EVALUATION OF THE PROCESS REQUIRED TO EFFECTIVELY EXPAND THE NATIONAL LABORATORY SYSTEM (NLS) TO ALL STATES

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Executive Summary

I. Statement of the Problem

Background

The lines between individual patient care and public health safety have become more blurred as private health care facilities deal with patients with AIDS and other health threats such as potential agents of bioterrorism, foodborne diseases, and antimicrobial resistance. Because of this, there is a need to coordinate and define roles so public safety is addressed as quickly as possible. For example, potential threats are often first encountered when a patient enters a private health care system. Clinical laboratory staff may isolate a dangerous organism, but may either not recognize it or may not notify public health officials in time to avert a public health problem. Some state public health laboratories are not sufficiently equipped to assist private laboratories due to staff shortages and lack of communication systems. The blurring of lines between the functions of private and public laboratories has led to the concern that information important for detection and surveillance could drop between the cracks. The need to clearly specify the core functions of public health laboratories has been called out by The Lewin Group,[1] the General Accounting Office (GAO),[2] state, and clinical laboratory directors, and addressed by the Association of Public Health Laboratories.[3] Many functions of clinical laboratories and public health laboratories are complementary and these must be carried out in concert in order to effectively detect and mitigate emerging public health threats.

Proposed Solution

Integration of the public and private laboratories for purposes of information sharing and collaboration is essential to address the problem and ensure timely response to public health threats. The Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) developed the idea of a National Laboratory System (NLS) to help improve the integration process. Although clinical and public health laboratories may currently collaborate about specific programs such as lead poisoning, newborn screening, and others, a systematic method of working together to improve all laboratory capabilities does not exist in most states. As the NLS concept is adopted by all states a national system will result and can be applied to a wide-range of public health issues. As envisioned, public health planning and response coordination would be provided by state and federal authorities in collaboration with professional organizations, universities, and other stakeholders.

Barriers

Barriers to the creation of an effective NLS include differences between public health and clinical laboratories' missions, geographic separation, resource limitations, specimen transport difficulties, problems with results of tests referred to laboratories in other states, and communication disparities. Clinical laboratories are focused on the health of individual patients while public health laboratories are focused on protecting populations from disease. Although both are essential to improving the health of the nation, the different "world views" can be a barrier to understanding, trust, and communication.

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[1] The Lewin Group, Public Health Laboratories and Health System Change, Prepared for the Office of Health Policy, Department of Health and Human Services, October, 1997

[2] General Accounting Office (GAO), Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance. GAO/HEHS-99-26. Washington, DC: US General Accounting Office, 1999.

[3] Witt-Kushner, Joyce, J. Rex Astles, John C. Ridderhof, Robert A. Martin, et al., Core functions and capabilities of state public health laboratories: A report of the Association of Public Health Laboratories. *MMWR*, Sept. 20, 2002,51 (RR14):1-9.

II. Evaluation Objectives

In 2000, the Division of Laboratory Systems (DLS) in the CDC Public Health Practice Program Office (PHPPO) set out to test the viability of a national laboratory system, and to explore opportunities and challenges for full implementation. CDC, in collaboration with APHL, funded three SPHLs (Minnesota, Michigan, and Nebraska) as NLS demonstration projects. A fourth demonstration project, funded by a different program, was based in an academic institution in the State of Washington. It is referred to as the Clinical Laboratory Initiative (CLI). Each project was given the charge of designing and implementing activities that would create more formalized relationships between clinical and public health laboratories as a means of ensuring their integration as a detection and response system. Funded SPHLs were expected to develop a profile of the clinical laboratories in their states and to develop and implement innovative ways to promote information exchange and to foster a sense of partnership between the public and private laboratories. The Washington demonstration project focused on enhancing antimicrobial susceptibility testing in the state's clinical laboratories.

In 2002, CDC funded Battelle to conduct a formative evaluation of the demonstration projects and the readiness for expansion of similar activities to other states. The goals of the evaluation were to:

- examine how the demonstration project teams set about increasing the degree of communication and coordination between the SPHL and the clinical laboratories, and what seemed to affect how these activities worked or didn't work;

- assess the readiness of other SPHLs nationwide to develop relationships with the clinical laboratories; and,

- assess how ready the clinical laboratories are to engage in activities with the SPHL beyond the traditional ones related to referral of specimens for outbreak investigations, newborn screening tests, and other testing offered by the State. This third objective was included to respond to recommendations of an advisory panel for this project.

This study was designed as a formative evaluation. It does not ask if the demonstration projects were successful, but seeks to capture what was learned from the demonstrations that can be useful to other SPHLs initiating NLS development in the future. The goal of the evaluation is to provide insight into the factors that facilitate or hinder SPHLs from implementing the NLS concept. From this information, recommendations are made about the processes needed to effectively expand the NLS to all states.

