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

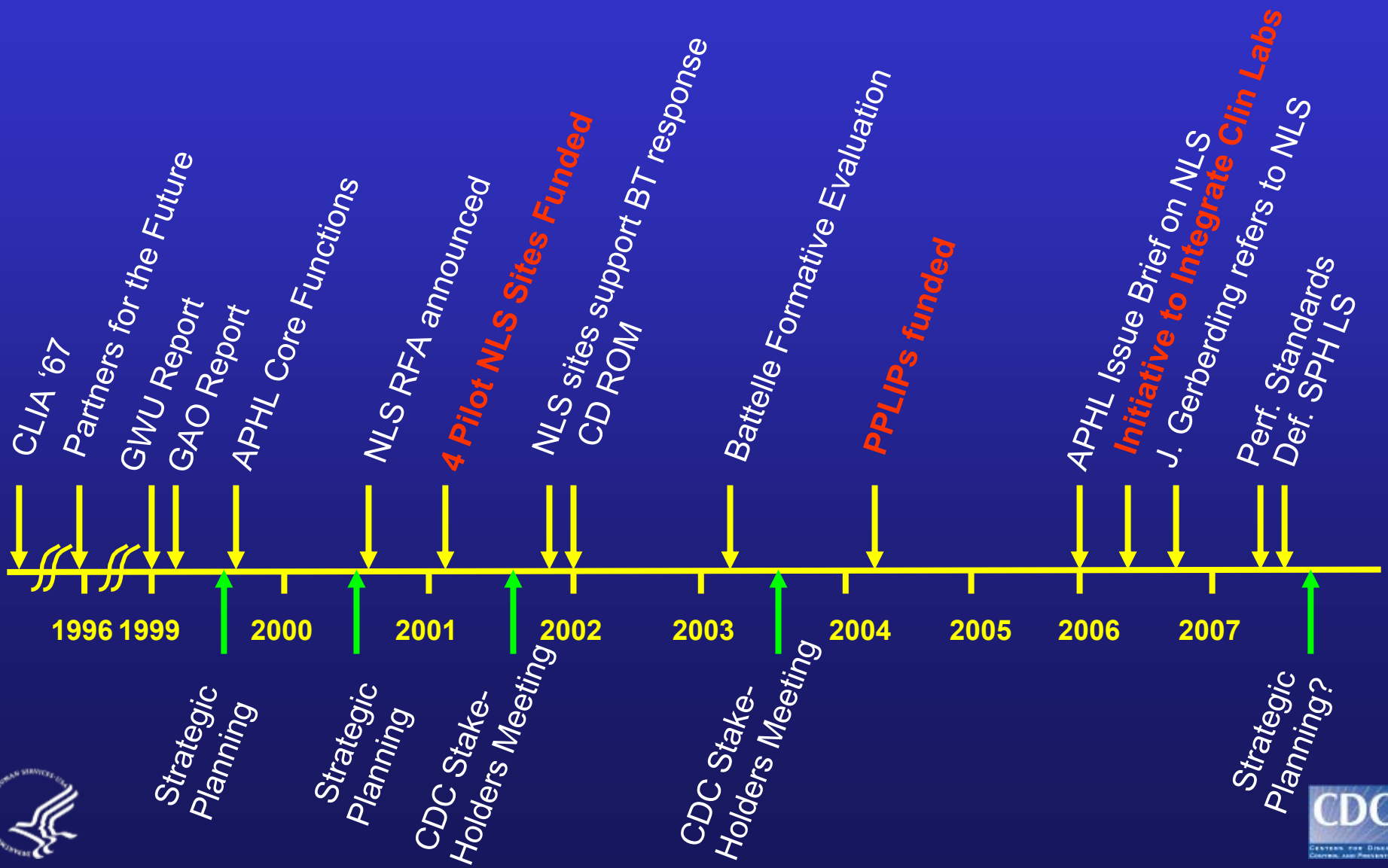
Linking public health, clinical, veterinary, food safety, and environmental laboratories to create seamless systems within each state for public health surveillance and laboratory support and improvement is the urgent mission of the National Laboratory System initiative

Critical point: the NLS depends upon strong State Public Health Laboratory Systems.

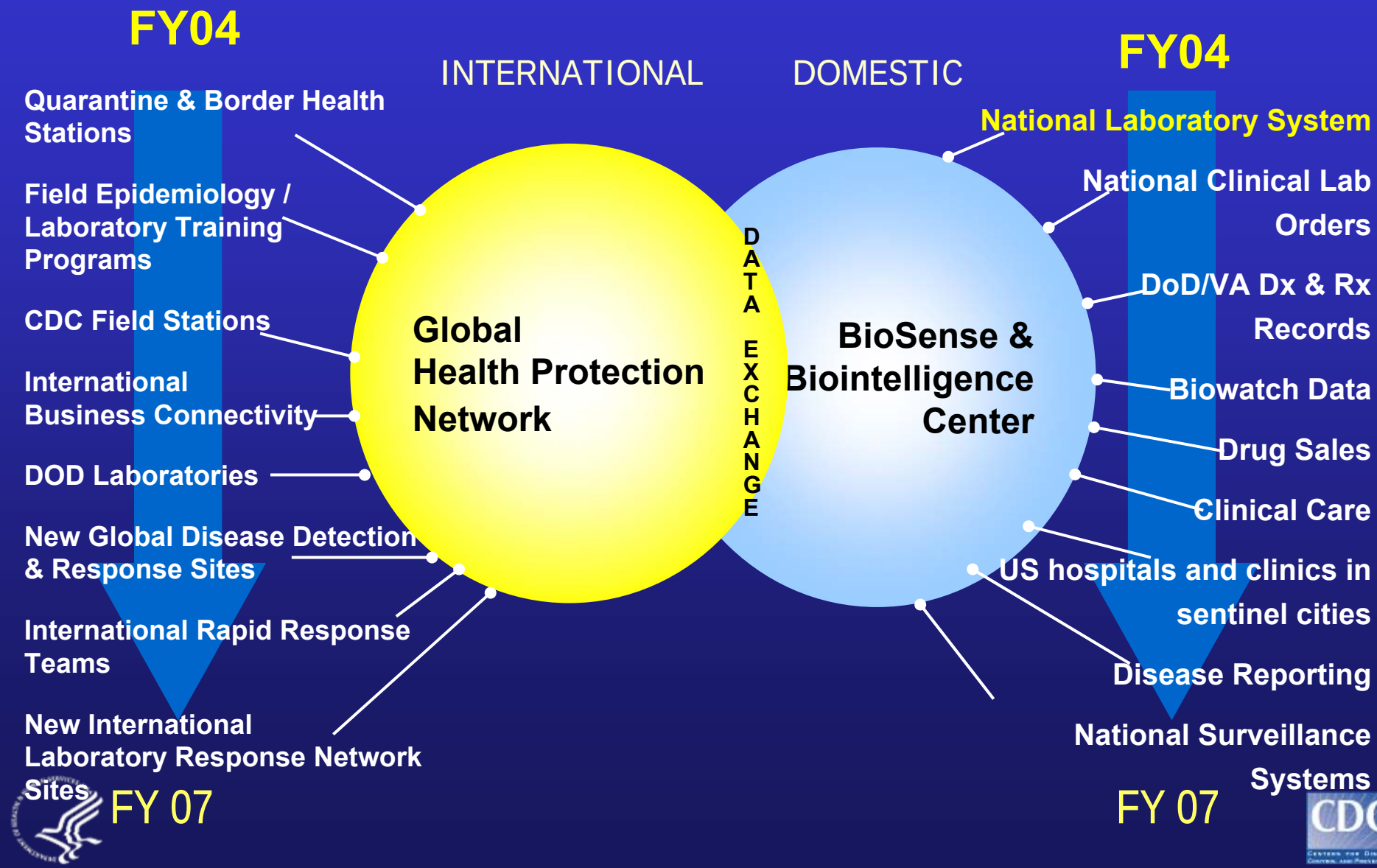
What is the "State-Level Public Health Laboratory System?"

- *…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

NLS Developmental Timeline



CDC's Global Health Protection Network



Look How Far We've Come

APHL Survey, Summer 2001

	YES	NO	TOT.
Started new activities to improve clinical testing	14	21	35
Lab Advisory Committee	9	26	35
Newsletter for at least some Clinical Micro Labs	18	17	35
Have a BT Liaison	16	19	35
Regional Agreements w Other PHLs	15	20	35
Contact Clin. Labs to Assure Surveillance of Dz's	19	15	34
*3 employed by SPHL; 16 empl. by state epi. program	3/16*		

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)

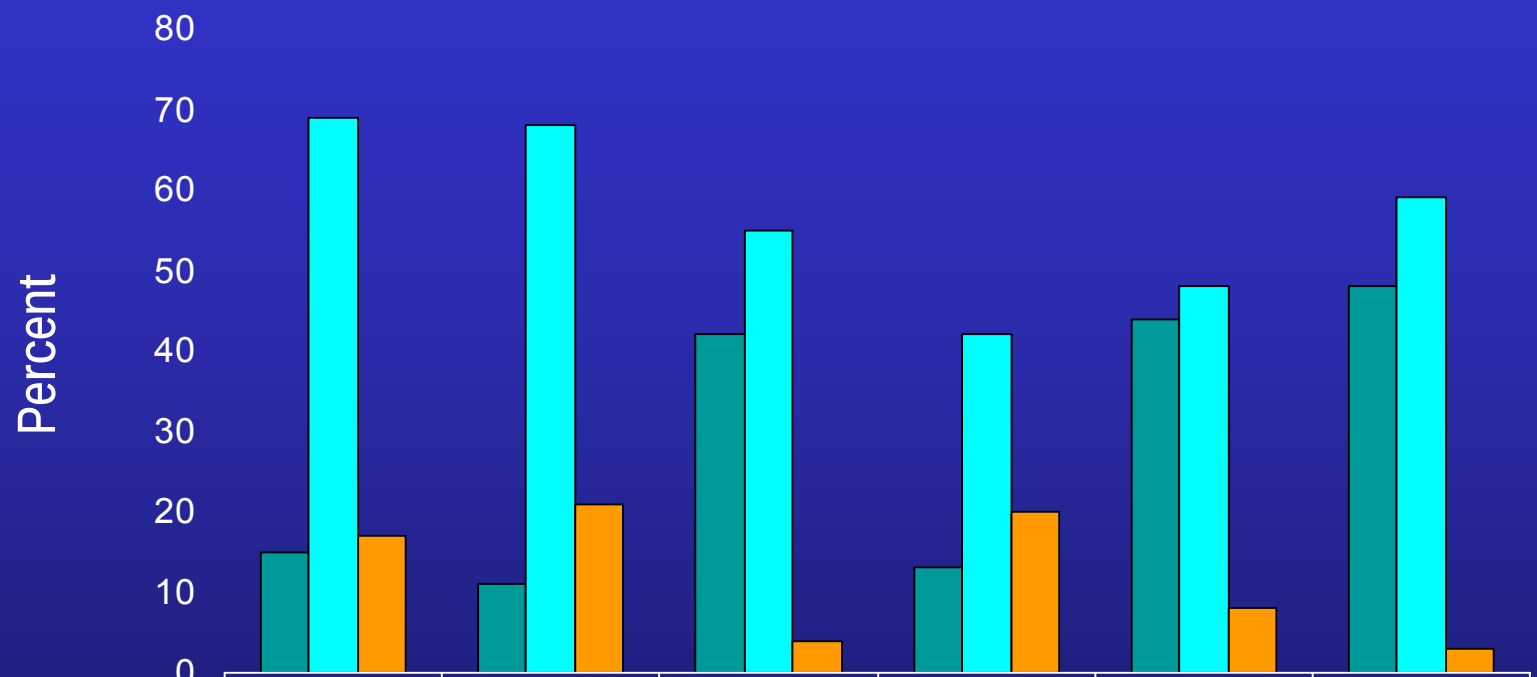
- Tools
  - Laboratory Program Advisors
  - National Center for PH Laboratory Leadership
  - National Laboratory Database
  - Core Functions
  - Performance Standards

