Electronic Reporting of Laboratory Information for Public Health

January 7–8, 1999

Summary of Meeting Proceedings

The meeting was planned and this report was prepared by CDC and the ELR Meeting Planning Group. Members of the group were: Greg Armstrong, Scott Danos, Ron Fichtner, Joy Herndon, Dan Jernigan, Denise Koo, Carol Pertowski, Robert Pinner, Steve Steindel, Suzanne Sutliff, Roberta Thornton, Warren Williams (CDC); Diane Dwyer (Maryland State Health Department); Jac Davies (Washington State Department of Health); Ralph Timperi (Massachusetts Department of Public Health); and Susan Toal (Public Health Consultant).

We gratefully acknowledge the participation of all who attended the meeting. We would like to acknowledge in particular those who provided comments on the draft report: Ray Aller, Rich Aranowski, Claire Broome, David Carpenter, Jim Cimino, Ann Hueber, Jim Rankin, and Perry Smith.

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Executive Summary

Laboratory reports are a critical component of public health surveillance. Public health agencies and laboratories recognize that information technology now permits this job to be performed more quickly and effectively. In March 1997, the Centers for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Laboratories (APHL) co-sponsored a meeting to design strategies for implementing effective electronic laboratory-based reporting (ELR). The primary recommendation that emerged from this meeting was the call for a unified approach to ELR through the use of Health Level 7, a national standard for communicating clinical health information.

To stimulate further progress, CDC, APHL, CSTE, and the Association of State and Territorial Health Officials (ASTHO) co-sponsored a second meeting on January 7 and 8, 1999. Presentations during the meeting explored state, laboratory, and informatics perspectives on ELR, and key issues such as modes of transmission, data privacy, software development, data quality, and data flow.

Meeting participants voiced consensus in support of the approach using HL7 and standard test and result codes to develop ELR for public health. Specific recommendations which emerged are as follows.

Leadership and Coordination

- ELR is an important component of CDC's public health information and surveillance systems integration efforts. Implementation of ELR should be undertaken in coordination with related efforts at CDC and in state and local public health agencies.

- CDC, through the Health Information and Surveillance Systems Board (HISSB), should consider convening a work group to foster ELR. An important next step would be further development of guides for implementation of HL7 public health reporting both for technical and non-technical personnel.

- CDC (HISSB) and the Council of State and Territorial Epidemiologists (CSTE) should collaborate with stakeholders to:
  - define and standardize required laboratory data elements for notifiable disease surveillance.
  - collect, maintain, and disseminate state and local requirements for reportable conditions.
  - encourage state and local health departments to provide easy access to various reporting requirements (e.g., tables for downloading from public health web sites).

Software Tools and Technical Support

- CDC should provide technical support for pilot implementations of ELR. Pilot efforts should include the development of informational materials about ELR implementation.

- As part of the CDC Integration Project, CDC should develop a model describing the flow of data from the laboratory, to the state and local health agencies, to CDC. The model should take into account individual programs (e.g., STD, TB, HIV, and immunization) at each public health level. Its description should be detailed and accessible, as it will be

valuable for ensuring that the needs of public health are understood by vendors, contractors, and systems analysts.

- CDC should continue evaluating government and commercial off-the-shelf (COTS) software tools for ELR implementation. This evaluation should not be limited to simple data mappers but should include software with other functions that would be useful in ELR systems.

- CDC should explore the utility of data entry through the Internet using web browser forms for small labs, which may not have the expertise or the incentive to develop ELR systems.

Policy Development

- CDC should assure that the interests of the public health community are well-represented within relevant standards development organizations, such as HL7.

- CDC should work with the Healthcare Finance Administration (HCFA) to identify opportunities to implement electronic laboratory reporting and to coordinate the reportable required laboratory data elements project with the Health Insurance Portability and Accountability Act (HIPAA) claims attachment process (see http://aspe.os.dhhs.gov/admnsimp/index.htm). Furthermore, the HL7 ELR implementation guide should be compatible with the HIPAA guide.

- CDC and its partners should develop strategies for identifying which results should be reported for specific tests (e.g., “flags” for abnormal results).

- CDC and its public and private partners should develop strategies for improving the completeness of demographic data in electronic reports, especially the patient address. In particular, approaches for linking health plan enrollment databases to databases of laboratory results should be pursued.

- CDC and its public health partners should develop strategies for simplifying the reporting requirements for laboratories. Special efforts should be made to harmonize reporting requirements across public health jurisdictions and to minimize the number of agencies to which laboratories need report.

Training and Education

- CDC should establish and maintain an electronic laboratory reporting listserv that includes interested public and private agencies and organizations.

- CDC should work with CSTE to develop a source of information, accessible through the CDC web site, on reportable diseases, LOINC, SNOMED, HL7, reporting sites, and implementation guides.

- CDC should update state health departments and laboratories on the HIPAA legislation and its anticipated impact on agencies, new legislative mandates that may impact electronic laboratory reporting, and websites that contain related information (e.g., http://aspe.os.dhhs.gov/admnsimp/index.htm).

- Basic electronic laboratory reporting information should be conveyed to public health practitioners, laboratory staff, health care providers, and laboratory information system developers. The information should be tailored for each audience, but content might encompass why electronic laboratory reporting is beneficial, what HL7 is, what diseases are reportable, how to use software, how to ensure data security, etc. Training delivery modes might include use of the Internet, distance learning, and conferences. Offering of continuing education unit credits would enhance motivation to attend. When possible, such training should make use of experts in informatics and in HL7.

Fostering Public-Private Collaboration

- Collaborative pilot ELR projects should be undertaken with CDC, large laboratories, and selected stated health departments.

- Large laboratories and laboratory associations (e.g., ACLA, CLMA, AACC, and CAP) should endorse and adopt the approach recommended at the 1997 ELR meeting (HL7-LOINC-SNOMED) for electronic reporting of results to public health agencies.

- CDC should work with laboratory information system vendors to incorporate electronic public health reporting capacity into their products.

Introduction

Laboratory reports are a critical component of public health surveillance. These reports are usually submitted as paper forms, voicemail, or facsimile. Public health agencies and laboratories recognize that information technology now permits this job to be performed more quickly and more efficiently. Connecting laboratories to public health agencies with automated, electronic communication will improve public health practice.

In March 1997, the Centers for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Laboratories (APHL) co-sponsored a meeting to discuss challenges to implementing effective electronic reporting and to determine creative, practical approaches to making progress. Three main perspectives were represented among meeting participants: the views of federal public health agencies, the views of state epidemiologists and public health laboratorians, and the views of the private sector. That meeting called for a **unified approach** to electronic reporting of clinical laboratory data, based upon the adoption and use of **standards** for formatting electronic messages and for coding of laboratory test names and results. As an accepted industry standard for electronic messaging of health information and the standard for development of the computerized medical record, **Health Level 7 (HL7)** emerged as the choice of a standard for ELR messaging format. Wide and increasing adoption by laboratories of Logical Observation Identifiers, Names and Codes **(LOINC)** for the specification of the test names made it the choice for coding of laboratory tests; and the Systematized Nomenclature of Human and Veterinary Medicine **(SNOMED)** was proposed as the standard test result coding scheme.

To facilitate progress toward expanded implementation of electronic laboratory reporting (ELR), a second meeting was held in Atlanta, Georgia on January 7 and 8, 1999. Entitled "Electronic Reporting of Laboratory Information for Public Health," the meeting's co-sponsors included CDC, APHL, CSTE, and the Association of State and Territorial Health Officials (ASTHO). The primary objective of the meeting was to design strategies for expanded adoption, use, and evaluation of ELR. The participant list was more extensive than the first meeting, and included representatives of state and federal public health agencies, laboratories, software vendors, and standards development organizations — all attending to share information on each others' perspectives and to discuss strategies for moving forward in a systematic fashion.