III. Methodology

The project had two major components: case studies of the NLS demonstration projects funded under a CDC-APHL cooperative agreement, and two mail surveys, one to all SPHL Directors and one to a national sample of clinical laboratory directors. Both components examined the level of interaction already occurring and the level of interest in topics suitable for public health and clinical laboratory collaboration.

A. Case Study Methodology

The four case studies documented how the objectives of the NLS were being met by the four NLS grantees. The case studies were descriptive and comparative in nature. Information was gathered in each demonstration site for the purpose of describing the context of the demonstration project and the lessons

learned about the factors that facilitate or hinder implementing the NLS concept. The case study included reviews of documents related to each of the four demonstration projects, site visits with interviews of NLS demonstration staff and stakeholders, and a telephone interview study with a sample of clinical laboratory directors in each of the demonstration sites. The document review covered the APHL request for applications for the demonstration, the proposals from the sites that were selected, and project progress reports.

For the site visits, Battelle prepared an interview guide for each of the demonstration sites, tailored to that state's activities and progress on specific activities. An overall framework for organizing the questions included the organizational context of the SPHL, approaches for building partnerships; approaches for improving communication and connectivity between the SPHL and clinical laboratories; education and training initiatives; approaches for assessing laboratory capabilities; and transport systems for specimens from clinical laboratories.
The liaison for the site visits was the Laboratory Program Advisor (LPA) engaged by each NLS grantee as a condition of their funding. The LPAs worked with Battelle to develop a schedule for the site visits and determine the persons to be interviewed. Interviews varied somewhat from site to site, but categories included the SPHL director, the LPA, the bioterrorism coordinator or emergency planning person, a laboratory information systems person, the Health Alert Network (HAN) coordinator, an epidemiologist or someone working with infectious disease surveillance, an education or training person, and an advisory group member or other non-SPHL stakeholder in laboratory communication.

The interviews with these key informants were conducted by the project leader, a sociologist, accompanied by a clinical laboratory scientist-educator who served as a consultant to Battelle for the evaluation project. The interviews were semi-structured in nature, with the interview guide used to ensure that all topics were covered. Full transcripts of the interviews were prepared from tape recordings of the interviews. The project leader and a medical anthropologist prepared a set of themes for coding the transcripts. A computer application for working with qualitative data was used to search across all transcripts and compile a "report" for each theme identified in the interviews. The project staff prepared profiles of each demonstration project based on compilations of data from the transcripts.

Three months after the site visits were completed, telephone calls were made to five clinical laboratories in each of the demonstration states to investigate whether the activities that the SPHL demonstration project respondents described in the interviews were recognized by the clinical laboratories. Another purpose was to speak directly to some clinical laboratory supervisors to see what words they used when they talked about the SPHL and the activities related to the NLS demonstration to help with the development of the survey questionnaires.

B. Survey Methodology

For the survey component of the project, two groups of respondents were surveyed – SPHL directors and a sample of clinical laboratory directors/managers. The purpose was to gain perspectives about the current state of communication and collaboration between these two groups, as well as to assess their willingness and readiness to increase their level of communication and collaboration. Separate questionnaires were developed for each of the target groups. Plans for the surveys were published in the Federal Register and submitted to the Office of Management and Budget (OMB) for approval.

Sampling Frames

All SPHL directors in the United States and the directors of the public health laboratories for the District of Columbia and Puerto Rico were invited to participate in the survey, resulting in a population for the SPHL survey of 52. Using the procedures described below, we were able to obtain a completed questionnaire from 48 SPHL directors for a response rate of 92%.

The sampling frame of clinical laboratories was generated from the National Laboratory Database managed by CDC/DLS and included those laboratories that currently perform proficiency testing in comprehensive bacteriology. These laboratories have the ability to rule out/or refer potential agents of bioterrorism and so comprise the Level A (sentinel) laboratories in the Laboratory Response Network (LRN). A total of 3,991 eligible laboratories were identified. The sample was stratified by state and the size of each state sample was determined for a confidence level of 95%. Of the 727 clinical laboratories invited to participate in the survey, 519 responded to the survey for a 71% response rate.

Survey Data Collection

After approval by OMB, the surveys for both the state public health laboratory directors and clinical laboratory directors were conducted using both written and web-based formats. Respondents could use either they preferred or could go through the questionnaire with a telephone interviewer. Multiple waves of written and telephone reminders were used to maximize the response rate for each survey. Battelle used SPSS for the quantitative data analysis.

IV. Major Findings and Recommendations

A. Findings from the Case Studies

The CDC set forth three primary questions to be addressed by the case studies.

- What are the strengths and weaknesses of each project in developing or strengthening communication links between state public health and clinical laboratories?

- How do different State Public Health Laboratories -- which operate in unique situations depending on the organizational structure of their states -- implement the NLS concept within these different organizational climates? What impediments and/or opportunities for collaboration exist?

- How do states in the NLS actually use their communication links to insure that potential public health threats will be identified and contained more rapidly?

