Genomic Testing for Early Breast Cancer: Assessing the Value of Next Generation Sequencing

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INTRODUCTION

In England and Wales, tumor profiling testing to guide adjuvant chemotherapy decisions in early breast cancer is recommended by NICE as part of standard of care for eligible patients.

NICE recommended testing in node negative patients in 2018, later including node positive patients (1-3 nodes) in 2024. The Prosigna® Breast Cancer Assay (Prosigna) is one of the recommended options.[1] The Prosigna test is currently processed on the Dx enabled nCounter® Analysis System (nCounter).[2]

OBJECTIVES

This study aimed to assess the economic, clinical, and organizational impact of offering the Prosigna test processed using Next Generation Sequencing (NGS).

METHODS

Starting from the NICE base-case developed in the 2024 guidance (Figure 1), we modelled the Prosigna test's cost-utility analysis following a change of platform, from nCounter to NGS, compared to no test.

The base case evaluated the Prosigna test's prognostic ability, and a separate sensitivity analysis explored the impact on the ICER of the potential predictive ability of the test.

Test costs upon NGS implementation and their impact on the incremental cost-effectiveness ratio (ICER) were also evaluated.

Using micro-level data from the Royal Surrey NHS Foundation Trust, which provided platform-specific resource requirements, we also analyzed batch processing capabilities, platform consolidation benefits, and optimal utilization scenarios. Organizational impact was assessed based on qualitative data from NGS and breast cancer specialists in the clinical laboratory setting.

RESULTS

With a probabilistic ICER of £16,037 QALY gained (deterministic: £16,397), implementing the Prosigna test on NGS remains cost-effective based on NICE thresholds[3] (Figure 2).

When assuming predictive ability (i.e., differential chemotherapy benefit across risk groups), the Prosigna test became the dominant strategy.

Micro-level data revealed five main categories of NGS impact (Figure 3). These included:

- Platform consolidation where NGS supports multiple genomic tests versus the nCounter single-test design (2, 3, 4 or 10 test kit)
- Scalability where NGS processes up to 28 tests simultaneously versus the nCounter maximum capacity of 10 tests
- Expanded molecular information where NGS enables comprehensive genomic profiling capabilities
- Integration potential where NGS platforms accommodate diverse future assay types anticipated for clinical adoption, despite possibly requiring more complex work flows
- Long-term stability where NGS represents a long-term solution with continuous development and alignment with future-ready laboratory work low

CONCLUSION

This is the first field study examining the economic, clinical, and organizational impact of offering the Prosigna test on an NGS platform, demonstrating potential economic and organizational benefits versus nCounter DX processing. These findings, and assumptions, warrant validation across different settings and perspectives, and future reassessment upon availability of OPTIMA study results.[4]

FIGURE 1

Model structure

Model stratifies patients tested with the Prosigna test into low, intermediate, or high genomic risk groups, with each receiving chemotherapy + endocrine therapy (ET) or ET alone, compared to a no test strategy. All pathways enter a Markov model with four health states: recurrence-free, distant metastases, long-term adverse events (AML), and dead.

