Summary of interviews with project participants and stakeholders to evaluate program objectives

The LIMS Project:
Summary of Evaluation Findings

June 2007

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Authors
Carol McPhillips-Tangum, MPH, Principal
Experion Healthcare Group, LLC

Kristin Saarlas, MPH, ScD, Deputy Director
Public Health Informatics Institute

Anita Renahan-White, MPH, Director of Project Management
Public Health Informatics Institute

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The Public Health Informatics Institute is dedicated to advancing public health practitioners’ ability to strategically apply and manage information systems.

The Institute assists federal, state, and local public health agencies and other public health stakeholders that are grappling with information systems challenges.

Our services provide clarity about the information systems problems to be solved and identify the solutions to those problems.

The Public Health Informatics Institute is a component of The Task Force for Child Survival and Development.

For more information about this document or other publications of the Institute, contact:
Kymberlee Estis, MPP
Communications Director
Public Health Informatics Institute
750 Commerce Drive, Suite 400
Decatur, Georgia 30030
E-mail: kestis@phii.org
Visit our website www.phii.org Call us toll-free (866) 815.9704
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EXECUTIVE SUMMARY

From 2002 to 2005, the Public Health Informatics Institute (the Institute), the Association of Public Health Laboratories (APHL), and numerous state and local public health laboratories (PHLs) collaborated on a project to address the critical needs of the nation’s PHLs for efficient laboratory information management systems (LIMS). The goals of the LIMS project were to:

1. Enhance the informatics knowledge base among participating PHLs with respect to developing a framework to maintain and update public health LIMS
2. Work collaboratively to develop requirements for LIMS
3. Assist PHLs to assess available options for implementing a LIMS
4. Foster the development of a logical design for public health LIMS.

In 2007, an evaluation was conducted to assess the extent to which the LIMS project was successful in meeting its goals. To meet this objective and communicate the benefits of the LIMS project to the end-users, we conducted 12 in-depth, structured telephone interviews with representatives of PHLs and two interviews with representatives from APHL.

Highlights from the LIMS project evaluation include the following:

- The project successfully developed LIMS requirements and assisted labs to move toward developing and/or enhancing their information management systems.
- Although nearly all the lab representatives interviewed described the requirements document as being extremely useful to their lab, some thought that the requirements document included more requirements than are actually used by most labs. Among those respondents, there was a general sentiment that the requirements were “too broad” and the breadth of the requirements prevented them from being “as deep” as they could have otherwise been.
- Most interviewees indicated that the project helped them to develop and/or implement their LIMS more efficiently and resulted in a much more comprehensive and robust final product than they would have been able to attain independently.
- While the LIMS project was highly successful in developing requirements for LIMS, the project’s greatest success may be related to its processes as much as to its products. In fact, many interviewees described the collaborative aspect of the project as having the greatest and most lasting impact.
- Several interviewees spoke about the impact that the LIMS project has had on their organizations – not only related to the development or enhancement of their information systems – but also related to how the project in some way changed their organization at a higher level.
- Several factors were related to the success of the LIMS project, including a sense of urgency and a defined window of opportunity to improve LIMS following the events of September 11, 2001; strong leadership on the part of the executive sponsors (APHL and the Institute); an agreed upon vision and mission for project participants; a combination of people from different backgrounds and with a broad set of skills; identifiable milestones and a structured process for reaching those milestones; and the necessary determination and fortitude on the part of participants to see the project through to completion.
The findings from this evaluation document the value of bringing state and local health departments together to collaboratively develop information system requirements. They also suggest that the systematic approach to requirements development was both effective and efficient and can be applied to other public health information system development projects.

Currently, the Institute is using the Collaborative Requirements Development Methodology as part of a national program funded by the Robert Wood Johnson Foundation, Common Ground: Transforming Public Health Information Systems. Common Ground brings together state and local health agencies to work together to develop information system requirements for public health preparedness and chronic disease prevention programs. Lessons learned from the LIMS project are also being used to shape future requirements development efforts in childhood obesity and newborn screening.
INTRODUCTION

Public health laboratories (PHLs) operate as the first line of defense to protect people against diseases and other health hazards. Working in collaboration with other segments of the nation’s public health system, PHLs provide diagnostic testing, disease surveillance, applied research, laboratory training, and other essential services to the communities they serve.

Clinicians, hospitals, emergency responders, and public health officials at local, state and federal agencies rely on the rapid, accurate, and complete communication of health-related information from local and state PHLs to diagnose, treat, prevent, and control diseases and other public health threats. As a result, there is a critical need for PHLs to have efficient electronic laboratory information management systems (LIMS).

