Laboratory Connectivity and Integration

APHL Annual Meeting
& First State Environmental Laboratory Conference
Jacksonville June 4, 2007
Rex Astles, PhD
Acting Chief, LSDB, CDC
OUTLINE

• Roots of the NLS and Recent Progress
• Case Studies
  – Washington Foundation for Healthcare Quality
  – Minnesota
  – Nebraska
• Progress with Antimicrobial Susceptibility Testing
  – Michigan
  – Current Multistate Consortium
• Discussion
The Old Paradigm

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

“Provide information for decision making”

Private Labs
- Diagnostic testing
- Some reference testing
- Medical management
- Focus = Individual health

Public Labs
- Some diagnostic testing
- Reference testing
- Surveillance and monitoring
- Focus = Public health

Interdependent Network

Improve the Public’s Health
A National Laboratory System

Linking public health, clinical, veterinary, food safety, and environmental laboratories to create seamless systems within each state for public health surveillance and laboratory support and improvement is the urgent mission of the National Laboratory System initiative.

Critical point: the NLS depends upon strong State Public Health Laboratory Systems.
What is the “State-Level Public Health Laboratory System?”

* ...More than the state public health laboratory
  - All public, private, and voluntary entities that contribute to public health laboratory practice in the state
  - A network of entities with differing roles, relationships, and interactions
CDC’s Global Health Protection Network

**FY04**
- Quarantine & Border Health Stations
- Field Epidemiology / Laboratory Training Programs
- CDC Field Stations
- International Business Connectivity
- DOD Laboratories
- New Global Disease Detection & Response Sites
- International Rapid Response Teams
- New International Laboratory Response Network

**INTERNATIONAL**
- Global Health Protection Network
  - Data Exchange
- BioSense & Biointelligence Center

**DOMESTIC**
- National Laboratory System
- National Clinical Lab Orders
- DoD/VA Dx & Rx Records
- Biowatch Data
- Drug Sales
- Clinical Care
- US hospitals and clinics in sentinel cities
- Disease Reporting
- National Surveillance Systems

**FY07**
- National Laboratory System
- National Clinical Lab Orders
- DoD/VA Dx & Rx Records
- Biowatch Data
- Drug Sales
- Clinical Care
- US hospitals and clinics in sentinel cities
- Disease Reporting
- National Surveillance Systems
### Look How Far We’ve Come
**APHL Survey, Summer 2001**

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<th>Activity</th>
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<td>Started new activities to improve clinical testing</td>
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<td>21</td>
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<td>Lab Advisory Committee</td>
<td>9</td>
<td>26</td>
<td>35</td>
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<td>Newsletter for at least some Clinical Micro Labs</td>
<td>18</td>
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<td>Have a BT Liaison</td>
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<td>Regional Agreements w Other PHLs</td>
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<td>35</td>
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<tr>
<td>Contact Clin. Labs to Assure Surveillance of Dz’s</td>
<td>19</td>
<td>15</td>
<td>34</td>
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<td>*3 employed by SPHL; 16 empl. by state epi. program</td>
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<td>3/16*</td>
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*3 employed by SPHL; 16 empl. by state epi. program*
Timely Opportunities

• Bioterrorism – Focal Area C
  – “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
• CDC Reorganization
System Components

“What Gets Measured Gets Done”

• Measurables
  – Core Functions
  – Healthy People 2010
  – COTPER Performance Goals
  – Performance Standards
System Components (cont)

• Tools
  – Laboratory Program Advisors
  – National Center for PH Laboratory Leadership
  – National Laboratory Database
  – Core Functions
  – Performance Standards

• Extrapolations from “lessons learned”
  – http://www.aphl.org/programs/LSS/partnership/Pages/default.aspx
Reasons CL Does Not Consult with SPHL - Battelle Formative Evaluation of the NLS Initiative

61% - Inability to quickly locate a point of contact
44% - Different hours of operation
19% - Not an appropriate source for some information
13% - Lack of confidence in SPHL expertise
10% - Concern about regulatory intervention
8% - Concern about interference in testing methods
Clinical Lab Interest in Collaboration – Specific Topics

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<tr>
<th></th>
<th>Lab Safety</th>
<th>AST</th>
<th>EID</th>
<th>Regs – QA/QC</th>
<th>Specimen Transport Req.</th>
<th>BT Agents</th>
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<td>4</td>
<td>20</td>
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PPLIP Activities

Information Technology
– Connecticut
– Iowa
– Nebraska
– Rhode Island

Communication
– Arkansas
– North Dakota
– Michigan

Environmental Issues
– Minnesota
– Wisconsin

Surveillance
– Massachusetts
Defining the System

Definition of a State Public Health Laboratory System

Association of Public Health Laboratories
June 2007

The State Public Health Laboratory System (SPHL) Laboratory System consists of all the participants in public health testing, including those who initiate testing and those who ultimately see the test results. The SPHL Laboratory System is part of the larger state public health system. The System includes individuals, organizations and agencies that are involved in testing; those who ultimately see the test results. The SPHL Laboratory System supports the 11 Essential Services of Public Health. The concepts of a SPHL Laboratory System are also embedded in the APHL, Core Functions and Capabilities of State Public Health Laboratories. These documents are available on the APHL website at www.aphl.org. Within the SPHL Laboratory System are primary stakeholders who are directly involved in creating and using laboratory data. Additional stakeholders include those who are concerned with compliance with Essential Services, such as Training and Education and Public Health Related Research. A successful National Laboratory System is dependent on the creation of a fully integrated and coordinated network in every state. The goals of the National Laboratory System are to: support voluntary, interdependent partnerships of clinical, environmental, agricultural and veterinary laboratories through public-private collaboration; for assurance of quality laboratory services and public health surveillance.