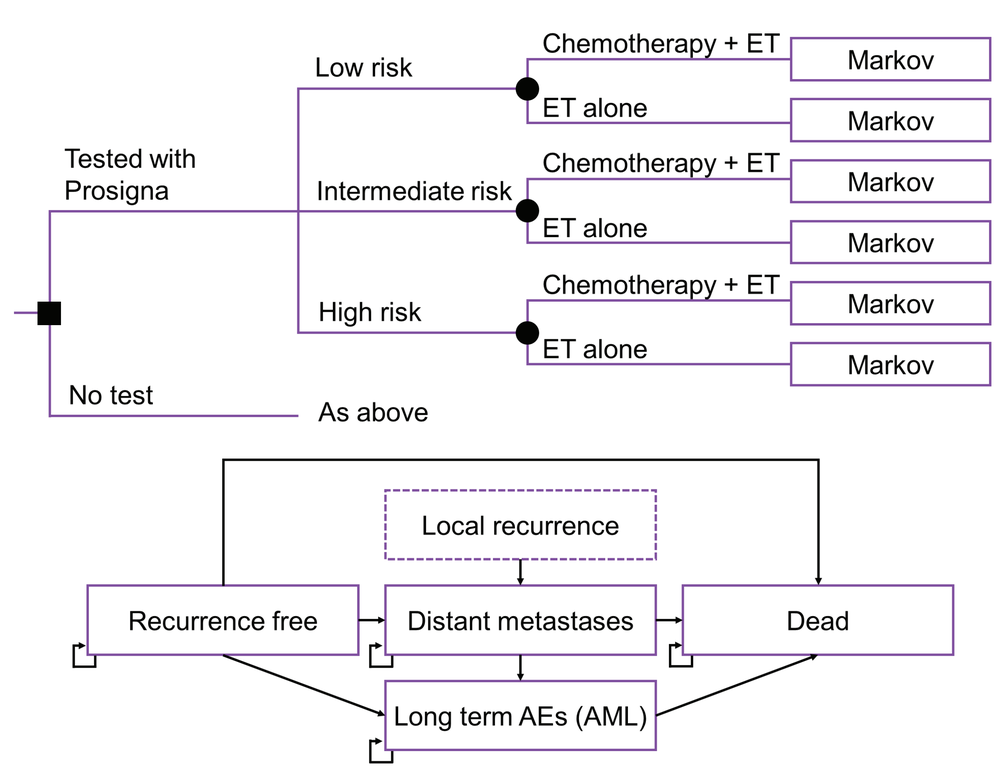

FIGURE 2

Incremental cost-effectiveness plane

1,000 probabilistic simulations (purple dots) of incremental costs and QALYs, with the mean probabilistic incremental cost-effectiveness ratio (ICER) indicated by the black dot. Most simulations fall in the northeast quadrant, indicating higher costs and greater effectiveness for genomic testing.

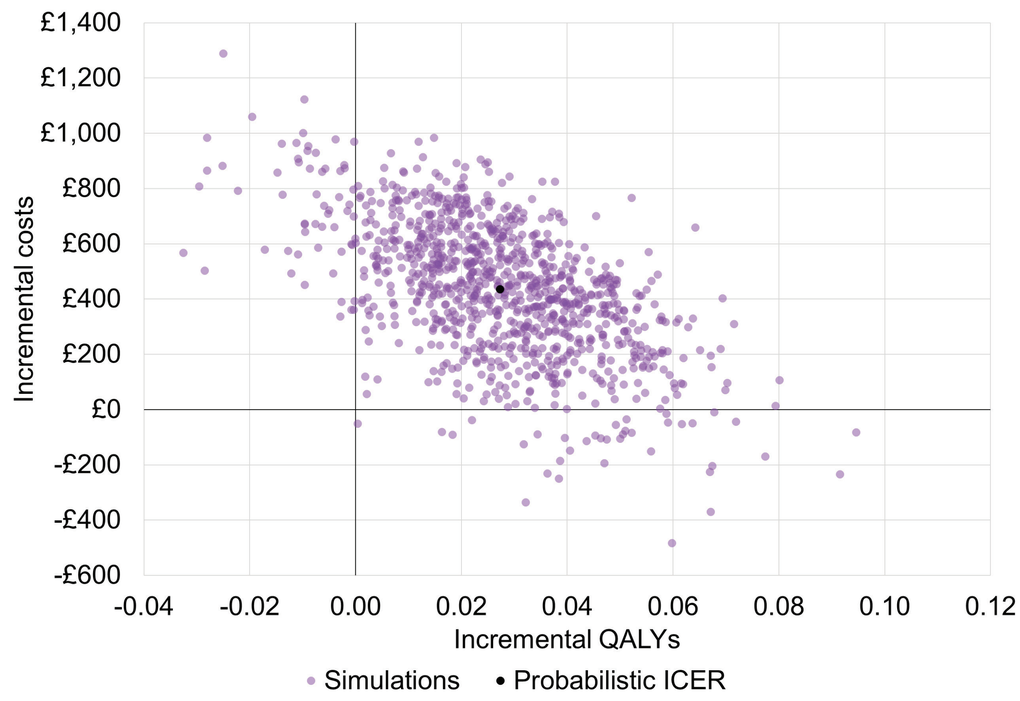

FIGURE 3

Five impact categories of NGS implementation

Comparison of key operational and strategic differences between NGS and nCounter platforms based on laboratory assessment and micro-level data from the Royal Surrey NHS Foundation Trust.

NGS Platform Implementation

Platform Consolidation	Scalability & Throughput	Expanded Molecular Information	Integration Potential	Long-term Stability
Multi-purpose platform supporting diverse genomic testing beyond Prosigna	Up to 28 simultaneous tests vs. maximum 10 tests for nCounter DX	Potential for comprehensive genomic profiling	Platform supports multiple assay types	Future proof solution with continuous development and support

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