



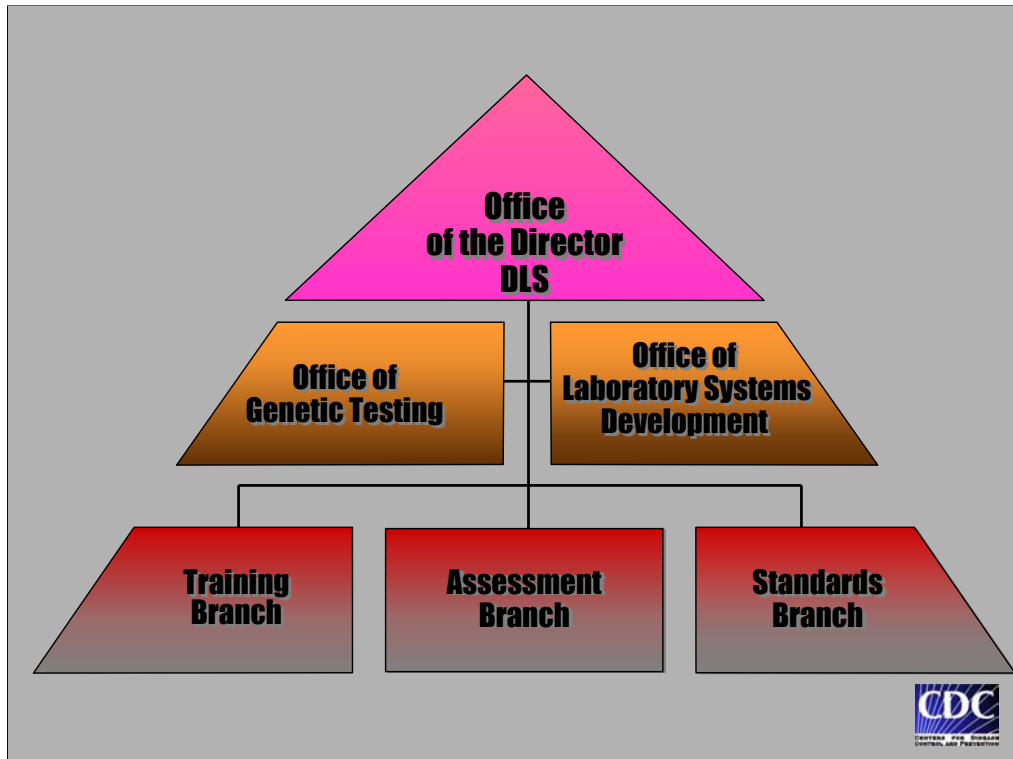
## **The National Laboratory System- Public and Private Benefits**

The National Laboratory System, when fully mature, will benefit both public health testing and private clinical laboratories.

Whether or not a laboratory professional considers themselves to be performing public health testing is to a large extent a matter of perspective. In reality all clinical testing is public health testing because it affects the public's health. The National Laboratory System is all about broadening that perspective to embrace that reality.

In recent years there have been tremendous changes to the delivery of laboratory testing; these have brought about a need to re-think how to control this technology and to determine what amount of control is necessary. In this activity the CDC Division of Laboratory Systems is deeply vested. One paradigm change at the Division has been a shift from keeping the status quo through regulation to promoting voluntary positive changes.

