Economic analysis of alternative genetic tests for BRCA1 and BRCA2 mutations

Stenehjem D.1,2, Jiao T.1, Brixner D.1,3
1Department of Pharmacotherapy, College of Pharmacy, University of Utah, Salt Lake City, Utah, USA
2Huntsman Cancer Institute, Salt Lake City, Utah, USA
3Program in Personalized Health Care, University of Utah Salt Lake City, Utah, USA

Methods:

A decision analytic model was constructed in TreeAge using standard cost-effectiveness modeling methods for 35-year-old women with a high risk of hereditary breast and ovarian cancer (HBOC) undergoing BRCA1/2 test. A 30-year time horizon and a U.S. third-party payer perspective were used.

Data inputs were derived from the literature and accuracy data were collected from data on file.

The list price for BRACAnalysis® is $4,040, and an estimated average list price was used for the alternative test.

Standard discounting off list price was used for both tests.

One-way sensitivity analyses of clinically meaningful variables were conducted.

Results:

Figure 1. Model Base Case Scenario of Populated Decision Analytic Tree

Figure 2. Average 30-years Cost per Member Tested

Cost based on 2012 USD

Conclusions:

The one-way sensitivity analyses identified the increased percentage of patients classified with a VUS, as a significant driver of the model results.

Compared with alternative tests, using BRACAnalysis® would save $624,000 and prevent 9 BC and/or OC per year for a 1 million members health system.

Future research will address the limitations in current model to more accurately reflect the true benefit of more accurate testing.

Limitations:

Assumed a fixed age of cancer occurrence (60 years) and cancer costs were included for 5 years after diagnosis.

Fixed 5 year survival estimates were used for BC and OC.

Assumed the risk of developing cancer was identical for BRCA1 and BRCA2 mutations.

The negative effects of preventive treatments received caused by false positive BRCA results were not considered.

The impact of BRCA testing in women with BC or OC was not considered.

The increased test performance of BRACAnalysis® translates into reduced overall costs for the prevention and treatment of additional cancer cases compared to alternative tests.

In determining the true costs between competing BRCA 1/2 tests, the performance of the test (analytic sensitivity and variant classification) and initial test price needs to be weighed against the overall impact on cancer occurrence, preventative treatment utilized and the overall survival.

Future research will address the limitations in current model to more accurately reflect the true benefit of more accurate testing.

Background:

• Until recently, BRCA1 and BRCA2 mutation testing was available through a single provider; Myriad Genetics, BRACAnalysis®. However, a June 2013 U.S. Supreme Court decision ruled against the patentability of human genes including BRCA1/2.

• Alternative tests are now available, and health insurers face decisions regarding test reimbursement based on differences in analytical sensitivity, rates of variants of unknown significance (VUS), variant classification accuracy and test cost, which ultimately impacts costs for preventive therapy and the occurrence and treatment of cancer. Therefore, economic analyses assessing competing tests are warranted.

• Assumed the risk of developing cancer was identical for BRCA1 and BRCA2 mutations.

• Fixed 5 year survival estimates were used for BC and OC.

• Assumed a fixed age of cancer occurrence (60 years) and cancer costs were included for 5 years after diagnosis.

• The negative effects of preventive treatments received caused by false positive BRCA results were not considered.

• The impact of BRCA testing in women with BC or OC was not considered.

• The increased test performance of BRACAnalysis® translates into reduced overall costs for the prevention and treatment of additional cancer cases compared to alternative tests.

• In determining the true costs between competing BRCA 1/2 tests, the performance of the test (analytic sensitivity and variant classification) and initial test price needs to be weighed against the overall impact on cancer occurrence, preventative treatment utilized and the overall survival.

• Future research will address the limitations in current model to more accurately reflect the true benefit of more accurate testing.

Results:

• The incremental cost-effectiveness ratio is dominant favoring BRACAnalysis®. Based on the model results, BRACAnalysis® testing resulted in prevention of 84.74% of cancer cases compared to 84.65% with an alternative test, which identical to 9 less incidence of cancer in 10,000 women.

• The one-way sensitivity analyses identified the increased percentage of patients classified with a VUS, as a significant driver of the model results.

• Compared with alternative tests, using BRACAnalysis® would save $624,000 and prevent 9 BC and/or OC per year for a 1 million members health system.

• The increased test performance of BRACAnalysis® translates into reduced overall costs for the prevention and treatment of additional cancer cases compared to alternative tests.

• In determining the true costs between competing BRCA 1/2 tests, the performance of the test (analytic sensitivity and variant classification) and initial test price needs to be weighed against the overall impact on cancer occurrence, preventative treatment utilized and the overall survival.

• Future research will address the limitations in current model to more accurately reflect the true benefit of more accurate testing.