Division of Laboratory Systems

OneLab

Public Health Laboratories (PHL) 101

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Erin Bowles, BS, MLS(ASCP)
Jasmine Chaitram, MPH, MLS(ASCP)

September 9, 2022

Agenda

- Introduction
  - *Today's Presenters:*
    - Robert Nickla RBP, QLS, M (ASCP) CM
    - Erin Bowles, BS, MT(ASCP)
    - Dr. Michael A. Pentella, PhD, D(ABMM)
    - Jasmine Chaitram, MPH, MLS (ASCP)
  - *Upcoming OneLab™ Resources*
    - Alicia Branch, PhD
- Main presentation: Public Health Laboratories (PHL) 101
- Q&A
- OneLab Network Updates

Today's Presenters

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Fellowship Program Manager

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Today's Presenters

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Wisconsin Clinical Laboratory Network Coordinator

Wisconsin State Laboratory of Hygiene

Communicable Disease Division

University of Wisconsin-Madison School of Medicine and Public Health

Today's Presenters

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Clinical Professor

University of Iowa

Today's Presenters

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Associate Director for Laboratory Preparedness

Division of Laboratory Systems (DLS)

Centers for Disease Control and Prevention (CDC)

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Coming Soon!

Laboratory Emergency Preparedness Response Guide

The Emergency Preparedness Response Guide covers available resources for biological, chemical, and radiological emergencies for laboratories to reference during an emergency. It can also help train new laboratory professionals hired to support emergency responses.

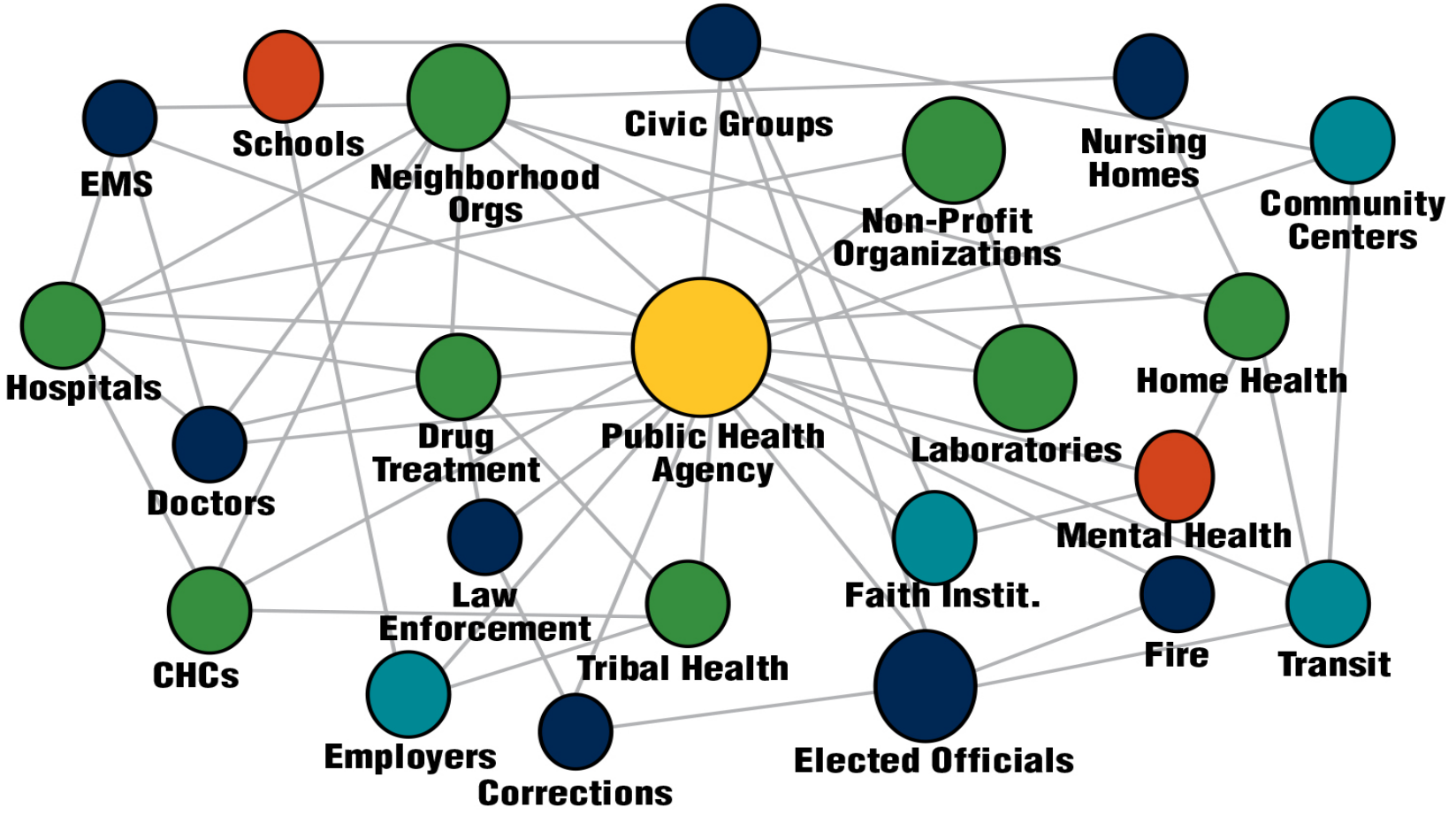
Disclaimer

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Objectives

1. Identify the core functions of public health laboratories.
2. Explain how the public health laboratory interacts with partners and customers, including other laboratories.
3. Describe the role of federal, state, and local agencies and organizations within the public health laboratory system.

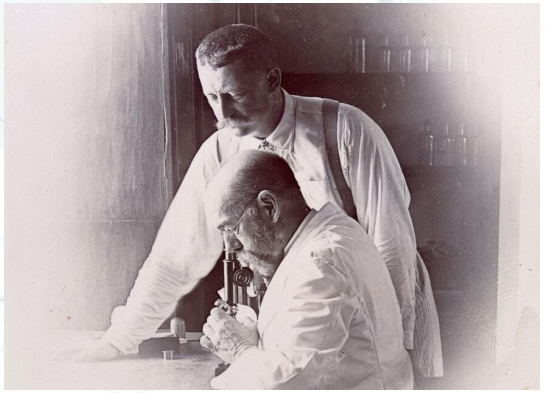
What is public health?



[1] https://www.cdc.gov/publichealthgateway/zz-sddev/essentialhealthservices.html

Evolution of Public Health Laboratories (PHLs)

As our knowledge increases, testing methods and safety practices improve.

