Cost-benefit analysis of prenatal diagnosis for Down syndrome using the British or the American 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
Prenatal diagnosis for Down's syndrome using nuchal translucency thickness or screening by using maternal age and maternal serum screening.

Type of intervention
Diagnosis and primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
A hypothetical cohort of pregnant women presenting for prenatal care in the USA.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data were collected from studies published between 1983 and 1997. Cost data were collected from a study published in 1997. The price year was 1998.

Source of effectiveness data
The effectiveness data were based on a literature review.

Modelling
A decision analytic model was used to compare the cost-effectiveness of the British and American approaches.

Outcomes assessed in the review
The review assessed the following outcomes: number of births, trimester in which women presented for prenatal care, age of presenting women, prevalence of Down's syndrome, genetic counselling rate, birth rate, abortion rate, and frequency of other chromosome abnormalities.

Study designs and other criteria for inclusion in the review
Not stated.
Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
At least 17 primary studies were included.

Methods of combining primary studies
Narrative method.

Investigation of differences between primary studies
The majority of the studies provided separate inputs to the model. The remaining studies provided the ranges of the sensitivity and the false positive rate of tests. These were used in the two scenarios of the British strategy: the best and worst scenarios.

Results of the review
The model assumed 4 million births in the USA.

75% of patients presented for prenatal care during the first semester, 18% during the second trimester, and 7% during the third trimester.

The prevalence of Down's syndrome in pregnant women was 1:500 in the first trimester, 1:700 in the second trimester, and 1:1000 in the third trimester.

10% of the pregnant population had a maternal age over 35 years.

66% of the available second trimester women aged under 35 years were actually screened by maternal serum studies.

If the prevalence of fetal Down's syndrome in the mixed group of women with either advanced maternal age or positive serum screening second-trimester approach was 1:150, then the detection rate for trisomy 21 of the second trimester screening approach was 60%.

All women with positive screening results and advanced maternal age would receive genetic counselling, but only 70% would accept invasive genetic procedures.

90% of women with prenatal diagnosis of Down's syndrome would abort.

50% of first-trimester fetuses with Down's syndrome and 70% of second-trimester fetuses with Down's syndrome would be born alive.

The frequency of other severe fetal chromosome abnormalities diagnosed in the first trimester was similar to Down's syndrome.

The procedure-related fetal loss rate from CVS was 1:100 and from amniocentesis was 1:200.
Measure of benefits used in the economic analysis
The following measures of benefit were used: the number of Down's syndrome cases born alive, the number of genetic procedures, the number of fetal losses, and the number of prevented Down's syndrome deaths.

Direct costs
Direct costs were adjusted using a yearly inflation rate of 2.5% to reflect 1998 dollars. Quantities and costs were reported separately. Direct costs included the cost of the screening test, genetic counselling, the cost of abortion, and the lifetime cost of each live-born infant with Down's syndrome (medical, developmental, and educational costs). The quantity/cost boundary adopted was that of society. The estimation of quantities and costs was based on actual data. Cost data were derived from a previous study. It appears that costs have not been subject to discounting, although this would have been appropriate given that the cost analysis extended over 2 years.

Indirect Costs
The lifetime cost of each infant born alive with Down's syndrome included costs due to lost productivity. Costs do not appear to have been discounted.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analysis was conducted on the accuracy of first trimester sonography in detecting Down's syndrome. The best scenario used a sensitivity of 80% and a false-positive rate of 5%. The worst scenario used a sensitivity rate of 50% and a false-positive rate of 10%. Sensitivity analyses of various costs per ultrasound examination and ultrasound accuracies were used to equate costs of the British and American approaches.

Estimated benefits used in the economic analysis
The number of Down's syndrome cases born alive was 4,000 for the "do nothing" approach, 2,221 (best case) and 2,788 (worst case) for the British strategy, and 2,589 for the American approach. The number of genetic procedures was 0 for the "do nothing" approach, 169,000 (best case) and 274,000 (worst case) for the British strategy, and 336,000 for the American approach. The number of fetal losses was 0 for the "do nothing" approach, 1,779 (best) and 1,212 (worst) for the British strategy and 1,411 for the American approach.

Cost results
Total costs amounted to $1,995 million (best) and $2,439 million (worst) for the British strategy and $1,904 million for the American approach. The "do nothing" strategy cost $2,000 million.

Synthesis of costs and benefits
Cost and benefit measures were not combined into a cost-effectiveness ratio as the American strategy and the best scenario of the British strategy dominated the "do nothing" approach and the worst scenario of the British strategy.

Authors' conclusions
The British strategy does not appear to be economically beneficial in the USA even under the most ideal scenarios of ultrasound accuracy, as it would cost approximately $91 million more annually, compared with the current screening practice.
CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used, namely currently available strategies. You, as a user of the database, should decide if these health technologies are relevant to your setting.

Validity of estimate of measure of benefit
The authors did not state that a systematic review of the literature had been undertaken. More details about the design and conduct of the review and the method of combining primary effectiveness estimates could have been provided as data may have been used selectively. Estimation of benefits was obtained directly from the effectiveness analysis and should also be treated with caution as insufficient details were reported by the authors regarding the methods and quality of the literature review.

Validity of estimate of costs
All categories of costs relevant to the perspective adopted were included. As acknowledged by the authors, the cost to society associated with losses of normal fetuses was not considered. These costs would not have changed the results substantially. Quantities and costs were reported separately. A sensitivity analysis was conducted on costs, but not on quantities. The price year was reported. Costs refer to the USA setting and might not apply to other countries. Also, although discounting was appropriate, it does not appear to have been applied to costs.

Other issues
The authors did not make appropriate comparisons of their findings with those from other studies and the generalisability of their results to other settings was not addressed. The study considered pregnant women presenting for prenatal care and this was reflected in the authors' conclusions. One of the benefits of the British strategy, the potential for increased numbers of patients presenting for prenatal care in the first trimester, was discussed but was not considered in the analysis.

Implications of the study
If future American studies show nuchal translucency accuracy comparable to the best scenario of the British strategy, introduction of the British strategy to the United States should be seriously considered. This possible implication of the study should, however, be interpreted in the light of the study limitations.

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