

Vision 2020: Building a Sustainable Public Health Laboratory System

A Candid Conversation with Public Health
Laboratory Scientists and Partners on the
Future of the US Public Health System



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This report is a tribute to the hundreds of current and emerging public health laboratory leaders who have contributed to these efforts and an attempt to move the discussion forward by capturing their insights and recommendations to further improve the public health laboratory system as we approach 2020.

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Executive Summary

Background and Purpose

The *Vision 2020* plan was developed in December 2010 to identify the drivers the public health laboratory (PHL) system must address before 2020 if it is to stay responsive to community needs; support national, reportable disease surveillance; remain aligned with the principles undergirding PHL core functions and capabilities requirements and align with the “10 Essential Public Health Services” framework. The 2010 drivers comprise issues PHL leaders identified then as potential challenges that needed to be better understood and addressed. Now, the Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL) are assessing progress toward addressing these drivers and determining what, if any, additional drivers demand attention, especially given technological advances.

Methods

Study participants were identified by their peers and then invited to take part in the effort, which totaled 140 encounters: (a) 120 candid, semi-structured individual conversations, (b) open discussions with senior staff at the North Carolina, Virginia and Wyoming PHLs, (c) presentations to the APHL Board of Directors and 14 APHL committees and working groups, and (d) two focus groups. At least 250 individuals participated in some or all of the encounters, which took place from October 2015 to April 2016.

Findings

Based on the discussions, the drivers from 2010 were updated (see Figure 1). There is consensus that the drivers accurately reflect what is needed to support a functional and relevant national public health system. Participants agreed that a connected, interoperable public health “cloud” is critically needed to enable near real-time information sharing across the public health community, including health officials, epidemiologists and laboratory scientists, as well as agricultural, environmental health, veterinarian, vector control and private/commercial entities. Trust, confidence and data security are essential and must be ensured through the use of standards and protocols that also facilitate appropriate data sharing. Participants agreed that CDC must set the standards and solve interconnectivity challenges. However, big data storage in a protected, public health environment has to be agreed upon. The OpenFDA site for PrecisionFDA is an example of such an environment that could be leveraged for public health needs.

The issue of how to connect healthcare providers, electronic health records and public health stakeholders remains unsettled and concerning. Public health partners

Figure 1: Vision 2020 Drivers

Vision 2020 drivers (2010)

- Pending healthcare reform impact
- Understanding new technologies
- Looming interoperability issues
- Emerging threat response
- Lagging workforce preparedness and skills
- Building more efficient and effective operations

Vision 2020 drivers (2015)

- Building the connectivity infrastructure for the PHL system to feed into the national surveillance platform
- Enabling the ability to explain the biological and environmental relevance of new technologies
- Ensuring PHL workforce pipeline and capabilities
- Planning for what traditional PHL techniques and procedures are to be maintained
- Determining how PHL will engage in new era of point-of-care diagnostics
- Engaging APHL members, especially those who are not active participants

have yet to define how they will take part in the exchange of reportable condition data, especially when the data originates in the private sector.

Workforce issues are also significant. A cohort of experienced scientists is retiring, new laboratorians may lack appropriate training, new technologies demand attention, and traditional skills are being lost. Fellowship programs, leadership training and sustainable model(s) to ensure the future PHL workforce are all critical needs.

In addition, there is a pressing need to define the role of the future PHL worker, as more testing is performed at the point of patient care, beyond the purview of the CLIA-compliant laboratory. Culture-independent diagnostic tests (CIDTs) represent a shift away from the traditional PHL role. How, then, to define what traditional testing should be retained and what new roles the PHL may assume? Some envision PHL personnel as “informaticians” and “explainers-in-chief” of the science of diagnosis for the public health community—a role laboratorians have been reluctant to take on. Yet, explaining the significance of a laboratory result to peers, epidemiologists, health officials and the general public is an evolving and important role.

Communication is critical, as more people seek information from social media and fewer seek out authoritative sources. The public health community can better utilize social media outlets and understand the algorithms behind self-learning, customer-preference software (e.g., Google and Amazon software), which are being used more and more for qualitative health studies.

Vision 2020 drivers are not laboratory specific and can only succeed if the entire public health community adopts and integrates them in its day-to-day operations. The steps to meet outstanding needs must support better surveillance, information sharing, workforce development, joint training and communication. Comments and recommendations from the focus group discussions will inform these next steps.

Recommendations

Informatics

- CDC should lead the effort to develop informatics and interoperability standards, working across public health sectors and with healthcare providers to ensure better disease surveillance and test results reporting.
- An internal CDC advisory committee should be established at the center level and led by the Office for Public Health Scientific Services to harmonize connectivity standards, funding and goals.
- APHL should work closely with CDC and other public health partners to ensure the alignment of informatics connectivity, to define data privacy policies and to harmonize informatics technologies through work with its committees and staff.

Traditional Methodologies/Culture Repositories

- PHLs should lead a discussion regarding the maintenance of traditional methods and culture repositories.
- APHL and CDC should provide the forum (e.g., regional consortiums) for the above discussion.
- CDC networks (e.g., infectious disease and bioterrorism networks) and clinical and research laboratories should participate in the above discussion.

Workforce

- Public health partners should develop a sustainable public health workforce pipeline plan.
- Recognizing that social media outlets are a vital link to the public, public health associations, relevant public health foundations and other public health partners should form a working group to share best practices using social media to raise awareness of public health successes and of the field of public health as an attractive career choice.
- APHL should work with its membership to use social media to raise awareness of PHL successes and of the field of PHL practice as an attractive career choice. APHL should encourage the participation of all its members in this effort.
- CDC and APHL should work together to seek ways to create a sustainable funding base to support public health fellowships.
- APHL should expand its work with industry, philanthropic organizations and academia to develop alternative funding streams for public health fellowships, workforce-related research and global health program capacity building.

Laboratory Testing

- APHL should take the lead in tracking and coordinating PHLs testing capabilities.
- APHL should seek ways to build trust and active collaboration between epidemiology and laboratory personnel to ensure appropriate PHL testing and test results reporting.
- APHL should seek ways, with CDC and its memberships, to develop a proactive policy on reference materials (collections) for validating new test platforms.
- APHL and PHLs should investigate opportunities for regionalization of testing services for surge capacity to support CDC.