LIMS provide the infrastructure for labs to effectively log and access specimen data with epidemiological, clinical, and test result data; and electronically report findings to public health partners. In addition, a complete LIMS incorporates other business processes essential to internal functioning, such as billing, test quality control and assurance, reagent and kit/forms inventory, etc. As a result, sophisticated, efficient, electronic LIMS are critical for PHLs to fulfill their public health mission.

Despite the important role that LIMS play in ensuring the health of the public, funding to develop, enhance and/or maintain LIMS was limited prior to the end of 2001 and many PHLs had been unable to take advantage of recent advances in information technology. In fact, at the end of 2001 many PHLs were still using paper-based tracking and surveillance methods along with obsolete computers, spreadsheet programs, and basic database software programs that were not automated or networked.

As new diseases, threats, and other health hazards emerged during this time, many PHLs struggled to fulfill their critical role in protecting the health of the nation. This was the challenging environment facing the Association of Public Health Laboratories (APHL) and the Public Health Informatics Institute (the Institute) in the project design. When the two organizations came together in September 2002 to define collaborative requirements for LIMS, they needed to address the emerging demand for a system that would advance the capacity of PHLs to efficiently use information tools to respond to bioterrorism and other public health threats.

<table>
<thead>
<tr>
<th>What are Information System Requirements?</th>
<th>What are Collaborative Requirements?</th>
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<td>The specific things the information system must do to make a process efficient and achieve its purpose.</td>
<td>A set of information system requirements that is common to all agencies that participated in the development of the requirements, but that can be tailored to meet individual agency needs.</td>
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A collaborative approach to requirements development has many benefits for PHLs and other public agencies. It enables public health agencies to reach agreement on a common vocabulary and definitions to describe business processes. It provides opportunities for agencies to review each other’s approaches for carrying out core business activities and to redesign those processes to improve quality and performance, as well as interoperability. Broad adoption and endorsement of those processes will advance public health’s ability to define information systems requirements that meet the needs of many states and communities. Widely endorsed
requirements increase the likelihood that vendors will want to build products for the public health market. Finally, broad adoption of uniform information systems requirements will provide public health agencies with the evidence necessary to gain financial support to acquire and/or sustain systems that align with their strategic goals and core services.

With funding provided by the Robert Wood Johnson Foundation (RWJF), the LIMS project began in the fall of 2002 as an innovative collaboration that brought together the experience of 16 public health laboratories, the oversight of APHL and its Informatics Committee, and the collaborative approach and public health informatics experience of the Institute.

One of the defining features of the LIMS project was the use of a cost-effective and rational approach to the development of collaborative requirements for public health LIMS. This approach has come to be known as the Collaborative Requirements Development Methodology.

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<th>What is the Collaborative Requirements Development Methodology?</th>
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<td>An approach in which public health agencies are brought together to:</td>
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<td>- Analyze their business processes by collaboratively thinking through the tasks they perform to meet specific public health objectives</td>
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<td>- Redesign business processes by rethinking the tasks to increase effectiveness and efficiency</td>
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<td>- Define system requirements by articulating what the information system must do to support those tasks.</td>
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During the period from 2002 to 2005, the Institute applied Collaborative Requirements Methodology to design requirements for the LIMS project. This methodology helped address several challenges and complete numerous tasks associated with the development of requirements for public health LIMS.

The initial challenge for the Institute and APHL was to develop a scope of work for the project that ensured successful outcomes in a relatively short time period. A number of specific circumstances complicated the project startup:
- This marked the first time that the Institute and APHL worked with one another on a project
- The collaborative approach to requirements development had not been previously pilot tested by the Institute among public health agencies
- PHLs had not collaborated previously in the development of LIMS requirements
- Participants in the collaborative were widely dispersed throughout the country and unable to meet in person on a regular basis
- Defining systems requirements that met the common needs of all laboratories was the project’s critical driver, yet no two public health laboratories were alike.

The first task of the LIMS project was to develop a clear and detailed project charter, a document endorsed by all parties in which they agreed to the project’s overarching structure, principles, and processes. At the initial meeting, the terms of the charter were reviewed and approved by the project participants and the executive sponsors (in this case, APHL and the Institute). The LIMS project charter included:
- Statement of the project, its purpose, and major deliverables
- Governance plan and decision matrix
- Detailed project plan
- Stakeholder analysis
- Communication plan and strategy
- Risk assessment and mitigation plan
## LIMS Project Timeline

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<td>Charter</td>
<td>September 2002</td>
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<td>Project Kickoff</td>
<td>October 2002</td>
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<td>LIMS Requirement Document:</td>
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<td>Electronic version</td>
<td>April 2003</td>
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<td>Final printed version</td>
<td>November 2003</td>
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<td>LIMS Vendor Assessment</td>
<td>May 2003</td>
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### Phase II and III

