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.

CRD summary
This study examined the cost-effectiveness of clinical breast examination, before conventional mammography, for women at a high risk of breast cancer, given their family history. The authors concluded that clinical breast examination appeared to be a cost-effective addition to mammography. The methods of the analysis were not clearly described, especially for the cost-effectiveness calculations. Caution is required when interpreting the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the cost-effectiveness of clinical breast examination, before conventional mammography, compared with mammography alone, for women at a high risk of breast cancer due to their family history.

Interventions
The usual care was a mammography, every three years for women aged 51 to 60 years. This was compared with mammography and clinical breast examination, every year for women aged 35 to 50 years, and every 18 months for women aged 50 to 60 years.

Location/setting
UK/primary care.

Methods
Analytical approach:
The analysis was based on a 22-year study. The perspective was not explicitly stated.

Effectiveness data:
The clinical data came from a prospective database of patients seen at the Manchester Family History Clinic, between 1987 and 2008. This clinic provided counselling, screening, and advice to women at a high risk of breast cancer, given their family history. For this analysis, the 7,475 women seen over the study were included. They underwent both clinical breast examination and mammography. Further follow-up information was obtained from the women's hospital notes and NHS databases. The numbers of cases detected and breast cancer genes BRCA1 or BRCA2 tumours were reported. The primary endpoints were the sensitivities of mammography, clinical breast examination, and both procedures.

Monetary benefit and utility valuations:
Not reported.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure.

Cost data:
The economic analysis included the costs of clinical examination (nurse time), mammography, breast magnetic resonance imaging (MRI), ultrasound, fine-needle aspiration, core biopsy, MRI-guided biopsy, surgical biopsy, and
mastectomy. The quantities of resources were based on the clinical data source and the costs were from the centres participating in that study and reference costs. All costs were in UK £.

Analysis of uncertainty:
Sensitivity analyses were not carried out.

Results
The authors reported that with clinical breast examination, nine cancers were detected, which would not have been detected by the usual three-yearly mammography. The additional cost per examination was estimated at £8.90, on the basis of nurse salary and the number of examinations per year.

Considering the additional costs of clinical breast examination over mammography, the total estimated cost per QALY with clinical breast examination, compared with mammography alone, was estimated to be £13,080.

Authors' conclusions
The authors concluded that clinical breast examination appeared to be a cost-effective addition to mammography.

CRD commentary
Interventions:
The selection of the comparators appears to have been appropriate and the screening strategies were likely to be applicable in other health care settings.

Effectiveness/benefits:
The clinical data were from a large sample of women enrolled in UK centres, but only a few cancer cases were detected and there was high uncertainty around the additional cases detected with clinical breast examination, as acknowledged by the authors. The patients' characteristics and types of cancer were described in detail. The impact of variations in the clinical parameters was not evaluated. The authors stated that QALYs were the summary benefit measure, but no quality adjustments were mentioned, so life-years appear to have been used. These were an appropriate measure, given the impact of breast cancer on life expectancy.

Costs:
The perspective was not clearly stated, but costs relevant to the UK NHS appear to have been included. The unit costs were presented for all items in the analysis. The quantities of resources reflected the screening patterns as observed in the patients enrolled in the clinical study. The price year was not reported, making reflation exercises impossible. The data sources were reported and were typical NHS sources, for most items. The impact of variations in the cost estimates was not considered.

Analysis and results:
The results were not clearly reported, as the calculations that led to the estimation of the cost per QALY were not clear. It was unclear how the QALYs were calculated, and it seems that the cost per life-year saved was presented. The uncertainty was not investigated; no sensitivity analyses were carried out. The analysis had important drawbacks, especially in the simplistic calculation of the cost-effectiveness ratios. The findings were specific to the UK and cannot be transferred to other settings.

Concluding remarks:
The methods of the analysis were not clearly described, especially for the cost-effectiveness calculations. Caution is required when interpreting the authors' conclusions.

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