

Public Health Laboratories: Integral Population and Clinical Health Partners

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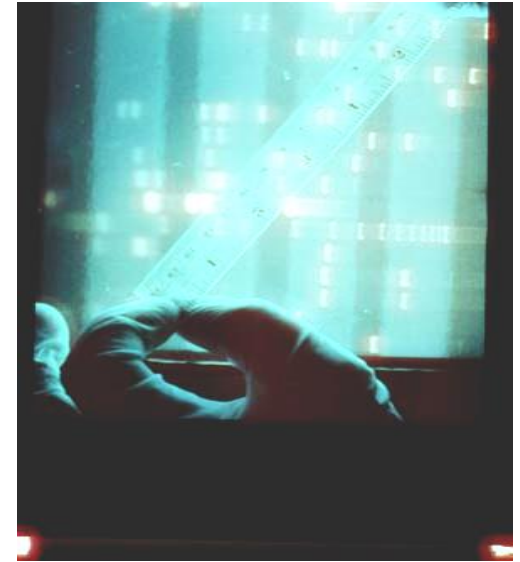
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Presentation Highlights

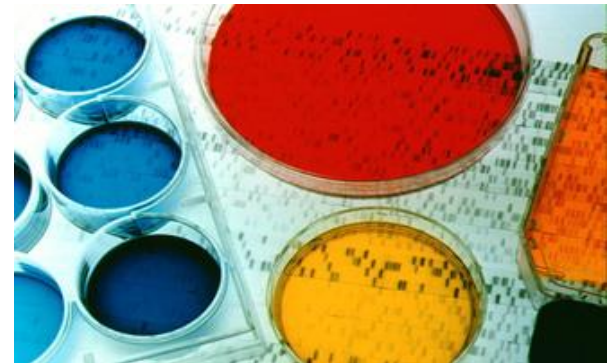
- Why Focus on Laboratories?
- The Public Health Laboratory System
- Preparedness and Response
 - LRN/Anthrax
 - Influenza
 - Ebola
- Surge Capacity
- Impacts on HIT
- Interconnectedness – a State PHL Perspective

Why focus on Lab Data?



**Lab results are a component in 70%
of clinical decisions.**

The U.S. Bureau of Labor Statistics reports that roughly 10 billion lab tests are performed annually, and demand is expected to climb.



Mission Differences

Clinical/Hospital Labs

- Diagnostic testing
- Some reference testing
- Medical management
- Focus = **Individuals**

Public Health Labs

- Some diagnostic testing
- Reference testing
- Surveillance, monitoring and outbreak response
- Focus = [Populations](#)