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<td>Logical Design, Part 1</td>
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<td>Options Paper</td>
<td>January 2005</td>
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<td>Project Completion</td>
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Within six months of approving the LIMS project charter, 16 PHLs, APHL, and the Institute used a facilitated group process to collaboratively develop the LIMS Requirements Document. During these six months, the workgroup met twice, site visits were conducted at three public health labs, two conference calls took place, and a final face-to-face meeting of the large group was held. The requirements document was produced and made available to all PHLs in November of 2003 and included:

- The conceptual framework for the work performed in a PHL, stated as 16 business processes and the relationships among them
- A statement of over 500 LIMS requirements that span all 16 business processes
- An explanation of the database interfaces between the LIMS and other relevant system databases
- A delineation of vendor-related requirements specifications commonly found in request for proposals (RFPs).

Concurrent with the development of the LIMS Requirements Document, another task was undertaken to conduct a detailed assessment of commercially-available LIMS vendor products. The products that emerged from this task included an assessment of LIMS vendors and a summary recommendation based on the comparison of the requirements definitions to commercially-available software products.

In November of 2003, a second phase of the project was initiated and again funded by RWJF. This phase of the project focused on refining the requirements to further identify available LIMS products and assisting PHLs to better develop their own LIMS. The refinement of the requirements is referred to as a logical design. Over a period of 18 months, a core workgroup representing a subset of PHLs met six times, with APHL providing coordination and oversight and the Institute contributing facilitation and IT expertise. The workgroup translated the requirements into a set of logical design specifications, which were then reviewed and approved by the larger collaboration.
The logical design document, completed in March of 2005, provides the basis for developing the actual specifications used by programmers to develop the information system. The logical design document:

- Provides the specifics for future implementations of LIMS that PHLs and commercial vendors alike require
- Ensures that public health LIMS will have a high degree of interoperability, thereby enabling better data flow among PHLs and federal and local agencies and improving the capacity of the PHL for mutual assistance in a crisis situation
- Offers a framework for future independent or collaborative development initiatives.

Concurrent with the development of the logical design, another task was undertaken to conduct a detailed analysis of the LIMS market, including forecasted costs, growth and demand for LIMS, and the strengths and weaknesses of different approaches to LIMS development and purchase. This information was intended to empower PHLs to make informed decisions about the options available to them: buy, build, or collaboratively develop LIMS with other public health agencies.

The LIMS project ended in March of 2005, and a decision was made in the winter of 2006 to conduct an evaluation of the project. Prior to this, there had been numerous anecdotal accounts of how the LIMS project had affected the development of LIMS in some public health agencies. However, there had not been a formal evaluation to document the overall impact of the LIMS project and assess the extent to which the LIMS project met its stated goals. The project goals were to: enhance the informatics knowledge base among participating PHLs with respect to developing a framework to maintain and update public health LIMS; work collaboratively to develop requirements for LIMS; assist PHLs to assess available options for implementing a LIMS; and foster the development of a logical design for public health LIMS.

The timing of the decision to conduct an evaluation of the LIMS project was related to the start-up of a new national program being sponsored by RWJF, using a similar collaborative approach to requirements development. The Public Health Informatics Institute is the National Program Office for the project, entitled Common Ground: Transforming Public Health Information System. Common Ground is a three-year, $15 million national initiative building upon the success of previous initiatives to strengthen the public health system and accelerate innovative and effective use of information technology. In designing the project, organizers sought to adapt the many valuable lessons learned from the LIMS project and apply them to new initiatives, such as the Common Ground project. Toward this end, a formal evaluation of the LIMS project was proposed as a means of documenting and sharing these lessons learned.

This report summarizes the findings from the evaluation of the LIMS project. The evaluation sought to document the overall impact of the LIMS project with a specific focus on the more qualitative aspects of the project. In this report, the findings from the evaluation are presented in four sections that correspond to the major goals of the LIMS project: 1) enhancing the informatics knowledge base; 2) working collaboratively to develop LIMS requirements; 3) assessing options for implementing LIMS; and 4) developing a logical design for public health LIMS.
This report will be shared with the numerous stakeholders involved in the LIMS project, including the leadership teams from APHL and the Institute, the APHL Informatics Committee, the labs who participated in the LIMS project, and RWJF. Additionally, the report will be accessible from the Institute’s website, thereby making it available to the public. It is expected that the lessons learned from the LIMS project will apply to other projects, especially those that strive to use collaborative approaches and methodologies to develop or enhance public health information system requirements.
METHODS

The Institute and external evaluator distributed invitations to 16 former participants of the LIMS project, one non-participant identified by APHL as someone who had experience using requirements developed by the LIMS project, and two representatives from APHL. Invitations requested that recipients participate in a telephone interview with the Institute’s external evaluator. The invitation described the purpose of the interview and requested that the prospective interviewee contact the external evaluator to arrange a date and time to be interviewed. Of the 19 individuals invited to participate in a telephone interview, 14 (74%) agreed to participate and completed an interview.