Dr. Claire Broome, CDC's Deputy Director for Science and Public Health, opened the meeting. In her introductory remarks, Dr. Broome noted the growing appreciation of information technology as having a tremendous benefit for public health. She emphasized the importance of standards in relation to ELR and, in particular, the importance of making them compatible with those developed in response to the Health Insurance Portability and Accountability Act's (HIPAA) administrative simplification provisions. She also stressed the importance of the public health community's engagement in the privacy debate with regard to assuring confidentiality and protection of personal information.

Finally, she noted that continued collaboration among public and private partners will be crucial if routine electronic reporting is to become a reality. She praised the commitment of the meeting's participants and applauded their willingness to be on the "leading edge" of public health informatics.

Dr. Robert Pinner, Director of the Office of Surveillance, NCID, CDC, followed by welcoming the broad array of participants and echoing the importance of partnerships in making progress toward implementation of ELR. He summarized the key recommendation from the previous (1997) meeting, namely, the need for an unified approach to ELR with a standard HL7 message.

Since that meeting, CDC, through its Health Information and Surveillance Systems Board

(HISSB), has endorsed this approach to guide ELR implementation efforts. In addition, CSTE and APHL have passed resolutions at their annual meetings embracing these standards. Efforts to test ELR systems using HL7 messages are either planned or underway in at least 14 health departments. Dr. Pinner challenged the group to be creative in proposing realistic strategies for making further progress with ELR. In particular, he shared several issues that present a challenge to broad implementation of ELR:

- Insufficient education, training, and communication — both general and technical — to establish a firm foundation for ELR.
- Lack of uniformity in enthusiasm and capacity among laboratories for ELR.
- Technical hurdles within state health departments that make it difficult for them to work with HL7 messages.

He urged participants to keep uppermost in their minds the vision of improved quality of public health surveillance. The proposed uses of surveillance data may vary, from case investigation, to monitoring of trends, to evaluation of interventions, to research. But the underlying principle remains consistent: ELR has the potential to capture relevant clinical laboratory data in an efficient and timely manner for the improvement of public health.

Following Dr. Pinner's remarks were a series of presentations covering the following topics:

- State perspectives on electronic laboratory reporting
- Laboratory perspectives on electronic reporting
- Perspectives from the informatics field
- Key issues: modes of transmission, data privacy, software development, data quality, and data flow.

Meeting participants then met in small groups to respond to the key issues raised by presenters:

- Technical issues
- Epidemiology/policy issues
- Training/education/communication issues
- Strengthening public/private partnership issues.

This report summarizes the presentations listed above and the recommendations that emerged from the meeting.

I. Electronic Laboratory Reporting: The State Experience

Presenters from the states of Hawaii and Washington described the evolution of their electronic laboratory reporting efforts, technical and political challenges they encountered along the way, and recommendations for other states considering or pursuing similar efforts. Panelists from Massachusetts, Georgia, New York and Pennsylvania then presented brief descriptions of how their states' approaches compared to those of Hawaii and Washington.

Hawaii

Paul Effler, Hawaii Department of Health

The Hawaii Department of Health chose to hire a private contractor to develop its electronic reporting system rather than to use health department staff. Prior to the competitive bidding process, an information technology expert was retained to prepare the request for proposals (RFP). The system is currently in a transition phase, with the Department collecting both electronic and paper reports until staff can verify the adequacy of the electronic reporting system.

The three commercial labs that participated in the initial electronic reporting effort are the source for between 70 and 80 percent of all laboratory-based disease reports in Hawaii. Two of the laboratories have strong in-house computer departments, while the third allowed the Department of Health's contractor to develop a data extraction program for its use. Reports from the three laboratories are sent daily to the Department of Health via modem as encrypted data files using proprietary software developed by the contractor. Within the laboratory, reports are transmitted in HL7 messages to a dedicated computer where they are then filtered and sent in encrypted batch files to the Department of Health.

The dual reporting during the transition made possible a comparison of electronic and paper transmissions between July 1, 1998, and November 30, 1998, for five different reportable laboratory findings: *Salmonella*, *Shigella*, *Giardia*, vancomycin-resistant enterococci, and *Streptococcus pneumoniae*.

Transmission Consistency

Daily electronic transmissions from all three labs were received on time an average of 74 percent of the time. A variety of technical problems accounted for delayed or missing reports, including such mundane problems as accidentally unplugging the computer used for transmission. On average, missing data were re-transmitted within three days, but re-transmission sometimes took over a week. Of the 11,000 records received by the Department of Health during this period, approximately 12 percent were either not reportable findings, were negative results, or were otherwise incorrect. This required considerable staff time for data cleaning and editing.

Completeness and Timeliness of Reporting

Even with an imperfect and transitional system in place, the electronic reporting yielded more than twice as many reports as paper reporting — a dramatic increase in the number of reports. It is worth noting, however, that there was significant variation among the three laboratories.

The improvement in completeness-of-reporting varied greatly between specific diseases. The number of reported cases of salmonellosis increased approximately 60% with the institution of electronic reporting. Reports of shigellosis increased by 100%. Reports of other, less recognizable

infectious diseases increased by even greater proportions.

When 24 data fields from the electronic and paper reports were compared, an average of 76 percent of the report fields were filled for the electronic reports, compared to 60 percent for the paper reports. For patient identifiers such as last name, first name, and sex, both types of reports tended to offer completed fields; however, the electronic records more frequently provided medical record numbers and birth dates. While both types of reports performed poorly in terms of information to be used to locate patients (i.e., address, city, and zip code), electronic reports were significantly better in providing patients' telephone numbers, which potentially can reduce staff time for follow-up.

In terms of fields related to specimen characteristics, the paper reports were more likely to provide specimen type, while the electronic reports were more likely to provide specimen numbers and test codes. Otherwise, the collection date, notification date, results, and lab names were consistently provided by both types of reports.

Physician identifiers were similar for the physician's name and address, but 60 percent of the electronic reports provided the physician's telephone number, compared to 20 percent of the paper reports.

Hawaii
Summary of ELR vs. Paper Reporting

- Shift from paper to ELR yielded a 2.3-fold increase in the number of reports
- Electronic reports were received 4 days earlier than paper reports
- 76% of data fields were completed in electronic reports, compared to 60% in paper reports
- Electronic reports were more likely to provide patient and physician telephone numbers

On average, the electronic reports were received five days earlier than the paper reports. (The delay was up to 8 days for one of the laboratories.)

Summary

Based on limited data from the recent transition to electronic reporting in Hawaii, electronic reporting seems to be more timely and complete than its paper counterpart and has increased the number of disease reports 2.3-fold.

Remaining issues include further analysis of what went wrong with the 25 percent of transmissions that contained various types of errors, cleaning and editing errors (and allocating sufficient staff time to do so), and determining whether the improvements in timeliness and completeness yielded an improved public health response.

