NHS Obstetric Ultrasound Examinations. Guidance on Sale of Images, Fetal Sexing, Commercial Considerations and Requests to Record.

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Imaging Services Accreditation Scheme (ISAS) mapping:

https://www.isas-uk.org/default.shtml

FR5; **section e**) 'The views of patients and their carers, staff and professionals should be sought and taken into account in planning service development. Patient involvement might be achieved through lay representation in department management structure, use of suggestion boxes and 'mystery patients', focus groups or formal public consultation'.

https://www.sor.org/system/files/article/201810/fr 5.pdf

PE1 commentary (c) - All patient information material should be patient-friendly, current, and have a review date. It should be updated frequently to take into account changes in: technique; staff; facilities; location; and public expectations. Involvement of lay people and patients in the preparation of materials is strongly encouraged. Processes should be in place to ensure that patient information conforms to local styles and templates and is approved before release. https://www.sor.org/system/files/article/201810/pe 1.pdf

1. Introduction

- 1.1 The Society of Radiographers (SoR) is very much aware that prospective parents welcome the opportunity to obtain images of their developing baby and to be able to share these with their family and friends. Parents will also often ask the sonographer to reveal what the fetal sex is. The SoR is also conscious that the time allowed to perform an ultrasound scan for diagnostic or screening purposes under NHS provision is limited. Adding non-essential services to the ultrasound scan increases the time required which can in turn have an impact on other patients with pressing clinical needs. It can also conflict with the purpose of the examination which, under NHS funded provision, will be performed for a specific clinical reason, or as part of a national screening programme for fetal abnormality. There can also be major distractions caused to the sonographer in a highly litigious area of practice at a time when very high levels of concentration are required.
- 1.2 There are many private providers advertising scans to obtain 3D/4D images and baby souvenirs, which has led to some NHS Trusts and Health Boards also looking for ways to generate income from ultrasound scans performed for clinical reasons during pregnancy.
- 1.3 This guidance relates solely to NHS commissioned ultrasound examinations performed for screening or diagnostic purposes as part of a national screening programme for fetal abnormality; or other scans performed for diagnostic or monitoring purposes that are funded as part of overall NHS maternity provision and are thus free to the mother. It does not extend to ultrasound examinations performed where a scan has been requested by the mother and is outside normal NHS provision.

1.4 Reference should be made to the British Medical Ultrasound Society (BMUS) safety guidelines. BMUS have published guidelines on general ultrasound safety and specific advice on 'souvenir' scanning.¹

2. Sale of Images

- 2.1 The sale of photographs of the fetus to women and their partners taken in the course of an NHS obstetric ultrasound examination is a long established and popular practice; many departments now offer these in a digital format.
- 2.2 In departments where the decision has been taken to provide these images there should be agreement to this amongst all members of the obstetric healthcare team as well as the employing authority, and there must be a written procedure with which all staff are familiar.
- 2.3 In all circumstances, clear notices should be displayed prominently to advise service users about whether this service is provided and the local policy relating to it.
- 2.4 If it is necessary to recover the costs of providing images from the service user, then the SoR considers a system based on donations is preferable to a fixed fee system.
- 2.5 If thermal images are provided, service users should be warned that these should not be subjected to heat (e.g. laminating). The long term stability of thermal images is also not known.
- 2.6 The SoR does not consider that handling money, dealing with credit/debit card transactions or issuing receipts are part of a sonographer's duties. Arrangements should be made for these to be dealt with by support staff or by a payment machine. When exceptional circumstances require that money is to be handled by the sonographer there must be clearly agreed local procedures that can be audited. The security and safety of the sonographer must also be considered if money is kept in the scanning room or has to be transferred at the end of a session. A risk assessment must be undertaken.
- 2.7 Since the last edition of this guidance document (2015) commercial online systems have become available that allow service users to select and pay for images taken during the examination. These can then be downloaded onto a range of digital devices including smartphones and tablets. Before introducing such a system there should be a full evaluation with service users and sonographers' views being taken into account. There may be a local Public and Patient Liaison Group who can assist with this evaluation.
- 2.8 Also since the last edition of this guidance document the new General Data Protection Regulation (GDPR) came into effect in May 2018. Consequently, the SoR has been contacted by members seeking advice on how this new regulation may affect the sale of images. GDPR has not essentially changed previous legislation but it has again brought the issues into focus.
 - If a patient requests a copy of an image and videos/screen shots/images of the investigation, clinical discussion or treatment are then kept as part of the medical record; under Subject

Access Request procedures the patient can request a copy of their medical record for free and the images would have to be included, unless they involve a disproportionate effort to retrieve. This request must be answered within 30 calendar days. However, if only notes are saved and videos/screen shots/images are not part of the medical record, then there is no image available for a Subject Access Request.

