulnerability or creates distress, it is advised that sonographers maintains 'strict professional boundaries'. The accompanying document 'Standards of Practice', which serves to complement the ASA Code of

Conduct state that sonographers should 'be familiar with the policies, procedures and protocols of their workplace and adhere to these documents'.⁴

Allegations of sexual assault against sonographers are reported to be rare, and most often occur due to the patient's perception of the nature of the examination.⁵ A recent high-profile case in the Australian media⁶ and the popularisation of the use of transvaginal probe in clinical settings raises concerns regarding the risk to patients and sonographers in the practice settings familiar to the authors.⁷

The potential for transvaginal ultrasound to be an at-risk area for practitioners and patients alike is inherent to the nature of the procedure itself. In a poorly lit room, a covered transducer is inserted into the vagina and moved around for up to 15 min to obtain the best possible ultrasound images. The subjects of the procedure are mostly young pregnant women, undertaking the procedure to confirm foetal welfare, and thus are most likely to feel pressure to have the procedure performed despite having reservations.⁸

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) statement regarding the doctor-patient relationship acknowledges that 'the patient may be vulnerable, or feel vulnerable, in the relationship. This should be recognised, respected and not exploited physically, emotionally, financially, or in any other way'.⁹ The same should apply to the sonographer-patient therapeutic relationship, brief though it may be. The Australasian Sonographers Association (ASA) states that 'the definition of an intimate examination may differ from patient to patient for religious or cultural reasons, because of previous experiences, sex, sexuality or age'.² The specifications of the General Medical Council (GMC) as to what constitutes an intimate examination include: 'Intimate examinations can be embarrassing or distressing for patients and whenever you examine a patient you should be sensitive to what they may think of as intimate. This is likely to include examinations of breasts, genitalia and rectum, but could also include any examination where it is necessary to touch or even be close to the patient'.¹⁰

An American study reported 14 cases of sexual assault allegations identified mainly between 1986 and 1996.^{7,11} Similarly, in Australia, there have been reported incidences of sexual misconduct by sonographers. In one such case, a sonographer registered with the Australian Sonography Accreditation Registry (ASAR) was convicted of nine counts of aggravated indecent assault on five female patients attending for ultrasound examinations of the breast, pelvis and groin. The charges were made based on the accusations that the sonographer displayed inappropriate behaviour which was deemed to be not clinically necessary. Additionally, it was alleged that the examination was not terminated in accordance with the patient's request. As a consequence of these charges, the sonographer was permanently banned from clinical practice and sentenced to 5 years imprisonment.⁶

The ASA is in the process of submitting a proposal to the Council of Australian Governments (COAG) Health Council, which will request that sonographers also be registered under AHPRA. In order for this to happen, it must be demonstrated that a sonographic examination has the potential to cause harm to patients, and that this potential for harm may be mitigated by having the profession come under government regulation.¹²

The process of investigation of assault claims against sonographers is time consuming and stressful. Even in the event of no criminal proceedings, the process is damaging to the sonographer, having far reaching consequences on their reputation, health and family life.⁵ It is thus in each practitioner's best interest that all available steps are undertaken to safeguard themselves from such an unfortunate occurrence.

Informed consent

There are many definitions of informed consent, all of which reflect the ethical and legal principle that the patient has a right to agree or decline treatment, after being given the relevant information. Table 1 lists the Queensland Health Guide to 'Informed Decision-making in Health Care' requirements that need to be fulfilled for the consent to be deemed valid¹³:

In addition, the Australasian Sonographers association (ASA) asserts that consent is only valid until the time that the patient withdraws the consent or there is a change in circumstances. The clinician must be alert to verbal and non-verbal communication indicating that consent has been withdrawn, and must immediately terminate the examination if it occurs.²

Certain groups who are considered to be especially vulnerable, may not be able to provide consent. These include patients who are children, those who are intellectually, mentally or physically impaired, injured, or in pain or shock, under the effect of drugs or alcohol, sleep deprived or from a non-English

Table 1: The Queensland Health Guide to Informed Decision-making in Health Care.

