Put It on the Board, 1/15

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Digitized slides spur patient engagement, ‘allow for democratized medicine’

Regulatory and reimbursement hurdles are key factors blocking broader adoption of digital pathology. But the technology is already having an impact, enabling patients to grasp a firmer hold of the wheel in directing their care, said Keith J. Kaplan, MD, a pathologist and laboratory medical director in Charlotte, NC.

“This may be a little uncomfortable for some, but the idea is that digitized slides allow for democratized medicine and for patient and consumer access to their slides in an open and transparent fashion,” Dr. Kaplan said in a CAP TODAY webinar presented last month in collaboration with Ventana Medical Systems and available for viewing on demand at www.captodayonline.com/cap-today-hosted-webinars/#enhance.

Firsthand experience with this kind of openness shows what pathologists and their colleagues in cancer care should expect to see more of in the months and years ahead, Dr. Kaplan said. At a recent tumor board meeting, the oncologist directing the board announced minutes before its scheduled start that a patient would be sitting in.

“There was probably about 100 years of experience in that room, and when the oncologist said that for the first case to be discussed, the patient would actually be in that room with his wife, I think there was shock and awe on the part of everybody,” Dr. Kaplan said.

“It did change the dynamic a little bit. We used appropriate titles when addressing each other in the discussion, for example,” he said. “Speaking for myself, I was a little more nervous presenting the patient’s malignancy directly to him and his spouse sitting 10 feet away from me, rather than doing it in the lab with the closed door and having the LIS transmit that information.”

The patient had already been to tumor board meetings at two other health care organizations, and following this meeting opted to pursue his cancer care with Dr. Kaplan and his colleagues. Digitization of slides will make this patient engagement easier and more commonplace, he said.

“We should recognize that pathology images, the products we create from our slides, should be part of the longitudinal health care record,” he said. “You can also think about other models in terms of patients having direct access to remote specialists for secondary consultation that are not available today. It could create an open market system that allows for patient control. I think it’s coming.”

While that may sound threatening, Dr. Kaplan said this development also offers an opportunity for pathologists to communicate directly with patients and demonstrate their value as members of the health care team within the changing payment environment.

“With fee-for-service transitioning to a bundled payment system, there’s a role here for pathologists serving as patient advocates,” he said. They can provide slide reviews to families in conferences or one-on-one meetings as part of a “personalized, concierge-like service.”

“With the increasing use of mobile technologies, this is going to be patient-centric and consumer-driven,” said Dr. Kaplan, who publishes the Digital Pathology Blog at tissuepathology.com.

Whatever the impediments to digital pathology may be, the time it takes to capture slides as images is no longer one of them, Dr. Kaplan said. “The speed of scanning is not a rate-limiting step. Even five or 10 years ago, scan times were five to 10 times what they are today.” He reported that scan times of less than a minute at 40× magnification are now possible.

—Kevin B. O’Reilly

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POC syphilis test earns CLIA waiver

The FDA has granted a CLIA waiver for a rapid screening test for syphilis.

The test is performed using a sample of whole blood from a fingerstick. All positive tests should be followed up with further syphilis serological laboratory testing and clinical evaluation before final diagnosis, the FDA said. The rapid result—available in as few as 12 minutes—means that if a patient tests positive, a second blood sample can be obtained at the same office visit so the result can be confirmed through further lab testing.

The FDA first cleared the Syphilis Health Check test in 2011 and categorized it under CLIA as moderate and high complexity. The test was intended for use by prescription only to detect Treponema pallidum antibodies in serum, plasma, and human whole blood.

The FDA granted a waiver under CLIA for the Syphilis Health Check test after the manufacturer submitted data demonstrating the test’s ease of use and accuracy. The agency reviewed data for fingersticks of whole blood samples from 417 subjects collected over four months at three testing sites representing typical CLIA-waived sites, such as doctors’ offices. Twelve individuals not trained in the use of the test performed the tests on the study subjects.

The Syphilis Health Check test is manufactured by Veda Lab for Diagnostics Direct, based in Cape May Court House, NJ. Trinity Biotech also distributes it.

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Acute kidney injury risk test available

Ortho-Clinical Diagnostics has made available to hospitals its Nephrocheck Test System, which helps in identifying patients at risk of developing moderate or severe acute kidney injury within 12 hours of patient assessment.

The Nephrocheck test result, called the AKI risk score, has ability to distinguish patients with AKI from those without AKI. Based on results from clinical studies, patients with a positive AKI risk score—greater than the cutoff of 0.3—have a 25 to 33 percent chance of developing moderate or severe AKI within 12 hours of assessment. In clinical studies, the Nephrocheck identified the majority of patients who developed moderate to severe AKI within a half day.

To calculate the AKI risk score, the Nephrocheck system measures the concentrations of two urinary biomarkers using the Astute140 Meter. The two novel biomarkers—tissue inhibitor of metalloproteinase 2 and insulin-like growth factor binding protein 7—are thought to be involved in G1 cell cycle arrest in the earliest phases of injury.

OCD is the exclusive U.S. sales agent for the Nephrocheck test and the Astute140 Meter, both developed by Astute Medical.

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Focus' flu and RSV Direct kit cleared for more influenza strains

Focus Diagnostics' Simplexa Flu A/B & RSV Direct kit received FDA clearance for eight additional influenza strains. The FDA, which originally granted 510(k) clearance to the test kit in July 2012, cleared additional analytical reactivity to include flu A H7N9 and H3N2v, among other strains, based on studies that demonstrated the test's analytical performance.

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Roche acquires Bina, enters genomic informatics market

Roche acquired Bina Technologies, a privately held company in Redwood City, Calif., that provides a big data platform for centralized management and processing of next-generation sequencing data. Bina's proprietary on-market Genomic Management Solution, Bina-GMS, enables basic, translational, and academic researchers to perform fast and scalable analyses to maximize the value of genomic data.

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FDA grants first CLIA waiver for nucleic acid-based flu diagnostic test

The FDA has granted the first waiver to a nucleic acid-based flu test, the Alere i Influenza A & B test.

The test uses a nasal swab sample from a patient with signs and symptoms of flu infection. The test provides results in as few as 15 minutes. Negative results do not rule out influenza virus infection; the test is intended to aid in diagnosis along with the evaluation of other risk factors.

The FDA first cleared the Alere i Influenza A & B test in June 2014 as a prescription-only device to detect influenza A and B viral RNA in nasal swab samples and categorized it under CLIA as moderate complexity.

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Myriad BRACAnalysis CDx approved as companion for olaparib

Myriad Genetics received approval from the FDA for BRACAnalysis CDx to be used as the only companion diagnostic in conjunction with AstraZeneca's drug Lynparza (olaparib).

Lynparza is the first poly ADP-ribose polymerase (PARP) inhibitor for patients with germline mutations in *BRCA1/2* advanced ovarian cancer who have had three or more lines of chemotherapy.