Strengths - Personnel

The studies revealed that the most important element for the three co-funded projects was establishing a full-time Laboratory Program Advisor (LPA) position, a requirement of the funding in the three SPHL-based projects. The staff in these positions was to focus solely on activities related to the demonstration project's objectives for building better communication and coordination between the SPHL and the clinical laboratories. LPA effectiveness was further enhanced by the fact that each of the persons selected to fill these positions had previous experience in a clinical laboratory setting. This provided the LPAs a clear understanding of the settings in which clinical laboratorians work, what type of information was useful to them, and why they don't tend to view their work as related to public health.

Other strengths included the extent to which the Nebraska and Michigan LPAs were able to engage in visits to clinical laboratories, the hands-on learning activities developed by the Minnesota LPA, the already developed network of contacts with stakeholders in laboratory capability of the Michigan LPA, and the Washington State project leader's legacy of the Clinical Laboratory Advisory Council to the Washington SPHL.

For the three NLS demonstration projects, the principal investigator was the director of the SPHL. Each of the state demonstration projects consisted, at a minimum, of a leadership team that included the SPHL director and the full-time Laboratory Program Advisor, a stipulation of the NLS demonstration funding.

The activities of the LPA were dedicated to those activities aimed at developing an integrated laboratory system in the state. The three states varied in the degree to which they were able to keep the LPA from having to help with emerging operations demands, but for the most part the LPAs were able to remain dedicated to their primary role, even after the funding source shifted from the cooperative agreement with APHL to each state's bioterrorism preparedness supplemental funds.

Value of Context

With respect to the contexts in which they worked, the ability of the SPHL directors to have discretion to engage in activities like the NLS demonstrations was important for all three sites, at least when they were able to obtain external funding for such an activity. To sustain the outreach efforts, these activities must be institutionalized into the department budget in the future. The existence of regional laboratories in Michigan and Nebraska, clinical or public health, enabled the LPAs to have venues from which to carry out training and information activities and provided the smaller clinical laboratories with information resources nearer at hand.

Communication Links

All three sites used communication links they had developed to create pathways for providing alerts about emerging public health threats to clinical laboratories. All LPAs in the state-based demonstration sites used the Health Alert Network as a source of some alert messages, but since the HAN did not include clinical laboratories, the LPAs formulated messages relevant to clinical laboratorians and created specific communication pathways and procedures for providing alerts. All also scanned various types of reference materials which they then boiled down into non-urgent informational transmissions to the clinical laboratorians in their states. This and other information, such as newsletters were provided on a frequent basis to the clinical laboratories.

Breaking Barriers

In the Michigan, Minnesota, and Nebraska SPHLs, the demonstration team acknowledged that efforts to create more active and cooperative relationships between the SPHL and clinical laboratories entailed the breaking down of vague or even negative images that each group of professionals held of the other. All three states noted a general lack of awareness on the part of the clinical laboratories about what the SPHL really does and a corresponding lack of sensitivity on the part of SPHL staff about the time-sensitive daily routines of clinical laboratorians. In addition, SPHL staff may have been unaware of the isolation of laboratorians who work in small clinics distant from state activities and who, as a result, frequently find themselves outside the professional mainstream.

Activities

The CLI project in Washington focused on improving the capabilities of clinical laboratories to detect antimicrobial resistance. This is in line with the objectives of NLS to carry out activities that will help improve clinical laboratory testing practices. The approach being used by the CLI demonstrates one of the ways in which a SPHL can work with clinical laboratories to improve critical capabilities needed to support public health functions.

Products. The activities carried out by the NLS demonstration projects can be loosely categorized as products and processes. Some activities were focused on creating what might be called *products* widely used for training. The NLS sites developed products such as state-specific training, CD-ROMs, posters or hand-outs to facilitate identification of the major bioterrorism agents, a laboratory manual with procedures to follow if a bioterrorism agent was suspected, graphic presentation materials for seminar participants, and a laminated card with relevant SPHL contacts.

Processes. An example of a *process* is building relationships.. Much of the LPAs' time was spent on developing linkages with clinical laboratories by obtaining contact information from them, answering

their specific questions, selecting and disseminating educational information and training, and other activities that created partnerships for leveraging resources. The state demonstration sites, in all three cases, took on as their first activity inventorying and determining the capabilities of the laboratories they wished to target in the first stage of the project. Each site made initial contacts with approximately 100 to 155 laboratories believed to have capabilities to perform advanced microbiology, the set of laboratories representing the foundation of the system for detecting and identifying infectious diseases including those that may cause public health threats.

The three state sites each initiated activities designed to develop an inventory of the testing capabilities of their target set of laboratories. These were originally labeled as "capability assessments," but turned out to be the cornerstone of relationship-building with the clinical laboratories. These efforts permitted the LPAs to introduce the notion of an integrated laboratory system for the state, to display interest in what the clinical laboratories could do, to become a personal connection between the clinical laboratory and the SPHL, and to tailor further communication to each of the laboratories. The LPAs were fairly tentative with regard to addressing the question of the quality testing because none of the sites wanted to risk damaging the emerging partnership by appearing to be critical or regulatory.