1. The patient has the capacity to make a decision
2. The consent is given voluntarily
3. The discussion between the patient and health practitioner must be transparent and involve two-way communication
4. The information is in a language the patient understands
5. The patient is advised in simple terms of the risks, benefits, alternative options and details of the proposed treatment
6. The information provided and consent given must be specific to the healthcare provided
7. Consent is obtained prior to procedure, and the patient has sufficient time to consider all information

Adapted from the Queensland Health Guide to Decision-Making in Health Care (2017).¹³

speaking background. Extra care must be taken to ensure that the autonomy and dignity of these individuals are respected, by way of arranging a chaperone and by modification of the consent process to ensure that the patient understands the procedure. It is important to note that although informed consent may not be necessary in a medical emergency where an examination is 'essential to prevent death or damage to one's health', or when the patient is in 'severe pain or distress', the sonographer is expected to act in the best interests of the patient at all times.¹⁴

Consent may be verbal, written or implied. Generally, the law does not require written consent, however, Queensland Health advises written consent for any healthcare circumstances which carry significant risks to the patient, where doubt exists about the patient's capacity to consent and where health care is controversial.¹³

The ASA suggests that written consent provides an additional safeguard for the sonographer and should be considered. The DIAS (Department of Health) released an advisory statement in April 2018 stating that verbal informed consent is sufficient for low risk transvaginal and transrectal ultrasound procedures. However, practices which already obtain written consent for transvaginal and transrectal ultrasound procedures can continue to do so. In addition, written consent must be obtained for all high-risk procedures, such as those that require transvaginal or transrectal scanning as imaging guidance (e.g. for biopsies) or are otherwise determined by the practice to be high risk for the individual patient.¹⁵ Though not directly stated, it may be assumed that intimate examinations such as breast, transvaginal and transrectal scans may have the potential to cause physical or psychological harm to the patient.

The Public Health Service of Queensland, Australia; has developed an optional consent form for transvaginal ultrasound and an accompanying patient leaflet, which focuses on essential physical information related to the procedure and provides an opportunity for the patient to elucidate any concerns in writing.¹⁶ While this is desirable, it is heavily dependent upon the practitioner providing sufficient information to the patient, including why the procedure is important (as opposed to a less invasive one) and adequate time for the patient to respond. The informed consent proforma also states 'there are no known risks of transvaginal ultrasound' which would seem to neglect the potential for psychological trauma in certain vulnerable individuals. This has been highlighted by Clement et.al. who stated that a small but significant percentage of women (1.6%) that underwent transvaginal ultrasound were psychologically affected by the procedure. This finding is probably even more noteworthy when it is contemplated that 44.8% of women in the study sample declined to have a transvaginal scan performed.¹⁷ Specific populations, especially survivors of sexual abuse, are likely at risk of having traumatic memories triggered when undergoing intimate procedures, as

has been evidenced by other studies looking at such examinations in this vulnerable population.⁸ It is important that the practitioner allows enough time for a sensitive but detailed description of the procedure permitting the likely anxious patient some time to reflect, clarify any uncertainties and express any concerns.

The assertion that there are ‘no known risks of transvaginal ultrasound’ is also problematic in that it fails to acknowledge the thermal and non-thermal effect of ultrasound on the tissues. Guidelines as to what constitutes the maximum safe level of exposure are based on the thermal index (TI), a measure of a beam’s thermal bioeffects, and differ across advisory bodies.¹⁸ Teratogenicity resulting from thermal effects has been demonstrated by many animal studies and a few human studies. However, it is considered that there is insufficient evidence of a direct causative relationship in humans and more research is required to elucidate subtle effects.¹⁹ It has been shown using transducers embedded in agar models, that 30 s periods of B mode colour flow and pulsed doppler resulted in average heating of 2.0°C for gynaecological presets, and 2.16° for obstetric presets. It was also found that the TI greatly underestimated the actual rise in temperature.²⁰ A survey of practitioners in the United Kingdom demonstrated that although there was a good understanding of the concepts of thermal and mechanical energy, and that respondents were aware of the guidelines around safe exposure, 40% of respondents reported that they rarely or never monitored the thermal or mechanical indices in their practice.¹⁸ Ultrasound must be regarded a medical procedure that carries a risk of psychological harm to the patient, as well as the potential for physical harm to the foetus, which is at this stage incompletely understood.

