Economic evaluation of prenatal screening for Down syndrome in the USA
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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
Maternal serum screening for Down's Syndrome.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of pregnant women in the USA.

Setting
The setting was a 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 1978 and 1997. Cost data were collected from studies published between 1978 and 1992. Benefit data were collected from studies published between 1994 and 1995. The price year was 1996.

Source of effectiveness data
The effectiveness data were derived from a literature review.

Modelling
A decision analytic model was used to determine the cost-effectiveness of the screening protocols.

Outcomes assessed in the review
The review assessed detection and false-positive rates of screening tests, maternal age-specific birth rates and incidence of Down's Syndrome, and the cost savings from preventing the birth of a child with Down's Syndrome.

Study designs and other criteria for inclusion in the review
Not stated.

Sources searched to identify primary studies
NHS Economic Evaluation Database (NHS EED)
Criteria used to ensure the validity of primary studies
Not stated.

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

Number of primary studies included
At least eight studies were included in the review.

Methods of combining primary studies
The narrative method was used to combine primary studies.

Investigation of differences between primary studies
Not stated.

Results of the review
The incidence of Down's Syndrome at birth was 1.3 per 1,000. There were 3,899,589 live births in the USA in 1995. The survival rate for Down's Syndrome between the second trimester and full term was 77%. The survival rate for unaffected fetuses between the second trimester and full term was 97%. The second trimester incidence rate was 1:551 for all maternal ages and 1:857 for maternal ages less than 35 years. The lifetime incremental costs of a child born with Down's Syndrome were $504,000.

Measure of benefits used in the economic analysis
The number of identified cases with Down's Syndrome was used as the measure of benefits.

Direct costs
Direct costs were not discounted given the short time frame of the study (less than 1 year). Quantities and costs were not reported separately. Direct costs per patient associated with a prenatal screening test consisted of the direct costs of a prenatal screening test, the costs of the amniocentesis following a positive screening test and the costs of a Down's Syndrome termination after a positive amniocentesis. The quantity/cost boundary adopted was that of society. The estimation of quantities and costs was based on actual data. Cost data were collected from studies published between 1978 and 1992. The price year was 1996.

Indirect Costs
Indirect costs were included in the total lifetime costs of a child with Down's Syndrome. Quantities and costs were not reported separately. The quantity/cost boundary adopted was that of society. The estimation of quantities and costs was based on previous studies. The price year was 1996. It was not reported whether, in the estimation of lifetime costs, discounting was applied.

Currency
US dollars ($).
Sensitivity analysis
Sensitivity analyses were conducted on the incidence rate, sensitivity/false-positive rate and benefits.

Estimated benefits used in the economic analysis
The screening tests identified the following numbers of cases with Down's Syndrome:

- alpha FP, 1,659;
- hCG, 2,281;
- uE3, 2,281;
- aFP+hCG, 2,296;
- aFP+uE3, 2,281;
- Triple, 2,903;
- Triple by LMP, 2,696;
- Triple by LMP+Scan, 3,027.

Cost results
The lifetime incremental costs of a child born with Down's Syndrome were $504,000. The costs of each test were not reported separately and only net benefits were given.

Synthesis of costs and benefits
The maximum net benefit of $126 for the triple test occurred at a detection rate of 70% and a false-positive rate of 8.6%. The most cost-effective test was the aFP+hCG combination with a net benefit of $135. hCG alone was second ($130), and the triple test ($126) had the third highest net benefit. The triple test was not demonstrably beneficial for women whose maternal age at the time of delivery was under 24. Offering triple testing to all women under the age of 35 would lead to 144,939 amniocenteses being performed, resulting in a loss of 725 fetuses. The net benefits of the triple screening test exceeded those of universal amniocentesis in every maternal age except 42 years of age and over. The net benefits of amniocentesis for each maternal age less than 36 years of age were negative. Universal amniocentesis led to the additional diagnosis of 266 cases of Down's Syndrome, the loss of $134 million in total net benefits, 234,875 additional amniocenteses and the loss of 1,175 fetuses. The results for the triple test were sensitive to changes in the incidence, sensitivity/false-positive rate and benefits. Addition of Inhibin A at a cost of $30 to the triple test would lead to a net benefit of $152 at 79% sensitivity and a 6% false-positive rate. This protocol would require a change in cut-off to 1:350.

Authors' conclusions
A broad range of screening strategies provides positive net benefits. For each prenatal screening test, optimal net benefits occur at different sensitivity and false-positive levels. The combination of aFP and hCG provided the highest net benefits.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used, namely current tests. You, as a user of the database, should decide if these health technologies are relevant to your own 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 could have been provided about the design of the review and the method of combining primary effectiveness estimates. The estimation of benefits was obtained directly from the effectiveness analysis.

**Validity of estimate of costs**
All relevant cost categories were included. Quantities and costs were not reported separately. Sensitivity analyses were conducted on quantities, but not on costs. Charges were used to proxy prices. The price year was reported. As acknowledged by the authors, the cost savings from preventing the birth of a child with Down's Syndrome did not include the value of time contributed by family members to the provision of care, the psychological and sociological costs of Down's Syndrome to the individual and family members, or other indirect costs (e.g. travel expenses) associated with the provision of care. The authors developed a general formula to calculate the per-case net social benefit of a screening test and applied it to data from the USA.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors did not present their results selectively. The study considered pregnant women in the USA and this was reflected in the authors' conclusions. The analysis was confined to the benefits of Down's Syndrome screening without including the effects of identification of other chromosome anomalies, fetal malformations, or high-risk pregnancies. A complete analysis would also take into account the complementary benefits achieved from the use of the aFP test in neural tube defect screening.

**Implications of the study**
The authors concluded that there is no justification for withholding screening from women of advanced maternal age, although this group needs to be advised of the increased risk for chromosome abnormalities other than trisomy 21 prior to screening. Screening policies should not be established solely on economic considerations, but must respect the individual patient's ethical values and sensitivities at every step of the prenatal testing pathway.

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None stated.

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**Other publications of related interest**

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Subject indexing assigned by NLM

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