



**Division of Clinical Laboratory
Devices -- an update**



DCLD Summary

- ◆ People
- ◆ Workload
- ◆ Performance
- ◆ Implementation of Least Burdensome Program
- ◆ Strategic Plan



People

- ◆ New Deputy Commissioner – Dr. Crawford
- ◆ Seasoned Chief Counsel – Dan Troy
- ◆ New Associate Director Science - Norris Alderson
- ◆ Seasoned Center Director – Dr. Feigal
- ◆ New Center Organization – Linda Kahan and Lillian Gill



People

- ◆ 60 FTEs
- ◆ New Genetics Hires
- ◆ No Growth



People -- Programs

- ◆ Premarket Review
- ◆ CLIA categorization
- ◆ Pharmacogenomics working group
- ◆ Bioterrorism initiatives
- ◆ TPLC initiative



510(k) Program

- ◆ Heart of workload
- ◆ 650 submissions
- ◆ Review times average 65 days (target 90)



Decreasing Workload

- ◆ Replacement reagent policy
- ◆ ASR policy
- ◆ Clarification in modification policy
- ◆ Business environment



PMA Program

- ◆ Variable workload
- ◆ Approved approximately 6
- ◆ Meeting all review targets



Protocol Review (pre IDE) Program

- ◆ Currently projected at 90/year
- ◆ High octane stuff
- ◆ 60 day reviews
- ◆ Multiple interactions



CLIA Review Program

- ◆ Active – more than 2000 determinations/year
- ◆ Remains program in evolution



FDAMA

- ◆ Improved market access
- ◆ Least burdensome pathways
- ◆ Premarket to postmarket balance
- ◆ Increased interaction with industry



Least Burdensome

- ◆ Appropriate questions
- ◆ Appropriate thresholds
- ◆ Non-academic pursuits



Least Burdensome

- ◆ Matter of law
- ◆ Matter of policy
- ◆ Matter of spirit



Least Burdensome

- ◆ Two Guidance Document
- ◆ Systems Approach – ensure appropriate process applied to use of regulatory tools
- ◆ Review Guidance



Least Burdensome

- ◆ Review changes are profound
- ◆ Parallel genetics initiative
- ◆ Shift to data summaries
- ◆ Shift to more focused labeling review
- ◆ Shift to use of clinical literature
- ◆ Shift to postmarket analysis



Strategic Plan -- Goals

- ◆ Mission related
- ◆ Total Product Life Cycle
- ◆ Knowledge Management



Total Product Life Cycle

- ◆ Cradle to grave
- ◆ Seamless oversight



Intellectual Appeal

- ◆ **Premarket review limitation**
- ◆ **Outdated law**
- ◆ **Snapshot approach**
- ◆ **Impact of scale-up**
- ◆ **Impact of wide-use**



Intellectual Appeal

- ◆ **Postmarket review strengths**
- ◆ Quality system regulations
- ◆ Require quality assessment
- ◆ Require process controls
- ◆ Require corrective actions
- ◆ Unrealized potential



Intellectual Appeal

- ◆ **Need for harmonization**
- ◆ **IVD directive**
- ◆ **ISO labeling initiative**
- ◆ **Growing regulatory program in Canada**



TPLC IVD Pilot

- ◆ Ideal target
- ◆ Stereotyped review issues
- ◆ Cadre of like minded scientists
- ◆ Engaged communities interested in partnering



Goals

- ◆ Increased transparency
- ◆ Expedited technology transfer
- ◆ Provide support and improvements application of ASRs
- ◆ Improve surveillance and use of surveillance



Core Mission

- ◆ Promote public health
- ◆ Apply good science
- ◆ Evolving program
- ◆ Relevant, focused, safe and effective

Towards A

NATIONAL LABORATORY SYSTEM



CLIAC
Sept. 11, 2002

Testing of Public Health Significance Numbers of Laboratories:

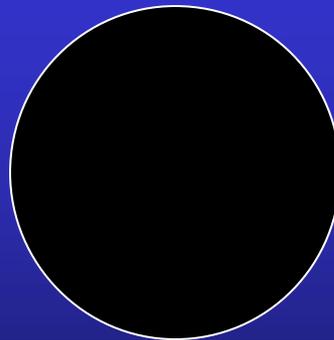
- 4,414 Level A “capable” for Bioterrorism
- 1,959 Mycobacteriology (TB)
- 2,516 HIV Antibody
- 5,074 Syphilis serology
- 824 Blood lead

Current Paradigm

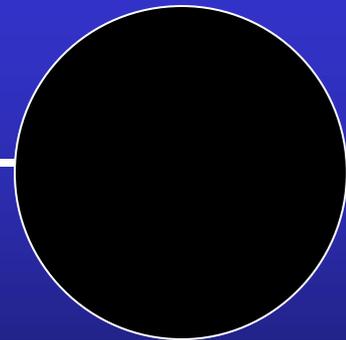
- The current network of laboratories that perform tests of public health significance is a loose association of public health (state, county and city), hospital, and independent laboratories throughout the country.



- Funding
- Consensus Standards
- Technology Transfer
- Training



Inconsistent
Collaboration



Program Support

Technical Capacity

- LRN / BT
- Pulsenet
- ELC / EIP
- TB - HIV - STD
- Blood lead
- Biomonitoring

System Capacity

•LIP

•NEDSS

•HAN

50

**State Systems
of
Public/Private
Coordination**



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

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

Identify Public Health Threats

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.**

Barriers To Overcome

Geographic separation

Resource limitations

Mission differences

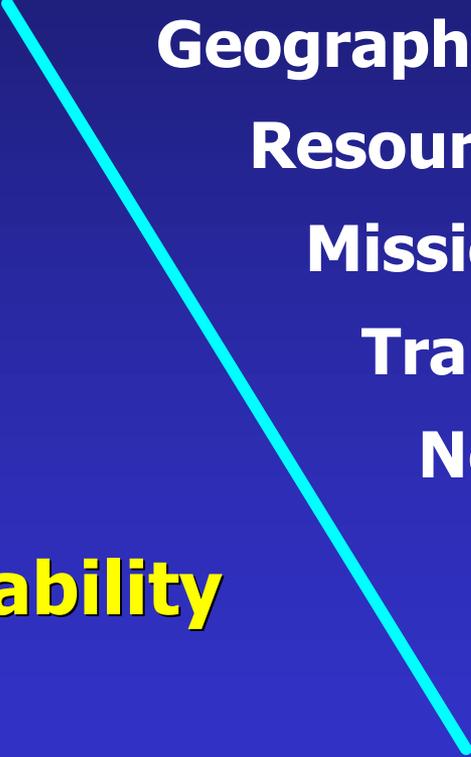
Transport difficulties

Non-culture methods

Out-of-state laboratories

Communication disparities

Sustainability





NLS Consultants Group

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

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

NLS demonstration projects

Michigan Bureau of Laboratories

Frances Pouch Downes, DrPH

John Dyke, PhD

Minnesota Public Health Laboratory

Norman Crouch, Ph.D.

Paula Snippes

Nebraska Public Health Laboratory

Stephen Hinrichs, M.D.

Tony Sambol

University of Washington

Jon Counts, DrPH

Demonstration Project Focal Areas



Assessment of AST Laboratory Practice

- Majority of labs do not have current NCCLS tables
- Poor understanding of tables
- Inconsistent testing for drug resistance in *Streptococcus pneumoniae*
- Priority training needs were identified
- Interventions
 - CDC staff involvement
 - Teleconference
 - Train-the-Trainer

Minnesota



MINNESOTA LABORATORY SYSTEM

A PUBLIC AND PRIVATE COLLABORATION

Norman Crouch, Ph.D.
Laboratory Director

Paula Snippes, MT (ASCP)
Laboratory Program Advisor

Minnesota Communications

MLS Laboratory Alerts

First Alert!