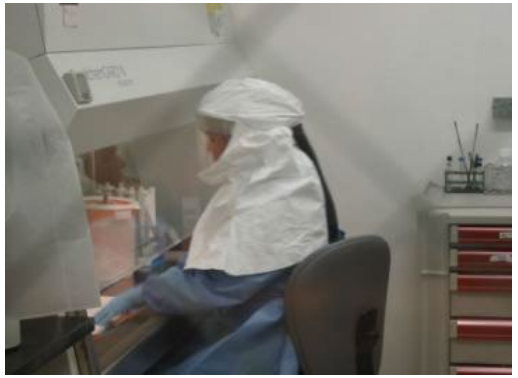


1890's

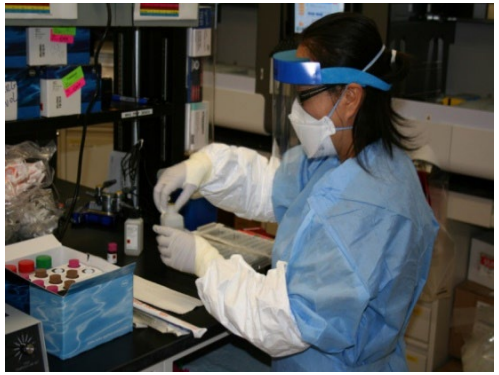
1930's

1950's

1980's



2000's



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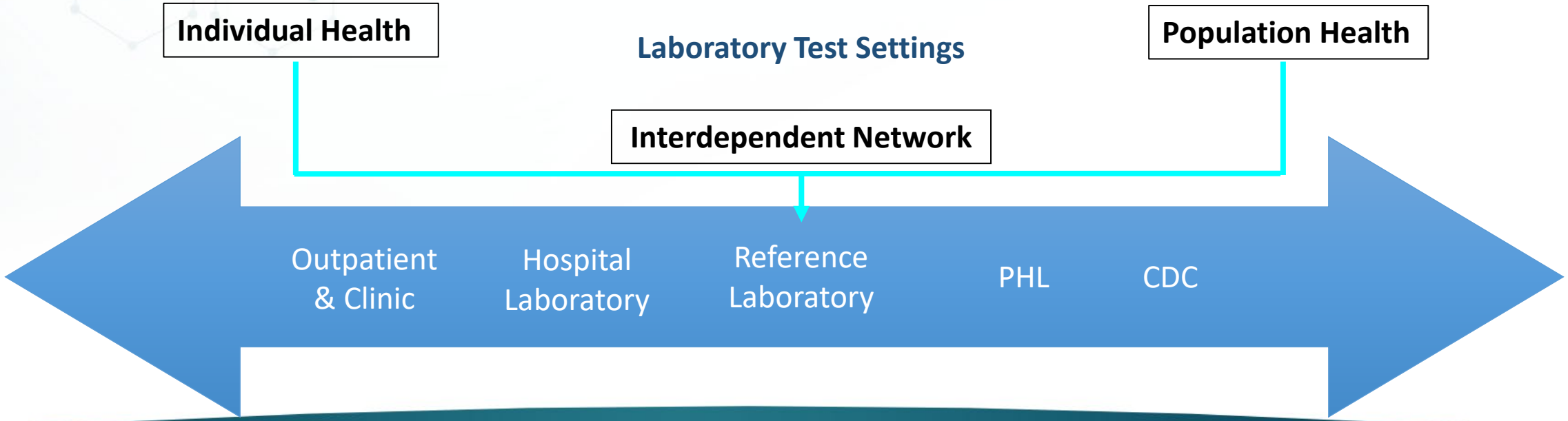
Role of Clinical Laboratories vs. PHLs

Clinical Laboratories

- Initial diagnostic testing
- Point-of-care testing
- Some reference testing
- Patient management
- Frontline response
- Provide specimens and data to PHLs

PHLs

- Specialized diagnostic testing
- Reference testing
- Surveillance and monitoring with CDC
- Guidance to clinical laboratories



The 11 Core Functions of PHLs

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MMWR

Recommendations and Reports

September 20, 2002 / 51(RR14);1-8

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Core Functions and Capabilities of State Public Health Laboratories

A Report of the Association of Public Health Laboratories

Prepared by

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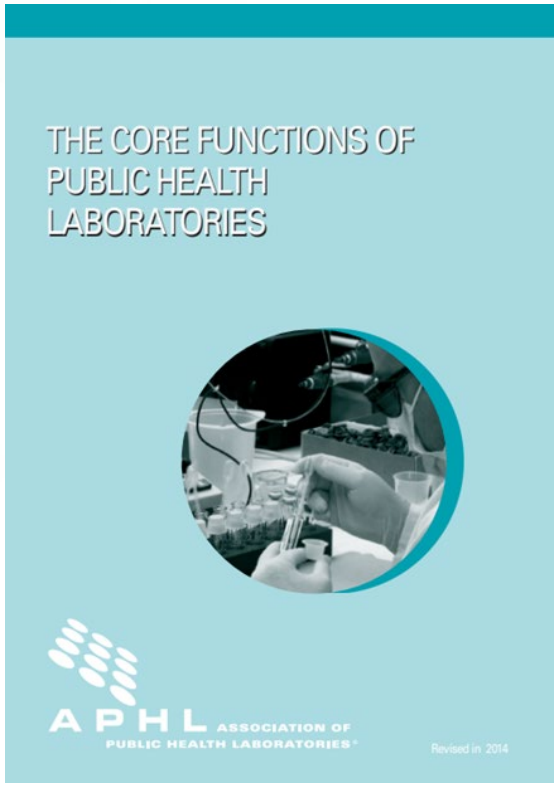
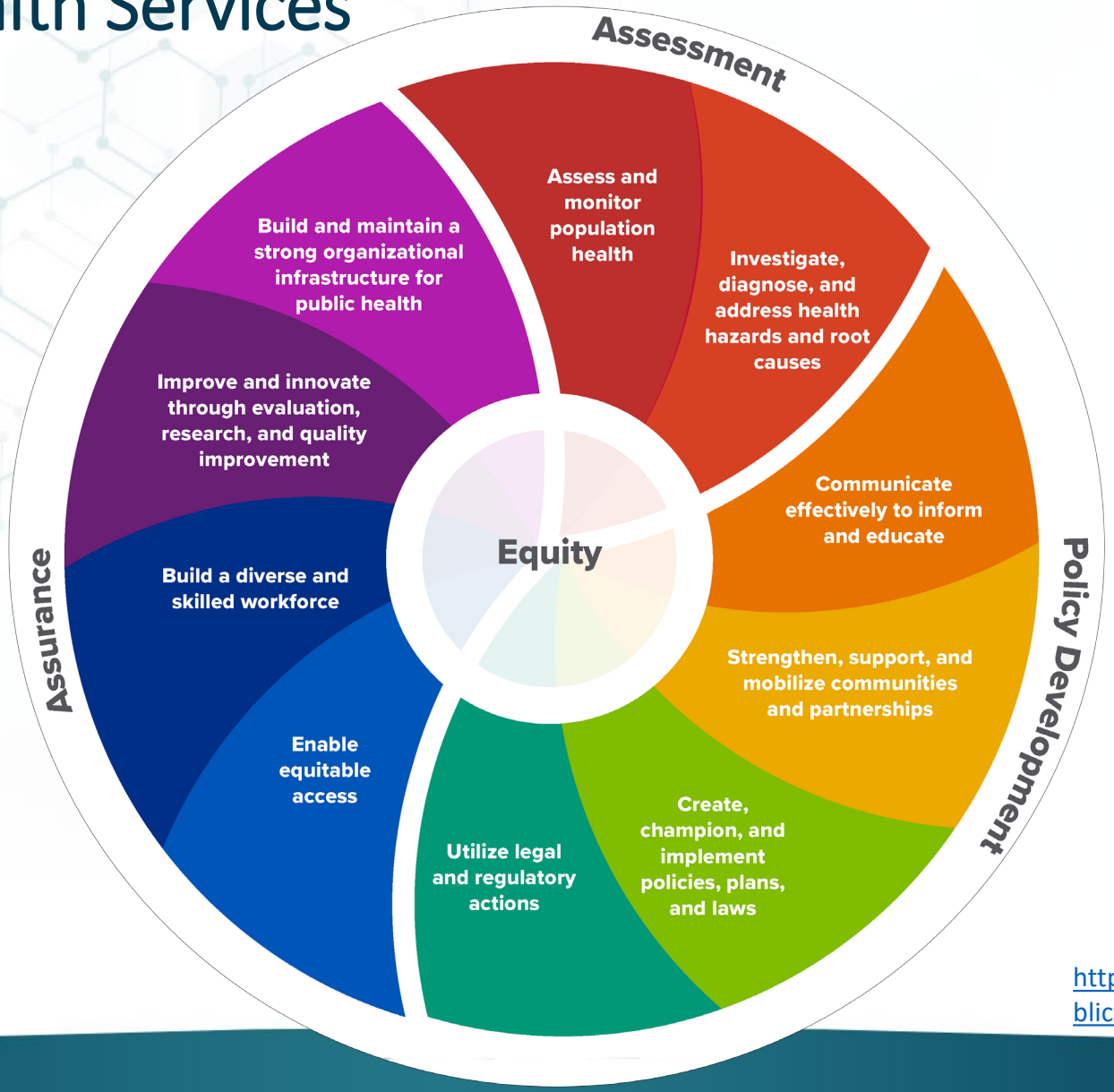
https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5114a1.htm [2]



https://www.aphl.org/aboutAPHL/publications/Documents/APHLCoreFunctionsandCapabilities_2014.pdf [3]

Essential Public Health Services [4,5]



https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html [4]

The 11 Core Functions of PHLs

- Disease prevention, control, and surveillance
- Reference and specialized testing
- Food safety
- Emergency response
- Environmental health and protection
- Partnerships and communication
- Training and education
- Integrated data management
- Public health-related research
- Laboratory improvement and regulation
- Policy development

Disease Prevention, Control, and Surveillance

PHL Key Services

PHLs conduct laboratory testing of public health significance.