The SPHL Laboratory System should ensure that:
1. public health threats are detected and intervention is timely
2. stakeholders are appropriately informed of potential threats
3. response conditions are maintained in a comprehensive awareness system
4. guidance and criteria for public health testing are sufficient to provide comprehensive public health surveillance and response
5. public health laboratory data are transmitted to appropriate state and federal agencies responsible for disease surveillance and control.

The state public health laboratory (SPHL) has a leadership role in developing and promoting the SPHL Laboratory System through active collaboration with stakeholders, including epidemiologists, first responders, environmental professionals in water, food and air surveillance activities, public health laboratories and local public health laboratories. The SPHL provides leadership to assure that essential and micro-focal laboratory services are provided to the clinical laboratories that perform public health testing on reportable infectious diseases submit results to the public health surveillance system using national testing guidelines. To provide leadership, the SPHL monitors essential components of the SPHL Laboratory System, such as completeness of reporting and accuracy of laboratory testing results. The SPHL also ensures that accurate results are reported in a manner that is appropriate and sufficiently timely for effective public health response. An effective SPHL Laboratory System requires the leadership by the SPHL to receive public health testing performed by clinical and environmental in-state laboratories. To assure that the SPHL Laboratory System is effective, the SPHL should at a minimum:

1. maintain an integrated information system that includes all stakeholders that rely on a state laboratory data
2. employ a full-time public health laboratory system coordinator
3. create a standing public health laboratory advisory committee
4. provide an innovative website or other electronic system to maintain regular communication channels for system purposes.

The document was developed by a subcommittee of the APHL Laboratory Functions & Standards Committee. It was adopted by the APHL Board on May 24, 2007.

Association of Public Health Laboratories
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Washington, DC 20006
Phone: 202-466-2210
Fax: 202-466-2798
Web: www.aphl.org

CDC
A **full-time** employee (preferably someone with commercial laboratory experience) to serve as **liaison** between the PHL and laboratory partners—the single most important resource on this list.

**Technology to enable rapid communication** between the PHL and its laboratory partners.

Resources to bring PHL staff together with laboratory partners for **face-to-face meetings, conferences and/or hands-on training workshops** of interest to laboratory partners.

A **database** containing information about all of a state or local jurisdiction’s laboratory assets and the expertise to manage it.

A **Web site** designed for laboratory partners.

**Marketing capabilities** to explain what the PHL does, requirements for disease reporting, the benefits of participation in a state laboratory network and more.

A **laboratory advisory committee** comprised of stakeholders committed to common goals.

From APHL white paper “Building A National Laboratory System” March 2006
http://www.aphl.org/about_aphl/products_and_publications/Documents/lab_systems_3-06.pdf
CLINICAL LABORATORY INITIATIVE

JON M. COUNTS, DR.PH, MPH
10/12/2006
Testing policies

Methodology
Technology

Laboratory Practice

Appropriate for patient care
Cost Effective
Reimbursement policy
Test Utilization
Adequate TAT
Competent staff
Workload

Laboratory Delivery System

Hospital
Commercial
Academic
Public Health

Clinician

Selection of Tests
Interpretation of Lab results
Use of practice guidelines
Collaboration between lab & clinicians

Communication
Courier Service
Request forms
Interpretative Guidelines
Consultation
PREVIOUS STUDIES
2000-2006

• Assessment/Improvement of AST

• Evaluation of Laboratory Delivery System

• Clinician Utilization of Laboratory Practice Guidelines
SUMMARY OF IMPROVEMENTS IN AST LAB PRACTICE

• Acquisition of CSLI lab practice standards
• Performance in Case Studies
• Development/change in lab testing policies
• Use of Referral Laboratories by small micro labs
LABORATORY DELIVERY SYSTEM

Good to Excellent

- Lab accessibility for physicians (by phone, internet, email)
- Consultation with either a board-certified MD or PhD lab director
- Readability of reports
- Laboratory reports (format, content, usefulness)
LABORATORY DELIVERY SYSTEM

Good – Excellent

- Reliability of lab’s courier service
- The information provided by lab on collection and submission of specimens/cultures
- Range of services performed by referral lab
- Willingness to accommodate special requests
LABORATORY DELIVERY SYSTEM
(Fair – Very Poor)

- Number and type of services provided on nights and weekends
- Quality of testing substandard
- Quality of technical consultation provided by lab
- Completion of request forms was onerous
- Lack of interpretative guidelines with reports
LABORATORY DELIVERY SYSTEM
(Fair – Very Poor)

- Turn-around time of tests
- Range of esoteric tests performed on-site
- Lab accessibility (physical location) for patients
- Failure to notify physician of critical test results
CLINICIAN STUDIES

- Utilization of laboratory practice guidelines by primary care and infectious disease physicians (approx 5,000)

- Utilization of computerized physician order entry (CPOE)

- ID physician recommendations concerning antimicrobial testing and reporting- to inform CLAC guidelines

- Assessment of microbiology services provided by laboratory delivery system
LABORATORY PRACTICE GUIDELINES

• Moderate awareness of CDC guidelines

• Low awareness of DOH/CLAC guidelines, but when aware, both were used for
  – Diagnosis
  – Testing
  – Communication with physicians

• Guidelines seen as difficult to use, complex, not helpful, not readily accessible

• Guidelines should be integrated into CPOE
PROPOSED STUDIES
2006-2009

• Assess the inter-laboratory variability of laboratory practice, policies and processes in clinical microbiology in small community hospital laboratories

• Study factors which influence management decision-making, establishment of laboratory practice, current policies, and processes

• Evaluate methodology used to improve laboratory practice, policy and process measures that overtime would promote "best practices" in small hospital laboratories.
PROPOSED STUDIES
2006 - 2009

• Implement individualized quality management systems in Alaska, Oregon and Washington SPHL

