

Title: Is the 21-gene breast cancer test (Oncotype DX®) cost-effective?

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Background: The Oncotype DX[®] Breast Cancer Test (ODX) is a validated 21-gene assay that predicts 10 year risk of recurrence and the likelihood of benefit from adjuvant chemotherapy in early-stage, node-negative and node positive (1-3 nodes) ER+ breast cancer. The cost-effectiveness of using ODX has been published in several countries but to date, there hasn't been any review of these studies.

Materials and methods: Pubmed and a selection of congress databases were searched using combinations of search terms designed to identify publications describing cost-effectiveness analyses of ODX in early stage breast cancer patients. Searches were limited to those published in the English language between January 2001 and April 2011. All records were screened for inclusion in the review. The methodological quality of selected publications was assessed using the 35 items methodological checklist from Drummond et al (1996).

Results: Five published health economics analyses and 3 abstracts (two posters and an oral presentation) were identified. The studies were carried out in several countries (US (2), Canada (2), Japan, Israel, Singapore and Hungary and have used a Markov modelling approach based on data from a large multicentre trial (e.g. NSABP B-20) to make estimates of long-term outcomes, and assess the cost-effectiveness of using the ODX recurrence score in patients classified as having a high or low risk of distant recurrence using other methods of assessment. All studies were carried out in the perspective of the healthcare payer, and therefore did not consider broader costs to the patients and the society. Study comparators, costs, characteristics of the population receiving the test and impact of using the ODX results on treatment decisions were adapted to each individual country clinical practice explaining the large range of cost-effectiveness results from these studies. In the US, using ODX was shown to be cost-saving when in one of the Canadian studies, it was likely to be cost-effective (incremental cost-effectiveness ratio of \$64,063 per QALY gained). Consistently across all five studies, use of ODX was projected to improve survival (where reported), quality-adjusted life expectancy and to reduce chemotherapy costs versus comparators. When looking at the methodological quality of studies, they generally scored well with positive responses to 24 or more of the 35 questions on reporting. The exception was the Lyman *et al.* (US) paper where only 17 positive responses were recorded. The two posters, as expected scored lower than the full scale articles with positive responses of 15 and 18 out of 35 items.

Conclusions: Published literature to date is of good methodological quality and consistently supports the cost-effectiveness of using ODX in the various settings. Further analyses should be carried out to assess the budget impact of funding ODX and to include a broader perspective of the costs.