Laboratory Information for Public Health Excellence

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LIPHE Initiative

A Public-Private Partnership
Eli Lilly, Fondation Merieux and RESAOLAB Partners, CDC and CDC Foundation, and GLI
The Global Laboratory Initiative identifies a need for an “urgent and massive scale-up of laboratory services” and more specifically states that “the critical lack of TB laboratory capacity constitutes a global crisis, requiring a paradigm shift in providing laboratory policy guidance, quality assurance and knowledge creation within a global and integrated laboratory network.”
Urgent Information Needs
Large Scale Problems Require Large Scale Solutions

- Laboratory capacity desperately insufficient
- Laboratory capacity building rarely considers data and information management
- Laboratory services are ‘bug’/specimen focused in contrast to clinical and population health programs
- Emerging diagnostics may change surveillance methods and/or sensitivity and specificity affecting surveillance trend estimates
- Critical need to integrate lab, clinical, population health program information systems
- Critical need for ‘operations’ systems to track activities such as infection control programs, therapeutics supply chains, etc
- Building information supply chains is work intensive but the public health impact could be enormous
Contents

• Diagnostics versus data and information
• Lab information management systems
• Public health information supply chains
TB Diagnostics

Simplify and improve detection of TB cases, including smear-negative, extra-pulmonary and childhood TB, through increased sensitivity and specificity and improved accessibility.

Create and distribute simple, accurate, safe and inexpensive tests that can be performed at the point-of-care level of the health care system and that produce same day results.

Enable more effective monitoring of TB treatment (latent and active).

Rapidly identify drug resistance to both first- and second-line anti-TB medicines.

Reliably identify latent TB infection and determine the risk of progression to active disease, enabling rational use of preventative therapy.

Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics by the New Diagnostics Working Group of the Stop TB Partnership. WHO. 2009
Diagnostic Test Development

Crossing the Information Chasm

Are we getting the diagnostics-derived information to the right places at the right times?

Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics by the New Diagnostics Working Group of the Stop TB Partnership. WHO. 2009
To Stop the Spread of TB Globally

To stop the spread of TB globally, the world needs:

- **Better TB diagnostics** — that are rapid, practical and accurate in resource-poor settings — are critical to ensuring that people receive proper and timely treatment.

- **New TB drugs** — that will shorten treatment, be effective against susceptible and resistant strains, be compatible with antiretroviral therapies used for HIV/AIDS and that will improve treatment of latent infection — will dramatically improve TB treatment and control.

- **A new vaccine** — that is both effective and safe for children, adolescents and adults, including people infected with HIV — will decrease TB incidence overall and, along with an effective drug therapy, could eventually control the disease.

http://www.finddiagnostics.org/programs/tb

And......efficient sustainable information supply chains
LIMS
Laboratory Information Management System
A Tool for Laboratorians
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
The laboratory manages great complexity which is often reduced to a simple result, positive or negative, for clinicians and epidemiologists.
Lab Information
Central Importance

• Strong national healthcare systems rely on robust laboratory capacity, including accurate and timely laboratory information networks

• Effective laboratory information management is a critical capability to support clinical service delivery, public health program operations and research activities

• Laboratory data support a wide spectrum of public health issues, including infectious diseases, chronic diseases and environmental health issues such as disease-free drinking water
LIMS Challenge
Scalable Approaches

• A systems approach, in contrast to an ad hoc approach, will develop two key capabilities:
  – Scalable approaches to building laboratory information processing capability
  – Ability to integrate data among laboratories, clinical programs and public health programs
• The systems approach will transcend a vertical single-disease-specific approach so as to factor in the imperative that information infrastructures must support diverse healthcare priorities and programs

There is a need for LIMS implementation in thousands of labs across the globe
Lab Information Management Capacity Building
LIPHE Initiative

Key components

• Network of laboratories, a community, dedicated to lab information management capacity building (not necessarily data sharing)

• Labs supported nationally and regionally through centers of excellence hubs

• Collaborative development of information management best practices and implementation

• Focus is on information and leveraging ‘technology’ but not about building technology
  – Platform agnostic
  – Information standardization
Technology Platform(s)
Lab information system, medical record, radiology system, etc.
Technology platform provides user interface and mechanism to leverage the information kernel.

Information Kernel
• 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.

Democratization of Platform

Standardization of Information
## Core LIPHE Technology Tools

<table>
<thead>
<tr>
<th>Tool</th>
<th>Purpose</th>
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</thead>
<tbody>
<tr>
<td>LAB Requirements Framework</td>
<td>Comprehensive list of LIMS requirements for laboratories</td>
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<tr>
<td>LIMS Assessment Framework</td>
<td>Comprehensive list of LIMS functionality by vendor product</td>
</tr>
<tr>
<td>LIMS Selection Framework</td>
<td>Dynamic LIMS recommendation tool utilizing LAB requirements and LIMS assessment framework</td>
</tr>
<tr>
<td>Diagnostic Framework</td>
<td>Details data generated by each diagnostic including sensitivity and specificity</td>
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<tr>
<td>Data standardization framework</td>
<td>Details data required for TB/DRTB control programs</td>
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<tr>
<td>Technology Infrastructure Framework</td>
<td>Recommendations for hardware and software (non-LIMS) to support laboratories</td>
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## Core LIPHE Business Tools

