Choosing options for ultrasound screening in pregnancy and comparing cost effectiveness: a decision analysis approach

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Alternative permutations of routine antenatal ultrasound screening in pregnancy for detection of four key anomalies: serious cardiac abnormality, spina bifida, Down's syndrome, and a group of lethal abnormalities. The Royal College of Obstetricians and Gynaecologists (RCOG) Working Party on Ultrasound Screening for Fetal Abnormalities defined 12 distinct options for the use of ultrasound in screening for abnormalities in pregnancy, based on combinations of one or more of the following types of scan: (1) first trimester dating scan T1(d) (early scan usually under 18 weeks); (2) first trimester anomaly scan (T1) (including nuchal translucency examination, usually 10-14 weeks); (3) second trimester scan (T2) (usually carried out at 18-20 weeks gestation); (4) third trimester scan (T3) (28-40 weeks). The 12 strategies considered were as follows: strategy 1 (no screening); strategy 2 (T1(d)); strategy 3 (T2); strategy 4 (T3); strategy 5 (T1(d) & T2); strategy 6 (T1(d) & T3); strategy 7 (T2 & T3); strategy 8 (T1(d), T2 & T3); strategy 2a (T1); strategy 5a (T1 & T2); strategy 6a (T1 & T3); strategy 8a (T1, T2 & T3).

Type of intervention
Screening and diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Hypothetical pregnant women.

Setting
Primary care or hospital. The economic study was carried out in the UK.

Dates to which data relate
The dates for the effectiveness and resource use data were not reported. The effectiveness data were mainly obtained from a consultation report (based on the best available data from the literature) published in 1997. The price year was 1995-1996.

Source of effectiveness data
The evidence for the final outcomes was based on the work of RCOG Working Party (expert opinion based on the best available data from the literature).

Modelling
A decision analytic framework was used to estimate the costs and effects associated with each screening strategy, incorporating effectiveness data based on the work of RCOG Working Party. The analysis focussed only on the use of
ultrasound screening and not on other commonly associated screening procedures, such as serum screening. In the study model, serum screening was included only as part of a package of further tests used for confirmation of diagnosis and not for screening purposes. A series of assumptions were made in the model. It was assumed that the probability of an abnormality being detected for each scan was independent and also the risks of each anomaly were assumed to be independent. It was assumed that all cases detected as positive after the combination of scans defined by the option path undergo a package of further non-routine tests for confirmation of diagnosis (the package of additional tests included a scan, serum screening and amniocentesis). It was further assumed that the package conclusively detected the true anomalies and ruled out any false positive diagnosis made after the routine combination of scans defined by each option. The model dealt with outcomes in terms of diagnostic success in the short term and did not address longer term survival and quality of life issues.

Methods used to derive estimates of effectiveness
Where possible the evidence for effectiveness probabilities was derived from an extensive literature search carried out on behalf of the RCOG Working Party. These data were subsequently graded by the Working Party committee according to their level of confidence in any particular estimate. These data were supplemented as necessary by professional judgements from individual members of the Working Party. The final estimates took the form of ranges of opinion within the committee and, where there was extreme uncertainty with no research evidence, it was indicated in the paper. It was impossible to ascribe specific references to each final estimate because of the methods of deriving consensus.

Estimates of effectiveness and key assumptions
The estimated/assumed sensitivity of each of the four types of scan for serious cardiac abnormality were 0% for T1(d), 0% for T1, 10-25% for T2 and 50% (clinical hunch) for T3. The corresponding values for spina bifida were 0%, 0%, 80-90%, and 70-80% (clinical hunch). For Down's syndrome the values were 30%, 50-85%, 10-20%, and 0-10%, respectively and for other lethal abnormalities they were >10%, 10-30%, 80-95%, and 80-95%, respectively. The combined ability for each strategy was calculated based on the above values. The average positive rate was 1% for overall congenital cardiac disease and 1-2% for serious cardiac disease, 1% for open spina bifida, 5-12% for Down's syndrome and less than 1% for lethal abnormalities. The corresponding values in terms of assumed prevalence per 1000 population were 8-10%, 2-4%, 1-4%, 1.5, and 1.

Measure of benefits used in the economic analysis
The measures of benefit were the number of malformation cases correctly detected antenatally and the number of missed malformations per 1000 women screened.

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities (such as staff, equipment, overheads and counselling) were not reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of routine screening tests, and additional non-routine tests (serum screening, amniocentesis), and counselling. The perspective adopted in the economic analysis was that of the health authority purchasing the screening. Most of the cost data were derived from the literature published between 1996 and 1998. It was reported that, in general, little explanation was provided on the methods or types of costs included in the cost calculations. Other cost items were obtained from the regional health authorities. The NHS Executive Hospital and Community Health Services pay and price inflation index was used to adjust the cost data to the price year adopted in this study, which was 1995-1996.

Indirect Costs
Not considered.

Currency
UK pounds sterling ($).

**Sensitivity analysis**
Because of the uncertainties of the quality of the data, it was decided to consider 'best' and 'worst' case scenarios for clinical effectiveness and cost data, based on the ranges of the effectiveness parameters estimated by the RCOG Working Party. Costs were varied within ranges obtained from the literature and Regional Health Authorities.

