



Effective Health Care

OncoDx and Her-2/Neu Tests for Cancer Nomination Summary Document

Results of Topic Selection Process & Next Steps

- OncoDx and Her-2/Neu tests for cancer was found to be addressed by three existing AHRQ products.
 - Seidenfeld J, Samson DJ, Rothenberg BM, Bonnell CJ, Ziegler KM, Aronson N. HER2 Testing to Manage Patients With Breast Cancer or Other Solid Tumors. Evidence Report/Technology Assessment No. 172. (Prepared by Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center, under Contract No. 290-02-0026.) AHRQ Publication No. 09-E001. Rockville, MD: Agency for Healthcare Research and Quality. November 2008.
<http://www.ahrq.gov/clinic/tp/her2tp.htm>
 - Marchionni L, Wilson RF, Marinopoulos SS, Wolff AC, Parmigiani G, Bass EB, Goodman SN. Impact of Gene Expression Profiling Tests on Breast Cancer Outcomes. Evidence Report/Technology Assessment No. 160. AHRQ Publication No. 08-E002. Rockville, MD: Agency for Healthcare Research and Quality. January 2008.
<http://www.ahrq.gov/clinic/tp/brcgenetp.htm>
 - Chin KM, Wessler B, Chew P, Lau J. Genetic Tests for Cancer. Technology Assessment. (Prepared by Tufts-NEMC Evidence-based Practice Center) Rockville, MD: Agency for Healthcare Research and Quality. January 2006.
<http://www.ahrq.gov/clinic/ta/gentests/>
- Given that these AHRQ reports cover this nomination, no further activity will be undertaken on this topic.

Topic Description

Nominator:	National non-governmental advisory group
Nomination Summary:	The nominator questions the comparative effectiveness of OncoDx and Her-2/Neu tests in the diagnosis of cancer.
Key Questions from Nominator:	None

Considerations

- Although HER-2/Neu is used for other cancers besides breast cancer, the OncoDx test is used only for breast cancer. Although there is not a single AHRQ systematic review that discusses both HER-2/Neu and OncoDx, there are reports that discuss each test individually. These tests are used to evaluate different aspects of breast cancer; therefore, this topic was found to have significant overlap with existing AHRQ reports on the clinical effectiveness of these two tests.

- Information on genetic tests used in cancer diagnosis and treatment is included in the 2006 AHRQ Technology Assessment titled *Genetic Tests for Cancer*. The purpose of this review is to identify the different genomic tests that are being promoted for clinical use in cancer prevention, diagnosis, and management. The project was organized into two distinct parts with separate aims and methodologies.
 - The goal of Part I was to answer the key question, “What genetic tests are currently available for cancer prevention, diagnosis, and treatment?”
 - The goal of Part II was to answer the key question, “What genetic tests are in development for cancer?”

- The topic of HER-2/Neu testing was found to be addressed by the 2008 AHRQ report titled *HER2 Testing to Manage Patients With Breast Cancer or Other Solid Tumors*. The key questions from this report include:
 1. What is the evidence on concordance and discrepancy rates for methods (e.g., FISH, IHC, etc.) used to analyze HER2 status in breast tumor tissue?
 2. For patients who are not unequivocally HER2 positive, what is the evidence on outcomes of treatment targeting the HER2 molecule (trastuzumab, etc.), or on differences in outcomes of a common chemotherapy or hormonal therapy regimen with versus without additional treatment targeting the HER2 molecule, in:
 - a. Breast cancer patients characterized by discrepant HER2 results from different tissue assay methods performed adequately; and
 - b. For those with HER2-negative breast cancer?
 3. For breast cancer patients, what is the evidence on clinical benefits and harms of using HER2 assay results to guide selection of:
 - a. Chemotherapy regimen; or
 - b. Hormonal therapy?
 4. What is the evidence that monitoring serum or plasma concentrations of HER2 extracellular domain in patients with HER2-positive breast cancer predicts response to therapy, or detects tumor progression or recurrence, and if so, what is the evidence that decisions based on serum or plasma HER2 assay results improve patient management and outcomes?
 5. In patients with ovarian, lung, prostate, or head and neck cancers, what is the evidence that:
 - a. Testing tumor tissue for HER2; or
 - b. Monitoring serum or plasma concentrations of HER2; either predicts response to therapy, or detects tumor progression or recurrence; and if so, what is the evidence that decisions based on HER2 assay results improve patient management and outcomes?

- The topic of OncoDx testing in breast cancer was found to be addressed by the 2008 AHRQ report titled *Impact of Gene Expression Profiling Tests on Breast Cancer Outcomes*. The key questions from this report include:

1. What is the direct evidence that gene expression profiling tests in women diagnosed with breast cancer (or any specific subset of this population) lead to improvement in outcomes?
2. What are the sources of and contributions to analytic validity in these gene expression based prognostic estimators for women diagnosed with breast cancer?
3. What is the clinical validity of these tests in women diagnosed with breast cancer?
 - a. How well does this testing predict recurrence rates for breast cancer when compared to standard prognostic approaches? Specifically, how much do these tests add to currently known factors or combination indices that predict the probability of breast cancer recurrence (e.g., tumor type or stage, ER and HER-2 status)?
 - b. Are there any other factors, which may not be components of standard predictors of recurrence (e.g., race/ethnicity or adjuvant therapy), that affect the clinical validity of these tests and thereby the generalizability of the results to different populations?
4. What is the clinical utility of these tests?
 - a. To what degree do the results of these tests predict the response to chemotherapy, and what factors affect the generalizability of that prediction?
 - b. What are the effects of using these two tests and the subsequent management options on the following outcomes: testing- or treatment-related psychological harms, testing or treatment-related physical harms, disease recurrence, mortality, utilization of adjuvant therapy, and medical costs?
 - c. What is known about the utilization of gene expression profiling in women diagnosed with breast cancer in the United States?
 - d. What projections have been made in published analyses about the cost-effectiveness of using gene expression profiling in women diagnosed with breast cancer?