INTRODUCTION

In the spring of 2012, the Association of Public Health Laboratories (APHL) conducted a series of key informant interviews with members from local and state public health laboratories (PHLs). The purpose of the interviews was to ascertain PHLs’ views on shared molecular diagnostic services for low incidence bacterial and viral vaccine preventable diseases (VPDs) in reference laboratories established at state or local PHLs. Use of VPD reference laboratories by PHLs would be voluntary. Interview questions focused on scope and functions of VPD reference laboratories and the benefits and barriers of becoming or using a VPD reference laboratory.

APHL’s Infectious Disease Committee convened a VPD Task Force in February 2012 to develop the questions for the key informant interviews. The VPD Task Force consisted of subject matter experts from APHL’s Infectious Disease Committee and CDC staff. An announcement was sent to APHL’s membership inviting interested laboratories to schedule an interview. In two weeks in late March and early April, interviews were conducted by APHL staff over the phone with 20 self-selected PHLs. Interviewees represented three local and 17 state PHLs from a wide geographic area. This report summarizes the findings from the series of key informant interviews and will help inform the development of a request for applications to establish VPD reference laboratories across the nation.

FUNCTIONS

Interviewees were asked what components of capacity should be offered by VPD reference laboratories (Figure 1). Eighty five percent (n=17) of interviewees would like a VPD reference laboratory to provide subject matter expertise to PHLs. Additionally, the same percentage indicated that proficiency testing panels should be available from at least one of the reference laboratories. Fourteen interviewees would also like diagnostic surge capacity and training, and 13 would like diagnostic method evaluation and confirmatory testing services provided. Serotyping/serogrouping and surveillance testing had less than half of participants requesting these services (40%, n=8). Provision of primary diagnostic testing for VPDs by reference laboratories was requested by one PHL and consultations to determine the need for testing was requested by another PHL.
Figure 1. Desired Components of Capacity in a VPD Reference Laboratory

Note: Total respondents = 20
CONCEPTUAL SUPPORT

Seventy-five percent of PHLs interviewed would like to serve as a VPD reference laboratory if funding was available (n=15; one local PHL and 14 state PHLs). Four laboratories, two local and two state PHLs, would not be willing to serve in this capacity, and one state PHL was uncertain if they would be willing to serve in this capacity. Infrastructure limitations, such as space, staffing and lack of mechanisms for billing, were the main reasons PHLs were unable to serve as a VPD reference laboratory. Additionally, two PHLs commented that they would be hesitant to put time and effort into establishing their PHL as a VPD reference laboratory if funding were not guaranteed beyond one year.

For the PHLs who would like to serve as a VPD reference laboratory, several common themes emerged. In addition to requesting funds for supplies and reagents, all PHLs would request funds for at least one additional staff member to support the function of serving as a VPD reference laboratory. While the need for formal agreements or a memorandum of understanding varied amongst the interviewees, PHLs agreed that expectations for turnaround times, testing methods, reporting format and costs would need to be established up front. With the exception of one PHL, no concerns regarding significant regulatory issues were expressed.

Fifty percent (n=10; 2 local PHLs and 8 state PHLs) of interviewees would be willing to send specimens for identification at a VPD reference laboratory, while 35% (n=7; 1 local PHL and 6 state PHLs) would not. Three state PHLs were uncertain. When asked about the challenges of using a VPD reference laboratory, laboratories stated that they would not send molecular testing services out because they already have in-house capabilities and would not want to incur additional shipping costs sending the specimen to the reference laboratory. Additionally, concerns about the turnaround time for critical diagnostic results or in the event of a regional outbreak was another reason for not utilizing a VPD reference center.
SHARED CONCERNS

Sustainability

In an effort to explore alternative, sustainable funding models beyond federal funding, interviewees were asked if they were willing to pay for VPD testing services in a fee for service model. The ability to operate under a fee for service model varied greatly among the interviewees. Some PHLs do not have funds available to contract out testing services. Other PHLs would not use a fee for service VPD reference laboratory because they already have the capability in-house and outsourcing testing would not be cost effective. For interviewees who were supportive of a fee for service model, surge capacity, confirmatory testing, and proficiency panels were among the common components PHLs were willing to pay for, whereas surveillance testing was not.

Interviewees questioned the sustainability of VPD reference laboratories beyond federal funding to support such a system. At least one laboratory would be unlikely to send specimens for testing at a VPD reference laboratory because of sustainability issues. There are significant concerns regarding eliminating or altering current test delivery models, without a plan for sustainability for shared service models.