Providing data for decision making

Interdependent Network

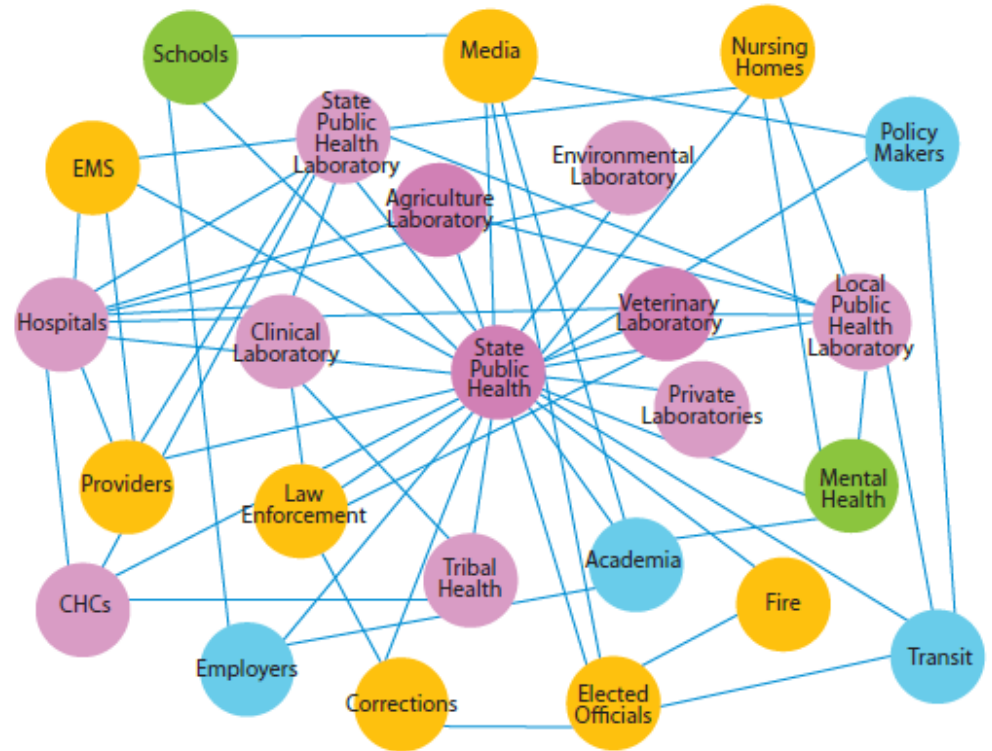
Identification of Public Health Threats



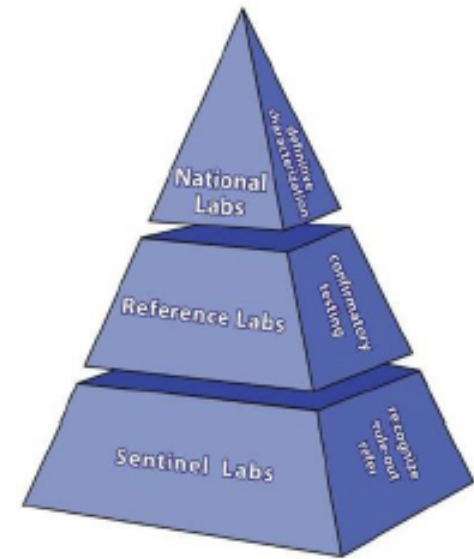
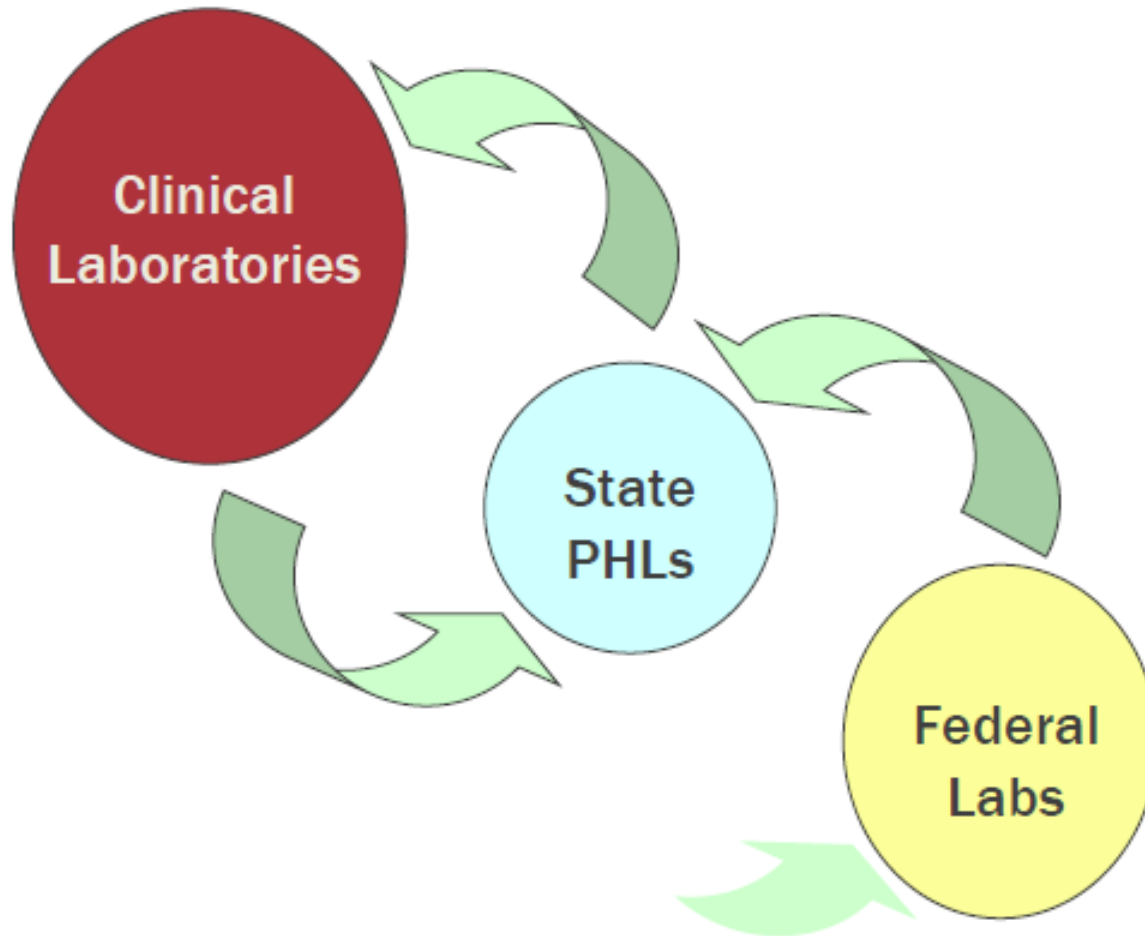
State Public Health Laboratory System

A group or system of interconnected people or things

State Public Health Laboratory System



Leadership, Connectivity and Collaboration



Examples of Critical PHL Contributions

- Rabies testing
- Newborn Screening
- Definitive testing for bioterrorism agents
 - Test “Suspicious white powders”
- TB testing
- Arbovirus surveillance
- Influenza surveillance for detection of novel strains of the virus
- Testing performed in response to outbreaks of food borne and waterborne illnesses
- Radiation monitoring for any nuclear power plant in the state



The 11 Core Functions of PHL*

- **Disease Prevention, Control and Surveillance**
- **Integrated Data Management**
- **Reference and Specialized Testing**
- Environmental Health and Protection
- Food Safety
- Laboratory Improvement and Regulation
- Policy Development
- **Public Health Preparedness and Response**
- Public Health Related Research
- Training and Education
- Partnerships and Communication



*Taken from the updated “Core Functions of Public Health Laboratories” 2014
http://www.aphl.org/AboutAPHL/publications/Documents/APHLCoreFunctionsandCapabilities_2014.pdf

PHLs work with Public Health Agencies on Disease Prevention, Control and Surveillance:

- Testing for emerging/re-emerging microbial agents; antibiotic resistance
- Screening for neonatal metabolic disorders
- Testing for environmental toxins and heavy metals
- Recognition of outbreaks
- Population-based surveillance

Public Health Laboratories

Prevent Disease And Save Money

Rabies: Annually, approximately, 8,600 animals are shown to be rabid, out of about 80,000 tested, over 71,000 individuals are spared the cost of rabies prophylaxis, a savings of over \$100 million yearly.

Chlamydia: In one year, 108,000 positive results were reported by PHL's. Estimates are that detection and treatment of these cases yielded an annual savings of \$100-400 million over the costs associated with complications of chronic infection.

Newborn Screening: The US government has determined that \$9 in medical treatment is saved for every \$1 spent in newborn screening for metabolic disorders, resulting in a savings of \$36 million annually.



