



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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March 18, 2019

U.S. Preventive Services Task Force
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Re: Draft Recommendation Statement: *BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*

To whom it may concern:

Thank you for the opportunity to submit comments on the draft recommendation statement, *BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing*, recently published by the US Preventive Services Task Force (USPSTF). AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from medicine, molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government and the in vitro diagnostics industry.

AMP is very concerned about the draft recommendations and strongly urges the USPSTF to expand the updated document to recommend screening for additional at-risk individuals prior to finalization. While we support the addition of recommending screening based on ancestry or ethnic background, we were disappointed that the proposed update fails to cover other high-risk patients. As the premiere association representing health professionals providing germline testing for hereditary cancer in the United States, we agree with the National Comprehensive Cancer Network (NCCN) criteria¹ for suspected hereditary breast or ovarian cancer syndromes as well as the guidelines published by the American College of Medical Genetics and Genomics² and the Society for Gynecologic Oncology.³ The latter two call for screening in patients with a personal history of cancer. While the draft statement notes that the USPSTF reviewed these established and accepted medical guidelines, it did not include any rationale as to why the task force reached different and inconsistent recommendations, especially as it pertains to individuals with a personal history of cancer.

¹ http://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf

² American College of Medical Genetics. Genetic Susceptibility to Breast and Ovarian Cancer: Assessment, Counseling and Testing Guidelines. Bethesda, MD: American College of Medical Genetics; 1999.

³ Society for Gynecologic Oncology Clinical Practice Statement; 2014; <https://www.sgo.org/clinical-practice/guidelines/genetic-testing-for-ovarian-cancer/>

Additionally, is not unusual for patients to have a small family, be adopted, or otherwise not have access to their family history information. Furthermore, many individuals are not aware of their ethnic background, including Ashkenazi Jewish ancestry, which may increase their chance of carrying a mutation in the *BRCA* genes. In these instances, a personal history of a cancer diagnosis that is suspicious of a hereditary cancer syndrome should be sufficient to recommend germline testing.

Last, AMP is concerned about the draft recommendations focused solely on women, and fails to acknowledge that men also develop breast cancer. Those men should receive genetic testing to understand if they have potentially harmful mutations in *BRCA1* or *BRCA2*. Among affected men, it is estimated that 10% have a genetic predisposition for the disease, most of which are due to inherited *BRCA* mutations.⁴ Given the rarity of breast cancer among men, any man who presents with breast cancer, regardless of family history, should be offered genetic counseling and testing.

Molecular diagnostics is a field dominated by next generation sequencing (NGS) based approaches and laboratories continue to migrate testing protocols to NGS-based platforms. For this reason, NGS has become the most frequently utilized laboratory method for standard-of-care germline and neoplastic tumor profiling. While other DNA sequencing techniques can be used to identify DNA aberrations or confirm NGS-findings, it becomes more expensive and time-consuming to sequence multiple genes sequentially using an alternative technology, in most clinical scenarios where DNA testing is warranted. For this reason, most clinical laboratories provide *BRCA* gene testing as part of a broader panel of genes associated with increased risk of hereditary cancer. Additionally, recent reimbursement policy, established via the local coverage determination (LCD) process, has led to Medicare contractors reimbursing laboratories offering testing for hereditary cancer panels for patients with cancer instead of individual genes. The USPSTF recommendations should reflect the current standard of care and technologies used and also support testing for *BRCA1* and *BRCA2* as part of a panel test.

AMP strongly recommends that the USPSTF screening recommendations be expanded to also include screening, counseling, and potentially testing for the following at risk individuals:

1. Women with a personal history of breast cancer diagnosed at or below age 50.
2. Women with a personal history of ovarian, tubal, or peritoneal cancer.
3. Men with or personal history of breast cancer.
4. Individuals with triple-negative (estrogen receptor-negative, progesterone receptor-negative, and HER2/neu [human epidermal growth factor receptor 2]-negative) breast cancer, particularly when diagnosed before age 60.
5. Individuals with multiple primary breast cancers either in one or both breasts.
6. Individuals with a family history of pancreatic cancer and/or prostate cancer with breast and/or ovarian cancer.

AMP believes that a molecular pathologist is a critical participant in the continuum of patient care with an evolving and increasing role in prevention due to recent advances in laboratory-based screening tests. As such, AMP has previously nominated molecular pathologists to serve on the USPSTF. While USPSTF did not respond to

⁴ http://ascopubs.org/doi/abs/10.1200/jco.2015.33.15_suppl.1538

our nominations, AMP continues to encourage USPSTF to consider the inclusion of a health professional trained and credentialed in molecular pathology to provide expertise on diagnostics. We believe that had a molecular pathology expert been part of the process, then the draft recommendations would have more accurately reflected currently accepted medical practice and standard of care. We request that on future recommendations that involve genetic testing, that a molecular pathology expert be engaged throughout the process with USPSTF.

Thank you very much for the opportunity to submit these comments for your consideration. If we may be of further assistance, please contact Tara Burke, AMP Senior Director of Public Policy and Advocacy at tburke@amp.org.

Sincerely,

Victoria M. Pratt, PhD, FACMG
President, Association for Molecular Pathology