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

Laboratory Capacity
A Global Crisis

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).

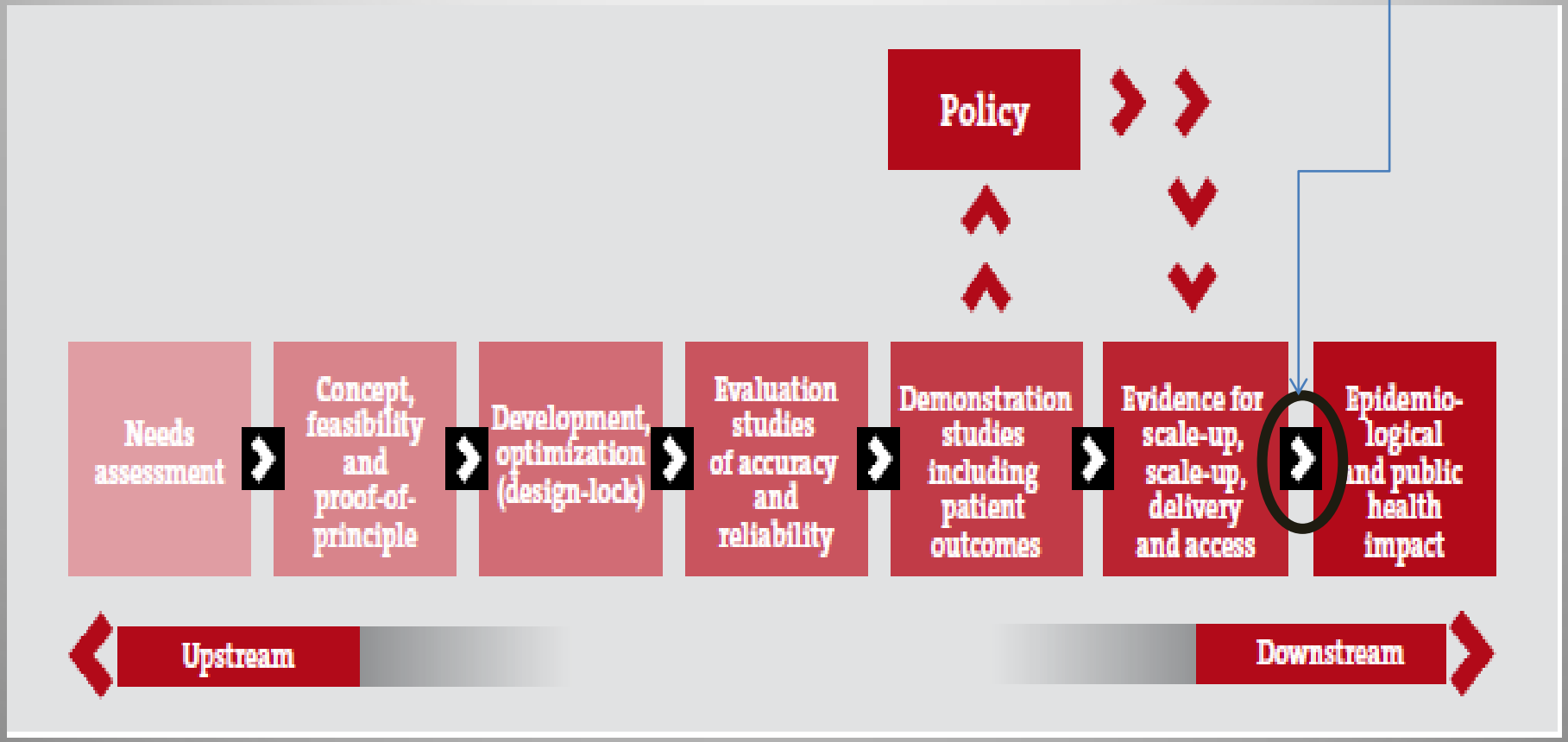
Rapidly identify drug resistance to both first- and second-line anti-TB medicines.