Background

The *Vision 2020* plan was developed in December 2010 to identify what drivers the public health laboratory (PHL) system must address before 2020 if it is to stay responsive to community needs; support national, reportable disease surveillance; remain aligned with the principles undergirding PHL core functions and capabilities requirements;¹ and align with the “10 Essential Public Health Services” framework.² The 2010 drivers comprised issues PHL leaders identified then as potential challenges that needed to be better understood and addressed: pending impact of healthcare reform, understanding new technologies, looming interoperability issues, emerging threat response, lagging workforce preparedness skills and building more efficient and effective operations (see [Figure 1](#)).

Since 2010, various public health stakeholders—including the Association of Public Health Laboratories (APHL) and other professional organizations; federal, state and local public health entities; philanthropic foundations; and commercial interests—have worked to address these drivers to ensure the nation’s PHL system remains robust and relevant to community needs.

The present study was initiated by APHL and the Centers for Disease Control and Prevention (CDC) to assess progress to date and determine what additional drivers, if any, need attention. As part of this effort, it was imperative to hear from the public health community, so as to benefit from stakeholders’ informed perspectives regarding new challenges and opportunities, barriers to addressing these and strategies to overcome those barriers. Study data may inform future “return-on-investment” research and constitute a baseline for tracking the evolution of peer opinion regarding the future of the US public health system.

APHL has collaborated with CDC to address its members’ needs and to assure adequate national capacity to carry out core PHL functions¹ within a sustainable PHL system. A hallmark effort is the APHL Laboratory System Improvement Program (L-SIP), developed in 2007 to support high performance levels of state and local PHL systems through continuous quality improvement. A second notable effort is the Laboratory Efficiencies Initiative (LEI), which was begun in 2011 to create guidance and tools to help PHLs become more sustainable and efficient.^{4,5} Among LEI products are an informatics self-assessment tool, recommendations to streamline PHL billing, a policy guide for PHL test service sharing, a PHL service database (PHLSD) and a manual of public health workforce competencies. The LEI partners have also provided information technology (IT) support to improve PHL connectivity, developed state-directed regional networks, provided LEAN training and certification to public health laboratorians and conducted workflow analyses at nine PHLs.

Study Design

This study uses a quasi-Delphi protocol^{6,7} suited to eliciting opinions and achieving consensus among a group of experts.

Data collection

Data were collected using four different approaches:

1. 45-minute, one-on-one, semi-directed conversations conducted via phone (n=91) or in person (n=29) and structured around the six *Vision 2020* drivers. APHL, CDC and partners nominated and invited 131 public health laboratorians to participate in the conversations. All participants were active or retired public health professionals familiar with the US PHL system. Participants’ current or pre-retirement job level ranged from technical to executive level. Only 11 of the 131

invitees were unable to take part in the study, yielding a 92% participation rate.

2. 20-minute presentations of *Vision 2020* drivers in person (n=10) or via teleconference (n=5) to groups of 4-25 APHL Board members, committee members and working group members, immediately followed by group feedback. During group presentations, topics were presented in the same order each time (See [Figure 1](#)).
3. Visits to state PHLs in North Carolina, Virginia and Wyoming to meet with state health officials, state epidemiologists and laboratory leaders and managers, ranging from 12-27 people per visit. Each visit lasted four hours, including a tour of the facilities and time to elicit feedback on *Vision 2020* drivers.
4. Two focus groups totaling 31 participants. Each of the groups convened for six hours over two days at APHL headquarters. The first focus group (held March 6-7, 2016) comprised 17 state and local public health laboratory directors and senior CDC officers who had not been part of the one-on-one conversations. Their role was to validate the focus areas and provide further insights. The second focus group (held April 7-8, 2016) comprised 14 individuals who had been part of the one-on-one conversations, including PHL directors, CDC office and center directors, representatives from partner public health organizations and Canadian Public Health Laboratory Network (CPHLN) staff. Their role was to provide a broader public health system perspective, to crystallize the issues and to determine the value/risk of potential strategies to address *Vision 2020* drivers. Focus group members discussed three topics based on a review of the first 80-100 one-on-one conversations:

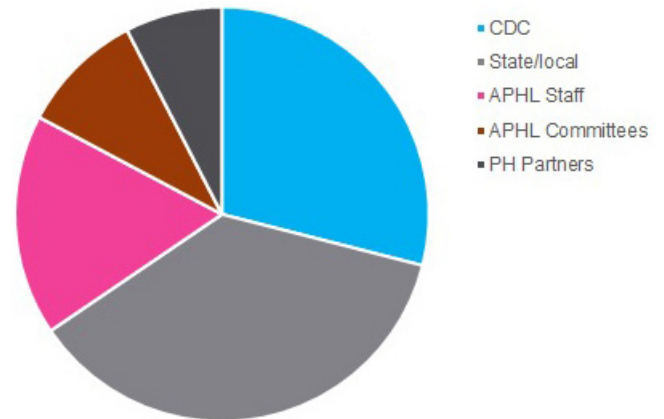


Figure 2: Vision 2020 Stakeholder Representation

- How do you envision future electronic data exchange—including test ordering and results reporting—among clinicians, PHLs and other public health entities?
- How can we encourage PHLs to retain traditional (classical) methods, while explaining the relevance and use of new technologies?
- Are the roles of various PHLs equitably distributed within the PHL system? If not, should current models (e.g., regional networks and centers of excellence) continue to be pursued?

Altogether, there were 140 individual or group encounters and more than 250 PHL participants. Figure 2 describes the interactions and participants' affiliations.

Privacy considerations

All participants were informed that their comments would be transcribed and were given pre-session materials, *Vision 2020* topic questions and terms of the dialogue. In accord with these terms, participants' comments are non-attributable except with written permission from an individual or group and are stored on the APHL SharePoint site and accessible only with APHL permission. (These documents will be stored for at least five years to enable comparative analysis in 2020.) Individuals provided verbal consent to these terms before each study encounter. Participants did not view the finalized transcribed notes, but these anonymized notes are available upon request to APHL.

Analysis of notes

Participant comments were coded and grouped in topical categories to identify thematic patterns. Similar phrases were simplified and bundled. In all, over 1,000 free text words and phrases were analyzed using several approaches:

- Manually comparing and categorizing comments for each of the *Vision 2020* driver topics, followed by scoring for word/phrase frequency and intended description of a subject.
- Text mining and use of computer-assisted qualitative data analytical software. Each group of topical comments was tagged and entered into the WordleTM web entry tool (<http://www.wordle.net/create>) to produce a “word picture” describing the overall frequency of particular words.^{8,9}
- Based on the manual and WordleTM analyses, thematic groupings were formed and illustrated with specific individual comments.

