Patient Summary

Can Tumor Gene Expression Profiling (GEP) Improve Outcomes in Patients With Breast Cancer?

Recommendations from the EGAPP™ Working Group

The independent Evaluation of Genomic Applications in Practice and Prevention (EGAPP™) Working Group (www.egappreviews.org/workingrp.htm) reviewed the scientific evidence to see whether gene expression profiling is valid and useful for determining the risk of breast cancer recurrence that could be prevented by chemotherapy, and developed a recommendation about the appropriate use of this testing in 2009. This brief summary of the EGAPP™ recommendation statement can help the general public understand what is intended by the EGAPP™ recommendation and where to find more information.

Disclaimer: Our office does not offer medical advice to individuals. If you have specific concerns about your health, please discuss them with your doctor.

Who do the recommendations apply to?

Women diagnosed with early stage (Stage I or II) breast cancer which has *not* spread to the lymph nodes (node negative). The majority of women treated for early stage node negative breast cancer will remain disease-free at 10 years without undergoing chemotherapy treatment. This is especially true for women with estrogen-receptor positive breast cancer treated with tamoxifen. However, some of these women will experience a recurrence of their disease (cancer coming back), which may be prevented with chemotherapy.

What is the purpose of the gene expression profiling test?

To predict the chance of the cancer recurring in the same or in other parts of the body, and help determine if chemotherapy is a good treatment option.

What does the genetic test look for?

Breast cancer gene expression profiles (GEPs) look at the activity of genes within breast tumor tissue samples. Certain patterns of gene activity are linked to a greater chance of breast cancer recurrence. GEPs do not look for genetic changes that are passed down in families (inherited). Several GEPs are clinically available that provide variations on "recurrence risk scores" intended to help doctors and their patients in treatment decision making.

Who developed this recommendation?

The EGAPP™ Working Group is made up of scientists and health care experts who review available research and evidence to make recommendations about the use of genetic tests. This independent panel includes representatives from clinical practice, public health, laboratory practice, genomics, epidemiology, economics, ethics, policy, and health technology assessment.

Did EGAPP™ recommend using gene expression profiling to determine breast cancer recurrence risk?

- **NO:** The EGAPP™ Working Group did not find enough evidence to indicate whether breast cancer gene expression profiling should or should not be used in cases of early stage breast cancer.
- The EGAPP Working group did find preliminary evidence to suggest that one type of GEP test (Oncotype DX) may help some women make treatment decisions. However, the evidence was not strong enough to be sure that the benefits outweighed possible harms. They also did not find clear evidence showing that this test had an effect on breast cancer recurrence or survival.
- Any patient considering GEP for breast cancer should be provided with counseling and educational materials about the potential benefits and harms.

Other Information

How do I find out more about this type of genetic testing?

Because there is still some uncertainty about this test, you should talk to your oncologist or other healthcare provider if you have questions about breast cancer GEP.

Note: You may qualify for a large research study being conducted in the United States to help answer the question of whether GEP for breast cancer leads to better outcomes for patients.

TAILORx Clinical Trial: http://www.cancer.gov/cancertopics/factsheet/therapy/tailorx

The Web sites below provide additional general information on breast cancer.

- General breast cancer information, Centers for Disease Control and Prevention (http://www.cdc.gov/cancer/breast/)
- What You Need to Know About™ Breast Cancer, National Cancer Institute (http://www.cancer.gov/cancertopics/wyntk/breast/)
- Learn About Breast Cancer, American Cancer Society (http://www.cancer.org/Cancer/BreastCancer/DetailedGuide/index)