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

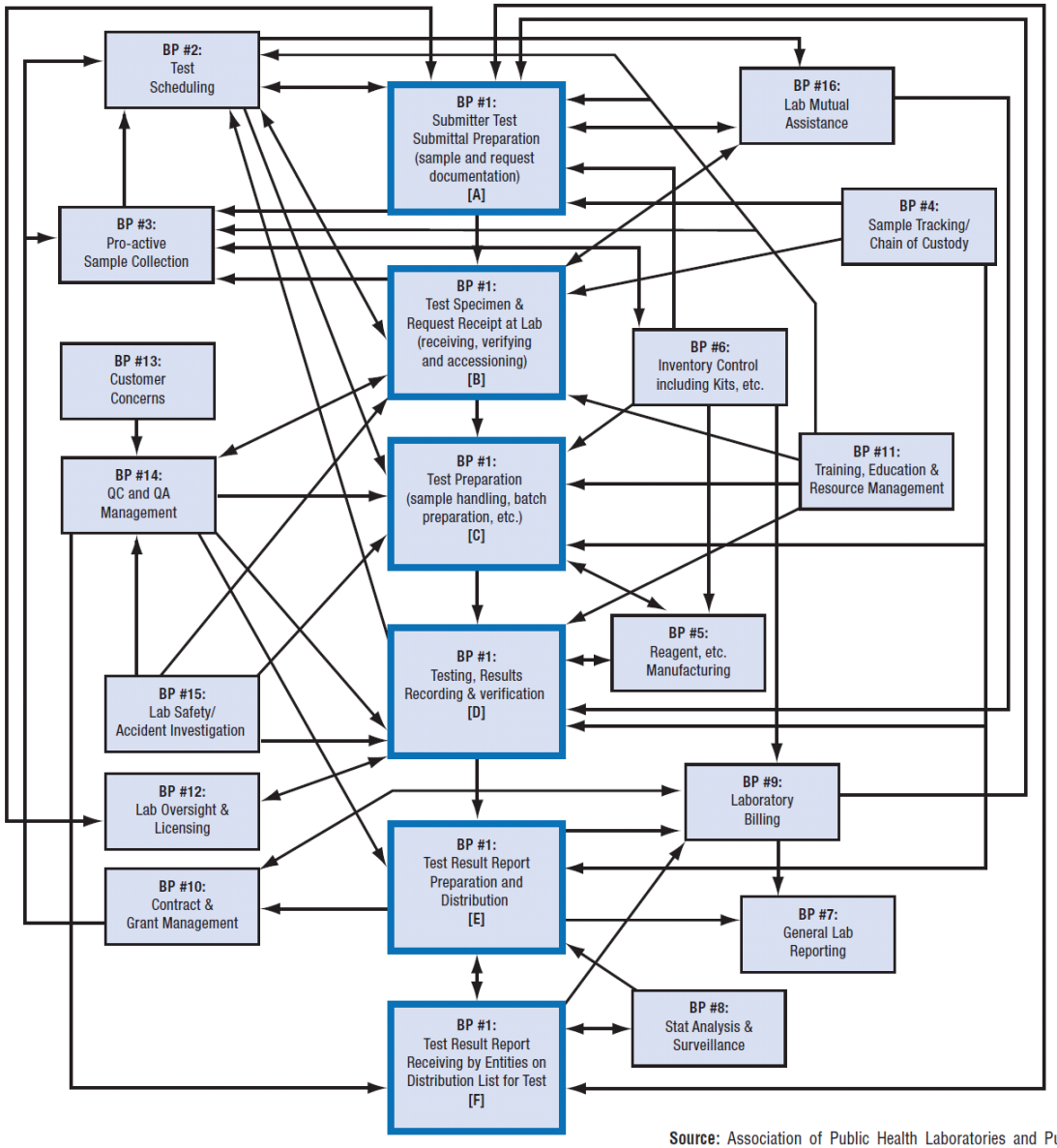
And……efficient sustainable information supply chains