All the LPAs acknowledged that keeping the master list of clinical laboratories current was a constant effort. Telephone and fax numbers and e-mail addresses changed with staff turnover, laboratory consolidations, and updates in the laboratories' own information system, among other reasons. The existence of a correct contact database can be an important feature for reinforcing the relationships, as it gives evidence that the SPHL is serious in its dedication to provide timely information. More importantly, it helps to ensure that truly critical and time-sensitive notifications needed by laboratorians are likely to reach them before negative consequences occur.

LPA's Target Group

In the view of the LPAs, each of whom had considerable experience working in clinical laboratories, much of the information that is made available for public health is geared to local public health departments, epidemiology, infection control practitioners, health care providers and so forth. There is much less information directed toward bench laboratorians in the microbiology laboratory, and that which is developed for them may not be in a form that is compatible with or useful in their day-to-day activities. One of the features of an SPHL position dedicated to conducting direct and intensive outreach to the clinical laboratories is the ability of the LPA, particularly those LPAs who have some clinical laboratory experience, to scan or screen potentially useful information from a variety of sources, and to then distill this information into a format and level of detail useful for laboratorians.

There is a strong conviction across the sites that true partnership with clinical laboratories is not likely to be achieved without simultaneously working to improve coordination and cooperation within the health department, especially with the epidemiologists. Putting a "face" on the SPHL through the communication activities of the LPA also is essential to developing partnerships with clinical laboratories as well as other external entities. Some of those interviewed spoke of the importance of "marketing" public health and of helping clinical laboratories gain a better understanding of how the work they do feeds into the public health mission, as well as the importance of raising awareness of how the SPHL could assist them.

Challenges

Challenges to building a network of SPHL and clinical laboratories capable of responding to a public health crisis include:

- The difficulty of maintaining an accurate and usable database of laboratory contacts because of staff turnover, location changes, and institutional mergers and buyouts.

- Inadequate or extremely limited computer access in many local public health agencies and clinical laboratories.
- Uneven electronic or digital coverage because of sparsely populated or remote rural areas (for instance, wireless devices will not work in some areas).
- Inadequate computer capabilities in smaller laboratories, and staff too busy to look up needed reference materials available on websites.
- "Old history" or "cultural barriers" between the laboratory and other state health agencies or departments, such as epidemiology.
- Time required to build intra-agency relationships and in "raising the profile" of the laboratory in the public health agency as an equal partner in detecting and responding to disease outbreaks.
- Resistance from clinical laboratories who do not want to be "graded" by the SPHL.
- Resistance from clinical laboratories that consider information on their testing capabilities to be proprietary and are concerned about competition from state or other laboratories.
- Bureaucratic barriers that hinder re-publication and dissemination of materials.
- Working conditions and salaries in the state health department may not be as desirable as in the private sector, making it difficult to hire LPAs with clinical backgrounds.
- Availability of training facilities with adequate laboratory space and equipment to carry out wet workshops that are not readily available.

B. Findings from the Surveys

1. Effectiveness of the NLS Demonstration Sites

One measurement of the effectiveness of the demonstration sites was comparing survey results of clinical laboratories in the three demonstration states with those of clinical laboratories in the other states. The sample of clinical laboratories was stratified by state, making it possible to separate out responses from each state. These comparisons provide important evidence of the effect of the intervention of the demonstration project in the three states. Many of the comparisons show a significant difference and in others the trends in the data are persuasive.

Examples of significant differences in the demonstration states compared to the other states include a greater likelihood of the demonstration site clinical laboratories to be aware of a regular point of contact at the SPHL for asking questions or voicing concerns; to have the perception that the SPHL understands the capabilities of the clinical laboratory; to be aware of a greater number of activities of specific types offered by the SPHL in the past year; to believe that the SPHL notifies them in a timely manner about emerging public health threats; and to be currently collaborating with the SPHL on topics such as emerging infectious diseases, agents of bioterrorism, and specimen transportation requirements.

More specific results may be found in the following tables which show that clinical laboratories in the NLS demonstration states; were more likely than laboratories in other states to have been invited to be a sentinel laboratory (Table 1); felt that their state laboratory better understood their capabilities (Table 2); were more aware of activities of the SPHL to reach out to them (Table 3); felt the SPHL notified them of public health threats in a timely manner (Table 4); and were more likely to say they collaborated with their SPHL on a variety of topics (Table 5).

Table 1. Has your laboratory been invited by your state public health

laboratory to participate as a sentinel laboratory in the Laboratory Response Network?" (March 2004)

	Demonstration Site Clinical Laboratories			*All Other Clinical Laboratories*	
Response	*Number*	*Percent*		*Number*	*Percent*
Yes	21	58%		220	48%
No	11	31%		143	31%
Don't know	4	11%		92	20%
Total	36	100%		455	100%
Missing	1			11	

Difference is not significant.