Washington State

Jac Davies, Washington State Department of Health

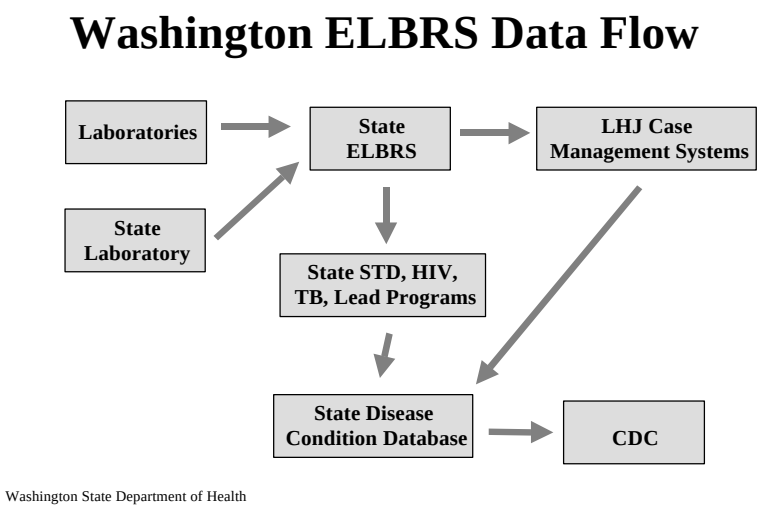
The Washington State Department of Health has been designing and implementing an Electronic Laboratory-Based Reporting System (ELBRS) for the past 3 years. The project began as part of an effort to reduce the reporting burden for clinical laboratories. Since early in its development, the project has embraced the standards endorsed at the 1997 ELR meeting: HL7 for messaging, LOINC for test codes, and SNOMED for result codes. After evaluating commercial off-the-shelf products, the project team chose to develop its own tool for reading HL7 messages. An "HL7 Reader" was developed for the Microsoft Windows environment and was piloted with messages from the Group Health Cooperative of Puget Sound to test its effectiveness.

Development of an HL7 Reader was not without hitches. The first approach was abandoned after two years when it became clear that the design was unnecessarily complicated and that several burdensome features were not needed. A second, component-oriented approach was then taken with the development of a program that parsed HL7 messages. The work of data manipulation (i.e., mapping) was performed in the database rather than in the HL7 Reader. However, even after many adjustments, the full pilot implementation (involving five counties served by Group Health Cooperative) was much more complicated than the team had anticipated.

Data Flow

In Washington, as in many states, data from laboratories are sent to internal programs within the state health department (such as sexually transmitted disease, tuberculosis, and blood lead programs) as well as local health jurisdictions (LHJs). Each state program keeps a separate database and reports separately to CDC. The state health agency intends to use ELR in a more integrated approach, shown in Figure 1.

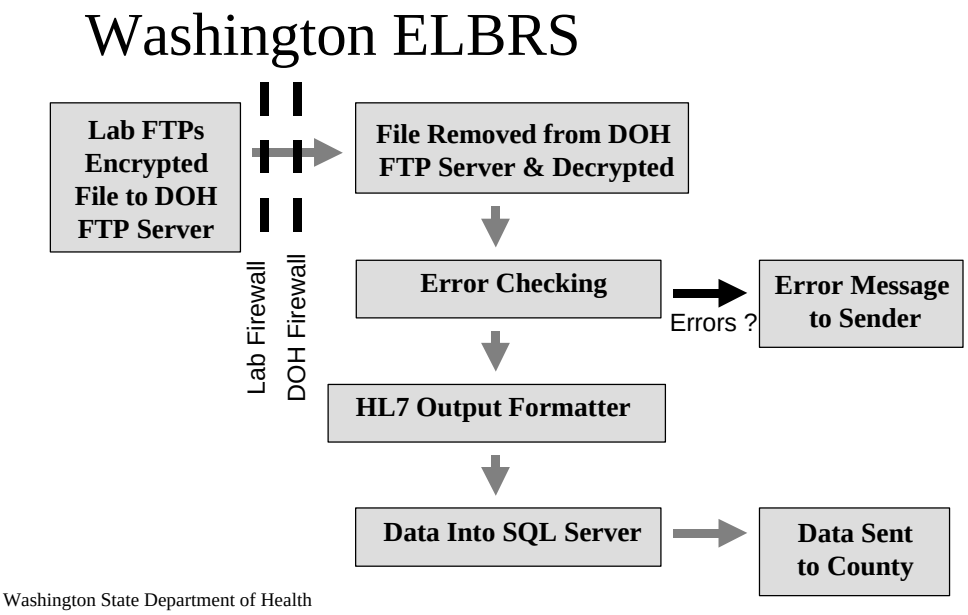
Figure 1



There are strong dependencies and connections in the flow of data among these different organizations. However, in the current system, inconsistencies in coding and data definitions complicate the reporting and communication process. The state lab, all state programs, and individual local health agencies each have different standards. Agreement on standards is necessary to move all agencies to an integrated system such as that depicted in Figure 1.

Washington's pilot ELR system is outlined in Figure 2.

Figure 2



As Figure 2 shows, the laboratories send encrypted files containing HL7 messages over the Internet to the Department of Health by file transfer protocol (FTP). The files are then automatically decrypted, parsed, and mapped to the communicable diseases database. The centralized architecture of this system increases the options for data use, both internally and with local health agencies.

Technical and Political Challenges

The technical and political challenges in Washington State's experience fall into six main categories:

- **Standards** – HL7 messages from different laboratories often appear very different due to differences in implementation. Because of this, it is important to work closely with partners when developing electronic reporting systems. Adherence to other standards is equally important. In Washington, the team initially believed that the Department of Health could process the multiple formats and codes which labs sent, but this was not practical. Instead, they have requested that the labs translate their own codes to LOINC and SNOMED codes.

"In Washington, the team initially believed that the Department of Health could process the multiple formats and codes which labs sent, but this was not practical. Instead, they have requested that the labs translate their own codes to LOINC and SNOMED codes."

- **Security** – The Department of Health, in cooperation with its commercial laboratory partners, has developed preliminary security procedures. These currently provide for data encryption and soon will provide for user authentication and non-repudiation (see definitions under "Data

Security"). These procedures are being evaluated and may be updated as better security mechanisms become available in order to ensure they remain robust and up-to-date.

- **Data dissemination** – The Washington State Department of Health identified two options for transferring disease reports to local health jurisdictions: (1) to send data individually to each agency; or (2) to store the data in a central repository and let the agencies obtain the data by dialing in to that central site. Although centralized storage would be more efficient from the state's point of view, several local jurisdictions prefer to have the data sent to them. The system that evolves will probably combine elements of both approaches.

- **Buy-in** – The discussions about electronic reporting have occurred mainly at the management level. Unfortunately, information has not always been consistently provided to line staff such as communicable disease nurses. This has created problems in the implementation process – for example, staff who conduct case investigations are sometimes not familiar with the overall effort and do not understand why the Department is shifting to electronic reporting.

- **Organizational expertise** – Every organizational partner should bring three types of expertise to the table: laboratory expertise, experience in information systems development, and epidemiology. Without buy-in and cooperation from all three, delays in implementation are inevitable.

- **Timing** – Electronic reporting speeds up each step in the process, and sometimes a laboratory may get ahead of a local health agency's ability to handle data. In other cases, a local health agency may call a laboratory to ask questions about a particular reported event, but because it was reported automatically, the lab or provider may not be aware that it was sent. On occasion, local health agencies may learn of laboratory results before the ordering physician and the patient.

"Every organizational partner should bring three types of expertise to the table: laboratory expertise, experience in information systems development, and epidemiology."

Advice for Other States

Drawing from Washington's experience, the chances of successfully implementing electronic laboratory reporting can be improved if the following steps are taken.

- **Pick the right partners**. Choose one or two laboratories with HL7 experience and make sure each partner brings the right expertise (laboratory, information science, and epidemiology) to the discussions.
- **Make sure that everyone agrees on the key issues up front:** security, standards (i.e., message format and content), process or data flow, and timing.
- **Communicate** well and often.