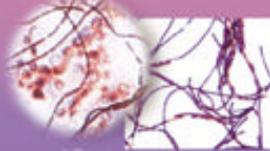
September 11, 2001

- Encouraged heightened suspicion
- Listed 4 “priority threat agents”
- Provided agent characteristics
- Listed phone number to call

Minnesota Promotional Poster

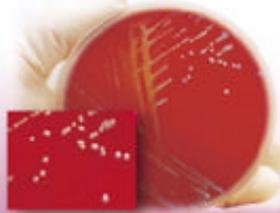


anthrax



Bacillus anthracis

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



tularemia



Francisella tularensis

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



plague



Yersinia pestis

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



brucellosis



Brucella species

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

BIOTERRORISM



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

612-676-5253

AFTER REGULAR HOURS CALL 612-676-5414

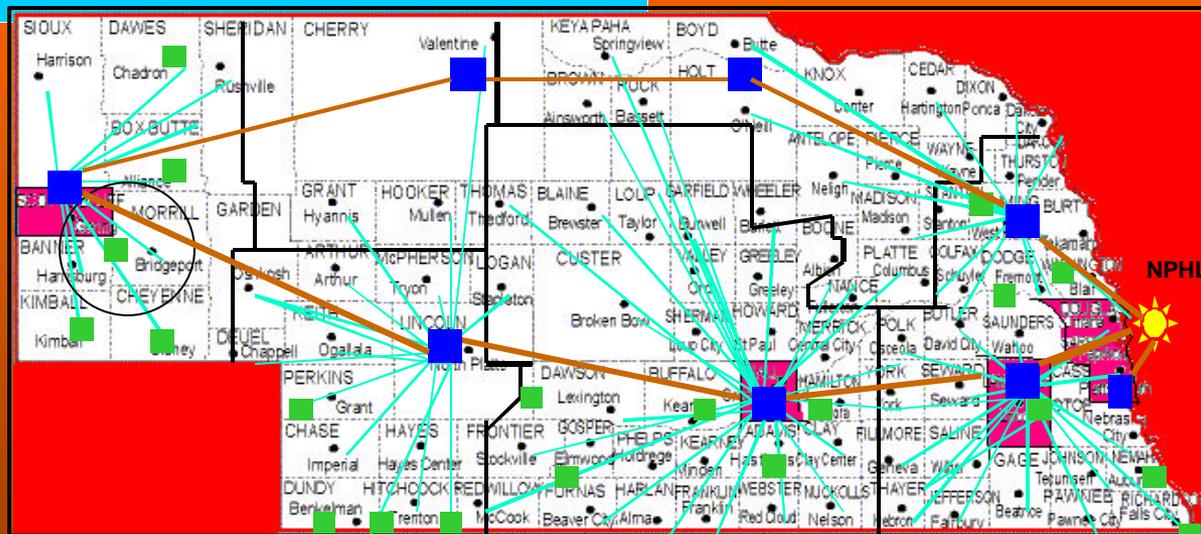
© 2002 Minnesota Department of Health

Minnesota Challenge Set

- 1. Bacillus megaterium**
- 2. Streptococcus pneumoniae**
- 3. E. coli O157:H7**

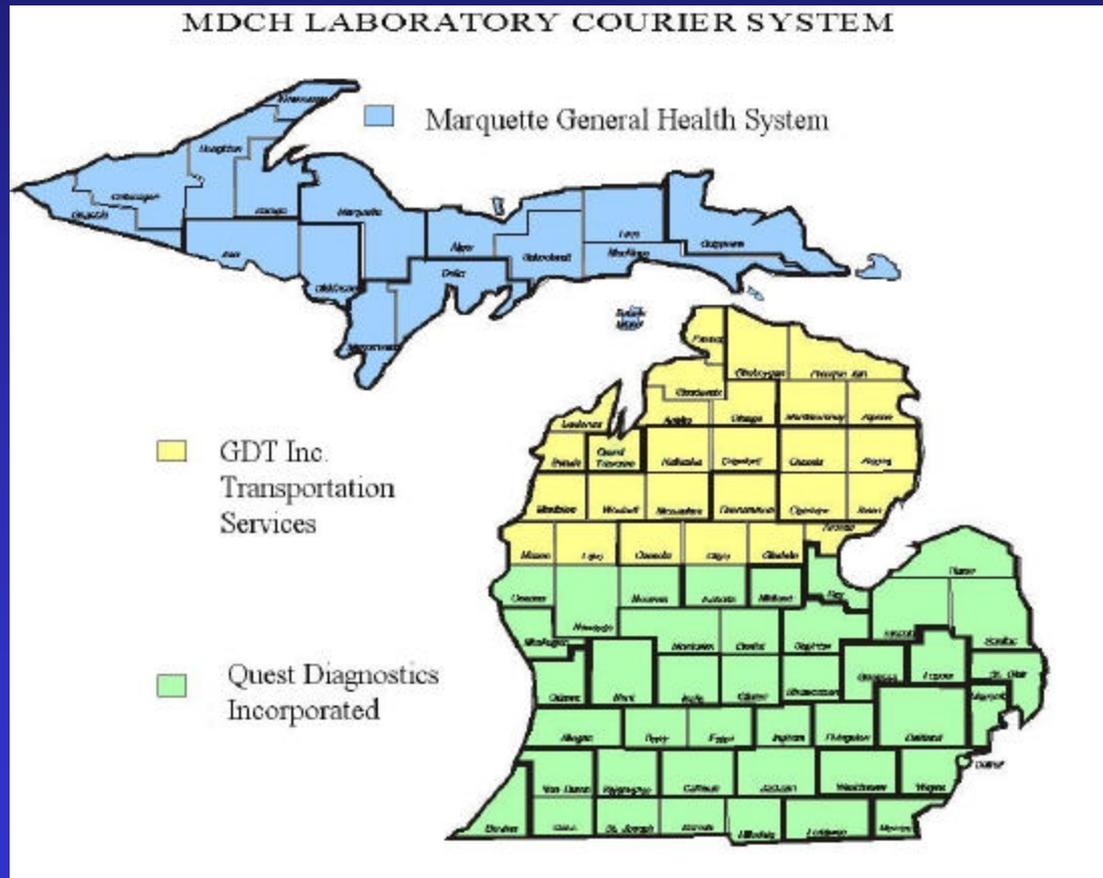
NEBRASKA

Networking of the N-LRS Hub Labs to Regional “Spoke” Labs



Blue: N-LRS Hub Labs Green: N-LRS “Spoke” Labs

MICHIGAN Courier System



Public Health Preparedness

Cooperative Agreement Award Guidance for FY
2002 Supplemental Funds for Public Health
Preparedness and Response for Bioterrorism

Ensure Nation is Prepared for

Bioterrorism

Other Infectious Disease Outbreaks

Other Public Health Threats and Emergencies

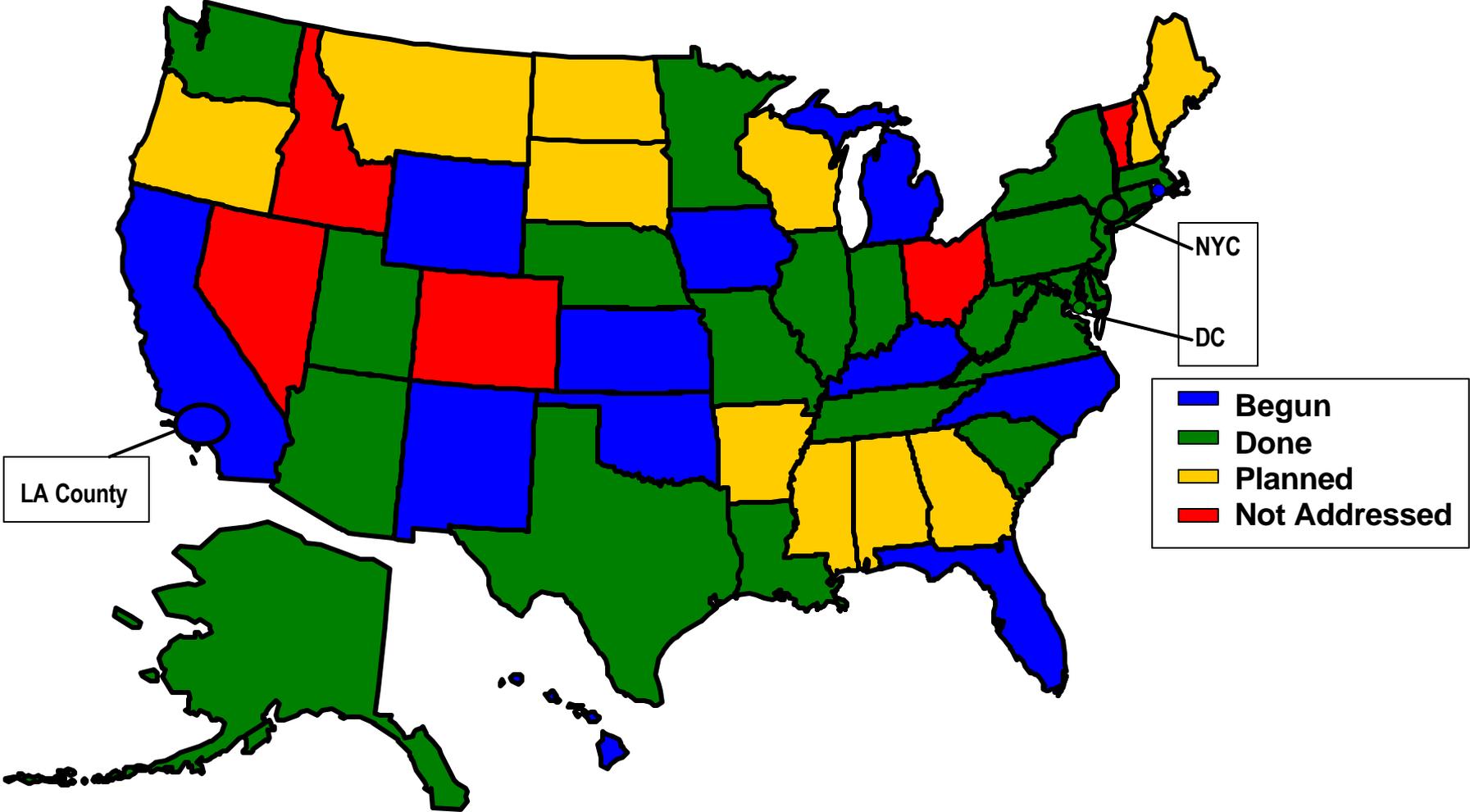
**Focus Area C:
Laboratory Capacity
Biologic Agents**