If departments do store images on a patient's medical record they will need to release these for free; printing at high cost is not necessary and a digital copy will suffice. Stored images on Picture Archive and Communications Systems (PACS) qualify as part of a patient's medical record.

2.9 It is recommended that policies relating to the sale of images should be developed in consultation with the Trust/Board data protection officer to ensure that they are compliant with the requirements of GDPR. There is an exemption from the regulation where personal data is processed by individuals for their own personal purposes. If a recording is made by or on behalf of a patient, or with their consent, then the ownership is with them and they may do with it as they wish.²

3. Providing an Opinion of the Fetal Sex

- 3.1 Sonographers are very commonly asked to provide an opinion of the fetal sex. Local policy with regards to providing this should be clearly displayed in the ultrasound department and service users advised of the policy in advance of the scan, for example, within the appointment letter.
- 3.2 There have been worldwide concerns that in some countries sexing of the fetus, either by ultrasound or other available tests such as non-invasive prenatal testing (NIPT), has led to selective termination for reasons of 'wrong sex', resulting in skewed male: female birth ratios. It is more common in some countries for a female fetus to be terminated than a male. There has been recent research published by the Department of Health concluding that there are no substantiated concerns of 'wrong sex' terminations occurring in England, Wales or Scotland, but that the situation will continue to be monitored.³ This guidance document does not explore the wider ethical or legal issues involved with this subject, and in the context of this document sonographers are simply providing information.
- 3.3 Where local policy is to determine fetal sex, procedures should be organised so that women are able to state clearly whether or not they want to receive this information. This should ideally be prior to the commencement of the scan. As it is the mother who consents to the ultrasound examination, the sonographer needs to be particularly sensitive to their wishes in this regard.
- 3.4 There have been instances where complaints and litigation have resulted from an incorrect opinion of the fetal sex being given. Information should be provided to the mother at the time of the scan about the accuracy of fetal sex determination by ultrasound. This will also be influenced by the gestational age at which the assessment is undertaken and departments may wish to consider the minimum gestational age at which they will provide an opinion of the fetal sex. It is not always possible to give an opinion owing to the fetus

lying in a technically difficult position or due to poor overall visualisation. Sonographers also need to be aware of the various complex factors affecting development of the fetal sex and the possibility of indeterminate sex on ultrasound.

- 3.5 Local policy should determine whether the opinion given by the sonographer with regards to the sex of the fetus should be recorded on the ultrasound report so as to form part of the formal medical record. Information provided to the mother as to the accuracy of the sex determination should be included.
- 3.6 There is no *requirement* to determine fetal sex within the Fetal Anomaly Screening Programme (FASP) in England. There is no FASP requirement to recall or re-book an appointment with the mother if fetal sex cannot be identified simply owing to poor visualisation or difficult fetal position.⁴
- 3.7 NHS Scotland has the following advice: ⁵ "The local policy regarding fetal sexing should be made available before the ultrasound examination appointment is made and supported by information available at the time of the ultrasound examination. If offered it should include information about the success rates from published and local figures".
- 3.8 Public Health Wales has the following advice on sex determination: ⁶ "Looking for the sex of the baby is not part of the scan and is not 100% accurate. If you wish to know the sex of the baby and the sonographer can see it they will tell the mother at the time of the scan. They will not write it down".
- 3.9 Sonographers are sometimes requested to write the sex of the fetus on a piece of paper and place it in an envelope without telling the sex to anyone present for the purposes of a 'gender reveal' party or similar to be held later. Whether or not this is facilitated must be determined locally following full discussion of the likely issues surrounding this request. It is important to avoid any reduction in the time available to perform the diagnostic scan.
- 3.10 Where Trust or Health Board policy is not to determine the fetal sex that policy must also extend to consider the situation where a service user is aware that the sonographer has identified the sex of the fetus, but that policy prevents the information being relayed to the mother.
- 3.11 Information for patients and the public on ultrasound scans including advice on obtaining an opinion of the fetal sex can be found on the NHS Choices website. ⁷
- 3.12 Once policies on determining the fetal sex have been agreed they should be followed by all and supported by management.