- 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



	Lab Safety	AST	EID	Regs – QA/QC	Specimen Transport Req.	BT Agents
Currently do	15	11	42	13	44	48
Would like to	69	68	55	42	48	59
Not Interested	17	21	4	20	8	3

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 (SPH Laboratory System) consists of all the participants in public health testing, including those who initiate testing and those who ultimately use the test results. The SPH Laboratory System is part of the larger state public health system. The System includes individuals, organizations and agencies that are involved in assuring that laboratory data support the 10 Essential Services of Public Health. The concepts of a SPH Laboratory System are also embodied 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 SPH Laboratory System are primary stakeholders who are directly involved in creating and using laboratory data. Additional stakeholders include those who are concerned with complementary Essential Services, such as Training and Education and Public Health Related Research. A successful National Laboratory System is dependent on the creation of fully integrated and coordinated networks 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 SPH Laboratory System should assure that:

1. public health threats are detected and intervention is timely
2. stakeholders are appropriately informed of potential threats
3. reportable conditions are monitored in a comprehensive statewide system
4. specimens and isolates 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 SPH Laboratory System through active collaboration with stakeholders, including epidemiologists; first responders; environmental professionals in water, food and air surveillance activities; private clinical and environmental laboratories; and local public health laboratories. The SPHL provides leadership to assure that essential and state-of-the-art laboratory services are provided and that 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 SPH Laboratory System, such as completeness of reporting and accuracy of laboratory testing results. The SPHL also assures that accurate results are reported in a manner that is appropriate and sufficiently timely for effective public health response. An effective SPH Laboratory System requires proactive leadership by the SPHL to monitor public health testing processes by clinical and environmental in-state laboratories. To assure that the SPH Laboratory System is effective, the SPHL should at a minimum:

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

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

APHL
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
Web: www.aphl.org

Reaching Out Beyond Public Health: Strategies for Success

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

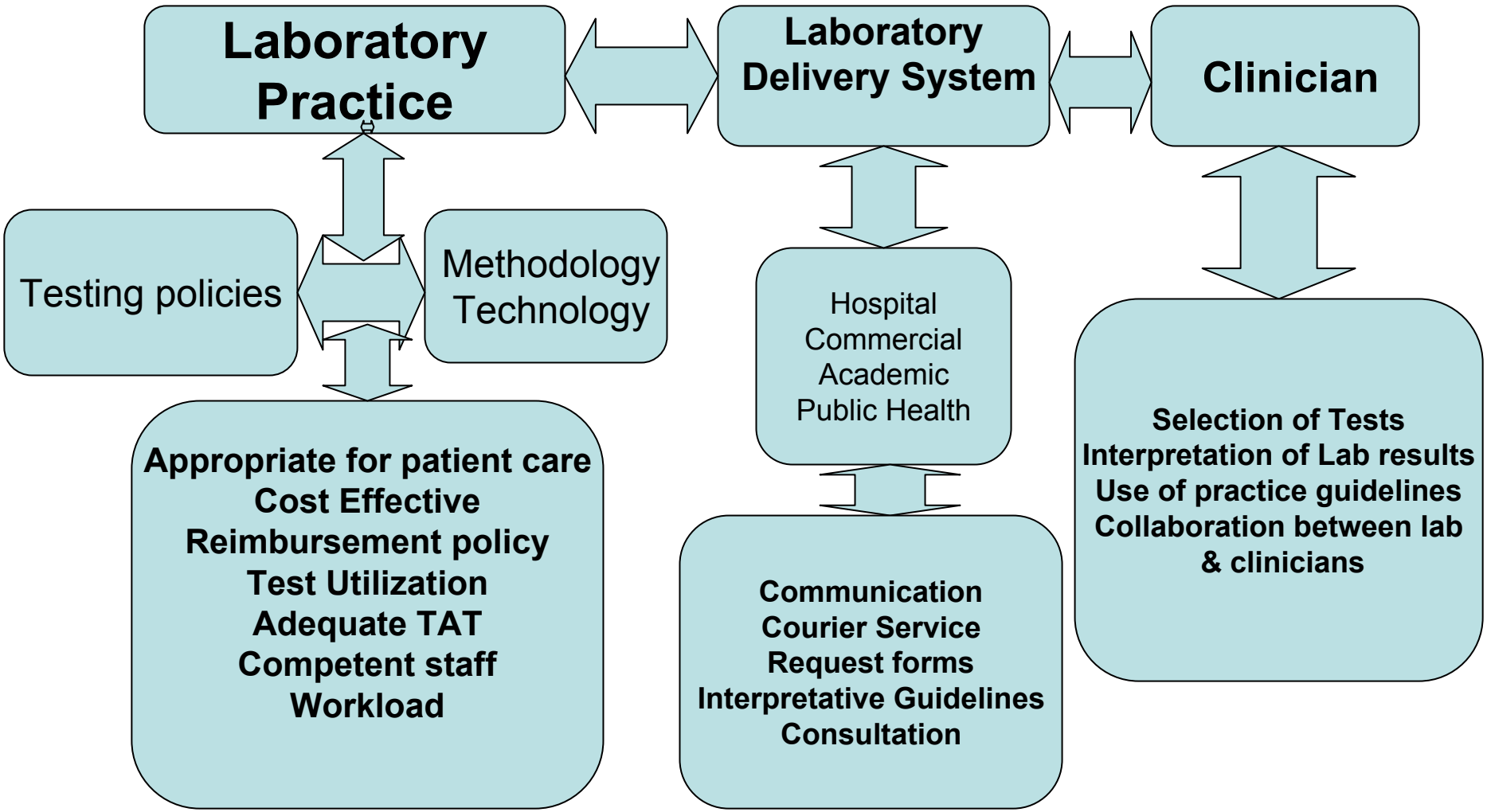
Foundation for Health Care Quality

CLINICAL LABORATORY INITIATIVE

JON M. COUNTS, DR.PH, MPH

10/12/2006

Foundation for Health Care Quality



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 SYSTEMG- 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

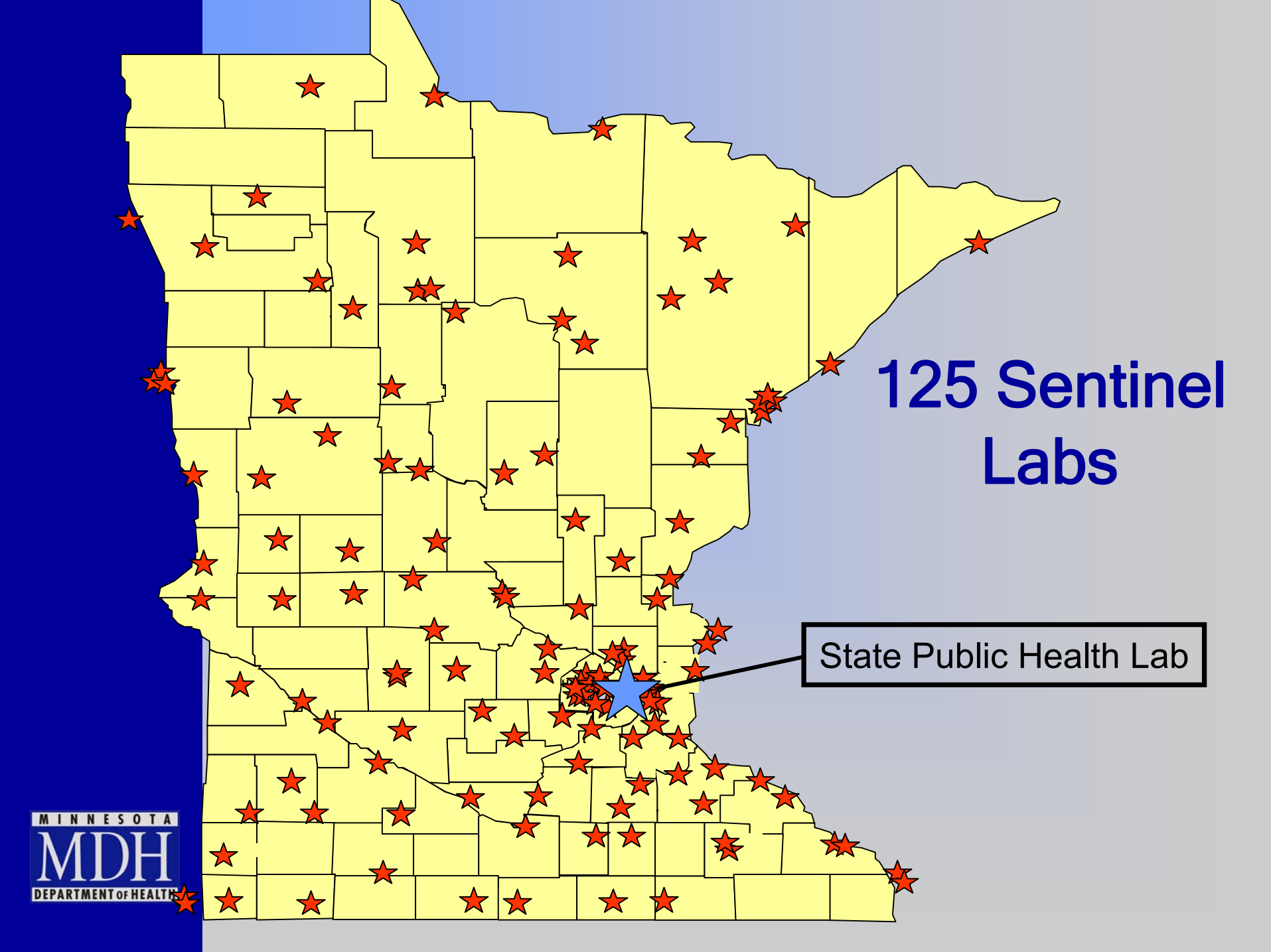
- Implement individualized quality management systems in Alaska, Oregon and Washington SPHL
- Improve their engagement and interaction with the laboratory delivery system in their state, including communication with the clinical laboratory community, quality of customer service and microbiology services 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