A total of twelve telephone interviews were conducted with representatives from PHLs and two telephone interviews were conducted with representatives of APHL. PHLs were initially selected to participate in a telephone interview by Institute staff. During the course of conducting the interviews, APHL and some participating labs suggested additional PHLs to be invited to participate in an evaluation interview. In each of these circumstances, PHLs were identified as potential interviewees based on their knowledge of the LIMS project, their role on the APHL Informatics Committee, and/or knowledge that they had used one or more of the products produced throughout the LIMS project.

All of the PHLs interviewed were state-level laboratories, and included a mix of small, large, urban and rural PHLs. This group of interviewees represented a variety of geographic areas and included the states of Alaska, Delaware, Florida, Iowa, Kansas, Maine, Massachusetts, Nebraska, New York, Virginia, Vermont, and Wyoming.

Each interview lasted approximately one hour and followed an interview guide that was developed specifically for this project. The interview guide (see Appendix A) was designed to collect the information necessary to assess the extent to which the LIMS project met its stated goals and objectives related to meeting the critical needs of the nation’s PHLs for efficient electronic LIMS. As such, the interviews focused on the following basic questions:

1. To what extent was the project successful in enhancing the informatics knowledge base among participating laboratories and APHL relevant to developing a lasting framework to maintain and update public health LIMS requirements?

2. To what extent can public health laboratories work collaboratively to effectively define LIMS requirements?

3. To what extent was the LIMS project successful in assisting PHLs to assess available commercial products in relationship to the agreed upon requirements?

4. To what extent was the project successful in using a collaborative approach to refine the requirements in such a way as to create a logical design for a LIMS?

5. To what extent was the project perceived to be valuable and useful from the perspective of APHL?

All interviews were conducted by the external evaluator.
Enhancing the Informatics Knowledge Base

The LIMS project was highly successful in meeting its stated goal of developing a set of LIMS requirements to serve a wide variety of PHLs, regardless of size or structure. Within six months of the beginning of the project, participants from sixteen PHLs, APHL and the Institute developed the document that came to be known as the “requirements document.” The document includes the conceptual framework for the work performed in a PHL, stated as 16 business processes, the relationships among them, and over 500 LIMS requirements that span across all 16 business processes. The document also includes an explanation of the database interfaces between the LIMS and other relevant databases, and delineates vendor-related requirements specifications commonly found in requests for proposals (RFPs).

In addition, the document marked a historic first in the arena of PHLs. Not only had participants agreed with the assumption that diverse labs could agree on standardized information systems requirements, they moved forward with creating and agreeing on the first comprehensive set. This signified the first time that information system requirements were created collaboratively by and for PHLs.

Many interviewees described the sense of frustration with information systems among public health labs that existed prior to September 11, 2001. This frustration resulted from their knowledge that better public health LIMS were needed but funding was not yet available. In addition to the lack of funding, a “lack of coming together as a community” was also identified as a barrier to the development of more efficient public health LIMS. Following the events of September 11, 2001 and the availability of bioterrorism funding that could be used for the development and enhancement of public health LIMS, PHLs came together with a new sense of urgency and purpose.

“The events of 9/11 empowered us to take action. Forming the partnership with the Public Health Informatics Institute at the right time galvanized us and allowed us to evolve into taking a leadership position on the critical need to provide timely and accurate health data to decision makers.”

Scott J. Becker
Executive Director,
Association of Public Health Laboratories (APHL)

The LIMS project was cited as helpful to APHL in “building a community” because the project itself provided PHLs with an important purpose for coming together, a plan for action, appropriate partners, and the necessary funding for convening labs via face-to-face meetings and teleconferences.

Nearly all interviewees described the requirements document as being extremely useful to their respective laboratories. The document was used by labs engaging in the process of developing an RFP to identify commercial LIMS vendors, and it was used by labs as they worked with their chosen LIMS vendors to be sure that the LIMS would meet the needs of their labs. PHLs who are currently working via open source technology to collaboratively build a LIMS (as opposed to purchasing a LIMS through a commercial LIMS vendor) also reported that the requirements document was useful to them in the design phase of their efforts.