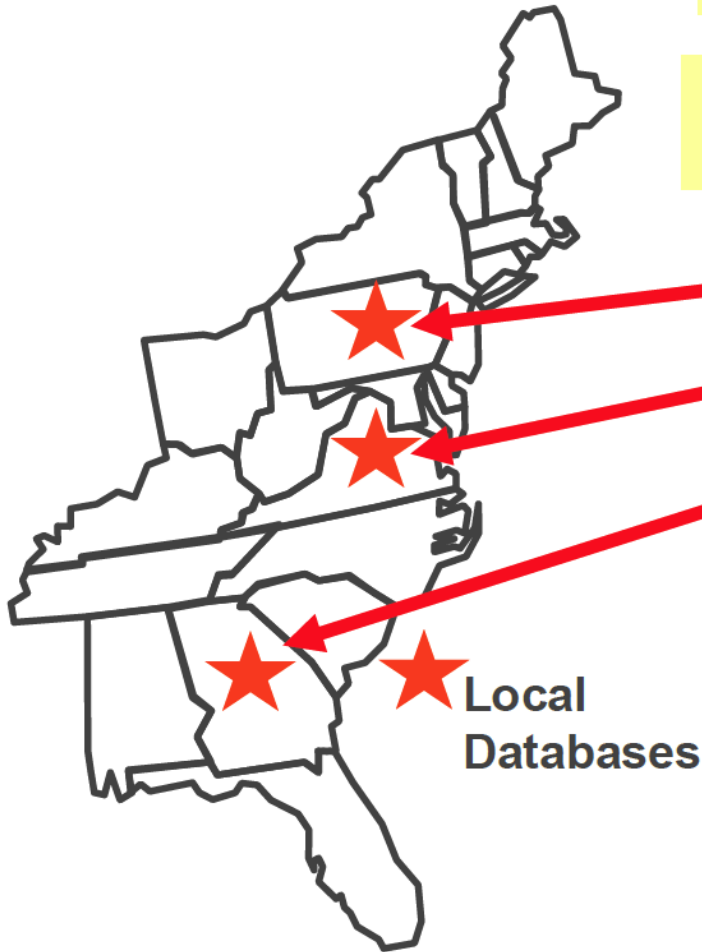
PulseNet Laboratory Network: DNA Fingerprinting

Participating Labs

PFGE Patterns & Demographic Data

PulseNet National Databases (CDC)

TAT from receipt to upload: ~4 working days

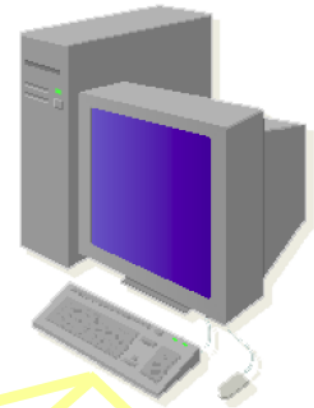


Cluster Follow-Up/Communication w/Epis



Database Management & Reports

Cluster Detection



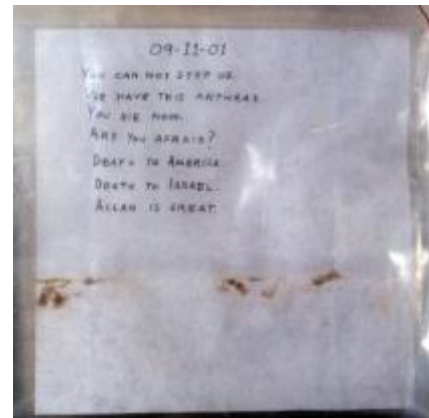
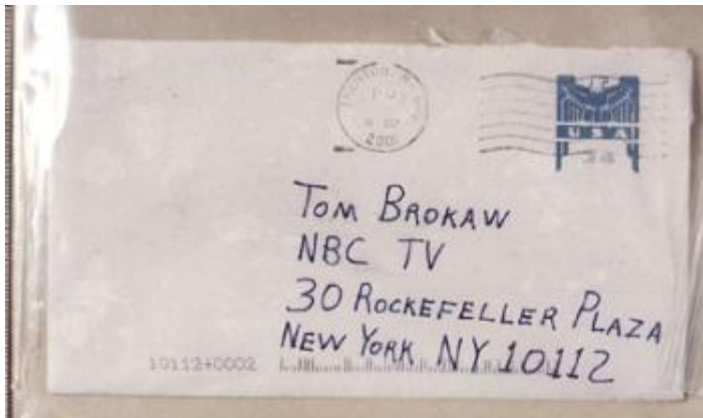
Database Management & Reports
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2/10/04 21:13:15
2/10/04 21:13:47

Public Health Preparedness and Response

- Fulfilling a key role in disaster preparedness and response (e.g. having a COOP)
- Rapidly identifying and investigating analyses of biological, chemical, and radiological agents, regardless of the source of exposure (i.e., unintentional, terrorist, or natural disaster)
- Providing surge capacity
- Participate in various lab networks (e.g. LRN)

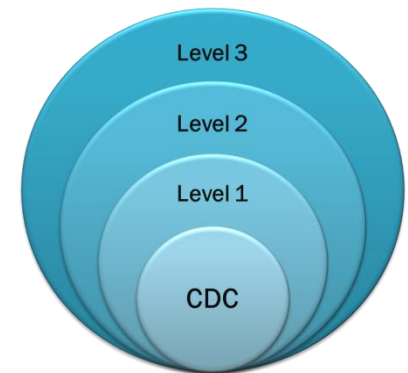
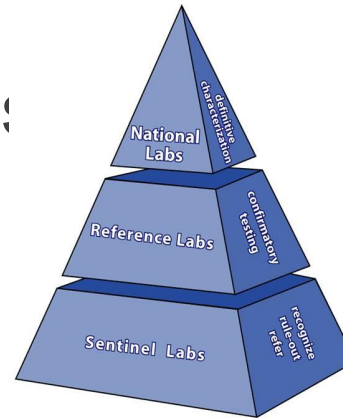


