G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

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Emerging Tests: New Genetic Tests May Be Better than PSA Screening in Assessing Prostate Cancer Risk

The U.S. Preventive Services Task Force (USPTF) recommends that men age 55 to 65 consider prostate cancer screening based on their specific circumstances. The reason that the USPTF does not directly recommend testing for every man in this age group is that current prostate specific antigen (PSA) screening methods are notoriously unreliable. But things may be changing thanks to the emergence of new genetic tests that rely on more sophisticated biomarker detection and algorithmic analysis to assess prostate cancer risk. In addition to the urine testing products currently on the market, last month, the U.S. Food and Drug Administration (FDA) cleared the way for final approval of a new blood-based assay shown to be more accurate than traditional PSA tests.

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Test Utilization: 'Cascades of Care' Cause Wasteful, Unnecessary and Anxiety-Producing Testing

Experts estimate that $200 billion is wasted annually on excessive testing and treatment. The typical dynamic is a chain reaction: Something "comes up" on diagnostic tests or screenings and triggers "cascades" of further testing and treatment. Thus, for example, 52% of radiology and laboratory tests produce incidental findings that result in further screenings and tests. In some cases, further evaluation of these findings may reveal a clinically important and intervenable discovery, such as an early-stage cancer. More often, however, subsequent evaluations find nothing significant.

A new national survey finds that 99% of physicians have experienced cascades of care firsthand and that when they happen their patients experience psychological harm, physical harm and financial burden—in addition to the frustration and anxiety physicians feel themselves. The findings were published in JAMA Network Open (the Study). Policy makers and health care leaders

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New Genetic Tests May Be Better than PSA Screening in Assessing Prostate Cancer Risk, *from page 1*

Problems with PSA Screening

The current PSA test can detect high levels of the prostate-specific antigen protein in the blood. The problem is in interpreting the results. Stated simply, PSA is not a reliable biomarker. High levels of PSA could be a sign of not only prostate cancer but infection, inflammation or other disease. In some cases, high PSA is caused not by disease but just the common age-related condition of an enlarged prostate gland. But given the risks involved, when screening tests show high PSA levels, biopsies are ordered to rule out cancer. Not surprisingly, a large percentage of these biopsies prove unnecessary.

Another problem with PSA testing is that it over-detects for low-grade cancer that does not pose a threat to the patient. This can result in treatment that leads to erectile dysfunction, urinary incontinence, and other side effects that do more harm than the cancer.

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The New Blood-Based PSA Test

On Oct. 17, 2019, Cleveland Diagnostics, Inc., a company partly owned by the Cleveland Clinic dedicated to developing next-generation diagnostic tests for early cancer detection, announced it has received FDA breakthrough device designation for a test that uses a new and more accurate methodology for detecting prostate cancer risk: The so-called IsoPSA test does not simply measure PSA levels but evaluates structural changes to the PSA protein. Specifically, the test accounts for the fact that not all PSA is created equal. The protein comes in different isoforms, i.e., similar but non-identical amino acid sequences. The presence, number, and nature of these isoforms is related to the disordered metabolism of cancer cells.

What distinguishes IsoPSA from other commercially available tests is its ability to measure all the different PSA isoforms in a serum tightly linked to prostate cancer. As a result, it allows for more accurate differentiation between cancer and non-cancerous conditions; it is also capable of identifying whether cancer detected is serious and needs to be treated or is benign enough to be left under what the urology community describes as "active surveillance" without biopsy or treatment.

The early results suggest that the test is effective in reducing both unnecessary biopsies and false positives. In a 2018 study of 271 men published in the *Journal of Urology*, use of IsoPSA was associated with a 43% reduction in the number of unnecessary biopsies. This study followed an earlier one linking IsoPSA to either a 45% or 48% reduction in false-positive rates, depending on whether the cutoff was selected to recommend biopsy or identify people at low risk of high-grade disease.