Critical Benchmark

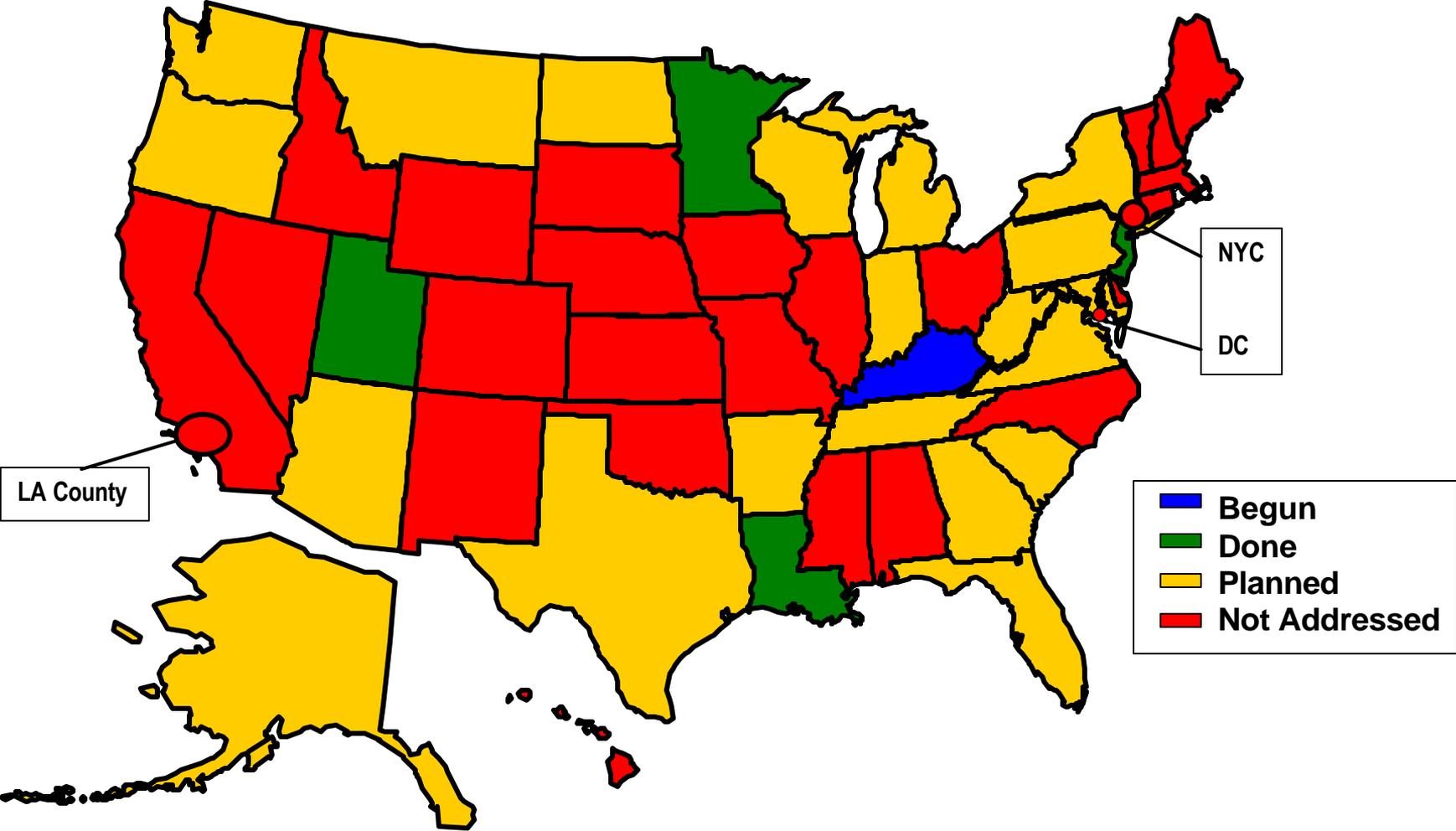
Laboratory Capacity Biologic Agents

- #10: 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.

