MDR-TB
Information Systems
Collaborating, Defining, Sharing, Scaling

Institute of Medicine
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While there has been impressive progress on many levels....

........we are still ‘envisioning’ the creation of a national or global information supply chain to support biosurveillance........

........realizing the vision remains elusive.
Information Supply Chain

Health Outcome Driven – Information Product Defined – Systems Delivered

Human Resources

Products/Hard Goods

MDR-TB Program

Information

Supply Chains Required to Support Public Health Programs

“...strengthening the public health information supply chain to better protect the health of people everywhere.”

CDC IT Strategic Plan, 2008-2012
Information Supply Chains
Making Information Available for Decision Making

• The information supply chain is very complex
  – Many information products and services, many supply chain components and many contributing entities....no coordination

• Provides coordination and a matrix for all activities, services, products, personnel, and processes that are required to assure the flow of data and information
  – Assures telephonic and internet access
  – Collaboration platforms
  – Systems platforms and configurations for use in the field
  – Portals for sharing status reports and policy statements
  – Data collection, storage, processing, analysis, provisioning, etc
  – Services and staffing: Design, develop, maintain
  – Information sharing
  – Logistics and operations coordination
Information is Communication

• The desire to share data is just emerging
• Desire varies by country, culture, and stakeholder group
• There are many constituents
  – Technology
  – Informatics
  – Scientific
  – Clinical
  – Management
  – Industry
  – Patient/consumer
  – Policy/government

People have to collaborate before functional information supply chains emerge
LIMS
Laboratory Information Management System
LIMS Requirements for Public Health Labs
Sixteen Essential Business Processes

1a. Test requisition
1b. Test receipt
1c. Sample management
1d. Testing and validation
1e. Report distribution
1f. Report receipt
2. Test scheduling
3. Sample collection
4. Sample chain of custody
5. Reagent manufacturing
6. Inventory control
7. General lab reporting
8. Stats and surveillance
9. Lab billing
10. Contract management
11. HR including training
12. Oversight/licensing
13. Customer service
14. Quality control
15. Lab safety
16. Lab mutual assistance

Cost Analysis
Public Health Laboratory LIMS

<table>
<thead>
<tr>
<th>Cost Component</th>
<th>Small Laboratory (in thousands)</th>
<th>Model Laboratory (in thousands)</th>
<th>Large Laboratory (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquisition (a)</td>
<td>$140–250</td>
<td>$300–430</td>
<td>$530–700</td>
</tr>
<tr>
<td>Implementation (a)</td>
<td>$ 35–70</td>
<td>$ 55–125</td>
<td>$ 70–175</td>
</tr>
<tr>
<td>Annual maintenance (b)</td>
<td>$100–135</td>
<td>$250–360</td>
<td>$450–650</td>
</tr>
<tr>
<td>Total cost (first year)</td>
<td>$275–400</td>
<td>$600–935</td>
<td>$1,000–1,500</td>
</tr>
</tbody>
</table>

Table 4: Total LIMS cost for the first year

(a) Acquisition and Implementation costs are one-time costs.
(b) Maintenance costs are recurring annual costs.

Public Health Informatics Institute, Brief Research, April 2004
The Path to ‘Babel’ is Downhill

Emerging Technologies are constantly challenging a community’s ability to standardize. Only through robust ongoing community collaboration does standardization prevail over entropy.

PHLIP
Public Health Laboratory Interoperability Project
Case Study
Variation of lab tests and coding by disease

**Influenza Test Descriptions in Six State Public Health Laboratories**

<table>
<thead>
<tr>
<th>State</th>
<th>Virus Isolation</th>
<th>Antigen Detection</th>
<th>Serology</th>
<th>Molecular Test</th>
<th>Sub Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Colorado</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Kansas</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Iowa</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Minnesota</td>
<td>1</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>South Dakota</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7 (12.9%)</strong></td>
<td><strong>19 (35.2%)</strong></td>
<td><strong>5 (9.3%)</strong></td>
<td><strong>23 (42.6%)</strong></td>
<td><strong>54 (100%)</strong></td>
</tr>
</tbody>
</table>

Variation across labs resulted in the inability of laboratories to share data efficiently and in a scientifically meaningful manner.
LIMS Adoption in the USA

• Emerging technologies adoption in public health labs
  – 50 State labs
  – 300 total public labs
  – Public and private labs
  – Secure (LRN) and non-secure networks

• Variations by lab
  – Public health priorities
  – Bench methodologies
  – Technology

• Influenza as a case study
  – More than 60 influenza-related tests identified to adequately describe and manage an influenza pandemic
  – Over 500 specific data and coding decisions developed by the national lab community to ensure data exchange

• About 75% of the 80+ nationally notifiable diseases have coding and exchange protocols described
### PHLIP Vocabulary Harmonization Process Timeline