Commercialization of IsoPSA

These studies and other evidence were instrumental in the FDA's decision

to grant breakthrough designation to IsoPSA. "We are very grateful that FDA recognizes the potential of IsoPSA," noted Cleveland Diagnostics CEO **Arnon Chait**. Securing FDA breakthrough designation expedites the approval process and brings the company significantly close to its goal of getting final approval to market the test in the U.S. in 2020. "We look forward to working closely with FDA to expedite the appropriate approvals and get this important new test into the hands of physicians," Dr. Chait said.

Other Genetic Early Prostate Cancer Detection Tests on the Market

Of course, when and if it reaches the market, IsoPSA would not be the only commercially available biomarker prostate cancer test designed to help patients avoid unnecessary biopsies. Others include:

- Prostate Health Index (PHI) (Beckman Coulter), which uses a mathematical formula calculating prostate cancer probability by combining PSA, free PSA and p2PSA tests into a single score;
- 4Kscore (OPKO Health), which calculates a patient's percentage risk for aggressive prostate cancer by combining four prostate-specific kallikrein assay results with clinical information in an algorithm;
- SelectMDx (MDxHealth), a urine test that measures the expression of two mRNA cancer-related biomarkers that, when combined with the patient's clinical risk factors, provides a score assessing whether patient needs a biopsy or active surveillance;
- ExoDx Prostate (IntelliScore), aka, The EPI Test (Exosome Diagnostics), which analyzes a urine sample for three biomarkers of aggressive prostate cancer and uses an algorithm to assess the results and generate a score for use in determining whether a biopsy is necessary; and
- Mi-Prostate Score (MiPS) (Michigan Medicine), which combines the amount of serum PSA with the amounts of two genes for prostate cancer in the patient's urine for early prostate cancer detection.

Testing Trends: New Study Suggests Blood Testing May Be Capable of Diagnosing PTSD

As post-traumatic stress disorder (PTSD) becomes more widespread, it may be becoming easier to diagnose. A new study suggests that it may soon be possible to detect PTSD by using a quick blood test instead of current diagnosis methods which rely on the results of complex psychological tests.

The PTSD Diagnostic Challenge

PTSD is precipitated by experiencing or witnessing actual or threatened

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death, serious injury or violence. Symptoms include re-experiencing, avoidance, negative thoughts or moods associated with the traumatic event and hyperarousal. War veterans exposed to combat are particularly vulnerable to PTSD. Defense Department and Veterans Affairs researchers estimate that as many as 25 percent of the individuals who served in combat zones in Iraq or Afghanistan suffer from PTSD.

Current methods of PTSD identification rely on self-reported symptoms and psychological testing. However, diagnosis is problematic due to biases in self-disclosure of symptoms, stigma within military populations, and limitations identifying those at risk. Personalized treatment selection is limited by errors of omission (failing to identify individuals who would likely benefit from a specific behavioral or biological treatment) and errors of commission (treating individuals who are unlikely to benefit from a specific treatment), in part because of the lack of validated diagnostic and prognostic markers.

The Study

Past studies have hinted at blood markers as a potential indicator of PTSD. The new study, which was published in the September issue of the *Journal of Molecular Psychiatry*, was a six-year project led by the NYU School of Medicine, the Harvard John A. Paulson School of Engineering and Applied Sciences and the U.S. Army Medical Research and Development Command to evaluate this diagnostic potential more thoroughly.

The Methodology

The researchers tracked blood samples from 165 war-zone deployed veterans, all of them male, recruited from the Manhattan, Bronx and Brooklyn Veterans Affairs (VA) Medical Centers, as well as from other regional VA medical centers, veterans' service organizations and the community. half of whom suffer from PTSD. The participants included 83 veterans of the Iraq and Afghanistan conflicts with confirmed PTSD and another 82 veterans serving as healthy controls. The researchers studied their medical histories and biochemistry, trimming down the list of potential identifying characteristics in their blood.

By measuring a large number of unbiased quantities, the team sought to determine which of them were associated with an accurate PTSD symptom diagnosis. The researchers tested nearly one million features with current genomic and other molecular tests and narrowed them to 28 markers, with the final group outperforming the larger groups in prediction accuracy.