MINNESOTA MDH DEPARTMENT OF HEALTH


125 Sentinel Labs
State Public Health Lab
MINNESOTA
MDH
DEPARTMENT OF HEALTH

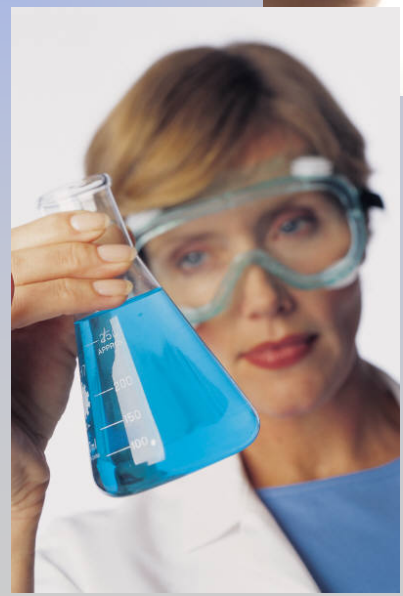
Basic Components

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

MINNESOTA MDH DEPARTMENT OF HEALTH

Dedicated Program Advisor

- Full-time position
- Clinical lab background



MINNESOTA MDH DEPARTMENT OF HEALTH

Recognizable System

Graphic Identifier

MLS
MINNESOTA
LABORATORY SYSTEM
A PRIVATE & PUBLIC COLLABORATION

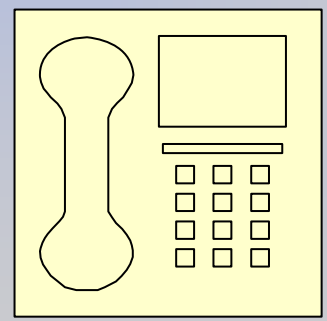
An integrated network of public and private clinical laboratories working together to protect and improve the health of all Minnesotans

MINNESOTA MDH DEPARTMENT OF HEALTH

Recognizable System – MLS Website

Robust Communication

- Robust database
- Blast email and fax capabilities
- Constant maintenance
- Listserve
- Website



MINNESOTA MDH DEPARTMENT OF HEALTH

Robust Communication – MLS Lab Alerts

Categories of Lab Alerts:

Laboratory ALERT

Conveys the highest level of importance; warrants immediate action, attention or response.

MINNESOTA MDH DEPARTMENT OF HEALTH

Robust Communication – [MLS: e-LAB] - Listserv

MNLabSystem - Mail From: Ron.Jadwin@NorthMemorial.com

File Edit View Actions Tools Window Help

Close Reply Forward

Mail | Properties | Personalize

From:

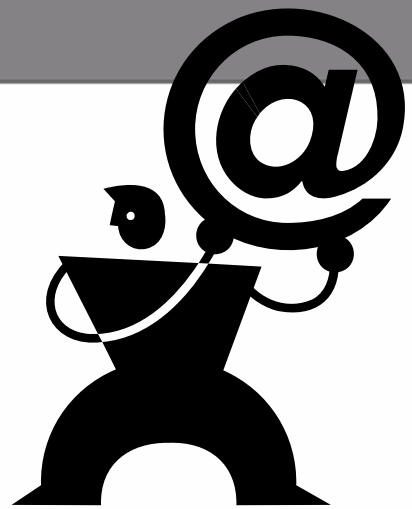
To: "Minnesota Laboratory System" <mnlabsystem@listserv.health.state.mn.us>

BC:

Subject: Re: [MLS:e-LAB] Screen plate for VRSA

We set it up for all S. aureus isolates at the same time the Vitek card is set up. This works well into our workflow.

>>> 9/1/04 12:48:09 PM >>>
Are labs setting up the vancomycin screen plate on ALL Staph areus isolates or only those that are positive for MRSA?



MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs

Education

Collaboration

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

Communication

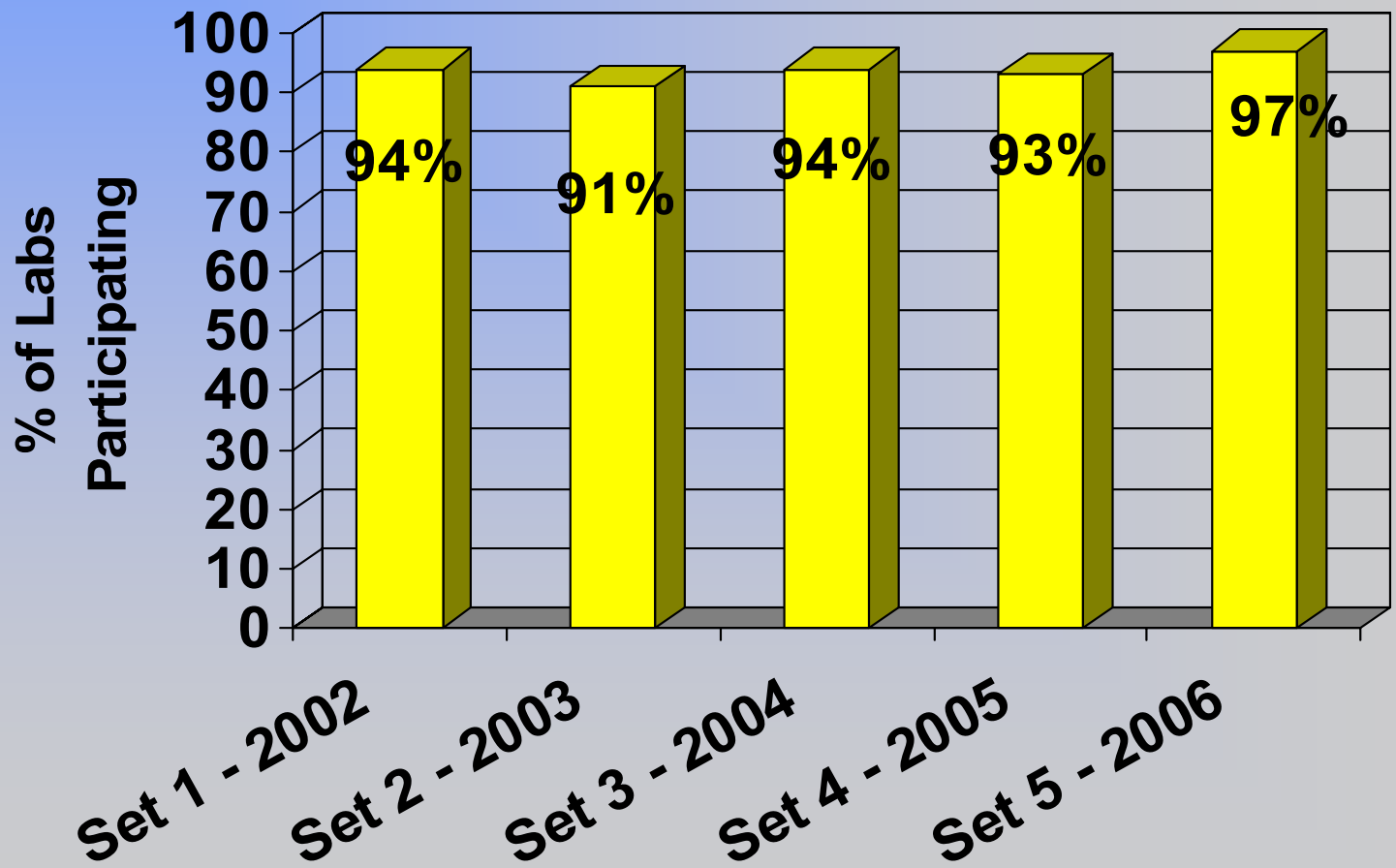
MINNESOTA MDH DEPARTMENT OF HEALTH

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

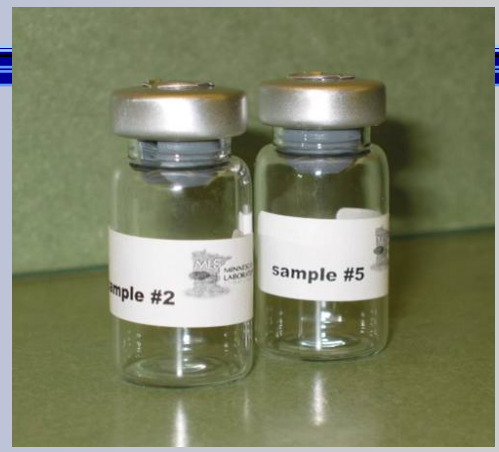
MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs Challenge Set



MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs Challenge Set



Goals

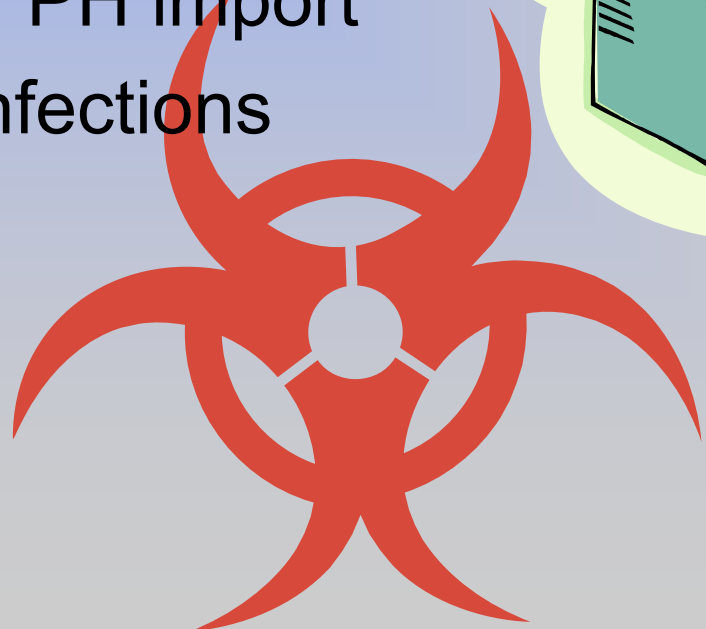
- Identify needs
- Monitor preparedness
- Assess practices/capabilities
- Provide educational resources
- Educate about diseases of public health importance

MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs Challenge Set

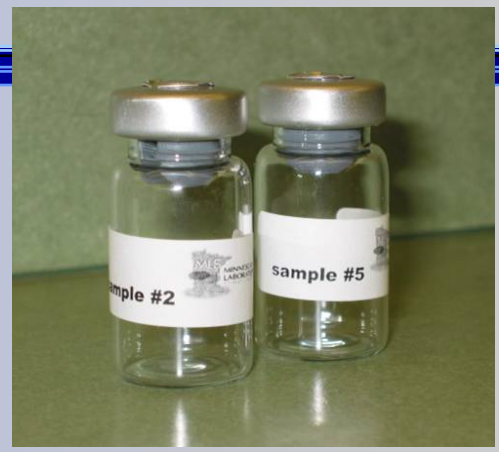
Organism Choices

- Terrorism-like agents
- Antibiotic resistance
- Diseases of PH import
- Emerging infections



MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs Challenge Set

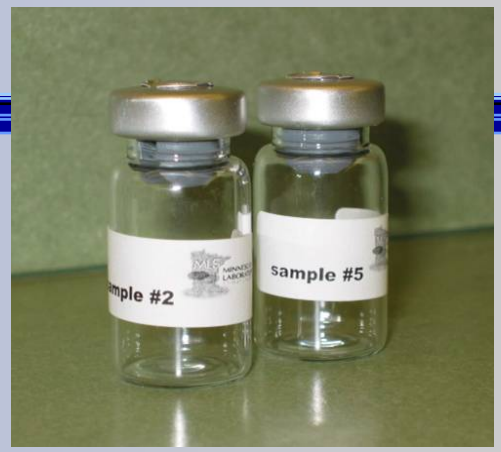


Organisms (Set 5)

1. *Oligella ureolytica*
2. *Mycobacterium abscessus*
3. *Listeria monocytogenes*
4. Streptococcus group B *(S. agalactiae)*

MINNESOTA MDH DEPARTMENT OF HEALTH

Valuable Products and Programs Challenge Set



Findings:

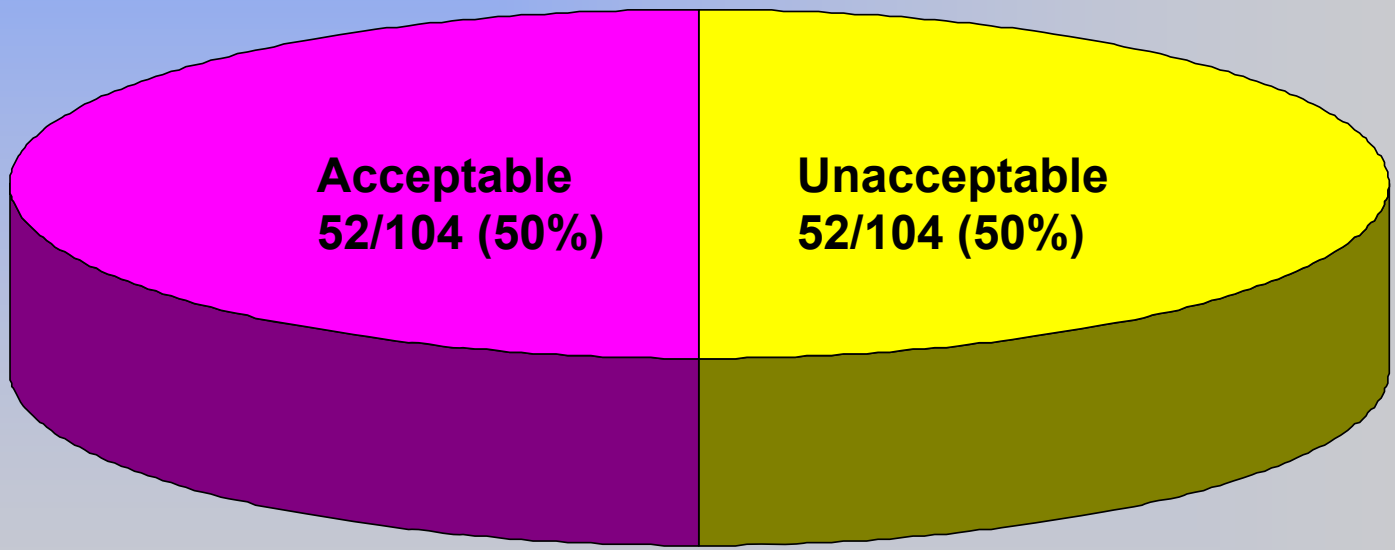
- Unusual gram-negative bacilli are difficult to ID
- Mycobacterium are not on the radar
- Changes in AST guidelines are a challenge
- Labs are interested - teleconference
  - 58 phone lines
  - 275 participants
  - 26 CDs

MINNESOTA MDH DEPARTMENT OF HEALTH

Challenge Set Findings

Brucella surrogate *(O. ureolytica)*

Identification (n=104)

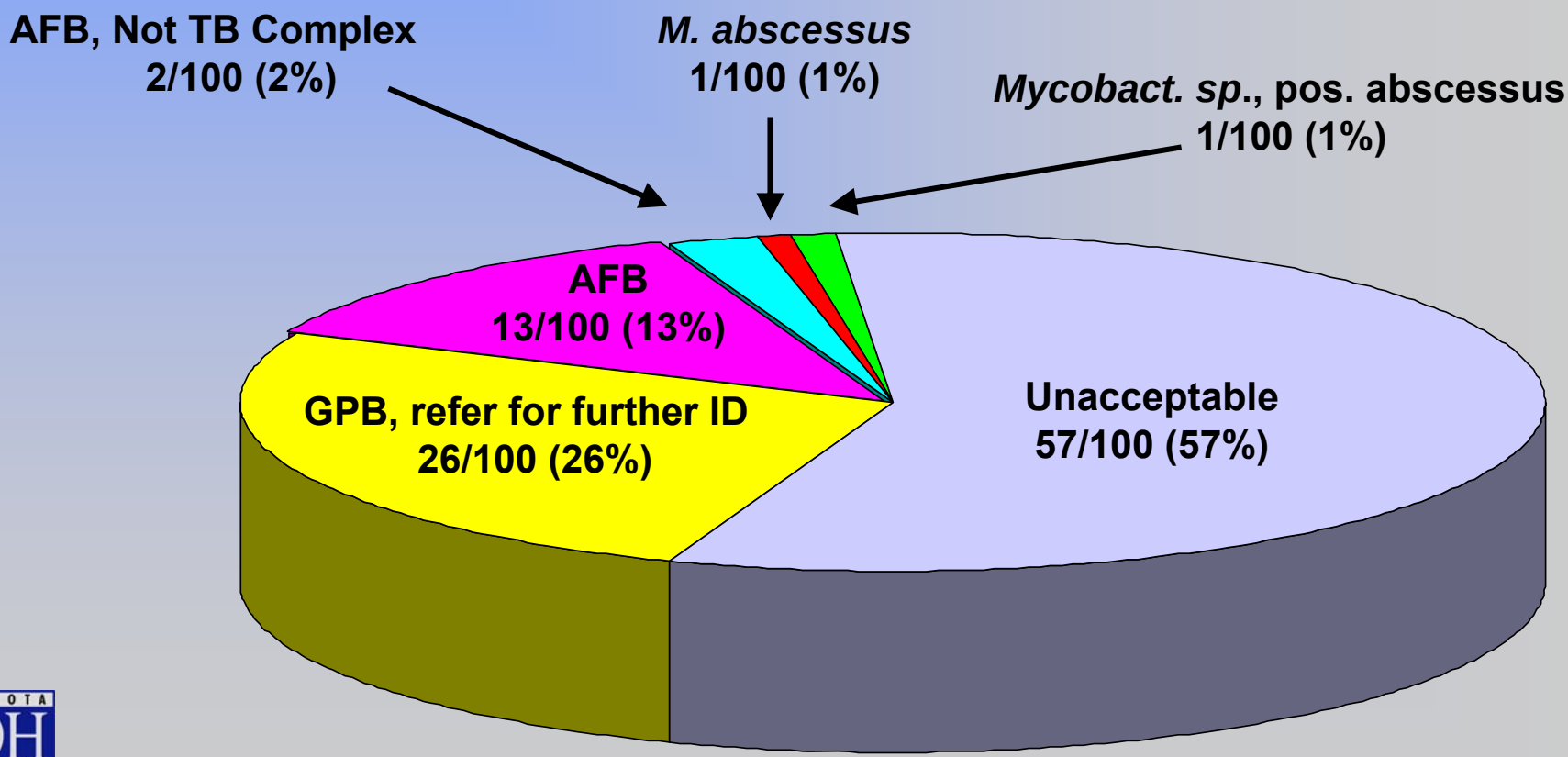


MINNESOTA MDH DEPARTMENT OF HEALTH

Challenge Set Findings

Mycobacterium abscessus

Acceptable Answers 43/100 (43%)

