

Executive summary

Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views

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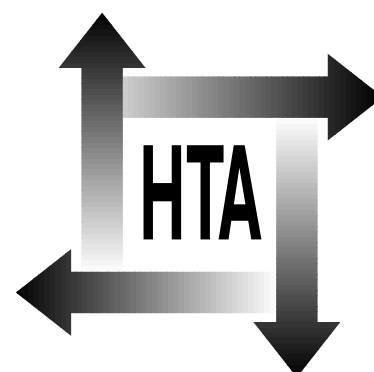
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**Health Technology Assessment
NHS R&D HTA Programme**





Executive summary

Objectives

- To update the pre-existing Cochrane review of ultrasound for routine fetal assessment in early pregnancy.
- To compile new Cochrane reviews of
 - routine ultrasound in late pregnancy
 - routine Doppler® ultrasound in pregnancy.
- To review the literature on the detection of fetal abnormalities by ultrasound screening examinations during pregnancy.
- To conduct a primary study to assess the consequences of a routine two-stage ultrasound regimen in pregnancy in a teaching hospital (clinical pathways).
- To compile literature reviews of (a) women's views on undergoing routine ultrasound examination and (b) estimates of costs and cost-effectiveness of routine ultrasound examinations.
- To conduct a primary study of costs of a routine two-stage ultrasound regimen in early or mid-pregnancy in a UK teaching hospital.
- To refine and update a decision model of cost-effectiveness of options for routine scanning for fetal anomalies.

Methods

Full details of search strategies for systematic reviews are in the appendices. Other methods are described in individual sections of the full report, as are methods for the primary studies of clinical pathways and costs.

Results

Routine ultrasound before 24 weeks:

- leads to earlier diagnosis of multiple pregnancies but has not been shown to have an important positive impact on the outcome of multiple pregnancies
- is associated with fewer inductions of labour for 'post-term' pregnancy
- reduces perinatal mortality rate if detection of fetal malformations is an important objective and a high level of diagnostic expertise exists and if termination of pregnancy for fetal abnormality is widely accepted in the population screened.

Routine ultrasound after 24 weeks:

- has not been shown to confer any clear benefit to mother or baby, except that assessment of placental appearances may, as an adjunct to fetal measurement, help reduce perinatal mortality.

Routine Doppler ultrasound in pregnancy:

- has not been shown to be of benefit and may even increase the risk of adverse outcome.

Detection of fetal abnormality by screening ultrasound examinations:

- detection rates vary with the organ system affected, with generally high rates of detection of abnormalities of the CNS, and low rates for skeletal and cardiac abnormalities
- similar variations are seen at both second and third trimester examinations
- data on the value of first trimester anomaly screening are lacking.

Clinical pathways:

- largely unrecognised consequences of routine ultrasound examinations exist that have health service resource implications as well as the potential to alarm women. Specifically:
 - 2.5% of booking scans are repeated
 - 7.6% of anomaly scans are repeated
- women present for antenatal booking at different gestations; hence, the coverage of any one scan regimen may be incomplete.

Women's views

- Ultrasound is very attractive to women and partners; this may be because it provides early visual confirmation of pregnancy and contact with their babies, and reassures about fetal well-being.
- Such features may augment the potential for anxiety, shock and disappointment when the scan shows a problem. Recent changes in the use of ultrasound may lead to more findings of uncertain clinical significance, which is likely to have important psychological and social consequences for women.
- Women's earlier fears, that ultrasound might harm the fetus, do not feature in later research, although this may be partly due to researchers not asking about fears.
- Reports of a reduction in anxiety after ultrasound examination are likely to reflect

increased anxiety before the scan rather than a real benefit of ultrasound.

- There is no reliable evidence of reduced smoking or any other positive health behaviour as a consequence of routine ultrasound.
- Trials comparing ultrasound with no ultrasound have not considered its psychological or social impact on both parents and babies.

Costs and cost-effectiveness

Literature review

- There are few good quality economic evaluations and primary cost studies of ultrasound scanning in pregnancy. Only one economic evaluation conducted alongside an RCT was included in the review.
- Routine scanning in the second trimester was shown to be relatively cost-effective.
- The skill of ultrasonographers in detecting anomalies and the time taken to perform a scan have a significant effect on the relative cost-effectiveness.

Primary costing study

- Costs to women of attending ultrasound examinations were significant compared with NHS service costs.
- It is important to include women's costs in economic evaluation of routine ultrasound screening, particularly where cost shifting may occur, because any change in the provision of routine ultrasound may shift the costs away from the provider on to women and their families and influence attendance.

Decision-analysis modelling

- The initial eight options considered were reduced to three dominating options:
 - one second trimester scan alone
 - one third trimester scan alone
 - a combination of one second trimester scan followed by one third trimester scan.
- More representative cost data are required before precise estimates of the additional costs and benefits of alternative screening options can be determined.
- One second trimester scan emerged as a clear reference case, being one of the cheapest options yet still detecting a significant number of anomalies.
- When termination is acceptable and available, a third trimester scan alone or the combination of one second with one third trimester scan, although comparable in economic terms, may be impractical because of the delay in identifying anomalies.

- The interaction of an anomaly scan(s) with a first trimester scan for dating purposes was not assessed.