The Findings

The team then applied their "PTSD blood test" to an independent group of veterans to see how well their new tool matched the diagnoses made

previously using standard clinical questionnaires like the Clinician Administered PTSD Scale (CAPS). This comparison yielded a 77 percent accuracy figure. Researchers believe that is sufficient for a potential screening test, with doctors following up the results of the blood test with in-depth examinations to confirm the PTSD diagnosis.

Takeaway: This is the first time a coherent set of measures has been detected for using blood markers to identify PTSD. While work remains to further validate the findings, the study authors believe it holds tremendous promise as the first blood test that can screen for PTSD with a level of accuracy useful in the clinical setting.

Kellison Public Service Award: Kellison and G2 Intelligence Honor Dr. Sidney Goldblatt

Dr. Sidney Goldblatt, MD, is the 2019 recipient of the Kellison Public Service Award. Dr. Goldblatt has been founder, medical director and CEO of Molecular Dx; founder and CEO of Goldblatt Systems; founder and expert pathologist for ForensicDx; and founder and CEO of Goldblatt Pathology Associates.

The award recognizes the dedication of his life and career as a medical doctor, pathologist, scientist, and entrepreneur to making health care better and to enable data-driven medical discovery. (Pictured here are **Scott Liff**, president and CEO of Kellison and Company; **Laura Voeghtly**, Chief Scientist at MolecularDx, who accepted the award on behalf of Dr. Goldblatt; and **Jonathan Ziebarth** of G2 Intelligence. The presentation was made at Lab Institute 2019, a conference presented by G2 Intelligence in November in Washington, D.C.)

After graduating from Temple Medical School, Dr. Goldblatt joined the NIH as a researcher. Later, as chairman at Conemaugh Memorial, he worked with the founder of digital equipment corporation to build one of the industry's first laboratory information systems, CliniLab. In 1979, he founded Sunquest Information Systems to enable the creation of clinical laboratory data to support patient care.

To facilitate inter-operability, Sunquest worked with UCSF and OAIS to deliver on the earliest implementation of HL7 transactions. Following

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Kellison and G2 Intelligence Honor Dr. Sidney Goldblattl, *from page 5*

the sale of Sunquest in 2001, Dr. Goldblatt began developing a clinical semantic network (CSN) to bring the same data paradigm to electronic medical records. The Clinical Semantic Network grew out of Dr. Goldblatt's work with SNOMED when he was working as the Governor of the College of American Pathologists. Delivered as a patient engagement tool, the CSN allows patients, caregivers, clinicians, and physicians to work together in using data to deliver a new model of health care.

Dr. Sidney Goldblatt, MD

In addition to his work at the CAP, Dr. Goldblatt was a Fellow at the National Cancer Institute where, as head of comparative cytology activities, he led the team creating the cytoanalyzer, automating PAP smear screening. He has also been an administrator and board member of a large community health system. As founder of MolecularDx, he is delivering molecular diagnostics and genomic data to precision medicine. Finally, his dedication to making health care better has also led to the creating of ForensicDx, an advanced forensic science center using technology such as CT and LODOX full body digital imaging, mass spectrometry, and NGS to study potential solutions to the current opioid crisis.

"These activities and accomplishments highlight the incredible passion and dedication Dr. Goldblatt has brought to the lab industry throughout his incredible career," said Kellison's Scott Liff in presenting the award at Lab Institute 2019.

Testing Trends: The Debate Continues Over Regular Colorectal Screening for Average Risk Adults

Should adults age 50 to 75 who are at average risk and show no symptoms of colorectal cancer have regular colorectal screening exams? Last month, a major medical journal came out against regular screening. But just a few weeks later, the powerful and influential American College of Physicians (ACP) issued New Guidance in favor of regular screening, the same position taken by the American Cancer Society (ACS) a year earlier. Here is a rundown of the ACP's recommendations.

To Screen or Not To Screen

Colorectal cancer is the second leading cause of cancer-related death in

U.S. adults. After declining overall from 1970 to 2004, colorectal cancer death rates among 20- to 54-year-old adults climbed by 1% annually from 2004 to 2014, according to a 2017 study published in the medical journal *JAMA*.