Results and Discussion of Findings

Based on the collective feedback of study participants, APHL and CDC updated the *Vision 2020* drivers from [Figure 1](#) as follows:

- Building the connectivity infrastructure for the PHL system to feed into the national surveillance platform.
- Enabling the ability to explain the biological and environmental relevance of new technologies.
- Ensuring PHL workforce pipeline and capabilities.
- Planning for what traditional PHL techniques and procedures are to be maintained.
- Determining how PHLs will engage in new era of point-of-care diagnostics.
- Engaging APHL members, especially those who are not active participants.

A word on participant quotations

Given the range of comments, notes were grouped into five categories:

1. PHL system needs
2. Barriers to meeting needs
3. Examples of positive PHL operations
4. Examples of negative PHL operations
5. Proposed solutions to identified problems.

Selected participant quotes reflect the sentiment of the grouped statements within a particular category. The quotes were reviewed for accuracy and edited using “[]” to denote insertion of words to smooth word flow and “....” to indicate elision.

One-on-One Conversation Findings

Vision 2020 driver: *Interconnectivity and infrastructure*

Although interviewees generally agreed that connectivity infrastructure is an important “whole of public health and healthcare issue,” no one understood the entire scope of what connectivity infrastructure represented. Comments ranged from descriptions of overarching systems to highly specific examples. However, everyone agreed that a common platform enabling public health stakeholders to share information in near real-time is critically needed. As one participant said:

“Unlike Coca Cola, Kaiser Permanente and some states which already run on platforms, we are behind. We also need to be sure that we do not build something we tried to do eight years ago; that would be futile. We need platform interoperability. The idea of platform interoperability is that your system has modular units [within] so that when you log into your system, you can access components on the platform (for example, human resources data and libraries) all at once.”

Some cited examples, such as electronic banking and Facebook posts, to illustrate that technology is not the barrier to interoperability;

“We should have [a] system like electronic banking. Then we can measure data from hospitals which feed to state [public health] data bank and nationally. Have to have enough capacity to do basic analytics. Reciprocity [in exchanging information] and explanation [of laboratory procedure] needed. Really need to see everything as it is happening...”

The barrier most often cited is trust, followed by governance and rules. If trust can be built among partners, building a connectivity infrastructure can be more collaborative. These views are presented in Figure 3.

Trust is an issue

Trust was mentioned as an issue by nearly everyone, regardless of position. Achieving connectivity via an interoperable platform was considered ideal, if accompanied by transparent procedures, standards and privacy protection rules. Many said the public health community needs to avoid fragmentation and employ a coordinated approach. In general, participants indicated that they would be willing to share information if appropriate procedures, standards and privacy safeguards were in place:

“Epidemiologists and state health officials have no idea how to make this transformation nor make it accessible. Right now [we] cannot map to the data, [we] cannot integrate. [To be able to do so, we] have to build trust and buy-in. [We] need a governing or advisory committee and . . . a laboratory connect[ion].”

“Informatics support has dealt with multiple changes and initiatives. We need to unite behind a single strategy to allow for interconnectivity and build trusted atmosphere to exchange

Figure 3: Comments in Interoperability and Infrastructure Needs



information. We have paid a high price [in our attempt] to develop a reasonable, sharing strategy. Contradictions and silos exist instead, and make it a harder hill to climb. Example, [the laboratory information management system] LIMS is fractured and we cannot link up. IT management at state is housed elsewhere, decisions made at health department [which we are not part of].”

Governance and rules

The general opinion was that in order to achieve an interoperable platform accessible to public health and healthcare communities, standards and rules are needed to govern what information may be transmitted, how data is integrated, who may access data and how privacy is safeguarded.

Participants generally found the APHL/CDC informatics assessment tool helpful for taking stock of informatics needs, but indicated that it does not go far enough to direct users to resources that will help them meet those needs. One participant noted that integrating epidemiology and laboratory data in the US Food and Drug Administration (FDA) Genome Trackr system is problematic, owing to issues of trust and lack of interoperability. Such issues are not limited to PHLs. Here is a comment from a CDC participant:

“We are still fragmented and must move to a less fragmented system. Laboratory-based reporting requirements are all over the map, no consistency in regards to standards. Need to set model laboratory-based surveillance metrics or guidelines or regulations and ask for states to adopt/enact. This is a crazy quilt. The connectivity infrastructure needs to be built and pressure [applied on] CDC to use it themselves. Need a joint initiative with pressure [to adopt]. CLIAC is wrestling with that in clinical setting. Electronic public health record [electronic case reporting] really needs the same (that is, guidelines and adoption of principles to making electronic reporting a reality).”

From a public health partner:

“Infrastructure in the Cloud is needed. Should have designated standards like Facebook, every program to have their own [locker]. Big data and privacy issues must be addressed.”

Coordination

To build an interoperable system, with guidance and standards in place, the next big challenge is stakeholder coordination. Participants recognize that CDC, the Council of State and Territorial Epidemiologists (CSTE) and APHL have supported efforts to build connectivity links, but are concerned that there is no master plan. They also stated that shared access to information and analytical software needs to be available via a Cloud entry portal. Given the uncertainty of future funding streams, the public health community needs to pool resources to make this a reality:

“You must build cloud architecture. For example, data and analytic tools need to be accessible in the Cloud to accommodate the expected huge influx of data and volume and be cost effective. Should partner up with someone [like clinical entities] to see how they are going to do it.”

“Impossible to be effective and efficient as long as partners are not coordinating.”

Some participants noted that specific CDC programs have made headway towards data sharing and interoperability. However, they expressed concern that these efforts are not coordinated and cited a need for a common, interoperable data sharing platform.

“Everyone is trying to do something. It would be a great help if we have a coordinated and unifying approach.”

Lack of connectivity is another barrier to interoperability. A unified system is needed to link records and case reports. Most participants cited the need for access to electronic health records and electronic case reports. Others wanted to remind funders not to forget the global public health system:

Figure 4: Views on Role of PHL in Explaining Relevance of New Technologies

This topic was not a high priority for participants. Their remarks focus less on explaining new technologies and more on gaps in the public health system in communicating science, sharing expertise and engaging in social media platforms. Most felt the ability to explain the relevance of new technologies is a workforce skill and quality control issue. Several noted the need for PHLs to create standard reference materials (e.g., calibration samples, proficiency panel) to assure comparability of test results generated on different platforms in different sites.