• Improve their engagement and interaction with the laboratory delivery system in their state, including communication with the clinical laboratory community, quality of customer service and microbiology services provided by the SPHL

• Identify factors that impede their clinical laboratory community from adhering to voluntary national laboratory practice guidelines, reporting of results and submission of isolates and specimens to SPHL
“Re-visiting the Minnesota Laboratory System”

Paula M. Snippes
MT(ASCP)
Program Advisor, MLS

APHL National Meeting
June 2007
125 Sentinel Labs

State Public Health Lab
Basic Components

- Dedicated Program Advisor
- Recognizable system
- Robust communication
- Valuable products and programs
- Measurable benchmarks
- Supportive administration
Dedicated Program Advisor

- Full-time position
- Clinical lab background
Recognizable System

An integrated network of public and private clinical laboratories working together to protect and improve the health of all Minnesotans
Recognizable System – MLS Website

www.health.state.mn.us/MLS
Robust Communication

- Robust database
- Blast email and fax capabilities
- Constant maintenance
- Listserve
- Website
Categories of Lab Alerts:

- **Laboratory ALERT**: Conveys the highest level of importance; warrants immediate action, attention or response.
Robust Communication – [MLS: e-LAB] - Listserv

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To reply directly to the MDH Public Health Lab: mnlabsystem@health.state.mn.us
To add, remove or change your subscriber information: mnlabsystem@health.state.mn.us
Minnesota Laboratory System website: http://www.health.state.mn.us/mls

The Minnesota Department of Health does not verify nor take responsibility for the accuracy of the statements posted on this listserv.
Valuable Products and Programs

**MLS Goals**

- **Enhance quality of microbiology practice**
  - Antimicrobial susceptibility testing
  - Pathogen detection and identification
- **Improve emergency preparedness**
  - Bioterrorism and Chemical terrorism
  - Outbreak detection
- **Provide resources/educational material**
- **Ensure communication and collaboration**
Valuable Products and Programs

- 85 CLSI guidelines sent – 2006/07
- 313 participants MLS Regional Lab Conference – 2006
- 61 participants 2006 - BT Wet Workshops
- 135 BT/CT posters
- Challenge Set
Valuable Products and Programs Challenge Set

% of Labs Participating

- Set 1 - 2002: 94%
- Set 2 - 2003: 91%
- Set 3 - 2004: 94%
- Set 4 - 2005: 93%
- Set 5 - 2006: 97%
Valuable Products and Programs Challenge Set

Goals

• Identify needs
• Monitor preparedness
• Assess practices/capabilities
• Provide educational resources
• Educate about diseases of public health importance
Valuable Products and Programs Challenge Set

Organism Choices

- Terrorism-like agents
- Antibiotic resistance
- Diseases of PH import
- Emerging infections
Organisms (Set 5)

1. *Oligella ureolytica*
2. *Mycobacterium abscessus*
3. *Listeria monocytogenes*
4. *Streptococcus group B (S. agalactiae)*
Findings:
• Unusual gram-negative bacilli are difficult to ID
• Mycobacterium are not on the radar
• Changes in AST guidelines are a challenge
• Labs are interested - teleconference
  • 58 phone lines
  • 275 participants
  • 26 CDs
Challenge Set Findings

*Brucella* surrogate (*O. ureolytica*)

Identification (n=104)

- Acceptable: 52/104 (50%)
- Unacceptable: 52/104 (50%)
Challenge Set Findings

*Mycobacterium abscessus*

Acceptable Answers 43/100 (43%)

Unacceptable 57/100 (57%)

- AFB, Not TB Complex 2/100 (2%)
- AFB 13/100 (13%)
- GPB, refer for further ID 26/100 (26%)
- M. abscessus 1/100 (1%)
- Mycobact. sp., pos. abscessus 1/100 (1%)
Challenge Set Findings
Group B Streptococcus (AST)
Performed D-zone Test (44/93 = 47%)

Positive for inducible clindamycin resistance
39/44 (89%)

Negative for inducible clindamycin resistance
5/44 (11%)
Measurable Benchmarks
Challenge Set

- Staph aureus D-test
  Direct comparison of two consecutive challenge sets indicated a 21% increase in the number of laboratories that perform the D-zone test.

- Group B strep
Group B Streptococcus
Disease Prevention

Penicillin allergy status information received by laboratory

- 2004: 26%
- 2006: 55%
Group B Streptococcus Identification

Identification of **ALL** GBS in urine cultures of pregnant women

- **2004**: 41%
- **2006**: 56%
Measurable Benchmarks
Challenge Set

Challenge Set - Evaluation Comments

• “….sometimes leads to changes in procedures--good feedback.”

• “It helps educate people who do not have a strong microbiology background.”

• “It gives us an idea about our performance with comparison with other labs.”
Supportive Administration

- Support: full-time position
- Resources
  - Funds
  - Staff
  - Tools
Barriers

- Resource Heavy
- Support: full-time position
- Resources
  - Funds
  - Staff
  - Tools
Final Words

- Change is slow
- Persistence is essential
- Impact is Positive
Paula M. Snippes
Program Advisor, Minnesota Laboratory System (MLS)
651-201-5581
paula.snippes@health.state.mn.us
Building Blocks of the Nebraska Laboratory Network (NLN)

Steve Hinrichs, M.D., Director, NPHL
Tony Sambol, MA, Associate Director, NPHL
Josh Rowland, MBA, MT(ASCP), State Training Coordinator, NPHL
Laboratory Demonstration Project (LDP)-Phase 1

- 2001-APHL
- Situational assessment
- Communication
  - Labs connected only by phone-no internet
- Large geographical area
  - “Distance” barriers for rapid testing
- Infrastructure
  - Loosely woven or non-existent with NPHL
Phase 1