Bioterrorism Testing



The Laboratory Response Network

- Established in 1999 by the CDC, FBI, and APHL
- Includes the following types of labs:
 - Federal
 - State and Local Public Health
 - Military
 - Food
 - Environmental
 - Veterinary
 - International
 - Australia, Canada, Mexico, South Korea, United Kingdom

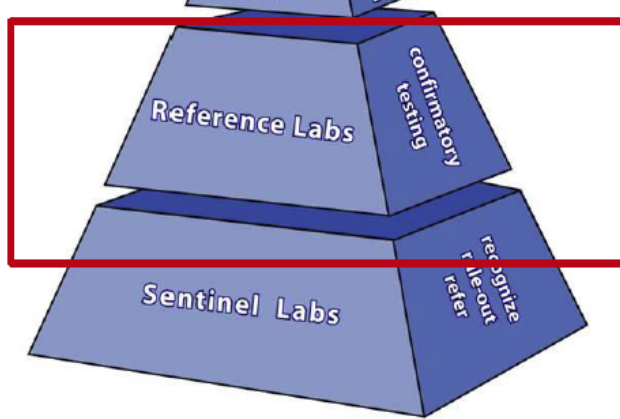
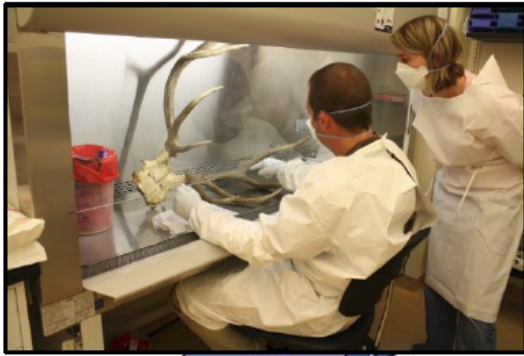


LRN-B



- Sentinel Clinical Labs
 - Recognize
 - Rule-out
 - Refer
- Hospital and private labs
- Some Local Public Health Laboratories
- ~4,200 across the U.S.

LRN-B



- Reference Labs
 - ~160; 70% are state and local PHLs
 - Confirmatory testing
 - Anthrax
 - Plague
 - Smallpox
 - Botulism
 - Other Emerging Threats
- BSL-3 capabilities

LRN-B



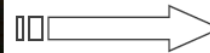
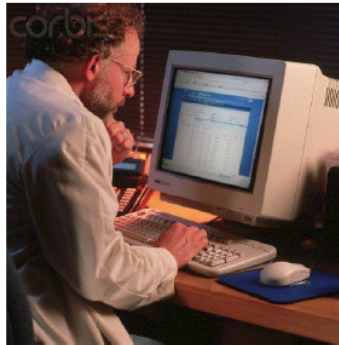
- National Labs
 - CDC
 - DoD (USAMRIID and NMRC)
- Assay Development
- Specialized testing
 - Strain characterization
 - Bioforensics
- BSL-4 capabilities

Reporting Lab Results Messenger and LIMS_i

Data Entry
In LIMS



Data Entry in
LRN Results Messenger

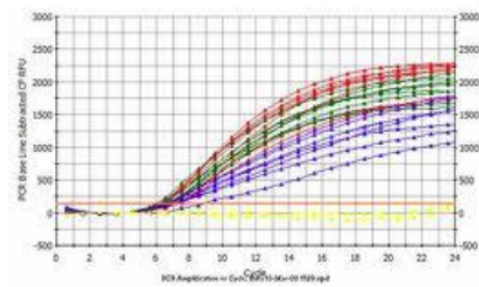


LIMS Integration (LIMS_i)



34 labs live with LIMS_i

Responding to Pandemic Influenza



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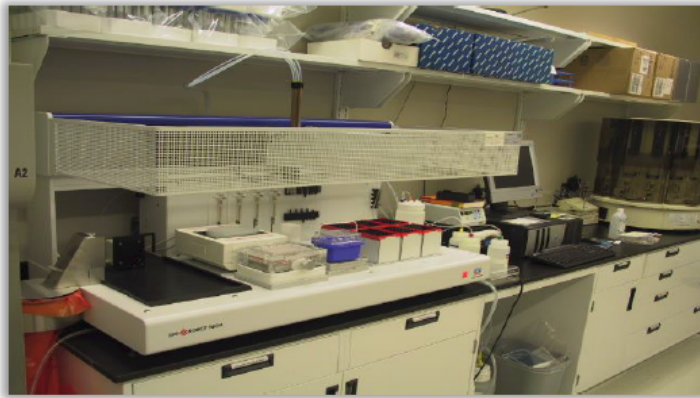
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Electronic Lab Surveillance Messaging for Influenza -



- 49 (SPHLs) can send laboratory results for Influenza directly to CDC using automated HL7 v2.3.1 messages.
- Efforts are now underway to expand the amount and quality of the information captured to include pyrosequencing and additional epidemiological data.
- PHLIP teams are preparing to apply the ELSM system to other Nationally Notifiable Diseases (NNDs).
- Using the PHLIP approach, APHL and its partners are establishing an ELSM message for Vaccine Preventable Diseases from State Centers of Excellence Labs to CDC.

Testing for Novel Influenza Viruses



H1N1 (in Texas)

- Two original cases detected in Southern California
- One of those, a 10-year-old boy, traveled to Dallas for an extended visit with relatives
- April 23 press release stated that swine flu had been confirmed by the CDC in two 16-year-old boys from Guadalupe County near *San Antonio*
- We received our first specimens on 4/24/09, one was reported as “Influenza A – Unable to type” on an 18-year-old boy from *Guadalupe County*
- Confirmed by the CDC as Swine Flu



Practitioners Responded

Day 1, April 24 th	8
Day 2, April 27 th	34
Day 3, April 28 th	530
Day 4, April 30 th	1139

The Texas Two Step

Begins with the pivot



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FLU ELSM

Return on Investment

RTI publication “Economic Analysis of the Public Health Laboratory Interoperability Project”

By 2018, ELSM for Influenza is predicted to reach
\$3.28 million in net savings for the system

Provides enhanced near real-time data to CDC Epidemiologists including epidemiologically important and sentinel data that is harmonized across the country!

