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Breast cancer testing guidelines; outdated?

The guidelines for the genetic testing of breast cancer patients were established about ▲ 20 years ago by the National Comprehensive Cancer Network, (NCCN), a nonprofit alliance of 28 cancer centers dedicated to improving patient care. Current guidelines for genetic testing of breast cancer are decades old and outdated, leaving many people atrisk for the disease unable to get tested, according to a study in the Journal of Clinical Oncology. However, because of outdated screening guidelines, some of these patients may never know their risk. Genetic testing of breast cancer patients limit the number of women who can get tested. Because of these restrictions, these tests miss as many patients with hereditary cancers as they find, according to study published by the Journal of Clinical Oncology. The result: Patients without genetic test results might not receive the appropriate treatment for their cancer, which could be a matter of life or death. Approximately 330,000 patients re-diagnosed with breast cancer every year in the United States and of these cases, an estimated 10% are likely due to hereditary causes. In 1999, doctors tested only for BRCA 1 and BRCA 2, tumor suppressor genes found in everyone. A defect or mutation in one or both of those genes increases the likelihood of breast cancer. Since then it has become known that 11 "major" gene mutations, including BRCA 1 and BRCA 2, can cause breast cancer, while 25 or 30 other genetic variants are also linked to the disease. Meanwhile, genetic testing "radically changed". It went from a difficult-to-do, and expensive, test to a quite inexpensive test; "The cost dropped from, say, \$5,000 for two genes to now we're doing 80 genes for about \$250." Despite their evolution, the guidelines became increasingly difficult to work with, if not unusable researchers claim. Researchers examined about one thousand female breast cancer patients, half who met the criteria sanctioned by the NCCN, the other half who did not. Among the 959 participants, all underwent a full panel of DNA testing for hereditary breast cancer. Based on recent studies, the results showed that 83 women, or 8.65 percent of the total participants, had breast cancer-linked genetic defects. Of these women, 45 met the National Comprehensive Cancer Network's criteria for testing, while 38 women did not. Ordinarily, these 38 women would not have been tested.



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Biography

Sandra Acosta has completed her BS Biology/Industrial Microbiology with Minor Degree in Music and Statistics with more than thirty (30+) years of extensive experience and expertise in validation principles, QA, GMP, Quality compliance, Engineering, regulatory in the Biotechnology/Pharmaceutical fields. She served fifteen years in the consulting business as a Scientist Consultant, Manager, and Director, within the Biotechnology/Pharmaceutical fields, Food, Spirits/beverage, Agriculture, Environmental, Medical, Cell-Therapy, OTC Cosmetic and Research Industries throughout her professional career. She participates as a workshop speaker within different disciplines of expertise within the Biotech/Pharmaceutical industries trends and most modern practices. She has ten years of experience in regulatory field between global marketing authorizations and plant documents/practices and more than ten years in Biotech/Pharma in addition of twenty years of experience in cGMP's, and global regulations. She participates in business unit adjudication processes and action plan execution in conjunction with Quality Units, and closely interfaces with stakeholders/FDA, managing multicultural professional groups in US/EU.

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