**Estimated benefits used in the economic analysis**
The number of detected malformations for the ultrasound screening strategies per 1000 women screened in the best and worst scenarios were:

- Scenario 2 - 0.53 and 0.55;
- Scenario 3 - 5.85 and 1.95;
- Scenario 4 - 6.30 and 2.50;
- Scenario 5 - 6.22 and 2.38;
- Scenario 6 - 6.66 and 2.97;
- Scenario 7 - 7.85 and 3.15;
- Scenario 8 - 8.18 and 3.56;
- Scenario 2a - 1.58 and 0.85;
- Scenario 5a - 6.89 and 2.65;
- Scenario 6a - 7.48 and 3.27;
- Scenario 8a - 8.77 and 3.83.

The number of missed malformations for the ultrasound screening per 1000 women screened in the best and worse scenarios were:

- Scenario 2 - 9.95 and 4.95;
- Scenario 3 - 4.65 and 3.55;
- Scenario 4 - 4.20 and 3.00;
- Scenario 5 - 4.28 and 3.13;
- Scenario 6 - 3.85 and 2.53;
- Scenario 7 - 2.65 and 2.35;
- Scenario 8 - 2.32 and 1.95;
- Scenario 2a - 8.93 and 4.65;
- Scenario 5a - 3.61 and 2.86;
- Scenario 6a - 3.03 and 2.23;
scenario 8a - 1.74 and 1.68.

**Cost results**
The estimated costs associated with the ultrasound screening strategies per 1000 women screened in the best and worse scenarios were:

scenario 2 - 30,450 and 216,671;
scenario 3 - 31,139 and 217,565;
scenario 4 - 31,198 and 217,798;
scenario 5 - 51,180 and 366,745;
scenario 6 - 51,244 and 366,998;
scenario 7 - 51,399 and 367,074;
scenario 8 - 71,442 and 516,246;
scenario 2a - 30,583 and 217,099;
scenario 5a - 51,274 and 366,860;
scenario 6a - 51,350 and 367,125;
scenario 8a - 71,518 and 516,360.

**Synthesis of costs and benefits**
Cost per case detected was calculated as the measure of cost-effectiveness ratio, resulting in the following values in the best and worse scenarios:

scenario 2 - 57,433 and 394,493;
scenario 3 - 5,323 and 111,527;
scenario 4 - 4,952 and 87,199;
scenario 5 - 8,228 and 154,095;
scenario 6 - 37,694 and 123,568;
scenario 7 - 6,548 and 116,531;
scenario 8 - 8,734 and 145,013;
scenario 2a - 19,356 and 255,410;
scenario 5a - 7,442 and 138,438;
scenario 6a - 6,865 and 112,271;
scenario 8a - 8,155 and 134,820.
Authors' conclusions
The range of uncertainty in the costs did not allow selection of any programme as a clear choice for NHS purchasers. The results suggested that overall allocation of resources for routine ultrasound screening in the UK is not currently economically efficient, but that certain scenarios for ultrasound screening are potentially within the range of cost effectiveness reached by other, possibly competing, screening programmes.

CRD COMMENTARY - Selection of comparators
The no ultrasound screening strategy was regarded as the comparator. It allowed the active value of the ultrasound strategies to be evaluated.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results can not be guaranteed due to the diverse quality of the evidence behind the probability estimates, the fact that professional consensus was required to reach the final estimates used, and generally because of the lack of evidence and the paucity of robust data, as acknowledged by the authors. Furthermore, the assumptions made regarding the independence of the risks of each anomaly and each test may not be justifiable, as the authors stated. However, this inherent limitation was corrected to some extent by performing worst-best case sensitivity analysis.

Validity of estimate of costs
The validity of the cost analysis was enhanced by the following features of the analysis. The price year and perspective adopted in the study were reported, adjustments were made for inflation, and best-worst case analysis were conducted. However, the following characteristics of the cost analysis, which may have adversely affected its validity. The literature sources of the cost data contained insufficient details of the methods of cost estimation, thus making it difficult to judge whether important costs have been omitted. Also a generic cost for scans which are conducted for different purposes was used and the effects of different screening strategies on indirect costs were not addressed.

Other issues
It appears that the authors’ conclusion is justified given the inherent limitations arising from the lack of evidence and the paucity of robust data in the literature in the context in question. The issue of generalisability was not addressed in the study (worst-best case analysis only addressed uncertainties associated with the data). Some comparisons were made with other studies in the literature. As mentioned by the authors, a cost-utility approach could have captured, in a single metric, the trade-off between benefit measures (cases of malformations detected and missed and the psychological effects of false positive results), which was not reflected in the cost-effectiveness measure chosen in the study.

Implications of the study
The model highlighted the weaknesses of the available evidence and demonstrated the need for more information both about current practice and about costs. The authors noted that, at the time of reporting the study results, they were engaged in further work to refine the model as part of a systematic review to assess the cost-effectiveness of antenatal ultrasound screening, alongside the Cochrane Pregnancy and Childbirth Review Group.

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None stated.

Bibliographic details

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Other publications of related interest

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