Put It on the Board, 9/17

Eliminating CK-MB testing in suspected ACS

Health care leaders and clinicians should design and implement hospital-wide educational campaigns and partner with information technology and/or laboratory medicine staff at their institutions to remove CK-MB from standardized acute coronary syndrome routine order sets, say authors of a blueprint that could be a "first step to finally putting the CK-MB laboratory test to rest."

"Once the cornerstone of AMI diagnosis, CK-MB has not yet been eliminated from practice despite considerable evidence supporting cTn as the preferred biomarker," write Matthew Alvin, MD, of the Department of Radiology, Johns Hopkins Hospital; Allan Jaffe, MD, Division of Cardiology, Mayo Clinic; and Roy Ziegelstein, MD, and Jeffrey Trost, MD, both of the Division of Cardiology, Johns Hopkins Bayview Medical Center, in *JAMA Internal Medicine* (published online Aug. 14, doi:10.1001/jamainternmed.2017.3597).

With evidence to support eliminating CK-MB for the diagnosis of ACS and using their own experiences to remove the test from their institutions, they created a blueprint for other institutions to use. In addition to designing and implementing a campaign and partnering with IT and/or the lab to modify order sets, they suggest partnering with IT and/or lab medicine staff to integrate an alert into the CPOE system to appear when CK-MB is ordered and measuring data preintervention and postintervention. They acknowledge that while the blueprint is straightforward to articulate, "significant barriers to implementation exist, and in this case," they write, "the biggest hurdle has been convincing physicians who have ordered CK-MB for years to change their practice."
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Roche launches Avenio Millisect System

Roche announced in August the commercial availability of the Avenio Millisect System, a tissue dissection instrument that uses an automated digitally assisted process to isolate clinically relevant cells from formalin-fixed, paraffin-embedded tissue slides.

In a study published in *Cancer Genetics* (Geiersbach K, et al. 2016;209[1–2]:42–49), sequencing samples prepared with the Avenio Millisect System identified mutations from seven out of 32 (22 percent) pancreatic cancer tissue samples that were otherwise missed by manual dissection. The study further suggests that the technology helped reduce false-negative results and case rejection rates associated with low tumor content.

The Avenio Millisect System is available in the U.S. and in countries accepting the CE mark.
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FDA clears syphilis assay for BioPlex 2200

Bio-Rad Laboratories received FDA clearance for its BioPlex 2200 Syphilis Total & RPR assay, a one-step universal testing method to aid in the diagnosis of syphilis infection.

The assay offers laboratories the first fully automated Treponemal/non-Treponemal dual assay, which simultaneously detects antibodies to *T. pallidum* and reagin antibodies as well as RPR titer determination for effective treatment monitoring. The BioPlex 2200 System is a fully automated multiplex technology platform.
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On Vitek MS, expanded pathogen ID cleared

BioMérieux's Vitek MS, a MALDI-TOF mass spectrometry system for rapid pathogen identification, received 510(k) clearance from the FDA for the expanded identification of mycobacteria, *Nocardia*, and molds. This database includes more than 15,000 distinct strains to provide extremely high accuracy and, for the first time, enables the safe identification of the *Mycobacterium tuberculosis* group, the most frequent nontuberculous mycobacteria, *Nocardia*, and the most medically important molds.
To gain new FDA clearance for these species, BioMérieux submitted data from a multicenter study consisting of 2,695 clinical isolates for 47 molds, 19 mycobacteria, and 12 *Nocardia*. The FDA clearance of *Mycobacterium* species was from both solid and liquid growth media.
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Data breaches in health care

Nearly 90 percent of health care organizations surveyed in recent years suffered a data breach, and 64 percent of organizations reported a successful attack on medical files, write William J. Gordon, MD, Adam Fairhall, ALM, and Adam Landman, MD, MIS, MHS, in the Aug. 24 *New England Journal of Medicine*.

In "Threats to Information Security—Public Health Implications," the authors, of Brigham and Women's Hospital, Massachusetts General Hospital, and Partners Healthcare, cite the findings of a survey by Ponemon Institute (http://bit.ly/health-data-security), which does independent research on privacy, data protection, and information security policy, and they recap ways to reduce the risk.

Although denial-of-service (disrupting and disabling systems by overwhelming them with network traffic) and ransomware attacks can significantly impair the ability to provide care, the authors write, "they do not necessarily expose patient information." Attackers value protected health information and personally identifiable information for two main reasons, they say: It has direct monetary value and it's durable.

They warn about the manipulation of patient data.

"An attacker with access to a laboratory system could modify data—changing potassium values, for example. Unsuspecting health care providers could react to the falsified potassium values, providing treatment that could harm the patient. Radiology protocols, diagnostic reports, genetic data, progress notes, and electronic prescriptions—the list of possible targets goes on," they write.

In addition to common best-practice security measures (data encryption, antivirus software and software updates, and risk analyses, for example), the authors highlight the benefit of designing systems with workflow in mind. "A highly secure system that is not usable (and therefore not used) is less secure than a moderately secure system that is adopted widely," they say. And regular employee training and education should be required for all members of the health care community.

"People are the weakest link in the security infrastructure: our systems are only as secure as the gatekeepers who use them," they write.