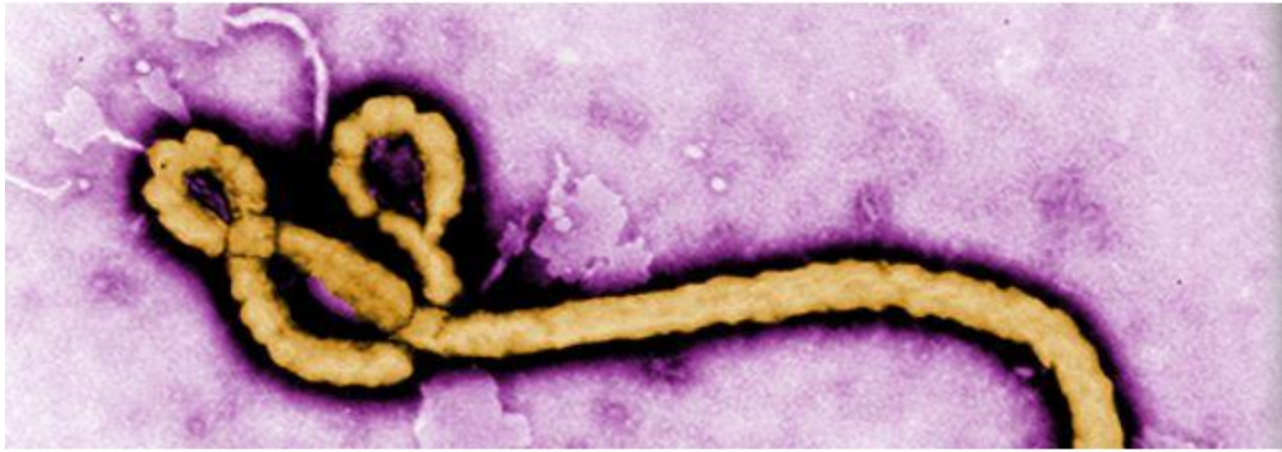
Rapid dissemination of standard codes expedited the deployment of necessary changes to capture information that could potentially reduce morbidity/mortality in the public health population.

Participating laboratories save \$8,300-\$10,500 per year by adopting FLU ELSM

State influenza virologist’s time is decreased for reporting during Influenza season (10%) and QCing data (2%)



2014 Ebola Virus Disease Outbreak



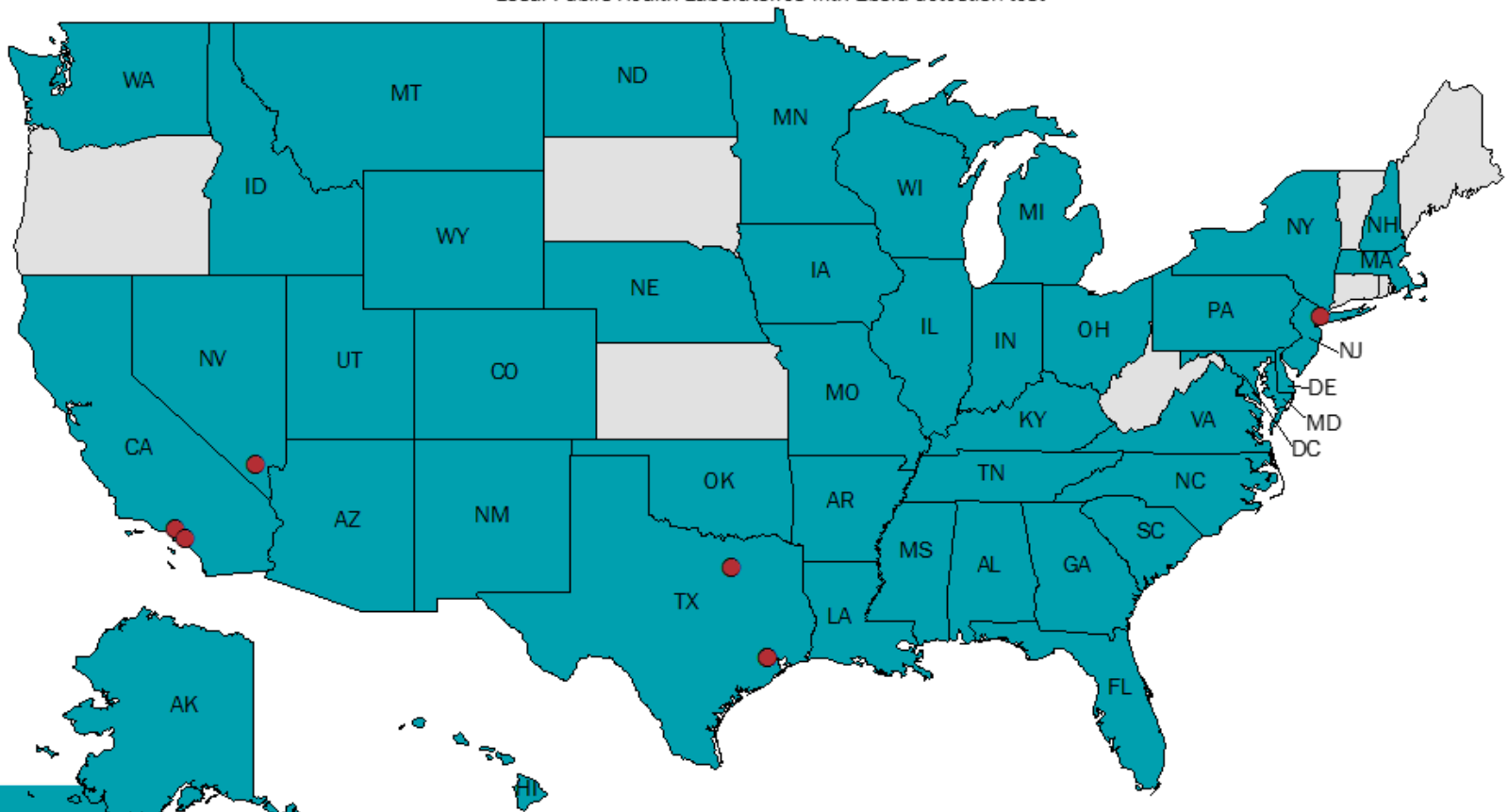
TX, CDC Confirm 1st Case of Ebola in US

This is what preparedness looks like. [Learn More »](#)