Public health laboratorians often expressed the wish for laboratory personnel to have a more impactful role communicating about their work to the public and to government leaders and peers. They described the tension among laboratorians, epidemiologists and state health officials who try to explain the significance of laboratory data. The attitude laboratorians most often expressed was that of resignation; they felt a lack of control over external communications about the science taking place in their laboratories (Figure 4).

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“Important to build PHL pipeline. Frustration in that we have a great model in the fellowship program and unable to establish. Seventy people have come through [the lab], but not all of them have been able to be hired. Hard to maintain, time intensive to teach and mentor lab rotations. . . . Most graduates gravitate to infectious diseases, NBS and environmental health. Sustaining interest is challenge.”

Fellowships and Training

Fellowships and training programs are urgently needed to prepare new workers and to update the skill sets of long-time staff as technology changes and new informatics, quality assurance, safety and biosecurity needs arise. Although successful programs have been implemented in the past, sustainability has always been an issue.

“Fellowships are critical to keeping the laboratory workforce fresh, but sustaining them continues to be a challenge.”

“Traditional microbiology is going away, and we need to ensure workforce to be able to adapt to new techniques. Hard to recruit new workforce.”

“Computational skills will be needed by 2020-2025 to deal with connectivity infrastructure. APHL has to start thinking about computer engineers. When you do not have such skills, you will be stuck in the mud.”

Vision 2020 Driver: Maintaining Traditional Methods

Participants agreed that maintaining traditional PHL techniques is important. Although this was not a priority for public health partners, they recognized the importance for the public health system (Figure 6). The majority view is that the PHL system is reactive, tending to offer services that are unavailable elsewhere. Public health laboratorians acknowledged that is, indeed, a role they play, and noted with understated pride that they have stepped up to the plate again and again.

“PHLs usually end up testing what is not [profitable] commercially.”

“PHLs had the traditional methods and still do to an extent, like with Ebola testing when the commercial and hospital laboratories didn’t want to run any samples that might be Ebola positive, the PHLs stepped up. In my opinion, traditional methods belong in the PHL.”

Why keep traditional test methods?

Participants cited several reasons for maintaining traditional microbiology techniques and sub-specialties, such as mycology, parasitology and tissue culture:



Figure 6: Views on Maintaining Traditional Knowledge and Uses

- Identifying pathogens—including novel, unknown pathogens—when other techniques fail.
- Serving as backup methodologies when sophisticated instruments break down. As one participant said, “What if the PCR fails? Who [will] know what to do? Who will know what alternative tests to perform?”
- Assuring the availability of microbial isolates for reference collections and pathogen panels (e.g., panels of drug-resistant microbes, TB strains, influenza strains and foodborne disease pathogens). These resources are vital for quality assurance, new test development and research. For example, MALDI-ToF results are only as good as the reference library to which test data are compared. Pathogen panels constructed from reference collections are commonly used to evaluate the performance of new tests in different laboratories and to serve as a comparative standard in the absence of a proficiency panel. And it is impossible to monitor microbes’ evolving genetic and phenotypic profiles or to identify recombinant viruses without historical isolates for comparison. Despite these compelling needs, however, reference collections are becoming difficult to build up in an era of increasing culture-independent testing. These collections also require expert curation to ensure their continued relevancy. Once isolates are destroyed, a pathogen’s molecular history is lost.
- Assuring the maintenance of critical thinking and trouble-shooting skills. One participant said, “... we depend on our staff’s knowledge about fixing the equipment and kinks that happen. We [used to be able to] resolve it on the spot, [but it’s] not so easy anymore with new equipment and a staff that has no ability to fix things. We are at the mercy of the manufacturers...”

Barriers and possible next steps

All agreed that the single most important factor influencing whether, and to what extent, traditional methods are preserved is funding. One suggestion was that CDC funding come with sufficient flexibility to support both new and traditional assays.

In addition to funding, a second issue is lack of a coordinated, national plan for retention of traditional methods and disease isolates: each laboratory now decides independently what it maintains or discards. Participants said, again and again, that absent a coordinated effort, the PHL system will end up with pockets of knowledge, further fragmentation and loss of response flexibility. One suggestion is to replicate the HIV/AIDS discussions of the 1990s, which produced a consensus approach to HIV/AIDS testing and service integration. Other proposed solutions include establishing centers of excellence for traditional techniques, as has been done for vaccine-preventable disease testing and a few other specialty areas, and having APHL duplicate and store virtual reference collections for safekeeping and sharing.

However, not everyone felt that all traditional techniques must be preserved, or preserved indefinitely:

“Old traditional is gone. Like an old car, hasta la vista.”

“[Although] some have said it is critical to keep the traditional, and especially reference strains, this may not be so in five years’ time when technology advances. Cannot cry about it.”

Given the large number of unculturable organisms being found in metagenomics studies,¹² and decreasing demand for traditional testing, some have called for specific research to inform decision-making, such as a direct comparison of whole genome sequencing and serotyping. Still others have suggested a hybrid practice model or “bridge plan” to span the transition from wholly traditionally

testing to wholly modern testing:

“It is like moving from DOS to Microsoft Office. We need to be aware of the shift and allow for time to learn, familiarize before we give up traditional practices.”

Suggested next steps include: (a) convening roundtable discussions to identify incentives for maintaining traditional methods; (b) recruiting retired laboratory experts to develop a process to address the issue of how to maintain traditional methods; (c) hold discussions on how traditional methods need to be used for transitioning to new technologies or problem/troubleshooting when there is a problem; and (d) convening roundtables to address the need for storage or repositories of special or unique cultures.

Vision 2020 Driver: Healthcare and public health links

All participants agree that healthcare providers and public health entities must work together to assure seamless electronic case reporting of reportable conditions—a goal that depends upon linkage of point-of-care (POC) electronic health record (EHR) data and laboratory test data. One concern is the challenge presented by POC test platforms that deliver more-or-less instantaneous bedside results. “Having these platforms moved closer to the patient and clinical care is exciting,” said one participant. “It will add value” via early detection of disease cases and antimicrobial resistance. However, as others pointed out, it may also delay case reporting and destroy patient specimens that might otherwise have been sent to the PHL for reference testing and disease surveillance. This loss of specimens could necessitate additional PHL work to recover live organisms when clinicians and clinical laboratories do not. At the same time, quality control measures, troubleshooting and interpretation of indeterminate or questionable results may become PHL responsibilities by default.