LIMS

Laboratory Information Management System

A Tool for Laboratorians

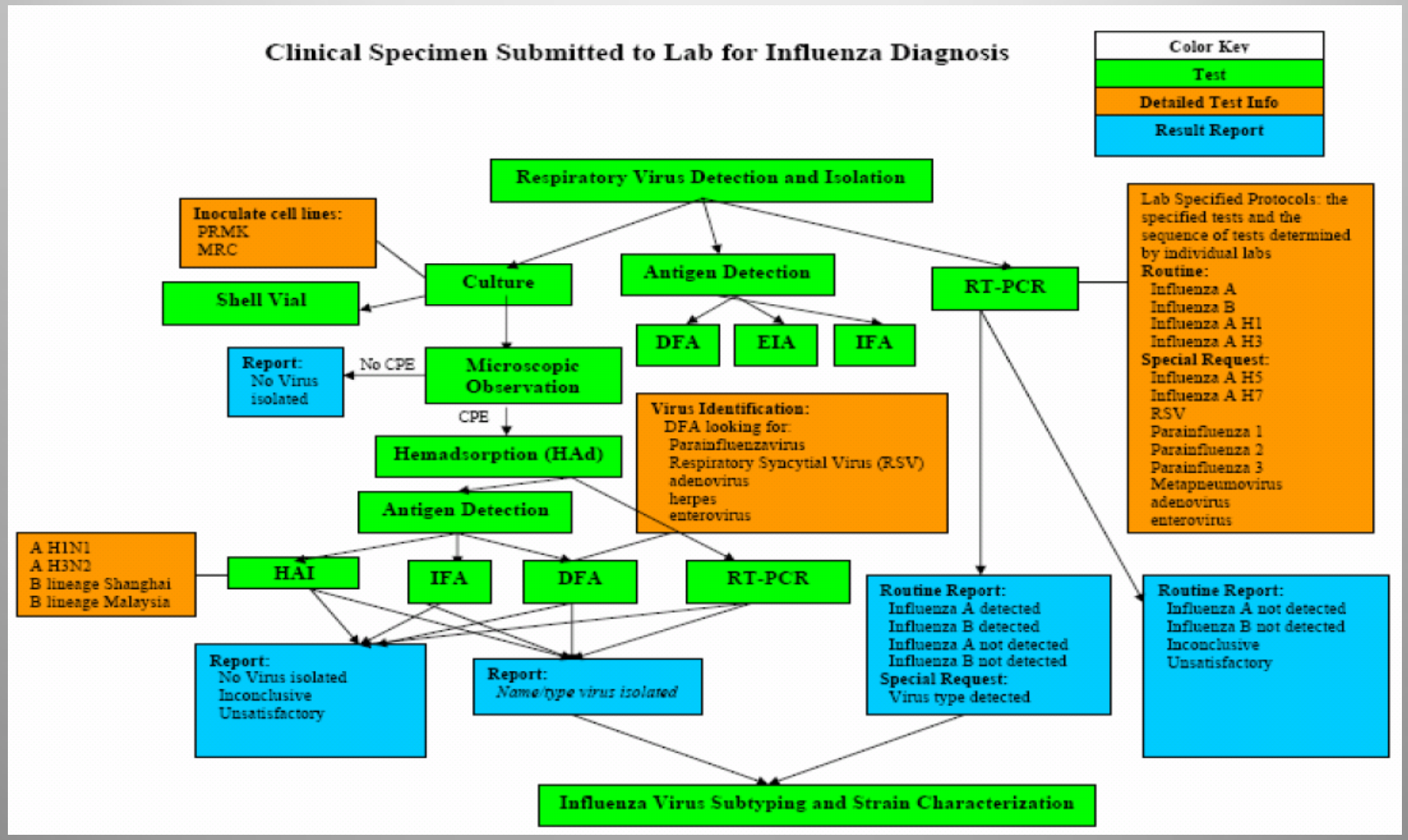
LIMS Requirements for Public Health Labs
Sixteen Essential Business Processes



Source: Association of Public Health Laboratories and Public Health Informatics Institute (2003). Requirements Document for Public Health Laboratory Information (LIM) Systems. 2003. Washington, DC: Association of Public Health Laboratories.

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

Defining and Standardizing Data



The laboratory manages great complexity which is often reduced to a simple result, positive or negative, for clinicians and epidemiologists

Diagram provided by Dr. Wenkai Li, CDC

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 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

Democratization of Platform

Standardization of Information

Core LIPHE Technology Tools

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

Core LIPHE Business Tools

Tool	Purpose
LIMS request for proposal (RFP)	Template that facilitates translation of laboratory information requirements into request for proposals
LIMS funding proposal development	Template that supports laboratory development of funding with focus on information products and services

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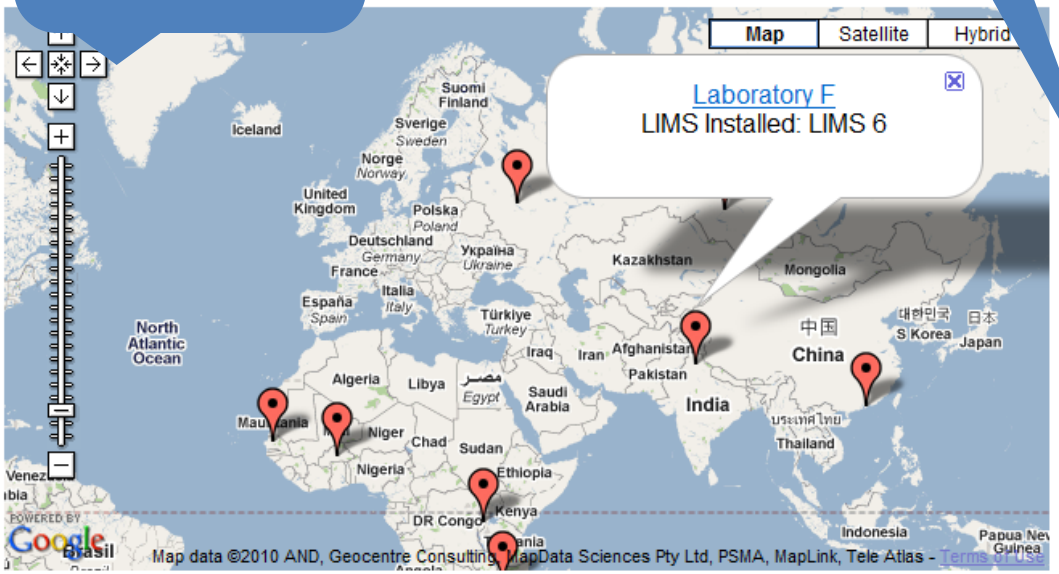
Mission