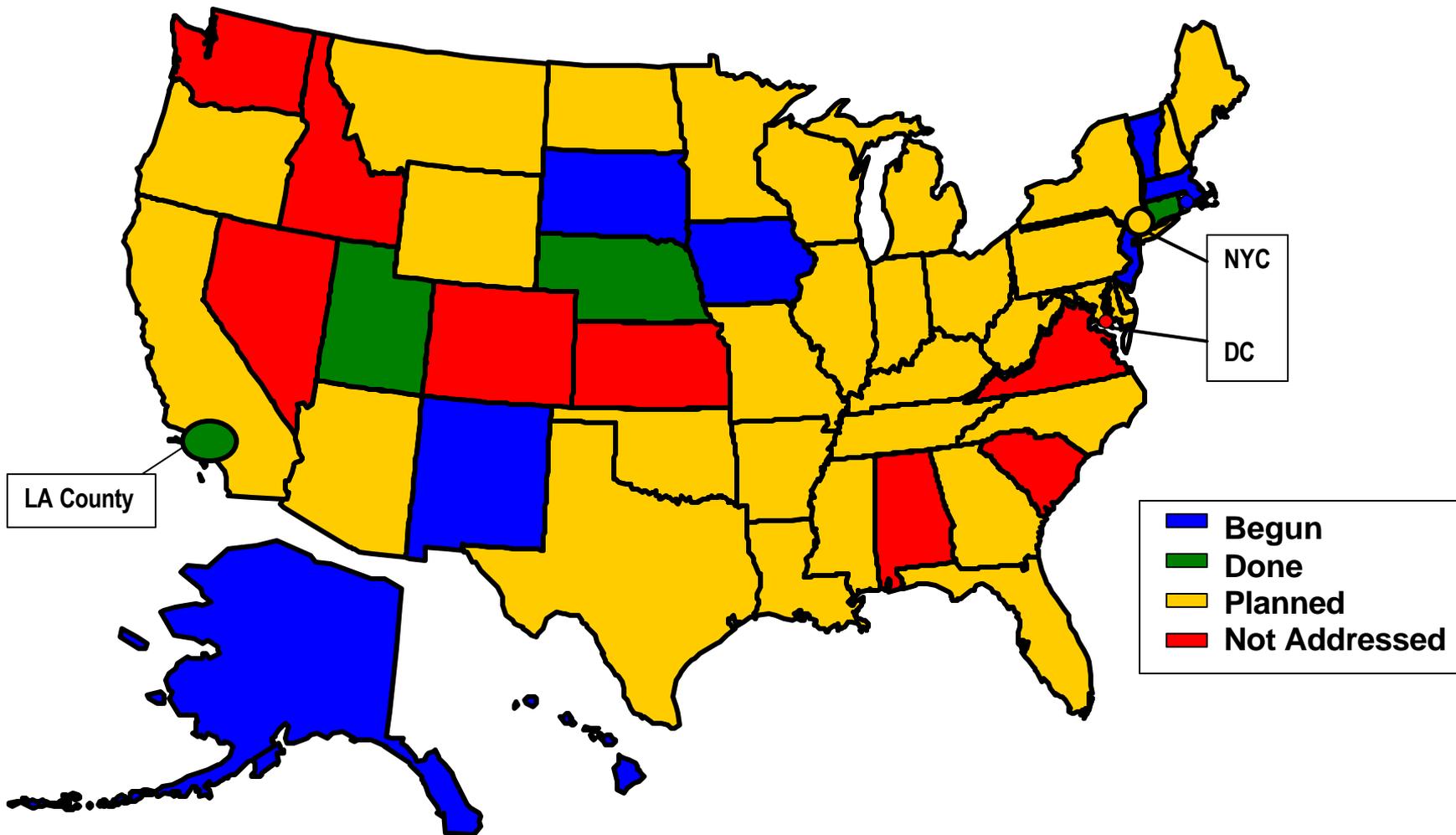
Identify All Clinical Labs



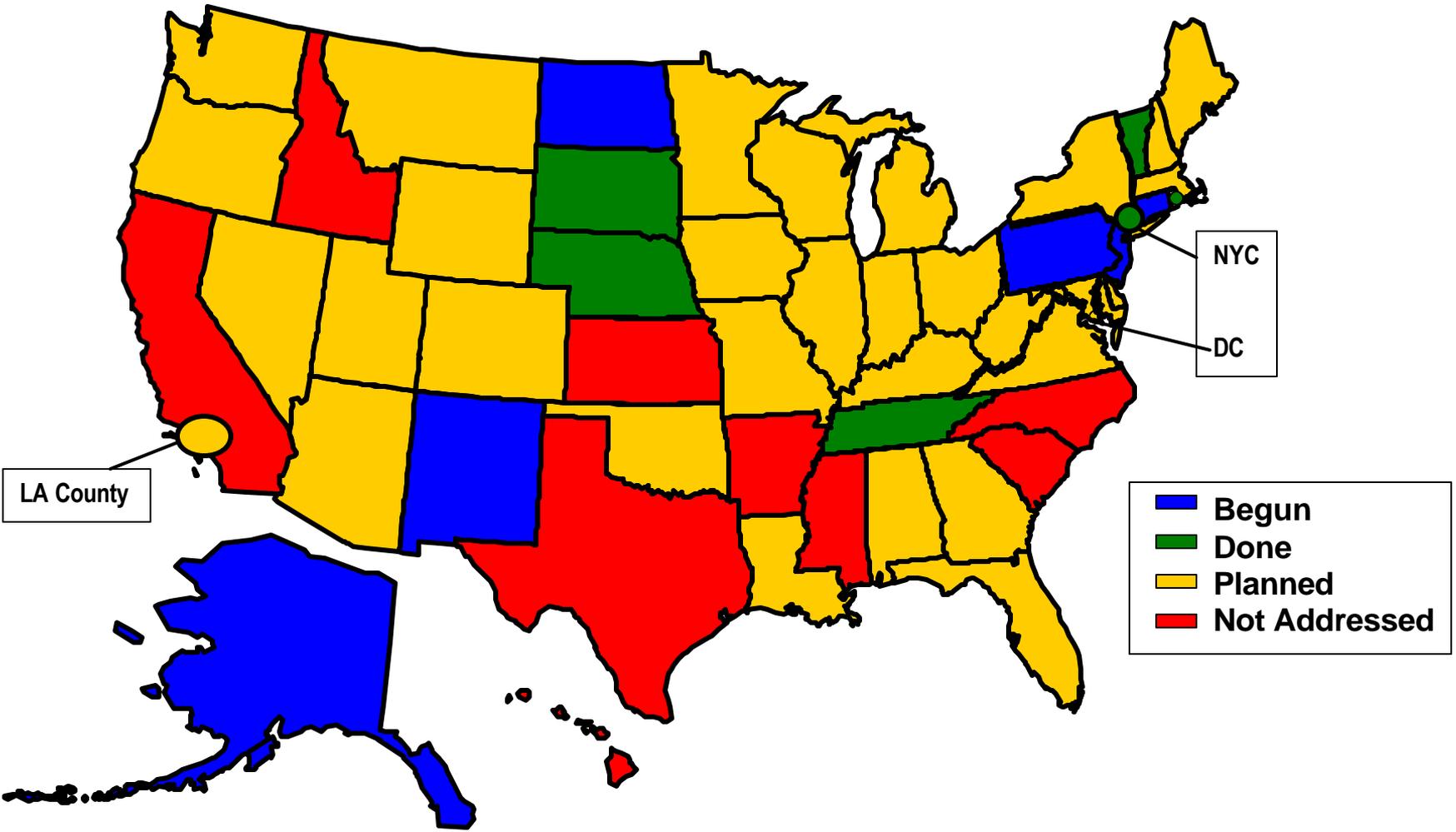
Searchable Laboratory Database



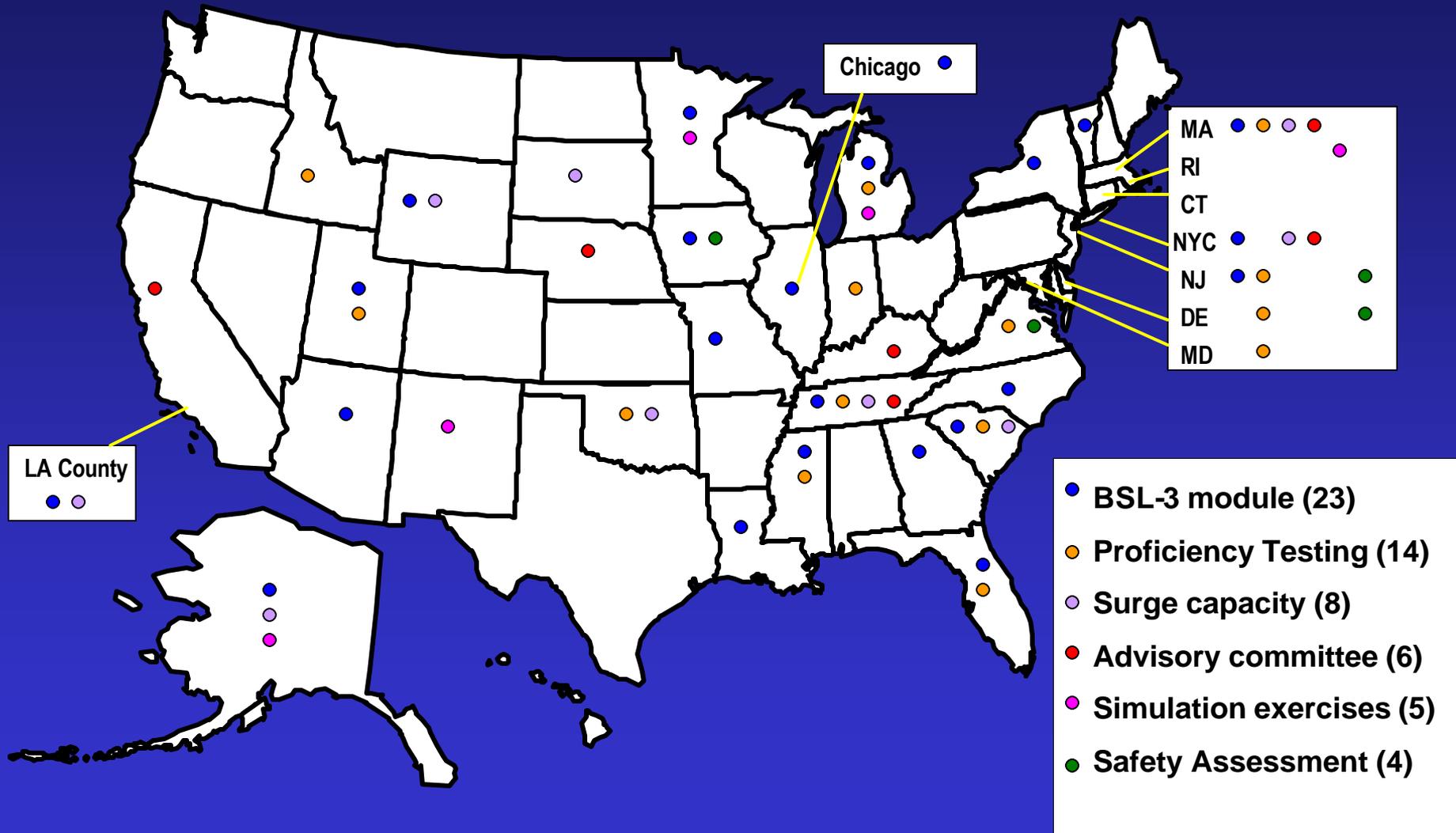
Enlist Clinical Laboratory Participation