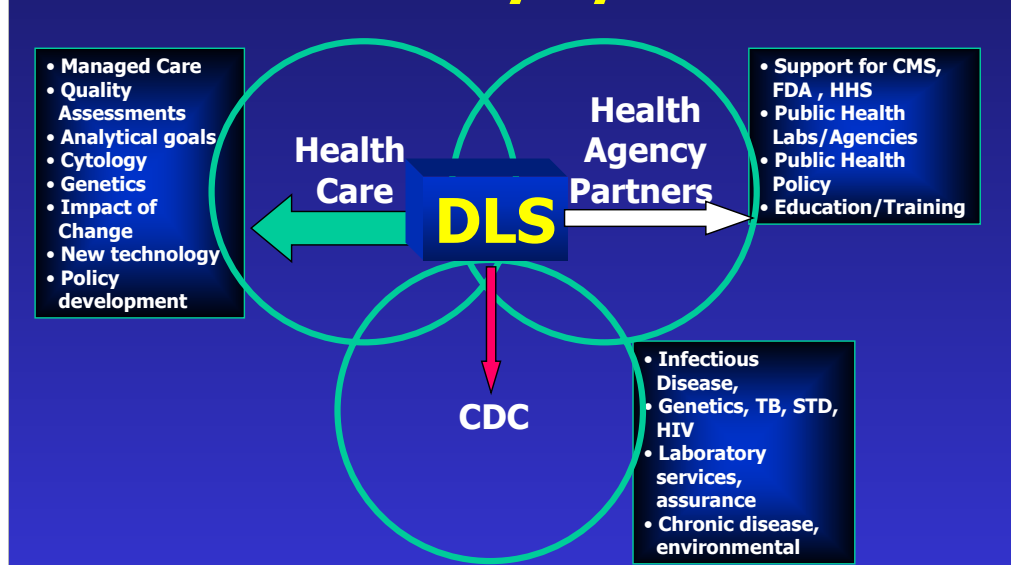
Despite the many advances in laboratory testing capabilities, the proper functioning of both public health and clinical testing continues to depend ultimately on interpersonal relationships. The National Laboratory System seeks to make every laboratory professional in a clinical setting aware of, and in fact proud of, the critical role he/she plays in the protection of the Nation's health. At the same time, we want to promote the development of leadership in public health laboratorians so they also assume responsibility to improve the quality of testing in clinical settings, testing that does indeed affect the Nation's health- one patient at a time.



The CDC Public Health Practice Program Office is uniquely positioned to interface between the public health and medical care community. In fact, the Division of Laboratory Systems, must constantly monitor the laboratory environment to try to determine the issues that will be of importance.

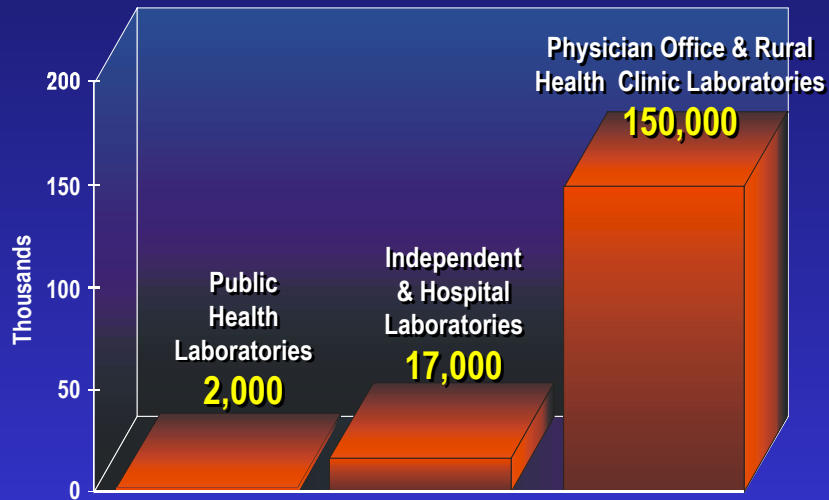
Our Office of Laboratory Systems Development works with domestic and international public health systems to assure the laboratory components are serving the needs of various public health programs and that their activities are integrated with the needs of the medical care community. The National Laboratory System is being supported and promoted by the Laboratory Integration Program for Public Health Testing, which operates out of this Office.