In May 2018, the ACS issued guidance recommending that average-risk adults start regular screening at age 45, diverging from the previous consensus recommendations that screening begin at age 50. Adding to the debate, in early October 2019, The BMJ issued guidelines recommending against colorectal cancer screening in healthy people aged 50 to 79 who are at low risk for the disease, citing a lack of evidence that the practice benefits this population. The journal did, however, recommend screening for people in this age group who have a 3 percent or greater colorectal cancer risk. For more on The BMJ recommendations, see *Diagnostic Trends and Emerging Technology (DTET)*, Oct. 16, 2019.

The question of how colorectal screening should be performed has also been subject to debate. Recommended screening methods include fecal-based tests, colonoscopy and sigmoidoscopy.

While the consensus view is that colonoscopy should be used as the primary screening tool, the Canadian Task Force on Preventive Health Care recommends not using colonoscopy as a primary screening test.

The ACP Weighs In

After analyzing the conflicting recommendations, the ACP issued guidelines published in the Annals of Internal Medicine in early November 2019 recommending regular colorectal cancer screening for asymptomatic adults age 50 to 75 who are at average risk for the disease. ACP defines "average-risk individuals" as those without a personal or family history of colorectal cancer, a long-standing history of inflammatory bowel disease or genetic syndromes such as familial adenomatous polyposis. Adults with a higher risk or family history of the disease should speak to their doctor and get screened more regularly, the ACP adds.

Relying on direct evidence from research studies over modeling data, the ACP's clinical guidelines committee (CGC) declined to recommend any one screening approach over the others since none of the reviewed guidelines directly compared screening interventions. "All screening tests are associated with potential benefits as well as harms," according to the CGC. It recommends that doctors and patients make individual decisions on selection of test methods based on benefits, harms, costs, availability, frequency and patient preferences.

However, the ACP did make recommendations on screening intervals depending on method, including:

- Fecal immunochemical test (FIT) or high sensitivity guaiac-based fecal occult blood test (gFOBT): every two years;

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The Debate Continues Over Regular Colorectal Screening for Average Risk Adults, *from page 7*

- Colonoscopy: every 10 years
- Flexible sigmoidoscopy: every 10 years with an FIT every two years.

Takeaway: Regular colorectal cancer screening for average, asymptomatic adults between age 50 and 75 remains a hotly debated topic. In the past 18 months, no fewer than three heavyweights have weighed in on the issue and offered conflicting recommendations.

The Scorecard:

- *American Cancer Society (May 2018): Yes*
- *The BMJ (October 2019): No*
- *American College of Physicians (November 2019): Yes*

FDA Watch: FDA Unveils New Process for Streamlined Review of IVD Tests Used in Cancer Drug Trials

Typically, in vitro diagnostic (IVDs) tests used in investigational cancer drug trials require two submissions: one for the IVD test and another for the drug. But on Oct. 9, 2019, the US Food and Drug Administration (FDA) issued final guidance setting out a streamlined process that allows companies to apply to have the IVD test involved in a cancer drug trial reviewed simultaneously with the drug itself.

The New Streamlined Cancer Drug Process

The new streamlined process is optional but the FDA "encourages sponsors to use it . . . when possible to reduce administrative burden on sponsors and FDA and to maintain the current level of regulatory approval." the agency said in its final guidance. Sponsors submit to the Center for Devices and Radiological Health (CDER) or Center for Biologics Evaluation and Research (CBER) all information about the oncology codevelopment program (including information about the investigational IVD) in the trial protocol for the investigational new drug application (IND).

One sponsor should take the lead in communicating with FDA about the IND. To indicate its intent to use the streamlined process, the sponsor should include the text "Streamlined IVD SRD" in either:

- In Section 11 (under "Other") of the Form FDA 1571, Investigational New Drug Application; or

- The cover letter it submits with the IND (along with a reference to which section(s) of the electronic common technical document contains relevant information).

