Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation: Evidence Synthesis Number 101

U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: Systematic Review to Update the U.S. Preventive Services Task Force Recommendation: Evidence Synthesis Number 101 U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality This systematic review is an update of the evidence for the U.S. Preventive Services Task Force (USPSTF) on the effectiveness and adverse effects of risk assessment, genetic counseling, and genetic testing for breast cancer susceptibility gene (BRCA)–related cancer in women who do not have cancer but are potentially at increased risk. Its purpose is to evaluate and summarize evidence addressing specific key questions important to the USPSTF as it considers new recommendations for primary care practice. In 2005, based on results of a previous review, the USPSTF recommended against routine referral for genetic counseling or routine BRCA testing for women whose family histories are not associated with increased risks for deleterious mutations in breast cancer susceptibility gene 1 (BRCA1) or breast cancer susceptibility gene 2 (BRCA2) (D recommendation). The USPSTF also recommended that women whose family histories are associated with increased risks for mutations in the BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing (B recommendation). The USPSTF concluded that the potential harms of routine referral for genetic counseling or BRCA mutation testing in women without family history risk outweigh the benefits, and that the benefits of referring women with family history risk to suitably trained health care providers outweigh the harms. Benefits included improved accuracy of risk assessment and pretest probability for testing and improved patient knowledge, risk perception, and psychological and health outcomes. Potential harms included inaccurate risk assessment; inappropriate testing; misinterpretation of test results; and ethical, legal, and social implications; among others. The 2005 USPSTF recommendation was intended for the primary prevention of cancer and applied to women without previous diagnoses of breast or ovarian cancer, consistent with the USPSTF scope of preventive care for the general population. Recommendations for men and women with cancer were not included. The 2005 USPSTF recommendation is included in the Affordable Care Act for covered preventive services, and provided the basis for a Healthy People 2020 objective to increase the proportion of women with family histories of breast or ovarian cancer who receive genetic counseling. The previous systematic review identified several research limitations and evidence gaps. The review concluded that a primary care approach to genetic risk assessment and BRCA mutation testing had not been evaluated, and evidence was lacking to determine the benefits and harms of this approach for women without cancer. Risk assessment, genetic counseling, and mutation testing did not cause adverse psychological outcomes, and counseling improved distress and risk perception in the highly-selected populations studied. Studies of intensive cancer screening approaches, such as earlier and more frequent mammography, were inconclusive. Trials of risk-reducing medications, such as tamoxifen and raloxifene, reported reduced breast cancer incidence in women with varying baseline levels of risk compared with placebo, but also increased adverse effects. Observational studies of risk-reducing mastectomy and salpingooophorectomy reported reduced breast and ovarian cancer outcomes in women who were mutation carriers.

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