Table 2. "How well would you say that the SPHL understands the capabilities of your laboratory?" (March 2004)

	Demonstration Site Clinical Laboratories			*All Other Clinical Laboratories*		
Response	*Number*	*Percent*		*Number*	*Percent*	
Completely. pretty well	24	71%		212	49%	
Somewhat well	7	20%		142	31%	
Not very or not at all	3	9%		91	20%	
Total	34	100%		445	100%	$p = .032$
No response	3			21		

Table 3. "Below is a list of activities that some SPHL's conduct with the clinical laboratories in their state. Please indicate whether your SPHL has conducted any of the following activities in the past year." (March 2004)

	Demonstration Site Clinical Laboratories			*All Other Clinical Laboratories*		*Signif.*
Each is a separate item:	*% yes*	*N*		*% yes*	*N*	$p =$
Alerts about topics of importance	97%	33		81%	336	.020
Newsletters	97%	31		55%	212	.000
Workshops, information sessions or seminars	94%	33		78%	331	.022
Surveys to obtain contact or capability information about your laboratory	84%	27		62%	241	.011
Teleconferences	82%	27		48%	176	.000
Procedures, guidelines, manuals or protocols	81%	26		53%	198	.002
Regional conferences	71%	22		39%	132	.001
Train the trainer workshops	73%	24		44%	161	.001
Site visits	52%	16		42%	160	n.s.

Table 4. "In your opinion, does the SPHL notify you in a timely manner about new or emerging public health threats?" (March 2004)

	Demonstration Site Clinical Laboratories			*All Other Clinical Laboratories*		
Response	*Number*	*Percent*		*Number*	*Percent*	
Yes	35	95%		304	66%	
No	0	0%		53	12%	
Don't know	2	5%		102	22%	
Total	37	100%		459	100%	$p = .002$
No Response	0			7		

Table 5. "Comparison of the extent of current collaboration between the clinical laboratories and the SPHL on a set of topics." (March 2004)

	Demonstration Site Clinical Laboratories			*All Other Clinical Laboratories*		*Signif.*
Currently collaborate with SPHL on:	*% yes*	*N*		*% yes*	*N*	*p =*
Laboratory Safety	22%	36		14%	423	.074
Antimicrobial susceptibility testing	**29%**	**34**		**10%**	**421**	**.001**
Emerging infectious diseases	**76%**	**37**		**39%**	**435**	**.000**
Regulatory issues such as QA/QC	6%	36		13%	419	n.s.
Agents of bioterrorism	**72%**	36		**46%**	435	**.024**
Specimen transportation requirements	**68%**	37		**42%**	423	**.021**
Laboratory information systems for tracking status of specimens submitted	**17%**	36		**9%**	419	**n.s.**
Mycobacteriology identification and susceptibility testing	26%	35		34%	424	n.s.
Biomonitoring for environmental contaminants	6%	33		5%	405	n.s.

2. Findings from the Survey of SPHL Directors

Forty-eight out of 52 SPHL directors who received the questionnaire responded to the survey. Responses from the 48 indicated that of the SPHL directors:

- 21% are political appointees.
- 33% report directly to someone in the health system who is appointed, such as a state health commissioner.
- 65% report directly to some other state health official who is a regular state employee.
- 60% of the directors interact fairly frequently with the epidemiology unit to plan, budget, prepare grants, and discuss technical aspects of disease control in their state.
- 76% have doctoral degrees including 10 with doctorates in public health.
- 73% reported having worked in a clinical laboratory prior to becoming the SPHL director.
- 71% indicated that they had had management training as part of their formal education.

Thirty-one percent have a staff person who is responsible on a full-time basis for communication with the clinical laboratories, and 40% have a person assigned part-time to this function. Only 29% of the states do not have a staff person who is assigned this responsibility. Fifty-three percent of SPHLS have a mechanism for feedback from the clinical laboratories. In addition SPHL directors who had worked in a clinical laboratory were more likely to have a forum for feedback from clinical laboratories than SPHL directors who had not worked in a clinical laboratory (56% vs. 40% respectively).

Interest in Collaboration

SPHL directors were asked whether they were currently collaborating with the clinical laboratories in their states on a variety of laboratory-related topics. From among the list of topics, collaboration on two topics -- antimicrobial susceptibility testing, and mycobacteriology identification was significantly related to the number of years served by the SPHL director, with SPHL directors who had served more than 15 years less likely to indicate current collaboration. Current collaboration on four of the nine topic areas (antimicrobial susceptibility testing, emerging infectious diseases, agents of bioterrorism, specimen transportation requirements) were significantly ($p < 0.10$) related to the director having worked in a clinical laboratory.

SPHL Information about Clinical Laboratories

Most of the SPHLs in the survey felt that they have basic information about the clinical laboratories in their state. All of them can access location and contact information. Eighty-four percent report that they have information on the testing capabilities of clinical laboratories. Ninety-one percent of the SPHLs indicate they survey clinical laboratories for contact or capability information from the clinical laboratories at least once a year.