<table>
<thead>
<tr>
<th>Step</th>
<th>Responsible Party</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of NNDs</td>
<td>Steering Committee</td>
<td>At least 1-2 weeks in advance</td>
</tr>
<tr>
<td>Orientation of the working group</td>
<td>The Vocab core group</td>
<td>1 week in advance for note and files; 1hr meeting; cover non-NNDs</td>
</tr>
<tr>
<td>Collection of data and information from PHLs</td>
<td>PHLs</td>
<td>Need 2-4 hrs; meet on Wed; data due by Wed next week</td>
</tr>
<tr>
<td>Development of summarized report</td>
<td>The Vocab core group</td>
<td>2 days; send 1st draft out COB Tue.</td>
</tr>
<tr>
<td>Discussion and revision of drafted PHLIP documents</td>
<td>The Vocab core group and lab SMEs</td>
<td>Two calls</td>
</tr>
<tr>
<td>Development of detail implementation guideline (mainly encoding guideline)</td>
<td>The Vocab core group</td>
<td>More time at beginning; try flu first; different for NNDs.</td>
</tr>
</tbody>
</table>

Diagram provided by Dr. Wenkai Li, CDC
Defining and Standardizing Data

Clinical Specimen Submitted to Lab for Influenza Diagnosis

Diagram provided by Dr. Wenkai Li, CDC
PHLIP
Community Driven and Defined Information Provisioning

Technology Platform(s)
Lab information system, medical record, radiology system, etc

Information Kernel
• PHLIP Preferred Test Term
• Usage of the Test Concept
• PHLIP Test ID or LOINC Code
• LOINC Short Name or PHLIP Name
• Expected Result Value Set
• HL7 V2.X Message
• Order: OBR-4, OBR-15
• Result: OBX-2, OBX-3, OBX-5, OBX-8, OBX-17

Democratization:
Technology platform provides user interface and mechanism to leverage the information kernel

Standardization:
The ‘information kernel’ is derived from a community harmonized description and modeling of the health problem in a digital format
• Dynamically adjusts as new scientific methodologies, technologies, and approaches emerge
USA LIMS Vendors*

- A 5
- B 3
- C 4
- D 3
- E 2
- F 10
- G 13
- H 8
- I 4

*Vendors designated by letters A – I

Data provided APHL based on survey of state labs, 2007

Democratization of platform
In the USA market
Tests Implemented by States*

- CT/GC NAAT
- GC Culture
- TB
- Mycobacteriology reference & clinical
- Pertussis
- Viral Isolation (w/Flu)
- Rabies
- Intestinal parasites
- Blood parasites
- Norovirus
- Enteric reference & clinical
- HIV (EIA & Western Blot)
- HIV Multi-spot
- ABO Rh/ Antibody Screens
- Hepatitis A
- Hepatitis B (core IgM & total, surface Ab, surface Ag)
- Hepatitis C
- Legionella Ag
- Lyme Ab & Western Blot
- Rickettsial Ab
- Syphilis RPR
- Syphilis VDRL
- Syphilis TPPA
- Syphilis FTA-ABS
- Blood Lead
- Sickle Cell screening

(+ all of newborn screening)

*For a single vendor, product from vendor F previous page

Will TB labs be stand-alone or be part of comprehensive public health labs?
Investment

Community Driven Funding, Design, and Implementation

• Resources required to develop a standards-based national laboratory data sharing network is under appreciated

• Public-private partnership and ‘board’ is required to facilitate funding and to coordinate funding to optimize

• Venture capital approach with accountability

• Community-based approach as demonstrated by APHL-CDC PHLIP project is a cost effective strategy to scale
Recommendations
Recommendations

1. Total health requires total information that is derived from an information infrastructure that supports the majority of health programs at the community, country, and global levels

2. Technology adoption theory must guide our strategy and tactics for the development of global programs for information supply chain development

3. Establishment of information supply chains must be driven by ‘surveillance data’ describing the state of technology by region, ‘prevalence data’ describing highlighting successes, and ‘incidence data’ identifying challenges

4. Technology has a ‘therapeutic index’ that must be heeded in the development of global programs for information supply chain development

5. A supply chain approach to information will place appropriate focus on ‘standardization of information products’ and ‘democratization of technology platforms’
6. Standardization, adoption, and sustainability of information supply chains are dependent on community, e.g. laboratorians working together to build a laboratory information supply chain.

7. Information supply chain development is a complex effort that is never finished.

8. Investment must be coordinated and sustained across the public and private sectors.

9. Isolated or regional anecdotal experiences in information supply chain development, both positive and negative, must be considered in a scientifically robust manner to optimally inform information supply chain development - strategy and tactics must be evidence-based.
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