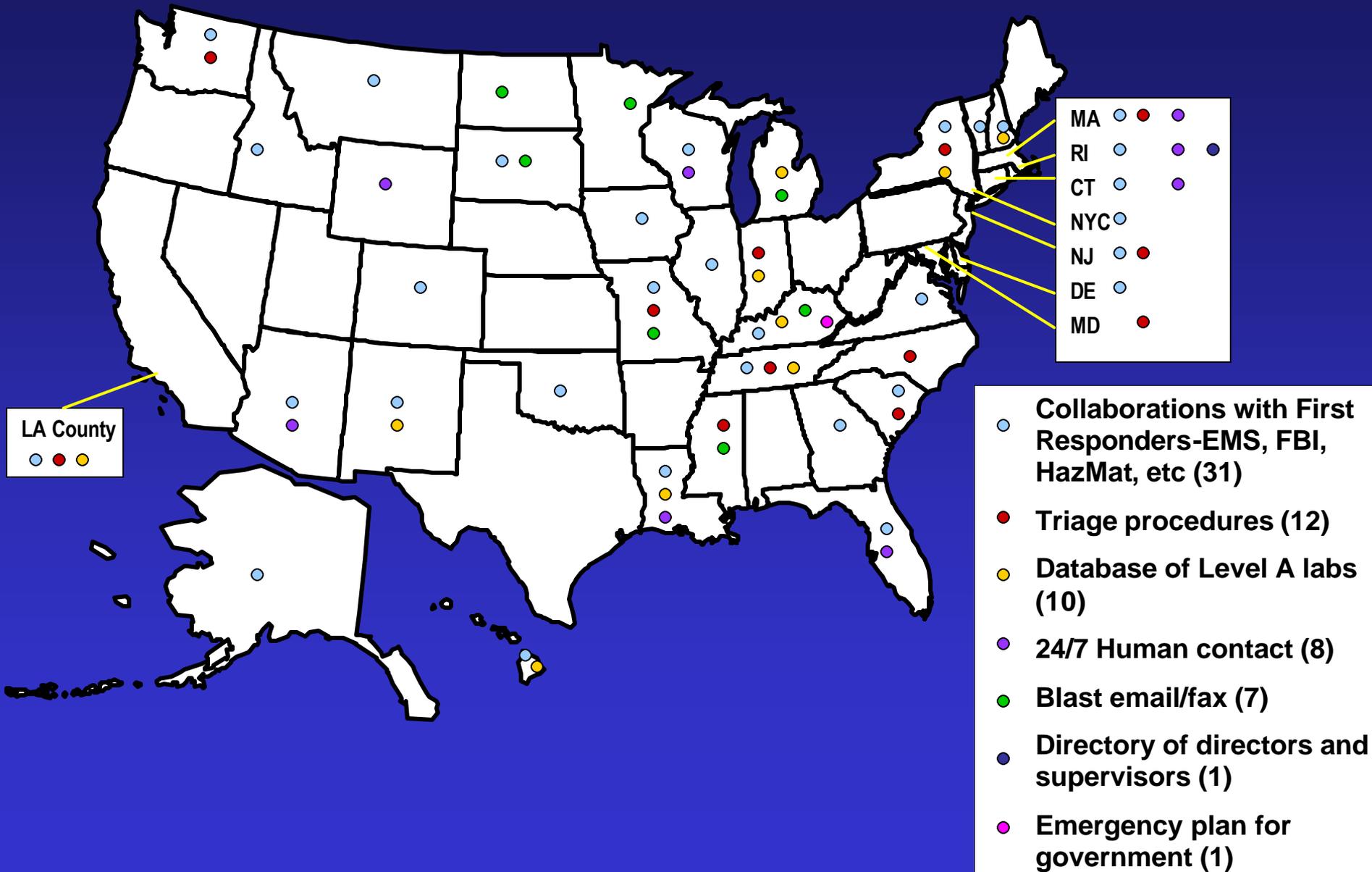
Convene Laboratory Forum or "Advisory" Committees