Many interviewees spoke about where they thought their lab would be today if the LIMS project had not occurred. Most of those we spoke with expressed that in the absence of
the LIMS project, their labs would have spent a far greater amount of time developing and/or implementing a LIMS. In addition, many interviewees expressed their belief that in the absence of the LIMS project the information systems that they built or implemented would have been far less comprehensive and less robust.

"If the LIMS project had not come about, it would have taken our lab much longer to implement a new LIMS and it would probably not have been nearly as complete."

Ming S. Chan
Director, Bureau of Laboratories
Florida Department of Health

One criticism of the requirements document was that some interviewees thought that the final document included more requirements than are actually used by most PHLs. One interviewee expressed concern that the large number of requirements compromised the document’s ability to provide more in-depth information about each requirement. However, the majority of interviewees appreciated the breadth of the requirements and expressed satisfaction with the number of requirements included in the document.

“When we started working with our LIMS vendor, we took another look at the requirements document and prioritized the requirements so that the vendor could see which ones were most relevant to the immediate needs of our lab. However, we know that we may need the other requirements later so we’re glad that they are included in the requirements document.”

Mary Jane Whalen
Laboratory Information Specialist,
Vermont Department of Health Laboratory

Similarly, several PHLs talked about the value of the requirements document as a starting point and described the need to take the requirements and processes and then “map out” their own functional requirements based on the unique structure and needs of their specific laboratories.

Working Collaboratively to Develop LIMS Requirements

The LIMS project demonstrated the feasibility and desirability of using a collaborative approach to develop LIMS requirements. Without exception, interviewees were highly supportive and complimentary of the collaborative aspect of the LIMS project. Several interviewees used words such as “inspirational,” “encouraging,” and “amazing” to describe the collaboration that occurred during the LIMS project.

Although words such as “daunting,” “exhausting,” and “overwhelming” were also used to describe initial reactions to the scope of work and short timeframe outlined in the initial LIMS project meetings, there was widespread agreement that the collaborative work and time put into the LIMS project was absolutely worth the effort. Even labs that were further along in the development of a LIMS prior to the inception of the LIMS project appeared to have benefited from participation in the collaborative project.

“Our lab was ahead of many labs in the development of a LIMS, so in some ways the collaborative slowed us down. However, in the end we knew that we had a much better LIMS design than we would have had if we had not participated in the LIMS project.”

Gary Jones
Information Systems (IS) Manager,
Minnesota Department of Health, Public Health Laboratory

Some of the LIMS project participants described the collaborative aspect of the project as “empowering” and described ways in which the project “opened eyes” to
possible solutions and opportunities that had not been previously seen or considered.

Several interview participants noted how difficult it was to get states together to work collaboratively prior to the LIMS project. While the cause of this problem was beyond the scope of the evaluation interviews, general comments made by interviewees suggest that LIMS brought about two influences: an opportunity for labs to work collaboratively and an organization willing to take the lead as a convener of such an activity. The previous lack of collaborative activity was perceived as a “major issue” and a “real barrier” to states addressing important issues and working together to find effective solutions.

“Although the LIMS project was successful in many ways, one of the most important benefits was that the project demonstrated that states could work effectively together.”

Bob Bostrom
(Former) Director of Sample and Data Management,
Division of Health & Environmental Laboratories,
Kansas Department of Health & Environment

Overall, it was noteworthy that so many interviewees defined the success of the LIMS project not only in terms of its products but also in terms of its processes. Nearly all interviewees provided detailed examples and enthusiastic responses to questions about the relationships and connections fostered through the collaborative nature of the LIMS project.

“The documents produced through the LIMS project were useful, but it was the personal connections and contacts that were tremendously valuable.”

Shelley Hood
Laboratory Information Analyst, Wyoming Public Health Laboratory

Many interviewees also noted that the LIMS project, and specifically the relationships built through the project, enabled them and/or their lab to become more involved in related issues and projects at the local, state and national level. Several state interviewees, as well as APHL, spoke specifically about their interest and/or involvement in a new project entitled the Public Health Laboratory Interoperability Project (PHLIP). Working in collaboration and with the support of CDC’s Coordinating Center for Infectious Disease and the National Center for Public Health Informatics, APHL recently launched the PHLIP project to foster collaboration in the areas of information technology and laboratory science with the ultimate goal of developing and piloting viable information technology architecture options and tools for the exchange of electronic laboratory data at all levels of public health laboratories. APHL and one of the PHLs we interviewed attributed their participation in the PHLIP project, in part, to their participation in the LIMS project.

“One of the unexpected benefits of the LIMS project has been our subsequent involvement in other IT and informatics activities. As a result of the LIMS project, Virginia’s state lab has become more involved in informatics and IT activities at the national level.”