Massachusetts

Tim Broadbent, Massachusetts Department of Public Health

The Massachusetts electronic laboratory reporting effort started small and remains a work in progress. One laboratory, Quest, which provides 60 percent of all notifiable disease reports from private reference laboratories, currently sends data daily in an ASCII flat file format. Both partners would like to switch to HL7 in the future.

ELR has improved communication between the clinical laboratory and the Department of Health. For example, in conversations with Quest staff about reporting procedures, health department staff became aware that the laboratory staff did not always know which reportable conditions were of interest to the health department, nor did the programmers understand this. The process of implementing ELR has caused the health department to be more explicit about the requirements for what, when, and how reportable findings should be sent.

Advice to Other States

Based on Massachusetts' experiences so far, staff offered the following advice to others considering implementation of electronic reporting systems:

- **Talk to laboratories** about which conditions are reportable. This can be done without any HL7 background.
- **Think through the current database systems** and standards.
- **Engage others within the health agency** – including non-infectious disease programs, such as cancer – in supporting the shift to electronic reporting.

Georgia

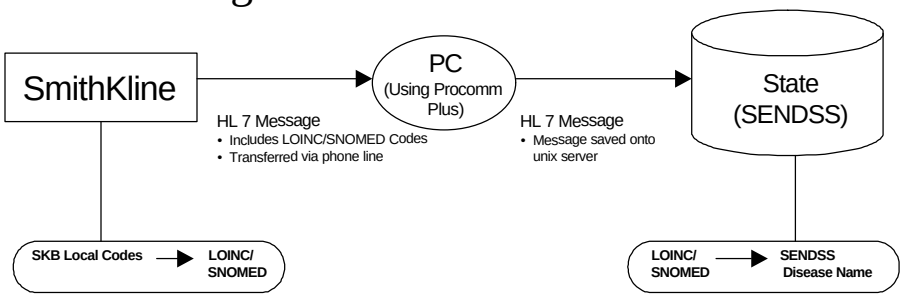
Jeff Berschling, Georgia Division of Public Health

Figure 3 shows the proposed data flow in Georgia's electronic reporting system. A stand-alone personal computer using standard communications software will dial into SmithKline's system nightly and log on with a series of identifiers and passwords. The computer will then download a batch file of HL7 messages containing notifiable results from the previous day.

At this point, the file will be transferred directly to a Unix server where the Statewide Electronic Notifiable Disease Surveillance System (SENDSS) resides. The HL7 messages will be validated and the LOINC and SNOMED codes will be mapped to disease names. A matching algorithm will remove duplicates. After this processing has finished, data will be sent promptly to local health jurisdictions. In the future, the SENDSS system will have the capacity to automatically produce summary reports for posting to the state's Internet site.

Figure 3

Georgia/SmithKline Beecham Model



Steps

1. PC dials into SKB nightly - Procomm script downloads file and saves it onto unix server.
2. HL7 message is validated.
3. LOINC/SNOMED codes are mapped to SENDSS disease names.
4. Data is posted to SENDSS.
5. Duplicate removal.

New York

Perrry Smith, New York State Department of Health

In New York, the Department of Health is currently receiving electronic reports of serum lead levels and CD-4 cell counts in ASCII flat file format. In the near future, the State will be acquiring capacity to receive other notifiable disease data in HL7 format.

System Design

At the core of the system will be a recently-completed wide area network that ties all 57 of New York's counties to the Department of Health host computer server. The State's communicable disease database resides on this server. Through a cooperative agreement, the state has been able to hire a programmer to develop an HL7 reader using MERCATOR (a commercial off-the-shelf data mapping tool). At this point, the reader has been tested, but has not yet been implemented. Although some development will continue in-house, the department also plans to hire a contractor to complete the project.

Major Challenges

Obstacles encountered in New York's development process include legal questions about whether the state has the authority to receive laboratory data on behalf of counties, and whether social security numbers can be obtained and then relayed to counties.

While the technical issues are critical, the non-technical issues are equally, if not more, important. For example, the Department of Health staff have found it very helpful to work with counties and laboratories to lay out the infrastructure and communication channels that will then support the technical aspects of electronic reporting.

Pennsylvania

James Rankin, Pennsylvania Department of Health

Pennsylvania intends to convert its 67 health jurisdictions from paper to electronic reporting. Currently, paper reports arrive (by mail) 21 days after results are known. With electronic reporting, the Department of Health hopes to cut this interval to 24 hours.

With federal funding, a contractor was hired to develop electronic reporting systems for serum lead levels and cancer programs. The plan is for the same contractor to develop the state's electronic reporting system for communicable diseases.

When the system becomes operational in June 1999, it will receive reports from SmithKline, Quest, and LabCorps in either HL7 or flat file format. Each file will be reviewed electronically for missing or incomplete data. Data will then be sorted and sent to local health jurisdictions either as paper reports or as data files through the state government's wide area network.

II. Electronic Laboratory Reporting: Views from the Laboratories

Representatives from two reference laboratories and a speaker from an association that represents most of the large commercial laboratories described the current issues facing them and their experiences in transmitting data electronically to public health agencies.

Data Flow from Laboratories to Public Health Agencies – An Overview

Daniel Jernigan, Centers for Disease Control and Prevention

Laboratory-based reporting is critical to health departments for investigating and controlling disease. Connecting laboratories to public health agencies with automated, electronic communication will improve the fundamental activity of reporting. Moving toward that kind of connection requires recognition of a number of factors that complicate the process. First, reporting requirements vary from state to state, and even within states. Second, reportable findings themselves may be sent by fax, mail, telephone, voice mail, or by several electronic means (for example, on computer disk, as flat ASCII files, or using HL7 messages). Third, laboratories vary in size and purpose, ranging from small outpatient facilities to large national commercial laboratories. Finally, public health agencies run the gamut from small county health departments to large state health departments, disease registries (such as cancer registries), divisions within state health departments (such as those tracking sexually transmitted diseases, blood lead levels, or tuberculosis), and larger federal agencies.

"A logical first step in implementing ELR may be to work initially with larger laboratories because they have greater control over their data and tend to have stronger technological capabilities."

While a large percentage of findings are sent from smaller laboratories, a few large commercial laboratories send a comparable if not greater percentage of findings to public health agencies. The methods of transmission vary, and technical capabilities of smaller laboratories are often limited. A logical first step in implementing electronic laboratory-based reporting may be to work initially with larger laboratories because they have greater control over their data and tend to have stronger technological capabilities.

As we engage in ELR implementation with laboratories, the process is facilitated when laboratories have:

- technological capability to appropriately code and format the information,
- available resources to make the investment in electronic reporting,
- broad coverage (i.e., strong national or regional representations),
- high volume of reportable findings, and,
- incentives to participate (e.g., decreased burden from paper reporting).

American Clinical Laboratory Association (ACLA)
Jo Anne Glisson

The American Clinical Laboratory Association (ACLA) was established in 1971 as an advocacy organization for commercial independent laboratories, which tend to be larger laboratories. Member laboratories process 60 percent of the laboratory tests provided by independent laboratories in virtually every state. In 1971, the association had 30 members; today, there are 11. Since only one member failed to renew, the decline in membership is largely the result of consolidation within the industry.

The challenges facing ACLA members are similar to those faced by other health care providers: the advent of managed care, overcapacity among providers, reimbursement rate schedules, inconsistent reimbursements, and keeping up with (and paying for) technological advances.