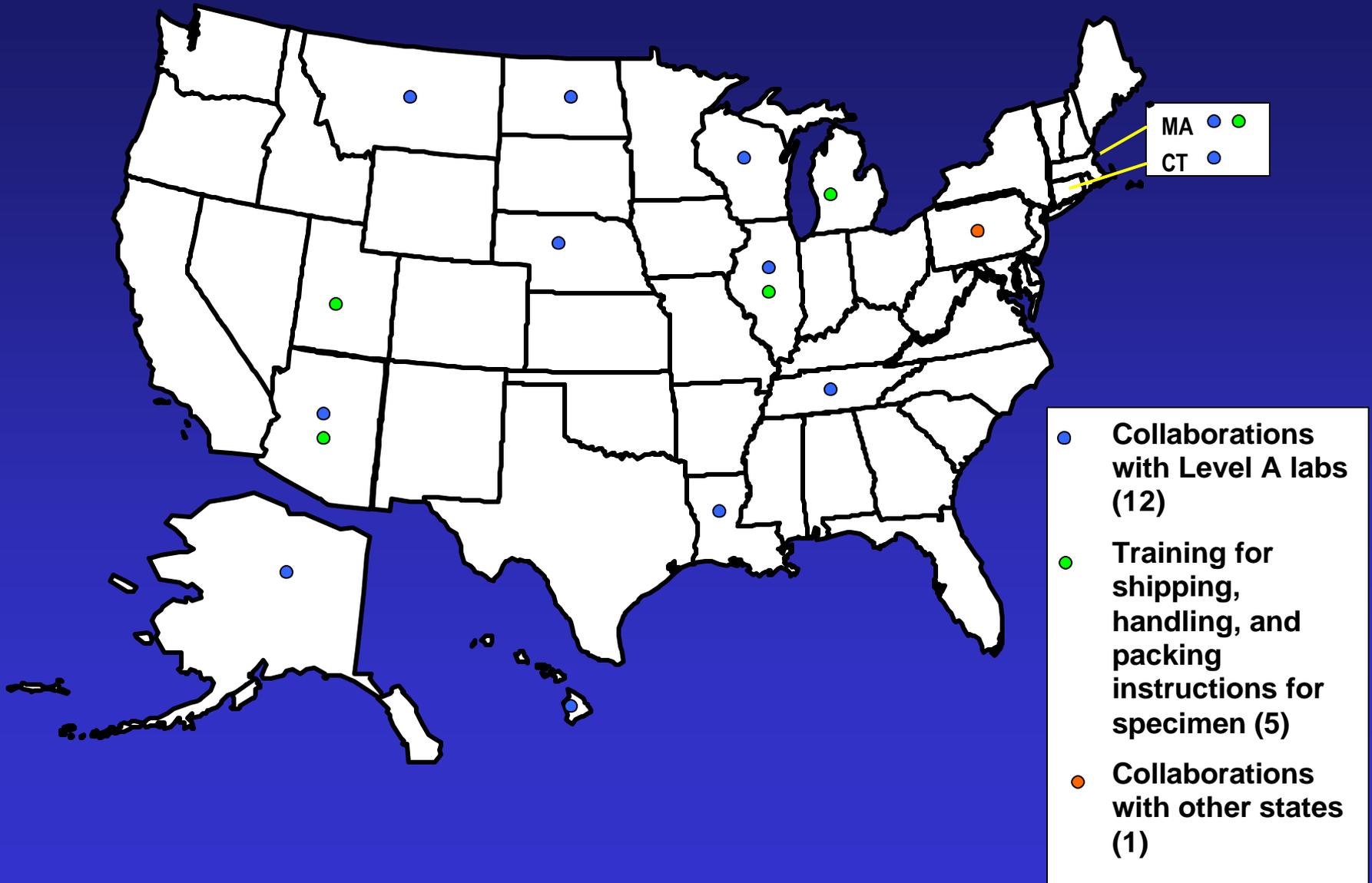
Best Practices: Assessment



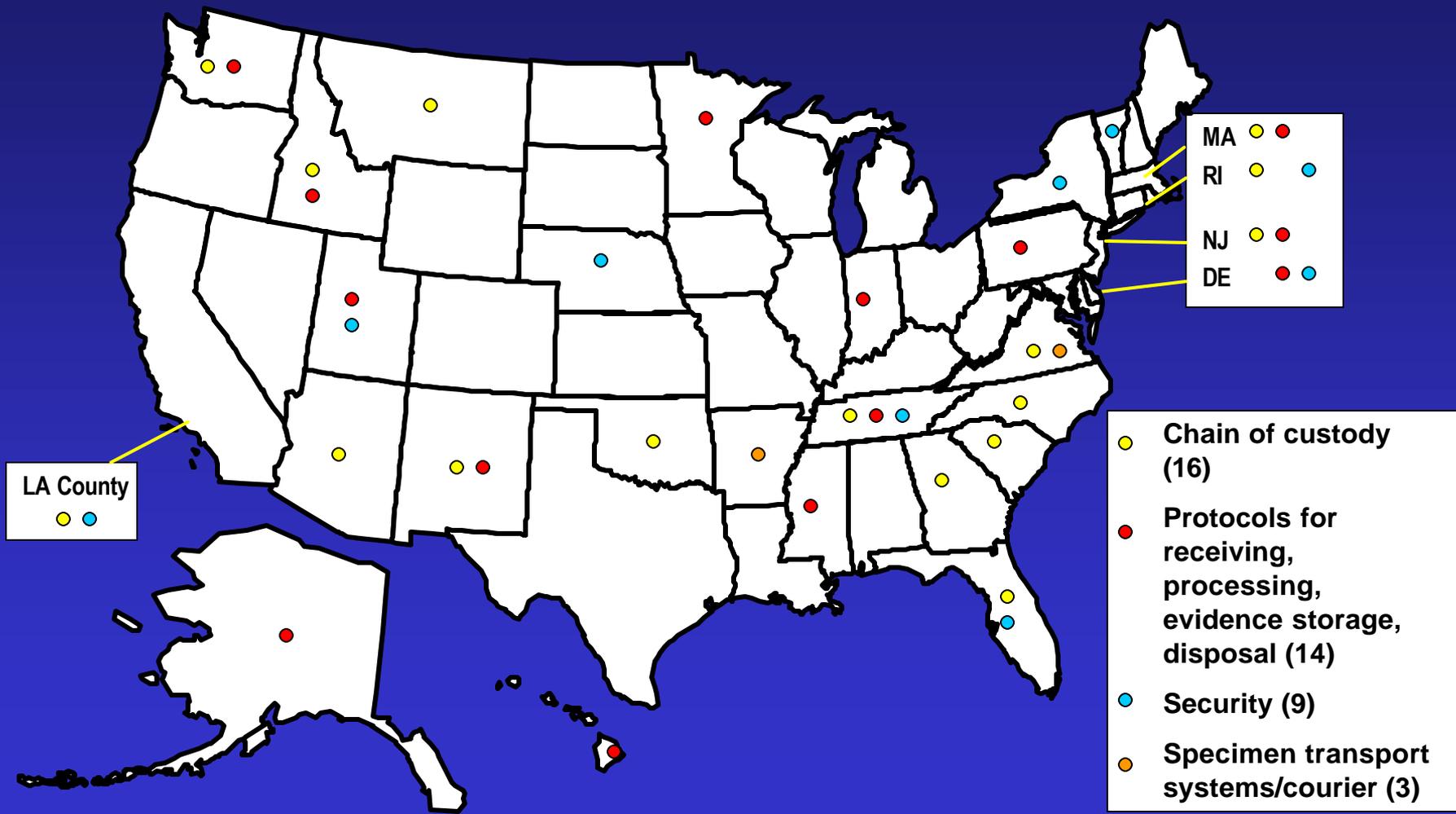
Best Practices: Communication



Best Practices: Training



Best Practices: Specimen Transportation

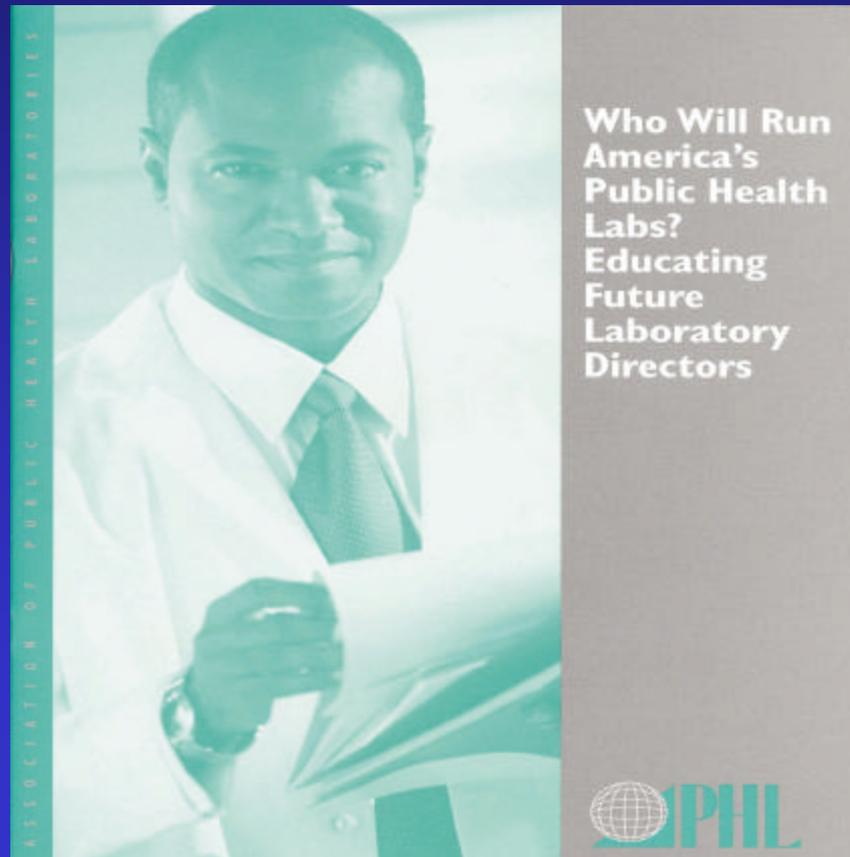


Laboratory Integration Program

Activities

- Convene the NLS Consultants Group
- Maintain the National Laboratory Database of laboratories and their testing services and assist with development of state databases
- Convene regular national conference calls between CDC, the LPC's & SLTC's
- With APHL, through the Leadership Institute, provide leadership training

Leadership for Public Health Laboratories



Laboratory Integration Program

Activities

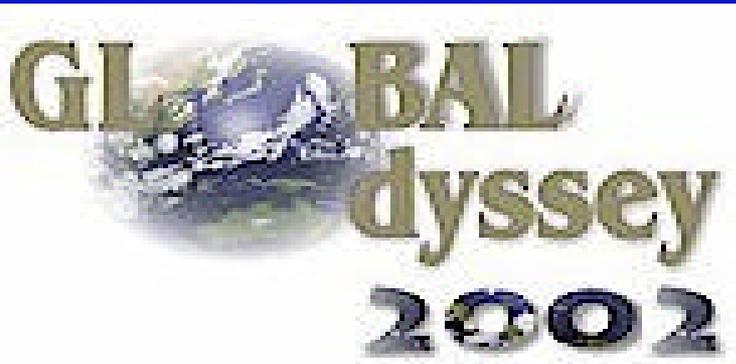
- Support dissemination of state's model activities
- Provide advice on the creation and maintenance of PT programs
- Provide consultation on laboratory management and administration
- With APHL and other stakeholders, create performance standards for PH laboratories

Expected Outcomes

- Formalized relationships between clinical and public health laboratories
- Coordination of activities
- Development of Intra- and Inter-state Collaborations
- Improved PH surveillance and response

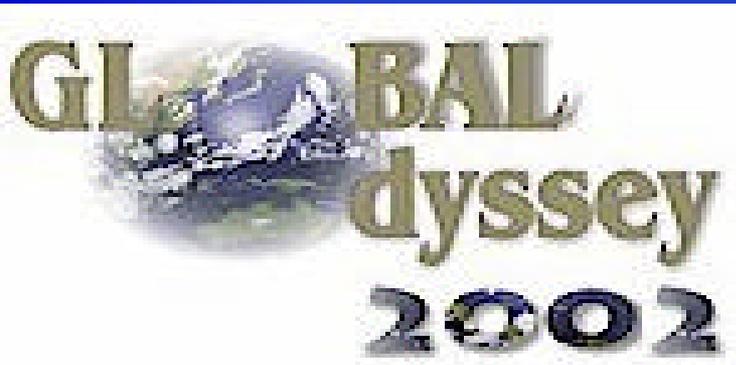
What are the next steps?

- Promote successful state models
- Develop connectivity and standardization for state-based assessments
- Foster the support of national organizations for state systems
- Support a leadership role for state public health laboratories



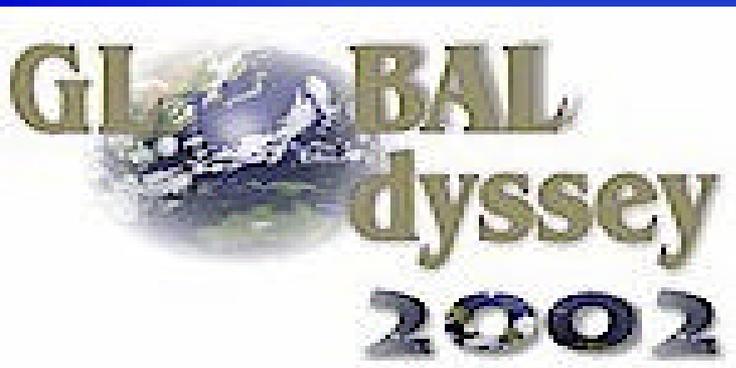
Summary of
International Conference on Proficiency
Testing for Medical Laboratories
February 24-26, 2002

D. Joe Boone, Ph.D.
September 11, 2002



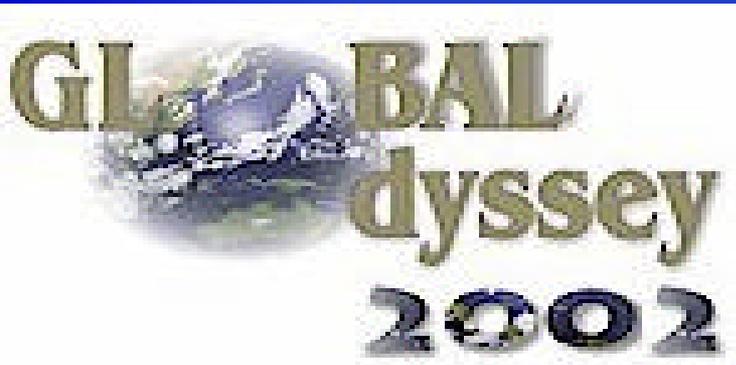
Objectives

- Explore Advances in EQA
- Create Opportunities for Sharing and Partnerships
- Promote Role of EQA in Global Health



