Analytic Services Inc. is a public-service institute, an independent, not-for-profit corporation chartered in California with the assistance of the RAND Corporation in 1958. The corporation provides analytic and technical support to government agencies throughout the national security, homeland security, and public safety mission areas.

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With Gratitude

Elin Gursky, on behalf of the meeting participants and stakeholders, wishes to acknowledge the invaluable assistance of Nicole Long of Analytic Services Inc.
Framework for Electronic Laboratory Reporting: Recommendations to Policymakers

A Report of the Electronic Laboratory Reporting Consensus-Building Meeting

held on
October 30, 2007
in
Arlington, VA
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BACKGROUND

The ability to electronically network medical laboratory results would constitute a cornerstone of early detection and rapid control for disease outbreaks. Electronic laboratory reporting (ELR) would also serve as the country’s key indicator for any health event that has the potential to seriously disrupt the continuity of government, strain all aspects of society, and result in mass numbers of seriously ill or dead. Programs initiated to capture sentinel health information, most notably BioSense, have been born from the imperative to merge biosurveillance efforts with health information technology (HIT).

The 2001 anthrax attacks illuminated critical gaps in disease-reporting mechanisms within the United States. Only after the death of the index case from inhalational anthrax in October 2001 did the importance of earlier, geographically dispersed, atypical dermatologic presentations bear significance for this deliberate attack of bioterrorism. As the attack unfolded, hospital, commercial, and public health laboratories in New York, Florida, and Washington, DC, were quickly overwhelmed processing thousands of samples of suspicious white powder. The results of all these tests were laboriously and inefficiently reported by telephone, fax, and occasional email back to the submitting provider. The slow and disorganized manner in which these results were reported provided very little real-time situational awareness for medical providers, public health officials, civic authorities, or law enforcement agencies. Without timely and accurate information, those responsible for managing and controlling an event cannot respond in time to prevent needless casualties.

ELR would promote rapid identification and mitigation of exposure. One could also ponder the possibility that the perpetrators of the anthrax attacks, still at large, may have been more likely to be identified if this event had been detected earlier through automated and efficient laboratory reporting systems. Yet six years later there is no national system that facilitates communication from local and private laboratories to federal reference laboratories and ultimately with coordinating and response organizations such as the Centers for Disease Control and Prevention (CDC). This is also despite the fact that the technology to enable a national ELR system has existed since the early 1990s and despite a number of relevant presidential and congressional initiatives.

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5 For example, in April 2004, President Bush signed Executive Order 13335, mandating the creation of the position of National Health Information Technology Coordinator, who is responsible for determining HIT standards for the federal government; addressing technical, scientific, and economic barriers to successful implementation to HIT; performing a cost-benefit analysis of HIT; and ensuring that privacy and security would be adequately protected through HIT—all this with the assumption that no “additional Federal resources” be provided “to accomplish adoption of interoperable” HIT. Also, Homeland Security Presidential Directive 21, “National Strategy for Public Health and Medical Preparedness” (http://www.whitehouse.gov/news/releases/2007/10/20071018-10.html), issued
What has kept an ELR system from being established nationally is the lack of resources required to create such a system and the lack of a consensus across stakeholders regarding how this goal can be accomplished. To address this situation, a meeting of subject matter experts (SMEs), including local, state, federal, and private-sector stakeholders, was convened to develop basic consensus on the way ahead for a national ELR system.

“By networking and automating uniform lab results, we have a powerful control and prevention tool.”

Meeting participant
October 30, 2007

October 18, 2007, specifies creation of a “biosurveillance capability” that can “provide early warning” of a biological attack or “naturally-occurring pandemic” and can provide “near real-time” information about an event as it unfolds.
METHODODOLOGY

Through modest support from the CDC, SMEs were assembled to develop a framing plan for ELR. Experts were selected to represent the stakeholder community from across a wide spectrum of sectors, including public health, hospitals, industry, animal health, and the military. (See Appendix A for a list of participants and affiliations.) This was a historic event, as it was the first time that stakeholders from so many varying backgrounds had convened to deliberate the most appropriate approach to addressing ELR issues. The number of participants convened was constrained by funding and by SME availability. The participating SMEs provided for substantial initial input; future discussions would benefit from incorporating a broader constituency of SMEs.

A pre-distributed framework and agenda guided the flow and focus of this one-day meeting. Although consensus was sought—and achieved—on the majority of issues raised, diverging opinions were encouraged, and these points are reflected in the following report. Notes on the meeting were kept for reference to ensure that all major discussion points were captured without individual attribution. A draft report was submitted for review and comment by all meeting participants.