Data-driven results

- Lead to actionable decision-making
- Key partnerships between PHLs, CDC, epidemiologists, clinicians, and other healthcare professionals

Surveillance systems

- Nationally notifiable disease reporting system
- State-specific disease reporting requirements

Tracking life-threatening infections

Disease Prevention, Control, and Surveillance

National Notifiable Disease Surveillance System

~120 diseases under surveillance

Infectious diseases

Noninfectious conditions

Basis for state-specific disease reporting rules

[6] https://www.cdc.gov/nndss/index.html

Disease Prevention, Control, and Surveillance

PHLs and Outbreak Detection

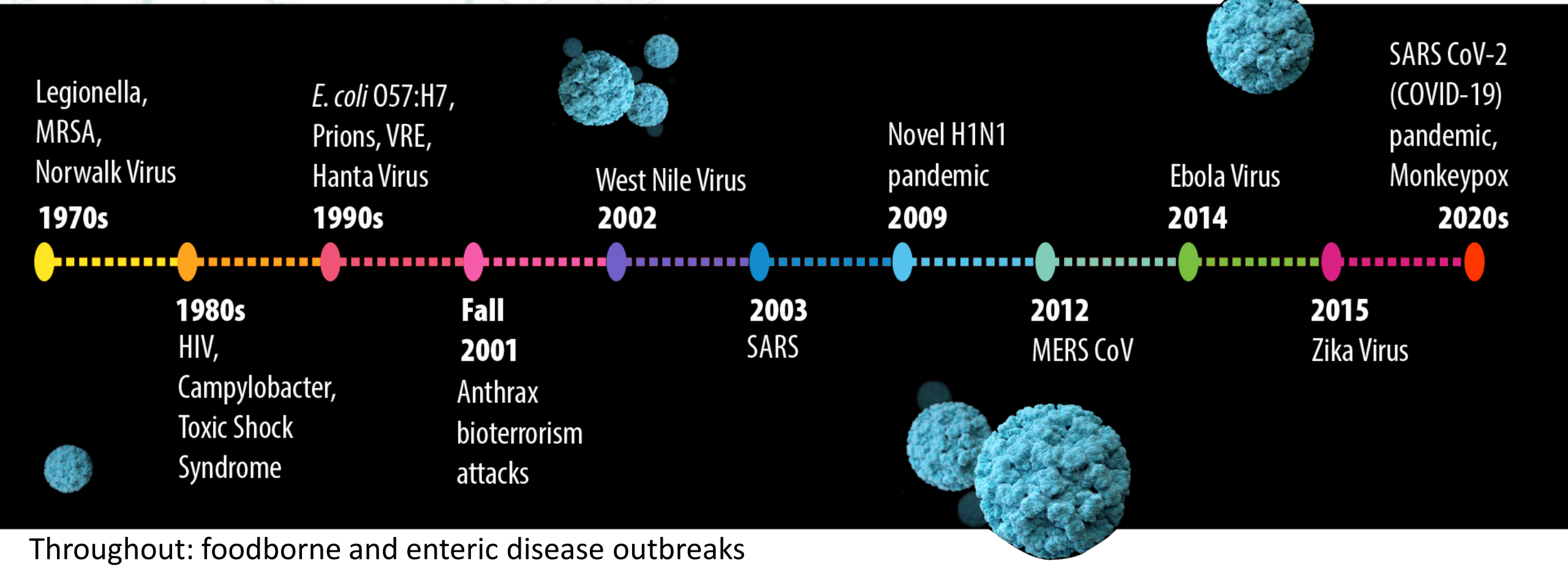
Outbreak detection → Disease control measures prevent spread

- Confirming diagnoses and detecting clusters of infections reveals common sources to address.
- Confirming early detection of emerging diseases by laboratory identification methods.
- Identifying drug resistance patterns ensures proper treatment.

Monitor emerging and/or circulating strains

Disease Prevention, Control, and Surveillance

Timeline of Significant Outbreaks and Events



Throughout: foodborne and enteric disease outbreaks

- Pictured: Norovirus

Reference and Specialized Testing

PHL Key Testing

PHLs perform millions of individual tests per year ranging from:

- Sexually Transmitted Diseases/Sexually Transmitted Infections (STDs/STIs)
- Biological, chemical, and radiological threat events
- Zoonotic diseases
- Blood lead testing
- Arboviral diseases surveillance
- Seasonal influenza testing
- Emerging and re-emerging pathogens

Reference and Specialized Testing

PHL Key Testing Services

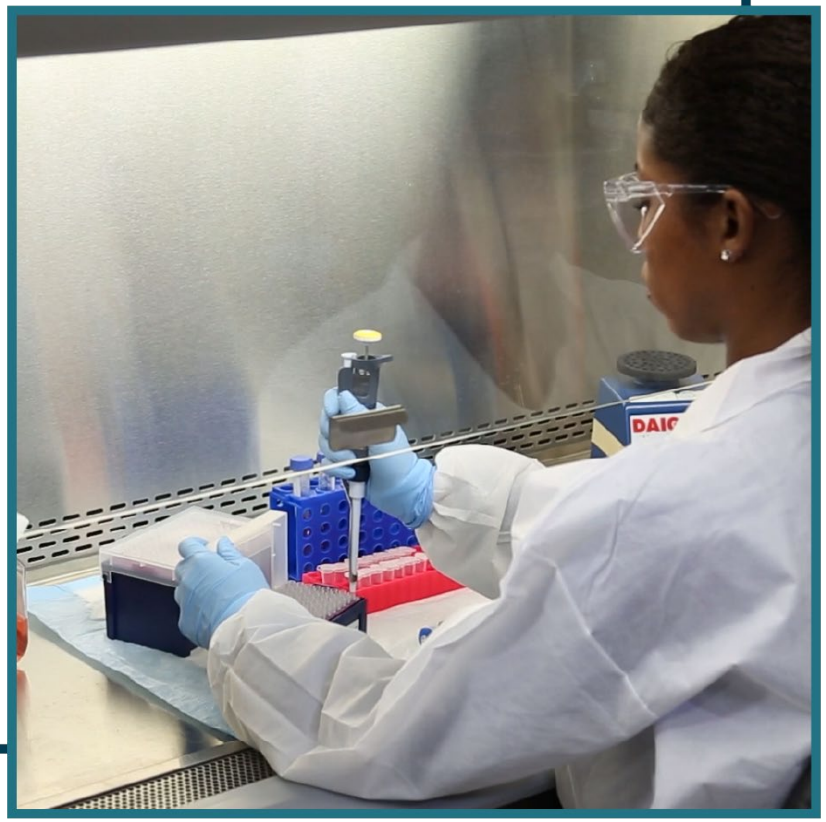
PHLs have high containment facilities such as Biosafety Level 3 (BSL-3) laboratories, critical equipment, and trained staff.

Maintain capacity to bring on new tests

- MERS-CoV
- Ebola virus
- Highly pathogenic influenza strains like H7N9 or H5N1

Members of the Laboratory Response Network (LRN)

- Biological and chemical threat preparedness and response
- Infectious disease surveillance networks with CDC



Reference and Specialized Testing [7]

Newborn Screening Programs and PHL Testing

Each year, almost 100% of all newborns in the U.S. are routinely screened for certain genetic, endocrine, and metabolic disorders. This is millions of babies each year.

Screening identifies serious but rare metabolic disorders and other conditions that can affect a child's long-term health or survival.