- Survey: site visits assessed BT knowledge and communication needs - identify sentinel labs
- Communication: possible satellite links and GIS
- Training: refine bioterrorism training material
- Product: CD-ROM with BT materials
- Laid groundwork for the future...
LDP-Phase 2

- 2002-2003 FAC funding
- Designated hub labs within the 6 regional population centers
- Regional level-A (sentinel) training-didactic lectures
- Improved communication infrastructure
- Hired a State Training Coordinator
- Developed lab “buy-in” through needs assessment survey
- Further buy-in with site visits of all facilities
Phase 2

- Continued “communication” enhancements
- Reinvigorated www.nphl.org, NPHL Newsletter, ELR …
- STATPack™ Ver 1.0
- Regional conferences and workshops
- Teleconferences - NLTN
- “The face of PH in NE”
LDP-Phase 3

- 2004 PPLIP-CDC funding
- Integration with environmental, food, and veterinary diagnostic labs into NLN
- STATPack™ and cross training workshops
- Now have MOU
To Date LDP Outcomes

- Enhanced opportunities to interact with NLN
- BT wet workshops offered since 2004, 38 of 45 labs
- Evidence that labs communicate with NPHL readily
- CT preparedness workshops well attended
- Too hard to quantify… but NLN better prepared future BT/CT/PH events
2006 Project

DLS/CDC-Initiative to Integrate Private Laboratories into Public Health Testing

Goal: assess/develop an antimicrobial susceptibility testing educational program in Nebraska

Paul D. Fey, Ph.D. Associate Professor/Associate Director, NPHL

Josh Rowland, MBA, MT(ASCP) State Training Coordinator
Specific aims:

- Determine needs through personal interview and AST survey
- Develop and implement “hands on” wet labs and lectures
- Develop a long term consultation solution through consultative telemedicine-STATPack, 6 additional units in 3 years
STATPack™

- **Secure Telecommunications Application Terminal Package**
- Remote electronic consultation-telemedicine
- HIPAA compliant
- Video/camera images
  - Macro/microscopic
- Education/case studies
- Priority Levels
- 20 sites in NE (11 in OK, 9 in KS)
STATPack™ Case Studies

- AST Case, February 2007
- Initial message to NE labs included AST results (Erythromycin R, Clindamycin S)
- Technique, interpretation, and methodology of the D-test (positive D-test shown) were discussed
Consultation

Malarial
Images sent by St. Mary's Hospital in Enid, OK to consult with Oklahoma Public Health Laboratory. One week after installation and training on STATPack, determined to be Plasmodium falciparum based on morphological characteristics.

Fungal
Images sent by the Nebraska Public Health Laboratory (NPHL) with a request for fungal consultation. Unable to rule out the etiology of lymphadenitis. Recommendation was for the submitting laboratory to send the specimen to a reference laboratory for further characterization.

Bacterial
Images received at the NPHL for consultation. Catalase positive, non-hemolytic, non-film. Large GPR from a blood culture. Sentinel laboratory could not rule-out Bacillus anthracis. Morphology was not consistent with Bacillus anthracis.

Education

VZV DFA
Six sentinel laboratories across Nebraska were trained to perform Varicella-Zoster Virus (VZV) Direct Fluorescent Antibody testing as a rule-out for Varicella virus (zoster). This picture represents a positive control slide that one laboratory sent to NPHL.

Competency Training
A series of Gram-stained slides serve as a repository for clinical competency training and documentation of proficiency. This is used by a clinical hospital laboratory in Nebraska to satisfy their College of American Pathologists (CAP) gram stain competency requirement (GC-21565).

Case Study
One example of a STATPack case study was sent to laboratories in Nebraska. The initial STATPack message included antimicrobial susceptibility testing results (Erythromycin R, Clindamycin S). Technique, interpretation, and methodology of the D-test (positive D-test shown) were discussed in this exercise.
National Laboratory System: Initiative to Integrate Private Laboratories into Public Health Testing

Laurina O. Williams, PhD, MPH
Project Officer
CDC/NCID/NCPDCID
Division of Laboratory Systems
# National Laboratory System – CDC Staff

**Initiative to Integrate Clinical Laboratories into Public Health Testing**

## Division of Laboratory Systems

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Joe Boone, PhD</td>
<td>Acting Director, DLS</td>
</tr>
<tr>
<td>John Ridderhof, DrPH</td>
<td>Acting Deputy Director, DLS</td>
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<tr>
<td>Laurina Williams, PhD, MPH</td>
<td>Project Officer</td>
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<tr>
<td>Rex Astles, PhD</td>
<td>Project Officer</td>
</tr>
<tr>
<td>Pam Robinson</td>
<td>Program Analyst</td>
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<td>Jesse Holder</td>
<td>Programmer</td>
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## Division of Healthcare Quality Promotion

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<tr>
<td>Roberta Carey, PhD</td>
<td>Branch Chief, ELB</td>
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<td>Fred Tenover, PhD</td>
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<td>Clifford McDonald, MD</td>
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<td>Brandi Limbago, PhD</td>
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<td>Jean Patel, PhD</td>
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<td>Shalein Banerjei, PhD</td>
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## Consultants

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<tr>
<td>Vanessa White, APHL</td>
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<td>Jim Hidalgo, APHL</td>
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<td>Rosemary Humes, APHL</td>
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<td>Janet Hindler, PhD</td>
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<td>NLTN</td>
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DLS is working with partners and through public-private laboratory integration projects to strengthen the NLS, an enhanced communication and collaboration network among public health and clinical laboratories to facilitate:

- High quality and timely public health laboratory testing
- Improved assessment of relevant laboratory practices
- Better detection of, response to, and tracking of public health threats
- An effective mechanism for making policy and adopting appropriate guidelines across states and regions
- Development of performance standards
National Laboratory System
States Ever Included as NLS Projects
Current NLS Activities