The final guidance also lists the additional information about the IVD and how it will be used in the trial that the sponsor should list in the protocol it submits for the IND, including:

- A description of the device;
- How the results from the investigational IVD will be applied in the clinical trial;
- A description of the population and information regarding what is known about the prevalence of the biomarker (evaluated by the investigational IVD) in the patient population;
- The specimen type that will be collected for investigational IVD testing (including the anatomical site) and whether any biopsy conducted exclusively for investigational IVD testing could present a potential for serious risk to the health, safety, or welfare of the subject.

By signing Form FDA 1571 (section 17) sponsors provide assurance of an institutional review board review of the complete clinical trial protocol and activities for the investigational IVD and the investigational drug, the final guidance specifies.

The CBER or CDER will then use the information to determine as part of the IND review and within the 30-day review period whether use of the IVD is significant risk (SR), nonsignificant risk (NSR) or exempt from investigational device exemption (IDE) requirements.

Determination	Consequence
NSR	• CBER or CDER confirms determination in appendix to Study May Proceed Letter + reminds sponsor to follow NSR procedures in obtaining biopsies for testing + submit unanticipated adverse device effect reports to IND
SR	• CBER or CDER confirms determination in appendix to Study May Proceed Letter + asks sponsor to submit IDE application to CBER or Center for Devices and Radiological Health (CDRH) + not start trial until after IDE is approved
Exempt	• CBER or CDER confirms determination in appendix to Study May Proceed Letter

FDA Watch: Agency Resounds the Alarm on Biotin Test Interference

In early November 2019, the U.S. Food and Drug Administration (FDA) updated a previous safety communication about the potential of biotin to significantly interfere with diagnostic tests. The update reiterates the warning to laboratory personnel, diagnostic test developers, providers, and patients that biotin can lead to incorrect lab test results.

Biotin Blinding

Biotin, or Vitamin B7, is a water-soluble vitamin commonly used as an ingredient in multi-vitamins, prenatal vitamins, and dietary supplements marketed for hair, skin and nail growth. Because biotin bonds with specific proteins that can be measured to detect certain health conditions, many laboratory tests rely on biotin-detection based methods and technology. The problem is that biotin can distort laboratory test results leading false highs and false lows, especially when tested patients consume high levels of biotin. And such high consumption is far from unusual given how much of it producers use. Thus, for example, dietary supplements may contain up to 650 times more biotin than recommended daily values.

FDA Reaction to Biotin Interference

In 2017, the FDA issued a safety communication addressing biotin interference with certain in vitro diagnostic tests and has since issued recommendations for laboratory personnel and test manufacturers to minimize the potential for interference. The FDA expressed specific concern about biotin interference resulting in falsely low levels of troponin—the biomarker that aids in diagnosis of heart attacks. Misleading diagnoses as a result of incorrect laboratory results could lead to potentially serious clinical implications, the FDA cautioned.

Since the 2017 safety communication, some laboratory test developers have been successful at minimizing biotin interference of their assays, according to the updated safety communication, but others have not yet addressed it. The troponin problem remains of particular concern as the FDA continues to receive adverse events reports indicating that biotin interference caused falsely low troponin results.

Visit the *Diagnostic Trends and Emerging Technology* website to read the rest of this story.

'Cascades of Care' Cause Wasteful, Unnecessary and Anxiety-Producing Testing, *from page 1*

should address cascades after incidental findings as part of efforts to improve health care value and reduce physician burnout, the Study recommends.

The Cascade Effect

The term "cascade" was coined to describe a sequence of events set irrevocably into motion after an incidental finding. Cascades are widely prevalent and often inevitable once an incidental finding is discovered. One study found that primary care physicians reported feeling "compelled but frustrated" to pursue the "quagmire" of costly follow-up evaluations for incidental findings that were unlikely to be significant.

The Study found that almost all US internists experienced cascades after incidental findings. Physicians reported that incidental findings frequently prompted telephone calls with patients and repeated tests; most had also seen their patients undergo new invasive tests, emergency department visits, and hospitalizations after an incidental finding. Many reported that they had experienced cascades as patients themselves. For the most part, the physicians reported that the cascades generally led to no clinically important or intervenable outcome for patients.

