Title: Cost-utility of the 21-gene breast cancer assay (Onco*type* DX®) in the Irish healthcare setting

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Objective: The Oncotype DX® Breast Cancer Test is a validated 21-gene assay that predicts the likelihood of benefit from adjuvant chemotherapy in early-stage, node-negative and up to 3-node-positive, ER+ breast cancer as well as the likelihood of distant recurrence 10 years after diagnosis. Study objective was to investigate the cost-utility (incremental cost per QALY gained) of using Oncotyper DX in early stage, node-negative, ER+ breast cancer patients, from the perspective of the Irish health care system.

Methods: A cost-utility analysis was performed over the life-time of the patient using a state transition model, which simulated the costs and quality-adjusted survival associated with and without the use of the ODX testing to inform adjuvant chemotherapy decisions. The model included 3 health states: no recurrence, recurrence and death. Transition probabilities between health states, utility scores associated with each of the health state, patient cohort characteristics and impact of Oncotype DX on chemotherapy decisions data were derived from published sources. Direct medical costs associated with chemotherapy were collected from a representative panel of 5 hospitals in Ireland. Costs and outcomes were discounted at 4% per annum and the analysis was conducted over 30 years (life-time horizon). Probabilistic and one-way sensitivity analyses were conducted.

Results: Costs associated with adjuvant chemotherapy (4 cycles of TC) included the following costs items: drug (€1,002); administration and monitoring (€1,646); adverse event prevention (€3,561) and adverse event management (€756). The average total cost of chemotherapy across hospitals therefore summed up to €6,965. The base case incremental cost per QALY gained with Oncotype DX was estimated to be €9,462. There was a 74% chance for Oncotype DX to be cost-effective at a willingness to pay threshold of €20,000. One-way sensitivity analyses will be described in the poster.

Conclusions: Using Oncotype DX as a decision tool for adjuvant chemotherapy in node-negative, ER+ breast cancer patients, is likely to be cost-effective in the Irish healthcare setting. This estimate is probably conservative as the cost and disutility of some of the adverse events (i.e. long-term adverse events such as cardiotoxicity, secondary leukaemia and potential cognitive impairment) have not been considered.