# CDC's Division of Laboratory Systems



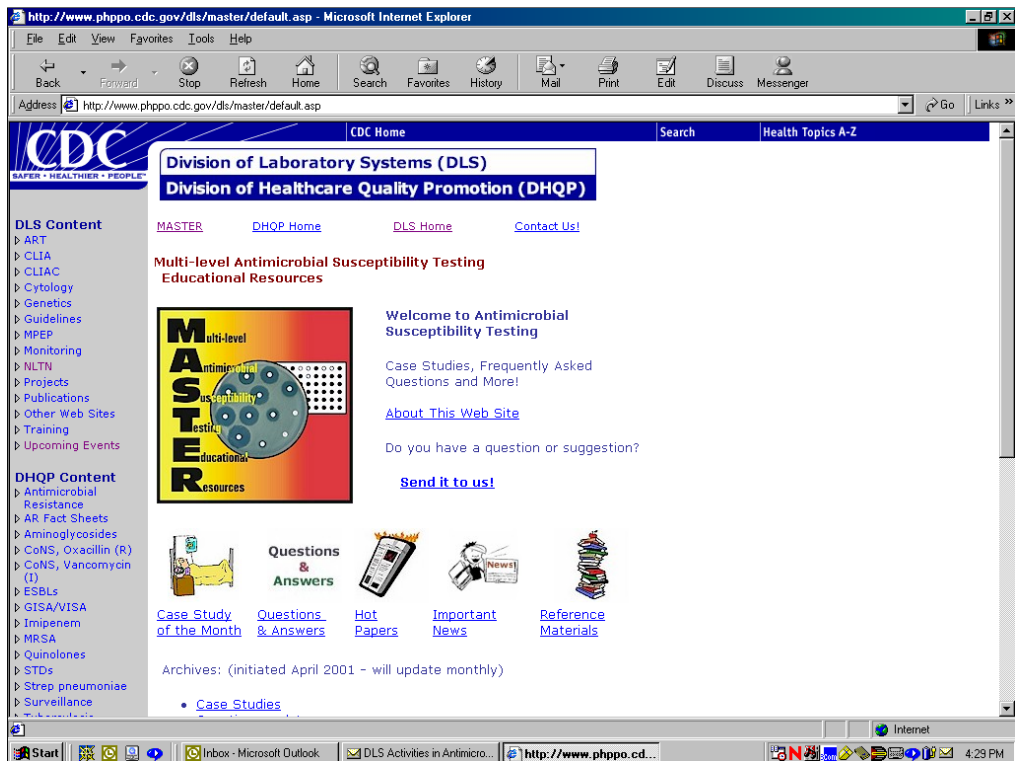
This slide is a graphic that depicts the inter-relationship of our Division with CDC, other parts of Federal government and with the health care industry. We have a central role in facilitating those interactions.