Public Health Laboratories Provide a Unique Role

Interviewees emphasized the unique role public health laboratories provide in testing for low incidence and rare diseases such as VPDs. The implications of sending testing to an outside reference laboratory would have to be considered. One PHL stated that VPD testing provides a high level of visibility to the public and to legislators, and if capability for testing was lost or provided outside of the state, there could be serious political implications such as loss of funding. Similarly, another laboratory mentioned that PHLs compromise their justification for existence if testing services for rare diseases are outsourced. Additionally, if a fee for service model was established in the absence of federal funds, VPD reference laboratories would potentially be competing with commercial reference laboratories who also offer this testing and several interviewees indicated that they would be required to put the testing service in question out for bid. These concerns, along with worries that subject matter expertise and skills will be lost if VPD testing is outsourced, will play a role in whether PHLs will utilize VPD reference laboratories.

Confidence in Quality Services

The quality of test results provided by VPD reference laboratories was a concern for many interviewees. Participants expressed the need to feel confident that VPD reference laboratories produce accurate test results in an efficient timeframe, especially for critical diagnostic results. VPD reference laboratories should be CLIA approved, use standard protocols and testing platforms, and already have significant experience and expertise in the offered testing services. One interviewee was concerned with the inability of submitting laboratories to provide input into the selection of testing methods offered by VPD reference laboratories. To address this, it was suggested that a group of subject matter experts periodically review these methods.
CHALLENGES

Key informant interviews highlighted several challenges and considerations that need to be addressed when establishing VPD reference laboratories.

Time and cost to ship specimens

In the event of an outbreak, shipping specimens to a VPD reference laboratory would inherently add 24 hours to test turnaround time. Nearly every interviewee expressed concern about turnaround times. This could be a barrier to PHLs utilizing a VPD reference laboratory when testing could be performed in-house with immediate results. Additionally, cost of shipping could potentially be prohibitive if it were more expensive and time consuming than providing testing in-house. Interviewees did not want to become a pass through for specimens nor did they desire to become a processing center to ship specimens to the VPD reference laboratory. To address this, it was suggested that submitting laboratories ship directly to VPD reference laboratories rather than routing it through the state PHL, however a mechanism to notify the state PHL and epidemiologists that a specimen was sent for testing would have to be put in place.

Billing

The ability to bill for testing services in a fee for service model varied greatly between interviewees. Some PHLs already have the ability to bill within their jurisdiction, receive Medicare and Medicaid reimbursements, and bill private insurance. Others do not have this capability. There was uncertainty amongst interviewees on how VPD reference laboratories would handle billing of submitting PHLs. Additionally, one PHL highlighted that even if reimbursements could occur between states, Medicare, Medicaid and private insurance may pay for primary diagnostic testing, but would likely cover only a fraction of the actual cost to run the test. Furthermore, these reimbursements would not pay for subtyping or other testing that does not have a direct impact of patient care.

Loss of subject matter expertise and skills

Outsourcing VPD testing to reference laboratories would remove the expertise from state and local PHLs. In addition to concerns about losing molecular subject matter expertise, interviewees were also concerned about the loss of serology expertise. Many PHLs stated that serology is more difficult to maintain for low incidence VPDs than molecular tests, because kits are expensive and have a shorter shelf life than molecular reagents. To address this, one interviewee suggested maintaining regional stockpiles of serology kits at VPD reference laboratories for rapid deployment to PHLs in the event of an outbreak. Interviewees would also like to see serology testing offered at VPD reference laboratories because for some VPDs serology is required for case confirmation.
Electronic ordering and reporting

In order to ensure timely results, many interviewees requested that VPD reference laboratories have the ability to receive electronic test orders and report electronic results to submitting laboratories. When asked about Health Level Seven (HL7) messaging capabilities, 90% (n=18; 2 local PHLs and 16 state PHLs) of interviewees currently have the ability to transmit data. However, it is unclear how this can be used in a state-to-state reporting format. Standard ordering and reporting formats will need to be considered when planning and establishing VPD referencing laboratories.

CONCLUSIONS

The information gathered from the VPD Key Informant interviews highlights the complexity involved in establishing shared service models to ensure testing capability for low volume, high complexity testing. Due to the considerable cost and time that will be involved in establishing the proposed VPD reference laboratories, APHL and CDC must put substantial thought into the development of a usable structure for the VPD shared services system, carefully considering the testing menu, test method selection, transport issues, ordering and reporting mechanisms, quality assurance and funding mechanisms.

APHL would like to thank all key informants who volunteered their time to participate in interviews. As APHL and CDC move forward, information and perspectives from this report will help develop a request for applications to establish VPD reference laboratories.