Newsbytes

In molecular testing labs, gaps between actual and desirable LIS capabilities

December 2018—Flashback to 2013: Alexis B. Carter, MD, then director of pathology informatics at Emory University Hospital, was contemplating whether other pathology labs nationwide were facing the same challenges managing molecular testing data as she and her colleagues. So she decided to find out. Dr. Carter conducted a survey, and the responses confirmed her suspicions: Most laboratory information systems fall short in providing the infrastructure for complex molecular and genomic testing.

Five years later, Dr. Carter and Charles Myers, MD, and Matthew Swadley, MD, who, as residents in the Department of Pathology and Laboratory Medicine at Emory, had collaborated with Dr. Carter on the survey, shared their findings in the *Journal of Molecular Diagnostics* (2018;20:591–599).

Priorities at work and other commitments delayed publication of the findings, says Dr. Carter, now pathology informaticist at Children's Healthcare of Atlanta. However, informal conversations she and her coauthors have had with molecular pathologists indicate that the results are still as relevant today as they were nearly six years ago.

So how did Dr. Carter go from pondering to publishing? She designed a 34-question online survey and sent it to members of the listservs of the Association for Molecular Pathology, American Society for Histocompatibility and Immunogenetics, American Medical Informatics Association, and Association of Pathology Informatics.

To encourage open, honest responses, the survey was constructed to protect the identity of the participants and the brand names of the LISs that were being evaluated. The questions focused on the size of the organizations, number of LISs the respondents used, and system capabilities.

"We also asked about the type of information system they were using," Dr. Carter says. "Was it something they developed at their institution, a custom-built LIS, was it an information system that was specifically designed for molecular and next-generation sequencing laboratories, or was it a clinical laboratory system they were using as best as they could, or some other system?"
The authors targeted professionals involved in molecular testing, including those who perform transplant molecular diagnostics. The majority of survey respondents were laboratory staff supervisors and medical directors.

"The fact that we had 80 people fully complete the survey [out of 142 who started it] shows there was a high degree of interest in this topic," says Dr. Carter. The length of the survey may have discouraged some of the initial 142 respondents from completing it, she adds.

The responses of the 80 participants revealed significant gaps between actual and desirable LIS capabilities. "To me, the biggest concern is the fact that a large percentage of laboratories reported having instruments and software in the laboratory that [are] not compliant with the HIPAA final security rule," Dr. Carter says. "The challenge is that laboratories don't always know to ask some of those questions because they assume that if a vendor is selling an instrument for this medical purpose, the instrument is going to be compliant by default." However, vendors may not bring their LISs up to specifications, especially when laboratories do not raise compliance concerns when purchasing the software.

Dr. Myers, now a clinical fellow in the Department of Pathology, Microbiology, and Immunology at Vanderbilt University Medical Center, agrees that noncompliance with the Health Insurance Portability and Accountability Act is the most troublesome finding of the study. Laboratories should be concerned about systems that don't allow them to create unique user names and passwords for their employees, making it difficult to track user histories and employees' access to data, he says.

Workplace practices that interfere with efficient workflow integration, such as not providing barcoding, are also

problematic, says Dr. Myers, as is the systems' inability to report test results to the target audience using the optimal formatting. Among the gaps in functionality that the survey respondents reported was the inability to use such special formatting as boldfacing, underlining, or italics to emphasize key information when transmitting results to clinicians. The respondents also identified tracking of quality control data and electronic communication of data via interfaces as areas that need to be improved.
Dr. Myers says the results confirmed many of his assumptions, but he was pleasantly surprised to find that a number of laboratories were using specialized LISs suited to molecular testing.

Since the survey was completed, he adds, specialized modules for LISs have become more widely available, replacing custom-made systems in some laboratories. "There has probably been more integration of barcodes and probably some of the reporting tools have been expanded on," Dr. Myers says. However, the advances have come primarily in the form of these new products designed for molecular testing labs. Institutions that continue to use basic clinical or anatomic pathology systems have not seen much improvement in reporting, he notes.

