US insurance program's experience with a multigene assay for 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
This study assessed the cost-effectiveness of the 21-gene recurrence score to aid decisions on adjuvant treatment for patients with oestrogen receptor positive, lymph node negative, early stage, breast cancer. The authors concluded that the 21-gene recurrence score targeted treatment and saved costs for the US payer. The cost-effectiveness methods were valid and the overall uncertainty was investigated. The authors' conclusions appear to be robust.

Type of economic evaluation
Cost-utility analysis

Study objective
This study assessed the cost-effectiveness of the 21-gene recurrence score (Oncotype DX) to aid decisions on adjuvant treatment for patients with oestrogen receptor positive, lymph node negative, early stage, breast cancer.

Interventions
The intervention was the 21-gene recurrence score breast cancer assay, which was compared against no test.

Location/setting
USA/hospital.

Methods
Analytical approach:
The analysis was based on a validated Markov model, with a lifetime horizon. The authors stated that it was carried out from the perspective of the US payer.

Effectiveness data:
The clinical inputs were from various sources. The key data for the test were from a sample of 925 women, whose data were on a health plan database and who were given the 21-gene assay between June 2006 and June 2010. The primary endpoint was the proportion of women who were predicted by the assay to have low, intermediate, or high risk of 10-year distant recurrence of breast cancer. Other clinical inputs were from trials and a meta-analysis of six published studies on the decision impact of the 21-gene assay.

Monetary benefit and utility valuations:
The utility values were from published sources. They included the disutility associated with breast cancer and with the complications of chemotherapy.

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

Cost data:
The economic analysis included the costs of the 21-gene assay, chemotherapy, supportive care, treatment of adverse events, and recurrence. Most of these costs were from the health plan; the cost of cancer recurrence was from a published study. All costs were in US dollars ($) and were discounted at an annual rate of 3%.

Analysis of uncertainty:
One-way sensitivity analyses were carried out to investigate the impact of varying individual inputs on the model outcomes, using published or assumed ranges of values. A probabilistic sensitivity analysis was carried out to evaluate the effect of uncertainty in the key parameters on the total cost to the payer; predefined probability distributions were used. A separate analysis included chemotherapy-induced second primary cancer.

Results

Of the 925 women tested with the 21-gene assay, 255 received adjuvant chemotherapy (27%). This included 10% of women classified as low risk, 36% of women at intermediate risk, and 72% of women at high risk.

The test saved $1,160 per patient and gained 0.162 QALYs. The savings were due to the 27% reduction in chemotherapy and the QALYs gained were due to fewer chemotherapy complications for low-risk women and the prevention of distant recurrence for high-risk women.

In the alternative scenario including second primary cancer, the test saved $1,579 per patient and gained 0.237 QALYs. Assuming a reduction in chemotherapy of 21%, instead of 27%, the test saved $25 per patient and gained 0.110 QALYs. The most influential input was the relative risk of recurrence with chemotherapy for patients at low risk.

There was an 81% chance that the 21-gene assay would be cost saving for the health plan and a 95% chance that the incremental cost per QALY gained with the test would be below $16,500.

Authors' conclusions

The authors concluded that the 21-gene recurrence score targeted treatment and saved costs for the US payer.

CRD commentary

Interventions:
The rationale for the selection of the comparators was clear as the proposed 21-gene assay was compared against no test or best supportive care.

Effectiveness/benefits:
No systematic review was reported to identify the clinical inputs. Most of the evidence was from a health plan database, including the proportion of patients receiving chemotherapy based on the assay and the complications of therapy. The chemotherapy treatment effect was from a clinical trial, while other data on the 21-gene assay were from a meta-analysis of studies. An extensive sensitivity analysis was conducted on uncertain parameters. QALYs were a valid benefit measure as they allow comparisons to be made with the benefits of other health care interventions and they capture the impact of the disease on survival and quality of life, which are key dimensions of health for breast cancer patients. Little information was provided on the sources for the utility weights.

Costs:
The economic analysis was carried out from the perspective of the US payer (the health plan) and included the direct medical costs only. Most of the costs were from the health plan database and were reported as totals. The unit costs and resource quantities were not presented separately, reducing the transparency of the analysis. The authors stated that the inclusion of costs paid by patients would have increased the savings for the test. Relfutation exercises will not be possible as the price year was not explicitly stated. The impact of variations in the key costs was tested in the sensitivity analysis.

Analysis and results:
The results were clearly presented, but only the incremental findings (additional costs and benefits of test over no test) were given. The authors stated that their results were sensitive to the prescribing patterns for chemotherapy and breast cancer management; a potential limitation was that the cost-effectiveness of the test was highly influenced by the cost of adjuvant chemotherapy and supportive care. Extensive information on the methods and results of the sensitivity analyses was provided. The authors did not discuss the transferability of their results, which appear to be specific to the USA. The model used to estimate the lifetime costs and benefits was not fully described.

Concluding remarks:
The cost-effectiveness methods were valid and the overall uncertainty was investigated. The authors' conclusions appear to be robust.
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