“Clinical healthcare and electronic health records are driven solely by desire for clinical use without consideration for PH needs, and especially, laboratory-based surveillance. With POC tests, the decision is now being taken out of the laboratory and that is a problem. The PHL community should oversee POC diagnostics use for quality assurance and surveillance, and the laboratory should serve a consultative role [to clinicians].”

“We need to know how [the PHL] fits into healthcare reform. This is an important point to know the quality measures [clinical performance site] and we risk not being able to share information like influenza [cases] and bioterrorism [events].”

“Expertise is in the analysis [of the test and test data]. [That] is the hard part [requiring experience] and breadth of pathogen knowledge.”

“We need an algorithm that can cope with this, that we are losing information from doctors’ offices and home use kits. A reporting system is critical and [will] provide insight into performance of the bedside tests. We do not have control over it.”

“The odd and the atypical results will need reference lab to evaluate. Some technology still needs an isolate, but that will quickly become unnecessary in the near future, so it could be that industry and public will forge ahead and public health will fail to be notified. This can be a sea change and CDC does not see that. Impact for public health is not considered, yet PHLs, as reference labs, may have to increase [their] troubleshooting ability and learn more about POC [testing].”

“APHL should take up the unsettled discussion around intellectual property considerations, since data, tests and equipment may carry proprietary restraints. Who owns the data if patient is in Wyoming and the test lab is in Connecticut? Need to work out what disclosure agreement or regulatory law needs to be in place to allow for rapid information exchange between the developer and public health. Need guidance on how to share the information in the public health Cloud.”

Participants encouraged discussions with clinical laboratories to discern what a workable paradigm might be.

Vision 2020 Driver: Engaging APHL members

In general, participants views of APHL are overwhelmingly positive (Figure 7).

Equity and regionalization

Asked why some APHL members are less active than others, participants immediately turned to the issue of regionalization. CDC, they said, should not divide up the country into programmatic health regions. In their view, it is unavoidable that states will have different public health capabilities, based on their history and resources.

Similarly, participants noted that it is not APHL’s role to make extraordinary efforts to achieve more equitable participation and representation in the association. Several PH laboratorians indicated that it is laboratory directors’ responsibility to encourage staff involvement with APHL and suggested that staff members who express interest in APHL should try to attend the association’s annual meeting. CDC Epidemiology and Laboratory Cooperative Agreement and APHL Cooperative Agreement funding should provide some flexibility to support this meeting attendance.

At the organizational level, APHL must ensure an open and transparent process for nominating individuals to committees to promote a more equitable distribution of committee assignments. A few participants voiced frustration with the current process, noting that some members have been unable to get the committee assignment of their choice. One suggestion is to allow APHL members to observe committee meetings to gauge whether a committee’s work aligns with their interests and skills. Some also mentioned that mentoring first time committee members is important.

Here are some complex issues/activities APHL may undertake so that it is easier for its members to engage and participate:

“APHL should understand why some states and members [have difficulties] and ease some of those issues, for example, creating a MOU template for a regional consortium model. Often CDC programs form the networks, but do not engage with the state/local PHL beforehand as to what the best model should be.”

Views of APHL by its members

APHL members cited several association services they particularly value: educational and training



Figure 7: What APHL means to its Staff, Members and Partners

opportunities, policy work, advocacy for PHLs, and serving as a voice for members. In addition, some cited “indispensable” services, such as access to funding opportunities, updates on legislative issues (e.g., federal Common Rule and LDT guidance), updates on budget issues and efforts to tackle complex, overarching concerns, including workforce challenges and leadership training. The association was lauded for the non-confrontational way it approaches members and the vital information it dispenses. Those actively involved with APHL were grateful for the personal opportunities afforded through the organization. For example, one participant said serving on an APHL committee was the “pinnacle” of his career.

Asked what APHL is not doing, but should be, the top response was assessing the impact of its own outreach and programs. Additionally, although participating APHL members said they recognize some ideas have to be repeated multiple times before they sink in, some said the association has to “find better and more ways to communicate,” especially about its own benefits. Most said APHL’s top priority between now and 2020 should be championing Cloud-based PHL solutions.

Another topic mentioned across several report sections was the desire for CDC programs should coordinate their support to allow for formation of regional networks or consortiums but having the model being driven locally. Specifically, CDC and APHL should create a bioinformatics network so more remote and less APHL engaged laboratories can access bioinformatics expertise and related analytics.

Views of APHL by CDC stakeholders

Overall, CDC participants hold APHL in high regard, especially for its work as a liaison between CDC and APHL members.

“APHL is really respected and has influence.”

“APHL is strong partner of LRN, biosafety. Works as convener, facilitator. . . . APHL responds to states, comes up with performance standards.”

“APHL is place to grow the connectivity.”

“Great working relationship with APHL, view as a real partnership, candid, approachable, very open.”

“Help goes both ways. Example, contacted by Saudi [Arabia] [regarding] their central reference laboratory, and APHL responded by sending [an] expert to assess that PHL. During [the] government shutdown, APHL messaging [helped] so that state PHLs knew who would be at CDC.”

“At the time of shutdown, it was APHL that took messages out to state labs and triaged questions and issues. It was extremely helpful and kept us in the loop”

Views of APHL from public health partners

Public health partners voiced the strongest positive views of APHL and the benefits of collaborating with the association:

“Excellent organization. Peer-to-peer consultation with CSTE very good practice. APHL and CSTE worked together with Hill to write same letter to improve government relationship and advocacy in lock step. CSTE works with APHL by 2020 for synergistic Field Epidemiology Training Program and surge response.”

“Challenges are the same at other associations. Do the outreach, webinars, skills updating, etc. Regional training is [a solution], engage private sector to join [like L-SIP, other like responders]. Think about a retirees/alumni association, it is an area of growth.”