The World Health Organization (WHO) Global Laboratory Initiat
and massive scale-‑up of laboratory services" and more specifi of
TB laboratory capacity constitutes a global crisis, requiring a pa y
policy guidance, quality assurance and knowledge creation with
network." The number of new laboratories needed numbers in t
challenge. The scale of need identified in the WHO Global Labor
response to this call to action must come from many quarters and from many partne
na robust laboratory capacity, including accurate and
la ective laboratory information management is a criti ility
to public health program operations and research activit
La ctrum of public health issues, including infectious disea
ch health issues such as disease-‑free drinking water.

Sections

Interactive map of laboratories



LIMS

Diagnostics

Business

Data Standardization

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LIMS

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

Laboratory: select lab

LIMS Requirements

Title	Section	Subsection	Req Name
R1	Functional	Laboratory Staff	1. User Accounts
R10	Functional	Laboratory Staff	10. Results Management
R11	Functional	Laboratory Staff	11. Reports Management

1 - 3

Add new item

Laboratories

New Actions Settings

Lab Name	Country
Laboratory A	Russia
Laboratory B	Russia
Laboratory C	Rwanda
Laboratory D	Malawi

LIMS Companies

New Actions Settings

App Name
Company A (LIMS 1)
Company B (LIMS 2)
Company C (LIMS 3)
Company D (LIMS 4)
Company E (LIMS 5)
Company F (LIMS 6)

Ranking LIMS applications

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http://www.wikipedia.org

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Ranking LIMS 1 system by the degree of support it provides for each LIMS Requirement.

New | Actions | Settings | View: All Items

Title	Section	Subsection	Req Name	Functionality	Description
R1 NEW	Functional	Laboratory Staff	1. User Accounts	5	This function allows different users to have access to the LIS based upon their role in the organization and the data they need acces... o that non-a... deleted at an...
R2 NEW	Functional	Laboratory Staff	2. Patient Management	5	The L... ge patien... person over ...
R3 NEW	Functional	Laboratory Staff	3. Provider Management	5	Provi... provi...
R4 NEW	Functional	Laboratory Staff	4. Test Catalog Management	3	The L... into categ... nes and Code... st Catal...
R5 NEW	Functional	Laboratory Staff	5. Request Management	2	This f... tests to be ...
R6 NEW	Functional	Laboratory Staff	6. Specimen Management	4	The L... y to dispo... atched back ...
R7 NEW	Functional	Laboratory Staff	7. Specimen Tracking Management	0	Besid... e stora... ments testing ... sms

Each LIMS will be ranked on every requirement

<u>For example:</u>

- *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*

Ranking Requirements by Importance

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Ranking LIMS Requirements by Importance for Laboratory 1.

New | Actions | Settings | View: All Items

Title	Section	Subsection	Req Name	Importance	Description
R1 NEW	Functional	Laboratory Staff	1. User Accounts	0	This fu access non-au at any
R2 NEW	Functional	Laboratory Staff	2. Patient Management	1	The LI patien over ti
R3 NEW	Functional	Laboratory Staff	3. Provider Management	2	Provid that ha
R4 NEW	Functional	Laboratory Staff	4. Test Catalog Management	3	The LI categ Codes Catalo
R5 NEW	Functional	Laboratory Staff	5. Request Management	4	This fu be per
R6 NEW	Functional	Laboratory Staff	6. Specimen Management	5	The LI dispos

they need m so that d or deleted

hange cific person

all providers

ed into Names and Test

t or tests to

way to e matched

back to the originating sample. Additionally, samples may be sent to third parties for confirmatory testing or as overflow.