Wanda “Willie” Andrews
Assistant Director,
Bureau of Analytical Services, Virginia Division of Consolidated Laboratory Services

Just as the PHLs spoke about the value of the collaborative aspect of the LIMS project, APHL also found the collaborative aspect of the project to be very valuable. The LIMS project has opened up opportunities for APHL to participate in new projects and with new partners.
“The collaborative process was very valuable to APHL and to our members. The role the Institute played as convener and project manager was vital.”

Patina Zarcone
Director, Strategic Initiatives and Research, Association of Public Health Laboratories (APHL)

Like so many of the PHLs that we interviewed, APHL understood that the LIMS project offered participants and the PHL community benefits and advantages in their effort to be cost-effective and resource-efficient. In addition, APHL credited the LIMS project and their working relationship with the Institute as catalysts for organizational transformation. In particular, the project and the Institute were credited for introducing new project management principles and techniques to APHL (i.e., the charter development process). The value of the charter was a common theme in the interview with APHL and several of the participants.

“We knew when we were designing and implementing the LIMS project that it was going to be a valuable project. But now that it is done there is no doubt that the project has been tremendously valuable. In fact, it was transformational.”

Scott J. Becker
Executive Director, Association of Public Health Laboratories (APHL)

Assessing Options for Implementing a LIMS

As described in the introduction to this report, the LIMS project aimed to assist PHLs to assess the various commercial LIMS products available to them. As part of this effort, an assessment of commercial LIMS vendors was performed and a model RFP was developed for PHLs. The vendor assessment was used by several PHLs who were just beginning to explore the possibility of purchasing a LIMS from a commercial vendor when the LIMS project began. However, some interviewees reported that they were “beyond the phase of identifying a vendor” at the time the assessment became available and therefore they were not able to use the assessment.

The vendor assessment was also described as “somewhat controversial” by one of the individuals we interviewed. In this case, the controversy was attributed to the fact that the vendor selected by this particular lab did not appear in the list of “top vendors.” Some of the PHLs we interviewed also noted that some of the vendors who did appear in the “top vendor” list were not perceived by them as fully meeting their needs.

Another finding was that the model RFP was used more widely by PHLs than the vendor assessment. However, several interviewees mentioned the urgency for developing RFPs and distributing them as soon as the funding became available for development and/or enhancement of their LIMS. Although many of these labs indicated that they would have used a model RFP at that time, it was not developed until a later segment of the project. Moving forward, most PHLs agreed that the model RFP is likely to be perceived as a useful and time-saving tool by labs and other agencies that are beginning to initiate activities related to the purchase of a LIMS.
Developing a Logical Design for Public Health LIMS

After the development of the requirements document, a subgroup of PHLs, APHL, and the Institute worked together to develop a logical design for a public health LIMS. As previously noted, the intent of the logical design is to translate the information systems requirements into a set of logical design specifications. From these specifications, a physical design can be developed to serve as a blueprint for physical implementation of a public health LIMS.

Although the logical design phase of the LIMS project was perceived in a positive light by nearly all of those we interviewed, one interviewee expressed concern about the fact that at this point in the project a small group of labs decided to work on their LIMS via open source technology. For this particular interviewee, this signaled a "division" of the group that may have distracted from building a "long-lasting LIMS product that all labs could use to move data from one state to another and from the state-level to the national-level."

In addition, a small number of interviewees expressed disappointment that the LIMS project did not result in a physical LIMS model. Although building a physical LIMS was never within the scope of the LIMS project, several people noted that it was "unfortunate" or even "frustrating" that the LIMS project itself ended with the logical design of a LIMS and did not get labs to the point where they all worked together to build a "physical model."

Yet overall, the vast majority of those we interviewed reported that they used (or are currently using) the logical design document along with the requirements document to develop and/or enhance their LIMS. In addition, PHLs in at least three states are now working collaboratively to design a public health LIMS directly from the logical design.

Although nearly all those we interviewed had been participants in the LIMS project, one interview was conducted with a lab that was not a participant in the project but had knowledge of the project through a working relationship with APHL. The interviewees from this lab noted that they used the requirements document and the logical design specifications to develop the RFP to identify a LIMS vendor, and found these documents to be very helpful and time-saving for their lab.

“It was unfortunate that we were not able to build the ‘physical model’ as part of the LIMS project. It would have been a tremendous benefit to public health laboratories if there had been an opportunity to build a LIMS that we could all use together.”

Ed Shaw
Assistant Bureau Director, Bureau of Analytical Services, Virginia Division of Consolidated Laboratory Services

Reflecting on the entire process of working with colleagues within her own lab to develop a LIMS, the interviewee stated, “One of the benefits of working on the development of a LIMS was that we all worked together and we were forced to take a look at ourselves and our processes to see what we were actually doing, how we could improve our business processes, and how our knowledge and skills could be used to enhance our overall efficiency.” Indeed, this statement captures the intent of the Collaborative Requirements Development methodology applied in the LIMS project.