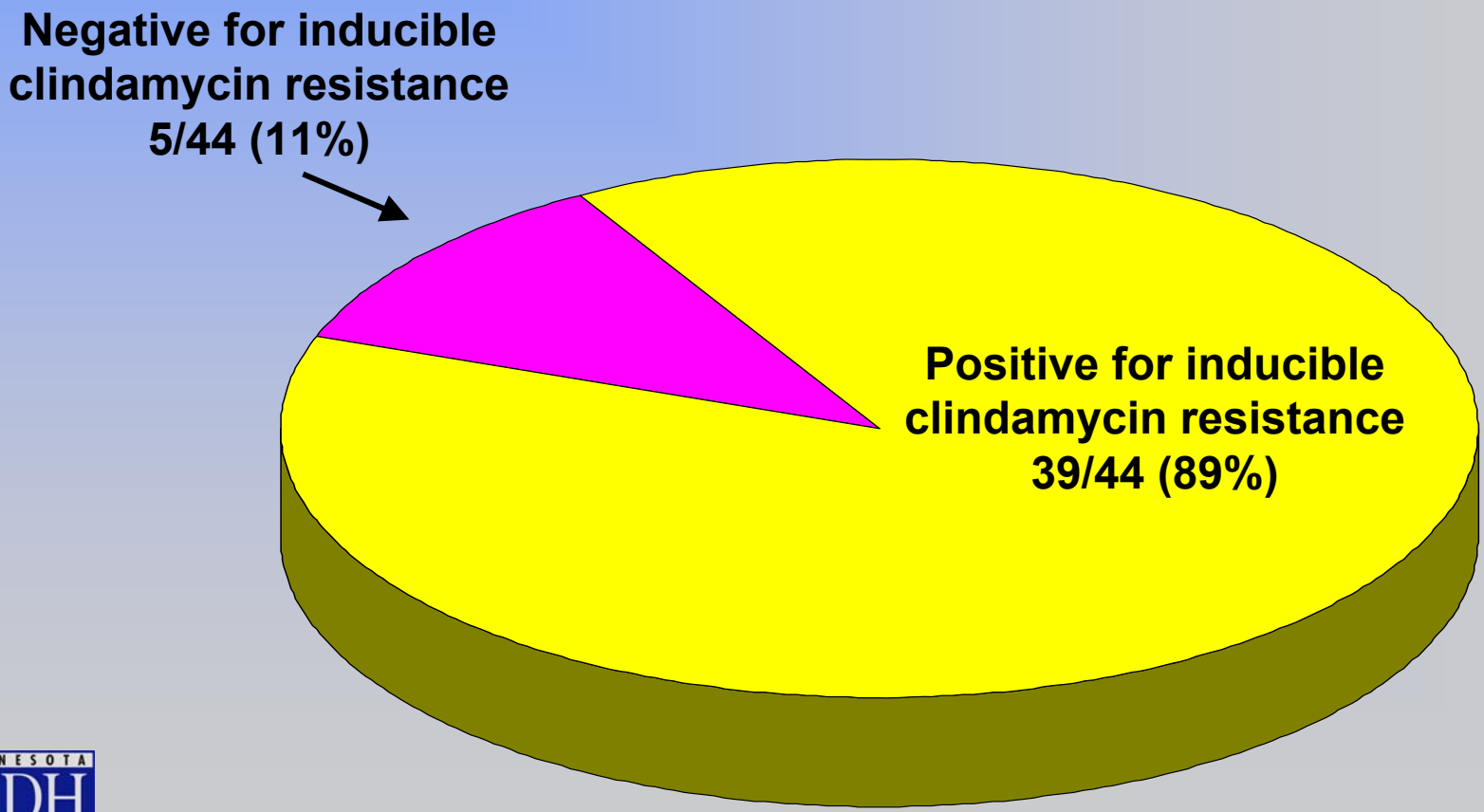


MINNESOTA MDH DEPARTMENT OF HEALTH

Challenge Set Findings

Group B Streptococcus (AST)

Performed D-zone Test (44/93 = 47%)



Measurable Benchmarks Challenge Set

- Staph aureus D-test

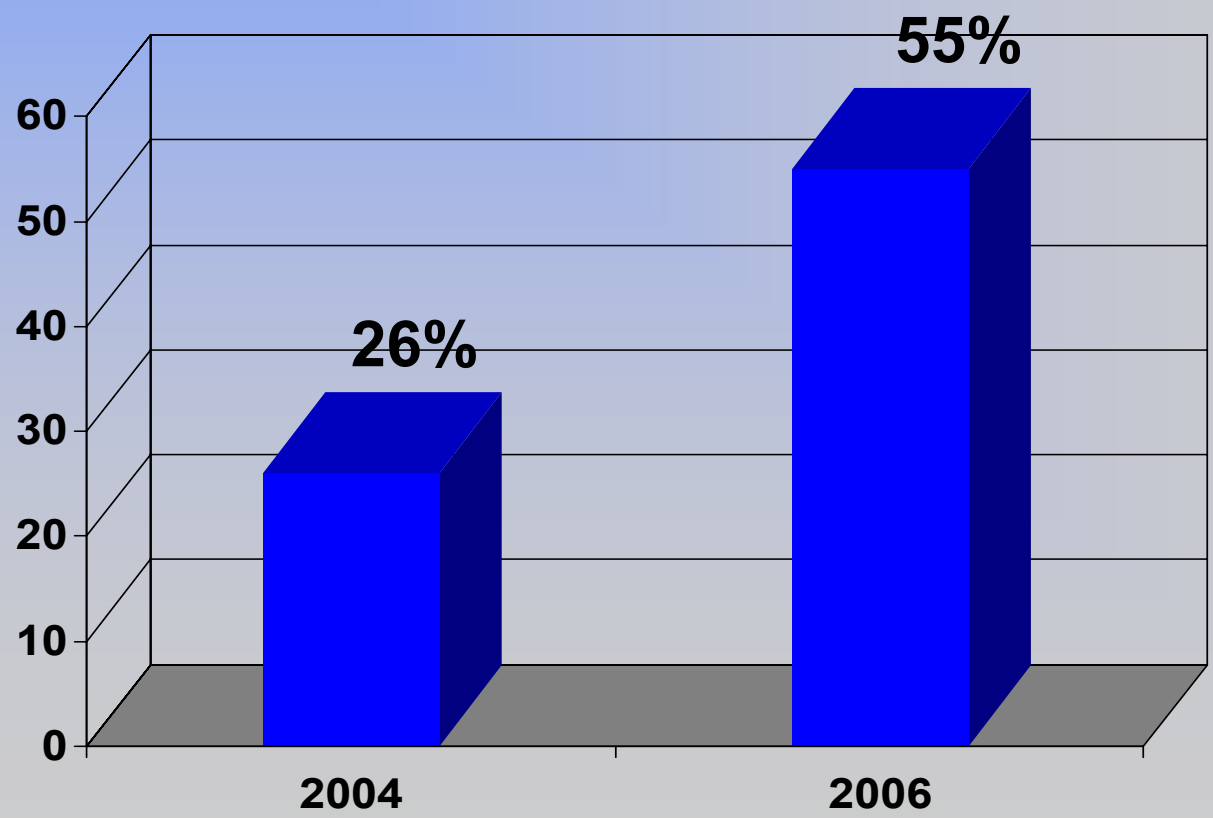
  Direct comparison of two consecutive challenge sets indicated a 21% increase in the number of laboratories that perform the D-zone test.

- Group B strep

MINNESOTA MDH DEPARTMENT OF HEALTH

Group B Streptococcus Disease Prevention

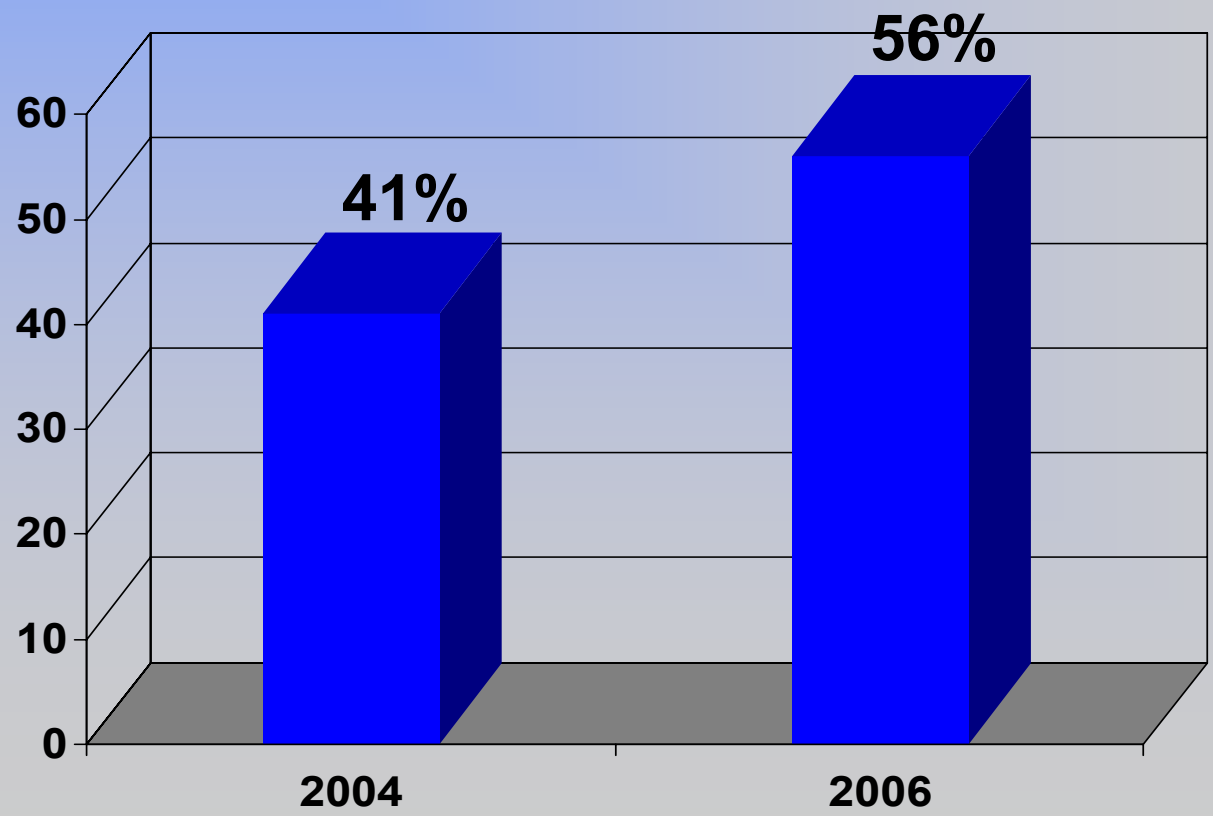
Penicillin allergy status information received by laboratory



MINNESOTA MDH DEPARTMENT OF HEALTH

Group B Streptococcus Identification

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



MINNESOTA MDH DEPARTMENT OF HEALTH

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."

MINNESOTA MDH DEPARTMENT OF HEALTH

Supportive Administration

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

Barriers

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

MINNESOTA MDH DEPARTMENT OF HEALTH

Final Words

- Change is slow
- Persistence is essential
- Impact is Positive

MINNESOTA MDH DEPARTMENT OF HEALTH

Paula M. Snippes

Program Advisor, Minnesota Laboratory System (MLS)

651-201-5581

paula.snippes@health.state.mn.us

MINNESOTA MDH DEPARTMENT OF HEALTH

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

NPHL
Nebraska Public Health Laboratory

Ag Calendar | Contact NDA | Laws & Regulations | Links | Media | NE Ag Facts | Site Map | Welcome | Webmaster

Nebraska Department of Agriculture

Greg Ibach, Director
Neil Moseman, Assistant Director

Nebraska Health and Human Services System

University of Nebraska Lincoln

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™

- **S**ecure **T**elecommunications **A**pplication **T**erminal **Pack**age
- 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
BIOHAZARD

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

STATPack™

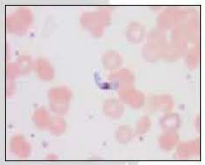
WWW.STATPACK.ORG

Connecting Medical Laboratory Networks

A.L. Fruhling[1], M.L. Lund[1], D.J. Rowland[2], R.K. Noel[2], B.K. Schweitzer[2], J.J. Mathewson[3], J.F. Murray[3], R.E. Flahart[4], S.E. Gabel[4], S.A. Riley[4], K.M. Weiss[1], G.A. Hoff[1], A.R. Sambol[2], S.H. Hinrichs[2].