Physical examination

An ultrasound examination requires that the patient be in a vulnerable position in dim lighting. In addition, the application of the probe to the patient’s body requires direct palpation. Even if the examination does not involve intimate regions such as genitalia or breast, this may be potentially unsettling for a patient.⁵ The patient must therefore be given a private place to dress and undress.^{1,21} According to guidelines set by AHPRA which may be taken as a guide, the clinician is not supposed to assist a patient to undress unless they are having difficulty and have directly asked for assistance.¹ The patient must be covered as much as possible while the examination takes place and gloves must be worn when performing an examination of the genitalia.¹ Additionally, light-hearted comments should be avoided, as there is a potential for misinterpretation.⁵ In the case of a vaginal examination, the sonographer may consider giving the probe to the patient to self-insert, if it is felt appropriate.¹⁴ Table 2 outlines the recommendations for transvaginal ultrasound examination made by The Australasian Society for Ultrasound in Medicine (ASUM).²¹

Table 2: Australasian Society for Ultrasound in Medicine recommendations on transvaginal examination.

At the time of the examination, the sonographer should:
Provide adequate explanation of what is involved. Many women expect the examination to be performed trans-abdominally – this may need time and explanation, in women who have not had a transvaginal scan performed in the past
Ensure adequate privacy to allow the woman to undress and lie on the examination couch. A sheet should be provided
Use an appropriate transducer. Offer the patient the option of introducing the transducer herself, as she would a tampon
Ensure the patient understands they have the right to terminate the examination at any point

Adapted from the ASUM Policy on Vaginal Ultrasound (2014).²¹

Patient experiences of transvaginal ultrasound examinations

Patients are individuals, and their experience of the transvaginal examination is a personal one, with varying degrees of comfort reported by patients in the literature. Many women undergoing pelvic interrogation by ultrasound may expect this to be performed abdominally and may have never previously undergone a transvaginal ultrasound.²¹ A survey from the USA of women undergoing a transvaginal ultrasound reported that most patients prior to the examination had feelings of concern (26%), uncertainty (26%), anxiety (22%) and hope (21%). After the ultrasound, most of the negative emotions had dissipated, replaced mainly with hope and any residual feelings of anxiety were thought to arise from the results not being immediately available.²² Another study looking at patient willingness to undergo transvaginal examination indicated that acceptance of the examination correlated with age (older patients were more willing to undergo an examination, $P = 0.004$), presence of vaginal bleeding in pregnancy ($P = 0.005$) and a history of dyspareunia ($P = 0.03$).²³ In addition, the level of education seems to correlate positively with a woman’s willingness to undergo a transvaginal ultrasound.²⁴ In a survey of 255 Nigerian women undergoing transvaginal ultrasound, 58% had attained secondary level of education, and the majority (129/147, 88%) of that subset had a positive attitude towards transvaginal ultrasound. A female sonographer was the clinician of choice for 63% of respondents. Whilst, 96.9% reported that the sonographers were professional, 46.7% felt that a chaperone was needed. It has been shown in another prospective survey from the University of Florida, that of 171 respondents, 82(46%) preferred or strongly preferred a female examiner.²³ These findings are relatively consistent across other studies with up to 63.1% of participants having a preference for a female sonographer.^{24–26} Furthermore, women feel more comfortable expressing their preference before the examination, as opposed to during the examination, after having met the practitioner and undergone

trans-abdominal ultrasound.²⁶ One study did show, however, that the tolerance of the examination was no different, whether the examiner was male or female. The gender of the examiner was irrelevant provided the examiner communicated well and with sensitivity and respect.²⁷