# Clinical and Public Health Laboratories in the U.S.

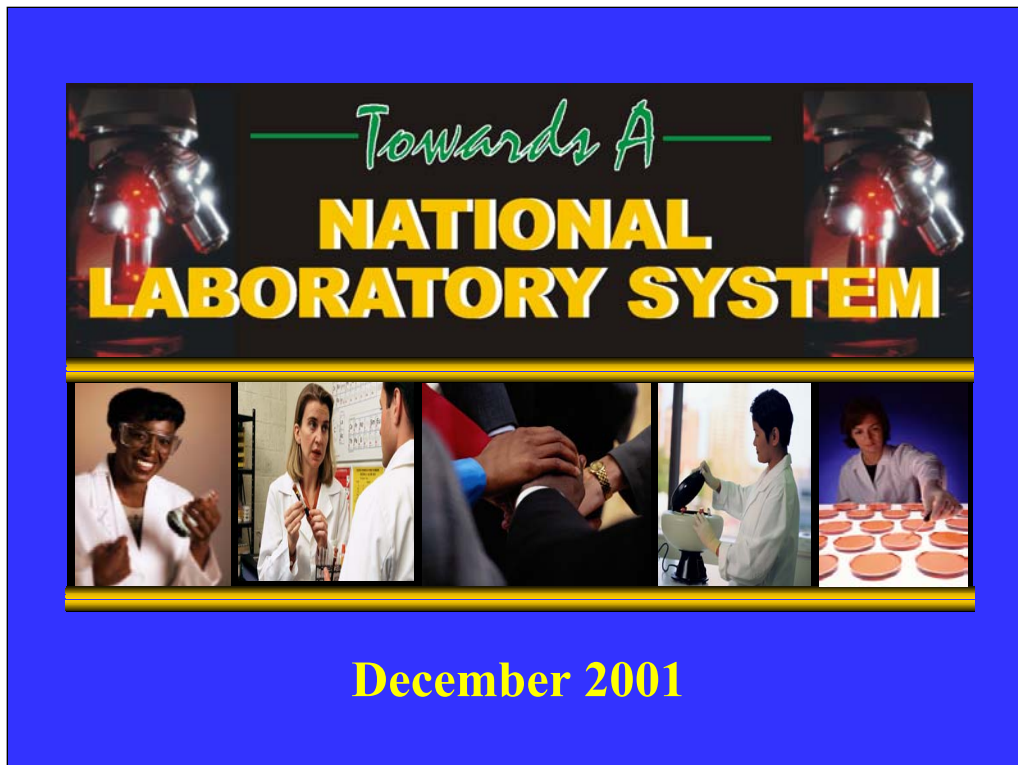


The scope of our responsibilities is broad. We need to interact with public health laboratories, independent and hospital laboratories, but also we need to understand the challenges and opportunities related to that large group of physician office and clinic laboratories that represent the largest group of laboratories that hold CLIA certificates.

The relatively few PH laboratories in the country depend critically upon the other private labs- especially the 17,000 hospital and independent labs- for proper functioning of the PH system.



This is an example of the kind of activities DLS conducts. MASTER was created jointly by DLS and the CDC Center for Infectious Diseases. It demonstrates how DLS works with experts both within CDC and in the private sector to effect improved laboratory practices. Master posts questions and answers concerning issues in laboratory diagnosis of antimicrobial resistance. The site address is [www.phppo.cdc.gov/dls/master/default.asp](http://www.phppo.cdc.gov/dls/master/default.asp)



The National Laboratory System seeks to build relationships between public health and medical care to address issues like, but not limited to, bioterrorism. For too long public health testing and clinical testing have been artificially disconnected. In truth, they depend critically upon each other. The NLS seeks to make that interdependence clearer and to build mutual trust and respect as we improve collaboration, communication and cooperation.

What are some public health issues in which the clinical laboratory plays a critical role? Really, we are talking about any public health problem for which a diagnosis is performed in whole or in part through laboratory testing. More specifically, we have recently been focusing on issues like food borne diseases, antimicrobial resistance, tuberculosis, and of course bioterrorism. In truth, however, assurance of all laboratory testing for disease diagnosis is a candidate for focused NLS activities—especially those areas where improved communication and better adherence to voluntary standards is needed. Moreover, we believe that the interpersonal relationships built for specific PH problems will be sustained making other problems more quickly addressed.

# Public Health Laboratories

## Unique Function

### Activities

- Detect outbreaks
- Monitor trends
- Conduct research
- Assure quality

### Impacts

- Intervention
- Policy

PH Labs have and will continue to have Activities and Impacts that are very different from clinical settings.

# Role of Laboratories

*"Provide information for decision making"*

## Private Labs

- Diagnostic testing
- Medical management
- Mission = Individual health

## Public Labs

- Some diagnostic testing
- Reference testing
- Surveillance and monitoring
- Mission = Public health

It is certainly true that Private and Public Health labs have fundamentally different missions. One very important difference is that for private labs money is an essential driver, regardless of whether the institution is for-profit or not-for-profit. Although money is not inconsequential for PH Labs, they do not see making or saving money as an element of their mission.

Note that we have often portrayed the two types of laboratories as distinct entities, but the public health lab clearly has a role in improving the quality of clinical testing and that private laboratories are also integral to public health testing.



# Current Situation

- The current network of laboratories that perform tests of public health significance is a loose association of public health (state, county and city), hospital, and independent laboratories throughout the country.



What is the issue? The current network of laboratories that perform tests of public health significance is a loose association of public health (state, county and city), hospital, and independent laboratories throughout the country.

While the CDC has traditionally supported the state PHLs for funding, which in turn has fostered the development of strong relationships, traditionally there has been no support from the state public health laboratories and little interaction with the private labs in their state.