Challenges and issues for APHL

In general, participants cited five key challenges for APHL:

- Resolving the continuing tension and mistrust between epidemiology and laboratory functions. This issue is mentioned elsewhere in this report as something that all stakeholders must address.
- Assuring maintenance/expansion of reference materials (collections). This could be a collaboration between PHLs, APHL corporate members and CDC.
- Supporting fellowship opportunities. APHL, CDC and public health partners should work together to find a long term solution.
- Expanding its work with corporate industry, philanthropic organizations and academia. A few participants—from CDC, PHLs and partner organizations—said APHL should broaden its membership to include healthcare entities (e.g., AthenaHealth), healthcare informatics (e.g., CERNA Solutions), pharmacy organizations (e.g., American Pharmacists Association), clinical labs (e.g., LabCorp), entities interested in health trends mapping (e.g., Google) and foundations (e.g., Bill & Melinda Gates Foundation). Could APHL form a consortium with corporate members for public health fellowships? Could APHL establish a mechanism to discuss the research and development pipeline?
- Championing public health Cloud solutions and other informatics issues.

APHL and CDC should form small working groups to monitor progress toward these outstanding needs.

Focus Group Findings

Two focus groups were convened after completion of the majority of the peer-to-peer conversations. The groups were asked to refine the *Vision 2020* drivers, to crystallize the issues and to identify paths forward.

Focus Group 1

Participants included state and local laboratory leaders from Florida, Georgia, Idaho, Maryland, New Mexico, Oregon and Wisconsin, Philadelphia and Fairfax County, Virginia; four CDC scientists from the National Center for Environmental Health, National Center for Emerging and Zoonotic Infectious Diseases and the Office of Surveillance, Epidemiology and Laboratory Services; and senior and support staff from APHL.

Three questions were posed to the group:

- How do you envision future electronic data exchange—including test ordering and results reporting—among clinicians, PHLs and other public health entities?
- How can we encourage PHLs to retain traditional (classical) methods, while explaining the relevance and use of new technologies?
- Are the roles of various PHLs equitably distributed within the PHL system? If not, should current

models (e.g., regional networks and centers of excellence) continue to be pursued?

Electronic data exchange

The group affirmed the value of linking EHRs and electronic case reporting (ECR), but identified several issues that must be addressed to realize this: privacy, data access, IT support and system sustainability. PHLs, the group said, still need to build an interoperable, preferably Cloud-based, data exchange system.

“There are so many hurdles to go over to get just the basic technology. We’d also need the staff that has the expertise. You can’t just set up this system and leave. How to communicate this need to higher up in the health agency? Currently, the data doesn’t match from one system to another.”

“We need IT support from a higher level. APHL needs to help communicate the importance of a competent IT system. There is a risk of misinformation trickling into the wrong hands. There’s no validation or quality assurance on the transferred data.”

“We have to consider different types of data. Some data is more time sensitive than others.”

“We need to get the issue in front of ASTHO. This is the kind of thing that we can work on together with CDC and CSTE and get a single united message. The pendulum has swung back to centralized IT.”

“We need to understand what members need in terms of data management. We might have an idea of what tools you need, so we need to have a better idea of what you’re looking for.”

“In the past, we looked at the data we needed to collect and then we put money into getting that data. But there’s a new world that we don’t understand. Now struggling with old structure but new needs. The technology creates ‘big data,’ but what does this information mean? The statistics and math [are] sometimes wrong! Public health is struggling to embrace this new way of doing things. Need to redefine what data is needed without bias.”

Retention of traditional (classical) methods

PHLs are challenged to keep pace with new technologies and to explain their impact on public health services. At the same time, many traditional services and expertise are being retired due to tight budgets, low demand and loss of skilled, retiring laboratorians. Although, bedside, culture-independent diagnostic tests (CIDTs) represent an exciting, pivotal point for the healthcare system, PHLs are still figuring out their most appropriate role vis-à-vis this technology. Some see CIDTs as an opportunity for PHL leaders to become “explainers-in-chief,” interpreting test results for other public health practitioners, the healthcare community and the public. The hardest decisions are what traditional methods, reference materials and expertise to retain, how to retain them and who to appoint as custodian.

“I think it depends on how fast technology advances. Testing still needs isolates, but as technology evolves there could be a decrease in the needs, such as what is happening with virology, where metagenomics is evolving and less culture is needed.”

“Perhaps we need to work with our academic partners to maintain this expertise.”

“Had to give up mycology, and long term employees are still very upset...”

“Virtual culture collection? Where are the culture repositories? Reference panels should be

made. When a new technique comes out, [we need to evaluate and calibrate with known reference standards].”

“There’s an emotional component to this that we need to separate. What is needed and why, and what is the impact? These assessments would take time, but the technology is advancing so quickly! Laws are potentially a bad idea because technology is advancing quickly. These are specialized services that people will have to pay for.”

“This is an exciting opportunity for PHL growth. The PHL was always viewed as [doing] exciting work, like molecular [testing], but now maybe [it is] time to give that technology to the clinical world, and the PHLs can take back the traditional work. We have reciprocal issues with the clinical laboratories. The workforce in the clinical world can do the training to crank out the results, but can’t explain what they mean. PHLs can give up their diagnostic work and trade for interpretation...”

“PHLs had the traditional methods and still do to an extent, like with Ebola testing [when] the Quests and LabCorps didn’t want to run any samples that might be positive, but the PHLs stepped up... Traditional methods belong in PHLs.”

Distribution of PHL Roles

APHL encourages its members to take advantage of grant-funded activities and has worked with CDC to ensure that funding disbursements and grant periods are reasonably spaced to allow for the completion of required work. Yet several challenges prevent some members from pursuing funding opportunities:

- Asynchronous federal, state and local budget cycles.
- The need to follow state or local dictates regarding grant applications.
- Onerous application deadlines.
- Inability to meet the technical requirements included in funding opportunities (especially for smaller PHLs).
- Insufficient staff to carry out grant activities (especially for smaller PHLs).
- Lack of staff with the appropriate skill sets to carry out grant activities.
- Lack of a connectivity infrastructure.

On the other hand, contracts are easier to apply for and require less laboratory infrastructure fewer demands on the laboratory workforce.

“Appreciate how APHL makes RFPs available. The expectations are explicitly written out. But [we] need six to eight weeks to respond, as we have to get approval from higher up, sometimes from the governor’s office.

