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ALEXANDRIA, Va. – The American Society of Clinical Oncology (ASCO) today issued an updated policy statement on genetic and genomic testing for cancer susceptibility. Published in the Journal of Clinical Oncology, the statement reviews the ways in which new technologies are transforming the assessment and identification of inherited cancer susceptibility, and makes a series of recommendations for the optimal deployment of these technologies in oncology practice.

“The sequencing and mapping of the human genome, one of science’s greatest modern feats, has launched an age of tremendous discovery and hope in the fight against cancer,” said ASCO President Julie M Vose, MD, MBA, FASCO. “As cancer diagnosis and treatment is becoming more genetically-driven, new opportunities and questions are emerging about screening for hereditary cancers. ASCO is releasing this updated policy statement at this critical juncture to ensure that all interested parties thoughtfully consider these concerns as the future of genetic and genomic testing for cancer susceptibility unfolds.”

Groundbreaking Genetics Technology Driving Cancer Care Breakthroughs

Powerful technologies have emerged to help identify inherited genetic mutations that increase an individual’s risk to develop cancer and, for individuals who have cancer, help identify tumor mutations that are associated with response to specific therapeutic agents. (As many as 10 percent of all cancers may be associated with an inherited mutation that contributes to cancer development.)

Genetic and genomic testing has become a major area of oncology research and therapy development, with the ultimate goal of improving patient outcomes. But, as ASCO notes in its updated statement, “new technology is introducing great complexity,” and presenting significant
implications for patients, providers, policy makers, and the entire healthcare system.

One such technology is “next generation” sequencing (NGS), which permits the cataloging of DNA sequence variations within a patient’s cancer much more quickly and at lower cost than traditional methods. When applied to tumors, “somatic mutation profiling” by NGS can identify therapeutic targets and improve patient outcomes when specific therapies are directed at those targets. At the same time, NGS can identify germ-line mutations, variations that are inherited and transmitted to offspring, challenging current cancer care practices of counseling and testing for inherited cancer susceptibility.

“Current cancer diagnosis and treatment is now tightly linked to our expanded understanding of what is happening at the genetic level of cancer,” said Mark E. Robson, MD, Chair of ASCO’s Ethics Committee and lead author of the ASCO policy statement. “As this promising field moves forward, we must ensure that providers are well versed in the diagnostic and treatment options available, that patients have access to genetic testing that identifies hereditary risk, and that these tests have appropriate regulatory oversight.”

ASCO Recommendations

“Genetic and Genomic Testing for Cancer Susceptibility,” the ASCO updated policy statement developed by ASCO’s Cancer Prevention and Ethics committees, reviews and makes recommendations in the following five key areas:

1. Germ-line Implications of Somatic Mutation Profiling

Recommends: ASCO calls for further research to develop best practices for the delivery of incidental and secondary germ-line findings. The Society also encourages research aimed at improving understanding of patient preferences, optimal pre-test education and informed consent, and multilevel outcomes (i.e., patient, provider, health care system delivery, and cost) in this area. Further, ASCO recommends that laboratories choosing to conduct secondary analyses should develop mechanisms to report only somatic results for patients who decline to receive germ-line findings.

Background: Although the primary purpose of somatic mutation tumor profiling or NGS is identification of tumor variants to inform therapeutic options, germ-line variants may also be identified by these tests. ASCO recommends that patients be educated before testing about the possibility that germline variants might be identified and that providers communicate the limitations and risks of receiving germ-line findings.
2. Multi-gene Panel Testing for Cancer Susceptibility

Recommendations: ASCO asserts that providers with particular expertise in cancer risk assessment should be involved in ordering and interpreting multi-gene panels that include genes of uncertain clinical utility and genes not suggested by the patient’s personal and/or family history. Further, ASCO encourages research to delineate the optimal use of panel-based testing, development of evidence-based practice guidelines as data emerges, and education of providers on the challenges of using these tests.

Background: Multi-gene panel testing, using NGS technology, looks at a number of genes at the same time making it possible to find the cause of an inherited cancer more quickly—offering time and cost efficiency, a decrease in testing fatigue for patients and providers, and other advantages. Multi-gene panels increase the likelihood of identifying genetic factors that predispose individuals to cancer risk, but these tests also may identify unexpected cancer risks or risk of other diseases, mutations with unclear cancer care recommendations, and variants of uncertain significance. ASCO raises the possibility of harm to the patient, including the potential for inappropriate medical intervention and psychological stress, and underscores the need for providers to review with patients the purpose of this test and its associated risks, and to receive educated pre-test consent from patients.

