



# Development of Public-Private Laboratory Systems

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CLIA Advisory Committee  
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# The Old Paradigm

- A loose association of public health (state, county and city), hospital, and independent laboratories throughout the country.



# System Design



- Strategic Planning
  - ❖ Internal
  - ❖ With APHL, ASCP and ACLA
- Guidance
  - ❖ Steering Committee
  - ❖ CLIAC Updates
  - ❖ Comprehensive CDC-wide planning
- Formative Research
  - ❖ One-Percent Evaluation

# Timely Opportunities



- Bioterrorism
  - ❖ “Develop a plan to improve working relationships and communication between Level A (clinical ) laboratories and Level B/C laboratories, (i.e. Laboratory Response Network laboratories) as well as other public health officials.”
- Threat of Chemical Terrorism
- Emerging Threats
- OIG Report
- OSCAR Database

# System Components



- Measurables
  - ❖ Core Functions
  - ❖ Healthy People 2010
  - ❖ OTPER Performance Goals
  - ❖ Performance Standards

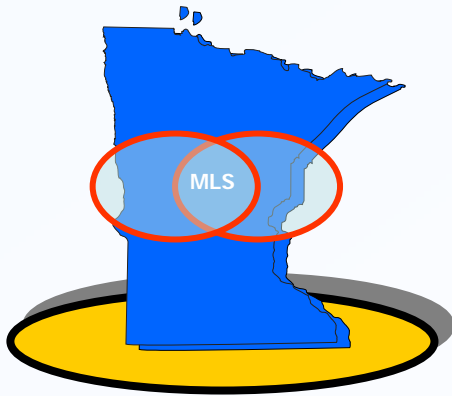
*“What Gets Measured Gets Done”*

# System Components (cont)



- Tools
  - ❖ National Center for PH Laboratory Leadership
  - ❖ Laboratory Program Advisor
  - ❖ APHL Clearinghouse
  - ❖ National Laboratory Database
  - ❖ Site visits by CDC staff
- Extrapolations from “lessons learned”
  - ❖ Specific
  - ❖ General

# Leveraging What Works



MINNESOTA LABORATORY SYSTEM  
A PUBLIC AND PRIVATE COLLABORATION

- Surveying Clinical Labs
- Establishing linkages
- Education
- Proficiency Testing

# Educational Tools

**anthrax**

**tularemia**

**plague**

**brucellosis**

**bacillus anthracis**

- Large, gram positive, spore forming bacilli
- Non-hemolytic
- Non-motile
- Catalase positive

**francisella tularensis**

- Poorly staining, tiny gram negative coccobacilli
- Slow growing, requires cysteine
- Oxidase negative
- Urea negative
- Nitrate negative

**yersinia pestis**

- Bi-polar gram negative bacilli
- Lactose negative
- Urea negative

**brucella species**

- Poorly staining, tiny gram negative coccobacilli
- Slow growing
- Oxidase positive
- Urea positive

**BIOTERRORISM**

Recognize the agents of bioterrorism.  
You are the first line of defense.

**612-676-5253**  
AFTER REGULAR HOURS CALL 612-676-5414

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# Educational Tools

**blood**

Hydrogen Cyanide  
Hydrogen Sulfide  
Carbon Monoxide  
Cyanogen Chloride

**Hydrogen Cyanide**

SYMPTOMS INCLUDE

- Vertigo
- Tachycardia
- Tachypnea
- Cyanosis
- Flu-like symptoms
- Nonspecific neurological symptoms

INDICATIVE TESTS\*

- Increased anion gap
- Metabolic acidosis
- Narrow pO<sub>2</sub> difference between arterial and venous samples

**nerve**

Sarin  
VX  
Tabun  
Somax

**Sarin**

SYMPTOMS INCLUDE

- Diarrhea, dysphoria
- Dilation
- Miosis
- Bradycardia, bronchospasm, brachycardia
- Emesis
- Lacrimation
- Salivation

INDICATIVE TESTS\*

- Decreased cholinesterase
- Increased anion gap
- Metabolic acidosis

**blister**

Sulfur Mustard  
Phosgene Chloride  
Nitrogen Mustard

**Sulfur Mustard**

SYMPTOMS INCLUDE

- Itching
- Erythema
- Yellowish blisters
- Flu-like symptoms
- Delayed eye irritation

