Put It on the Board

Pathologists and population health—first steps

December 2018—Pathologists who want to become involved in population health initiatives can take five main steps, say pathologists and laboratory leaders interviewed for an article published online last month in *Archives of Pathology & Laboratory Medicine* (doi: 10.5858/arpa.2018-0223-CP).

In "The role of the pathologist in population health," the authors report on the interviews they conducted and their review of the literature to answer several questions, among them whether pathologists in both large settings and smaller community-based settings can engage in population health (yes), and whether pathologists are in a position to analyze data for population health ("The data are there," they say, "but getting to the data—and providing meaning out of it—is the hard part").

One of the first steps to becoming involved in any type of population health management activities, the authors write, is to understand the philosophy of the institution's CEO and senior management. How do they define population health and strategize its implementation, and do they view laboratory data as essential to their population health management goals?

In addition, understand your health care system's landscape and the role of laboratory data within that landscape. If the health care system is part of an accountable care organization or regional health information organization, how are laboratory data sent and stored? Who can retrieve cloud-based data? If the system isn't part of an ACO or RHIO, "how are data collected and stored across your institution and other institutions" within the system?

Also important: "[W]hat laboratory data inform the metrics for the value-based payment performance?" and what EHR systems does the institution use?

"Whatever the circumstance," the authors say, "it is important to understand whether data are accessible across the hospitals of an enterprise or are limited to single institutions. It is also important to understand what information in your LIS is also in the EHR and what information remains only in the LIS."

Second, ensure the integrity of the laboratory data by standardizing the data within the network, particularly if there are multiple EHR and/or LIS platforms in the organization. "Creating and maintaining a data dictionary that standardizes test names, units of measure, terminology, and associated coding systems across the enterprise will greatly simplify analysis when analytics are used to compare outcomes," the authors write.

Third, make it clear to leadership that laboratory data are actionable and have analytic and predictive value. Focus on "the pre-preanalytics—the decision-making of ordering the right test at the right time—as well as the post-postanalytics—defining and deriving maximum value from analysis using laboratory data."

Fourth, be proactive, even "intrusive" and "persistent," according to the experts interviewed for the article. "Few administrators may initially reach out to pathologists unless pathologists have inserted themselves into the decision-making process," the authors write, "not only of the data analysis but also of the overall population health program design and execution."

Last, once an intervention is in place, demonstrate the success of that intervention and the role the laboratory data had in it.

"Not all pathologists need to be actively involved in these types of activities," they write, "but there should be a champion within the institution that can represent the value of laboratory data to administration."

Roche launches first IVD pan-TRK IHC assay

Roche launched the Ventana pan-TRK (EPR17341) assay, the first automated in vitro diagnostic

immunohistochemistry assay to detect tropomyosin receptor kinase proteins in cancer.

With the launch, Roche says, laboratories are now able to identify wild-type and chimeric fusion proteins through detection of the TRK C-terminal region. This assay can be used to perform analytic studies, including prevalence in solid tumors.

The assay is available for use on Roche's BenchMark series of IHC/ISH automated staining instruments. It is designed to detect C-terminal protein expression, which allows for the detection of TRK-fusion as well as wild-type protein expression. The epitope detected by the antibody is encoded downstream of the tyrosine kinase domain within the 3 prime coding region of the neurotrophic tyrosine receptor kinase (NTRK) 1, 2, and 3 genes and is conserved across all three TRK proteins, A, B, and C.

FDA clears DiaSorin Molecular GBS Direct assay

The FDA cleared DiaSorin Molecular's new Simplexa GBS Direct assay for diagnostic use.

Designed for use on the Liaison MDX instrument, the assay enables qualitative detection of group B *Streptococcus* nucleic acid from 18- to 24-hour Lim broth enrichments of vaginal/rectal specimen swabs obtained from antepartum women. Assay results can be used as an aid in determining the colonization status of antepartum women. The company says the new assay can replace traditional culture testing methods and features an efficient, fast workflow.

This is the ninth assay for infectious disease on DiaSorin Molecular's PCR platform to obtain FDA 510(k) clearance.

Breakthrough device designation for Enhanced Liver Fibrosis Test

The FDA granted a breakthrough device designation for the Advia Centaur Enhanced Liver Fibrosis Test from Siemens Healthineers.

The ELF Test would support clinicians, in conjunction with additional clinical evidence, in assessing the fibrosis stage of chronic liver disease through a simple blood test, which may help determine if a patient requires treatment. The ELF Test is designed to analyze data regarding three serum biomarkers—hyaluronic acid, procollagen III amino-terminal peptide, and tissue inhibitor of metalloproteinase 1—in an algorithm that provides a single ELF score.

Siemens Healthineers is collaborating with Gilead Sciences as part of its work to seek FDA clearance of the ELF Test.

NeuMoDx Molecular launches 288 and 96 molecular systems

NeuMoDx Molecular launched its FDA-cleared NeuMoDx 288 Molecular System and its FDA-listed NeuMoDx 96 Molecular System.

The fully automated systems integrate the molecular diagnostic process, from extraction to detection, with the first result available in about one hour. Operators can load up to 288 and 96 patient samples in a continuous, random-access workflow, resulting in on-demand, high-throughput sample processing with an operator walkaway window of up to eight hours.

The proprietary NeuDry reagents used with the systems require no refrigeration and have an onboard stability of up to 60 days and ambient temperature shelf life of greater than one year.

Expanded use approved for Vitros HIV Combo test

Ortho Clinical Diagnostics' Vitros Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator received FDA approval for use on the Vitros ECi/ECiQ Immunodiagnostic Systems. The Vitros HIV Combo test was previously approved for use on the Vitros 5600 Integrated System and Vitros 3600 Immunodiagnostic System.

Vitros HIV Combo, a fourth-generation test, detects both HIV-1 and HIV-2 antibodies and the p24 antigen.