[1]College of Information Science & Technology, University of Nebraska at Omaha, Omaha, NE, [2]Nebraska Public Health Laboratory, University of Nebraska Medical Center, Omaha, NE, [3]Oklahoma State Department of Health, Oklahoma City, OK, [4]Kansas Department of Health and Environment, Topeka, KS.

Consultation



Malarial

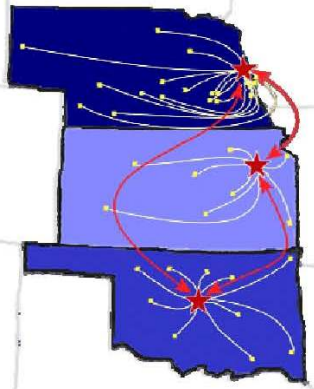
Images sent by St. Mary's Hospital in Enid, OK to consult with Oklahoma Public Health Laboratory one week after installation and training on STATPack. Determined to be *Plasmodium falciparam* based on morphological characteristics.

Fungal

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

Bacterial

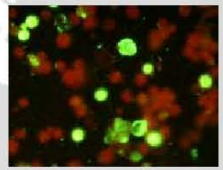
Images received at the NPHL for consultation. Catalase positive, non-hemolytic, non-motile, large GPR from a blood culture. Sentinel laboratory could not rule-out *Bacillus anthracis*. Morphology was not consistent with *Bacillus anthracis*.



Education

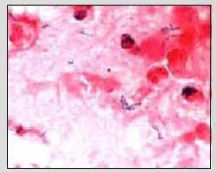
VZV DFA

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



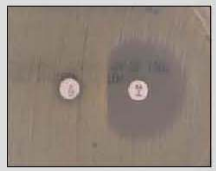
Competency Training

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 Pathologist (CAP) gram stain competency requirement (MIC.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.



University of Nebraska Omaha

NPHL Nebraska Public Health Laboratory

Oklahoma State Department of Health

University of Nebraska Medical Center

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

Joe Boone, PhD
Acting Director, DLS

John Ridderhof, DrPH
Acting Deputy Director, DLS

Laurina Williams, PhD, MPH
Project Officer

Rex Astles, PhD
Project Officer

Pam Robinson
Program Analyst

Jesse Holder
Programmer

Division of Healthcare Quality Promotion

Roberta Carey, PhD
Branch Chief, ELB

Fred Tenover, PhD

Clifford McDonald, MD

Brandi Limbago, PhD

Jean Patel, PhD

Shalein Banerjei, PhD

Consultants
Vanessa White, APHL
Jim Hidalgo, APHL
Rosemary Humes, APHL
Janet Hindler, PhD
NLTN

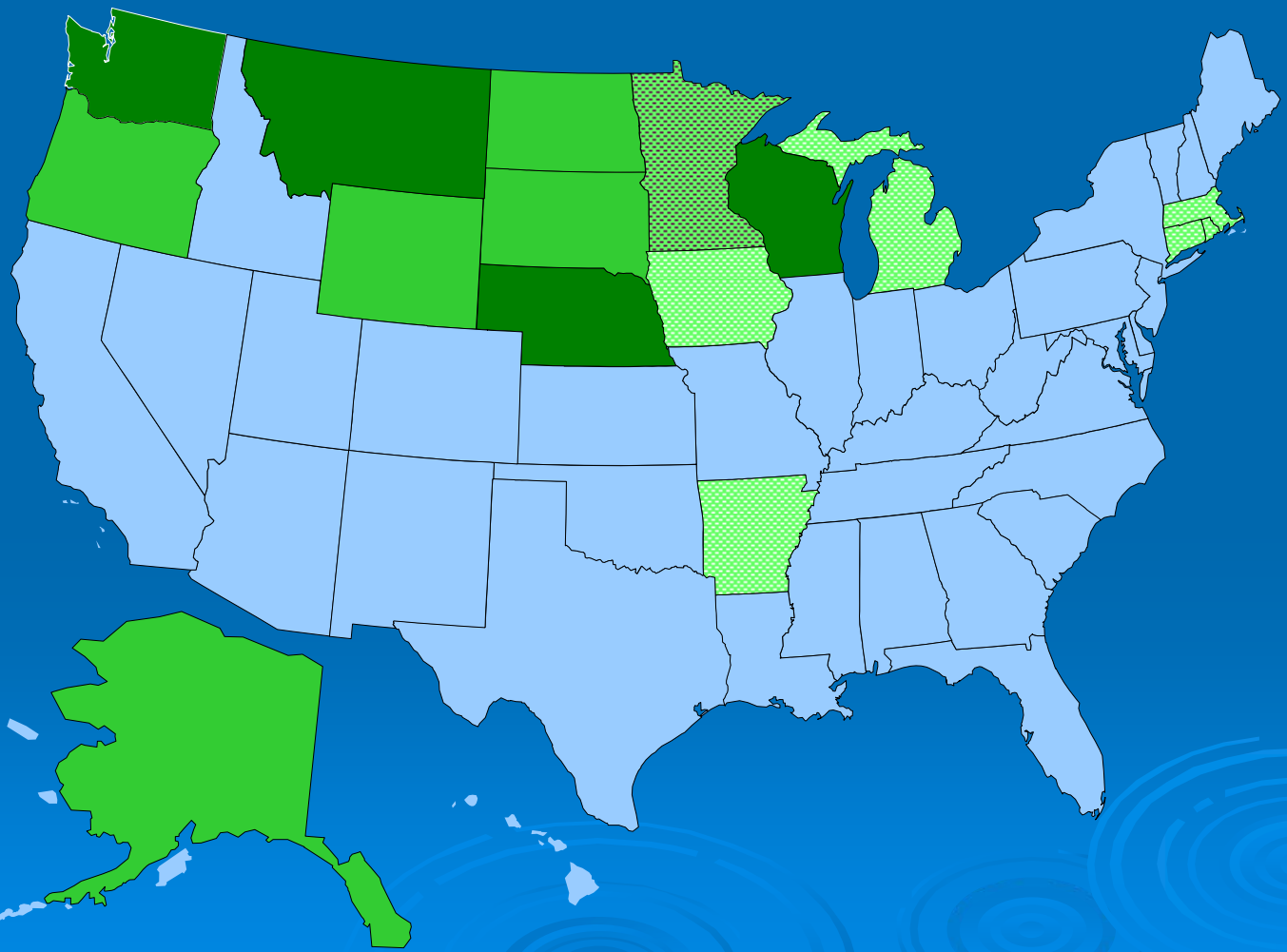
National Laboratory System (NLS) Initiatives

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

Methods-Chair:	**Paul D. Fey** **Jean Patel** **Roberta Carey** **Fred Tenover**
Demographics-Chair	**Jon M. Counts/ Rex Astles** **Anne Pollock** **Brandi Limbago**
Guidelines-Chair	**Joni Wedig** **Clifford McDonald**
Outcomes-Chair	**John LaRue** **Laurina Williams** **Pam Thompson** **Debbie Gibson** **Steve Marshall** **Susie Zanto**
Statistician	**Shalein Banerjei**

Survey Development Process

Consensus Process – Modeled after CLSI Document Process (November 2006)

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

The AST Questionnaire

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.**

Organism	1 **AST is performed on organism (Check Box)**	2 **Estimated Annual AST Volume for 2006**	3 **Screening test methods**	4 **Primary test methods**	5 **Secondary or confirmatory testing methods**	6 Comments
Enterococcus spp.	☐					
Staphylococcus aureus	☐					
Coagulase negative *Staphylococcus*	☐					
Streptococcus pneumoniae	☐					
Streptococcus agalactiae	☐					
Enterobacteriaceae	☐					
Haemophilus influenzae	☐					
Pseudomonas aeruginosa	☐					
P. aeruginosa from cystic fibrosis	☐					
Non-*Enterobacteriaceae*[1]	☐					
HACEK group[2]	☐					
Gram positive anaerobes	☐					
Gram negative anaerobes	☐					

List of Codes

A=Do not perform this method with this organism	**I**=BD Phoenix	**P**=D-zone test for inducible clindamycin resistance
		Q=Cefoxitin disk test for MRSA
B=Oxacillin Screen agar (MHA+Salt)	**J**=Microscan Walkaway Rapid	**R**=Latex agglutination (PBP) testing method for MRSA
C=Vancomycin Screen agar (BHI agar)	**K**=Microscan Walkaway Conventional	
D=PCR	**L**=Microscan auto or touchscan	**S**=ESBL confirmation test with clavulanic acid (Disk Diffusion)
		T=ESBL confirmation test with clavulanic acid (E-test)
	M=Trek (Sensititre/Aris)	**U**=ESBL confirmation test with clavulanic acid (automated testing)
E=E-test methodology		**V**=β-lactamase production (e.g. nitrocephin disk)
F=Kirby Bauer disk diffusion	**N**=Vitek 2	
G=Agar Dilution MIC methodology	**O**=Vitek Legacy	**W**=Other testing procedure (please specify in **Column 6.**)
H=Broth microdilution MIC methodology (manual reading)		**X**=Unknown

[1] **Includes** *Acinetobacter*, *Burkholderia*, **and** *Stenotrophomonas*
[2] **Includes** *Haemophilus* (**not** *H. influenzae*), *Actinobacillus*, *Cardiobacterium*, *Eikenella*, **and** *Kingella*

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/DHQP
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 data base may require calls to the participating facilities. In order 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 data base, 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 Cummulative Antibiogram Data CY 2006