3. Quality Assurance in Genetic Testing

Recommendations: ASCO recommends appropriate regulation of tests that detect inherited genetic variants and supports a risk-based approach to FDA regulation for laboratory-developed tests and commercial tests—in a manner that does not compromise innovation or limit patient access to testing. High-quality standards should be adopted that allow providers and patients to understand the accuracy, benefits, and limitations of genetic tests conducted by individual laboratories.

Background: Since the year 2000, explosive growth has occurred in new genetic diagnostic tests. More than 200 genetic tests are currently available to help determine risk of developing a variety of different cancers. Laboratories performing these tests use different classification and reporting methods leading to difficulties in interpretation of results by providers and patients. ASCO asserts that the absence of a uniform regulatory framework for new genetic sequencing technology could lead to compromises in patient care. Further, ASCO supports efforts to catalog and annotate all genomic variants and to create rigorously curated, open access libraries of the variants for use by all laboratories.
4. Education for Oncology Professionals

Recommendations: ASCO recommends continued education of oncologists and other healthcare professionals in cancer risk assessment and the management of individuals with inherited predisposition to cancer. Further, ASCO recommends that oncology training programs develop a set of core skills for new trainees and ensure adequate time for achieving these skills.

Background: ASCO notes that the skills required to provide cancer risk assessment services are not specific to a particular discipline, but incorporate elements from oncology, medical genetics/genetic counseling, and other fields. Oncologists are optimally positioned, however, to advise patients regarding the management of their primary cancer and also regarding the risk of second malignancies and treatment-related cancers. In fact, germ-line risk assessment is regularly integrated into standard oncology practice. Although the identification and management of individuals at increased hereditary cancer risk is a core oncology competency, the work of oncologists today requires a level of knowledge about genetics that exceeds what most received during training. For oncologists participating in clinical practice who have completed oncology training, ASCO stresses that continuing medical education is crucial to maintaining an up-to-date understanding of the complex field of oncology and the changing environment for evaluating and treating neoplastic disease.

5. Access to Cancer Genetics Services

Recommendations: ASCO calls for coverage policies that support access to cancer risk assessment and prevention services for individuals who are suspected to be at increased genetic risk. Further, ASCO opposes any payment policies that have the potential to negatively impact the care of cancer patients by serving as a barrier to the appropriate use of genetic testing services.

Background: ASCO is committed to ensuring access to high-quality cancer genetic services and supports continued expansion of third-party reimbursement of evidence-based genetic and genomic tests and preventive care in keeping with the rapid pace of scientific advances. Coverage of cancer genetic counseling and testing has improved over the last several years, but some payers still provide inadequate access to these services. In addition to ensuring adequate coverage, ASCO is committed to ensuring coverage restrictions are not imposed that limit patient access to cancer genetics services. ASCO continues to support pre- and post-testing counseling when a patient is considered to be at risk for a hereditary susceptibility for cancer by a qualified health professional so that patients have the benefit of informed decision-making regarding genetic testing.
ASCOT Leadership Underscores Importance of Updated Policy Statement

Published in the same issue of the *Journal of Clinical Oncology*, an accompanying editorial by ASCO volunteer leaders notes that the “increase in genetic sequencing capability combined with the decrease in the cost of testing has altered both regulatory policy and clinical practice and led to this ASCO policy statement update.” ASCO President Julie M. Vose, MD, MBA, FASCO, Past-President Peter Yu, MD, FACP, FASCO, and President-Elect Daniel F. Hayes, MD, FASCO, write that “Robust discussions among a diverse set of stakeholders will be needed to ensure that all perspectives are listened to and that genetic cancer susceptibility services are comprehensive and patient-centric.”

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**About ASCO:**

Founded in 1964, the American Society of Clinical Oncology (ASCO) is the world’s leading professional organization representing physicians who care for people with cancer. With nearly 40,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds groundbreaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit asco.org. Patient-oriented cancer information is available at Cancer.Net.