“We participated in the logical design phase of the project and we are now participating with a small number of other states to build a physical LIMS. In this way, the LIMS project has had a lasting impact in that the networking and dialogue that was initiated through the LIMS project is still in place and valuable today.”

Dariush Shirazi
Information Technology (IT) Manager, University of Iowa Hygienic Laboratory
The evaluation results indicate that the LIMS project was highly successful in meeting its goals to enhance the informatics knowledge base with respect to the public health LIMS, to develop collaborative requirements for LIMS, to assist PHLs to assess available options for implementing a LIMS, and to foster the development of a logical design for public health LIMS. In addition, interviewees underscored the fact that the collaborative aspect of the LIMS project was tremendously valuable and the relationships and connections formed through the collaborative process have had a positive and lasting effect on those who participated in the project.

Based on our interviews with PHLs and APHL, the events of September 11, 2001 and the anthrax scare that followed in the ensuing months provided the necessary catalyst to initiate the collaborative LIMS project. As we were told, this series of events not only confirmed what the PHLs had already known about the inadequacies of many public health LIMS, but they also demonstrated these inadequacies to decision-makers and legislators who were able to provide the funding to address these inadequacies. In many ways, these events also seemed to empower PHLs with the knowledge that they had an important role to play. As the keepers of critical public health data, PHLs were described as a “lynch pin” and one interviewee said that he “visibly saw the attitudes of people in PHLs change when they saw that they were so critical” to the process of ensuring the health of the nation.

Along with the window of opportunity for action and a new sense of empowerment among PHLs, several other factors appear to have contributed to the success of the project. These factors included strong leadership from the project’s executive sponsors (APHL and the Institute), an agreed upon vision and mission by project participants, a combination of people from different backgrounds and with different skills, identifiable milestones, a structured process for reaching those milestones, and the necessary determination and fortitude on the part of participants to see the project through to completion.

“The critical success factors in the LIMS project were uniformity of vision among the workgroup members, recognition and acceptance of defined tasks, and the ability and willingness to work toward a common goal.”

Steven H. Hinrichs, MD
Director,
Nebraska Public Health Laboratory

The findings from this evaluation suggest that the collaborative approach to developing requirements for LIMS can be applied to the development of other public health information systems. Currently the Institute is using the Collaborative Requirements Development Methodology as part of the RWJF-funded Common Ground national program. Common Ground brings together state and local health agencies to work collaboratively to develop information system requirements for public health preparedness and chronic disease control and prevention programs. Lessons learned from the LIMS project are also being used to shape future requirements development efforts in childhood obesity and newborn screening.

Our intent is that public health agencies will be encouraged by the results of the LIMS evaluation to approach information system requirements development in a
new way. By working together, public health agencies will be able to learn from each other and define a set of requirements that allow them to work more effectively with the vendor community.

A collaborative approach to requirements development also enables public health agencies to reach agreement on a common vocabulary and definitions of their business processes. It provides opportunities for agencies to review each others’ approaches for carrying out core activities and redesign those processes to improve quality and performance as well as interoperability. Broad adoption of uniform information system requirements, like those created for LIMS, provide public health agencies the evidence necessary to gain financial support to acquire systems that align with their strategic goals and core services.
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APPENDIX: Interview Guide

I. Introduction

Thank you for agreeing to participate in a telephone interview. My name is Carol McPhillips-Tangum. I am an independent health services researcher and I have been asked by the Public Health Informatics Institute (“the Institute”) to serve as an external evaluator to conduct an evaluation of the LIMS project. The telephone interview that you have agreed to participate in today is an important part of the evaluation. You should have received an email from me that contained an overview of the types of questions that I would like to ask you today. Did you receive that? Do you have any questions before we begin?

II. Questions Related to Objective #1

One of the primary objectives of the evaluation is to assess the extent to which the LIMS project was successful in enhancing the informatics knowledge base among participating laboratories relevant to developing a lasting framework to maintain and update public health LIMS requirements. To accurately assess the extent to which this objective was met, it is important for us to have a greater understanding of what the informatics knowledgebase was prior to the beginning of the LIMS project, as well as a greater understanding of what it is now. From what I have been told, much of the impetus for the LIMS project came about as a result of the events of September 11, 2001 which demonstrated a critical need for PHLs to have efficient electronic laboratory information management systems (LIMS) that could be used to effectively respond to bioterrorism and other public health threats.