This report summarizes the consensus and divergence of these experts regarding the goal, scope, strategy, and funding considerations that policymakers should consider as they move forward, through legislative initiatives, to implement the process of building critical, 21st-century public health surveillance, detection, and reporting tools.

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6 The CDC provided funding through the Association of Public Health Laboratories Cooperative Agreement #U60/CD303019. The meeting was hosted by ANSER/Analytic Services Inc., a 501(c)(3) not-for-profit, independent public-service research institute.
RECOMMENDED ELECTRONIC LABORATORY REPORTING POLICY FRAMEWORK

Framework Overview

This framework is based upon the draft discussed during the ELR meeting. It consists of seven sections: (1) goal statement; (2) scope; (3) who; (4) how; (5) standards; (6) how long? how much? and (7) oversight. The goal statement is the consensus of the meeting participants on what the aim for ELR should be. The scope defines the near- and long-term objectives for the span of ELR. The “who” statement defines the entity that participants felt was most appropriate to have responsibility for building national ELR infrastructure. The “how” statement provides the general mechanisms and operational concepts for ELR. “Standards” focuses not on which standards should be used, but on which mechanisms are appropriate for selecting standards for an ELR system. “How long? how much?” focuses on the timeline to develop a fully operational national ELR system and the financial resources estimated to be required for this endeavor. The oversight section provides recommendations on the type of oversight body and level of stakeholder involvement needed for a national ELR system to have effective stakeholder buy-in.

Each section provides the consensus statement and comments reflecting the major points of discussion and departure.

I. Goal

To protect public health and enhance security by continuously making relevant nationwide laboratory orders and results available to authorized users, allowing timely identification of, analysis of, and response to specific problems in a manner consistent with individual privacy and confidentiality.

Discussion: There were extensive discussions regarding the length, complexity, and specific terms that were ultimately included in the goal. The term continuously replaced real time due to lack of consistent definition and potential infeasibility of the latter. The term authorized users was deemed sufficiently broad to facilitate agility as a result of different types of events requiring a spectrum of expertise. Implied but not specified is the notion that the ELR would enable response at all levels of government: federal, state, and local. Although exigent events stress the balance between discretion and protection, the terms privacy and confidentiality were included to withstand critical review of this initiative by the public and to acknowledge the sensitivity of personal and identifying information.

II. Scope

Initial development and implementation efforts of the electronic laboratory reporting system will focus on human test orders and results. Include educational activities, dissemination of lessons learned, and development of communities of practice for collaboration during implementation. Include annual user conferences when implementation begins. Allow incentives for completing work early or on time.

Discussion: Once the system’s basic infrastructure is implemented, incrementally incorporating other key data sets, such as animal and environmental data, will increase the breadth and robustness of the system and will require only marginal costs. This system may
benefit from the inclusion of laboratory data on U.S. citizens outside the United States and integration with entities (such as the Department of Defense and World Health Organization) that ultimately contribute to and align with efforts making up a comprehensive system of global disease detection. This is consistent with the current Health and Human Services (HHS) Department Framework for HIT.\(^7\) One domestic hurdle recognized by the group is that although the International Classification of Diseases, Clinical Modification (ICD-9-CM), provides some level of national commonality on reportable diseases, there is still a high level of diversity in reporting requirements across the United States. The expert panel urges that incentives for this effort be promulgated by the CDC in parallel to building the ELR.

III. Who

The ELR system should be built under the guidance and direction of HHS, with primary responsibility allocated to the CDC.

Discussion: The ELR will require a cooperative and integrated effort across many agencies and the private sector. A number of key stakeholders could convene this effort, including the Department of Homeland Security. However, HHS was identified as the appropriate lead agency for a number of reasons, including its medical and public health expertise, its close working relationships with state and local health agencies, its breadth of capabilities (CDC, Office of the National Coordinator, Office of the Assistant Secretary for Preparedness and Response, etc.), and its relationships with a wide scope of relevant stakeholders that play key roles in providing and/or consuming laboratory data. (Please see Appendix B for an exemplar [not comprehensive] list of stakeholders discussed at the ELR meeting.) Additionally, the ELR will play a critical dual-use role, supporting disease detection and response not just for issues of national security but also routine disease control efforts by federal, state, and local public health agencies.

