

NATIONAL SCREENING COMMITTEE

Fetal Anomaly Screening Programme (FAsP)

FETAL ANOMALY CONSENT FOR SCREENING WORKING GROUP

1 Background

- 1.1 This paper describes the underlying principles and standards for fetal anomaly screening consent. Legal, ethical, practice and service delivery implications have been considered.

2 Underlying principles

- 2.1 Fetal anomaly ultrasound examination is a screening test that may have significant clinical and emotional consequences. A rigorous approach to the provision of information and to the consent process is therefore required. Although the focus of the consent standards is the 18-20 week fetal anomaly scan, these underlying principles apply to all ultrasound scans in pregnancy.
- 2.2 Department of Health (DH) consent requirements form the basis of these standards. (Supporting documents that have informed the standards are listed in Appendix 1). Consent is a crucial aspect of the screening process. It is a professional obligation and a matter of basic respect between health professionals and women.
- 2.3 Women and those close to them will vary in how much information they require. However, all women should have a broad understanding of the purpose, risks, benefits, limitations and consequences of fetal anomaly screening. An element of clinical judgement will be required in determining individual requirements, but the presumption should be that women wish to be informed. In some cases, discussions will remain brief and very generalised. In other instances, women will ask detailed and complex questions about possible anomalies that may be suspected or detected.
- 2.4 Fetal anomaly screening should be described as an option rather than an inevitable aspect of routine antenatal care. If the process of seeking consent is to be meaningful, it must be clear that refusal is an option. If a woman declines fetal anomaly screening, all other appropriate care must still be provided. If a woman consents to ultrasound examination, but refuses certain aspects of the screening programme, the possible consequences and other available options must be explained. This discussion should be documented. Individual requirements should be taken into account, where possible. It should be clear that women are free to change their minds. Gestation specific treatment choices and screening effectiveness should also be described in this instance.
- 2.5 Seeking consent is a process that incorporates information provision, discussion and decision-making.
- 2.6 Consent is only valid when women have received sufficient information and are not acting under duress. Women should also be aware that they can withdraw their consent at any time and will be fully supported in that decision.

- 2.7 Gillick Competence / Fraser Guidelines should be applied to fetal anomaly screening. As such, pregnant young people under the age of 16 can give their consent, so long as they understand the nature, purpose and consequences of this ultrasound examination. They have the same right to confidentiality as adults. If a pregnant teenager is not judged sufficiently mature to make a decision about screening, advice should be sought from appropriate colleagues who work with children and young people. Young people under the age of 16 should be strongly advised to inform their parents of their pregnancy and screening decisions.
- 2.8 Consent for ultrasound is only valid when the woman has the capacity to comprehend and to retain information that is material to the decision. Capacity should not be confused with the health professional's assessment of the reasonableness of the decision. If an adult lacks capacity to give consent, others cannot give consent on their behalf. The procedure may still be performed if it is deemed to be in the individual's best interests. The law permits necessary interventions when adults are temporarily without capacity (e.g. when unconscious or sedated).

3 Standards for obtaining consent

- 3.1 Written and verbal information about ultrasound scans and the fetal anomaly screening scan should be provided early in pregnancy. Written and verbal information should be provided by 8 weeks gestation, where possible.
- 3.2 Women who attend for emergency early pregnancy ultrasound scans should be provided with ultrasound scan information that is relevant to their gestation and clinical history. Once pregnancy viability has been confirmed, more detailed fetal anomaly screening information should be provided during midwifery consultations.
- 3.3 Trusts should ensure that systems are in place to provide the required information when there are language or other communication barriers.
- 3.4 There should be documentary evidence of information provision within the woman's healthcare record.
- 3.5 The health professional who generates the initial ultrasound examination referral (usually the community midwife or general practitioner) should have sufficient knowledge and understanding of the procedure and its implications to describe in broad terms:
- The nature, purpose and limitations of ultrasound fetal assessment (including pregnancy localisation, dating, viability and fetal development)
 - The fact that women are normally offered two scans – an early pregnancy scan and a more detailed mid-pregnancy fetal anomaly scan
 - The implications of the procedure (including the reporting of fetal structural and potential chromosomal anomalies)
 - The fact that a termination of pregnancy may be offered when serious anomalies are detected
 - The option to decline an ultrasound scan
- 3.6 Women should have a further opportunity to discuss the 18-20 week fetal anomaly screening scan with a health professional before they attend for the test. This will normally take place at the 16 week appointment.
- 3.7 There should be documentary evidence of pre-test discussions, so that key

consent issues are apparent to the person performing the scan.

- 3.8 The health professional carrying out the investigation is ultimately responsible for ensuring that the woman has a broad understanding of the procedure and that she gives her consent.
- 3.9 There should be written evidence that the woman has given her consent to undergo fetal anomaly screening. *(This evidence may be in the form of an entry in the woman's healthcare record to indicate verbal consent. Completed and signed tick boxes can also indicate the issues that have been discussed. Alternatively, the woman may sign a consent form that contains the relevant information. Irrespective of format, the woman's agreement to the investigation and the issues that were discussed prior to that agreement must be clearly documented to show that the consent is valid).*
- 3.10 There should be an audit trail of pre-test information provision, discussion and consent.
- 3.11 Trusts will be required to conduct annual audit in relation to these standards. The results will be incorporated into a screening programme annual report.

4 Standards for audit and monitoring

Standard 1

Core standard

There should be documentary evidence that 90% of pregnant women have received the national information booklet and verbal information at least 24 hours prior to the fetal anomaly scan. (Supplementary local information booklets may also be provided).

Developmental standard

There should be documentary evidence that 95% of pregnant women have received the national information booklet and verbal information at least 24 hours prior to the fetal anomaly scan. (Supplementary local information booklets may also be provided).

Standard 2

Core standard

There should be documentary evidence that 100% of pregnant women who present for the fetal anomaly scan have consented to or declined to undergo this test. (When women lack capacity to give consent, discussions and decisions should be clearly documented).

Appendix 1

Supporting Documents

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The College of Radiographers., (2004) [Statements for Professional Conduct](#), London, The College of Radiographers