The most common inquiries received from clinical laboratories by SPHLs are requests for consultation on testing procedures or for laboratory training. The most frequently (77%) noted area of concern about why clinical laboratories might not use the SPHL as a resource was that some may not understand the capabilities of the SPHL.

Notification of Public Health Alerts

SPHL directors were asked how they would quickly disseminate information about a public health emergency. Twice as many said they would use broadcast fax (44%) than broadcast e-mail (20%). For the eight who indicated another response, four utilized a fax in combination with some other mode. More than one-half (54%) of the SPHLs estimated such a message would reach at least 90% of the clinical laboratories the first time sent out, or at least within 12 hours.

The SPHLs were asked how quickly they believe they can assemble data on incidence and location of a threat with the information they typically have available. Over one-half of SPHL respondents (53%) believed they could do so within 24 hours, and many of those believed they could do so in less than 12 hours. The implementation of more agile reporting systems is expected to be an important factor in increasing the degree to which threats can be identified in less than 12 hours so that response can be initiated. This type of performance is one of the major objectives of the NLS and is of particular concern given that nearly one-half (42%) of the states would take more than 25 hours to assemble the incidence data.

Sample Transport

The SPHLs were asked how the clinical laboratories send samples to the SPHL. Eight (8) of the laboratories indicated samples were sent by courier only, 12 indicated a combination of courier and mail and the remaining 28 indicated some combination of modes.

Website

Twenty-four (24) of the 48 SPHLs in the survey say they maintain a website for clinical laboratories to view or download information, such as protocols, procedures, or health alerts. Fifteen (15) say they send a notice to alert laboratories when something important has been added. One hundred percent (100%) have demonstrated their readiness to engage in at least some activity to provide information to clinical laboratories, such as a workshop, information session, or seminar. Around three-fourths or more have initiated other types of activities for the clinical laboratories, including alerts of topics of importance; the distribution (and perhaps development) of procedures, manuals, or protocols; site visits; train-the-trainer workshops; and about one-half have provided regional conferences and newsletters. But 15% of the SPHLs reported they had not sent an alert to clinical laboratories about a topic of importance during the past year.

3. Findings from the Survey of Clinical Laboratories

The number of usable questionnaires for the analysis of the clinical laboratories is 503. Hospital-based clinical laboratories, including university hospitals, were the most common type from which responses were received. In response to the question about the laboratory role of respondent, 32% (n=154) said they were the director and 64% (n=320) said they were the laboratory manager or supervisor. Of the other 29, 23 had non-supervisory roles and 6 did not respond to the question.

While 73% of the SPHL directors had some previous experience in a clinical laboratory, only 19% of clinical laboratorians have either educational background or experience in public health. However, a very high percent (93%) of clinical laboratory respondents reported that they will notify the SPHL or epidemiologist if test results indicate a public health threat. Ninety-six percent of SPHLs provide reference services, but only 59% of clinical laboratories use their SPHL as a reference laboratory. It is assumed that most of the clinical laboratories that do not use the SPHL use the services of larger hospital laboratories or commercial reference laboratories.

Request for Information

Most of the clinical laboratories (94%) indicated that they do not seek information from the SPHL even once a month. Seventy-eight percent never or seldom (less than 5 times per year) contact the SPHL about new procedures or public health threats. The seven (7) laboratories reporting that they make more than 20 inquiries per year may have counted questions about the intake and tracking of specimens. For the question on whether they had a point of contact at the SPHL to whom they can address questions, 70% of the 491 clinical laboratories answering the question reported that they do, a figure consistent with the proportion of the SPHL directors (70%) who said they had a designated person for communication with the clinical laboratories. Ninety percent of the 391 who responded that they do consult with the SPHL rated the responses that they received as "good" or "excellent."

Barriers and Benefits

The clinical laboratories indicate that they might consult with the SPHL more if they had a better understanding of the SPHL's capabilities, roles, and services. The second most important factor cited by clinical laboratories as promoting their greater reliance on the SPHL was to have a clearer idea of how the clinical laboratories fit into the public health system. When asked what the benefits of increased interaction with the SPHL would be, ninety percent felt that being part of a laboratory network or community would be a positive benefit. This answer suggests that clinical laboratories would view working within the NLS concept as a positive experience.

Website Recognition

One-half the SPHLs reported that they maintain a website for making information available to clinical laboratories. With respect to the usefulness of such a dissemination pathway, virtually all the clinical laboratories report there is access to the Internet in their office, and about one-half of the clinical laboratories are aware of the state laboratory website.

Preferred Method of Receiving Information

The clinical laboratories were asked their preference for the communication mode the SPHL could use for relaying information about a public health emergency. There was a high level of congruence between what clinical laboratories preferred and what the SPHLs were using. The preferred mode was fax, and was twice as likely to be mentioned as was e-mail. Almost 70% of the clinical laboratories felt that the SPHL notified them in a timely manner about new or emerging public health threats. An appreciable proportion (20%) said they didn't know.