IV. How

The ELR should be built as a combined federal and state project, with appropriate input from and interaction with local, private, and professional agencies, assuring interoperability while providing maximum flexibility at the state and local levels. Sufficient options should be in place to provide direct assistance as well as mechanisms that help overcome procurement hurdles, such as the insertion of onsite expertise and management at the state and local government levels. An independent Steering Committee should be convened to provide oversight and guidance throughout the course of project development and implementation and to recommend policies for authorizing access to the ELR system. Project planning and system design should be a collaborative and transparent process, guided through the Steering Committee and a Stakeholder Advisory Committee.

Discussion: Participants expressed concerns regarding the flexibility that should and can be afforded to local and state public health entities. There was much discussion about enabling

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\(^7\) Tommy G. Thompson, Secretary of Health and Human Services, and David J. Brailer, National Coordinator for Health Information Technology, “The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care,” Framework for Strategic Action, released July 21, 2004. Goal 4 of the framework requires the improvement of population health by development of the capability to collect timely, accurate, and detailed clinical information and the real-time reporting of critical findings to public health officials.
state and local agencies to develop systems that would meet their needs while concomitantly ensuring sufficient commonality for the systems of multiple states to work together.

V. Standards

Standards for the ELR should be selected with extensive public and private input, and funding provided to states for this effort should be conditional on standards compliance. The Steering Committee should identify areas where standards are not available and work collaboratively to promote their development through existing standards organizations such as Health Level 7, Inc., the Regenstrief Institute—which promulgates use of Logical Observation Identifiers Names and Codes (LOINC®)—and the International Health Terminology Standards Developmental Organization, formally known as SNOMED International. The development of new standards should occur in parallel with building the ELR. Efforts should also focus on nationally harmonizing both the reporting format for specific diseases and conditions that are considered reportable. All funding should be conditional on standards compliance. Also, lack of availability of all needed standards should not delay the project; the initial focus should be on areas that are immediately feasible.

Discussion: While standards for HIT and for coding health reports do exist, they offer flexibility in interpretation. One participant indicated that a survey of 14 labs provided with the same standard yielded only 2 labs providing the same code. Improving the ultimate interoperability of an ELR through standardization is necessary to ensure that data can be shared across jurisdictions. Moreover, the diseases and conditions that are reportable vary across—and occasionally within—state lines. It would not be appropriate for all states to have the same reporting requirements (for example, it is common for small outbreaks of plague to occur in Colorado or the desert Southwest of the United States due to high incidence of disease carriers in the ground squirrel and prairie dog populations there). However, for all relevant data to be usable within a national ELR system, all information on each reportable condition or disease must be reported in the same format. Participants indicated that the most appropriate method for addressing this issue would be a tiered approach: standard reporting formats should first be determined for diseases that are reportable nationwide. Then, additional reporting standards could be developed for diseases that are reportable for a majority of states, and so on.

“This effort lends itself to accelerating the establishment of critical information infrastructure and providing ongoing value to public health and private infrastructure.”

Meeting participant
October 30, 2007
VI. How Long? How Much?

The meeting participants determined that the project would benefit from a three-phase approach:

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase One: Planning</td>
<td>18 months</td>
<td>• $25 million for planning and system design</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• $25 million for building state public health LIMS*</td>
</tr>
<tr>
<td>Phase Two: Implementation</td>
<td>3 years</td>
<td>• $200 million/year ($600 million total)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Of this, $3 million/year for each state—appropriate federal and private-sector support and interfaces</td>
</tr>
<tr>
<td>Phase Three: Operations</td>
<td>Continuing</td>
<td>• $100 million/year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Consider financial incentives through operational funding for states that achieve ELR goals early</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Consider the possibility of increasing state match over ten years</td>
</tr>
</tbody>
</table>

* About half of all states do not have a public health laboratory information management system (LIMS) in place.

Discussion: According to participant information, 24 states do not currently have any form of public health LIMS in place. Without capabilities for electronic records management in all states, it would be impossible for a national system to be implemented. Therefore, Phase One includes providing funding to ensure that all state public health laboratories have some form of LIMS in place. The dollar amounts for Phase Two and Phase Three are estimates. One outcome of the planning and design of Phase I would be a more detailed and thorough assessment of the funding requirements of this endeavor. There was discussion among participants that it would be possible for policymakers to view this in terms of real options—that is, policymakers can, with this system, fund each phase in turn in lieu of earmarking funding for all three phases at once. All numbers are estimates based on SME discussion during the meeting. A more thorough assessment of cost requirements should be conducted for each phase.

