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*Title* **Cost Effectiveness of Using Prognostic Information to Select Women With Breast Cancer for Adjuvant Systemic Therapy**

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*Reference* Health Technol Assess 2006;10(34). September 2006.
www.hta.ac.uk/execsumm/summ1034.htm

## Aim

To examine the evidence for the cost effectiveness of systemic adjuvant therapies of early breast cancer.

## Conclusions and results

Prognostic and predictive factors may be used to indicate the status, future behavior, and likelihood of response to various therapies by women with breast cancer. Some systematic attempts have been made to establish guidelines for using prognostic and predictive information in breast cancer. None of these guidelines have examined the cost effectiveness of basing adjuvant systemic therapy on such information.

*Quality of prognostic studies:* A characteristic was the lack of empirical evidence to support the importance of particular features affecting the reliability of study findings and avoidance of bias. Multiple small and unvalidated studies were common. *Systematic review of studies of prognostic factors:* A few potentially reliable reviews were found for 18 different factors. The lack of good quality systematic reviews and well-conducted studies of prognostic factors in breast cancer was striking. There was clear evidence of a relationship between tumor size, proliferation indices, P53, cathepsin D, and urokinase and its receptors and survival. *Prognostic models:* Few published prognostic models have been independently re-examined. Where validation studies have been done, the samples were often ill-defined and smaller, with short followup and different patient outcomes. Evidence from validation studies support the prognostic value of the Nottingham Prognostic Index (NPI). Improvement of this index depends on finding factors that are as important as, but independent of, lymph node, stage, and pathological grade. Predictive factors ER/PgR and HER2 predict response to hormone and trastuzumab respectively as these drugs require intact receptors. No evidence was found that other factors were useful predictors of response/survival. *Survey of UK practice:* This survey confirmed pathological nodal status, tumor grade, tumor size, and hormone receptor (ER) status as the most clinically important factors when selecting women for adjuvant systemic therapy, but much variation exists. Some centers used NPI-based protocols while others did not use a single index score. Consensus appeared greatest when selecting women for adjuvant hormone therapy, based primarily upon ER/PgR status rather than combinations of factors.

*Cost-effectiveness of prognostic models:* Only 5 papers were identified, and these varied in quality. By combining methodologies used in determining prognosis with those used in health economic evaluation, it was possible to simulate the effectiveness (survival and quality-adjusted survival) and cost effectiveness associated with the decision to treat individual women or groups of women with different prognostic characteristics. A set of patient data on prognostic factors, treatments, and outcomes of women diagnosed with early breast cancer made it possible to directly estimate a regression-based risk equation. The model showed that effectiveness and cost effectiveness of adjuvant systemic therapy has the potential to vary substantially depending upon prognosis.

## Recommendations

For some women, therapy may prove effective and cost effective, whereas for others it may prove detrimental. Outputs from models based on the methods described may be useful at the patient level (where a clinician must determine whether net benefits can be obtained from adjuvant therapy) and at the policy-making level.

## Methods

See Executive Summary link above.

## Further research/reviews required

Research needed includes: the quality of studies of prognostic and predictive factors and models in general (robust tools to score quality and templates to improve the research quality are likely to be beneficial); the cost-effectiveness of prognostic and predictive factors; and the most effective ways to present data from studies of prognostic and predictive factors.

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