Cost-effectiveness of 21-gene assay in node-positive, early-stage breast cancer

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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.

CRD summary
The objective was to assess the cost-effectiveness of a 21-gene assay to decide on adjuvant chemotherapy for women with early stage, node positive, oestrogen receptor positive, human epidermal growth factor receptor (HER) 2 negative, breast cancer. The authors concluded that the 21-gene assay could improve health outcomes at no additional cost. The methods were valid and, despite some limitations in the reporting, the authors’ conclusions seem appropriate.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of a 21-gene assay to determine the need for adjuvant chemotherapy for women with early stage (one to three), node positive, oestrogen receptor positive, human epidermal growth factor receptor (HER) 2 negative, breast cancer.

Interventions
The 21-gene Oncotype DX assay was used to predict each patient's recurrence risk, to determine subsequent treatment. This was compared with usual care, which was treatment of early stage breast cancer according to the National Comprehensive Cancer Network (NCCN) guidelines.

Location/setting
USA/secondary care.

Methods
Analytical approach:
A deterministic decision-analytic model was developed to synthesise the cost and outcome data from published sources. A 30-year time horizon was used and the authors reported that a payer perspective was adopted.

Effectiveness data:
The effectiveness data were from a variety of sources, including published literature, randomised controlled trials, and national statistics. The incidence of early stage, node positive, oestrogen receptor positive, breast cancer was from the Surveillance, Epidemiology and End Results database of the National Cancer Institute. The probability of chemotherapy-related events was from published studies, including randomised controlled trials. Mortality was based on national statistics. The main measure of effectiveness was the reduction in chemotherapy-related second primary tumours and adverse events.

Monetary benefit and utility valuations:
The utility values were from published studies.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the main measure of benefit and they were discounted at an annual rate of 3%.

Cost data:
The economic analysis included the costs of chemotherapy drugs and administration, including those for distant recurrence; adverse events; supportive care; and the assay. Chemotherapy drugs and administration and supportive care...
costs were from the Centres for Medicare and Medicaid services. Adverse events and distant recurrence costs were from published sources. The resource use data were from published sources. The price year was 2009 and the costs were reported in US dollars ($) and discounted at an annual rate of 3%.

Analysis of uncertainty:
A one-way sensitivity analysis was conducted by varying the key model parameters, including the assay use, the reduction in chemotherapy with the assay, and the treatment costs.

Results
For a population of two million, the assay was estimated to provide an additional 4.44 QALYs and save $13,476 per year, compared with no assay. The assay was dominant, as it was less costly and more effective.

The results were sensitive to variations in the testing costs and reduction in chemotherapy with testing. For example, at low treatment costs, the assay was no longer dominant and the cost per QALY gained was $5,567.

Authors' conclusions
The authors concluded that the 21-gene assay could improve health outcomes at no additional cost for patients with early stage, node positive, oestrogen receptor positive, HER2 negative, breast cancer.

CRD commentary
Interventions:
The interventions were clearly reported and were relevant to the authors' setting. The usual care was appropriately included.

Effectiveness/benefits:
It was unclear if a systematic review was undertaken to ensure that all the best available evidence was included, but the sources appear to have been appropriate for the authors' setting. These published sources should be accessed to fully assess their validity. Further details on the derivation of the utility values would have been useful in assessing their validity. QALYs were an appropriate outcome measure, capturing the impact of the intervention on quality and length of life, as well as allowing comparisons with other disease interventions.

Costs:
The authors reported their perspective and the relevant costs appears to have been included. The sources for the cost data were reported and appear to have been appropriate. The costs were reported as category totals rather than for individual items, which reduces the transparency of the analysis. The sources of some of the resource use data were unclear, making it difficult to assess their suitability. Details, such as the price year and discounting, were reported.

Analysis and results:
The analytic approach was described and a diagram of the model was provided. The results were clearly reported and an incremental approach was appropriately used to synthesis the costs and benefits of the two strategies. The results appear to have been robust, but the sensitivity analysis only investigated variations in selected inputs and no probabilistic analysis was carried out. A probabilistic analysis could have assessed the overall uncertainty in the model. The authors identified and discussed a number of limitations to their analysis including the limited evidence base for some of their estimates. The results are likely to be specific to the authors' context.

Concluding remarks:
The methods were valid and, despite some limitations in the reporting, the authors' conclusions seem appropriate.

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