


SUCCESSSES OF PUBLIC HEALTH LABORATORY SYSTEMS:


“SYSTEMS IN ACTION”

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Disclosure

- Nothing to disclose




Goals for Today

- Describe the Public Health Laboratory System
- Connect Global Health Security Agenda
- Provide examples of public health laboratory systems in action



What is the Public Health Laboratory System?

Short Answer:
It's MUCH more than a State Public Health Laboratory




What is the Public Health Laboratory System?

An **alliance of laboratories and other partners within a state** that supports the ten essential public health services under the aegis of the state public health laboratory. The system members and stakeholders **operate** in an **interconnected** and **interdependent** way to **facilitate**:

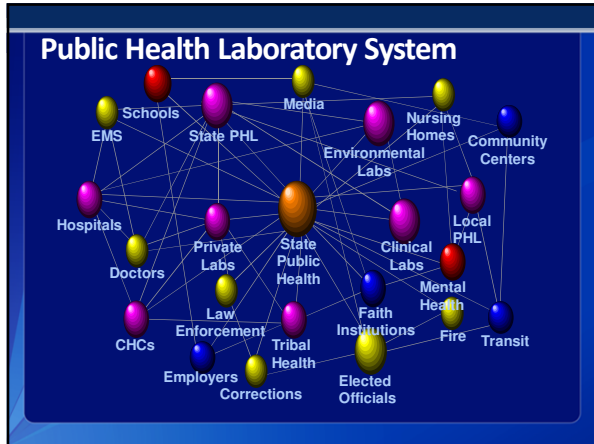
- **exchange of information**
- **optimize laboratory services**
- **control and prevention of disease and public health threats**

http://www.aphl.org/MRC/Documents/LSS_2010Jun_Definition-of-a-State-Public-Health-Laboratory-System.pdf



What is the Public Health Laboratory System?

- Intricate system of many partners
- Complex
- Dynamic
- Scale down (county, city) – scale up (state, region, nation)



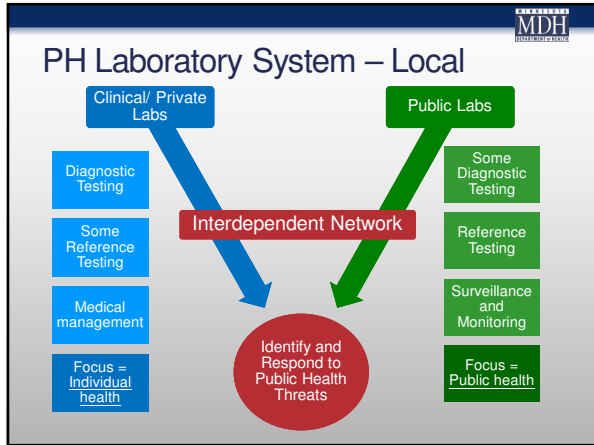
PH Laboratory System – National

52 state PHL are the interface between federal labs, and the local, hospital and private labs

Federal CDC, FDA, USDA, EPA, others

Hundreds of Local (county & city) PHL

Thousands of hospitals, private labs



PH Laboratory System – Local


Minnesota Laboratory System (MLS)

An integrated network of public and private clinical laboratories working together to protect and improve the health of all Minnesotans



Global Health Security Agenda (GHSA)


- Antimicrobial Resistance
- Biosafety and Biosecurity




Antimicrobial Resistance - GHSA

Desired National Impact:

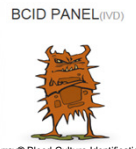
- Enhance infection prevention and control activities to prevent the emergence and spread AMR, especially among drug-resistant bacteria
- Strengthen surveillance and laboratory capacity






Antimicrobial Resistance - Local


- Goal towards rapid POC diagnostics




mecA, van A/B, KPC



CTX-M (ESBL); IMP, KPC, NDM, OXA, VIM







Antimicrobial Resistance – White House

National Strategy for Combating Antibiotic-resistant bacteria:


- Prevent, detect, and control outbreaks of resistant pathogens recognized by CDC as urgent or serious threats -
 - Carbapenem-resistant Enterobacteriaceae (CRE)
 - Ceftriaxone-resistant *N. gonorrhoeae*
 - *C. difficile*
 - *S. aureus* (MRSA)






Antimicrobial Resistance – CDC

Urgent: high-consequence antibiotic-resistant threats because of significant risks identified across several criteria.