One aspect of health care in which laboratories are unique is that they do not see patients. Because large commercial laboratories are, in a sense, one step removed from the patients, they must rely on physicians and submitting clients to provide all the demographic information important to the public health community. For laboratories, the lack of demographic data is additionally problematic since it is often needed for submitting claims for reimbursement. The cost to laboratories of tracking down diagnostic information and physician signatures often outstrips the payment received, especially with regard to Medicaid claims.

To address this problem, the ACLA recommended a joint educational activity for laboratory staff and physicians. The education should be sponsored by the public health sector, with participation from the ACLA, and should emphasize the importance of providing diagnostic and demographic information. Improving the collection of these data elements at the point of service would lead to improved public health reporting and more timely disease control activities.

Quest Diagnostics Incorporated
Eileen Koski

Quest Diagnostics is a large commercial laboratory that grew by acquisition, incorporating 17 formerly independent regional laboratories. As a result, Quest has some of the same data variation problems internally that are faced by outside organizations with incompatible systems such as large hospital consortiums and state health departments. Given the complexity of data flow and the variety of data formats among the component laboratories of Quest, centralization and standardization are viewed as the best solution. Information is stored and retrieved through a data warehouse, HL7 is used as the transmission protocol for sharing data among the Quest laboratories, and a migration to LOINC coding is underway.

In terms of public health reporting, the first task facing Quest and other laboratories is understanding the reporting requirements. Since these requirements vary from state to state and across municipalities, this is no small feat. In some cases, laboratories report to multiple states, adding to the complexity. This variation is yet another reason why Quest is trying to make use of centralized data warehousing and standard data reporting throughout its laboratories, regardless of their location.

Approaches to Standardization

There are generally two approaches to dealing with the problem of varying requirements: (1) to continuously track and update current requirements; or (2) to collate requirements and apply whatever is most comprehensive to all the requirements. Although the second option seems

advantageous because it would be a single process with no duplication and fewer changes, it still requires that current requirements are tracked and updated to make sure they are the most comprehensive. In addition, laboratories would still have to adjudicate conflicts between requirements. For example, HIV reporting requirements differ in terms of confidentiality requirements. Even if this comprehensive approach were successful, the laboratories may likely amass enormous data sets that may not be easily accommodated by public health agencies.

Shifting from manual reporting to electronic reporting offers many advantages for Quest and other laboratories, particularly by creating consistent data formats and reducing reporting burdens. However, such a shift involves high up-front costs and a shift in requisite skills among staff. The staff who complete paper reports and make follow-up telephone calls have different skills and training from information technology and programming staff. Security issues involved in transmitting data over the Internet also remain a concern.

> "ELR implementation in commercial laboratories will be easier if reporting can be made more centralized and reporting requirements more standardized."

Activities that would help commercial laboratories to participate in public health electronic reporting include: centralized portals for submitting data to public health, a standard list of reportable findings that removes conflicting requirements, a standard list of demographic data elements that are requested by public health, and assistance in improving submission of these data by providers, and a standard approach to data security.

SmithKline Beecham Clinical Laboratories
Rich Aranowski

SmithKline has six large laboratories across the country, 770 satellite patient service centers, and 400 jointly operated patient service centers. All of these facilities operate within a national standard technical database that uses the same order codes, test names, and reference ranges for the large volume of tests handled by SmithKline laboratories. Because this internal system is in place, re-coding results using LOINC and SNOMED does not benefit SmithKline internally. However, the company does see itself as providing data and information to its customers, and increasing the usefulness of that information is an important goal.

Current Reporting System

Approximately 40,000 test results — one percent of all SmithKline test results – have to be reported to state and local health departments each month. These reports are sent to 300 different state and local health agencies, each of which has its own reporting requirements. The majority of the reports are sent on paper, although nine state agencies use electronic interfaces. Even when states use electronic interfaces, however, they do not use them consistently across programs, which can make the electronic process cumbersome and complicated.

The current reporting system is automated, secure, and confidential, but has limited flexibility. SmithKline is trying to report and use the HL7 format, but the system is still limited in terms of the data it can provide (e.g., family history and ethnic origin are not required). Because lab reports are not case reports, a laboratory's ability to format an HL7 message does not necessarily mean that the laboratory will have all the data available for all the possible fields in HL7. These are two separate processes and, while they can be addressed in parallel, any change has an associated cost implication. There are costs for developing an electronic reporting message, and there are also costs to changing requirements on the test order forms, printing them, and distributing them to customers. In one request for a change, SmithKline calculated this cost to be

32 cents for each requisition form.

Georgia Electronic Reporting Pilot

SmithKline has developed a program to extract reportable findings and place them in HL7 messages which are then stored in batch files on a secure "common gateway" (essentially an electronic safe deposit box). The Georgia Division of Public Health retrieves the laboratory data on a daily basis from the SmithKline common gateway using a standard modem. The system yields data of high quality, and is both secure and cost-effective. This solution could potentially be implemented in all SmithKline laboratories since data storage and test codes are standardized across the system.

A major advantage of using the common gateway approach is that the agency can use any communications software that supports the z-modem protocol. The public health agency controls the transfer, which is password-protected and therefore both secure and confidential. Should the messages be corrupted during transmission, there are provisions for retransmission.

Despite these advantages, a few challenges remain. First, the expense of creating accessible data systems can be considerable. For example, obtaining additional information – such as ethnic origin or employer information – is costly not only in terms of redesigning forms and requirements, but also in terms of follow-up with physicians' offices. Second, security issues also remain a concern. Third, SmithKline is considering using the Internet for data transfer, but is cautious about taking this step until strong fire walls are established. A standardized approach to secure Internet-based electronic reporting is needed.

III. Electronic Laboratory Reporting: Views from the Informaticians

The third panel represented the science of informatics, particularly medical informatics, and its application to electronic laboratory reporting. The three speakers were asked to comment on laboratory report message formats, codes used to describe laboratory tests, and appropriate ways for health jurisdictions to access the information collected at the state.

HL7 Challenges and Opportunities

George W. Beeler, Health Level Seven, Inc.

Health Level Seven (HL7)'s mission is to provide standards for the exchange, management, and integration of data to support the management, delivery, and evaluation of health care services. HL7 is more than the message; it is a collaborative project that includes both writing the standard and making that standard a reality through the work of people in government, industry, and academia.

Version 2.3.1 of HL7 is currently being balloted and will be released later this year. In addition, specifications have been drafted for secure transmission of HL7 messages over the Internet. The specifications attempt to verify and authenticate the user, and will hopefully be approved within a year.

Although HL7 is truly a standard (i.e., it is accredited by the American National Standards Institute [ANSI]), it incorporates a variety of options for segments, fields, and components within fields. The choices are intentional, allowing a multitude of users to participate in the consensus process without having to select only one method as the "best." The difficulty with HL7 arises when deciding what to send and how to interpret the messages for sharing data among a multitude of partners.

Implementation of HL7

Explicit implementation guides and/or interface profiles **must** be added to the standard to create a workable system. In other words, the optionality must be defined and well-described so that both senders and receivers of data are using HL7 efficiently for the intended project. Different groups have chosen different implementation options, sometimes because of data availability and other times because of the underlying system architecture. The challenge is to identify how to best integrate the data and where to focus that responsibility.

It is important to recognize, however, that this is a good time to "be in the game." The popularity of HL7 is on the rise, with an estimated penetration of 97 percent in large hospitals and 80 percent in all health organizations. Providers are facing strong incentives to implement reimbursement claims attachments using HL7. Public and private health organizations should take advantage of this momentum.