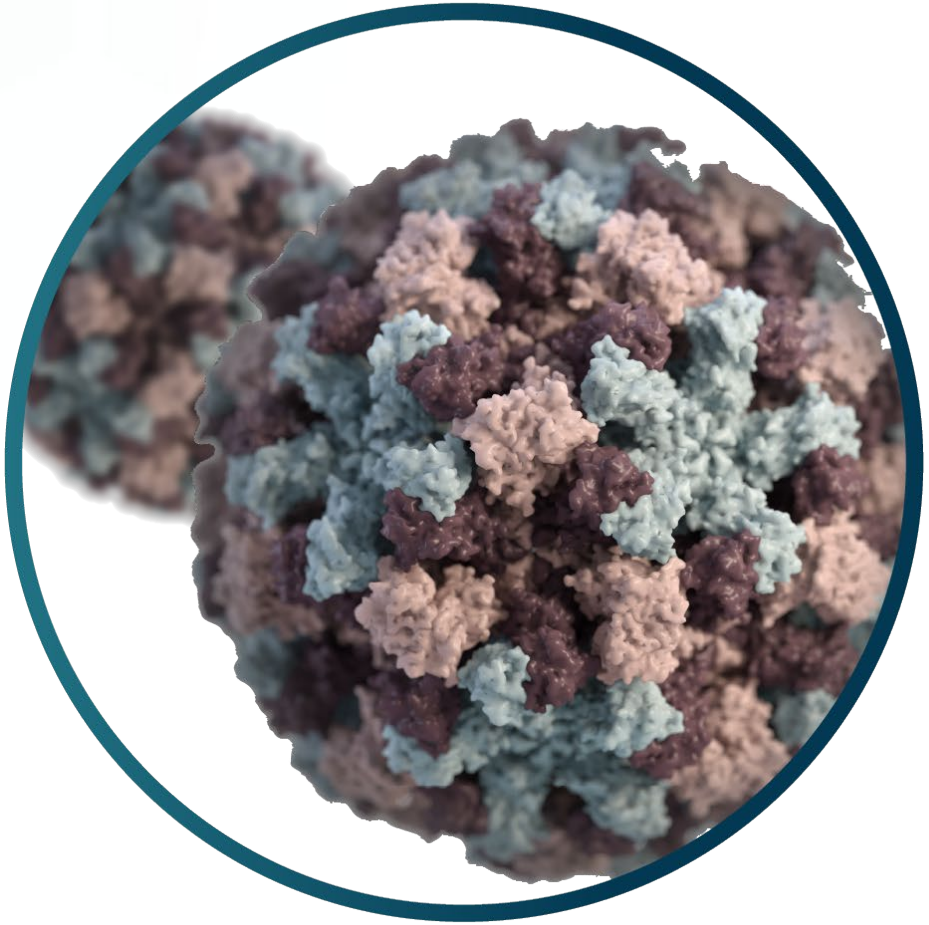
Early detection, diagnosis, intervention, and treatment can prevent death or disability and enable children to reach their full potential.

Reference and Specialized Testing

State and Local PHL Key Testing Services

PHLs maintain unique, rare, and specialized “gold standard” diagnostic tests and methods.

- Ability to safely handle and confirm biological Select Agents
- High confidence, rapid molecular testing of air samples for bioterrorism agents
- Sequencing capabilities for further strain characterization
- Ability to differentiate the 2000+ serovars of Salmonella
- Testing for environmental contaminants in soil and water



Food Safety

PHLs and Foodborne Pathogen Key Services

PHLs are central for foodborne outbreak detection, surveillance, and response.

Laboratory testing supports molecular epidemiology in partnerships with CDC, FDA, and USDA.

- Detect bacterial foodborne pathogens
- *Salmonella*, *Campylobacter*, Shiga Toxin-producing *E. coli* (STEC), *Listeria*, and other targets of interest

Partnership workflows for routine testing:

- Clinical specimens (CDC)
- Retail meat (FDA)
- Food animal products (USDA)

Food Safety

PHLs and Foodborne Pathogen Key Services

Epidemiologists, regulators, and policymakers use this information to:

- Monitor foodborne disease trends
- Plan food safety programs
- Develop and evaluate food safety policies

Food Safety

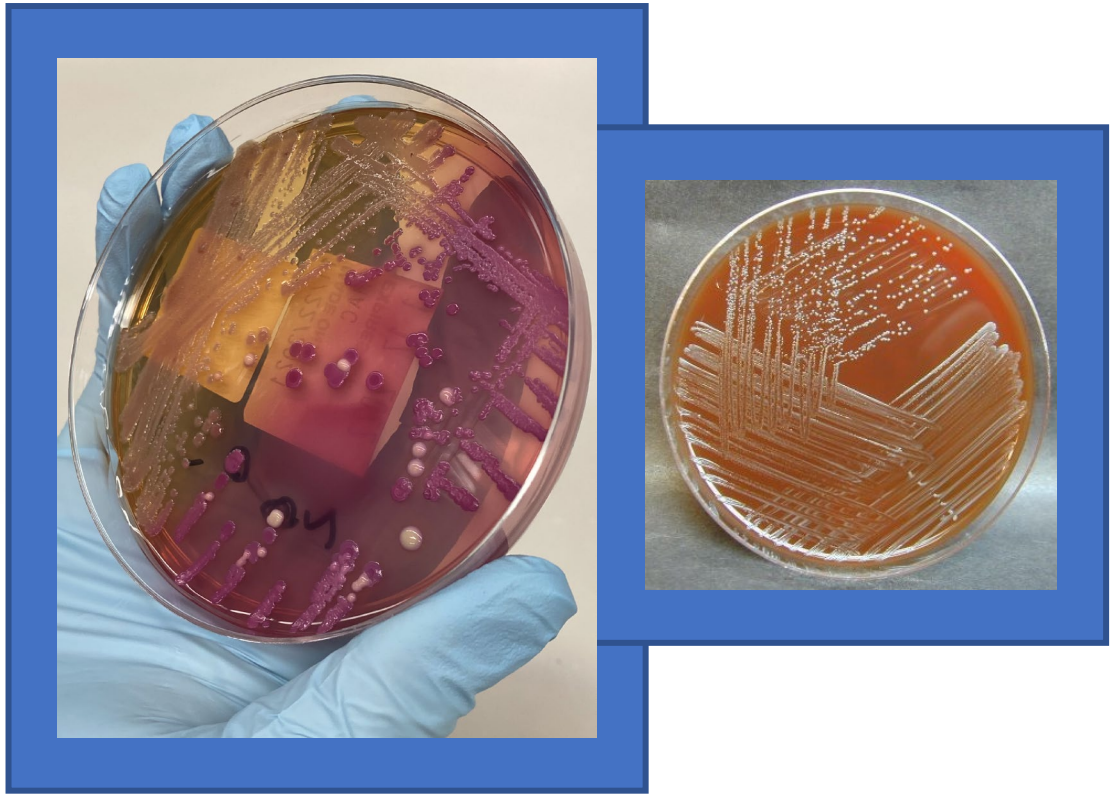
PHLs and Foodborne Pathogen Key Services

PHLs perform specialized testing of tens of thousands of samples annually from commercial and clinical sources.

- Identify and send isolates to CDC for enhanced surveillance
- Monitor new or existing environmental contaminants impacting human health

Key PHL foodborne pathogen programs and network systems:

- National Antimicrobial Resistance Monitoring System (NARMS) for Enteric Bacteria
- PulseNet: Pulse Field Gel Electrophoresis (PFGE) → Genome sequencing

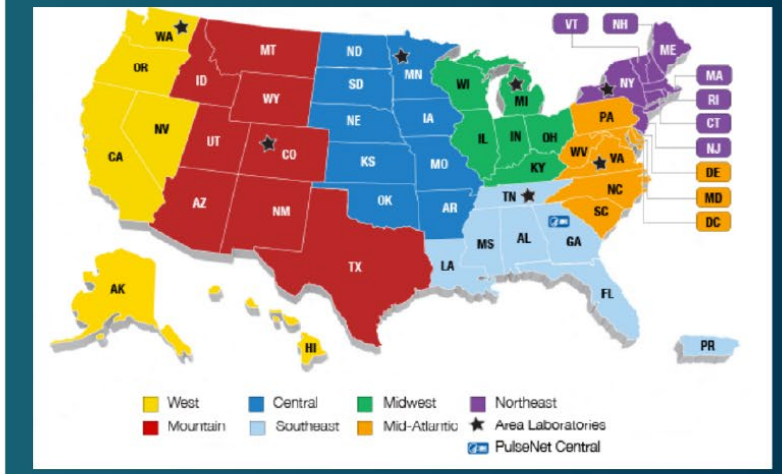


Food Safety

PulseNet and Foodborne Pathogens[8]

PulseNet: National molecular subtyping network for foodborne disease surveillance.

- Developed in 1996 as a response to the 1993 *E. coli* O157 H:7 outbreak
- DNA fingerprint bacteria to link person to person and person to food
- Provide standardized test methods, technology, and data analyses
- National network of labs and international system
- Perform standardized next-generation sequencing of foodborne bacteria
- Share sequences electronically in real-time via PusleNet



Emergency Response

PHL Emergency Preparedness and Response

PHLs with key partners provide a framework for national emergency preparedness and response.