Untreatable and hard-to-treat infections from carbapenem-resistant Enterobacteriaceae (CRE) bacteria are on the rise among patients in medical facilities. CRE have become resistant to all or nearly all the antibiotics we have today. Almost half of hospital patient bloodstream infections from CRE bacteria die from the infection.

http://www.cdc.gov/drugresistance/biggest_threats.html






Antimicrobial Resistance – Local – MN

The Public Health Lab System in Action...






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Antimicrobial Resistance – Local - MN

Carbapenem Resistant Enterobacteriaceae CRE:

- Epidemiology and Laboratory Capacity (ELC)
- Emerging Infections Program (EIP)
- Multi-site Resistant Gram-negative bacilli Surveillance Initiative (MuGSI)







Antimicrobial Resistance – Local - MN

Carbapenem Resistant Enterobacteriaceae CRE:

- 2009 – first identified KPC – started passive surveillance and isolate submission
- June 2011 – started active surveillance
 - 2-county metro area – 11 labs
 - Queries set-up on automated instruments - monthly
 - Breakpoints not adjusted down (FDA vs CLSI)
 - Challenging and complex
- 2015 – will be reportable statewide







Antimicrobial Resistance – Local - MN

CRE Surveillance:

- Challenges –Laboratory & Epidemiology/IP
 - Definition difficult to apply
 - Lack of understanding of complexities
 - CRE vs CP-CRE
 - Carbapenemases
 - Breakpoints
 - “expert systems”
- Non-standardized reporting of results







Antimicrobial Resistance – Local - MN

CRE Laboratory Capacity at MN-PHL:

- KPC/NDM PCR
- Multi-plex PCR: VIM, IMP, OXA, CTX-M (ESBL)
- CarbaNP
- Connected to CDC
- Outreach to Clinical Labs
 - Consultation
 - Provide CLSI M100
 - Communication – MLS messages






Antimicrobial Resistance – Local - MN

CRE Surveillance:

- Regional collaboration – Epidemiology & Lab
 - Minnesota
 - North Dakota
 - South Dakota
- Provide testing
- Training – sharing of testing algorithms
- Screening protocols (*up next*)






Antimicrobial Resistance – Local – IN

The Public Health Lab System in Action...

Indiana State Department of Health Lab







Antimicrobial Resistance – Local – IN

Carbapenem Resistant Enterobacteriaceae CRE:

- Assess the needs
 - Automated systems, training, CLSI
- Built testing capabilities
 - Sentinel labs – workshops, CRE guidelines
 - ISDH Lab - KPC/NDM PCR, MBL, MHT, 12-disk
- Provided testing and technical support
 - CRE confirmation, feedback, isolate submission

Dr. Lixia Liu, Indiana State Dept. of Health Labs




Antimicrobial Resistance – Local – IN

Carbapenem Resistant Enterobacteriaceae CRE:

- Expanded efforts beyond the lab
 - Formed Indiana Antibiotic Resistance Advisory Committee
- Established CRE surveillance guidelines
 - Recommends best practices and guidelines

Dr. Lixia Liu, Indiana State Dept. of Health Labs



Global Health Security Agenda (GHSA)

PREVENT
LEARN MORE

- Antimicrobial Resistance 
- Biosafety and Biosecurity 

Biosafety and Biosecurity - GHSA

Desired National Impact

- A cadre of **biological risk management experts** possessing the skillset to train others
- Strengthened sustainable **biological risk management best practices** in place using common educational materials
- National oversight program for biosafety and biosecurity, including the **Select Agent Program**, management, storage, disposal and containment of pathogens.




Biosafety and Biosecurity - GHSA

Desired National Impact (cont.)

- Goal towards POC diagnostics

Consequences

- Good News – no isolates to worry about
- Bad News – no isolates to characterize



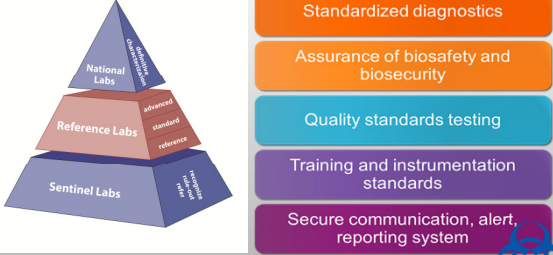

Biosafety and Biosecurity - Local - MN

The Public Health Lab System in Action...