Invitation to be Sentinel Laboratories

Clinical microbiology laboratories have been called "sentinel" laboratories because they would be the first to encounter a potentially dangerous organism in a patient's specimen, and, if staff is properly trained, would subsequently initiate a public health response. Only 49% of the laboratories surveyed in this study report they have been invited to participate as a sentinel laboratory in the Laboratory Response Network (LRN); 31% said they had not been asked, and 20% responded that they didn't know. Clinical laboratories in the NLS demonstration states were somewhat more likely than those in other states to report that they had been invited to be a sentinel laboratory (58% to 48%) and somewhat less likely to say they didn't know (11% to 20%), although the difference is not significant.

Use of SPHL for Information

The survey of clinical laboratories asked who the microbiology laboratorians would turn to if they had a question on susceptibility testing or on testing for potential bioterrorism agents. For susceptibility testing, 75% of respondents were most likely to turn to someone else in their own organization. However, for testing for bioterrorism agents, 72% were very likely to turn to the SPHL. The strongest reasons for not turning to the SPHL were the inability to locate the SPHL point of contact (61%) or the fact that the SPHL may not be operating when the question comes up (44%). Less than 20% indicate that the reason would be because the SPHL is not the appropriate source for the information.

The main benefit the clinical laboratories mentioned as having received from their SPHL since September 2001 was information on bioterrorism agents. In the coming year, the leading-edge states are expected to develop activities that are focused less specifically on bioterrorism agents and more generally on laboratory integration for the overall purpose of quick detection of any emerging public health threat. The challenge may prove to be that of making the integration objective compelling enough to the clinical laboratories that a high proportion can be actively engaged in collaborative efforts focused on enhancing the level of private-public laboratory integration. "Collaboration" implies that the private and public laboratories work together and adjust behavior to solve problems and address issues that affect them both.

Current and Desired Levels of Collaboration

From our two surveys, the comparison of the SPHL and clinical laboratory responses regarding the current state of "collaboration" suggests a difference in perception between the two groups, at least in this aggregate reporting across all laboratories. For example, in every category the SPHL directors estimate a higher level of current collaboration than do the clinical laboratories
However, more than 50% of the clinical laboratories said they would be interested in future collaboration on laboratory safety, antimicrobial susceptibility testing, emerging infectious diseases and agents of bioterroism. Less than 10% of clinical laboratories reported collaborating with the SPHL on regulatory issues, but more than 40% said they would like to, while less than 20% said they were not interested.

Collaboration Requirements

The concept of the NLS has been developed and is being fostered by CDC and the APHL because of the need for the timely movement of critical information back and forth between the SPHL and the clinical laboratories in a state. The means to achieve this, state by state, is the creation of effective working relationships between clinical and public health laboratories, especially those focused on testing and reporting capabilities. These relationships are the means of fostering such features as two-way communication about public health threats including bioterrorism, and how to detect and respond to them. Such communication in turn requires structures, processes, and standards in the SPHL and clinical laboratories that are congruent with each other for the purpose of disseminating current information and alerts, moving specimens through screening and testing, and obtaining and distributing test results. And there must be mutual understanding and trust between the SPHLs and the clinical laboratories, based on their complementary functions related to public health.

In general, the results of the surveys indicate that many important features related to better communication and understanding between the two types of laboratories are already in place, at least to some degree. There is at least some readiness to make good use of resources, educational tools, and leadership focused on a National Laboratory System.

Activities Provided by the SPHL

A high proportion of the 503 clinical laboratories responding to the survey are aware of informational and training activities provided by the SPHLs. Over 80% are aware of workshops or other types of informational seminars that the SPHL in their state has offered in the past year. Further, with the exception of site visits from the SPHL, over 70% of the clinical laboratories are positively disposed toward the SPHL offering more informational activities. Thus, many seem ready to partake of the various informational activities that the SPHL can make available.

Development of an effective NLS will involve an integrated set of actions by both the public health and clinical laboratories. The clinical laboratories need to be able to make quick and accurate assessments of what specimens to refer to the SPHL, and also need to get them properly packaged and sent. The SPHL needs to be able to manage the specimens as they come in so that they are carefully logged and tracked, quickly tested, and results reported quickly back to the clinical laboratories. To some extent, improvements could be made through developing more effective work processes, and by the adoption of new and quicker testing technologies. Recently, an increasing number of SPHLs, due to the bioterrorism funds for improvement of laboratory capabilities, are beginning to put sophisticated information systems in place for tracking and reporting, including on-line systems that can be used by the clinical laboratories to order tests and by the public health laboratories to report results almost as soon as testing is completed.

Need for Electronic Reporting Systems

Electronic reporting systems are important for enabling the SPHL to know more quickly about disease patterns emerging from clinical laboratory testing as well as its own, and for informing the clinical laboratories to be aware that there may be an outbreak in progress that they need to be alert to. The clinical laboratories were asked both if their state had the capability to electronically send test results to them, and if they had the capability to electronically send test results to the SPHL. The majority of the clinical laboratories (69%) reported that neither their state nor their own laboratory has an electronic reporting capability in place. Only about one-third of the clinical laboratories can electronically send their test results to the SPHL. Nonetheless, tools for communication and information exchange can be developed, and in most cases, probably are being developed or put in place at a fairly rapid rate, partly due to the availability of bioterrorism preparedness funding.