Every Laboratory will rank LIMS Requirements by their importance to this lab

<u>For example:</u>

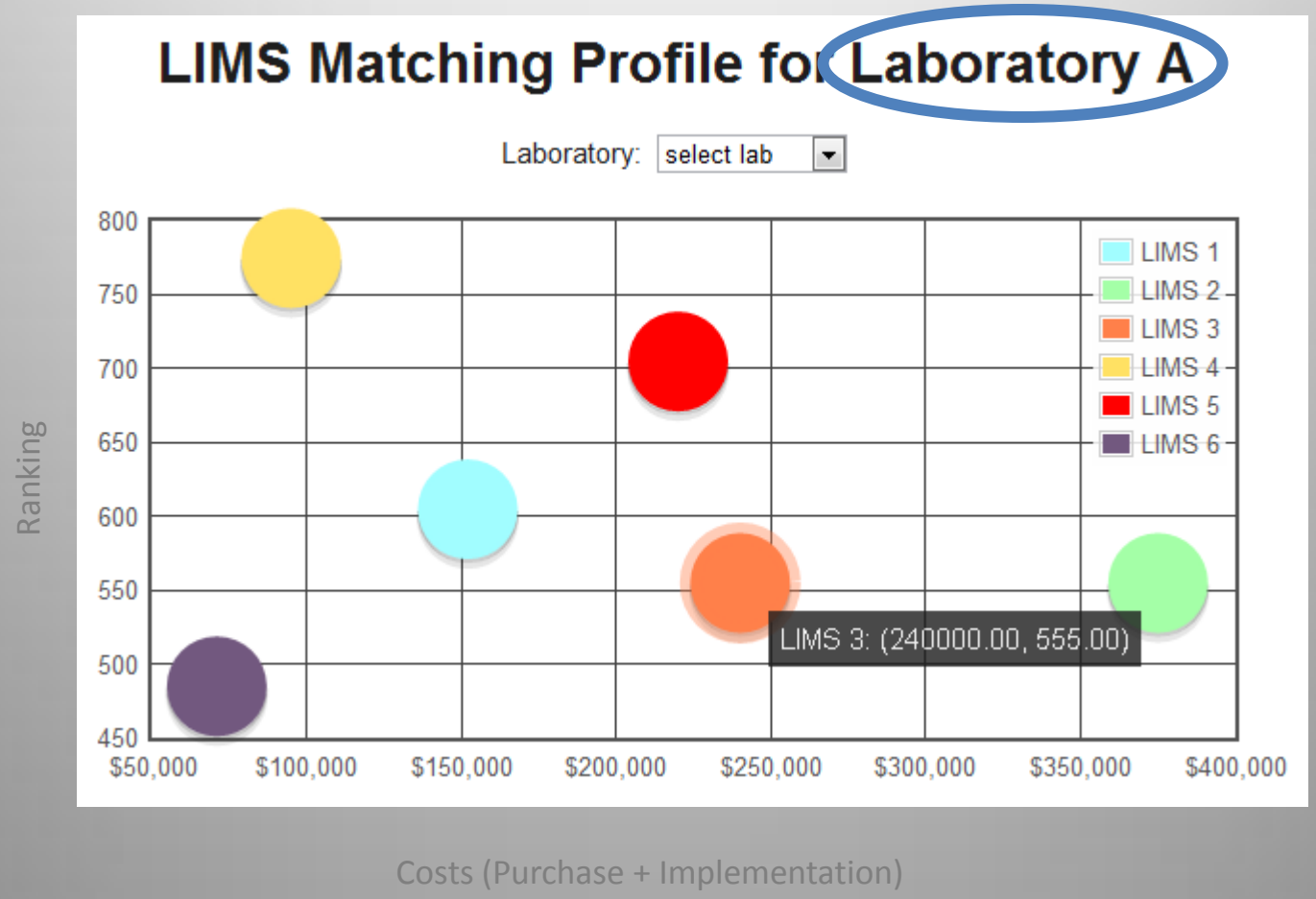
- *Requirement R1 is of no importance for Laboratory 1 – rank 0*
- *Requirement R4 is of medium importance for Laboratory 1 – rank 3*
- *Requirement R6 is of crucial importance for Laboratory 1 – rank 5*