Conclusions

Implications for policy and practice

- There is evidence that routine ultrasound in early pregnancy provides:
 - (i) better gestational age assessment
 - (ii) earlier detection of multiple pregnancies
 - (iii) detection of clinically unsuspected fetal malformation at a time when termination of pregnancy is possible. These effects have not been shown to improve ultimate fetal outcome. No convincing evidence of benefit from routine examination in late pregnancy (> 24 weeks) was found, whether using imaging or Doppler ultrasound.
- Clinicians, women and health planners need to decide if these effects are sufficient to justify routine ultrasound. Clinicians in the UK seem convinced of the benefits, given the very widespread use of the technique. As seen from the systematic review of women's views, imaging is popular with women (provided the appearance of the baby is normal). The study in Liverpool indicates that the average cost to the hospital of providing a 20-week anomaly scan is £15. This seems modest in the UK but will be prohibitively high in many developing countries.
- If routine ultrasound is to be offered before 24 weeks, what timing is optimal? The Royal College of Obstetricians and Gynaecologists' (RCOG) Working Party report of 1997 recommended a two-stage regimen of booking ultrasound at about 12 weeks, followed by a second ultrasound anomaly scan at 20 weeks – the regimen offered at Liverpool Women's Hospital. When this report was initially drafted, no comparative information was available about the clinical impact of different regimens. Since then, an RCT comparing the two-stage regimen with a 20-week scan alone has demonstrated less need for readjustment of dates at the mid-pregnancy scan in the two-stage group (with possible consequences for timing serum screening, if available) and less anxiety among the women. Again, clinicians, women and health planners have to decide whether such benefits justify the costs.
- The systematic review of the effectiveness of anomaly detection has highlighted substantial variation in, and limits to, detection rates of certain structural abnormalities. This information should be made available to

clinicians and women, and may also be relevant to the medico-legal arena. Given these limits, the RCOG Working Party's recommendations, that ultrasound examinations should be conducted only by appropriately trained personnel and using equipment no more than 5 years old, seem appropriate. Quality control mechanisms should be set in place to audit performance. The system of reporting suspected anomalies to regional fetal anomaly registers should be encouraged where these exist.

- A number of inefficiencies in the routine ultrasound screening programme were identified (including the need for repeat scans and that not all women book at early gestations), some of which are unavoidable, but which have implications for both its clinical and cost-effectiveness.

Research recommendations

Within each category below, the research recommendations are prioritised.

Guidelines on research methods

All future work evaluating uses of ultrasound in pregnancy should take account of the following methodological points.

- Published reports from clinical departments of detection rates of fetal abnormalities by ultrasound screening may not represent general standards. General detection rates should be assessed by linkage with high-ascertainment fetal abnormality registers at a regional level.
- Reporting of costs and cost-effectiveness of routine ultrasound screening should take account of recommended standards for economic evaluation.
- New or extended uses for pregnancy ultrasound should be evaluated in psychological and social, as well as healthcare efficiency and clinical terms.
- Studies of women's views of ultrasound, clinical effectiveness and costs of technologies should report the date and place of the research and describe the clinical contexts and purposes for which ultrasound was used for those research participants.

Priorities for research

Effectiveness of newer applications of ultrasound screening and alternative forms of care

Some forms of ultrasound screening are being introduced into routine practice without strong evidence on effectiveness; others are promising but need more evaluation.

- Nuchal translucency scanning and other types of ultrasound screening for anomalies during the first trimester of pregnancy are topical and controversial issues in obstetric care. None of the limited number of reports on these topics met our criteria for inclusion in systematic reviews and have therefore not been considered in detail. Researchers should be encouraged to study rigorously not only the effectiveness of detection of anomalies but also adverse clinical sequelae, psychological impact on women and their partners, and economic consequences. Until these data are available, the evidence does not support screening in the clinical service.
- More representative data are required on the clinical and psychological effects and cost implications of first trimester anomaly scanning.
- The possible value of routine mid-pregnancy uterine Doppler ultrasound to predict pre-eclampsia, intrauterine growth restriction and other adverse outcomes should be assessed in randomised trials.
- A single trial has suggested that placental texture grading during the third trimester may be helpful; this merits further study.

Documenting current practice, clinical pathways, costs and outcomes

In order to develop relevant guidance for the NHS, more needs to be known about current practice.

- Research is needed to assess the effects and costs of detection of fetal abnormalities amenable to *in-utero* intervention and neonatal surgery on substantive outcomes, such as short- and long-term morbidity and mortality for both mother and child, including parental psychological consequences.
- The findings of the primary studies of costs and clinical pathways undertaken to augment anticipated gaps in knowledge in this review need to be repeated and validated in other settings.
- Further evaluation is required on the impact of changes in routine antenatal care practice and its influence on family economy, clinical attendance or healthcare efficiency.

Defining options for screening

Developments in ultrasound technology provide information with uncertain implications.

- There is continuing controversy about the significance of ultrasound 'soft markers' and their relationship to, in particular, chromosomal abnormalities. There should be ongoing clinical

research into the significance and implications of detection of all sonographic soft markers in unselected and low-risk populations. These findings should be interpreted in the light of other screening programmes for chromosomal abnormalities (e.g. biochemical screening).

Ethical and cultural issues

Current practice is not based on a strong basis of knowledge of women's needs and understanding of ultrasound.

- Ways of improving women's understanding of the information gained from ultrasound should be developed and evaluated.
- There is scope for further investigation into the values women attach to their own time and to attending for a scan in different circumstances.
- Comparative research into the ways in which prenatal ultrasound is carried out and experienced in different countries and cultures would be valuable.

Cost-effectiveness

This is not constant over time and regular updating of models should be based on research as recommended above.

- Further development of economic models of cost-effectiveness of ultrasound screening in pregnancy should include assessing the effects of including a first or second trimester dating scan, and considering longer-term consequences and changing evidence on technologies, effectiveness and outcomes.

Publication

Bricker L, Garcia J, Henderson J, Mugford M, Neilson J, Roberts T, *et al.* Ultrasound screening in pregnancy: a systematic review of the clinical effectiveness, cost-effectiveness and women's views. *Health Technol Assess* 2000;4(16).

NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

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The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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