PHL's Perform Ebola Testing

Public Health Laboratories Approved to Conduct Preliminary Testing for Ebola Zaire Virus

- State Public Health Laboratories with Ebola detection test
- Local Public Health Laboratories with Ebola detection test





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Lab Challenges and Outbreak Response

- Volume of specimens (testing demand)
 - Assure quality specimens
 - Store appropriately
- Triage
 - Identify most critical
 - Sort and maintain organization
- Required additional staff
 - DSHS
 - Temporary Employees (Documentation of education and experience)
- Training
- Equipment, Supplies, Reagents



Surge Capacity Challenges

- No predictability to an epidemic
- Expectations that “testing will be available”
- Balancing public health needs with individual patient management and worried well needs and expectations
- Limited laboratory and reagent supplies
- Defining “community” for testing to confirm introduction
- Lack of federal guidance
- Need to maintain other lab testing capacity



Reporting issues

- Testing performed by other state laboratories
 - Could not readily get data into LIMS system to report
 - One state laboratory did not include CLIA number on influenza reports
- Testing done by laboratory without CLIA certification
 - No method to reconcile
 - Eventually all specimens retested in state laboratory
- Luminex RVP
 - Results for multiple viruses; only influenza result reported



IT Needs during Surge



- Interoperable, standards based IT systems for rapid sharing of results
- Laboratory resources skilled and trained in informatics systems and capabilities
- Reporting and “Big Data” capabilities for evaluating trends and response effectiveness
- Flexible, adaptable and readily accessible configuration capabilities (i.e. Ebola response required rapid re-configuration of systems to accommodate new and evolving information)
- Scalability to ensure bandwidth and processing capacity for test and report volume spikes.
- Bidirectional data exchange with Federal Agencies – NOT just during surge!

**Chris – this is where we envisioned you
transitioning to present.**



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INTEROPERABILITY AND CURRENT NATIONAL IT INFRASTRUCTURE

So what does all this mean for the movement of population data?



The Problem: Data Disjointed Across Health Care Entities



EHRs focused on personal healthcare

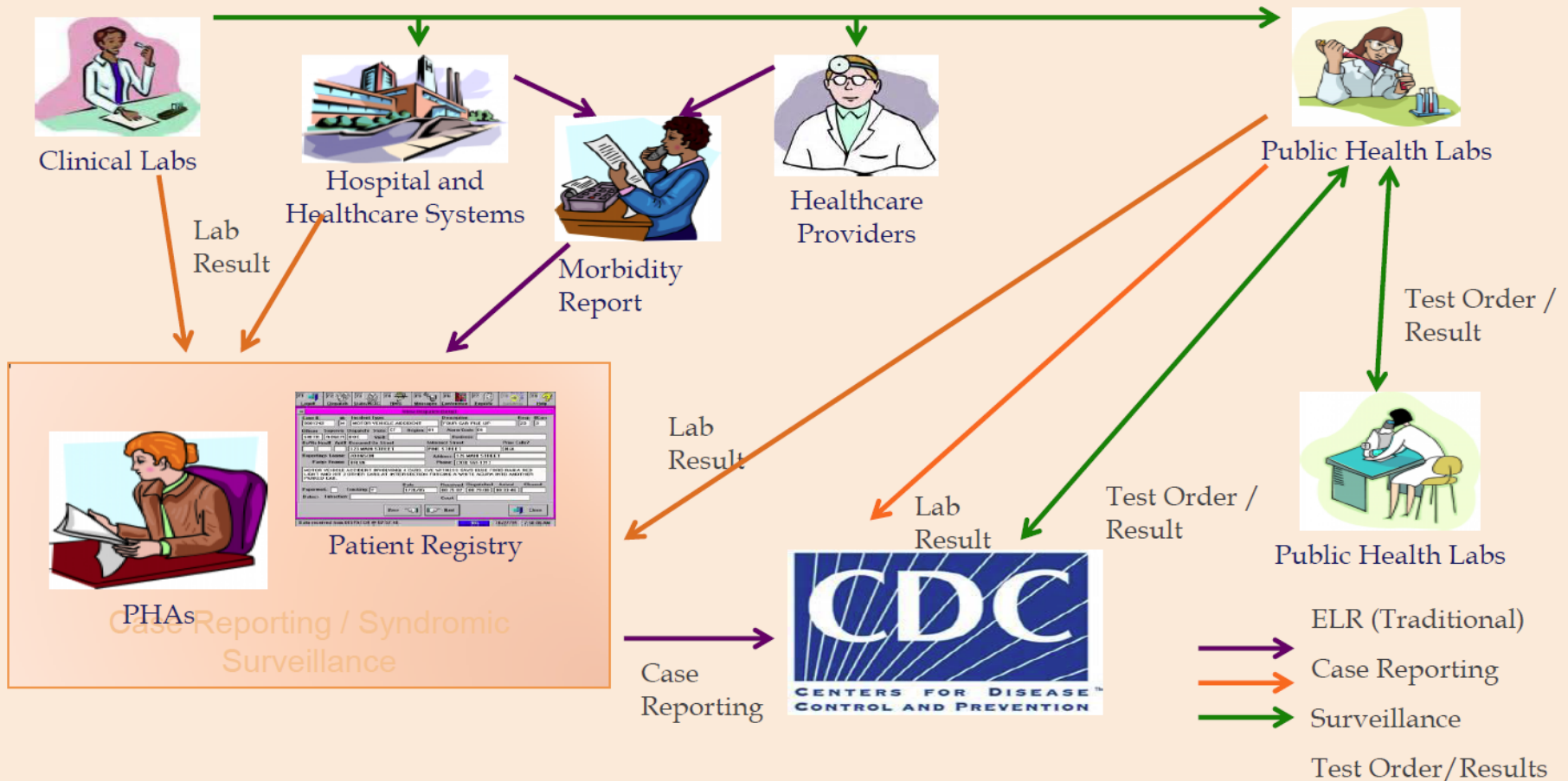
- focused on the important objective of enabling the coordination of personal care between providers and patients and over time.
- Systems to provide the context for this include patient centered care, medical homes and accountable care organizations.