<table>
<thead>
<tr>
<th>Tool</th>
<th>Purpose</th>
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<tbody>
<tr>
<td>LIMS request for proposal (RFP)</td>
<td>Template that facilitates translation of laboratory information requirements into request for proposals</td>
</tr>
<tr>
<td>LIMS funding proposal development</td>
<td>Template that supports laboratory development of funding with focus on information products and services</td>
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Interactive map of laboratories

Sections

[Map link to Laboratory Information for Public Health Excellence (LIPHE) website]
LIMS Requirements:
A common set of needs from a laboratory information system

Laboratories:
A list of labs with contact and geo info

LIMS Companies:
LIMS applications and their vendors
Ranking LIMS applications

Each LIMS will be ranked on every requirement

For example:
- LIMS 1 fully supports requirement R1 User Accounts – rank 5
- LIMS 1 partially supports requirement R4 Test Catalog Management – rank 3
- LIMS 1 does not support requirement R7 Specimen Tracking Management – rank 0
Every Laboratory will rank LIMS Requirements by their importance to this lab

For example:
- Requirement R1 is of no importance for Laboratory 1 – rank 0
- Requirement R4 is of medium importance for Laboratory 1 – rank 3
- Requirement R6 is of crucial importance for Laboratory 1 – rank 5
LIMS-Lab Match

- For each LIMS, the **Match Index** with every Laboratory will be calculated, based on summarizing the **product** of the **LIMS rank for each and every requirement** and the **importance of this requirement for the Laboratory**
- For each LIMS, the **cost of purchase and implementation** will be calculated per lab, based on:
  - Licensing fees
  - The customization needed to suit lab's needs
  - Hardware needed to host the LIMS
  - Customization costs based on location, and other factors

<table>
<thead>
<tr>
<th>Req ID</th>
<th>Importance for the Lab</th>
<th>Rank of LIMS</th>
<th>Match Index</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>5</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>R2</td>
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<td>2</td>
<td>8</td>
</tr>
<tr>
<td>R3</td>
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<td>2</td>
<td>4</td>
</tr>
<tr>
<td>R4</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>R5</td>
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<tr>
<td>R6</td>
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<tr>
<td>R15</td>
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<td>1</td>
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Total Match Index: **125**
Based on the Match Index, the Lab-LIMS Match chart will be dynamically generated.
Lab-LIMS Match

LIMS Matching Profile for Laboratory B

Costs (Purchase + Implementation)

Ranking
Capability Assessment

• Core tools enable dynamic capability assessment
• Capability assessment supports
  – Accreditation
  – Capability development
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
• Requirements vary 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
The DEOC and Incident Management Structure Develop and Operate Supply Chains

During a response, there are at least three critical supply chains that support a successful public health response.

- Information
- Products/Hard Goods
- Human Resources

Information and technology products and services HAVE NOT BEEN provisioned in a systematic and coordinated fashion.

eRISC was established to fill this gap and provide coordination and integration of all technology products and services across CDC.

DEOC = Director’s Emergency Operations Center
A Public Health Information Supply Chain
Usually, at best, a vague idea in a person’s mind

Information supply chains must be engineered.

A disciplined approach to data and information provisioning will enable measurement of data/information quality and impact.

Measurement will enable performance improvement.

A subset of data and information flow for Pandemic Influenza
The Supply Chain Components

- **Information Products** – Questions that drive decision making
  - The ability to enumerate information requirements is critical for event preparedness and response. By definition, all supply chains must have a clear idea of the product(s) that it must produce
  - Information products support the CDC business functions critical for emergency response

- **Source of raw materials** – Data systems
  - Data systems that provide the data for information products

- **Human resources** – Staffing
  - Staffing that build and operate the systems as well as create the information products

- **Standard operating procedures** -- A logistics-based approach
  - Processes that manage the data to produce information
  - Includes all aspects of managing the supply chain including staffing, hardware, software, data integration, data analysis, report generation, continuity of operations, etc
Emerging Technologies are constantly challenging a community’s ability to standardize. Only through robust ongoing community collaboration does alignment of vision, mission, and execution prevail over entropy.
Information is an Intervention
Some Examples

• It drives the right therapeutic to the right patient
  – It prevents emergence of drug resistant strains
  – It treats patients more cost effectively

• It improves operations
  – It prevents nosocomial spread by tracking infection control risks
  – It improves contact tracing and follow up

Given the cost of disease spread, years of treatment, impact on productivity, and overall morbidity and mortality, investment in the information supply is very cost effective
The Cost of ‘Not Knowing’
Research Gap and Operations Tool

- Design the ‘model’ information supply chain for TB/DRTB control
- Assess gaps within one or more communities
- Quantify the impact of the information gaps in terms of treatment timeliness, treatment appropriateness, drug supply chain, etc
- Calculate the ‘cost’ of information gaps in terms of spread of disease, emergence of resistance, morbidity and mortality, etc
- The model can be used as an operations tool to support the development of TB/DRTB information supply chains at the community, district, provincial, and national levels
Thank You

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