Generally, there is a high level of willingness of patients to undergo an invasive examination on the recommendation of their practitioner, especially in the context of an acute obstetric complication such as bleeding.²³ The majority (99%) of respondents expressed that they would be willing to undergo a transvaginal ultrasound in future if it were recommended,²⁸ similar to the findings in other published literature.^{28,29,30}

Pain and embarrassment levels are typically low with transvaginal ultrasound^{17,24,29} however, experiences of pain do appear to affect compliance with future transvaginal scans (OR = 0.87).³⁰ Painful examinations have been shown to be related to factors such as young age, previous hysterectomy and perceived increased scanning time.^{22,30} It was demonstrated, however, that only 40% of women experiencing pain reported this to the sonographer.³⁰ A questionnaire of patients who presented with early pregnancy complications indicated that women with symptoms such as pain and bleeding in early pregnancy are more concerned about their pregnancy than the transvaginal examination (P < 0.0001).²⁸ Only 1.9% of participants declined the examination, on the basis of pain and embarrassment related to the intimate nature of the exam. There did not seem to be a significant difference in experiences of discomfort in patients who had undergone transvaginal scans previously, as opposed to those who had not. None of the patients felt that the scan was worse than expected, and 58% reported that it was in fact better than anticipated.²⁸ It appears that close consideration to respect of dignity is likely to reduce patients' perceptions of embarrassment.²⁹ In addition to ensuring patient autonomy, some sites recommend the patient to insert the probe themselves, thereby instituting an extra safe guard for the sonographers.¹⁴

The location and the clinician performing the examination have also been investigated. A preference was expressed for a doctor rather than a sonographer. One theory regarding this preference is that patients may perceive the examination as a medical procedure.²⁷ Certainly the 'embarrassment level' has been demonstrated to be no less with an examination in the radiology department as opposed to the emergency department.²⁵

It has been shown that many women would like to receive more information prior to undergoing the examination,²⁴ though prior knowledge or experience of transvaginal ultrasound does not necessarily result in reduced levels of anxiety for women with first trimester complications.^{24,29} A study from the United Kingdom, of post-menopausal women undergoing transvaginal ultrasound for ovarian cancer screening reported that sonographers were professional, sensitive and reassuring.³⁰

There is no literature relating to specific populations who may be more vulnerable to psychological effects related to the treatment. As alluded to previously, intimate obstetric and gynaecological examinations can be highly problematic for survivors of childhood sexual abuse.⁸ It is hypothesised that this group are more likely to feel disempowered and potentially feel guilt-induced duress to undergo a potentially retraumatising experience for the sake of their infant's health. This situation may be prone to misinterpretation without clear guidance and sensitivity with a higher risk of patient distress and consequent risk to the health practitioner. A high level of compassion to patient discomfort is critical to avoid retraumatising an already traumatised individual and secondarily, to reduce the likelihood of a complaint against the practitioner.

Chaperone

The ASA and ASUM strongly encourage offering a chaperone to all patients undergoing a transvaginal ultrasound.²¹ The chaperone may be a qualified practitioner such as a nurse, doctor or any other person who is deemed suitable. This recommendation although highly desirable does not, however, appear to be a mandatory requirement. The patient may decline to have an observer present, at which point the clinician may proceed or not proceed with the examination, and find a practitioner who is comfortable to proceed without a chaperone.^{1,10} This recommendation contradicts that of Thomson and Moloney, who state that 'where possible, a trained chaperone should be made available. The use of a support person is inadvisable as they lack the status of an "impartial observer" as well as the background and necessary training'.⁵ The implication of having a chaperone who is an impartial, trained individual is twofold. Firstly, the presence of a trained chaperone reduces the risk of a false sexual allegation, whether they be motivated by malice or misunderstanding, as it was put in a recent opinion piece.³¹ Secondly, the presence of an observer such as a family member, partner or friend may compromise the disclosure of important information such as abuse by the patient³². The advice to use a trained chaperone thus provides protection to the sonographer and the patient, although it may not always be practical in smaller centres where access to trained chaperones or time is limited.³³ An Australian survey of general practitioners reported that providing patients with the option of a chaperone takes precedence over the actual provision of one.³⁴ However, there do not seem to be any studies or guidelines available that discuss the issue of chaperone availability in the context of sonography. The General Medical Council (GMC) recently published a Set of Guidelines regarding the use of Chaperones (Table 3).¹⁰