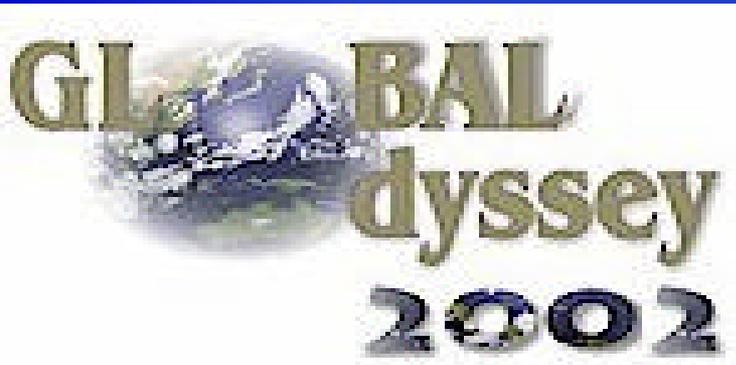
Conference Participants

- Attendance - 202
- Attendees - 54 Countries
- Posters - 22 Countries



Conference Outcomes

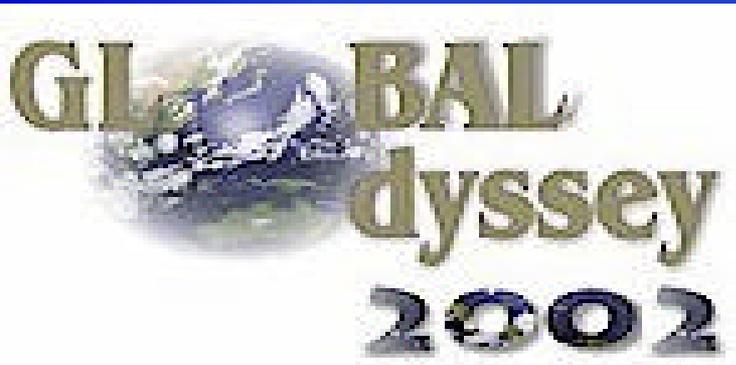
- Developed Global Inventory of EQA Programs
<http://www.phppo.cdc.gov/mlp/eqa.asp>
 - Currently 151 EQA Programs in the Inventory
 - Information on 106 Programs in Printable List
- Created Web-site for Conference Presentations
- Proceedings Published in
Accreditation and Quality Assurance,
September 2002 by Springer-Verlag
<http://link.springer-ny.com>



Conference Outcomes

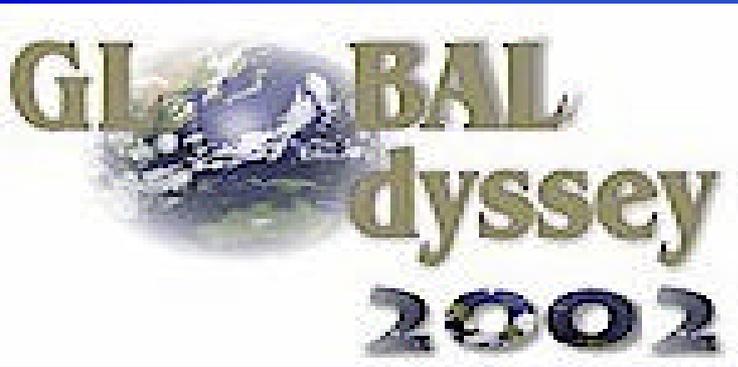
Defined Seven Post-Conference Workgroups

- Coordination – ISO, EQALM, CLIA, etc.
- Information – Programs and Meetings
- Matchmaking – Country Partners
- Advocacy – Brochure
- Logistics – Trade, Transportation Barriers
- Developmental – New Tests/Technology
- Information Technology – EQA Specific

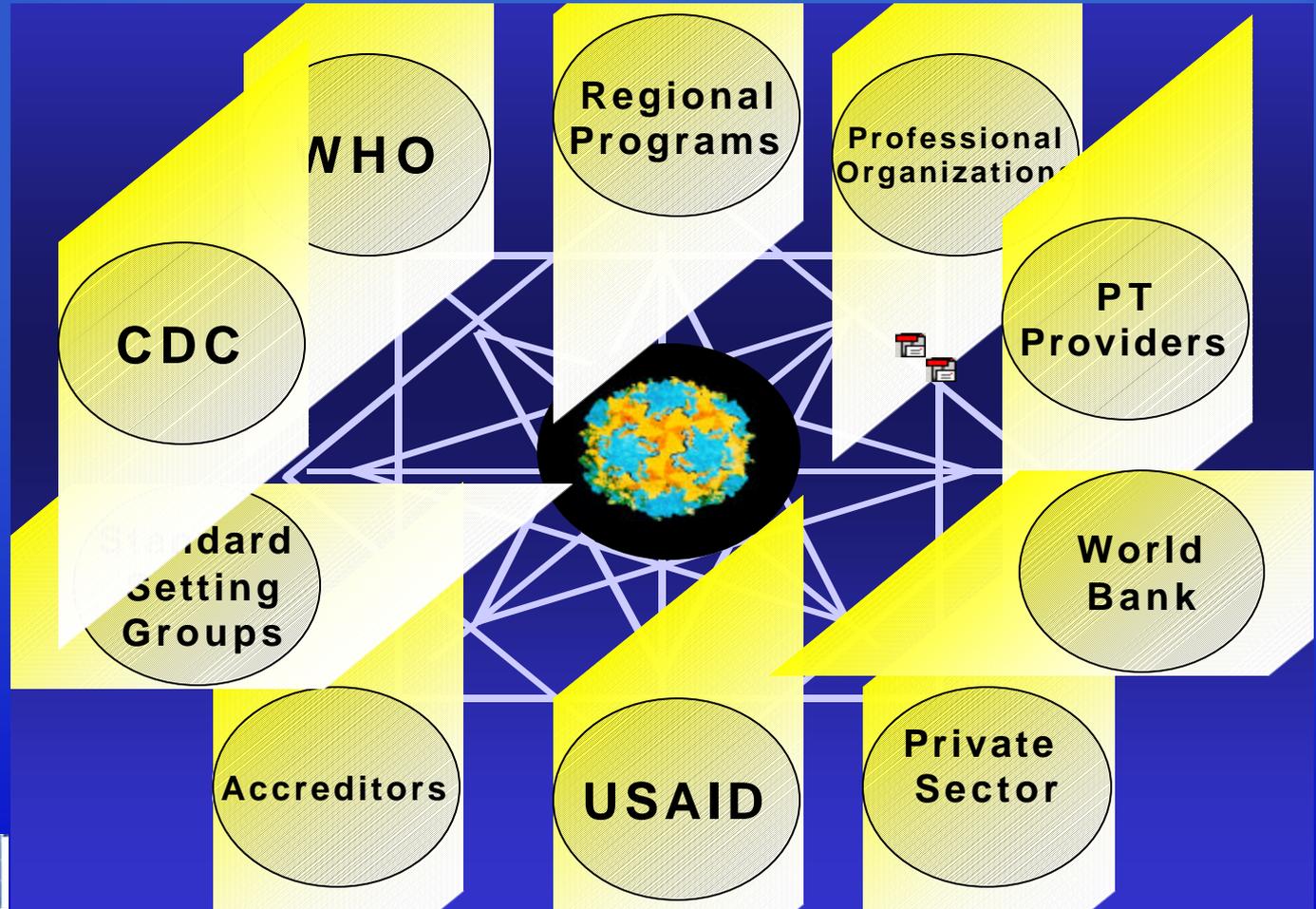


Vision

- Better communication – PT Inventory, Future Meetings, Publications, Internet
- Better collaboration – Resources, Mentors
- Better global health – Quality Testing
- Ongoing collaboration – Coalition



Global Partnership Quality Assurance



9/11/02





9/11/02

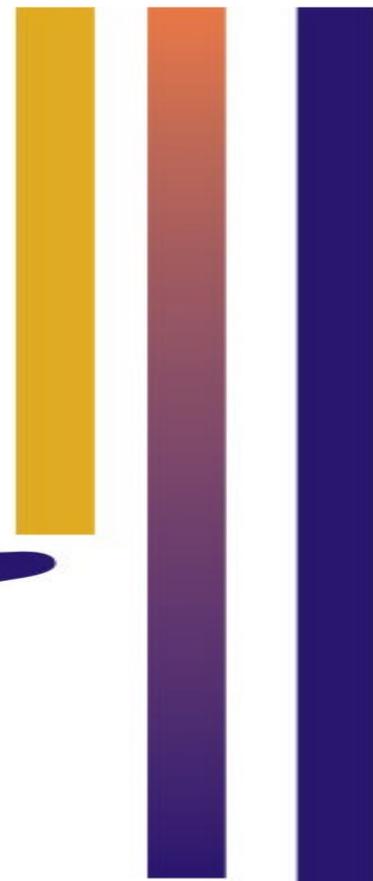


Supporting EQA Programs Worldwide





**Quality
Institute
Conference
2003**



***Making the Laboratory a
Key Partner in Patient Safety***

Joe Boone, Ph.D.
9/11/02





Conference Information

- Location - J.W. Marriott Hotel
Lenox Rd, Atlanta, Georgia
- Dates - April 13-15, 2003
- Starting Time – Noon, April 13
- Maximum Attendance - 400



Why?