> "It is encouraging to see that the CDC ELR implementation guide is unwavering in its adherence to the HL7 standard ... consistent with the proposed HL7 laboratory reporting format being developed by the HCFA."

The key is to accept HL7 as the standard "pipe" — and then to focus energy and resources on finding the most cost-effective ways to use this pipe for meaningful data input and output. It is encouraging to see that the CDC ELR implementation guide is unwavering in its adherence to the HL7 standard, and therefore is fully consistent with the proposed HL7 laboratory reporting format

being developed by the Health Care Financing Administration (HCFA). An important next step would be to actively participate with HL7 and its partners to make certain that the needs of public health agencies are incorporated into the standard.

Standard Codes for Laboratory Reporting

Stan Huff, Intermountain Health Care

By choosing HL7 as the format for sending reportable findings, the work of sharing understandable clinical information has been improved greatly, but further work must still be done. The terms that are used to describe the names of tests and the results from those tests must also be standardized. Use of common codes facilitates automated filtering, processing, and updating of databases. The goal in ELR, as well as in other projects, is to see LOINC and SNOMED codes used consistently in HL7 messages. Although progress has been made towards this goal, more work is needed to expedite this conversion.

LOINC

A slow but steady increase is being seen in the movement from local codes to standard codes. This movement is driven in part by mergers of large commercial laboratories and the need among hospitals and healthcare institutions to warehouse data centrally. The transition is a deliberate one in which decision makers wait for a reason to change such as a new mandate, a new business opportunity, or a more cost-effective method. The adoption of LOINC codes has substantial, and increasing, support but will not be a universal code for some time (if ever a universal code is adopted). Large automated laboratories and health care organizations have been among the first to see the real opportunities presented by the use of standard LOINC codes. Some important early adopters include: Quest Diagnostics, LabCorp, Smith-Kline, ARUP, Specialty Labs, Veterans Administration, Care Group, Kaiser Permanente, US Navy, Aetna US Healthcare, Empire Blue Cross, IHC, and CPMC.

LOINC consists of over 19,000 codes (in version 1.0L). Anecdotal reports indicate that current LOINC codes include about 90 percent of what is ultimately needed, but studies are underway to better evaluate the extent of completeness. The LOINC Committee is willing to add any codes that are needed. LOINC is free and can be downloaded from the LOINC site on the web.

SNOMED

SNOMED is frequently used in anatomic pathology; however, no standard codes are in common use for microbiology. SNOMED is as good or better than other systems for organism names but, again, additional codes may need to be adopted to ensure completeness. There may be a cost to using SNOMED for public health reporting.

Mapping of Codes

The difficulty in mapping is not unique to LOINC or SNOMED; rather it is an inherent problem related to the use of standard codes. It is always easier to use an isolated system with unique codes than it is to share codes. The benefits of mapping to a universal code are not realized until the second or third time a particular type of interface is needed. Better tools are needed to make such mapping and interfacing easier. Some tools exist (e.g., RELMA, the Regenstrief Institute's LOINC Mapping Application, programs for autoencoding of results into SNOMED), but new approaches should be explored. One such approach might be to coordinate with software vendors to produce "starter sets" of LOINC and SNOMED codes that laboratories could build upon and expand to suit their individual needs.

Other Issues

Routing of messages may be a problem in some systems. Two possible solutions are to develop greater internal expertise in producing routing software, or to use commercially available interface engines. Public health staff need more education and information so that they are better qualified to make decisions about interface solutions.

Even if HL7, LOINC, and SNOMED are adopted as standards, there are still multiple ways to represent the same data. This is an indication that public health is in some ways at the forefront of the standardized laboratory reporting issue. Because of the nature of public health work, the need for standards has presented itself most prominently, and likewise, the areas needing further clarification are uncovered. One significant contribution so far is the development of a spreadsheet which associates reportable findings with the variety of LOINC and SNOMED codes used to report those findings. Maintenance of the spreadsheet (i.e., the Dwyer Tables) is an important activity for public health to perform. Additionally, participation in the development of "clinical templates" (i.e., strictly defined implementations of HL7 for specific purposes) through the HL7 organization would also benefit public health.

Putting It All Together

> "HL7, LOINC, and SNOMED are still the best approach....don't get weary in a good cause."

HL7, LOINC, and SNOMED are undoubtedly the best approach to standardizing data transmission. Achieving universal adoption of these standards is hard work, but well worthwhile. Persistence is key, with a focus initially on the high volume, automated laboratories that process 80 percent of all tests. Close collaboration with terminology developers is also essential, to identify missing codes and request balloting by the relevant LOINC or SNOMED committees. Lastly, new tools and strategies for mapping must be developed to make mapping more cost-effective and easier for all.

Implementing ELR

James Cimino, Columbia University

Columbia Presbyterian Medical Center is in the process of constructing a clinical information system. A number of the observations made there are directly applicable to ELR.

Laboratory Issues

Hospital laboratories differ from commercial laboratories. What works for large laboratories processing 40,000 reportable tests per month may not work for smaller laboratories processing only 1-2 reportable tests per day. The smaller volume laboratories may be able to operate with a low-tech system, while the larger laboratories will achieve economies of scale with a more automated system. Additionally, smaller laboratories are often dependent on the laboratory information system vendor for changes that are required for ELR; this can be expensive and slow. An overall approach to ELR should account for these differences and allow for different levels of participation.

For laboratories with some control over their technology, a series of steps are needed in the implementation. First, reportable test results must be identified. Larger laboratories often have the ability to flag "Government Reporting" results and place them in a queue for printing or faxing. Having the reportable disease/test spreadsheet (i.e., Dwyer Tables) greatly facilitates the identification of conditions and tests that should be reported. Second, the reportable tests must be associated with demographic information. Many laboratory information systems manage only the

laboratory activities. Billing, admission, pharmacy, and patient demographic information are often kept on separate systems in the hospital. Thus, the demographic information must be extracted from another system and associated with the laboratory data. Third, the codes used in the laboratory (i.e., the "local codes") must be translated (i.e., mapped) to standard codes such as LOINC and SNOMED. This essentially can be done by having a table which lists the local and standard codes side by side; however, someone with an understanding of both coding systems is required to build the table. Finally, the local format of the report must be translated to HL7. Many vendors have incorporated an HL7 output into their commercial laboratory information systems, although, some of these may not offer the greater functionality needed to fully implement ELR. For this reason, many hospitals have a separate "HL7 Generator." These "interface engines" take the local code and local format and form an HL7 message with standardized codes. These generators are used mostly to integrate the hospital's own disparate data systems; however, they can be used to send an outbound message to public health as well.

Public Health Agency Issues

Once the information is received at a public health agency, the whole package needs to be unwrapped and put into a format familiar to the agency staff. Whereas the incoming data was taken from disparate systems in different formats and standardized, the data will now need to be routed to their appropriate destinations — possibly in different formats as well. There are two approaches to solving this problem. First, the laboratory process above could be reversed, where the HL7 message and standard code is translated into multiple different formats with local codes familiar to the agency staff. This could be costly and resource-intensive. County health departments and disease-specific control programs at the state level may want very different formats, or, more likely, may not have the technological capability to handle electronic messaging. Because of the technological and resource limitations, it may be more desirable to try a second approach using a "central repository" for the findings. In this approach, the data is translated from HL7 and is available in a database that can be accessed by agency staff using a tool like Microsoft Access or a web-page over the agency local area network or intranet.

There is great variability among submitting laboratories and receiving public health agencies. No one solution is likely to be applicable at every level of laboratory-based reporting. Identifying a few "best-fit" solutions for certain settings and working through the implementation process in those environments will go a long way toward greater acceptance of ELR.

