April 12, 2017

FORCE response to the USPSTF Draft Research Plan for BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing

http://www.uspreventiveservicestaskforce.org/draftresplan.htm

Facing Our Risk of Cancer Empowered (FORCE) is a national nonprofit organization that advocates for individuals and families affected by hereditary breast, ovarian, and related cancers, and families with a BRCA or other inherited mutation that increases risk for these cancers.

FORCE recognizes that the USPSTF develops recommendations which impact two important areas of patient preventive care:

1. The panel provides evidence-based guidelines for primary care clinicians and health systems on topics of preventive health.
2. Additionally, the USPSTF guidelines are cited in the Patient Protection and Affordable Care Act (PPACA), and therefore these guidelines impact patient access to care and insurance coverage for members of our constituency under the PPACA.

“Coverage of Preventive Services

PHS Act section 2713 and the interim final regulations[5] require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to, the following:

• Evidenced-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved;”

The following are FORCE’s recommendations to the USPSTF for their research approach to updating the guidelines. Our comments fall into one of the two areas of impact mentioned above.

1. Patient population under consideration:
   KQs 1–3: These recommendations apply to women without preexisting breast or ovarian cancer whose BRCA mutation carrier status is unknown.
- We recommend a review of the data and extending the evaluation and letter grade to women who have been diagnosed with breast cancer who have no measurable disease and who have completed treatment.
  - A large body of research indicates that women with a BRCA mutation who have already been diagnosed with breast cancer and have completed treatment are at very high risk for a new primary breast cancer and for ovarian cancer.

  - These second cancers are not related to the first diagnosis and therefore, as with any other recommended preventive health service, should be accessible to these survivors who have completed treatment and are expected to survive their breast cancer. Research has shown that this cohort has an increased risk for new cancers similar to high-risk women who never received a diagnosis. Therefore, any steps to prevent additional cancers are truly preventive and not part of their cancer treatment plan. Research has conclusively demonstrated decreased ovarian cancer associated mortality in these patients (1-8).

  - In May 2015, the Dept. of Labor issued a clarification that the guidelines also apply to women who have “previously been diagnosed with cancer, as long as she is not currently symptomatic of or receiving active treatment for breast, ovarian, tubal, or peritoneal cancer.”


**KQs 4,5: These recommendations apply to women without preexisting breast or ovarian cancer with potentially harmful mutations in the BRCA1 or BRCA2 genes.**

- We recommend a review of the data and extending the evaluation and letter grade to women who have had ovarian or breast cancer and to men who have had breast cancer who have no measurable disease and who have completed treatment.

  - Testing within a family is more cost-effective and most likely to yield a conclusive result if it begins with someone who has had a cancer diagnosis consistent with a hereditary cancer syndrome (9). Omission of this population under “Patient Populations Under Consideration” implies that testing unaffected women in a family where there has been no identified mutation is a more appropriate approach than testing survivors. Further, omission of survivors from these guidelines will impact access to care and coverage for preventive services in this population under the PPACA. This may inadvertently lead to increased inappropriate BRCA tests being
ordered first in unaffected members of a family rather than beginning with the candidate in a family most likely to test positive.

2. Interventions:

KQ 1: Risk assessment by a nonspecialist in genetics, genetic counseling, and genetic testing

KQs 2a, 3a: Risk assessment by a nonspecialist in genetics

- We recommend defining a nonspecialist in genetics.
  - Genetics is a rapidly evolving area of medicine, and most primary care providers are not trained nor required to have demonstrated competency in genetics. Like any specialty area of medicine, there are established training programs in genetics, medical boards to assure competency, continuing education, and oversight.

3. References:


