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ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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by Nancy Maddox, writer

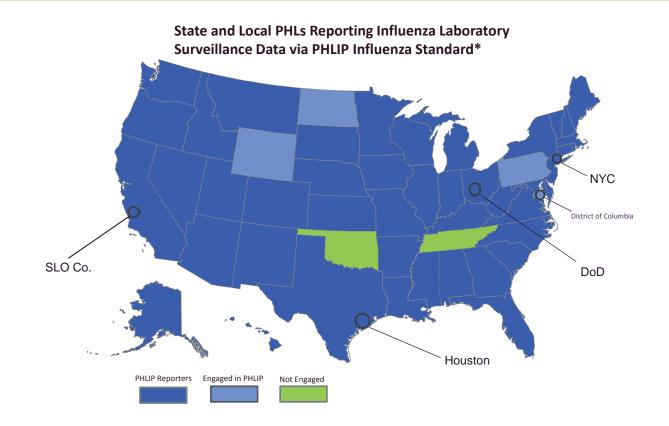
The Alabama Bureau of Clinical Laboratories generates about 2,000 lab reports a day. Seven years ago, each of those had to be printed on paper, folded, stuffed into an envelope and mailed. Today, said Keith Higginbotham, IT systems manager for the Alabama Department of Public Health, "roughly 85 to 90% of our test volume comes in through electronic orders, either bidirectional HL7 [messaging] or through our web portal."

he dramatic shift is a reflection of what APHL has dubbed "the brave new world of laboratory informatics." But while this new world offers vastly increased efficiency and, in many cases, near real-time data, it has also created new frustrations.

An Alabama effort some years back to institute electronic test ordering and results reporting (ETOR) with some of the state's large community health centers, for example, was largely scuttled.

Said Higginbotham, "One of the barriers we ran into is that every electronic health record (EHR) had its own version of electronic ordering..... No one was able to generate the [HL7] message we needed. So we're kinda faced with the decision that, if we want to do this, we have to create custom one-off interfaces with all of our clients. That's not really appealing to me from a maintenance and time perspective."

Mary Wedig, the electronic laboratory reporting coordinator for the Wisconsin State Laboratory of Hygiene, has faced similar problems. She said, "For each hospital or other partner we connect to, it's always different mapping; every hospital uses its own internal codes."



The frustration is not limited to the states. CDC's Bill Bellini, PhD, has a dream that is undoubtedly shared by others in public health. "If I had a magic wand," said the chief of the agency's Measles, Mumps, Rubella and Herpes Viruses Laboratory Branch, "I would make one particular [electronic messaging] system be present in all the public health laboratories." Right now, he said, "All the LIMS systems and electronic surveillance systems reporting back to CDC could be very different. Some are more malleable and alterable than are others. They're very expensive. Adding new fields is no mean feat."

Yet, despite the hassles, no one expects to go back to the pre-Internet world or wants to give up the new digital conveniences.

Wes Kennemore, MD, APHL's manager of health information technology (IT), takes a broad view of the evolution of the field. There was a time, he said, "we thought everyone ought to have the same IT system. And you start down that path and get down that path a certain distance, and you realize that the light at the end of the tunnel really is an oncoming train."

Today, said Kennemore, there is increasing recognition that "everybody needs their own specialized information" and their own specialized IT systems to manage that information. The current goal is to figure out how to share that information in a standardized way.

G More than 50 institutions send or receive messages through the [AIMS] platform, with traffic averaging between 10,000 to 14,000 messages per month.

No one said it would be easy.

"The past few years we've been in this sort of helter-skelter situation in which [the federal government] had to incentivize the electronic exchange of data, because data exchange was hard, and data exchange was expensive," said Kennemore, alluding to the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act, which rewards hospitals and providers who achieve *meaningful use* of electronic health information and penalizes those who don't. [Meaningful use, in turn, is defined broadly as (1) use of federally certified EHRs, (2) improving quality-of-care through electronic data exchange and (3) reporting on select health and quality measures to the US Department of Health and Human Services. Specific *meaningful use* objectives include public health reporting and incorporating clinical lab test results into certified EHR technology as structured data.]

Although the HITECH Act provides for electronic data exchange and health IT standards — set by the Office of the National Coordinator for Health Information Technology (ONC) — in practice, those standards have been somewhat loose. Stage 1 *meaningful use* standards, said Kennemore, "didn't really adequately meet the demands of data exchange. It was a good first step." Current, Stage 2 standards, he said, are "more rigorous," but still leave room for improvement. Proposed rules for Stage 3 data exchange and ONC-certified health IT standards were released March 30.

In the meantime, health IT managers, like Higginbotham, are struggling with one-off interfaces. Messages from "supposedly ONC-certified health systems," Higginbotham said, are "typically close, but not exactly compliant with the standard." He also points out that accepted HL7 message formats have many built-in options, and that *meaningful use* allows states to add their own state-specific data fields, thereby necessitating some degree of customization.

"I always say, 'If you've done one HL7 interface, you've done one HL7 interface,'" he said.

From point-to-point to hub-and-spoke and data to metadata

But there is hope for a simpler future. The way around the one-off interface, said Kennemore, is to move from point-to-point connections with individual data exchange partners to the next big IT innovation: the hub-and-spoke connection, as exemplified by APHL's own APHL Informatics Messaging Service (AIMS) platform.

The AIMS platform offers a secure, cloud-based environment and, importantly, has the ability to validate electronic messages and to transform them into the recipient's preferred format and coding system, such as LOINC® codes for laboratory procedures and SNOMED® terms for clinical data.







In addition, the platform serves as a single messaging hub, through which message senders can transport electronic data to multiple partners at once; hence the hub-and-spoke analogy. Thus, not only does the AIMS platform negate the need for local message transformation, it also negates the need for users to maintain electronic security certificates with each of their messaging partners; they need only maintain a security certificate with the hub (as long as partners are also hub users).

Currently, more than 50 institutions send or receive messages through the platform, with traffic averaging over between 10,000 to 14,000 messages per month.

One longstanding client is the CDC Influenza Division, which funded APHL's first messaging initiative in 2005, the Public Health Laboratory Interoperability Project (PHLIP), focusing on national, electronic influenza reporting.

Today, 45 state public health laboratories (PHLs), Wright Patterson Air Force Laboratory and three large local PHLs send influenza test data to CDC using PHLIP protocols, many using the AIMS transport platform. Four additional PHLs are in the process of setting up and testing PHLIP influenza messages.



From left: Keith Higginbotham, Neelima Vundela and Ron Howard

Desiree Mustaquim, MPH, a CDC Influenza Division epidemiologist, said a preliminary analysis for an upcoming study shows that many influenza reporting laboratories now average a day or less to deliver PCR test data to CDC (based on data from the current and past two flu seasons).

Such timely electronic reporting, she said, boosts situational awareness and makes the nation "much better prepared for an emergency."

Timely electronic data also informs CDC administrative decisions, such as planning for amounts of testing reagents needed to support PHLs and better understanding PHL testing practices to gauge potential training needs.

When H3N2v influenza sickened over 300 people in the Midwest in 2012 — mostly children exposed to pigs at county fairs — PHLIP laboratories were able to add the new flu variant to their reporting systems quickly and easily. Similarly, said Mustaquim, when avian influenza H7N9 emerged in China in 2013 — raising alarms because of its potential for human infection — "we added it [to our reporting systems] right away." She said, "We've gotten much better about coordinating vocabulary with new tests and communicating with the states. If [H7N9] comes ashore, we're prepared." The current PHLIP influenza message supplements test data with optional metadata addressing such things as patient travel history and hospitalization status. During the current flu season, Mustaquim and colleagues examined this data to discern whether greater disease severity was associated with drifted influenza A H3N2.

"We didn't have enough evidence to draw a firm conclusion," said Mustaquim. "If we could get more states to supply that additional epidemiologic metadata as they have it available, we could answer more surveillance questions."

A new Influenza Division project entails the sharing of PHLIP data with CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS) — a laboratory-based system that tracks respiratory syncytial virus, human parainfluenza viruses, rotaviruses and respiratory and enteric adenoviruses.

"This is a natural partnership for us, because a lot of the specimens tested for flu also get tested for other respiratory pathogens and we ask for all related tests for those flu specimens," said Mustaquim. The result is a win-win situation: reporting laboratories no longer need to manually enter NREVSS data into the program's weekly, aggregate reporting system, and NREVSS's staff get more timely and detailed information than ever before, including both positive and negative test results.

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"It's not just a matter of the cases you know about ... "

Bellini knows firsthand the value of such enhanced electronic surveillance. APHL and CDC's Measles, Mumps, Rubella and Herpes Viruses Laboratory Branch jointly support four vaccine preventable disease (VPD) reference centers, which send electronic surveillance data to CDC in near real-time. Two of the centers — the Minnesota Department of Health, Public Health Laboratory Division and the Wisconsin State Laboratory of Hygiene — send the data via the AIMS platform.

"The reason I got into electronic lab results messaging," said Bellini, "is because we never got the whole picture of disease occurrences three or four years ago. We would get reports in from the states, but they were usually in the form of phone calls or electronic submissions of cases after the cases were confirmed; it could be a month or two [after disease onset]. Some of the sporadic cases and smaller outbreaks could be going on for days or weeks without us knowing about them."

For VPDs officially eliminated in the United States, such as measles and rubella, Bellini said, "We really had no chance of obtaining the information mandated to assure maintenance of elimination."

Now, CDC VPD groups get results from the VPD reference centers at virtually the same time as specimen submitters, roughly a few hours after PCR testing is completed and about 24 hours after the specimens arrive at the reference centers. Moreover, CDC officials can format the messages coming through the AIMS platform "however we want to," said Bellini, and create internal reports "almost instantaneously."

Rapid data delivery makes a huge difference for VPD surveillance, especially in places with concentrations of people who refuse vaccination for philosophical, religious or other reasons. "Surveillance of VPDs in those [non-vaccinating] communities is virtually impossible," said Bellini. "You really have to set up a network of surveillance indicators in areas surrounding those communities and do the best you can at rapid identification of small outbreaks. And that's where a lot of the informatics come in; it's not just a matter of the cases you know about, it's the cases you don't know about that show up as rash illness or other illness with nebulous symptoms. They can occur in clusters and, without sophisticated surveillance systems, you don't recognize that a lot of them are related. You can use electronic surveillance of concordant disease as sentinels."

Last year, near real-time surveillance was responsible for identifying a possible new syndrome associated with influenza H3fluA. Clusters of patients with cold-like symptoms and clinical parotitis (swelling of the major salivary glands) were thought to have mumps. Said Bellini, "Finally, someone in Wisconsin had the bright idea to put [the suspected mumps specimens] through their respiratory panel, and it turned out to be H3flu."

Dissemination of this finding had important public health implications: "It changes people's mindset. Although the frequency of parotitis-associated H3fluA infections is still being evaluated, you have to start thinking about contacts and rapid follow-up, because flu spreads like wildfire."

In addition, testing algorithms may need to be changed. Up to this point, the only known cause of epidemic parotitis was mumps, and, thus, specimens from suspected mumps cases are not routinely screened for other respiratory viruses.

Finally, enhanced surveillance data — with both positive and negative test results — is necessary to demonstrate continued disease elimination. As Bellini explained, knowing that you have an endemic measles-free or rubella-free area requires a certain amount of testing. He said, ". . . at the end of the day we can say we've done a sufficient job of surveillance to document continued elimination, because we did x number of tests, with so many positives, which match those in the National Notifiable Disease Surveillance System (NNDSS), and we can verify how they got here (mostly imported) and verify that we have no endemic threat, but only because we also have the denominator data."



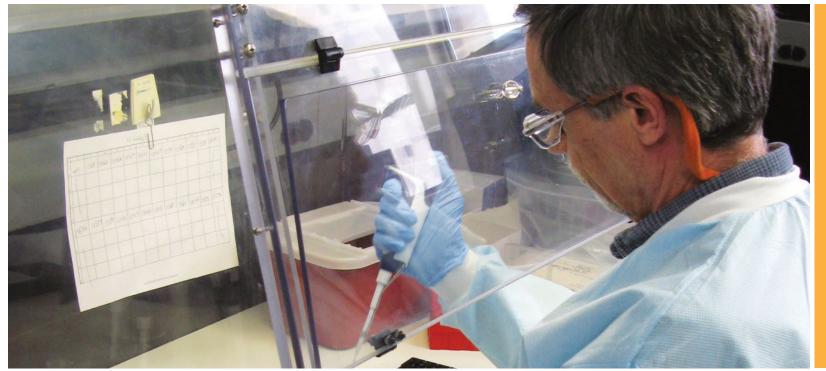
Alabama Department of Public Health, Bureau of Clinical Laboratories

Before the VPD reference centers were established, many states found it too cumbersome to report negative test results. But today, 70-80% of state PHLs refer suspected VPD specimens to those four centers, and the data is more-or-less simultaneously reported to the submitting PHL and to CDC.