- Serves as a national critical infrastructure to support efforts by maintaining the facility capabilities, trained staff, network membership, laboratory equipment, and critical testing
- Provides rapid and confirmatory laboratory tests of biological and chemical agents of interest
- Supports hospital testing for emerging infections with biosafety guidance and training

Emergency Response

PHL Emergency Preparedness and Response

Department of Homeland Security (DHS) BioWatch Program and PHL testing support

- Maintain chain of custody through laboratory testing for early warning pathogen detection system
- Test samples daily from priority sites across the U.S.
- High-consequence pathogen surveillance system

PHLs and the Laboratory Response Network (LRN)[9]

- Biological threats (LRN-B)
- Chemical threats (LRN-C)

Emergency Response

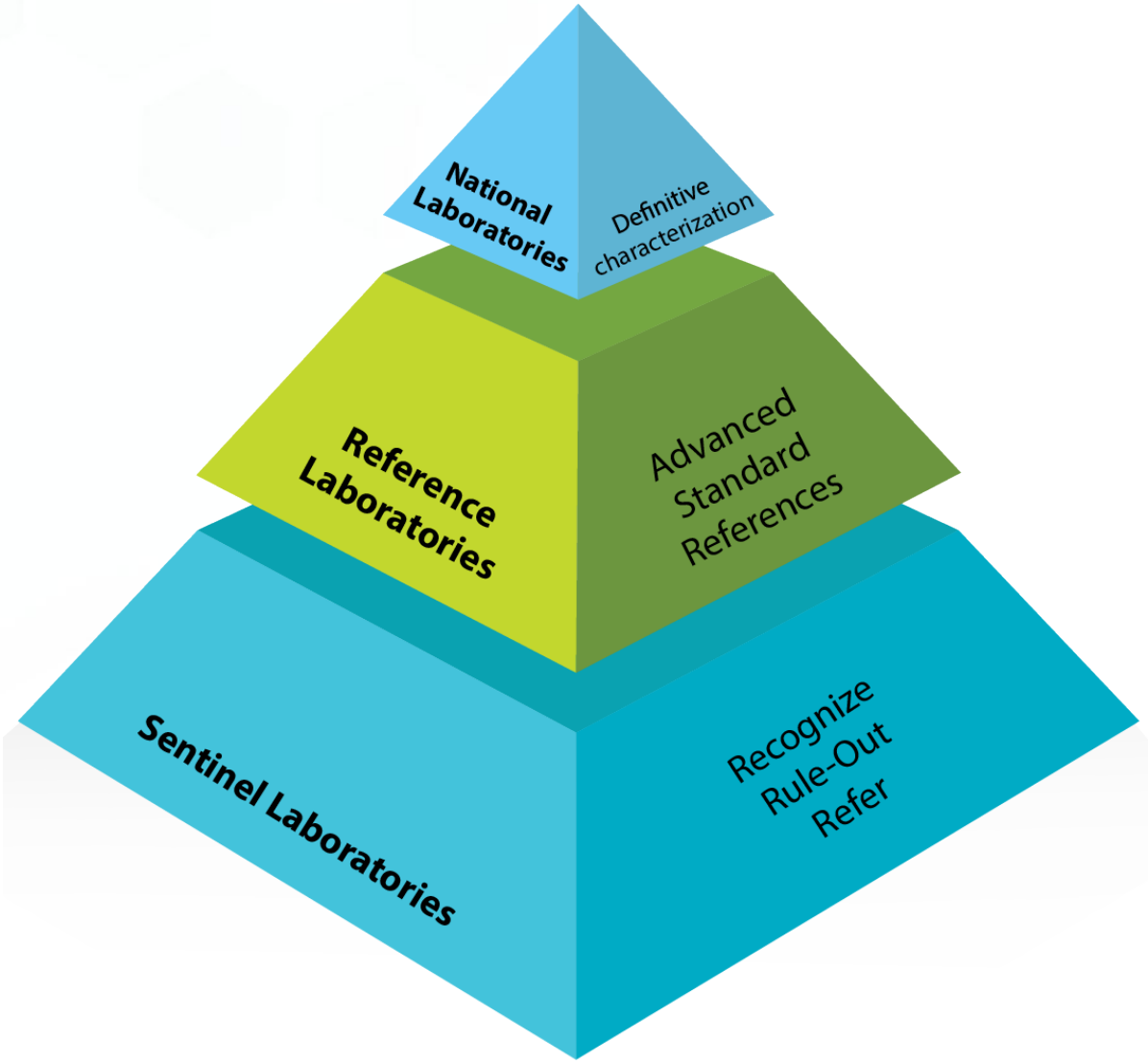
LRN-B and Biological Threat Response

The LRN-B program was established in 1999 but grew exponentially after the 2001 Anthrax bioterrorism attacks.

- Perform molecular and traditional culture tests to rapidly identify and confirm rare and unusual pathogens
  - Biological Select Agents
  - Toxins

- Essential link between clinical sentinel laboratories[10], CDC, and federal agencies

- Pathogen examples: Anthrax, Botulism, Plague, Smallpox, Ricin toxin, Tularemia, Brucellosis, Glanders, Melioidosis, Q fever, viral hemorrhagic fevers, and other agents of concern.

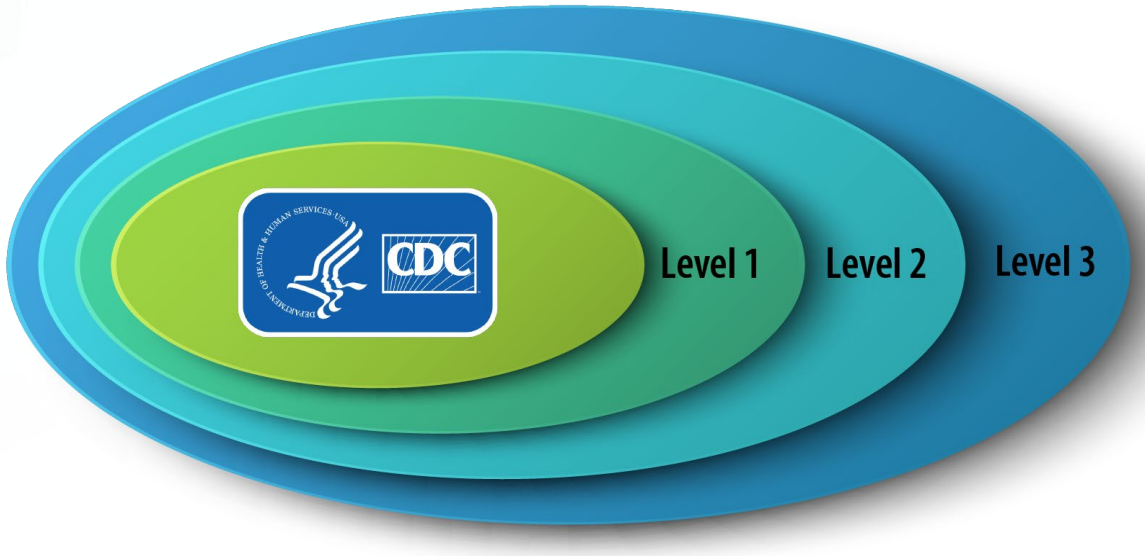


Emergency Response

LRN-C and Chemical Threat Response

The 3-tiered LRN-C system is capable of rapidly detecting and responding to a wide range of chemical threat agent exposures.

- PHLs work with and train key partners for early detection, awareness, and response measures.
  - Hospital teams
  - First responders
- Level 1 and 2 LRN-C laboratories provide essential testing support.
- Level 3 laboratories focus on proper sample collection and shipping.
- Chemical agent examples: cyanide and metals in blood, nerve, blister, and toxin agent metabolites in urine.



Knowledge Check #1

How many PHL core functions are there as outlined by APHL and CDC?

A. 1
B. 3
C. 5
D. 11
E. 12

Environmental Health and Protection

Environmental Activities in the PHL

The extent and sophistication of testing vary widely.

Broad analytical testing focus on capabilities that may include:

- Inorganic chemistry
- Organic chemistry
- Microbiology
- Radiochemistry
- Workplace safety

Sample types vary widely.