V. Conclusions and Recommendations

Conclusions

Only through sustained, focused communication efforts can the needs of public health organizations to guard the public health be met. Both public and private laboratory respondents in this study cited the need to improve the quality and timeliness of communications with each other. Efforts should be consolidated rather than program-oriented if broad-based public health issues are to be addressed appropriately. The state public health laboratory (SPHL) directors who responded to the survey clearly recognize the promise of active communication and the sharing of technical information between the SPHL and clinical laboratories as critical to improving surveillance and enabling the public health system to react more quickly to emerging public health threats. Thus, they see better collaboration with clinical laboratories with respect to information of public health importance as one key to meeting the public health laboratory core function of disease prevention, control, and surveillance.

Both public and private laboratory respondents cited significant barriers to improving the quality and frequency of communication. For example, the SPHL directors are most likely to attribute the inadequate communication with the clinical laboratories to overburdened staff, lack of or outdated electronic information management systems, and insufficient funding to alleviate the situation. Many perceive this to exist both at their end and in the clinical laboratories. Most believe that more staff time to dedicate specifically to the effort of actively engaging with the clinical laboratories and better laboratory information management systems for sharing test results are needed if they are to expand their interactions with the clinical laboratories.

The case studies, though variable in strategy and program elements, seem to demonstrate that relatively modest investments in strengthening communications between the public and private laboratories have an impact. That is, the NLS concept can be brought closer to reality by providing resources to focus on communication, awareness, and training within individual states and for laboratory directors.

Information gathered from the demonstration sites corroborates the CDC/APHL emphasis on the importance of having a staff position committed to overseeing the mechanism put in place to ensure that specimens, test results, and new information move quickly between the SPHL and the clinical laboratories. Each of the SPHL directors saw it as important that the SPHL take the lead in creating a system for sharing information of public health importance, as exhibited by their interest in implementing the NLS concept. Each of the LPAs had an increasing awareness of what was most useful and relevant to clinical laboratorians if both partners were to benefit from the increased interaction.

Recommendations

The recommendations for strengthening the NLS contained in this report are those that can take place with relatively modest investments of resources, and within the current structure of the public-private partnership. In many instances, the recommendations offered here have generally been cited by the Laboratory Program Advisors (LPA) or SPHL directors in the demonstration sites studied or in the state survey, or have been advanced by CDC or other interested parties.
The CDC needs to promote a clear understanding among all the elements of the NLS program about the need for, the dimensions of, and operational best practice in the NLS as it is being implemented by demonstration sites. The NLS has been an emerging concept, and, given the case study results, appears to be worth advancing with a more aggressive developmental program. The first step is to create and implement the communication and awareness strategy that can be used in each state to increase public and private laboratory understanding of the what and why of the NLS.

1. **Recommendation:** All SPHLs should institute the position of a laboratory program advisor (LPA) specifically assigned to developing and maintaining communication with clinical laboratories.
2. **Recommendation:** CDC or APHL should develop a position description for the laboratory liaison employee based on lessons learned from the previous or current LPAs about what the job entails and how it can fit into state personnel systems or be funded through some other mechanism.
3. **Recommendation**: CDC should work with states to find ways to fund LPA positions.
4. **Recommendation:** SPHLs should examine their practices to see what changes would enable them to provide information back to the CLs more quickly so that any issues related to patient care are known in time for treatment modification, if necessary.
5. **Recommendation**: CDC and APHL should determine critical topics that produce public health improvement based on the level of CL and SPHL collaboration. For example, SPHLs

should work with CLs to insure that reportable diseases identified in the CLs are actually reported to the state epidemiologists**.**

6. **Recommendation:** CDC and APHL should develop ways to measure the degree of change in the flow of critical public health information as a result of laboratory integration efforts.
7. **Recommendation**: CDC should continue to fund demonstration projects and add new states that are ready to participate.
8. **Recommendation**: State laboratory administrators should enable LPAs from demonstration sites to meet together periodically.
9. **Recommendation**: SPHLs in demonstration sites should allow existing demonstration site staff to mentor states that have not yet formally entered into NLS development but are interested in understanding why and how they might take up laboratory integration activities.
10. **Recommendation:** Professional organizations and laboratory educators should create a working group of medical technology (clinical laboratory science) educators and public health leaders to develop a small but focused teaching unit on public health functions to add to the curriculum for medical technology training.
11. **Recommendation:** The SPHLs should institute the practice of reporting back to the clinical laboratories how the information the clinical laboratories provided helped solve a public health problem.
12. **Recommendation**: SPHLs should promote greater awareness on the part of SPHL personnel of what clinical laboratorians do by developing a process of periodic exchanges and training events between the two types of laboratories.