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Signs of progress

In the states, electronic surveillance offers additional advantages. Even though connections can be time-consuming to set up, said Wedig, once they're established there is a huge time-savings: "The laboratory staff aren't as aware of reportables, because they go automatically. You don't have microbiologists taking time away [from the bench] to upload a spreadsheet or fax reportables out."



Wisconsin State Laboratory of Hygiene Advanced Microbiologist Jim Powell pipetting in preparation for vaccine-preventable disease testing. VPDs such as measles, mumps and rubella are reportable conditions in Wisconsin



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Wedig oversaw a study in which hospital and clinical labs both faxed reportable disease results to the State Laboratory of Hygiene and also sent them electronically. She found that electronic reports arrived at least daily and as quickly as 15 minutes post-testing, while faxed results took days to reach the state laboratory, and up to weeks for outliers.

Despite growing pains, electronic laboratory reporting is no longer optional. It is increasingly necessary to achieve optimal disease surveillance and to carry out the complex work of a modern public health laboratory.

"We're not at the point where it's just plug and play, open the box and it works," said Kennemore. "But new technologies are making it easier for us to get closer to that every day."

In Alabama, Higginbotham's team of microbiologists and programmers is working on at least two new projects:

- An interface to enable electronic transmission of HIV genotype sequence information to the state's HIV surveillance division, which, in turn, will share the information with CDC
- An upgrade of the state's PHLIP message from HL7 2.3.1 to HL7 2.5.1, which will enable the PHL to send more metadata to CDC with its influenza test results

Alabama's two largest health departments — in Birmingham and Mobile — have had an ETOR interface with the state PHL since 2011. "When we physically receive the specimen," said Higginbotham, "we scan a barcode and it pulls the test orders, demographic information, billing information into our LIMS. We conduct the test. Then the final report is an HL7 result message that goes back to their EHR system and is automatically integrated into the patient's electronic medical record." The laboratory averages 400 orders/day through that interface. The Alabama Department of Public Health is in the process of purchasing an EHR system for the rest of the state's local health agencies, and eventually they too will be linked to the PHL's messaging system through a bidirectional ETOR interface.

Overall, as of July 2013, roughly 62% of 20 million lab reports sent to CDC Epidemiology and Laboratory Capacity grant recipients were received electronically, compared with 54% in 2012. CDC's new agency-wide surveillance strategy calls for 80% of laboratory reports to public health agencies to be sent electronically by next year.

Looking ahead, Bellini foresees a day when uniform surveillance reports can be translated into maps with GPS coordinates and then projected onto a screen. He also longs for the day when national surveillance programs can get "everybody's anonymized test results, even from the commercial sector."

To achieve the most effective surveillance, he said, "you have to look at the big picture. And the big picture is only available through timely electronic laboratory results coupled with epidemiologic data."



Desiree Mustaquim, MPH, CDC Influenza Division epidemiologist

		Score	Similarity	Indels	Mismate
)19847 3-2-15 .		708/708	100.00	0	0
003336 11-10-14		697/708	98.81	0	11
018046 3-2-15		692/708	98.27	0	16
panel 4 07-22-08		667/708	95.57	0	41
LQ1 09-05-08		665/708	95.35	0	41
oscontrolLO 09-03-08		663/708	95.14	0	45
LQ 09-03-08		654/708	94.16	0	40 54
panel 2 07-22-08		653/708	94.05	0	55
panel 3 07-22-08		640/708	92.54	0	53 69
IQ 09-03-08		622/708	90.70	0	86
M1502019847 M1502019847_3-2-15 20150306 Lab lab 0.864 3-2-15 Cer.poscontrolLQ_09-03-08.seq union of libraries sequences Mismatches: 45 Indels: 0 Alignment Score: 663.00000 Similarity: 95.14	M1502019847 35XME082282 HIV PR RT 98892				

Alabama's work on a project to electronically transmit HIV Genotype Sequences to CDC