# Statement of Problem

- GAO Report (February '99)  
"Emerging Infectious Diseases"
  - **The nation's public health surveillance of infectious diseases critically needs improvement with Federal leadership**
- GWU Report – (January, 1999)  
"Reporting by Out-of-State Laboratories"
  - **Under-reporting is due to: out-of-state testing, lack of experienced personnel, and cost-shifting under capitation**
- Lewin Group Report (October 1997)  
"Public Health Laboratories & Health System Change"
  - **There has been a lack of proactive leadership from the public sector. The entire system should be carefully reviewed.**

The problem with connectivity between public and private labs, and that missing interaction is at the heart of many problems which have been well documented.

# NLS Consultants Group

- ASM
- ACLA
- ASCP
- APHL
- CDC- NCID
- CDC- BPRP
- CSTE
- ASTHO

The Consultants Group has met several times and will be expanded to include additional interests

In developing the NLS, we have been working not only with colleagues in CDC, but with professional organizations to develop this concept over the past two years.

# Barriers To Overcome



We recognize that there are a variety of knotty issues facing public health testing and that the relative importance of each depends upon local factors affecting each state differently. In addition each state has different resources available.

Through the Demonstration Projects, we hope to make the benefits of local systemization obvious in a credible and scientifically defensible way.

# Demonstration Project Focal Areas



The demonstration projects are intended to uncover problems, strengths and the impacts of differences in resource availability. We arrived at an initial approach that funded states to demonstrate activities that would enhance the relationships and show increased communication resulting in a measurable public health impact. These demonstration projects were to focus on developing partnerships, assessing capabilities and capacities, providing training where there were identified gaps, and monitoring standards that are accepted by the laboratory community (e.g., NCCLS guidelines on antimicrobial susceptibility testing).

## NLS Demonstrations

### WA State Clinical Laboratory Initiative

- Partners: U. WA School of Public Health, Foundation for Health Care Quality, CDC, CLAC
- Steering Committee
- Assess lab practices, identify gaps, educate
- Understand motivational factors that change lab practices
- Antimicrobial Resistance & BT Testing

In Washington State, Jon Counts, former Director of the State Laboratory, is continuing his activities with the Clinical Laboratory Initiative, which has been ongoing since the mid 1990's. Dr. Counts is now a professor at the U. Washington School of Public Health. This model is, therefore, an academic prototype, rather than one that emanates from the state public health laboratory as is the case for the other demonstration sites. It is important to note, however, that the state laboratory participates through the Steering Committee. In addition to direction from the Steering Committee, which is composed of experts in microbiology, epidemiology and medical practice, Dr. Counts is frequently in touch with front-line microbiologists through regional focus groups and the Washington Clinical Laboratory Advisory Council which meets regularly.

Dr. Counts recently conducted a survey of the clinical microbiology labs in Washington concerning their knowledge of, and use of, voluntary standards for antimicrobial susceptibility testing, including NCCLS standards. Interestingly, while nearly all clinical microbiology labs claim to adhere to NCCLS standards, the survey results suggest that there is room for improvement. Many labs were not using current NCCLS tables. Disturbingly, many did not know the NCCLS recommended procedure for testing when presented with a specific clinical scenario.

Using both local and CDC experts, Dr. Counts is launching an educational series on general QA issues in microbiology and specific issues in testing for antimicrobial resistance. He'll be televising his programs to hospital and commercial labs throughout the state. We also plan to make video tapes available for those who

## NLS Demonstrations Nebraska

- Enlist stakeholders
- Develop buy-in strategies
- Web-based bi-directional information sharing
- Develop specimen submission protocols, expand specimen courier routes, CD ROM
- Surrogate specimen challenges sent to labs

In Nebraska the Laboratory Liaison sent letters of invitation to the approximately 100 private clinical microbiology labs. The Liaison, Tony Sambol, is visiting each of the interested labs to create a system of 6 regions across the state composed of “Level A” labs with a “Level B” lab to which testing could be referred.