But....

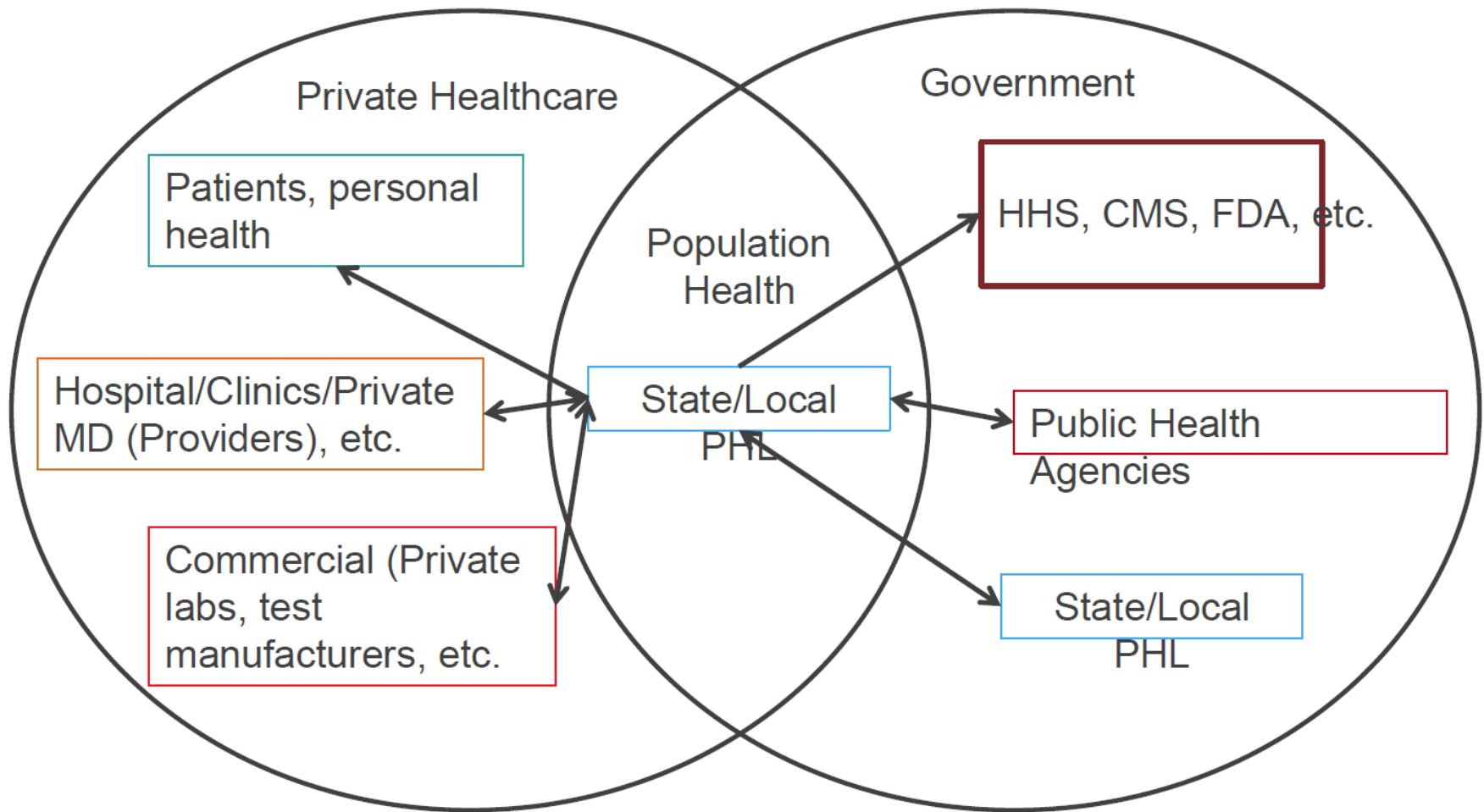
But what happens when rare, novel or highly communicable diseases can change the context of the disease management system from personal care to population focused public health services?



The Big Picture



Flow of data today with focus on the PHL



*PHL – Public Health Laboratory

Essential Capabilities of PHLs

- Identification – surveillance
 - Reference testing
 - Centralized repository for reportable or unusual conditions
- Interoperability – Semantic
 - Shared case definitions
 - Shared testing methods
- Interoperability – Transport
 - Connectivity
 - Transparency
 - Surge capacity
- Analytics
 - Bioinformatics (Future capability)

Existing structures enabling/funding the public health response:

- Laboratory Response Network
- Epi-Lab Capacity grants
- Public and private agency protocols
- NGO grants
- PHP grants