4. Commercial Considerations

4.1 There have been instances brought to the attention of the SoR where there have been proposals to charge for determining the fetal sex and/or performing a 3D/4D extension to

scans requested under NHS provision. These proposals are often linked to the 18w 0d to 20w 6d fetal anomaly scan.

- 4.2 The SoR is of the view that to charge for determining fetal sex and to add other commercial considerations into the NHS obstetric screening scans (beyond the already long established provision or sale of images discussed above) is inappropriate. These scans have a serious clinical purpose which is to screen for and, if present, to diagnose fetal abnormality, with the mother's informed consent. Other scans requested during pregnancy within the NHS provision should only be for diagnostic or monitoring purposes related to specific maternal or fetal conditions.
- 4.3 Accordingly, the SoR does not support the commercialisation of scans that are being funded by the NHS for screening, diagnosis or monitoring.

5. Requests to record the Examination, e.g. using a mobile phone or other digital device

Please also refer to the SoR guidance document 'The recording of images and clinical discussions by patients during diagnostic imaging, interventional procedures and radiotherapy treatment' ².

5.1 There are specific issues encountered within obstetric ultrasound where the 'social' experience for the service user must be considered alongside the clinical reasons that scans are requested; this includes the two national screening programme scans for fetal anomaly at 11w 2d to 14w 1d and 18w 0d to 20w 6d*. Sonographers undertaking these examinations are responsible for the scan and the accompanying report, they will also need to inform the service user during the scan of any problems or abnormalities detected and make suitable arrangements for referral. Although valid, informed consent is sought and given for what is a clinical examination there is also a natural 'social' element to these scans which are looked forward to with high expectations by those attending. Service users will usually be accompanied by their partner or the intended parents and perhaps children and extended family or friends. In this situation video recording, e.g. by mobile phone is often requested for 'social' rather than clinical discussion reasons and may then be widely circulated via social media or forwarded directly to others. General conversations with the sonographer may also be recorded and the sonographer may be included in video recordings. These recordings may later be shared on social media and can be very difficult to have removed. Most service users attending these scans are considerate and will make a reasonable request of the sonographer if they wish to record during the examination but some will simply assert that they have a right to do so. A sonographer may not wish to be included in any general audio or video recording and their views should be respected. Instances of covert recording have also been reported to the SoR.

- 5.2 Very high levels of concentration on the part of the sonographer are required during obstetric ultrasound examinations. The examinations take at least twenty minutes and any pathology relating to the fetus or mother is identified as the scan proceeds, the stored images are only a record. It is also a highly litigious area of practice. Video recording by a third party during the examination can be very distracting as can tensions arising from misunderstandings over what might and might not be permissible. These distractions can lead to an error being made when it might not otherwise have been.
- 5.3 It can be helpful if there are information leaflets made available prior to the obstetric ultrasound scan explaining local policy. A clear verbal explanation before commencing the scan can also be very helpful in avoiding these problems that can sometimes arise.
- 5.4 There is a statement within documentation from Public Health Wales as follows that the SoR endorses: 'Video recording or the use of mobile phones within the ultrasound room and during a pregnancy scan is not allowed' ⁶
- 5.5 A sonographer must be able to feel comfortable within their own working environment and know that if they have concerns about distractions, that they are being considered and treated with respect. As healthcare professionals they have a duty to ensure that ultrasound examinations are conducted competently and that service user safety is not compromised. 8 Local Trust/Board management must ensure that the working environment and published locally agreed policies allow for this.

^{*}In England the two screening examinations are under the remit of the Fetal Anomaly Screening Programme (FASP). There are equivalent organisations to FASP in the devolved countries although the 11+2 w to 14+1w scan is not offered as a screening scan in Northern Ireland.

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