- **AST Assessment**
  - Montana (Northern Plains Consortium); Nebraska, Wisconsin
  - 250 participants (full participation needed)
  - Survey covers demographics, methods, guidelines, outcomes

- **STD-related Activities**
  - Montana - Northern Plains Consortium
  - Foundation for Healthcare Quality

- **General Clinical Microbiology Practices**
  - Foundation for Healthcare Quality
Current NLS Project Management

- **Montana – Northern Plains Consortium**
  - Project Director – Anne Weber
  - Project Supervisor – Susie Zanto
  - Program Coordinator – Debbie Gibson
  - AST Project manager – John LaRue

- **North Dakota:**
  - Myra Kosse
  - Eric Hieb
  - Representative: Danita Hunke

- **Wyoming:**
  - Rich Harris
  - Representative: Jim McKinna

- **South Dakota:**
  - Mike Smith
  - Representative: Yvette Thomas

- **Wisconsin:**
  - Project Directors: Steve Marshall and Carol Kirk

- **Nebraska:**
  - Project Directors: Paul Fey and Josh Rowland

- **Foundation for Healthcare Quality:**
  - Project Director: Jon Counts
AST Assessment Activities

AST Laboratory Practices Survey
Consensus Process
Data Analysis Consensus

Antibiogram Worksheet and Tools

Interventions
ASCP Course
Onsite Training and Consultation
STAT-Pak implementation (Nebraska)
## Survey Development and Committees

<table>
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<th>Role</th>
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<tr>
<td>Methods-Chair</td>
<td>Paul D. Fey, Jean Patel, Roberta Carey, Fred Tenover</td>
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<tr>
<td>Demographics-Chair</td>
<td>Jon M. Counts/Rex Astles, Anne Pollock, Brandi Limbago</td>
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<tr>
<td>Guidelines-Chair</td>
<td>Joni Wedig, Clifford McDonald</td>
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<tr>
<td>Outcomes-Chair</td>
<td>John LaRue, Laurina Williams, Pam Thompson, Debbie Gibson, Steve Marshall, Susie Zanto</td>
</tr>
<tr>
<td>Statistician</td>
<td>Shalein Banerjei</td>
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Survey Development Process


Content Committees
-- Demographics
-- Methods
-- Guidelines
-- Outcomes

Committees composed questions

Consensus Conference Calls

CDC compiled “final” first draft

Statistical Review
-- Types of questions vs. statistical power

Pilot testing by the Montana Consortium

Final Consensus Questionnaire (March 2007)

Individual States could add questions at end of survey
Antimicrobial Susceptibility Testing (AST) Questionnaire

Cover Page:

Today’s Date __/__/____ (MM/DD/YYYY)

Please provide information about yourself:

Name:

Laboratory Name:

CLIA Number:

Street Address:

City: ___________________________ State: ___________ Zip Code: _________

Telephone: (_____) _____-_________

Email Address:

Additional information about yourself:

- Medical laboratory director
- Laboratory manager - administrative
- Technical consultant
- General supervisor
- Specialty supervisor
- Non-supervisory testing personnel
- Other, please specify: ____________________________
53. Please complete the table by following the steps below.

**STEP 1.** Complete column 1 by putting an "X" in the box next to the organism if testing of any type is performed at your laboratory. For any organism you checked, complete Steps 2 and 3. Do not complete Steps 2 or 3 for organisms you did not check.

**STEP 2.** Complete column 2 by entering the estimated number of isolates tested for each organism.

**STEP 3.** Complete columns 3, 4, and 5 using the codes below to list screening and primary and secondary/confirmatory testing methods for each organism. (Please use capital letters to fill in the table.) Rather than leave a space blank, use code 'A' if your laboratory doesn't perform a test method. If code 'W' is selected, please specify the procedure in column 6. If more than one comment is needed per organism, be sure to clarify which column number the comment addresses.

<table>
<thead>
<tr>
<th>Organism</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enterococcus spp.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coagulase negative Staphylococcus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptococcus agalactiae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P. aeruginosa from cystic fibrosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Enterobacteriaceae</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HACEK group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram positive anaerobes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gram negative anaerobes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**List of Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Do not perform this method with this organism</td>
</tr>
<tr>
<td>I</td>
<td>BD Phoenix</td>
</tr>
<tr>
<td>Q</td>
<td>Cefoxitin disk test for inducible clindamycin resistance</td>
</tr>
<tr>
<td>B</td>
<td>Oxacillin Screen agar (MHA+S/A)</td>
</tr>
<tr>
<td>J</td>
<td>Microscan Walkaway Rapid</td>
</tr>
<tr>
<td>R</td>
<td>Latex agglutination (PBP) testing method for MRSA</td>
</tr>
<tr>
<td>C</td>
<td>Vancomycin Screen agar (EHI agar)</td>
</tr>
<tr>
<td>K</td>
<td>Microscan Walkaway Conventional</td>
</tr>
<tr>
<td>S</td>
<td>ESBL confirmation test with clavulanic acid (Disk Diffusion)</td>
</tr>
<tr>
<td>D</td>
<td>PCR</td>
</tr>
<tr>
<td>L</td>
<td>Microscan auto or touchscan</td>
</tr>
<tr>
<td>T</td>
<td>ESBL confirmation test with clavulanic acid (E-test)</td>
</tr>
<tr>
<td>E</td>
<td>E-test methodology</td>
</tr>
<tr>
<td>M</td>
<td>Tsak (Sensitive/Resistant)</td>
</tr>
<tr>
<td>V</td>
<td>ß-lactamase production (e.g. nitrocephin disk)</td>
</tr>
<tr>
<td>F</td>
<td>Kirby Bauer disk diffusion</td>
</tr>
<tr>
<td>N</td>
<td>Vitak 2</td>
</tr>
<tr>
<td>G</td>
<td>Agar Dilution MIC methodology</td>
</tr>
<tr>
<td>O</td>
<td>Vitak Legacy</td>
</tr>
<tr>
<td>H</td>
<td>Broth microdilution MIC methodology (manual reading)</td>
</tr>
</tbody>
</table>

Includes Actinomyces, Envelopes, and Streptococci
Includes Haemophilia (not H. influenzae), Actinobacillus, Cardiobacterium, Ethanol, and Enoila.
57. When testing a community-associated methicillin resistant *Staphylococcus aureus* (CA-MRSA) strain that is resistant to penicillin and oxacillin, which of the following antimicrobials would you report as resistant? (Check all that apply, even if you do not report them in your laboratory.)