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

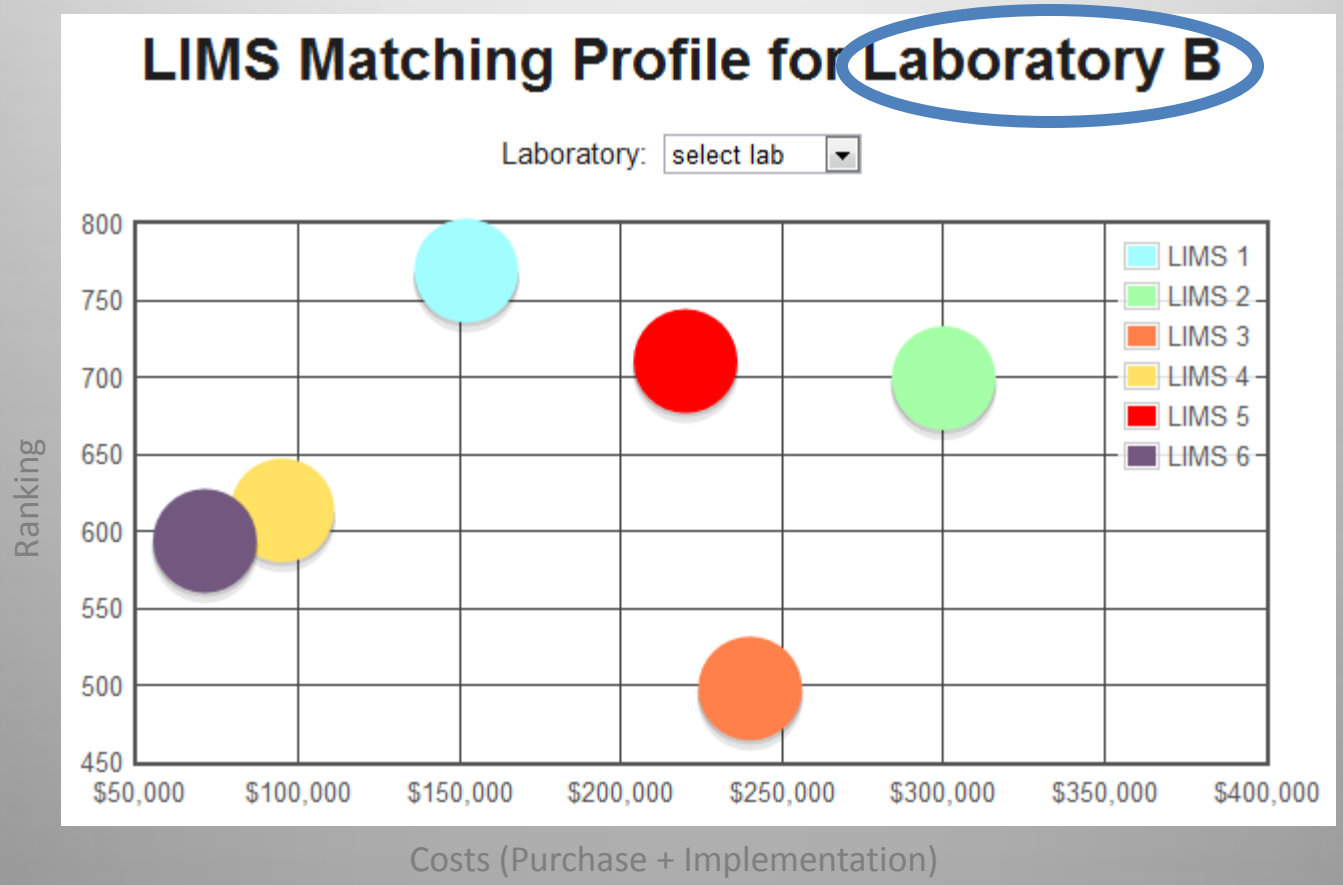
Req ID	Importance for the Lab	Rank of LIMS	Match Index
R1	5	4	20
R2	4	2	8
R3	2	2	4
R4	2	2	4
R5	3	2	6
R6	0	2	0
R7	0	5	0
R8	0	5	0
R9	5	5	25
R10	4	5	20
R11	5	5	25
R12	5	1	5
R13	3	1	3
R14	2	2	4
R15	1	1	1
		Total Match Index	**125**