“Fellowships [are needed] to fill gaps at the state level. What if we had a reverse fellow? The fellow disseminates information by going to PHLs for a period of time instead of getting an inexperienced fellow learning something. It’s a way to get the expertise customized in-house. You can go to the training, but then when you get back, you have to customize it to your laboratory, which takes time most do not have.”

“Fellowships for epidemiology have increased, but fellowships for lab have decreased. Why?

The fellows need to do the things that the states need them to do! Where did all the money go?”

Focus Group 2

Participants included representatives from the American Public Health Association (APHA), CSTE, de Beaumont Foundation, the Public Health Accreditation Board (PHAB), CPHLN, the University of Vermont, CDC (from the Office for Public Health Preparedness and Response, Office for Surveillance, and Epidemiology and Laboratory Sciences) and directors of the Iowa and New York state PHLs. Senior and support staff from APHL also participated.

Prior to the focus group, participants were sent the discussion topics and briefed on the feedback from 104 peer-to-peer conversations and Focus Group 1. This group was asked to provide a broader view of the topics within the context of the future, national PHL system. Specifically, participants were asked how best to make gains, in the next five years, in three areas:

- Connectivity infrastructure for data exchange, analysis and reporting.
- Workforce.
- Adoption of new technologies and retention of classical methods.

Historical recap

The group recalled CDC’s Winnable Battles initiative, launched in 2010, when federal budgets were tight and the agency was examining how to achieve a much leaner and more efficient PH system. At that time, *Vision 2020* drivers were being developed with the expectation that there could be an uncomfortable review of future PHL system requirements. Thus, APHL and CDC were more interested in exploring efficiencies in the PHL system than in the broader *Vision 2020* goals.

Impact of social media

A discussion on the impact of social media preceded a discussion of the assigned topics. All participants agreed that social media impacts how public health entities communicate and conduct business. Given the prevalence of social media usage, many felt that it is incumbent upon public health officials to learn how the public seeks health information and how the public health system can best use social media outlets to disseminate information.

“People use social media to get their information. We need to rethink how we package useful information for these archetypes of audiences. Also, I feel like we are making assumptions on what public health picture looks like. What is our bread and butter? With Ebola and Zika, we have an opportunity to show what our value is as PHLs, in a time where there is a lot of fear and uncertainty. People are now leaning on laboratories to provide a sense of security and evidence-based answers. PHLs have the ability to tell you who is at risk and who isn’t. We aren’t leveraging this opportunity. We need to build back traditional public health capabilities (the bread and butter of PHL testing) because technology isn’t going to have all the answers.”

“In this conversation about social media, at a university, I feel like we’re still stuck in the mindset [of] ‘okay, let’s set up a website.’ There’s this other universe of information exchange, and I don’t think we have a full understanding of the social context in which this dialogue is occurring. And we’re deluding ourselves if we think we can just put up a website.”

“Yelp is now doing hospital ratings...information that Center for Medicare and Medicaid Services (CMS) ratings don’t get at. And they aren’t doing it in any structured way. They

are pulling data from the text entries where people can say something about how their appointment was late, and that information gets coded into data. I use Twitter a lot to get to critical sources. Most of the journal articles that I see are posted on Twitter. Connectivity is importing information from all these different sources, but is also how we get information out.”

“Perhaps we need more qualitative research/behavioral science? Maybe we need to reach out to our colleagues in community health in a more active way. One of the challenges is how can we get more schools involved? How can we bring in our social science cousins?”

Connectivity infrastructure

Discussants highlighted two key issues: (a) the need to map how information can be shared across the public health system, given ‘big data’ privacy concerns and (b) the need for a comprehensive plan for maintaining the public health Cloud.

“This is not just a PHL problem. Are you the performer of things or the integrator of things or the strategist of things?”

“....wanted to have laboratory surveillance data for influenza be transmitted directly into CDC so we could cut down on the time for epidemiologists to do the analysis. We wanted it to be more in real time. This was a proof of concept project from six-seven years ago. We now have 49 states sending production-level data to CDC. It goes into [the APHL Informatics Messaging Service] AIMS cloud, and CDC goes in and grabs what it needs. It’s done in a secure way.... APHL is working with CSTE and CDC on electronic case reporting.... not confident that [it will] have long term support. “

“...All these [test ordering and reporting] initiatives are being funded currently by CDC. Where this is going, I do not know. We’ve seen some not very effective mechanisms in the informatics sphere before. I think we’re at one of those tipping points. What is the plan?”

“We need to better define Cloud computing. The sender of the data still owns the data, and they send it however they want to send it to a platform, and it goes to some server farm. The data ownership is key. The hospital or PHL can send it de-identified. We are working on making sure that the data that’s produced is standardized—data harmonization. I don’t see having a national public health data network is the solution. I think having a regional level is more reasonable.”

“We need to also address who owns the data. If someone goes into a pharmacy and the pharmacy has to submit that data to the Cloud, does the individual know that’s going to happen, and do they want it to happen? Public good versus individual rights. If I go online and order a test online, nothing has to be reported.”

Workforce needs/gaps

The public health system has struggled with workforce development and retention for many years. An entire cohort of experienced professionals is retiring and not all are being replaced. At the same time, new hires often bring different skill sets from their older colleagues. The challenge is to transition the workforce and absorb new ideas into the system, with minimal disruption, recognizing that the PHL system of 2025 will not be the same as the PHL system of 1985.

A second issue is the need for proactive efforts to attract students at all levels to the field of laboratory science and, specifically, to public health laboratory practice.

“Where is our workforce coming from? What do you teach folks in three to five years, instead of a 40-year career?”

“I think for future consideration, two words really jump out at me: data and information. Data in, information out. But there needs to be some analysis somewhere in there. We need to think through that, converting data into information and what are the roles within the PHL to get that done? We don’t have enough people that have that skill to do that translation.”

“My proposal would be to create an undergraduate minor in public health that would allow students from other disciplines—biology, chemistry, etc.—to get an understanding of public health. For some reason, there is [the perception] that public health is a graduate level [field], but by doing that, we’re cutting out a bunch of people interested in public health.”

“The competencies for epis are constantly changing. I’m not sure that labs are anywhere in there. Our applied epi fellows that we put out in the field [have] master’s degrees in public health, and they go into various programs, not just infectious disease.”

“There are some laboratory purists that wouldn’t think to teach a laboratory science course to a non-laboratorian. I think it would be great to have that cross [training]. We have some of our students take an undergraduate course in epidemiology, and it’s a huge benefit to them. I think it’s a great idea to have epidemiologists have some laboratory understanding.”