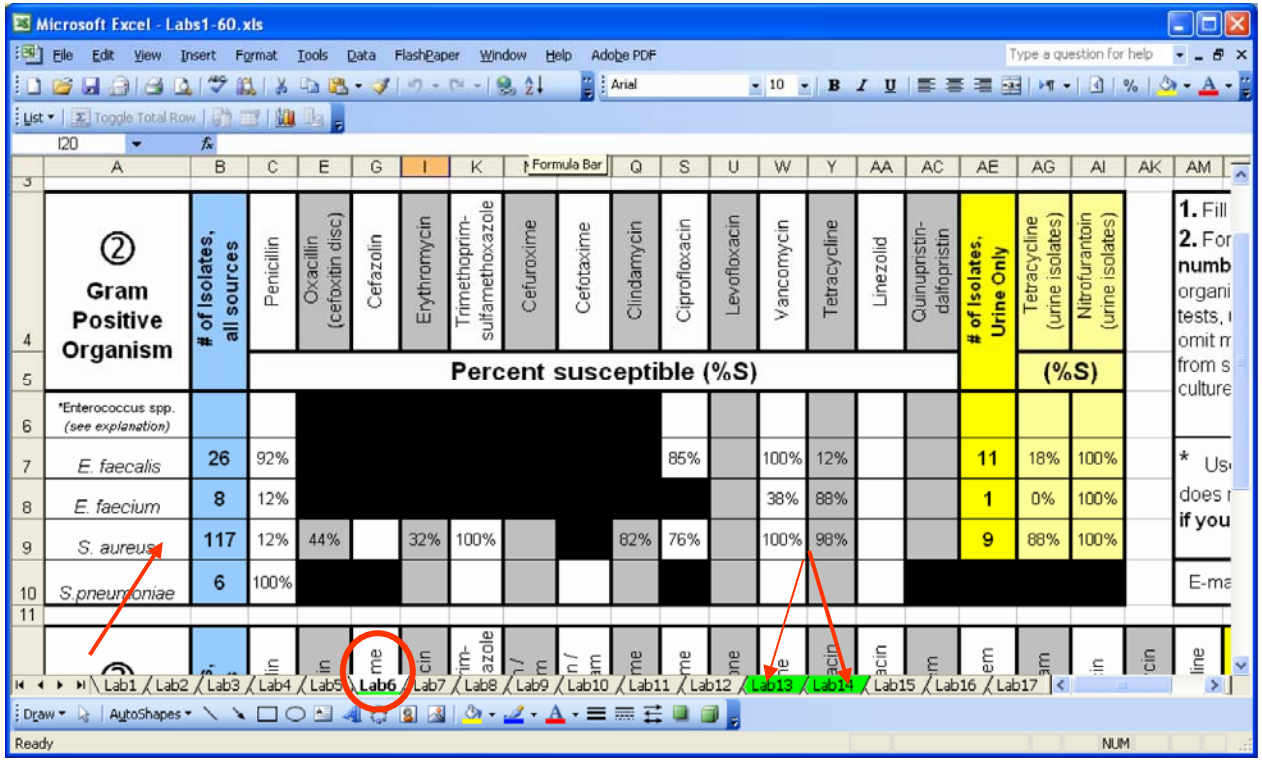
Gram Positive Organism	# of Isolates, all sources	Penicillin	Oxacillin (cefoxitin disc)	Cefazolin	Erythromycin	Trimethoprim-sulfamethoxazole	Cefuroxime	Cefotaxime	Clindamycin	Ciprofloxacin	Levofloxacin	Vancomycin	Tetracycline	Linezolid	Quinupristin-dalfopristin	# of Isolates, Urine Only	Tetracycline (urine isolates)	Nitrofurantoin (urine isolates)
		Percent susceptible (%S)															(%S)	
*Enterococcus spp. (see explanation)	304	98%								71%	65%	100%	40%	96%	ND	63	33%	100%
E. faecalis	1672	98%								64%	71%	99%	28%	96%	ND	323	32%	99%
E. faecium	126	32%									25%	74%	71%	95%	92%	20	65%	75%
S. aureus	5807	9%	60%	58%	46%	99%	75%		76%	67%	70%	100%	95%	99%	100%	173	91%	97%
S.pneumoniae	406	63%			63%	79%	84%	94%	46%		100%	100%	85%	100%				

Gram Negative Organism	# of Isolates, all sources	Ampicillin	Cefazolin	Ceftazidime	Gentamicin	Trimethoprim-sulfamethoxazole	Ampicillin / sulbactam	Piperacillin / tazobactam	Cefuroxime	Cefotaxime	Ceftriaxone	Cefepime	Ciprofloxacin	Levofloxacin	Imipenem	Meropenem	Aztreonam	Amikacin	Tobramycin	Tetracycline	# of Isolates, Urine Only	Ciprofloxacin (urine isolates)	Levofloxacin (urine isolates)	Norfloxacin	Tetracycline (urine isolates)	Nitrofurantoin
		Percent susceptible (%S)																				(%S)				
E. coli	11594	64%	94%	98%	95%	85%	72%	98%	92%	99%	99%	100%	93%	93%	100%	100%	99%	100%	96%	82%	3902	84%	84%	79%	71%	44%
K.pneumoniae	2079		97%	98%	99%	96%	89%	94%	91%	98%	98%	100%	98%	98%	100%	100%	98%	99%	99%	91%	665	78%	77%	74%	71%	31%
P. mirabilis	719	84%	95%	99%	95%	84%	91%	99%	97%	99%	99%	99%	89%	95%	98%	100%	98%	98%	95%		204	69%	65%	70%		
P. aeruginosa	1369			91%	83%			98%		12%	22%	89%	75%	80%	90%	95%	75%	95%	95%		237	35%	36%	44%		

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_wrkst07**" 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

ASCP Course

"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 enterobacteriaciae

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

STATPack™

- **S**ecure **T**elecommunications **A**pplication **T**erminal **Pack**age
- 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

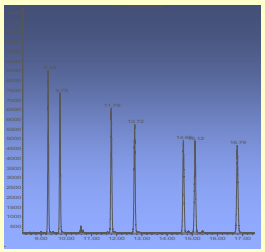
- **NLS Partners**
  - Quarterly Reports to CDC
    - Activities
    - Obstacles
    - Proposed Solutions
    - Progress toward Expected Outcomes

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



Michigan Antibiogram QA Project:

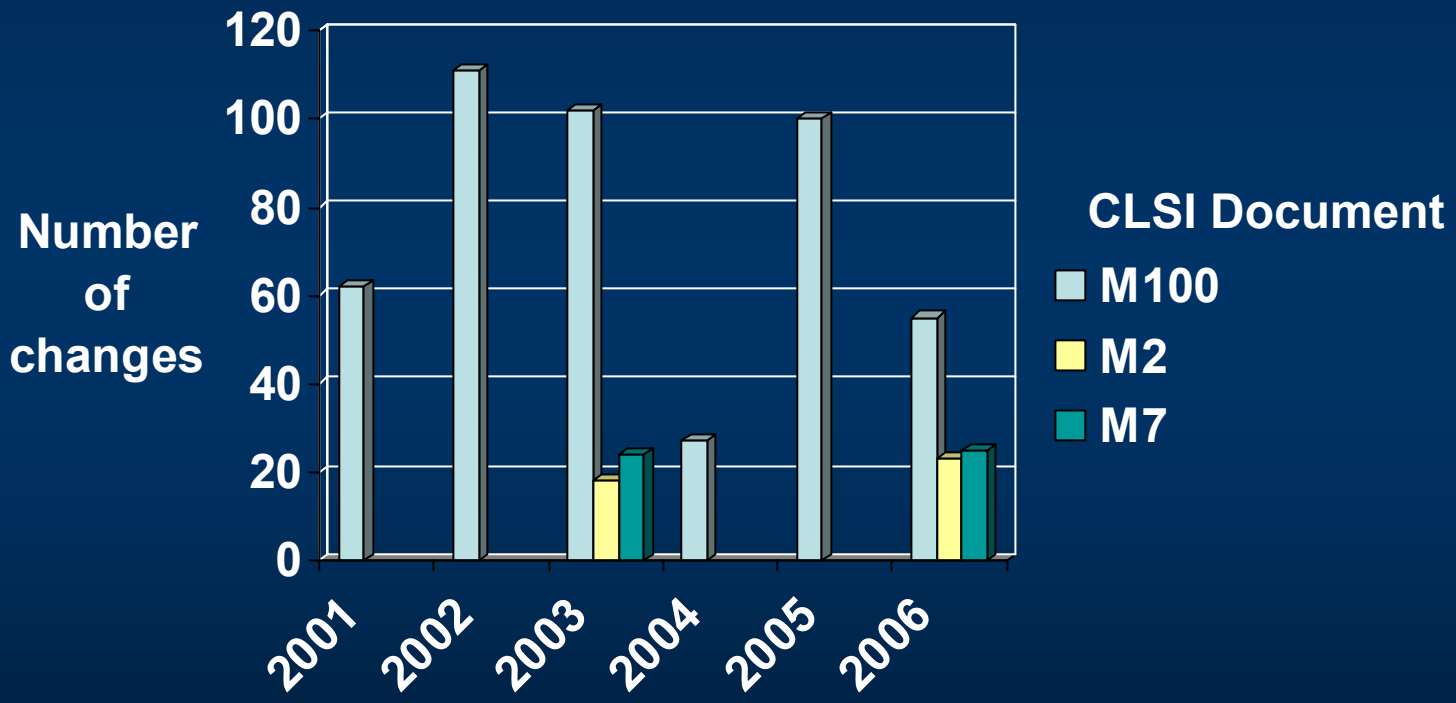
Part of the Initiative to Integrate Clinical Laboratories in Public Health Testing

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

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

Antibiogram Example

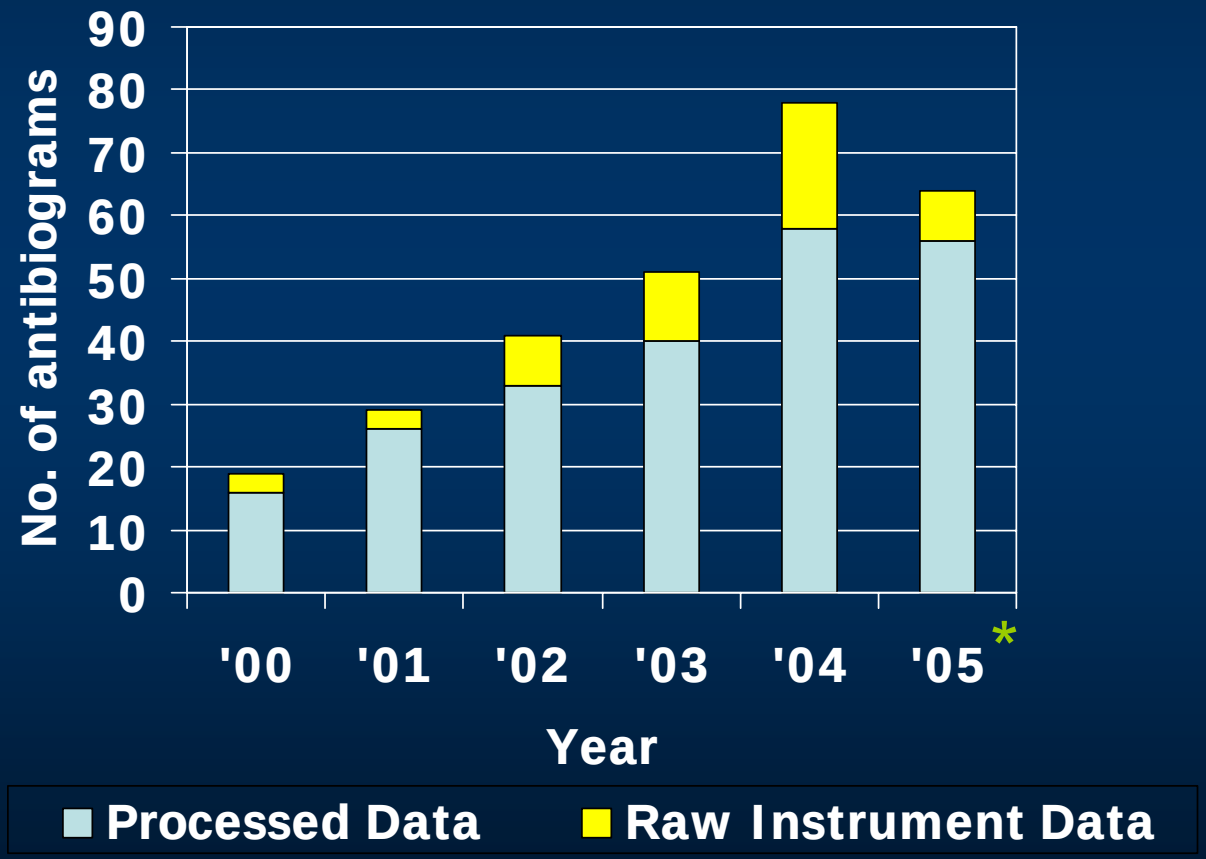
Antimicrobials tested

Percent of organisms from specific group of patients over defined period of time that were susceptible to each antimicrobial agent