The Study

The Study was a population-based survey using data from a 44-item cross-sectional, online survey of 991 practicing US internists in a research panel representative of American College of Physicians national membership. The survey was emailed to panel members on Jan. 22, 2019, and analysis was performed from March 11 to May 27, 2019.

The Study achieved a 44.7% response rate and weighted responses to be nationally representative. Key findings:

- Almost all respondents—99.4%—reported experiencing cascades, including cascades with clinically important and intervenable outcomes (90.9%) and cascades with no such outcome (94.4%);
- When asked about their most recent cascade, 33.7% of 371 respondents reported the test revealing the incidental finding may not have been clinically appropriate.
- During this most recent cascade, 53.2% of physicians reported that guidelines for follow-up testing did not exist to their knowledge;
- To lessen the negative consequences of cascades, 376 respondents (62.8%) chose accessible guidelines and 44.6% chose decision aids as potential solutions;
- 69.1% of physicians reported that they wasted time and effort due to cascades as well as frustration (52.5%), and anxiety (45.4%);
- More than two-thirds (68.9%) of all respondents reported

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'Cascades of Care' Cause Wasteful, Unnecessary and Anxiety-Producing Testing, *from page 11*

experiencing at least one of these harms in the past year;

- Physicians working in rural areas and those who had greater discomfort with uncertainty were more likely to report experiencing at least one of these harms in the past year.

Potential Solutions to the Cascades Problem

One key intervention may be to avoid that initial test whenever possible. One-third of physicians in the Study reported that the initial test in their most recently experienced cascade may not have been clinically appropriate: harms are unlikely to be offset by any benefits from testing in such cases. Physicians themselves also suggested potential options to address cascades:

- 62.8% believed that accessible guidelines on how to manage incidental findings would help limit the negative consequences of cascades;
- 48.1% cited patient and clinician education on potential harms from unnecessary medical care as potentially beneficial;
- 44.6% recommended use of decision aids, i.e., shared decision-making tools; and
- 42.0% suggested that malpractice reform to alleviate physician liability concerns would help solve the problem.

Fewer physicians thought that patient cost-sharing (18.1%) or value-based payment models (16.2%) would help.

Takeaway: A lot of time, energy and money is wasted when something "comes up" during a screening or test, which more often than not turns out to be nothing. Both patients and doctors needlessly worry, and patients often have to endure additional financial burdens. New treatment guidelines and decision aids for incidental findings, as well as better education, could help alleviate the problem—saving both patients and doctors time and money.

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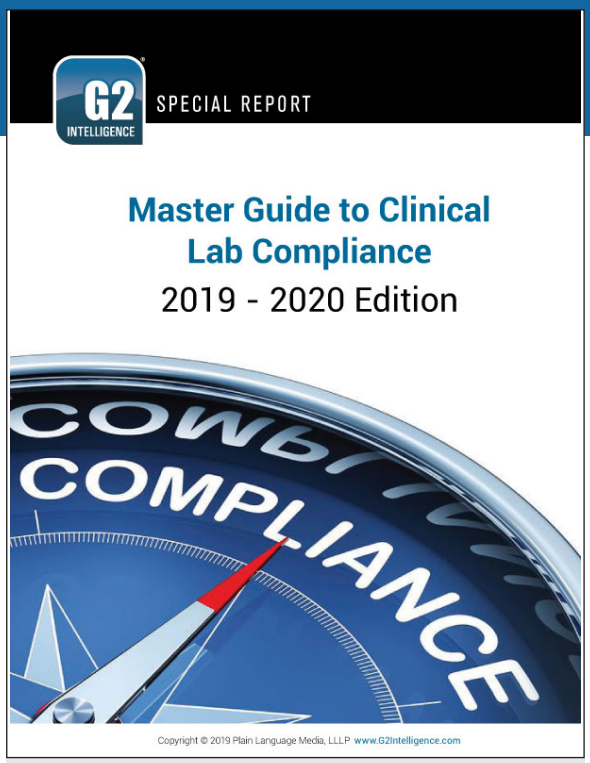

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