LIMS-Lab Match



Based on the Match Index, the Lab-LIMS Match chart will be dynamically generated

Lab-LIMS Match



Capability Assessment

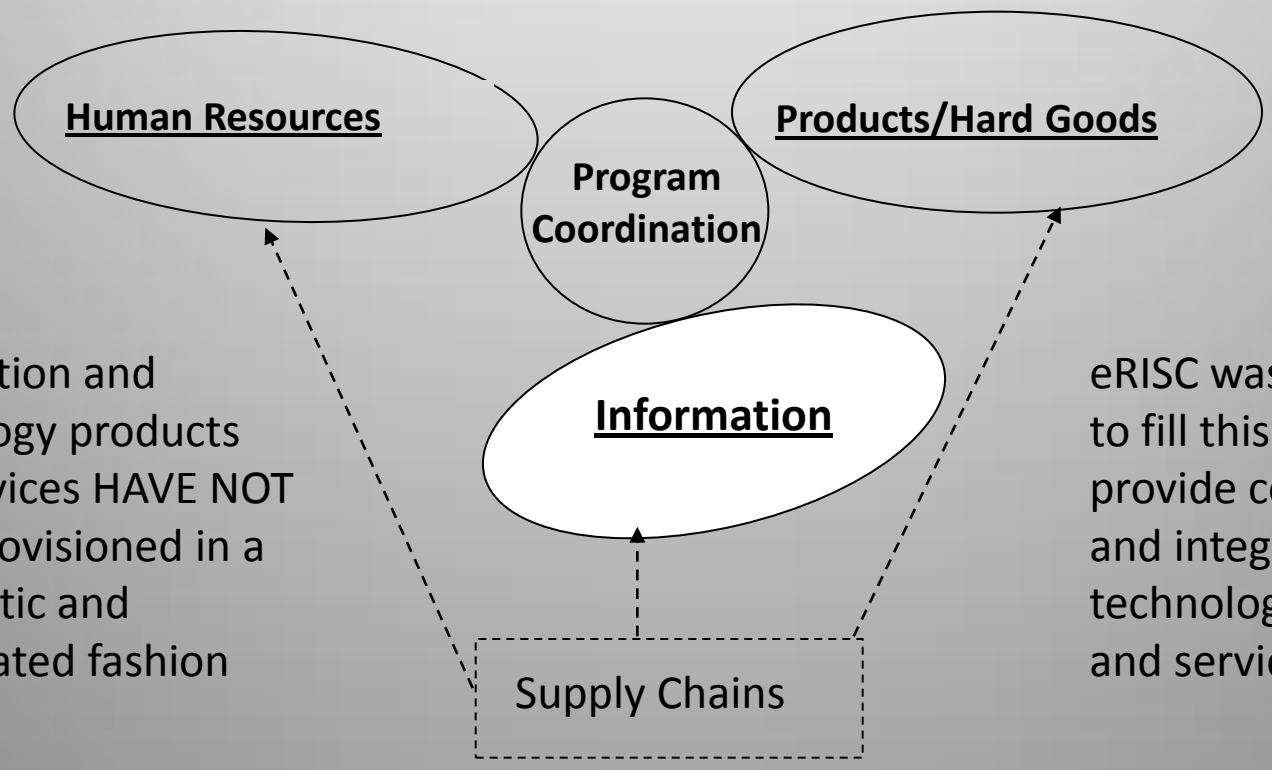
- Core tools enable dynamic capability assessment
- Capability assessment supports
  - Accreditation
  - Capability development

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



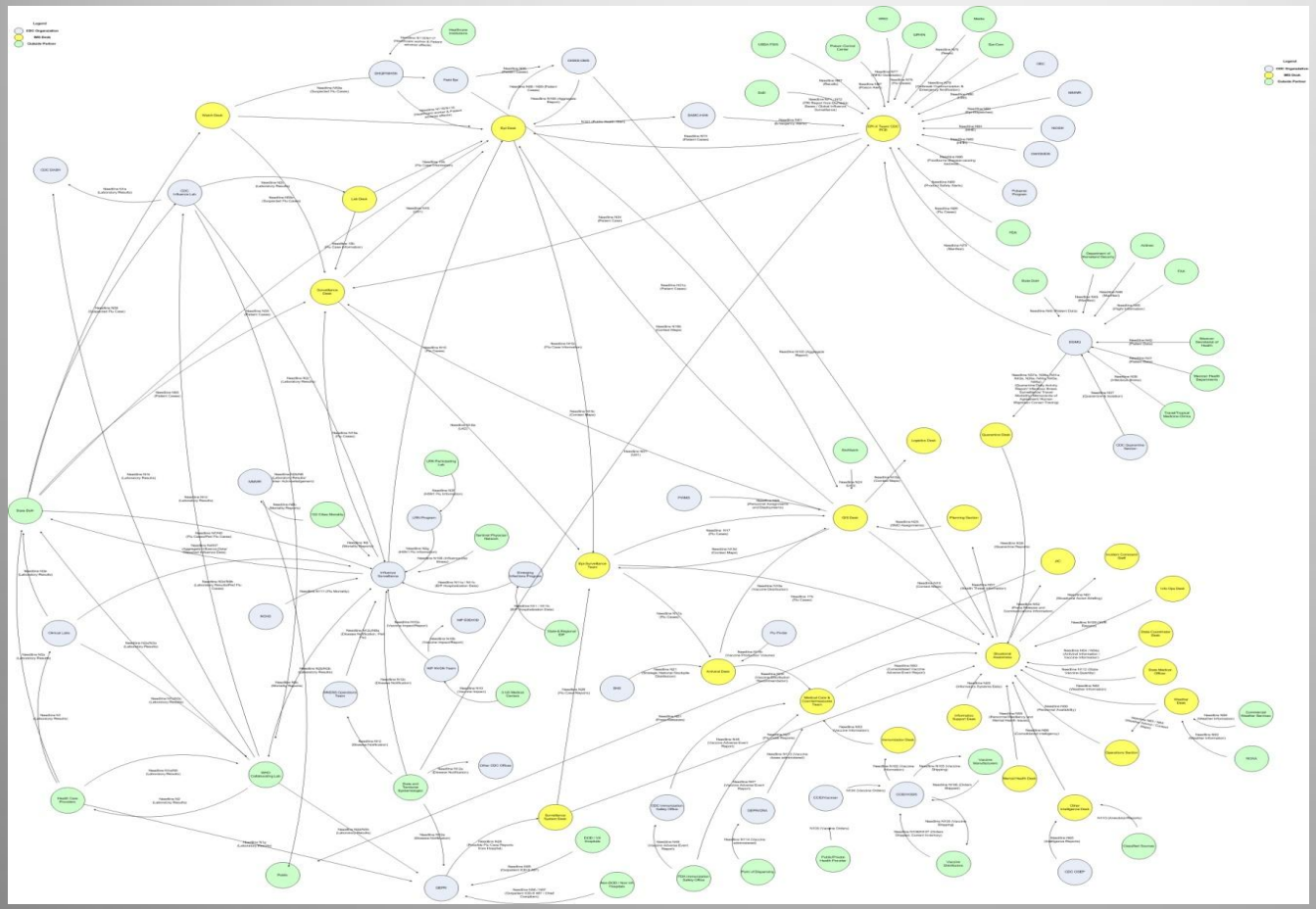
Information and technology products and services HAVE NOT BEEN provisioned in a systematic and coordinated fashion