All bacterial isolates from sterile sites recovered from patients at Hospital XYZ from January 1, 2003 - December 31, 2004

Organisms	# Isolates	Ampicillin	Ampicillin/sulbactam	Aztreonam	Cefazolin	Cefotaxime	Cefotetan	Ceftazidime	Ceftriaxone	Cefuroxime	Ciprofloxacin	Erythromycin	Gentamicin	Imipenem	Levofloxa		Tetra	Ticarcillin	Tobramyc	Trimethop	Vancomy
Gram-Negative																					
Escherichia coli	577	68	69	99	96	96	99	99	99	97	98		96	100	96		74	82	95	99	86
Enterobacter cloacae	32	13	34	82	3	74	58	78	78	50	100		100	100	100		78	92	74	100	100
Klebsiella pneumoniae	103	6	87	100	99	100	100	100	100	93	99		100	98	99		86	91	98	100	96
Proteus mirabilis	56	91	88	100	84	95	98	100	96	89	98		98	98	100		91	4	98	98	95
Pseudomonas aeruginosa	144			75			26	92	27		81		74	91	78		95		90	97	
Gram-Positive																					
Staphylococcus aureus all	439				55							47	86		71	55				98	100
Staphylococcus aureus MRSA	198				0							14	76		17	0				97	100
Enterococcus faecalis	175	99									42	15	62*(s)		46						98
Enterococcus faecium	45	0									0	5	22*(s)		0						32
Streptococcus pneumoniae	42								99	80		71			94		68				100

Number of Antibiograms Submitted Increased each year (2000-2005 data)



* Data still being submitted and analyzed

Internal Antibiogram 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

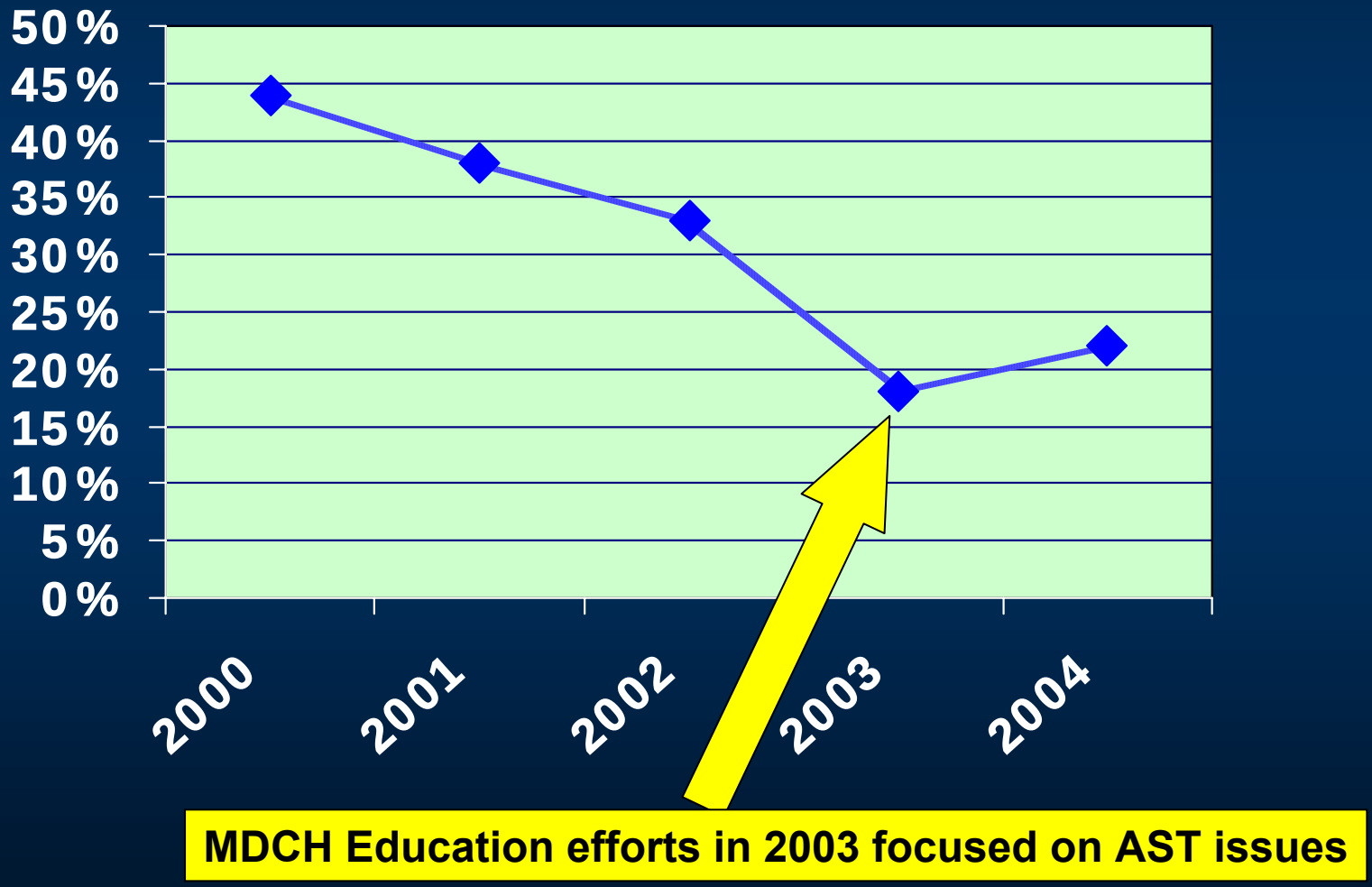
Results

- **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

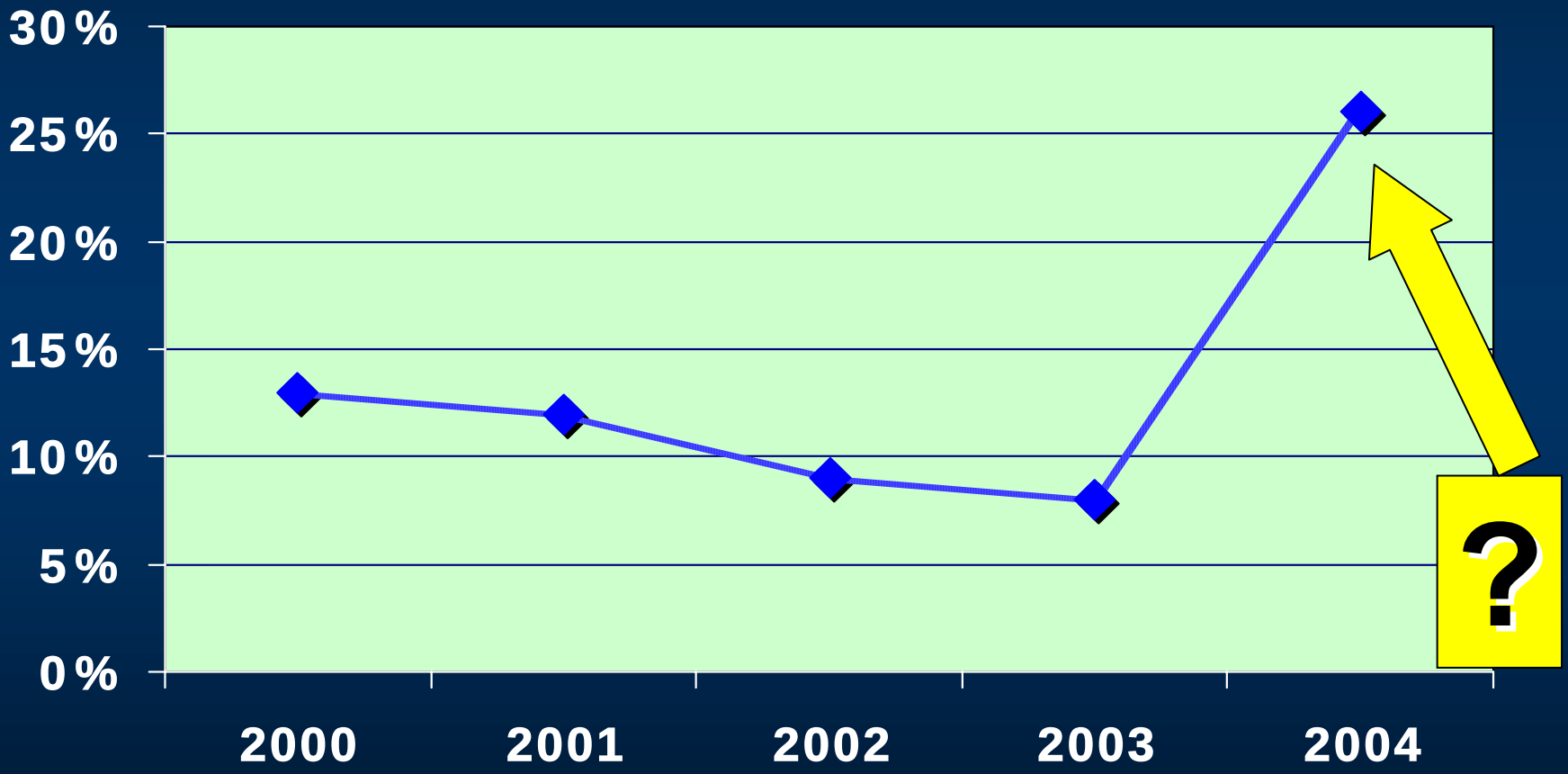
MDCH Actions to Address Gaps

- 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

Percentage of Antibiograms with Major Errors (2000-2004)



Percentage of Antibiograms 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.