- I don’t know
- Ampicillin-sulbactam
- Amoxicillin-clavulanic Acid
- Erythromycin
- Vancomycin
- Cefazolin
- Ceftriaxone
- Imipenem
- Tetracycline

62. Which of the following isolates, or presumptive isolates does your laboratory refer to a reference laboratory for additional testing/confirmation? (Check all that apply.)

- We do not refer
- VISA or VRSA (vancomycin intermediate or resistant *Staphylococcus aureus*)
- *Streptococcus pneumoniae* from a sterile site
- VRE (vancomycin resistant enterococci)
- MRSA (methicillin resistant *Staphylococcus aureus*)
- ESBL (extended spectrum beta-lactamase producers)

65. In your opinion was this survey: (Check all that apply.)

- Important
- Relevant
- Educational
- Appropriate
- None of the above

67. Were the questions clear?

- Yes
- No

If no, which questions were unclear? ____________________________________________
Survey Data Group

John LaRue - Montana
Neil Squires, Programmer - Montana
Debbie Gibson - Montana
Susie Zanto - Montana
Bonnie Barnard - Montana
Kammy Johnson, Epidemiologist – Montana
Eric Hieb – North Dakota
Gale Stevens - Wyoming
Yvette Thomas – South Dakota
Chris Carlson – South Dakota
Steve Marshall – Wisconsin
Joni Wedig – Wisconsin
Dave Warshaer - Wisconsin
Paul Fey - Nebraska
Josh Rowland - Nebraska
Shalein Banerjee, Statistician – CDC/DHQ
Jesse Holder, Programmer – CDC/DLS
Laurina Williams – CDC/DLS
Survey Data Group Process

- **Consensus Process for Editing Instructions**
  - Reviewed each question – interpretation; validity
  - Statistical Review - “reasonableness” and analytical considerations

- **Period of Review by data group and by entire survey group**

- **Editing Rules**
  - Extra information
  - Conflicting information – in most cases requires verification by state

- **Programming by Montana Consortium**
  - Incorporating editing rules and skip patterns
  - Comment section by data entry personnel
  - Future web version - compatible with ACCESS and SEQUEL
  - Concatenating data
Data Entry Rules for 2007 NLS-AST Questionnaire

General Rules
Some of the problems encountered while entering data into the database may require calls to the participating facilities. In order to simplify this process, do not make a call to a facility until the entire survey has been reviewed; then you can verify all of the necessary information at one time.

If a question is left blank, you may skip the question until you are able to verify the data. It is suggested that each data entry person keep a handwritten log designating the facility and of all of the questions that need data verification. When the verification call is made, the log may be used as a reference. This handwritten log will need to be saved in the event that it needs to be reviewed at a later date. An Excel spreadsheet has been created to input this data for safe keeping.

Please be sure that the “knowledge-based” questions (54-62 and either #48 or #51) all have some type of answer collected. We will need as many participants as possible to answer these questions in order to compute a knowledge index.

The following “general” guidelines have been developed in an attempt to address the majority of translation problems, and they may be used for all questions unless the data editing instructions for a question explicitly overrides these guidelines. If any of the guidelines are unclear, please contact Debbie at 406-444-5970 for further clarification.

1. The six digit accession number: The database will automatically enter the first two digits, which will be the FIPS code for each state. The data entry person will need to assign the remaining four digits, which should be a unique four digit laboratory identifier.

2. This same unique accession number will be used each year for the same laboratory. Each year in the preference section of the database, you will change the year to the current year, keeping the accession number the same. This way you will easily be able to look up data from a certain facility, designated by year.

3. For all questions in which “other” is an option, the database will require a comment. If “other” is marked in a question and nothing is specified in the blank, please enter “No Comment”.

4. Some questions will require call for data verification. After the call is made, you may change the answer from ‘No Comment” to the actual comment gathered on the phone call.

John LaRue, Montana
# Statewide Cumulative Antibiogram Data CY 2006

## Gram Positive Organisms

<table>
<thead>
<tr>
<th>Gram Positive Organism</th>
<th># of Isolates, all sources</th>
<th>Percent susceptible (%)</th>
<th># of Isolates, Urine Only</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Brenneria aerogenes</em></td>
<td>304</td>
<td>88%</td>
<td>63</td>
</tr>
<tr>
<td><em>E. faecalis</em></td>
<td>672</td>
<td>88%</td>
<td>323</td>
</tr>
<tr>
<td><em>E. faecium</em></td>
<td>126</td>
<td>92%</td>
<td>20</td>
</tr>
<tr>
<td><em>S. aureus</em></td>
<td>5807</td>
<td>92%</td>
<td>173</td>
</tr>
<tr>
<td><em>S. pneumoniae</em></td>
<td>406</td>
<td>93%</td>
<td>100%</td>
</tr>
</tbody>
</table>

## Gram Negative Organisms

<table>
<thead>
<tr>
<th>Gram Negative Organism</th>
<th># of Isolates, all sources</th>
<th>Percent susceptible (%)</th>
<th># of Isolates, Urine Only</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>E. coli</em></td>
<td>11594</td>
<td>84%</td>
<td>3902</td>
</tr>
<tr>
<td><em>K. pneumoniae</em></td>
<td>2079</td>
<td>97%</td>
<td>665</td>
</tr>
<tr>
<td><em>P. mirabilis</em></td>
<td>719</td>
<td>94%</td>
<td>204</td>
</tr>
<tr>
<td><em>P. aeruginosa</em></td>
<td>1369</td>
<td>91%</td>
<td>237</td>
</tr>
</tbody>
</table>

*Note: Percent susceptible values may vary based on specific antibiotic.*
The A-cumulator Tool

Laboratory 300006’s antibiogram is stored under Lab6 worksheet in the Labs 1-60 workbook (Figure 4).