Progress, in general, is likely to be slow, Dr. Carter says. Because molecular testing laboratories do not generate significant revenue, hospitals are reluctant to invest in sophisticated, expensive LISs. And laboratories using inadequate systems are likely to encounter new challenges in the era of next-generation sequencing with regard to processing large numbers of genetic variants. The lack of interoperability remains a major concern, says Dr. Carter, as many laboratories still rely on flash drives and other manual means of data transfer.

As molecular testing volume climbs, Dr. Carter says, she hopes the survey findings will give vendors the information they need to build better systems and will give laboratories an idea of the questions they need to ask before bringing in new systems or software. *—Iulia Filip*

MediPath signs contract for NovoPath anatomic pathology system

NovoPath has announced that Coral Gables, Fla.-based MediPath LLC will install the NovoPath anatomic pathology software platform at its new state-of-the-art facility.

"We look forward to partnering with MediPath to help create workflows that emphasize quality and accuracy and take advantage of the latest technology," said Rick Callahan, vice president of sales and marketing for NovoPath, in a press release.
According to Sandra Aponte, MD, medical director and lead pathologist for MediPath, when compared with other companies' products, "NovoPath's solution best aligned with MediPath's needs and offered the most robust and flexible capabilities at a competitive price."

NovoPath, 877-668-6123

Xifin introduces RCM offering with machine learning-driven capability

Xifin has unveiled Xifin Revenue Performance Management 10, a diagnostic-specific revenue cycle management system that incorporates machine learning-driven functionality and next-generation business intelligence visualization and analytics.
RPM 10 is FASB, GAAP, and SOX compliant and general ledger ready. Its new business intelligence offerings include subject-oriented and aggregated data, data visualization, and analytics to help users benchmark their performance, enhance business decision-making, and negotiate better payer contracts. The system also features a patient responsibility estimator and patient-friendly statements, as well as a prepayment option.

"RPM 10 provides Xifin customers with new features, including enhanced patient demographic and insurance discovery automation, expanded Web service capabilities for integration and interoperability, and capabilities that support lab acquisition and divestiture needs," according to a press release from the company.

Xifin, 858-793-5700

Technidata releases new version of anatomic pathology system

Technidata has launched version 13.41 of its TDHistoCyto software for anatomic pathology laboratories.
The new version includes an integrated rapid process tracking feature for enhanced traceability. “The ability to computerize and track the preparation stage not only makes specimen identification more secure, thus reducing the risk of errors, it also speeds up the turnaround time for blocks and slides and simplifies information searches,” said François Tourres, marketing manager for Technidata, in a press statement.

Also new in version 13.41 is a statistics tool that allows laboratories to define customized indicators and perform multidimensional extractions, as well as an integrated tissue bank that allows laboratories to independently qualify and store specimens.

Technidata, 514-270-7777

Congenica partners with Digital China Health on genomics platform

The global diagnostic decision support platform provider Congenica has entered an agreement with Digital China Health Technologies Cooperation Limited, further extending its presence in the Chinese market.

“The new partnership will see Congenica develop a version of its Sapientia platform designed to enable clinicians and patients in China to benefit from the clinical genomics and personalized medicine revolution,” according to a press release from the United Kingdom-based company. “DCHealth will use its significant commercial depth and experience in the Chinese hospital market to accelerate the commercialization of this locally-adapted version of Sapientia.”

Users of the Sapientia platform and expert support services can interrogate the human genome to identify disease-causing variants.

Congenica, 800-721-0210

Visiun announces installation

West Allis, Wis.-based ACL Laboratories has implemented Visiun’s Performance Insight laboratory analytics system throughout its laboratory network. As part of Advocate Aurora Health, ACL Laboratories services 27 hospitals across the Midwest and performs more than 26 million laboratory tests annually.

Visiun, 877-226-6356

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