During his visits, Mr. Sambol is assessing laboratory professional’s knowledge of approved testing practices for agents of bioterrorism, including when and how to refer specimens. Based upon his site visits, Mr. Sambol and the State Laboratory Director, Steve Hinrichs, appreciated the need to create and disseminate educational materials for agents of bioterrorism. This product so effectively fills the void for education that we plan to disseminate it immediately nation-wide to all labs that would qualify for Level A testing.

Dr. Hinrichs understands the need to find incentives for laboratorians. He will be providing protocols for testing and referral of various public health threats, including threats to food safety, such as *E. coli* and salmonella. As another incentive, Dr. Hinrichs will be investigating the potential use of a geographic information system (GIS) to provide real-time data to clinicians and laboratorians on the incidence of public health threats.

Surrogates

## NLS Demonstrations Minnesota

- Increasing connections to clinical labs
- Assessing clinical laboratory capabilities
- Using the assessment to improve laboratory practices
  - “Blinded” challenge specimens
  - Educational materials
- Preparing clinical laboratories for bioterrorism

In Minnesota, the Laboratory Program Advisor, Paula Snippes, working with the State Laboratory Director, Norman Crouch, has been conducting comprehensive assessment of the capabilities of the clinical microbiology laboratories throughout the state. Surveying the capabilities of clinical laboratories is the first step in ascertaining where public health testing could be diverted in case of emergency. Based on this survey, challenging “blinded” specimens will be sent to clinical laboratories to assess accurate and timely reporting for public health threats.

### ***Increasing connections to clinical laboratories***

Minnesota Laboratory System has invited 150 clinical microbiology laboratories in the state to participate in the system, with a 89% favorable response rate. Through these initial activities, e-mail addresses were obtained for an additional 60 laboratories, so that the Minnesota State Laboratory can reach all clinical microbiology labs in the state using either fax or e-mail.

### ***Assessing clinical laboratory capabilities for infectious disease testing***

Paula Snippes, the Laboratory Program Advisor is conducting phone interviews that will allow tailoring of an on-site comprehensive survey of capabilities and practices in microbiology testing.

### ***Using the assessment to improve laboratory practices***

.Based on phone assessment, will send out “blinded” challenge specimens in November to assess baseline laboratory practices and testing accuracy.



## NLS Demonstrations Michigan

- Convene MLS Advisory Group
- Develop a specimen transport system that includes specimen tracking
- Collaborate w Bioterrorism Training Coordinator to refine training material
- Solving problems on a broad front
- Define surrogate organisms

In Michigan, the Liaison, John Dyke, has met with stakeholders in focus groups across the state to better understand the issues affecting public health testing. From these stakeholders, he has created an Advisory Group with broad interests including public health nurses, a variety of laboratory professional, infection control experts and a commercial proficiency testing provider.

Recognizing the need for a reliable specimen transportation system to get specimens to the state public health laboratory, Michigan is focusing on a network of transportation contractors who will be available on an “as needed” basis to pick up emergency specimens, such as rabies samples. We hope that this prototype transportation system will grow into a more broadly functioning system that would routinely pick up specimens for public health testing. One of the capabilities that was most severely affected by recent events was the ability to move specimens for public health testing. It is surprising how many specimens depend upon air travel for movement to CDC or to commercial reference labs; when that flow was interrupted state public health labs were called on to pick up the surge.

Dr. Dyke has been solving problems on a broad front. Among his accomplishment has been

- \*Development of a fax network to improve rapid communication between the state PHL and private clinical labs
- \*Assessing practices for E. coli to improve surveillance for the H57:O157 strain
- \*Partnering with a proficiency testing provider to create samples for tuberculosis and meningococcus

## Expected Outcomes

- Formalized relationships between clinical and public health laboratories
- Coordination of activities
- Development of In-state Collaboration
- Regional and National Laboratory System

# Envisioned Impact



Assurance of availability of consistent laboratory capacity for public health across the nation

Of course, we are confident that these demonstration sites will lead to refinements and expansion that will ultimately be successful and will bring about assurance of availability of consistent laboratory capacity for public health testing across the nation.