Biosafety and Biosecurity – Local

Laboratory Response Network (LRN)


Biosafety and Biosecurity - Local - MN

- Leveraging the LRN – distribution of Ebola assay
- Lab Safety – Biosafety risk assessment
- Trained staff and documented competency
- Available 24/7
- Sentinel Laboratory Outreach
 - MLS alerts
 - MLS state-wide conference calls
 - Packaging and Shipping
 - Specimen transport
 - On-site biosafety risk assessments

Biosafety and Biosecurity - Local - MN
Ebola Preparedness - Gaps


- Disagreements about safety of lab testing
- Unsafe practices common place in lab settings – did not trust Universal Precautions
- Disconnect with manufacturers of lab equipment/instrumentation - decontamination



Biosafety and Biosecurity - Local - MN
Ebola Preparedness - Gaps

- Lack of experts in Lab Biosafety – Infectious Agents
- Labs short-staffed – not enough time dedicated to biosafety issues
- Lack of a “culture” of biosafety


How many had performed a biosafety risk assessment before Ebola?



Biosafety and Biosecurity - CLIAC
CLIAC – April 2015:
Clinical Laboratory Improvement Advisory Committee


Made four recommendations to the Secretary of HHS

Acceptance and implementation of committee recommendations is at the discretion of the agency




Biosafety and Biosecurity - CLIAC
CLIAC – April 2015: With regard to emerging infections, HHS should:

- Provide oversight that ensures assessment of the safety and decontamination of laboratory instrumentation by manufacturers.
- Ensure that biosafety training and assessment is required of all CLIA-certified laboratories, including personnel responsible for pre-analytical, analytical, and post-analytical phases of testing.



Biosafety and Biosecurity - CLIAC
CLIAC – April 2015: With regard to emerging infections, HHS should:

- Ensure oversight, input, and resources into studies evaluating the safety of all laboratory practices, instrument testing, etc., so that studies are sound, robust, evidence-based, and applicable.
- Develop a process for investigating and reporting laboratory acquired infections.



Biosafety and Biosecurity - Local - MN
 The Public Health Lab System in Action...

85 LRN
 Advanced Sentinel
 Labs

LRN Reference Lab
 - State Public Health Lab

Biosafety and Biosecurity - Local - MN
 The Public Health Lab System in Action...

Inhalational Anthrax Case

Biosafety and Biosecurity - Local - MN

- 61 yo male from FL spent 3 weeks traveling through MN, ND, MT, WY, SD
- On return to MN developed headache, cough, rigors and fatigue
- Sought care at hospital
- Noted to have shortness of breath on admission and a right sided infiltrate

Biosafety and Biosecurity - Local - MN

- Gram Stain: gram positive, spore-forming bacillus
- Catalase positive

Biosafety and Biosecurity - Local - MN


"Our job is to rule out and refer, which means that if we suspect an organism of bioterrorism, and can't rule it out with the testing in house, we must refer it to the MDH (instead of our normal reference lab) for further testing"

Dawn Henkes

Global Health Security Agenda (GHSA)

DETECT
 LEARN MORE


- Real-Time Surveillance
- National Laboratory System




Real-Time Surveillance - GHSA

Desired National Impact:


- A functioning and strengthened PH surveillance system capable of identifying potential events of concern for public health, animal health and health security.






Real-Time Surveillance - GHSA

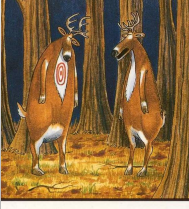
- Surveillance for at least 3 core syndromes indicative of potential PH emergencies:
 1. Severe acute respiratory syndrome
 2. Acute flaccid paralysis
 3. Acute hemorrhagic fever
 4. Acute watery diarrhea with dehydration
 5. Jaundice with fever
- Includes early warning surveillance data and lab findings







Real-Time Surveillance – Local – MN PH Laboratory System in Action...

- ER Doc that notices something unusual...
- Two high school students visiting ER:
 - Bloody diarrhea
 - Outdoor Adventures Class
 - Helped butcher deer
 - Made venison kabobs, grilled and ate...



"Bummer of a birthmark, Hal."







Real-Time Surveillance – Local - MN

6 lab-confirmed STEC infections

- 5/6 had only Shiga toxin 1 by MDH PCR
- 1/6 negative for Stx1 – grew non-O157 *E. coli*
- 2 hospitalized students = O103:H2
- 2 students = O145:NM (1 also had norovirus)
- 2 students = isolates not typeable

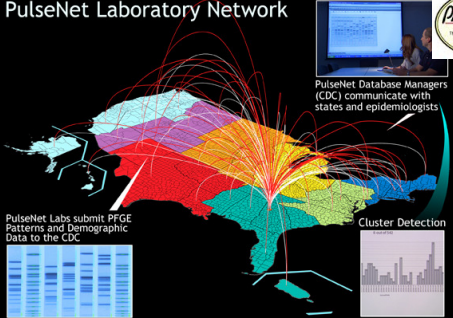
22 cases not lab-confirmed





Real-Time Surveillance – National


PulseNet Laboratory Network




PulseNet Labs submit PFGE Patterns and Demographic Data to the CDC

PulseNet Database Managers (CDC) communicate with states and epidemiologists

Cluster Detection



The National Network of Public Health Laboratories
in Partnership with the Centers for Disease Control and Prevention






Global Health Security Agenda (GHSA)




- Real-Time Surveillance 
- National Laboratory System 




National Laboratory System - GHSA

5 Year Targets

- A nationwide lab system able to reliably conduct at least 5 of 10 core tests...
- on appropriately identified and collected outbreak specimens...
- transported safely and securely to accredited labs...