Figure 4. S. aureus data for laboratory 300006 stored in Lab6 worksheet.

What happens then? The data from the Labs 1-60 workbook is pulled into and distributed to the appropriate pathogen worksheets in the A-cumulator workbook. At the bottom of each of the pathogen worksheets, the aggregated % susceptibility (%S) for each antimicrobial is calculated.

J. LaRue, Montana
Getting Started:
Before you begin copying and pasting antibiograms, here are some additional actions that you will want to accomplish.

1. **Rename the archived files:** Montana has chosen to rename all of the antibiograms that have been returned with the accession number of the laboratory. *(Figure 2)* To save space, you may wish to delete the instructions worksheet that has been returned with each antibiogram file.

*Figure 2.* Renamed antibiograms in archive file.

- **Transcribe hardcopy data** *(if necessary):* Hopefully the majority of the antibiograms that are returned to you are in electronic format however we are finding a significant number of laboratories are printing the worksheet, filling it out by hand, and faxing or mailing it back to us via snail-mail. It is for this reason that the “template-Antibiogram_wrksto**7” was included *(Figure 2)*. The data entry person will need to manually transfer the hard-copy susceptibility information into the template worksheet and save it as the appropriate laboratory.

1. **Change laboratory numbers in pathogen worksheets:** Another change that will need to be made is with regard to the A-cumulator workbook. Each pathogen sheet aggregates the susceptibility data from all of the laboratories that submit. See the example of the *S. aureus* worksheet in *Figure 3*. Each state that uses this workbook will need to change the accession numbers in **Column A** on each pathogen worksheet so that they correlate with the accession numbers they have assigned the laboratories in their respective states.

   Each row represents the data from one laboratory. In *Figure 3*, Row 9 contains the data for laboratory 300006. Laboratory 300006’s antibiogram is stored under **Lab6** worksheet in the **Labs 1-60** workbook *(Figure 4)*.

John LaRue, Montana
“The Clinical Laboratory Standards Institute and the Microbiology Laboratorian: Putting Guidelines Into Practice”

I. Course Introduction
Case Studies
Case studies on using the CLSI susceptibility testing guidelines to solve common questions and problems in the microbiology laboratory

Section 1: Using Tables 1 and 1A

III. (Suggested groupings of U.S. FDA-approved antimicrobial agents that should be considered for routine testing and reporting on nonfastidious organisms by clinical microbiology laboratories)
A. Case 1. Site-specific reporting of susceptibility results
Case 2. Selective reporting of susceptibility results
Case 3. Susceptibility reporting by antibiotic class
Case 4. Organism-specific reporting of susceptibility results
Case 5. Susceptibility reporting by antibiotic class (2nd example)

Section Two: Using Tables 2A-2I
Case 6. Detecting and reporting inducible clindamycin resistance in staphylococci
Case 7. Detecting and reporting extended-spectrum beta-lactamase (ESBL) resistance in enterobacteriaceae
Case 8. The changing epidemiology of Methicillin-resistant Staphylococcus aureus (MRSA)
Case 9. Susceptibility testing of Staphylococcus lugdunensis

Section Three: Using Tables 4 (M2) and 8 (M7)
(Suggestions for verification of antimicrobial susceptibility test results and confirmation of organism identification)
Case 10. Detecting testing errors and unlikely or unusual susceptibility results

Section Four: Other susceptibility testing issues
Case 11. Susceptibility testing when there are no CLSI-approved methods or interpretation breakpoints
Case 12. Design and use of an institution antibiogram

Additional Resources and CLSI Documents
Some Questions from Laboratorians & Answers
Secure Telecommunications Application Terminal Package

Remote laboratory consultation on a variety of specimens (bacteria, fungal, AST…)

20 units currently in Nebraska (6 more to be deployed in three years of CDC AST grant)
  - 11 in Oklahoma, 9 in Kansas

www.statpack.org

Josh Rowland, Nebraska
Project Reporting

- From each State Leader
  - Monthly reports to Consortium Leader (Montana)
  - Progress, Obstacles, Outcomes

- NLS Partners
  - Quarterly Reports to CDC
    - Activities
    - Obstacles
    - Proposed Solutions
    - Progress toward Expected Outcomes
Project Outcomes/Evaluation

- **NLS Partners in collaboration with CDC**
  - Completion of Logic Models
    - Ongoing
      - Annual
      - Overall Project

- **Overall project outcomes – CDC/NLS Mission**
  - Improve communications and collaboration between clinical labs and public health laboratories
    - Improve laboratory testing practices
    - Improve public health
Vision: Integrated System

Federal Laboratories

State & Local Public Health Labs

Hospital, Independent, Physician Office Labs
Michigan

Antibiogram QA Project:
Part of the Initiative to Integrate Clinical Laboratories in Public Health Testing

Martha Boehme, Project Lead
Patricia Somsel
Michigan Department of Community Health
Objectives

• QUALITY IMPROVEMENT of AST
  – Increase awareness/promote compliance with current standards of practice:
    • CLSI antimicrobial susceptibility testing standards
    • CLSI antibiogram guideline

• Develop/strengthen relationship with sentinel laboratories

• Develop effective training program for public health education of clinical laboratories
Changes in CLSI Recommendations 2001-2006

Number and frequency of changes make it difficult for laboratory staff to keep current.