“We have not been able to modernize the human resources system in state/local government. It’s not nimble. The federal system is the worst. It’s just deplorable....You have to [have] creative leadership.... We have a ton of different opportunities in the laboratory that may not [require] bench [science work]. Of course there are opportunities!”

Adopting new technologies and retaining classical methods

The PHL system should have core capabilities and then add on from there to meet defined needs. PHL leaders have to separate the emotion from the need. Many want to retain traditional services out of a sense of nostalgia. Instead, leaders need to think in terms of the concrete benefits offered by traditional practices. Most participants indicated that they are reluctant to lose a laboratory capability, but would be willing to do so if there is credible evidence that a newer technology will improve the quality of the science.

“...I think systems should have a base of core capabilities. I think depending on how the system is structured, traditional techniques reside somewhere as you build up from that base. That base may very well include capabilities to do some molecular. Those traditional methods have to be preserved. It’s not like clinical laboratories can do everything either, i.e. Ebola response. They don’t have the staff that’s fully versed in or trust the standard safety procedures, which many of us grew up with. We have to have those capabilities to back up that clinical system. So it’s a matter of where do we distribute these capabilities in that system. I think it’s a tiered system. What additional capabilities are needed at the next step?”

“I think certain things should stay at CDC. I don’t think this is a black and white issue. I think there’s a gradation depending on where the technology sits at the present time. I think losing all culture capability would be really sad, but I think that can be contracted to other labs to maintain that capability.”

“You don’t really know what questions to ask. It’s an argument for maintaining capabilities. How it’s done in terms of tiered networks or some other mechanism, I think that’s fine. But what I’ve seen is a lot of molecular biologists coming into public health and fewer

microbiologists traditionally trained, and we're seeing the impact of that. I think the risk assessment ... knowledge base is important. This is a value added issue. There is a lot of stuff we don't know. One of the value propositions of maintaining microbiologists' traditional training is that we don't know everything. We have dabbled in a lot of different parts of biology that aren't DNA based. DNA sequencing is important, but it's not the Holy Grail that answers everything."

"One of the things in selling labs, advocating for labs, is the notion that we are public entities. If you're trying to draw young talent into the workforce, you really want to be able to say that you're the last stop."

"What are the things that we need, and where can we move not-so-important things into a regional approach?"

Recommendations

Informatics

- CDC should lead the effort to develop informatics and interoperability standards, working across PH sectors and with healthcare providers to ensure better disease surveillance and test results reporting.
- An internal CDC advisory committee should be established at the center level and led by the Office for Public Health Scientific Services to harmonize connectivity standards, funding and goals.
- APHL should work closely with CDC and other PH partners to ensure the alignment of informatics connectivity, to define data privacy policies and to harmonize informatics technologies through work with its committees and staff.

Traditional Methodologies/Culture Repositories

- PHLs should lead a discussion regarding the maintenance of traditional methods and culture repositories.
- APHL and CDC should provide the forum (e.g., regional consortiums) for the above discussion.
- CDC networks (e.g., infectious disease and bioterrorism networks) and clinical and research laboratories should participate in the above discussion.

Workforce

- Public health partners should develop a sustainable public health workforce pipeline plan.
- Recognizing that social media outlets are a vital public link, public health associations, relevant public health foundations and other public health partners should form a working group to share best practices using social media to raise awareness of public health successes and of the field of public health as an attractive career choice.
- APHL should work with its membership to use social media to raise awareness of PHL successes and of the field of PHL practice as an attractive career choice. APHL should encourage the participation of all its members in this effort.

- CDC and APHL should work together to seek ways to create a sustainable funding base to support public health fellowships.
- APHL should expand its work with industry, philanthropic organizations and academia to develop alternative funding streams for public health fellowships, workforce-related research and global health program capacity building.

Laboratory Testing

- APHL should take the lead in tracking and coordinating PHLs testing capabilities.
- APHL should seek ways to build trust and active collaboration between epidemiology and laboratory personnel to ensure appropriate PHL testing and test results reporting.
- APHL should seek ways, with CDC and its memberships, to develop a proactive policy on reference materials (collections) for validating new test platforms.
- APHL and PHLs should investigate opportunities for regionalization of testing services for surge capacity to support CDC.

Summary and Conclusions

This study assesses the current and future state of the US PHL system and updates a list of factors—the *Vision 2020* drivers—that are propelling change within that system. The project is the first in-depth, qualitative study to gauge the challenges and views of PHL professionals, CDC officials and public health partners as they grapple with an evolving public health landscape.

As a result of this project, the original list of *Vision 2020* drivers, developed in 2010, has been updated to include the following six items:

- (a) building the connectivity infrastructure for the PHL system to feed into the national surveillance platform
- (b) enabling the ability to explain the biological and environmental relevance of new technologies
- (c) ensuring PHL workforce pipeline and capabilities
- (d) planning for what traditional PHL techniques and procedures are to be maintained
- (e) determining how PHLs will engage in a new era of point-of-care diagnostics
- (f) engaging APHL members, especially those who are not active participants.

Of the more than 250 public health professionals participating in this study, none was satisfied with the status quo. Most felt that not addressing the updated list of drivers will threaten the relevance of the public health community, impair its ability to connect with the healthcare system and render it less able to carry out its mission to promote health security.

While affirming the value of current public health frameworks—including the 11 core functions and capabilities of PHLs—participants noted that perhaps the biggest challenge facing the US PHL system is the lack of predictable, sustainable funding. A second major challenge is assuring the future PHL workforce. Not only is an entire cohort of highly trained laboratorians retiring—and taking their institutional memory and knowledge of classical laboratory techniques with them—but the pool of appropriately skilled replacement candidates is generally inadequate. And yet a third challenge

is insufficient “master planning” to coordinate the efforts of programs, projects, working groups, committees, consortiums and networks. Some said it is time to “reboot” the PHL system.

An ongoing theme in this report is transitioning: to the use of new laboratory technology, to a healthcare system that increasingly employs EHRs and CIDs, and to the use of social media communications. Some participants suggested that PHLs need to carve out new roles, possibly including that of “explainer-in-chief” for PHL science.

Ultimately, addressing *Vision 2020* drivers falls largely to PHL leaders. They must commit to efficient, effective information sharing and decision-making to move the system forward.

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Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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