IV. Key Issues for Expanded Electronic Laboratory Reporting

The final panel discussed four issues affecting expanded adoption of electronic laboratory reporting: modes of transmission and data security, software development, data quality and negative reporting, and data flow.

Modes of Transmission and Data Security
Meade Morgan, CDC

Over the next few years public health will increasingly conduct its business over the Internet. Although the issue of data security is relevant regardless of the mode of transmission, it is especially important as dependence on the Internet grows. Critical elements of data security are fourfold: encryption, authentication, non-repudiation, and data integrity.

Encryption

The goal of encryption is to make data unreadable should it ever "fall into the wrong hands." There are two types of encryption: (1) symmetric key, where the same key used to encrypt and decrypt data; and (2) asymmetric key (sometimes called public key/private key encryption), in which two different keys are used — one which encrypts the data (the public key) and one which decrypts the data (the private key). With asymmetric key encryption, anyone possessing the public key can encrypt data with the knowledge that only the holder of the private key will be able to decrypt the data.

The bigger the key, the more secure the data. United States law currently allows only 40-bit keyed encryption technology to be exported.

Authentication and Non-repudiation

Authentication assures the data sender that the receiver is whom that person claims to be, and vice-versa. The most common form of authentication is the user I.D. and password. A more sophisticated form is the use of digital certificates, in which a trusted third party (a "certificate authority") verifies the identity of the user. Non-repudiation services prevent the parties involved in the data exchange from later claiming they did not send or receive the data.

Data Integrity

When a system checks for data integrity, it is looking to make sure that the data have not been corrupted in any way. Commercial algorithms are available for this purpose.

CDC's Integration Project Solution

CDC is developing comprehensive security standards as part of its program to integrate its surveillance software systems. (In conjunction with this, it is testing a data security system with such features as a 128-bit asymmetric key, Blowfish algorithm for encryption, X.509 digital certificates for authentication, and MD5 digests to ensure data integrity.) Key design issues include: what level of standards is needed; how efforts should be coordinated with HIPAA, HL7, and HCFA; what other players should be involved; and whether interim standards are needed.

Further reading

Garfinkel S and Spafford G. *Web Security and Commerce*. O'Reilly & Associates, Inc: 1997.

Feghhi J, Feghhi J and Williams P. *Digital Certificates — Applied Internet Security*. Addison-Wesley: 1998.

Software Tools for Electronic Laboratory Reporting

Terri Johnson, EDS

Electronic Data Systems (EDS) has been contracted by CDC to examine software for processing electronic laboratory reports. EDS' approach is to assess a sample of state electronic laboratory reporting internal development work and architectural designs; assess a sample of commercial products used to parse or translate data; construct a requirements and tools matrix; and develop recommendations and options to facilitate electronic laboratory reporting at the state and local levels.

The states visited by EDS for this project include Georgia, Washington, Nebraska, Maryland, and New York. Conference calls were also conducted with the states of Massachusetts and Illinois.

Specific products being evaluated are: TSI's Mercator, Paperfree's Winmap/Winserver, PHILIS HL7 Reader, Orion's Symphonia, Neon/CAI's MQIntegrator/Impact!, and HIE's Cloverleaf Interface Engine.

In general, the products fall into three categories:

- Data mappers/parsers – tools capable of transforming data from one format to another.
- Data loading tools – tools usually capable of transforming data formats in the same manner as data mappers/parsers, but in addition can put data into existing databases and manipulate those data.
- Interface engines (message brokers) – tools with even more functionality than data loading tools that are often used as an "information hub" by businesses.

Requirements for Immediate Solution

Based on the state interviews, a number of requirements emerged for establishing electronic laboratory systems in the near future. Such systems should be able to:

- Read, parse, and validate batch files of standard HL7 version 2.3 ORU messages for public health.
- Support state variations in data format and content.
- Handle complex table lookups.
- Create multiple output formats.
- Provide error handling/checking.
- Be compatible across multiple hardware/operating system platforms.
- Optimize ease of use and maintenance.
- Balance cost and resources.

Future Requirements

As systems are established and refined, additional requirements might include being able to:

- Handle additional HL7 message sets and standards.
- Automate the process of sending/receiving files.
- Support program-specific business rules.

- Automate routing of output to multiple systems.
- Supply standard acknowledgments to sending systems.
- Migrate to new versions of standards.
- Be flexible enough to change as CDC, state, and local systems develop more integration strategies.

Data Quality
Steven Steindel, CDC

Electronic laboratory reporting represents a new way to look at primary source data, direct from the reporting system storing it – with little or no filtering. In theory, the data in paper reporting systems should be identical to the data in electronic systems. In practice, however, filtering in paper systems affects the completeness of data, reliability of patient identifiers, and quantity of data.

Data Quality

An important issue regarding data quality involves multiple tests on the same person. These may be at the same or different sites, and may occur at the same or different times. In all instances, a minimal demographic data set should be collected to help match specimens, tests, and patients.

A second issue is how to check for data quality. The quantity of laboratory data is potentially huge. It may not be practical for one person in the public health agency to review the data consistently to identify important clusters, trends, etc. Instead, computer tools are needed to review the data and trigger automated requests for supplemental or corrected data. Electronic laboratory reporting must be understood in the context of the present surveillance system in order to truly interpret the data correctly.

Finally, in electronic reporting systems laboratory results will often be sent directly to public health agencies without having been reviewed first by clinicians. For this reason, public health officials need to be aware of issues such as the sensitivity and specificity of the tests being reported.

Negative Data

The potential to receive all results generated, not just positive ones, exists with electronic reporting. Such data allows a more precise estimate of the affected population and thus enables calculation of rates. It may be advisable, however, to collect negative data only in certain circumstances (for example, when an entire population is tested for lead) to ensure that the resulting numbers and rates can be interpreted with validity. Requiring negative test reporting comprehensively would likely produce voluminous data that would strain systems' ability to store and handle those data, and would challenge privacy and confidentiality concerns.

Data Flow

Jac Davies, Washington State Department of Health

The national notifiable disease surveillance system encompasses hospitals, clinical laboratories, and state, local, and national health agencies. The data flow process (who receives reports and when) varies depending on the state where the reporting occurs. The transition from paper-based to electronic reporting systems for notifiable disease data may result in changes to current data flow processes.

Current Data Flow

Twelve states responded to a survey about their data flow processes. All are currently using paper-based reporting systems, although some transition is occurring to electronic reporting. All states currently have a mechanism requiring laboratories to report to the local health agency; some require reporting to the state health agency. Some states have a mixed model, depending on the specific disease.

In the survey, states were asked if they were exploring changes in their data flow. Roughly half of the states were considering asking laboratories to report directly to the state health agency rather than to county health agencies once electronic reporting was implemented. This trend raises both political and technical questions. Current state regulations require reporting to local health agencies, and may need to be revised to allow reporting to the state or other centralized body. Enforcement of such regulations is another complicated issue. States' attorneys general need to look into these issues further.

States noted the challenges in getting buy-in for data flow policies, which can require considerable negotiation with local laboratories and local health agencies. On the one hand, the laboratories are delighted to have a central site for reporting; however, local and state health departments want to ensure prompt reporting of information needed for case investigations.

Issues to Consider

Issues that arise consistently include timeliness, merging and matching, and cleaning of data. Any state considering changes in data flow should address a few important questions:

- Are regulatory or other policy changes necessary to implement a centralized system?
- How will the switch to a centralized system affect internal agency programs, local health agencies, and laboratories?
- How will the transition be managed?
- Is a parallel testing period necessary?
- What is the plan for transition?

