OCNA/Bright Pink Comments on BRCA Testing Recommendations from USPSTF

Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: U.S. Preventive Services Task Force Recommendation Statement DRAFT

*The U.S. Preventive Services Task Force (USPSTF) recommends that primary care providers screen women who have family members with breast or ovarian cancer with one of several screening tools (see the Clinical Considerations) designed to identify a family history that may be associated with an increased risk for potentially harmful mutations in breast cancer susceptibility genes (*BRCA1 *or* BRCA2*). Women with a positive screen should receive genetic counseling and, if indicated after counseling, BRCA testing.*

The Ovarian Cancer National Alliance and Bright Pink are pleased to take this opportunity to comment on revised draft Task Force recommendations regarding testing for a genetic mutation that increases the risk for breast and ovarian cancers. We applaud the Task Force for its revised recommendation in that they now encompass testing, not merely counseling, for women with a high likelihood of having a potentially harmful genetic mutation.

Ovarian Cancer National Alliance

The Alliance advocates for policies, programs, and investments to support the development of an early detection test; improved health care practices; access to life-saving therapies; and improved awareness among health professionals and the public of the risks and symptoms of ovarian cancer. Too many women are unaware of their risk of developing ovarian cancer; tens of thousands each year are diagnosed too late and, therefore, lose their lives unnecessarily. It is our mission to improve these outcomes.

Ovarian cancer is the deadliest gynecological cancer. According to estimates from the American Cancer Society, in 2013 approximately 22,240 new cases of ovarian cancer will be diagnosed and 15,500 women in the U.S. will die from ovarian cancer. Ovarian cancer mortality rates have remained virtually unchanged for nearly 40 years, while we have seen improvements in many other cancer types. The majority of women have at least one recurrence and the disease has an overall five year survival rate of 45 percent.

Bright Pink

Bright Pink is the only national non-profit organization focusing on the prevention and early detection of breast and ovarian cancer in young women, while providing support for high-risk individuals.

Bright Pink serves a diverse population of women between the ages of 18-45. In a country that tends to under-emphasize preventative medicine, and a breast cancer community that focuses on cancer fighter/survivors, Bright Pink fills a critical niche in the cancer community by targeting young women who are not yet affected by these diseases. The need for preventive education among young women is drastic, as more than 20,000 women were diagnosed with breast cancer under the age of 40 and approximately 3,000 women under the age of 45 were diagnosed with ovarian cancer in 2009. Bright Pink aims to reduce the overall incidence of

breast and ovarian cancer by informing young women about their lifetime breast/ovarian cancer risk, helping them develop a prevention/early detection strategy based upon risk and offering support and a sense of community to women who are at high-risk for these diseases.

Testing and Counseling

The National Cancer Institute reports that women at average risk have a 12 percent change of developing breast cancer and 1.4 percent chance of developing ovarian cancer.[1] Women with a BRCA1 or BRCA2 mutation have a 60 percent and up to 40 percent chance of developing breast and ovarian cancer, respectively. There is no screening test for ovarian cancer, and screening is not recommended for women under age 50.

Therefore, it is important that people getting genetic testing are appropriately counseled before the test to both ensure that they have the proper context and support for testing and that the right people are identified as needing testing. The currently available tests are not accurate for all people, and proper counseling can help patients understand the results.

We applaud the inclusion of testing into the draft recommendation:

Testing for BRCA mutations should be done only when an individual has personal or family history features suggestive of inherited cancer susceptibility, access to a health professional trained to provide genetic counseling and interpret test results, and test results that will aid in decision making

Concerns/Questions

While we are thankful for the inclusion of testing into these recommendations, we still have some questions.

We need clarification that those with a diagnosis of cancer are eligible for counseling and testing. The recommendations "apply to women who have not received a diagnosis of breast or ovarian cancer but who have family members with breast or ovarian cancer whose BRCA status is unknown." However, women with one cancer and a family history may consider testing to determine next steps to prevent another cancer.

Additionally, people who know they have a family history of a BRCA mutation should have access to counseling and testing to determine if they have inherited the mutation.

We are concerned that men are specifically excluded from these recommendations. Half of genetic material is inherited from the father, and so identifying a genetic mutation in a man may help family members decide if they should be tested and take preventive action.

Lastly, we remain concerned that prophylactic steps, such as surgery, are not covered by all payers. The Alliance and Bright Pink will work with payers to ensure that all women have access

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[1] BRCA1 and BRCA2: Cancer Risk and Genetic Testing at http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA.

to timely and appropriate personalized care, including, when appropriate, prophylactic bilateral mastectomy and/or salpingo-oophorectomy. As the draft recommendations state:

In high-risk women and mutation carriers, cohort studies of risk-reducing surgeries (mastectomy and salpingo-oophorectomy) showed substantially reduced risks for breast or ovarian cancer, with breast cancer reduced by 85% to 100% with mastectomy and by 37% to 100% with oophorectomy, and ovarian cancer reduced by 69% to 100% with oophorectomy or salpingo-oophorectomy.

Conclusion

We thank the Task Force for its attention and recommendations regarding this important issue. We stand ready to work with the Task Force and other stakeholders to ensure that women at high risk of developing breast/ovarian cancer get the right care at the right time.