Cost-effectiveness of one-stage ultrasound screening in pregnancy: a report from the Helsinki ultrasound trial

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
Standardized one-stage ultrasound screening in pregnancy.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was pregnant women. No other clinical or demographic characteristic of the participants, at the outset of the study, was reported.

Setting
The clinical setting was the outpatient department. The economic study was carried out in Helsinki, Finland.

Dates to which data relate
The dates for the effectiveness and resource data were between 1986 and 1988. 1990 prices were used.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Resource use data for direct costs, and some indirect costs, were collected prospectively on the same patient sample as that used in the effectiveness study. Resource use data for remaining indirect costs were collected retrospectively on a random sample (13%) of the screened women.

Study sample
9,310 pregnant women, who were eligible and consented, were randomly allocated to receive routine ultrasound screening (4,691), or to a control group (4619). 95% of all pregnant women in the Helsinki metropolitan area consented to participate. It is not stated whether power calculations were used to determine the sample size.

Study design
The study was a two-centred, randomised controlled clinical trial. The randomisation method used was not specified.
Ultrasound examinations for the screening group took place between the 16th and 20th gestational weeks. Repeat ultrasound was necessary for 6.5% of the intervention group. Patients were followed up until the outcome of delivery was known. Loss to follow up was 4/9310, 1 in the intervention group and 3 in the control group. No blinding took place.

**Analysis of effectiveness**

The basis for the analysis of the study was not reported. The primary health outcome used in the analysis was a reduction in the perinatal mortality rate. The groups were not demonstrated to be comparable in demographic and clinical characteristics.

**Effectiveness results**

In the intervention group, 19 fewer babies died, relative to the control group with perinatal mortality being 4.6/1000. The rate for the control group was 9.0/1000 (p<0.05).

**Clinical conclusions**

The statistically significant difference in the perinatal mortality rate of the intervention group was achieved by better early detection of malformations and subsequent induced abortions.

**Measure of benefits used in the economic analysis**

The measure of effectiveness, the perinatal mortality rate, was not converted to a health benefit for the economic analysis.

**Direct costs**

Costs were analysed from a societal perspective. Quantities and costs were reported separately. Staff, equipment, material and floor space costs to the hospital were derived from the actual use of those resources in the hospitals. Staff cost was calculated from the reserved time per patient plus office work time. The equipment cost included capital, interest and variable costs of the ultrasound machine. Floor space was derived from the market price for comparable space. The cost of overheads was calculated from the average overheads for comparable examinations in the department, according to the screening hospital’s internal accounting. The costs of antenatal outpatient and inpatient care were obtained from the Ministry of Social Affairs and Health. All costs were discounted to 1990 values, but the rate used was not reported. The total cost of routine screening was calculated and three incremental costs were calculated, incorporating successive categories of antenatal health care costs.

**Statistical analysis of costs**

The proportional strata sizes were used as weights when calculating the sample sums and means. The differences in resource use between the groups were evaluated by Student’s t-test.

**Indirect Costs**

The cost to the woman’s employer of the screening was estimated on the basis of lost working time. Cost-accounting data were collected via a questionnaire to all attenders and by measurements at the screening examination, and were later completed by a postal questionnaire to 534 (13%) of the 4,073 screened women (a stratified random sample to equal sample size by health centre). Actual wages plus social overhead costs were used to estimate the lost working time cost. The cost of the screened woman was estimated on the basis of travel time and expenses.

**Currency**

Finnish marks (FIM). FIM were converted to US dollars ($) using the average exchange rate in 1990 (FIM 1 = US$ 0.26).
Sensitivity analysis
Sensitivity analysis reveals how vulnerable the cost-effectiveness ratio is to value changes in chosen cost items. The analysis was applied to proportionally large or uncertain cost items, and the changes used were +/- 5% and +/- 10%.

Estimated benefits used in the economic analysis
The effectiveness results were used to proxy health benefit.

Cost results
The total per-patient costs of the two regimens were not reported. The total average cost of a routine ultrasound screening examination (including indirect costs and the cost of screening-induced advanced examinations and procedures) was FIM 393 ($102). The incremental cost, incorporating all other antenatal care costs, of a screening examination was estimated to be negative, saving FIM 700 ($182). Two-thirds of this saving was accounted for by a lower inpatient cost in the intervention group. Costs were reported in 1990 prices. Costs were discounted, but the rate used was not reported.

Synthesis of costs and benefits
The gross cost of avoiding one perinatal death was FIM 84,378 ($21,938). The incremental cost-effectiveness ratio was negative, yielding a cost saving of FIM 65,680 ($17,077). This ratio changed +/- 19% when the cost of inpatient days was changed by +/- 5% and by +/- 37% with a +/- 10% change in inpatient day costs. The effects of changes in other cost items were reported to be 'marginal'.

Authors' conclusions
Longer ultrasound examination time and more numerous advanced examinations were rewarded by clearly fewer perinatal deaths and a better cost-effectiveness ratio. One-stage second-trimester ultrasound screening is cost-effective when all significant costs and effects are taken into account. One-stage ultrasound screening can be clearly useful from the perspective of the national economy.

CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator, no routine screening, is clear, namely that it served as a control. You, the user of the database, should consider whether the alternatives are relevant in your own setting.

Validity of estimate of measure of benefit
The authors implicitly assumed that the rates of perinatal mortality in the control and intervention groups would have been the same if no screening had taken place. Although the patients were randomly assigned to the groups, these were not shown to be comparable. This assumption may not therefore be justified. Furthermore, the study population may not be representative of other settings, but without evidence on clinical and demographic characteristics, this cannot be determined.

Validity of estimate of costs
Costs were comprehensively estimated. However, the results were selectively reported, and the findings cannot therefore be verified. A statistical analysis of resource use data was performed.

Other issues
The cost of inpatient days was found to have a significant impact on the cost-effectiveness ratio. However, the difference in inpatient days between the two groups was not statistically significant. Any difference between the inpatient days of the two groups is likely therefore to be a result of chance, and the cost-effectiveness findings are
therefore unstable. The authors acknowledged that the cost-effectiveness ratio is highly dependent on the rate of malformation detection and the subsequent decision on termination. This factor would affect the generalisability of the findings to other settings.

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**Other publications of related interest**


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