VII. Oversight

The Steering Committee, with input and guidance from stakeholders through the Stakeholder Advisory Committee, shall provide oversight to the project plan and the development of metrics and milestones. Progress reports will be required every six months until the system is operational, with the third report including final overall project plan,

“"We must collect and disseminate case studies of how this system actually helps in public health situations and disseminate examples of epidemiologic improvements brought about by the new system."”

Meeting participant
October 30, 2007

“In the short run this may create more operational costs in public health; in the long run the total cost savings to the health care system should be the real benefit. It will allow us to streamline processes and instate public health measures earlier.”

Meeting participant
October 30, 2007
metrics, deliverables, and milestones. Periodic systematic assessment by users should be instituted to assure that their needs are being met. Once the system is operational, annual reports should be generated.

Discussion: In addition to the Steering Committee, a Stakeholder Advisory Committee is recommended because stakeholder input and buy-in will be critical to ensuring success of the ELR system. However, it is neither advisable nor feasible for all stakeholders to participate in the Steering Committee. Therefore, meeting participants recommended that stakeholders be included in an advisory capacity; they will then be able to provide input and divergent opinion for consideration and decision by the Steering Committee.
CONCLUSION

To address the need for better situational awareness and to facilitate laboratory reporting of events that threaten the public health, there is an urgent need to develop electronic communication from local and private laboratories to local, state, and federal public health authorities, including the CDC. Currently, there is no national system that facilitates communication of this sort, despite the fact that the technology to enable a national ELR system has existed since the early 1990s and despite a number of relevant presidential and congressional initiatives.

The SMEs convened at the ELR Consensus-Building Meeting unanimously agreed that building an ELR capability is critical to the nation. They generated a basic approach to developing a national ELR system and defined the basic tenets of the governance structure and processes required to make ELR successful. This approach allows flexibility while promoting consistency and interoperability, which are required in order for an ELR system to become established nationally.

This meeting should not be construed as an isolated activity but, rather, as a critical component of larger national efforts to build a comprehensive public health detection and reporting system. The suggested ELR framework also provides dual-use LIMS-ELR systems that justify the significant investment. Development of LIMS-ELR in each state will (1) improve public health capability to realize early detection and rapid intervention in emerging infectious diseases (pandemic influenza, avian flu, SARS, and others); (2) address the need to accelerate the implementation of critical information infrastructure to enable improvements in laboratory information management for population and individual healthcare as envisioned nationwide; and (3) enable active participation by public health agencies and laboratories in advancing the use of HIT in public–private-sector initiatives.

This report and the findings herein will be distributed to all SMEs who participated in the meeting as well as to the CDC. In addition, it will be distributed to relevant members of the policy community.

“Implementing ELR nationwide is feasible, attainable, and the most important informatics activity in public health today”
Meeting participant
October 30, 2007

“Investing in ELR now will help prevent a Katrina-like response in the face of an infectious disease or bioterrorism event.”
Meeting participant
October 30, 2007
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APPENDIX B—EXEMPLAR ELR STAKEHOLDER LIST
(NOT COMPREHENSIVE)

Federal Stakeholders

Department of Health and Human Services
  Office of the National Coordinator for Health Information Technology
  Centers for Disease Control and Prevention
  Food and Drug Administration
  Centers for Medicare and Medicaid Services

Department of Homeland Security

Department of Defense

U.S. Department of Agriculture

Department of Veterans Affairs

Environmental Protection Agency

National Stakeholders

The National Labs

Association of Public Health Laboratories

American Clinical Laboratory Association

American Society for Clinical Pathology

College of American Pathologists

Other laboratory professional associations and organizations

National Association of County and City Health Officials

Association of State and Territorial Health Officials

Council of State and Territorial Epidemiologists

Additional public health professional associations
State/Local Stakeholders
State departments of health
State public health laboratories
Local departments of health
Local public health laboratories

Private-Sector Stakeholders
Quest Diagnostics Incorporated
RPM Incorporated
Additional commercial laboratories
Hospital laboratories

Additional Stakeholders
Regional health information organizations
Information technology vendors
U.S. public
Analytic Services Inc. is a public-service institute, an independent, not-for-profit corporation chartered in California with the assistance of the RAND Corporation in 1958. The corporation provides analytic and technical support to government agencies throughout the national security, homeland security, and public safety mission areas.

For more information regarding this report, please contact Elin Gursky, Sc.D, Fellow and Principal Deputy for Biodefense in ANSER’s National Strategies Support Directorate.

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With Gratitude
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eLR
electronic Laboratory Reporting

FRAMEWORK FOR ELECTRONIC LABORATORY REPORTING

RECOMMENDATIONS TO POLICYMAKERS

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November 2007