that includes samples from patients with benign lesions that mimic cancer.

"If the performance characteristics are sufficient, I think it will be something that should be relatively easy to implement as part of care, and that is very appealing," he says. –*Catherine Caruso* ■

ctDNA Analysis for Cancer? Not So Fast

In 2016, the FDA approved the first test to analyze circulating tumor DNA (ctDNA)—one that detects *EGFR* mutations in patients with non–small cell lung cancer. In addition, many clinicians use more comprehensive but non–FDA-approved ctDNA panels, offered by companies such as Guardant Health and Foundation Medicine, to guide treatment decisions. Recently, however, experts reviewed evidence of the clinical validity and utility of ctDNA testing, warning that more research is needed before these tests become standard practice (J Clin Oncol 2018 Mar 5 [Epub ahead of print]).

"There has been a proliferation of potential tests with little or no discipline regarding how to do them, when to do them, or how to use them," says Daniel F. Hayes, MD, of the University of Michigan Comprehensive Cancer Center in Ann Arbor, a member of the expert panel convened by the American Society of Clinical Oncology and the College of American Pathologists.

He explains that laboratory-developed tests, including many ctDNA assays, do not need FDA approval if they are performed in Clinical Laboratory Improvement Amendments–approved laboratories. This means that clinicians lack FDA guidance about when to order such tests.

"Frankly, I hope this will make clinicians a bit more wary of ordering a test without knowing its accuracy or whether it has clinical utility," says Hayes. "More importantly, I hope it will help set a road map for clinical research to answer these questions."

Chris Abbosh, MB, of the University College London Cancer Institute in the UK, who did not participate in the review, says that one of the expert panel's most valuable contributions was its discussion of how blood samples should be handled prior to analysis.

"Significant variability can be introduced into ctDNA analyses through differences in sample handling," he explains. For example, avoiding white blood cell lysis is important to prevent ctDNA from being diluted with normal cellular DNA, which can compromise ctDNA detection. The type of blood collection tube and the time it takes to process a sample can both affect white blood cell stability, but no head-to-head comparison of all tube types used has yet been reported. More research is needed, but "this is a first step toward a consensus statement for how blood for cell-free DNA extraction should be handled, processed, and stored."

Abbosh concurs with the panel's cautious take on the utility of ctDNA assays, explaining that although research has showcased the potential of ctDNA to improve cancer care in a variety of ways, the review is a "call to arms for clinical researchers to design and carry out ambitious studies to translate progress in the research setting into clinical benefit for patients."

Alberto Bardelli, PhD, of the University of Torino in Italy, who also did not participate in the evidence review, believes that despite the research challenges, ctDNA testing will change clinical practice in the next decade, most likely by allowing clinicians to monitor residual disease in patients who have undergone surgery for colon or breast cancer.

However, he wonders how the ambitious studies needed to establish the utility of ctDNA testing will be funded—whereas pharmaceutical companies have the resources and motivation to fund large drug trials, supporters for large ctDNA studies are scarce. "How do we prove that ctDNA tests work? Will trials be funded by the industries that promote ctDNA testing? Or the health systems that decide to invest in ctDNA testing?" asks Bardelli. "I think this needs to be discussed openly if we want to demonstrate the clinical validity of ctDNA tests." –*Kristin Harper* ■

For more news on cancer research, visit *Cancer Discovery* online at http://cancerdiscovery.aacrjournals.org/CDNews.

NOTED

Congress approved a **federal budget for fiscal year 2018 that will include a $3 billion increase for the NIH,** bringing the agency's budget to $37.1 billion. The NCI will receive $5.965 billion, including $300 million designated for the National Cancer Moonshot Initiative through the 21st Century Cures Act. The FDA's Oncology Center of Excellence will receive $15 million.

Gynecologic cancer research is disproportionately underfunded. In an analysis of funding for 13 common cancers presented at the Society of Gynecologic Oncology Annual Meeting on Women's Cancer in New Orleans, LA, ovarian, cervical, and uterine cancers ranked 9th, 10th, and 12th, respectively. Ovarian cancer had a mean expenditure of $85,000 per year of life lost per 100 new cases, compared with a mean of $1.81 million for prostate cancer.

The American Association for Cancer Research (AACR) launched the "2020 by 2020" initiative to improve understanding of cancer outcomes for African-Americans. The initiative aims, by 2020, to combine genetic sequencing data from tumor and normal tissue samples from 2,020 African-American patients with their clinical records.

Chlamydia is associated with increased risk of ovarian cancer, according to findings presented during a media preview for the AACR Annual Meeting 2018. Researchers established that women who had antibodies against the protein pgp3, which is a highly accurate marker for chlamydia, were twice as likely to have been diagnosed with ovarian cancer as those lacking the antibodies.

Several public health organizations are suing the FDA for delaying regulation of electronic cigarettes (e-cigarettes) and cigars. The lawsuit challenges the agency's decision to extend the deadline for manufacturers to submit product-review applications to the FDA from August 2018 to August 2021 for cigars and August 2022 for e-cigarettes.

The University of Michigan Comprehensive Cancer Center received a $150 million gift from Richard and Susan Rogel. The money will support cancer research through various avenues including grants, endowed professorships, and scholarship assistance for scientists-in-training.

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