- Water: drinking (municipal and well), non-potable, waste
- Air: grab samples, passive absorbers, volume-linked on sorbents or filters
- Soil, sediment, contaminated or spill sites
- Animal tissue, plant tissue, foods, biota

Environmental Health and Protection

Environmental Sample Origin and Purposes

Samples received from diverse submitters:

- Department of Natural Resources (DNR), Environmental Protection Agency (EPA), or Department of Defense (DOD)
- Industries, water or electrical utilities including nuclear power plants
- Consultants, law enforcement, researchers, the public

Primary reasons for environmental testing:

- Emergency response
- Legal enforcement
- Regulatory compliance
- General health and safety
- Remediation
- Investigation

Environmental Health and Protection

Current and Emerging Areas of Interest

Microbiological wastewater monitoring[11]

Microbiological source tracking

Non-targeted testing

Testing related to climate change

Emerging contaminants

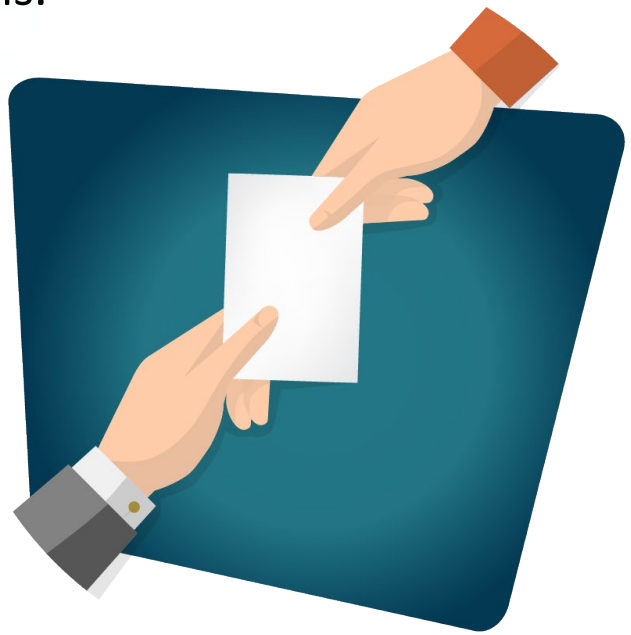
- Per- and polyfluoroalkyl substances (PFAS)
- Neonicotinoid insecticides
- Cyanotoxins

Partnerships and Communication

Establishing and Maintaining Relationships

Public Health requires strong partnerships and effective two-way communications.

- Must commit time and energy to build the relationship
- Always communicate honestly and clearly to build trust and earn respect
- Establish a mutually beneficial relationship with each partner gaining something
- Touch base regularly to connect and update information



An emergency is not the time to exchange business cards.

Partnerships and Communication

Who are Our PHL Partners?

Partners are different for each section of the public health laboratory.

Laboratory Partners

- Local, state, and tribal public health laboratories
- Clinical laboratories
- Commercial Laboratories
- Veterinary laboratories
- Military laboratories
- Food laboratories
- Research laboratories
- CDC laboratories

Other Partners

- Association of Public Health Laboratories (APHL)
- Local, state, and tribal health departments
- Hazmat and other emergency first responders
- Local, state, and federal government
- Local police department
- Regulation agencies
- Infection prevention
- Clinicians
- Department of Corrections
- Commercial couriers
- WHO
- DOT
- DOD
- FBI
- FDA
- DNR
- USDA
- USPS
- EPA
- DHS
- Nursing homes
- Schools

Partnerships and Communication

Consider Establishing an Advisory Group Comprised of Partners

Example: Wisconsin Clinical Laboratory Network (WCLN) Laboratory Technical Advisory Group (LabTAG)

- State divided into regions with a member from each region
- Additional at-large members
- Establish mission statement and objectives
- Provide guidance on outreach activities
- Results in win-win for partners and for PHL

Partnerships and Communication

What Do PHLs Communicate? How?

What:

- Emerging threat situations or pathogens affecting public health
- Routine testing information, test results, and any required actions
- Aggregate surveillance data
- Resources and documents

How:

- Routine or emergency messages and newsletters
- Listserv and online community groups
- Telephone calls and texts
- Webinars, conferences, and workshops
- Site visits and consultations
- Drills and exercises

Education and Training

Who Do PHLs Need to Train?

Internal Employee Training:

- New hires – initial training
- All employees – refresher training
- All employees – continuing education and enrichment training

External Training:

- Fellowships, internships, and practicums
- Outreach and education for sentinel clinical laboratories
- Outreach and training for hazmat teams and first responders
- Outreach and education for other partners and customers

Education and Training

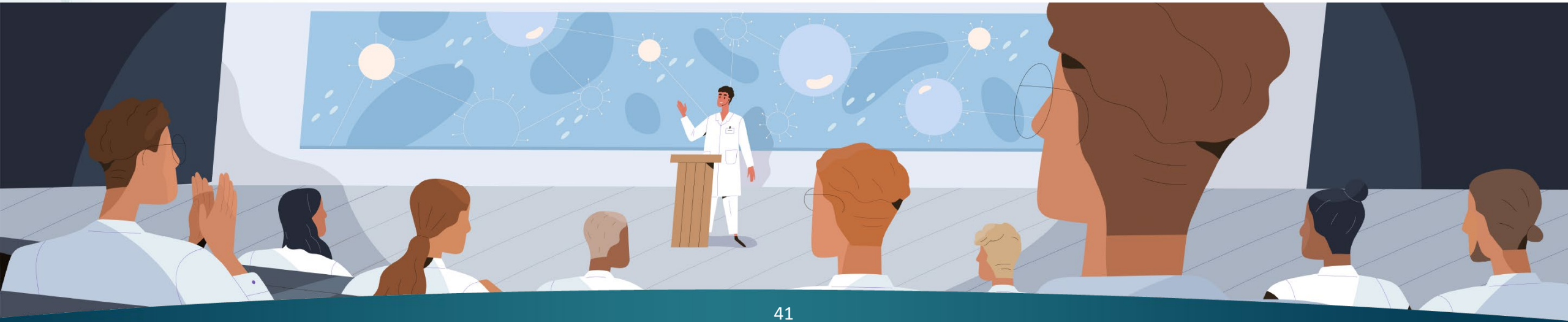
Methods and Examples of Outreach and Training

Methods

- Webinars and online training
- In-person training, workshops, conferences
- Visits with partners in their facilities
- Drills and Exercises
- Reference materials
- Games

Examples

- Packaging and shipping training
- Biothreat agent wet workshop
- Biothreat agent challenge exercise
- Biosafety webinars, conferences, or in-person consultations
- Hazmat collection training



Education and Training

Provide Necessary Training and Then Think Outside the Box

Think Outside the Box!

Provide training on traditional topics.

- Specimen collection
- Packaging and shipping
- Biosafety

Provide training on topics the laboratories want to learn more about.

- New technologies
- Antimicrobial susceptibility testing
- Quality assurance
- Gram stains

Knowledge Check #2

The public health laboratory receives an emergency page that there is an unusual smell in a grocery store that has caused several customers and employees to leave the store and go out into the parking lot because they feel lightheaded, dizzy, and nauseous. The store manager looked around the store and found a spill of some liquid on the floor where the odor seems to be strongest. The laboratory has been paged to do testing to determine what the spilled liquid is. What partners would likely be contacted to work with the laboratory in this situation?

A. FDA, Hazmat, ER Clinician

B. Local police, Hazmat, ER Clinician

C. USPS, Infection Prevention, ER clinician

D. Hazmat, Homeland Security, EPA

Integrated Data Management[12,13]

What is Integrated Data Management?