V. Recommendations

Strong consensus exists in support of the approach using health communication standards (HL7) and data coding standards (LOINC,SNOMED) to develop electronic laboratory-based reporting (ELR) for public health. CDC should work closely with partners in public health, laboratories, and information system vendors in the areas of:

- Leadership and coordination
- Software tools and technical support
- Policy development
- Training and education
- Fostering public-private collaboration

Leadership and Coordination

- ELR is an important component of CDC's public health information and surveillance systems integration efforts. Implementation of ELR should be undertaken in coordination with related efforts at CDC and in state and local public health agencies.

- CDC, through the Health Information and Surveillance Systems Board (HISSB), should consider convening a work group to foster ELR. An important next step would be further development of guides for implementation of HL7 public health reporting both for technical and non-technical personnel.

- CDC (HISSB) and the Council of State and Territorial Epidemiologists (CSTE) should collaborate with stakeholders to:
  - define and standardize required laboratory data elements for notifiable disease surveillance.
  - collect, maintain, and disseminate state and local requirements for reportable conditions.
  - encourage state and local health departments to provide easy access to various reporting requirements (e.g., tables for downloading from public health web sites).

Software Tools and Technical Support

- CDC should provide technical support for pilot implementations of ELR. Pilot efforts should include the development of informational materials about ELR implementation.

- As part of the CDC Integration Project, CDC should develop a model describing the flow of data from the laboratory, to the state and local health agencies, to CDC. The model should take into account individual programs (e.g., STD, TB, HIV, and immunization) at each public health level. Its description should be detailed and accessible, as it will be valuable for ensuring that the needs of public health are understood by vendors, contractors, and systems analysts.

- CDC should continue evaluating government and commercial off-the-shelf (COTS) software tools for ELR implementation. This evaluation should not be limited to simple data mappers but should include software with other functions that would be useful in ELR systems.

- CDC should explore the utility of data entry through the Internet using web browser forms for small labs, which may not have the expertise or the incentive to develop ELR systems.

Policy Development

- CDC should assure that the interests of the public health community are well-represented within relevant standards development organizations, such as HL7.

- CDC should work with the Healthcare Finance Administration (HCFA) to identify opportunities to implement electronic laboratory reporting and to coordinate the reportable required laboratory data elements project with the Health Insurance Portability and Accountability Act (HIPAA) claims attachment process (see http://aspe.os.dhhs.gov/admnsimp/index.htm). Furthermore, the HL7 ELR implementation guide should be compatible with the HIPAA guide.

- CDC and its partners should develop strategies for identifying which results should be reported for specific tests (e.g., "flags" for abnormal results).

- CDC and its public and private partners should develop strategies for improving the completeness of demographic data in electronic reports, especially the patient address. In particular, approaches for linking health plan enrollment databases to databases of laboratory results should be pursued.

- CDC and its public health partners should develop strategies for simplifying the reporting requirements for laboratories. Special efforts should be made to harmonize reporting requirements across public health jurisdictions and to minimize the number of agencies to which laboratories need report.

Training and Education

- CDC should establish and maintain an electronic laboratory reporting listserv that includes interested public and private agencies and organizations.

- CDC should work with CSTE to develop a source of information, accessible through the CDC web site, on reportable diseases, LOINC, SNOMED, HL7, reporting sites, and implementation guides.

- CDC should update state health departments and laboratories on the HIPAA legislation and its anticipated impact on agencies, new legislative mandates that may impact electronic laboratory reporting, and websites that contain related information (e.g., http://aspe.os.dhhs.gov/admnsimp/index.htm).

- Basic electronic laboratory reporting information should be conveyed to public health practitioners, laboratory staff, health care providers, and laboratory information system developers. The information should be tailored for each audience, but content might encompass why electronic laboratory reporting is beneficial, what HL7 is, what diseases are reportable, how to use software, how to ensure data security, etc. Training delivery modes might include use of the Internet, distance learning, and conferences. Offering of continuing education unit credits would enhance motivation to attend. When possible,

such training should make use of experts in informatics and in HL7.

Fostering Public-Private Collaboration

- Collaborative pilot ELR projects should be undertaken with CDC, large laboratories, and selected stated health departments.
- Large laboratories and laboratory associations (e.g., ACLA, CLMA, AACC, and CAP) should endorse and adopt the approach recommended at the 1997 ELR meeting (HL7-LOINC-SNOMED) for electronic reporting of results to public health agencies.
- CDC should work with laboratory information system vendors to incorporate electronic public health reporting capacity into their products.

Appendix A: Glossary

authentication – the act of verifying the identity of an entity such as a computer server or user. This is one of several elements of computer security. A common form of authentication employs a user name and password to identify a user. Digital certificates are often used to authenticate the identity of computer servers and are widely used for authentication in electronic commerce.

blowfish algorithm – one of several mathematical algorithms used for encrypting and decrypting data.

digital certificate – a set of information, stored in a file on a computer, issued and downloaded via the Internet from a trusted party (most often a "certificate authority") that allows a user to confirm that a third party is in fact who that party claims to be, and not an imposter.

Dwyer tables – the now-common name for tables that link LOINC and SNOMED codes with the names of the notifiable diseases to which they correspond. These tables are maintained with the assistance of the Regenstrief Institute in Indiana (which maintains LOINC).

electronic laboratory reporting (ELR) – more correctly called electronic laboratory-based reporting; the transmission of data of public health importance from clinical laboratories to public health agencies in electronic format.

encryption – in the context of electronic data interchange (i.e., ELR), involves transforming data using a mathematical algorithm into a form that is unreadable except to a person who has been trusted with the key needed to decrypt the data.

flat file format – a method of organizing data in a database. The data in the box appear as it would in a flat file format. In this particular format, columns 1 through 10 contain the patient's name, columns 11 and 12 the patient's age (in years), column13 the patient's gender, and columns 14 through 20 the patient's medical record number.

Health Level Seven (HL7) – a standard developing organization accredited by the American National Standards Institute (ANSI) that develops standards for the exchange, management, and integration of data supporting the management, delivery, and evaluation of healthcare. Detailed information can be found at http://www.hl7.org or http://www.mcis.duke.edu/standards/HL7/hl7.htm.

Example flat file with 3 records:

```
          11111111112
12345678901234567890

Jones       6M8376378
Smith      66F6947658
Carter-Smi32F9915432
```

HL7 reader – software for processing HL7 messages.

LOINC – Logical Observation Identifiers, Names, and Codes; a standardized system for coding test names. See http://dumccss.mc.duke.edu/standards/HL7/termcode/loinc.htm for more information.

non-repudiation – ensuring that a party involved in the electronic exchange of data cannot later deny having participated in the exchange. For example, a hospital might use non-repudiation services when submitting a bill electronically to an insurance company so that the latter could not later deny having received the bill.

relational database – a database in which several tables (data arranged in rows and columns) are linked by relations. In a hospital's database, for example, a laboratory results table could be linked to a laboratory request table by a laboratory request serial number. If a request for "culture and susceptibility" produced susceptibility results for 8 different antibiotics, the ordering information would only have to exist in one record in the laboratory request table rather than having to be repeated 8 times in the laboratory results table. Similarly, the request table could be linked to a patient admission table, which could in turn be related to a table with the patient information, such as address, telephone number, and primary physician.

SNOMED – Systematized Nomenclature of Human and Veterinary Medicine; a proprietary standardized medical nomenclature that is used in the ELR to code the test result. See http://www.snomed.org for more information.

Appendix B: Meeting Participants

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