Newsbytes

Editors: Raymond D. Aller, MD, & Hal Weiner

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

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.

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Influenza testing

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keeping up with an efficient turnaround time."

Now, SMG is poised for a more sweeping change. "We are putting Roche Diagnostics rapid PCR Liats in all of the testing locations that do strep and influenza testing, so they will do the molecular test on site."

> "We have sequestered all of our reagents with our supplier for the entire year."
>
> **Mary Kay O'Connor**

SMG is just one of the large physician groups that have made significant new instrument purchases, particularly for CLIA-waived rapid PCR tests, and have no plans to return to rapid antigen testing.

Training at SMG's pediatric offices, which are slated to get eight Liats each, and urgent care centers started Dec. 4. "Once we have rolled out those sites, we will go out into the other offices. We'll be installing about 100 Liats in multiple locations for internal medicine, family medicine, and several other service areas," O'Connor says.

One problem she expects to avoid with the Liats is running out of reagents. "We have sequestered all of our reagents with our supplier for the entire year, and we have one lot number. Last year, we ran 15,243 flu tests, so we've sequestered about 16,000 tests for the coming year."

The turnaround time of rapid PCR is a major selling point. "Obviously we were doing it in the core lab in less than a day, but it's better if it's done at point of care because the doctor can give a prescription or not give a prescription."

As SMG integrates new physician groups that perform in-office antigen testing, they will be set up with Liats for immediate results. "This will be particularly helpful for pediatric practices, where they have a high volume of patients with upper respiratory and pharyngitis symptoms," O'Connor says. Since the Liat testing has been linked to the laboratory information system and electronic health record via Roche's IT 1000, the Liats will ease a lot of the offices' paperwork burden, she adds.

Five-hospital Norton Healthcare in Louisville, Ky., is in the midst of an even larger change at its 32 primary care locations, 14 immediate care centers, and 21 pediatric offices, says Joshua Honaker, MD, MBA, chief medical administrative officer of Norton Medical Group. Until this season, the system had been using traditional rapid antigen tests for respiratory syncytial virus and flu as well as strep, with follow-up culture if negative. After comparisons of rapid PCR instruments, testing at pilot sites, and correlation studies, Norton Medical Group purchased 250 Liats. "Now we have rolled out Liats across the board in the last month, and we're in the process of educating and moving our team and changing our culture to using the rapid PCR."

Easing the shift is that the hospitals within Norton Healthcare have been doing the PCR testing for more than a year. "So they gave us really good guidance about heading in that direction as well," Dr. Honaker says. The Food and Drug Administration's recent reclassification of traditional rapid flu tests, mandating that they address poor sensitivity by meeting higher standards, was another factor behind Norton Medical Group's decision to move to rapid PCR.

During the transition to rapid PCR, the rapid antigen tests are still playing a part. "We have old tests still in inventory so we will use them as needed if capacity is an issue with the rapid PCR this first flu season," Dr. Honaker says. But this year, "We also wanted to make sure we had residual inventory for peak times. If an immediate care center that can see up to 40 patients an hour found they all came in with flu and we only had 10 instruments there to run it, they can go back and *—continued on 18*

PAMA Today: Five Things to Know to Take Action Now

After a year that saw slashes to numerous test fees, many labs are asking what they need to do to succeed in the coming year. Here are five items savvy labs are focusing on:

1) Final Physician Fee Schedule has significant implications for PAMA reporting. CMS issued the final Physician Fee Schedule on November 1, 2018 and two key changes have altered the PAMA reporting dynamic.

First, CMS eliminated the Medicare Advantage program from the calculation used to identify applicable labs, paving the way for many more labs being required to report that previously did not meet the threshold.

Second, CMS broadened the definition of applicable lab to include those that bill under a 14x bill type, which will cause most hospital outreach laboratories to now be required to report. With these two changes in effect, not only will many more laboratories be required to collect and submit data in the next round, but the hope is the inclusion of these other labs will result in higher, more representative pricing than what surfaced in the first round of PAMA submissions. Laboratories that did not previously meet the applicable lab definition must carefully assess whether they are now impacted, keeping in mind that reporting errors or failure to report carry hefty fines of up to $10,000 per day per infraction.

2) Next data collection period begins in just a few weeks. With January 1, 2019, marking the start of the second six-month window of PAMA data collection,

laboratories need to prepare to accurately collect the requisite data. To avoid the high error rates seen in the first round that clearly impacted subsequent pricing, we recommend diagnostics providers use source documents and closely check expected vs actual payments.

3) Don't look to private insurers to shore up pricing. Our analysis shows that as contracts expire, private payors are reworking pricing; already independent labs have seen a 3% erosion, and hospital outreach a 3.5% reduction in private payor prices this year.

4) Carefully manage your private payor contracts, keeping an eye on your test menu and associated cost structure. Where possible, laboratories should avoid tying rates to Medicare or static fee schedules, and instead work to obtain rates that reflect the value of the tests in question. Understanding the financial basis of test offerings and renegotiating contracts where rates are too low is arguably the single most important action laboratories can take to protect their businesses.

5) Don't leave money on the table unnecessarily. In addition to improved private payor contracting, laboratories do have other options to improve their margins, including diversifying test menus and expanding into more specialized testing; and taking advantage of process improvements and workflow automation to improve collected revenue and operating costs.

In an increasingly challenging environment, labs must fight to prove that their revenue streams are justified and part of the larger healthcare value chain. With another round of PAMA cuts looming, the time to take action is now.

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