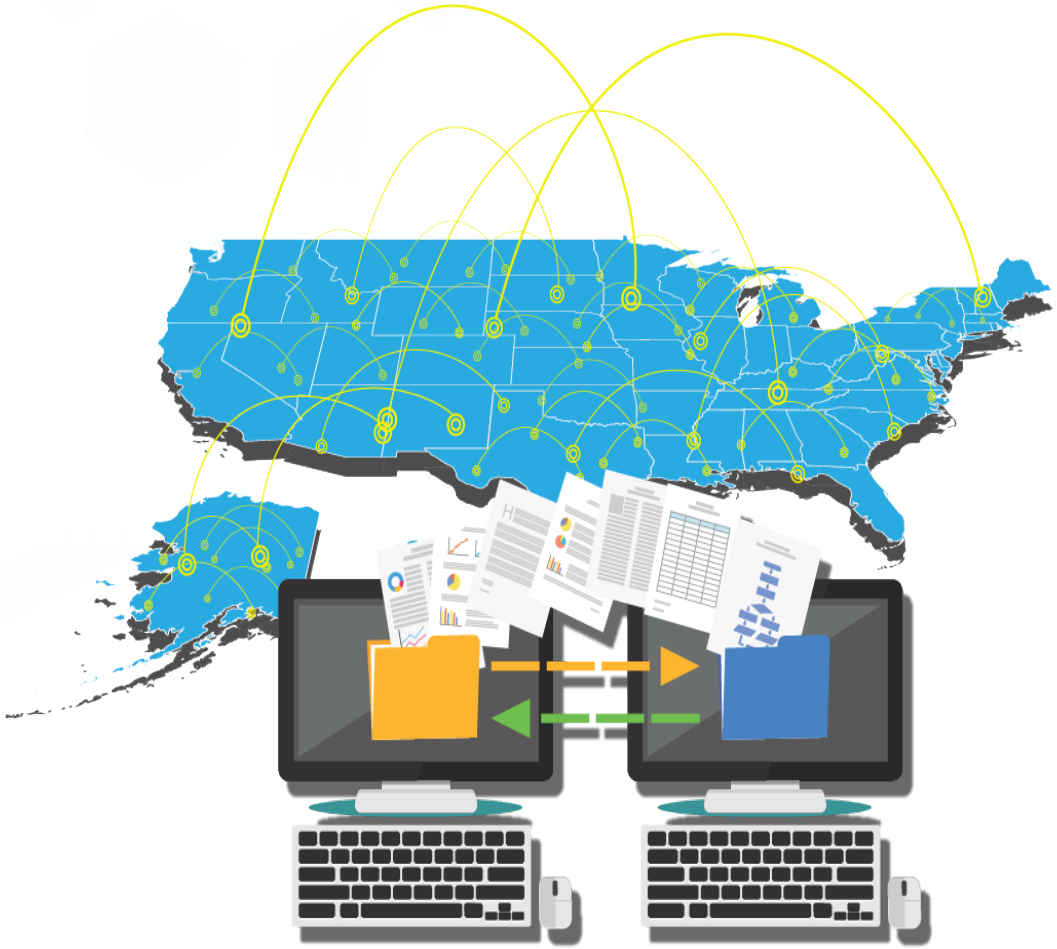
- Electronic Test Orders and Results (ETOR)
- Web Portals
- Interfaces

Integrated Data Management

PHL Key Services

Capturing the laboratory data is essential for PH analysis and decision-making.

- Use of standardized data formats
- Influencing public health policy
- Participation in statewide disease reporting networks
- Linkage with CDC and other national or international surveillance databases
- Collaboration with state and national laboratory systems
- Continuous improvement of laboratory data systems



Public Health-Related Research

PHL Key Services

Developing, evaluating, and implementing new technologies and methodologies

Partnering with other public health disciplines

Collaborating with academic institutions to carry out clinical and translational science

Conducting public health systems and service research

Working with the private sector to foster scientific innovation

Public Health-Related Research

Examples of Collaborations at Iowa State Hygienic Laboratory

Sequencing projects for Legionella found in hospital water systems

Drinking water monitoring and analysis, collaborating with the Center for Health Effects of Environmental Contaminants

Effects of copper on tumor growth (glioblastoma multiforme), collaborating with the Department of Radiation Oncology

Laboratory Improvement and Regulation

PHL Key Services

Promoting quality improvement programs for partner laboratories through activities such as training, consultation, and proficiency testing

Developing and overseeing statewide laboratory improvement programs to ensure the reliability of laboratory data used for environmental monitoring and communicable disease surveillance and control

Promoting safe laboratory practice through education, training, and consultation

Assessing and improving the State Public Health Laboratory System by implementing the Laboratory System Improvement Program (L-SIP)

Guiding the creation of and supporting the enforcement of regulations and laws that contribute to laboratory improvement

Laboratory Improvement and Regulation

PHL Key Services

Varies by state

Iowa Department of Inspections and Appeals contracts with State Hygienic Laboratory (SHL) for Clinical Laboratory Improvement Amendments (CLIA) inspectors

Iowa Department of Natural Resources (IDNR) contracts with SHL for accreditation of environmental laboratories

Policy Development

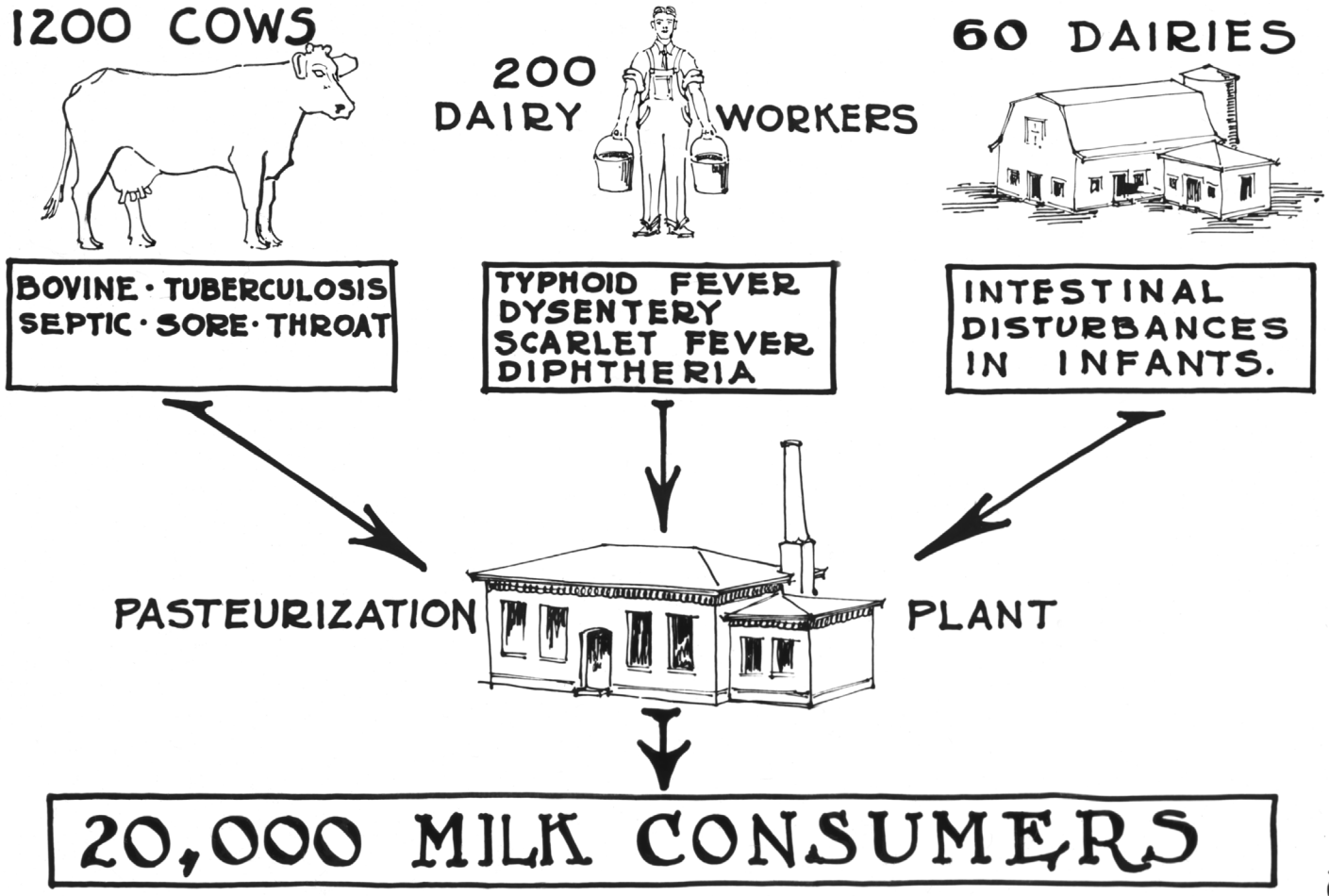
PHL Key Services

Provides unbiased data for decisions or actions by state agencies and legislators

- Water data
- Air quality data

Resource for expertise in public health-related issues

- Provides expert testimony
- Written comment on a variety of issues such as the sale of raw milk



https://phil.cdc.gov/Details.aspx?pid=8650

Policy Development

PHL role in policy development

Generating scientific evidence that informs public health practice and law

Monitoring the impact of PHL practice on health outcomes

Serving as centers of expertise, reference, and resources for biological, chemical, and radiologic issues

Advocating for use of sound reasoning in the application of laboratory science and system infrastructure sustainment

Engaging in strategic planning at local, state, and national levels

Knowledge Check #3

A PHL supplies data to the Department of Natural Resources (DNR) about the amount and locations of arsenic found in well water. This data will be used to determine the need for remediation efforts. This is an example of which core function?

