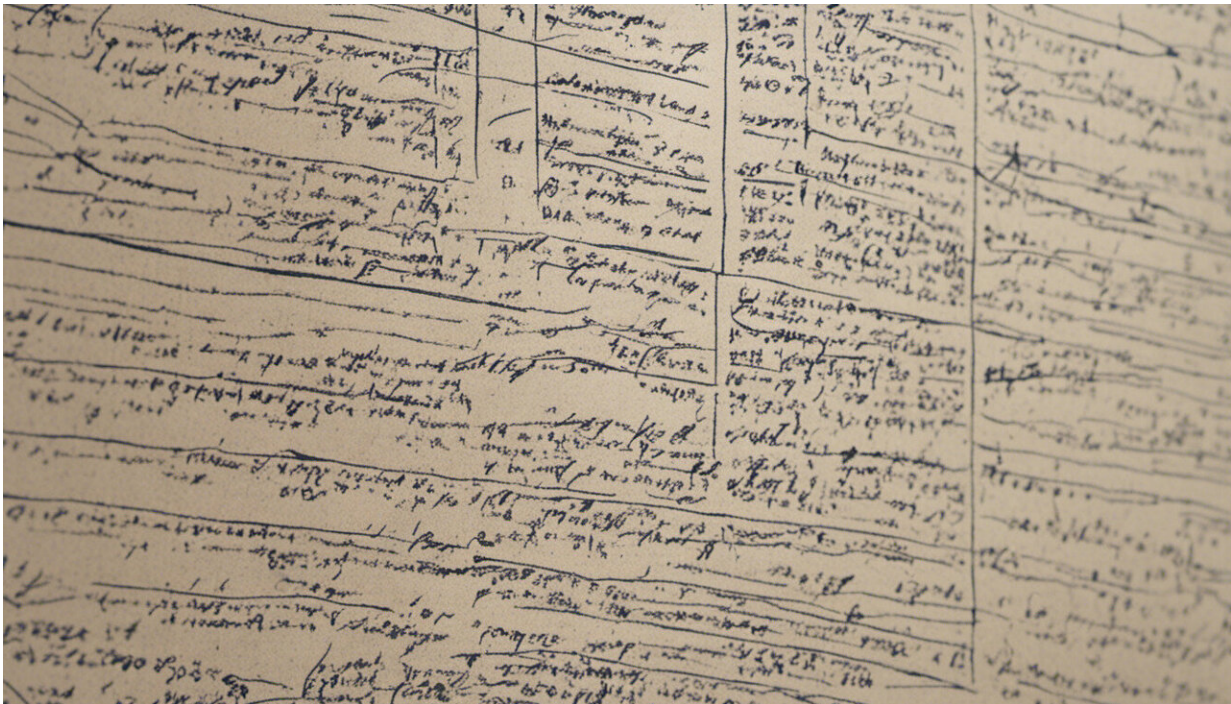


# Economic evaluations of genomic testing may have misleading conclusions

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Credit: AI-generated image ([disclaimer](#))

Research led at the Yale School of Public Health have found that the majority of published papers analyzing the cost-effectiveness of a widely used test for breast cancer used a study design that can increase bias.

Oncotype DX, a gene-expression profiling test, is used in clinical care to

guide chemotherapy decisions for patients with early stage breast cancer. Several cost-effectiveness analyses (CEAs) concluded that Oncotype DX is cost-effective, yet clinical guidelines suggest Oncotype DX testing for select rather than for all patients.

Lead author, Shi-Yi Wang, M.D., Ph.D., assistant professor at Yale School of Public Health and his co-authors were interested in why literature has yielded different conclusions. In the study, published in the *Journal of Clinical Oncology*, the research team conducted a [systematic review](#) of Oncotype DX CEAs and applied mathematical modeling to examine the extent to which the study designs and assumptions may influence their results. They also explored whether industry funding was associated with study designs that favor Oncotype DX.

"Reviewing 27 analyses, we identified eight issues that might compromise the accuracy and validity of the results. We also found that industry-funded studies tended to favor Oncotype DX," said Wang. "Our findings suggest that the majority of existing CEAs of Oncotype DX for women with early-stage [breast cancer](#) have problematic issues that may result in misleading conclusions."

By combining systematic review with simulation modeling, Wang and his team identified factors that had large impact on CEA conclusions. For example, whether or not using prevalence information from population-based studies could lead to an opposite conclusion. An intervention with an incremental cost-effectiveness ratio less than \$50,000 per quality adjusted life year is generally viewed as cost-effective. The incremental cost-effectiveness ratio of Oncotype DX is \$42,000 per quality adjusted life year if using prevalence from a clinical trial (cost-effective), but is \$167,600 per quality adjusted life year if using population-based prevalence data (cost-ineffective).

"As precision medicine is the mainstream for future practice, assessing

the relationship between costs and benefits of expensive precision medicine gene tests is important.," said Cary Gross, M.D., professor of medicine and [public health](#) and the study's senior author. "Our results could provide critical insights for value-based frameworks, which rely on rigorous independent cost effectiveness analyses to help between high and low value clinical settings for specific tests.

**More information:** Shi-Yi Wang et al. Cost-Effectiveness Analyses of the 21-Gene Assay in Breast Cancer: Systematic Review and Critical Appraisal, *Journal of Clinical Oncology* (2018). [DOI: 10.1200/JCO.2017.76.5941](#)

Provided by Yale University

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