Cost-effectiveness of a cardiovascular disease risk reduction program aimed at financially vulnerable women: the Massachusetts WISEWOMAN project

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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
The Well-Integrated Screening and Evaluation for Women Across the Nation (WISWOMAN) project, a cardiovascular disease (CVD) risk reduction programme that targeted old women on a low income, was examined. Two levels of the programme were considered, CVD screening and a minimum lifestyle intervention (MI) versus CVD screening and enhanced lifestyle interventions (EI).

The MI consisted of screening and one-on-one counselling sessions with a nurse or other health practitioner, focusing on CVD risk. Screening covered the measurement of total and high-density lipoprotein cholesterol (HDL), glucose levels, blood pressure, height and weight, and an assessment of balance, power and walking. The EI included the activities mentioned already plus other activities aimed at reducing CVD risk, focusing on improving physical activity levels and nutrition. Most of the activities in the EI referred to the New Leaf approach designed by researchers at the University of North Carolina.

Type of intervention
Screening and primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women aged 40 to 64 years, who were living in families whose combine annual income was less than 200% of the US federal poverty level.

Setting
The setting was the community. The economic study was carried out in the state of Massachusetts in the USA.

Dates to which data relate
The effectiveness and resource use data were gathered in 1996. The price year was not explicitly stated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out on the same sample of patients as that included in the effectiveness study.
Study sample
The use of power calculations was not reported. Eligible sites were selected on the basis of performance criteria and formed part of the National Breast and Cervical Cancer Early Detection Programme (NBCCEDP) in Massachusetts. Women were screened at a variety of locations, including churches, libraries, hospitals and local health centres. The sample comprised 819 women (84.4% of those in 50- to 64-year age group) in the MI group and 767 women (82.5% of those in the 50- to 64-year age group) in the EI group. It was not stated whether some women refused to participate, or whether any were excluded from the initial study sample.

Study design
This was a prospective randomised controlled trial that was carried out in 12 sites. The sites included 2 visiting nurse associations, 6 hospitals and 4 health centres. The sites were paired on the basis of type of site and the demographic characteristics of the provider's target population (e.g. rural versus urban). Then, the two members of each matched pair were randomly assigned to one of the two interventions. The unit of randomisation was the site. The length of follow-up was 12 months. Approximately 72% of the MI women and 80% of the EI women completed the baseline and follow-up screenings.

Analysis of effectiveness
Only patients whose data were available at follow-up assessment were considered in the analysis of effectiveness (per protocol analysis). The primary health outcomes were the changes in unadjusted means for risk factors subsequently used in the decision model (total and HDL cholesterol, systolic and diastolic blood pressure, age, diagnosis of diabetes and status of current smoker). Comparability of the study groups at baseline was not discussed.

Effectiveness results
The changes in the unadjusted means (unit of measurement not reported) were:

- for total cholesterol, from 227.8 (+/- 46.1) to 228.3 (+/- 42.2) in the MI group and from 236.5 (+/- 47.5) to 231.2 (+/- 41.4) in the EI group;
- for HDL cholesterol, from 53.1 (+/- 15.8) to 53.1 (+/- 15.3) in the MI group and from 53.1 (+/- 15.8) to 53.4 (+/- 15.9) in the EI group;
- for systolic blood pressure, from 132.5 (+/- 18.9) to 128.7 (+/- 18.2) in the MI group and from 136 (+/- 21) to 131.4 (+/- 18.1) in the EI group;
- for diastolic blood pressure, from 78.14 (+/- 9.9) to 76.6 (+/- 9.7) in the MI group and from 80.8 (+/- 10.6) to 79.3 (+/- 9.6) in the EI group;
- for age, from 59 (+/- 7.4) to 59.9 (+/- 7.2) in the MI group and from 59 (+/- 7) to 59.9 (+/- 7) in the EI group;
- from 6.6 to 8% (MI group) and from 9.1 to 9.3% (EI group) for the percentage of those with a diagnosis of diabetes; and
- from 18.3 to 15.2% (MI group) and from 21.1 to 17.4% (EI group) for the percentage of those with the status of current smoker.

Clinical conclusions
The effectiveness data estimated in the study were used as inputs in the analytic model.

Modelling
A developed model (see Other Publications of Related Interest) was used to predict the 10-year probability of coronary heart disease (CHD) such as angina pectoris, myocardial infarction, coronary insufficiency and CHD death. The
approach used a scoring methodology to assign points to risk factors such as age, total and HDL cholesterol, hypertension, smoking status and diabetes status.

