MDR-TB
Information Systems:
Challenges and Approaches to Enhance Laboratory Information Management Capacity

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The New Profile of Drug Resistant Tuberculosis: A Global and Local Perspective

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Laboratory Capacity
A Global Crisis

The World Health Organization (WHO) 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 programs are ‘bug'/specimen focused and therefore have very different information system requirements than clinical and population health programs
• Emerging diagnostics may change surveillance methods and/or sensitivity and specificity for TB/MDRTB testing thus affecting surveillance trend estimates and outbreak control
• 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
“Knowing is not enough; we must apply. Willing is not enough; we must do.”

Goethe

What happens if we “don’t know” how to enable thousands of labs?

“Can’t apply” and can’t do the public health work effectively.
Contents

• Diagnostics versus data and information
• Lab information management systems
• Public health information supply chains
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
**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
LIMS
Laboratory Information Management System
A Tool for Laboratorians
LIMS Adoption in the USA

• Emerging technologies adoption in public health labs
  – 50 State labs – after about 7 years 70% - 80% of labs have a LIMS
  – Several different LIMS being adopted across laboratories
  – 300 total public laboratories
  – National public health laboratory network is in early evolution
• 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
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
  – Research activities

• Laboratory data support a wide spectrum of public health programs
  – Infectious diseases
  – Chronic diseases
  – Environmental health issues such as disease-free drinking water
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.
Technology vs. Information

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
Challenges to System(s) Development
Expectations and Innovation are Accelerants to Babel

Technology = development reality
Magic = user expectations

Adoption of v2.0 begins before v1.0 adoption is completed

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.

A systems approach, in contrast to an ad hoc approach, will develop important capabilities:
- Scalable approaches to building laboratory information processing capability
- Intentionally designed dynamic systems that can be optimized through continuous performance improvement
- The 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 robust laboratory information supply chains, including LIMS systems in thousands of labs across the globe.
Lab Information Management Capacity Building
Public-Private Partnership

Key components
• Network of laboratories, a community, dedicated to lab information management capacity building (not necessarily data sharing)
• Labs linked nationally, regionally, and internationally 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

This activity functionally provides a ‘Chief Information Officer’ capability to hundreds or thousands of laboratories to support technology adoption and information supply chain development
Lab Information Management Capacity Building
Attributes of Public-Private Partnership

• Sustainable
• Cost effective
• Scalable
• Leverages and builds local expertise
• Science driven
• Stakeholder governed
• Recognizing diversity of baseline capability, the program provides a clear path to robust capability
The Event Response Information Supply Chain....

A Comprehensive Logistics-Based Approach to Data and Information Provisioning for the DEOC

A Pandemic Influenza Case Study

The eRISC slides were prepared in 2007 while Dr. Nordenberg was working at the CDC
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 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 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
Linking Public Health Functions to Information and Data Flow

- Document the **public health functions**, **information required**, and **work flow needed** to prepare and respond to a pandemic are documented.
- Document through enterprise architecture process the **information exchange** required to support public health functions and work flow.
- Document the **system and data flow** associated with the information exchange discovered by enterprise architecture.

*This critical process presents difficult challenges as a consequence of the need to translate public health practice into technical architectures.*
The Information Supply Chain is Complex

- Information products for pandemic influenza
  - More than 200 critical information products were identified
  - These information products support effective event management
- Numerous uncoordinated entities deliver information products and services across numerous
  - Informatics centers
  - Stakeholders
- More than 45 systems/platforms were identified (FY06 spend > $100M) with up to 60 systems likely involved

*No activity or entity responsible for or working on creating the framework to ensure CDC knew what information is required, where it should come from, how to configure it into meaningful products, nor for the design and maintenance the required processes*
Information is an Intervention
Impact of TB/DRTB Information Supply Chain

- 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 chain 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
Recommendations

• Development of country plans for information supply chains to support MDRTB/TB control
• Sustainable multinational collaboration of TB laboratorians to develop shared best practices
• Develop plans to migrate labs at all levels of information technology capability to same target capability
• Tight linkage between diagnostic development and data/information activities
Recommendations (con’t)

• Technology adoption and information capability tracking to guide programs
• Track metrics related to time from specimen acquisition to diagnoses and then treatment
• Annual assessment of information plans to dynamically respond to new conditions, e.g. diagnostics, drugs, intervention programs, etc
• Ensure integration of HIV and TB data systems to support management of co-infected patients
• Educational programs to ensure that there is clear understanding of the specific needs of laboratories versus clinical and epidemiologic activities
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But we have yet to arrive at knowing!
Thank You

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