1. Can you start by telling me about what type(s) of electronic LIMS your lab had in place prior to the events of September 11, 2001?
   a. To what extent did the systems your lab had in place prior to September 11th meet the demands your lab faced after September 11th?
   b. Did your lab face any particular challenges or obstacles relevant to the management of laboratory information as a result of September 11th?
      i) If so, please describe.
   c. What barriers do you think your lab faced prior to 2001 that might have kept them from developing effective electronic laboratory information management systems (LIMS)?

2. Since 9/11/01, what changes have taken place in your lab with regard to the management of laboratory information?
   a. To what extent do you think these changes occurred as a result of the LIMS project?
   b. What other factors, if any, could have accounted for these changes?

3. In your opinion, to what extent would the laboratory infrastructure of your lab be different today if the LIMS project had not happened?
   a. In other words, how do you think your lab would manage laboratory information today if the LIMS project had not happened?
4. In your opinion, did the LIMS project empower, motivate or empower your lab to engage in other relevant projects?
   a. In other words, do you think that your lab’s participation in the LIMS project made it possible for your lab to participate in other relevant projects?
      i) If so, please describe.

III. Questions Related to Objective #2

The second objective of this evaluation is to assess the extent to which the LIMS project assisted public health laboratories to work collaboratively to define requirements (or essential elements) of effective LIMS.

5. To what extent do you feel that the collaborative process was useful to your lab in its efforts to define the requirements of effective LIMS?
   a. If you feel that the collaborative process was helpful, can you tell me more about how it was helpful?
   b. If you feel that the collaborative process was not helpful (or not entirely helpful), can you tell me more about why it was not helpful?
   c. How would you feel about using a collaborative process, such as the one used in the LIMS project, again in the future?
      i.) Why?
      ii.) Why not?
      iii.) In what situations do you feel such a collaborative process would be most helpful?
      iv.) In what situations would you feel such a collaborative process would not be helpful, or be less helpful than some other process?
   d. Would you recommend the use of a collaborative process, such as the one used in the LIMS project, to other PHLs?
      i.) Why?
      ii.) Why not?

6. As you know, the LIMS project resulted in the development of requirements that defined the common laboratory information management needs of PHLs. To what extent do you think the requirements developed through the LIMS project met the needs of your lab?
   a. On a scale of 1 to 10, where 10 indicates that all needs were met, how would you rate the requirements developed through the LIMS project with regard to the extent that they met (or did not meet) the needs of your lab?
      i.) If less than 10 – why? In what way(s) did the requirements not meet the needs of your lab?
   b. How easy were the requirements to apply and/or use?
   c. Did the requirements need to be altered or modified to meet the specific needs of your lab, or did they work “as is”?

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i.) If modifications were made, please describe.

ii.) In other words, in what way(s) did the requirements need to be tailored or customized to meet the specific needs of your lab?

7. To what extent do you think your lab’s participation in the LIMS project has enabled it to make progress toward meeting its goals and objectives?

   a. In other words, do you think your lab would have met certain goals and objectives if it had never been involved in the LIMS project?

      i.) Please describe.

IV. Questions Related to Objective #3

Another important objective of this evaluation is to assess the extent to which the LIMS project was successful in assisting PHLs to assess commercial products in relationship to the agreed upon requirements.

8. To what extent do you think the LIMS project assisted your lab to increase its knowledge about available commercial products related to the development of LIMS?

   a. Did the project assist your lab to increase its knowledge about available commercial products related to the development of LIMS?

      i.) If yes, please describe.

      ii.) If no, why?

9. To what extent has the assessment information produced through the LIMS project been useful to your lab?

   a. If useful, please describe how it has been used (solicit stories).

   b. If not useful, why?

V. Questions Related to Objective #4

One of the final objectives of this evaluation is to assess the extent to which the LIMS project was successful in assisting PHLs to analyze the options available to them for meeting their LIMS requirements.

10. To what extent do you feel the LIMS project was successful in assisting your lab to increase their knowledge about the options available to them for the purpose of meeting the requirements that were developed for the purpose of effectively managing laboratory information?

    a. What type of knowledge was gained?

    b. How was the knowledge used?

11. To what extent has the information produced through the LIMS project relevant to options (such as build-or-buy) been useful to your lab?

    a. What type(s) of information was most useful? Least useful?

    b. How has the information been used?

12. In the absence of the LIMS project, how do you think your lab would have analyzed the options available to them for meeting LIMS requirements?
a. What do you think the implications might have been?

VI. CONCLUSION

Those are all the questions we have for you today.

13. Are there any other comments you would like to provide related to your organization’s participation in the LIMS project, or any other comments in general?

On behalf of the Institute and myself, thank you very much for your time.