INDICATIVE TESTS\*

- Thiolyglycol present in urine

**choking**

Phosgene  
Diphosgene  
Chlorine

**Phosgene**

SYMPTOMS INCLUDE

- Upper respiratory tract irritation
- Stridor
- Coughing
- Choking
- Delayed pulmonary edema

INDICATIVE TESTS\*

- Decreased pO<sub>2</sub>
- Decreased pCO<sub>2</sub>

**metal**

Dimethylmercury  
Lead - Copper  
Mercury - Arsenic  
Gadolinium

**Dimethylmercury**

SYMPTOMS INCLUDE

- Cough
- Metallic taste
- CNS effects
- Shortness of breath
- Flu-like symptoms
- Visual disturbances

INDICATIVE TESTS\*

- Proteinuria
- Blood mercury
- Urine mercury

**CHEMICAL TERRORISM**

Call Poison Control 24/7 For Treatment Information  
**1-800-222-1222**

\* Call the MDH Clinical Chemistry for appropriate specimen collection, packaging and shipping information at 612-676-5763  
AFTER REGULAR HOURS CALL MDH AT 612-676-5414

# Lessons Learned – PPLIP - Information Technology

- Connecticut
  - ❖ Plan a new LIMS compatible with the CT electronic disease surveillance system
- Iowa
  - ❖ Implement automated fax system to reduce TAT and complement electronic reporting for reportable disease
  - ❖ Survey effectiveness of autofax system
- Nebraska
  - ❖ Develop and assess communication using secure information exchange (including image transmission of isolates) using STATpack®
  - ❖ Add videoconferencing
  - ❖ Conduct “challenge” exercise of an event using a bioterrorism mimic
- Rhode Island
  - ❖ Create a centralized clearinghouse for electronic reporting
  - ❖ Build capacity to link into the National Electronic Disease Surveillance System

# Lessons Learned – PPLIP - Communication

- Arkansas
  - ❖ Increase awareness of role of SPHL in 84 hospital-based labs using promotional material and training
- North Dakota
  - ❖ Develop and promote SPHL website for laboratory information; post agent specific quizzes and proficiency testing results
- Michigan
  - ❖ Promote statewide adoption of glomerular filtration rate calculation to monitor kidney function
  - ❖ Improve reporting of diseases identified by non-culture methods (i.e. serology, molecular)

# Lessons Learned – PPLIP – Environmental Lab Networks



- Minnesota

- ❖ Improve knowledge and laboratory practices in private and municipal water treatment laboratories
- ❖ Promote epidemiological investigation of coliforms
- ❖ Provide professional development for laboratory personnel

- Wisconsin

- ❖ Establish a public health and environmental protection laboratory system
- ❖ Conduct a survey of laboratory capacity and needs to open dialogue with laboratories
- ❖ Address professional training needs

# Lessons Learned – Michigan Integration Program

- Clinical laboratory added or modified an existing procedure due to state laboratory intervention

	Added N (%)	Changed N (%)
GBS Screening of pregnant women	7 (9%)	20 (26%)
GBS AST	9 (12%)	8 (11%)
Vancomycin screening agar for VRSA	45 (59%)	21 (28%)
D-zone test for inducible clindamycin resistance in Staphylococcus	29 (38%)	12 (16%)
Diseases/isolate/test results that are reportable to the state health department	17 (22%)	15 (19%)

# Lessons Learned – Systematic Research - Jon Counts, DrPH



- Laboratory survey
  - ❖ Effect of various interventional strategies on AST
  - ❖ Utilization of voluntary lab practice guidelines
  - ❖ Their opinion of microbiology services provided by the WA laboratory delivery system
- 5000 physicians to be surveyed
  - ❖ Use of laboratory practice guidelines
  - ❖ ID specialists will be surveyed regarding AST and reporting

# Lessons Learned – Systematic Research



- What factors affect implementation of voluntary guidelines?
- Focus groups to explore why labs can or cannot implement MMWR recommendations for prevention of Perinatal Group B Strept Infection
- Capture general lessons to help CDC and others better craft voluntary guidelines in the future

# National Laboratory Database



- Updated OSCAR data
- Searchable online
- Registration information
- Proficiency testing enrollment
- New-
  - ❖ Patient Treatment Data
  - ❖ Testing Capacity Based upon CPT-coded billing





# The Future is Bright



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