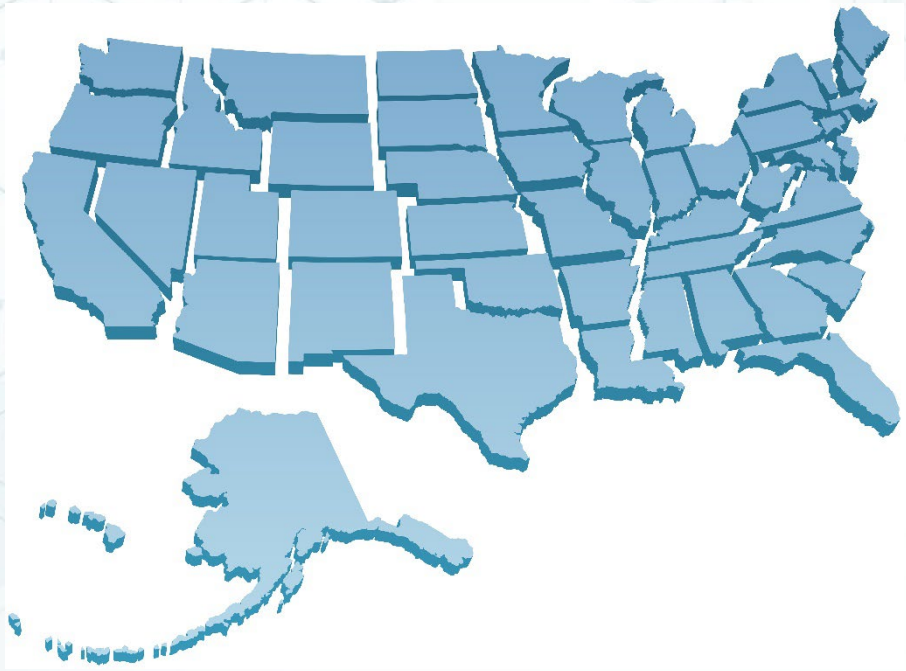
A. Reference and specialized testing
B. Training and education
C. Policy development
D. Laboratory improvement and regulation

Knowledge Check #4

Which of the following is not a core PHL function?

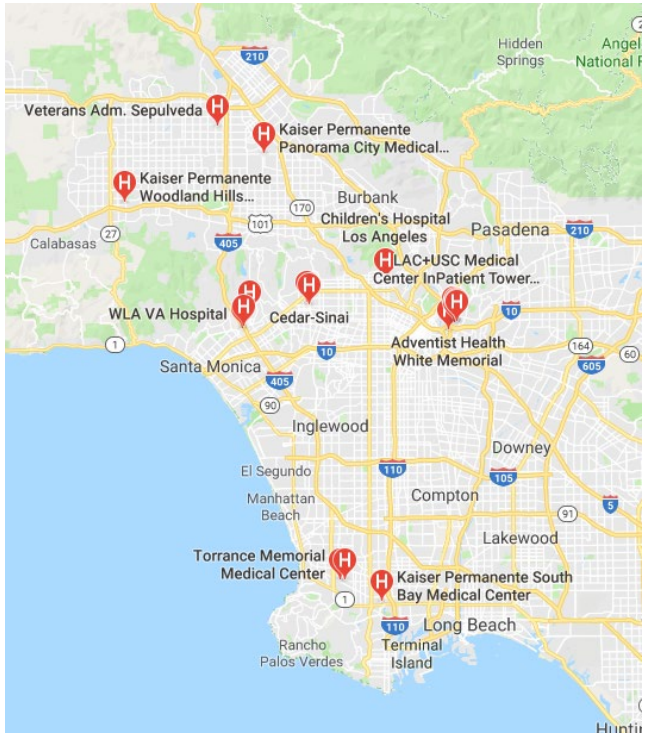
A. Training and education
B. Policy development
C. Infectious waste management
D. Partnerships and communication
E. Emergency response

CDC and the Public Health Laboratory System



Centers for Disease Control and Prevention

State Public Health Laboratory System



Clinical Laboratory System

CDC Laboratories

- Research
- Support surveillance
- Reference diagnostic testing
- Field testing
- Produce high quality data
- Maintain vast collections of pathogens
- Develop advanced technology
- Provide support to public health and clinical laboratories

How CDC Helps PHLs

- Reference testing
- Procedures and reagents
- External quality assessment
- Technical consultation
- Guidance and testing recommendations
- Workforce development
- Training
- Funding

CDC-Managed Networks and Programs

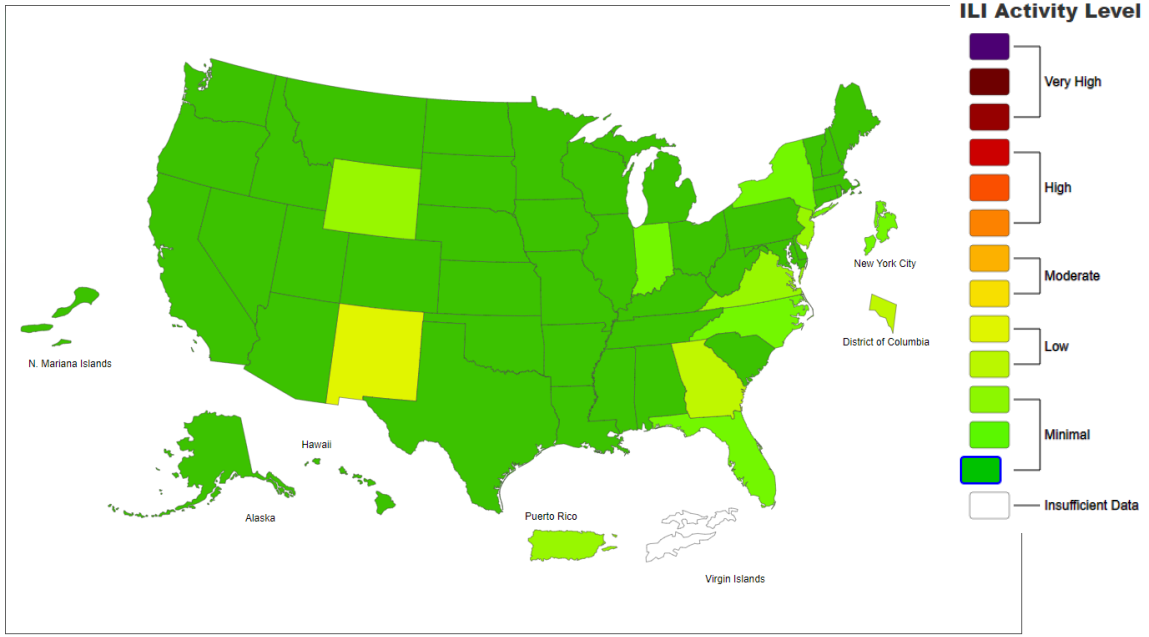
PulseNet USA
The National Molecular Subtyping Network for Foodborne Disease Surveillance

LRN
LABORATORY RESPONSE NETWORK

ARLABnetwork

U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet)

2021-22 Influenza Season Week 32 ending Aug 13, 2022



CDC Funding for PHLs[14]

- Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)[15]
- Public Health Emergency Preparedness (PHEP) Cooperative Agreement[16]
- Strengthening U.S. Public Health Infrastructure, Workforce, and Data Systems[17]

Knowledge Check #5

How does CDC support PHLs?

A. Provides reference testing
B. Established testing guidance for procedures and reagents
C. Conducts external quality assessment
D. Provides technical consultation
E. Develops guidance and testing recommendations
F. Supports workforce development
G. Conducts training
H. Provides funding to support operations
I. All of the above

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Questions

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