National Laboratory System - GHSA

Desired National Impact:

Effective use of a nationwide laboratory system capable of **safely and accurately detecting and characterizing pathogens causing epidemic disease**, including both known and novel threats, from all parts of the country.

Expanded deployment, utilization, and sustainment of modern, safe, secure, affordable and appropriate **diagnostic tests or devices**.







National Laboratory System - GHSA

A nationwide lab system able to reliably conduct at least 5 of 10 core tests

1. Influenza PCR
2. Poliovirus culture
3. HIV serology
4. *M. tuberculosis* – microscopy
5. *Plasmodium spp.* – rapid Dx
6. Salmonella Enteritidis serotype Typhi – culture
7. 4 other tests – major national public health concern





Diseases Reportable to the Minnesota Department of Health

(List of reportable diseases with checkboxes)

Poliomyelitis


Malaria (*Plasmodium sp.*)


HIV

Salmonellosis, including typhoid

Influenza, hospitalized cases

Tuberculosis






National Laboratory System – Local – NH


The Public Health Lab System in Action...


New Hampshire Public Health Laboratories



Helping Protect the Community Through Service & Education


Jill Power, NH PHL






National Laboratory System – Local – NH


New Hampshire – Hep C/drug diversion

- May 15, 2012: suspected HCV cluster reported by hospital to NH DPHS 
- Epidemiology Response
- Laboratory Response – PH and clinical
- CDC Collaboration
- HCW worked in 7 states



National Laboratory System – Local – NH

- Investigation ongoing for one year
- >150 staff - epidemiologists, PH nurses, lab staff, emergency services unit workers, administrators, and support staff
- July 19, 2013: HCW arrested




National Laboratory System – Local – NH

Two phases of investigation/testing:

- **Phase 1:** Cardiac cath lab/recovery room patients
 - 1214 tests – 32 patients + for outbreak “strain”
- **Phase 2:** ICU/OR expansion
 - 1167 tested – all POC retested
 - 22 patients screen +
 - subsequent testing = not related to the outbreak “strain”



<http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/documents/hepc-outbreak-rpt.pdf>



National Laboratory System – Local – NH

Leveraging the PH Lab System

- PHL notified LRN labs (13) via HAN message to recruit volunteers for 8 clinics
- 24 PH and clinical lab testing personnel were recruited and trained

Hospital tech who spread hepatitis C through drug use sentenced to 39 years



This undated file photo provided by the U.S. Attorney's Office in New Hampshire shows David Kwiatkowski, a former lab technician at Exeter, N.H. The traveling hospital technician was sentenced to 39 years in prison on Monday, Dec. 2, 2013. AP

CBS News/AP December 2, 2013, 2:47 PM



Strong PH Laboratory Systems...How?

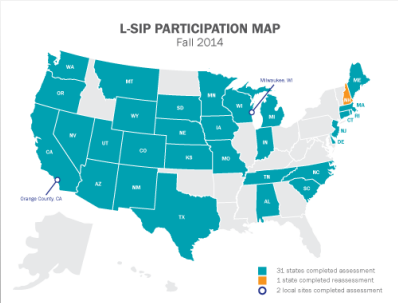
How does it happen?

- CDC programs and support
 - Laboratory Response Network – LRN
 - PulseNet
 - Grant funding – ELC, EIP, MuGSI
- APHL programs and support
 - Laboratory System Improvement Program (LSIP)


Strong PH Laboratory Systems...How?

Laboratory System Improvement Program


L-SIP PARTICIPATION MAP
Fall 2014



L-SIP
Make the Connections

 Strong PH Laboratory Systems...How?


- Lab Program Advisor
- Partnership
- Outreach
- Communication
- Relationship Building
- Mutual Respect


 Public Health Laboratory System

Conclusions

- Many strong PH Lab Systems
- Important to continue to strengthen and sustain

Strong Local/State/Regional Public Health Laboratory System = a Strong National Laboratory System





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