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

The summary benefit measure was the change in the average 10-year probability of CHD. This was derived from the analytic model. An annual discount rate of 3% was applied. The consequent increase in life expectancy was also calculated. A regression analysis approach was used to calculate the change in the 10-year probability of CHD.

**Direct costs**

Discounting was not applied since the costs were incurred during one year. The unit costs and the quantities of resources used were not presented separately. The health services included in the economic evaluation were grouped into four main categories. More specifically, outreach and follow-up, CVD screening, EI activities (EI group only), and administrative duties. Both labour and materials components were considered for each category. The initial cost of the programme was excluded, as were Massachusetts Department of Public Health staff costs. The cost/resource boundary of the study was not reported. Resource use was estimated using actual data derived from the sample of women included in the effectiveness study. The price year and the source of the cost data were not reported.

**Statistical analysis of costs**

The costs were treated deterministically.

**Indirect Costs**

The indirect costs were not considered.

**Currency**

US dollars ($).

**Sensitivity analysis**

Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**

The average 10-year probability of CHD changed from 9.4 to 9.2% in the MI group (difference -0.2%), and from 10.3 to 9.8% in the EI group (difference -0.5%). The difference between the changes in the two groups did not reach statistical significance. Therefore, the two interventions were considered equally effective in reducing the 10-year probability of CHD.

The discounted increase in life expectancy was 0.038 in a 59-year old woman, 0.020 in a 69-year-old woman, 0.002 in a 79-year-old woman, and 0 in both 89- and 95-year-old women.

**Cost results**

The average total per capita cost was $487 in the MI site and $603 in the EI site. If only administrative and EI programme costs were considered, the EI strategy led to an incremental cost of $191 in comparison with the MI intervention.

**Synthesis of costs and benefits**

An incremental cost-effectiveness ratio was calculated to combine the costs and benefits of the two alternative strategies. The incremental cost to achieve a 1 percentage point larger decrease in the 10-year probability of CHD with
EI relative to MI was $637. This led to a cost per life-year gained of about $5,000.

**Authors’ conclusions**

Due to the lack of statistical significance between the study interventions, it was not possible to reject the hypothesis that the enhanced lifestyle intervention (EI) did not result in greater reductions in CHD risk relative to the minimal lifestyle intervention (MI).

**CRD COMMENTARY - Selection of comparators**

The authors did not provide an explicit justification for the choice of the comparators. However, the selection of the two levels of the programme appears to have been appropriate. It was unclear whether the MI strategy represented standard care. You should decide whether they represent valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**

The basis of the effectiveness analysis was a prospective, randomised controlled trial, which was appropriate for the study question. The length of and loss to follow-up were reported, as were the characteristics of the study groups. The study sample is likely to have been representative of the study population because unselected women were enrolled in the trial. The unit of randomisation was the site, not the patients. However, the baseline comparability of the two groups was not discussed. No power calculations were reported and the authors acknowledged that the study was likely to have been underpowered. The units of measurement were not reported for all the outcome measures. Neither the patients nor the outcome assessors were blinded to the allocation of the sites to the study groups. This may have introduced bias into the effectiveness results. These issues tend to limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**

The summary benefit measure was obtained from a published analytical model, which was appropriate for assessing the long-term impact of the intervention on life expectancy. The use of survival as the benefit measure means that comparisons with the benefits of other health care interventions are possible. Discounting was appropriately applied due to the long-term horizon of the analysis.

**Validity of estimate of costs**

The authors did not state which perspective was adopted in the study. As such, it was unclear whether all the relevant categories of costs were included in the analysis. A breakdown of the cost items was provided, but information on the unit costs and quantities of resources used was not presented clearly. Some categories of costs were excluded from the analysis and a justification for their exclusion was provided. The price year was not reported, which would make reflation exercises in other settings difficult. The source of the costs was unclear. Overall, it would be difficult to replicate the study in other contexts.

**Other issues**

The authors compared their findings with those from other studies that showed similar modest effects of the intervention programmes. The authors stated that their cost per life-year gained was well below that reported in other published studies assessing medical interventions aimed at reducing CVD risk, although it compared favourably with other lifestyle interventions. The issue of the generalisability of the study results to other settings was not addressed and no sensitivity analyses were carried out. Consequently, all the estimates were specific to the study setting, which limits the external validity of the analysis. The study referred to old women on a low income and this was reflected in the authors’ conclusions.

**Implications of the study**

After the results of the WISEWOMAN program, Massachusetts made substantial changes to the way the intervention was delivered. To reduce intervention costs, a primary care model was implemented where women received services on
an individualised basis within the context of the primary care setting.

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**Other publications of related interest**


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