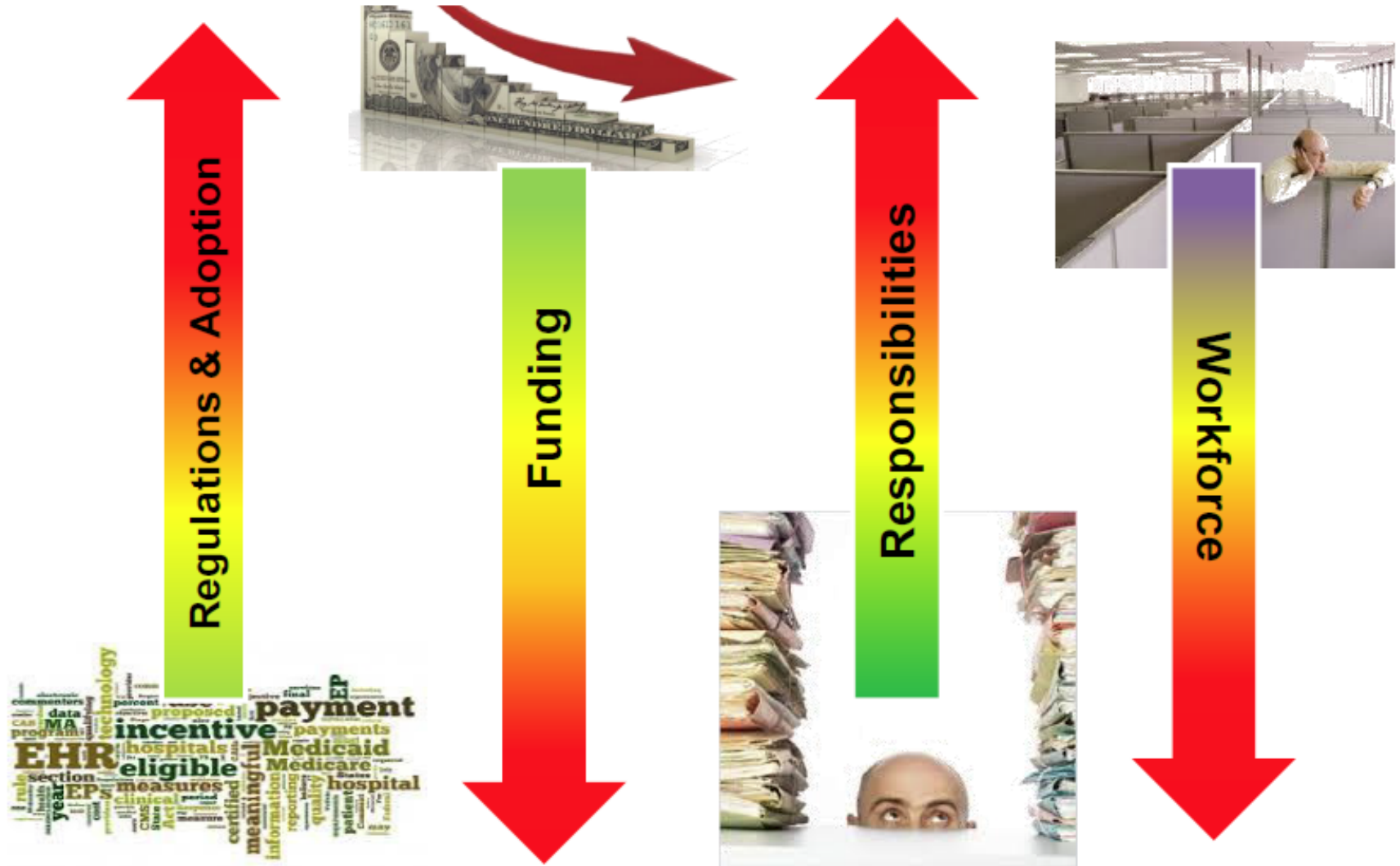
Funding and support from all these sources are shrinking every year....

Areas for HITPC Consideration

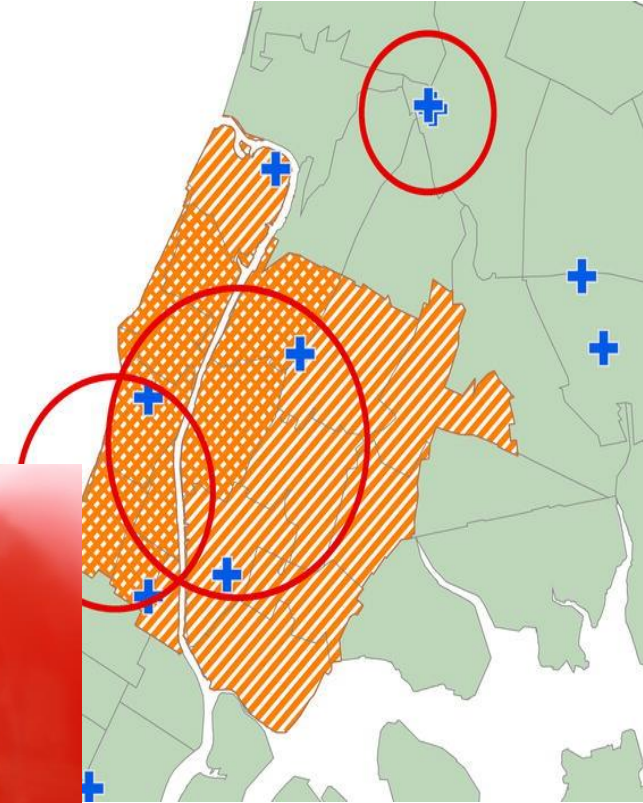
- Outbreak response is a joint effort across the public health system (lab and Epi)
- More attention on the governmental public health IT needs
- More attention to Federal IT needs



The current landscape



What we want: Early Detection, Early Warning and Surveillance



Top Concerns

- Federal Partners should be held accountable to the same technical and timing standards as commercial and PH entities
- Public health needs to be an equal and important partner/party to all HIT policy discussions and decisions.
- Public Health should be equally funded/incentivized as commercial and other healthcare entities.
- The unique and critical role of the PH community in general and the PH lab in particular must be accounted for in future policy/funding considerations.

Thank You
Questions?



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