Number of changes

CLSI Document
- M100
- M2
- M7

2001 2002 2003 2004 2005 2006
Michigan Clinical Laboratory
Demographics
2002-2006

110-115 sentinel labs
  - (fluctuates due to closures and mergers – we use 110 as "average" number)
53/110 (48%) in hospitals with < 100 beds
Only 11 had PhD-level microbiologist on staff or available for consult
**Methods**

- Lab Survey 2003
  - 64/110 responses:
    - >25% did not have newest (January 2003) CLSI document
    - 8% of those did not even have 2002 document (M100-S12), which had many significant updates
    - One-third do not purchase CLSI documents yearly due to cost (~$100)
    - 41% are “not usually aware” that new documents have become available
Methods

• Collect cumulative antibiograms from hospital laboratories
  – Provides info about some of their testing practices
  – Provides info about their post-analytical practices
  – No additional burden for laboratory
• Compare to CLSI recommendations
• Address gaps through educational offerings
All bacterial isolates from sterile sites recovered from patients at Hospital XYZ from January 1, 2003 - December 31, 2004

<table>
<thead>
<tr>
<th>Antimicrobials tested</th>
<th>Organisms</th>
<th>Percent of organisms from specific group of patients over defined period of time that were susceptible to each antimicrobial agent</th>
</tr>
</thead>
<tbody>
<tr>
<td># Isolates</td>
<td>Gram-Negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Escherichia coli</td>
<td>577 68 69 99 96 96 99 99 99 97 98 96 100 96 74 82 95 99 86</td>
</tr>
<tr>
<td></td>
<td>Enterobacter cloacae</td>
<td>32 13 34 82 3 74 58 78 78 50 100 100 100 100 78 92 74 100 100</td>
</tr>
<tr>
<td></td>
<td>Klebsiella pneumoniae</td>
<td>103 6 87 100 99 100 100 100 93 99 100 98 99 86 91 98 100 96 99 86</td>
</tr>
<tr>
<td></td>
<td>Proteus mirabilis</td>
<td>56 91 88 100 84 95 98 100 96 89 98 98 98 100 91 4 98 98 95 91 4 98 98 95 95 90 97</td>
</tr>
<tr>
<td></td>
<td>Pseudomonas aeruginosa</td>
<td>144 75</td>
</tr>
<tr>
<td></td>
<td>Gram-Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Staphylococcus aureus all</td>
<td>439 55</td>
</tr>
<tr>
<td></td>
<td>Staphylococcus aureus MRSA</td>
<td>198 0</td>
</tr>
<tr>
<td></td>
<td>Enterococcus faecalis</td>
<td>175 99</td>
</tr>
<tr>
<td></td>
<td>Enterococcus fecium</td>
<td>45 0</td>
</tr>
<tr>
<td></td>
<td>Streptococcus pneumoniae</td>
<td>42 99 80</td>
</tr>
</tbody>
</table>
Number of Antibiograms Submitted Increased each year (2000-2005 data)

* Data still being submitted and analyzed
Internal Antibioticogram

QI Assessment Tool

- Developed uniform checklist based on CLSI M100 document
- Classified errors as major/minor
- Included only “processed” antibiograms (not raw instrument data summaries)
- Looked for errors, inclusion of select CLSI recommendations
Results

• Examples of “major” errors:
  – Unverified or unusual resistance patterns
    • e.g. *S. aureus* < 100% S to vancomycin
  – Inappropriate drugs reported
    • e.g. Oxacillin (instead of penicillin) reported on *Streptococcus pneumoniae*
  – Incongruent results
    • e.g. MRSA > 0% S to β-lactams

• Examples of “minor” errors:
  – Obvious math errors (e.g., 93% of 20 isolates!)
  – Organisms and/or /drugs misspelled
MDCH Actions to Address Gaps

• Purchase and distribute CLSI AST-related documents to sentinel labs
• Provide educational offerings on AST topics:
  – MDCH workshops
  – MDCH lab newsletter and fax broadcasts
• Collaborate with SCACM at Michigan fall meetings and encourage participation by providing free registration for clinical labs
MDCH Education efforts in 2003 focused on AST issues
Percentage of Antibiotics with Minor Errors (2000-2004)
Many Improvements Noted over Life of the Project

- Explanatory footnotes and comments increased
- *Streptococcus pneumoniae* data, dual (mening/non-mening) interpretations were added
- ESBL data included
- Explanations of how data calculated, source of isolates
- Antimicrobial names spelled out or abbreviations defined
Conclusions

• Clinical laboratories now rate “source for updates and documents” as one of most valuable services provided by MDCH

• Project established key “go-to” people at MDCH
  – 2004 Battelle study: 46% of labs made >=5 inquiries of MDCH lab per year
  – Substantive inquiries to MDCH Integration Project coordinator increased 20-50% each year (2002-2006): 30-52% were AST-related
Conclusions (cont’d)

• Increase in antibiogram errors (2004 data) may be due to increased number of antibiogram submissions from new participants

• Ongoing outreach to clinical laboratories is essential to maintain progress

• Intangible benefits evident, though harder to measure:
  – Better working relationships, greater trust, ease in communications, more cooperation
Thank you

- CDC - for supporting the Initiative to Integrate Clinical Laboratories in Public Health Testing
- Clinical Laboratory Staff in Michigan – for their dedication and commitment to the people they serve
- Exceptional MDCH Bureau of Laboratories staff - who recognize their responsibility to the citizens of MI for quality does not end at the walls of their laboratory.