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.

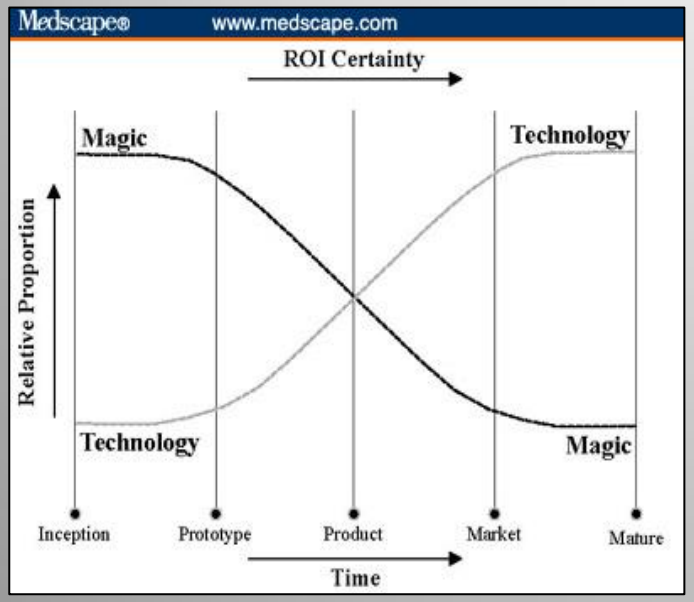
A subset of data and information flow for Pandemic Influenza

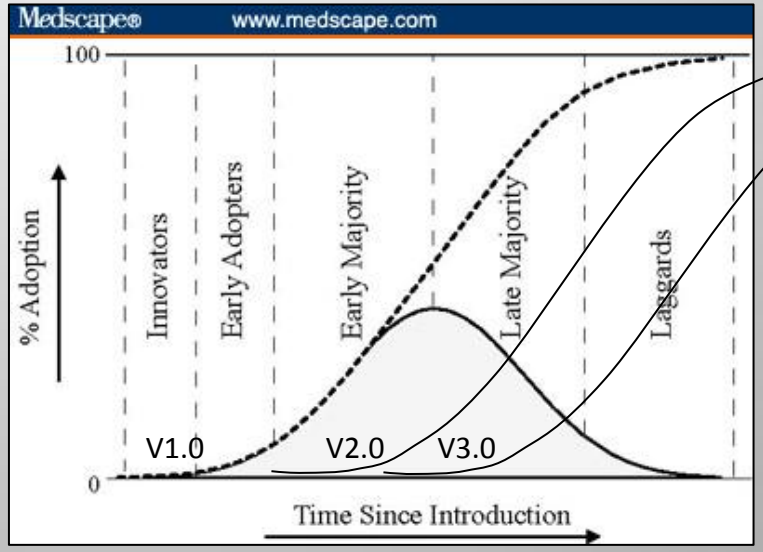
The Supply Chain Components

- **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

Challenges to System(s) Development

Expectations and Innovation are Accelerants to Babel





Emerging Technology

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.

Diagrams adapted from: Achieving Clinician Buy-in to Technology, Medscape General Medicine 4(4), 2002. © 2002 Medscape

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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