The published literature indicates that preference for the presence of a chaperone varies and while male patients tend not to be overly concerned regarding the option of a chaperone,

Table 3: General Medical Council guidelines on chaperones.

Provide the patient the option of having an impartial observer, irrespective of gender
A chaperone should usually be a health professional and the health practitioner must be satisfied that the chaperone will:
Be sensitive and respect the patient's dignity and confidentiality
Reassure the patient if they show signs of distress or discomfort
Be familiar with the procedures involved in a routine intimate examination
Stay for the whole examination and if practical, be able to see what the doctor is doing
Be prepared to raise concerns if they are worried about the doctor's behaviour or actions
A relative or friend of the patient is not an impartial observer
Delay the examination to a later date when a suitable chaperone may be available, without adversely affecting the patient's health
If the procedure is declined in the absence of a chaperone, clearly document this, and consider referring the patient to a colleague, as long as a delay would not adversely affect the patient's health
Record the details of the chaperone and make a note of their identity. If the patient refuses the offer of a chaperone, record that the offer was made and declined

Adapted from the General Medical Council Guidelines on Chaperones (2020).¹⁰

women do prefer the presence of a chaperone.^{27,35} A Nigerian survey demonstrated that out of 50% of respondents who elected to have a chaperone present, the majority (44.7%) preferred to have their spouse present, instead of an unknown person acting as a chaperone.³⁶ Additionally, the results of a retrospective survey from the United States indicated that patients undergoing a transvaginal examination were more likely to prefer a chaperone if their sonographer was male than if their sonographer was female.²² With this in mind, it may be prudent to avoid generating an assumption about a patient's preference regarding a chaperone based on their age, sex, cultural background or the nature of the examination.¹⁴ Furthermore, employers should have an established policy regarding the provision of a chaperone, which should be read and understood completely prior to the procedure.

Limitations and further research

The data on which we base our understanding of how patients experience the transvaginal ultrasound examination is largely based on patient surveys and case studies in which allegations of misconduct have been made and unfortunately represents the highest quality of evidence available to us. This is due to the ethical implications of performing controlled studies which

may cause significant emotional distress to the subjects and the difficulty in collecting objective measures for a subjective outcome such as patient distress. The potential for bias may be limited by delivering surveys online or on paper so that respondents may remain anonymous, by carefully wording the questions so as not to lead respondents towards certain answers, and by making surveys accessible and user-friendly to maximise the response rate.

It may be useful to conduct a controlled study as to how the presence of an appointed, trained chaperone influences the patients experience of an examination, as there is currently inconsistency in the guidelines. Furthermore, consideration may be given to undertaking a controlled study of patients and sonographers to explore how a clear explanation of the indication and the protocol for the test, and the potential for psychological disturbance to the patient influences the feelings of safety and reassurance around the procedure.

Conclusion

Allegations of sexual misconduct are a rare, but real concern for sonographers. It is recommended that they protect themselves by always obtaining informed consent, offering a chaperone wherever possible, and being familiar with site-specific guidelines for professional conduct. Due to the litigative nature of transvaginal scanning, it may be prudent to register sonographers under AHPRA in the interest of safeguarding both patients and sonographers. Detailed documentation of the informed consent process, identification of the chaperone and their contact details, and whether the patient declined a chaperone should be completed for all encounters. In addition to enforcing practise standards, it would also ensure patient safety and provide an appropriate complaints and investigative process. Special care should be taken to consider potential psychological consequences of a vaginal examination on vulnerable patients. Good communication and sensitivity will assist in patients feeling more at ease with the intimate examination.

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