- Healthcare System Changes Affect Health Laboratory Services – Access, Cost, Quality and Patient Safety
- Significant Role of Health Laboratory Services in the Healthcare System
- Improvement in Health Laboratory Service Depends on Better Collaboration and Coordination within the Healthcare System



Conference Goals

- Develop Framework for National Report on the Quality of Laboratory Services
- Develop Criteria for Quality Indicators for Laboratory Services
- Develop a Process for Ongoing Data Collection and Analysis – Quality Institute



Program

- Keynotes - Dr. Lucian Leape
- Dr. Brent James
- Perspectives:
Healthcare Providers, Policy Makers, Laboratory Professionals, Accrediting and Standard Setting Groups, Diagnostics Industry, Patient Advocates, Hospital Administrators, Payers/Insurers
- Experiences
- Workgroups



Program

- Perspectives in the Healthcare System
 - 1) Patient Experiences
 - 2) Providers of Care
 - 3) Organizations that Provide Care
 - 4) Environment of Care
- Reactor Panel



Program

- Perspectives:
 - Introduction and Overview
 - 1) Patient Experiences
 - Patient Example
 - 2) Providers of Care
 - Anesthesiology Example
 - Pharmacy Example



Program

- Perspectives:
 - 3) Organizations that Support Care
 - Hospital/HMO Example
 - 4) Environment of Care
 - Government's Role
 - Payer/Purchaser's Role



Program

- Experiences:

Introduction and Overview

1) Four Presentations

2) Reactor Panel



Program

- Workgroups:
 - Introduction and Overview
 - 1) Creating National Report
 - 2) Criteria for Quality Indicators
 - 3) Creating a Quality Institute



Long- and Short-Term Conference Outcomes?

- Better Collaboration and Coordination between Health Laboratories and other parts of the Healthcare System
- Disseminated National Report Highlighting Successes and Identifying Needs of Health Laboratories
- Measures for Quality in Health Laboratory Services: Safety, Timeliness, Effectiveness, Efficiency, and Patient-centeredness
- Ongoing Process to Collect and Analyze Data related to the Quality of Nation's Health Laboratory Services



September 10, 2002

The Honorable Claude Allen
Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Allen:

The undersigned organizations are writing to you with a concern over the possible waiver of regulations for rapid HIV (Human Immunodeficiency Virus) tests.

We believe that a test as critical as HIV screening must be conducted in a controlled and monitored environment, and conducted by trained personnel. Additionally, there is fear that rapid HIV tests, once waived, may be used in hospital and clinical settings. In these settings, there is great potential for immediate pharmacological treatment, due to false test results. The accuracy of rapid HIV tests must be improved prior to the use of these tests in a clinical setting.

The rapid HIV antibody screening test has a lower specificity and sensitivity than Enzyme Linked Immunoabsorbent Assay (ELISA) tests. For example, a specificity of 98% might sound good for a rapid HIV test. Unfortunately, if this test is used by members of a population with a low prevalence of HIV infection, such as normal healthy blood donors, most of the people who get a positive test result are getting a wrong test result.

We understand the desire for patient accessible HIV testing. However, due to the inaccuracy of rapid HIV tests and the implications for both patient and public safety, we respectfully ask that any recommendation for waiver of these tests be denied.

If you have questions or need additional information, please contact any of the organizations below, or call Rachel Judas at (202) 347-4450. Thank you for your attention to this important public health matter.

Sincerely,

American Association of Bioanalysts
American Society for Clinical Laboratory Science
American Medical Association
American Society for Clinical Pathology



Update on Rapid HIV Tests

CLIAC

September 10, 2002

Elliot P. Cowan, Ph.D.

*Senior Regulatory Scientist
Office of Blood Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration*

Purpose of This Presentation

To inform CLIAC of progress made toward the approval of new rapid HIV tests since the last meeting

Discussion of Submission Status

- ◆ FDA is prohibited from releasing any information related to submissions, as this is considered proprietary
- ◆ Limited to discussion of public information only, or information authorized for release by the applicant

Public Information Related to Rapid HIV Test Submissions

- ◆ On May 1, 2002, MedMira Incorporated announced, “the completion of a site inspection of the Company's facilities in Halifax by the U.S. Food and Drug Administration in connection with MedMira's application for Pre-Market Approval of its Reveal™ Rapid HIV Test.”
(http://www.medmira.ca/press_releases_f.htm)
- ◆ In addition, MedMira has given FDA permission to disclose that they received an approvable letter for their PMA on May 24, 2002

Public Information Related to Rapid HIV Test Submissions, cont.

- ◆ On May 13, 2002, OraSure Technologies, Inc, announced, "it has received notification from the U.S. Food and Drug Administration ('FDA') that the OraQuick[®] Rapid HIV-1 Antibody Test is approvable... Final approval is subject to the Company submitting product labeling and resolving specific validation and design control issues identified during FDA's recent pre-approval inspection of the Company's manufacturing facilities..."

(http://www.orasure.com/news/default.asp?art_id=185)



Toby Merlin, M.D., Chairperson
Clinical Laboratory Improvement Advisory Committee
5400 Gibson Boulevard, S.E.
Albuquerque, New Mexico 87108
(505) 262-7949:toby.merlin@lovelace.com

September 12, 2002

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20220

Dear Secretary Thompson:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's deep concern that rapid tests for human immunodeficiency virus (HIV) infection are being promoted for a waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) without presentation and review of data demonstrating that the CLIA waiver criteria are met. Data must be evaluated before an appropriate decision regarding waiver can be made.

As you know, CLIAC was chartered in February, 1992 to provide you and the Assistant Secretary of Health with scientific and technical advice and guidance relative to quality laboratory testing. CLIAC has, at several of its meetings, discussed in-depth the criteria used to obtain waiver under CLIA and the process for waiver review. CLIAC has also reviewed the potential public health benefits and risks of a waiver of a rapid HIV test. On September 11-12, 2002, CLIAC again considered this issue. After careful review and thoughtful discussion, the Committee's voting members unanimously requested that I share with you our concerns in this matter.

We believe that consideration of rapid HIV tests for waiver under CLIA requires a review of objective data for the following reasons:

- The results of HIV tests are of enormous consequence to the persons being tested.
- Erroneous HIV test results – both false positives and false negatives – pose a substantial risk to the persons being tested and their partners.
- Even the simplest HIV testing device requires oversight, training of personnel, quality control, proficiency testing, and quality assurance to provide accurate results.
- Waiver under CLIA provides no mechanism to assure proper oversight, personnel training, quality control, proficiency testing, and quality assurance.
- Studies performed by the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services and the Office of the Inspector General have shown that CLIA-waived tests are often incorrectly performed.
- Incorrectly performed waived tests have resulted in harm to patients.

Page 2 - The Honorable Tommy G. Thompson

We agree that HIV testing should be made broadly and rapidly available, and we believe this can be accomplished without waiver under CLIA. Mechanisms exist within CLIA to permit rapid HIV tests to be performed in mobile and non-traditional settings with a minimum of burden, while assuring appropriate oversight, quality control, and quality assurance.

Although we support broad dissemination of rapid HIV testing as soon as these tests are approved for market, we urge you to require careful review of objective evidence of test performance by waived testing personnel in waived settings before these tests are considered for waiver under CLIA.

We welcome the opportunity to work with you and other interested parties in this matter and thank you for your consideration.

Sincerely yours,

Toby L. Merlin, M.D.
Chairperson
Clinical Laboratory Improvement Advisory
Committee

cc:

Joseph O'Neill, M.D.
Director, Office of National AIDS Policy
The White House
Washington, DC 20502

Claude Allen, J.D.
Deputy Secretary
Department of Health and Human Services

Louis W. Sullivan, M.D.
Co-Chair, Secretary's Advisory Council on HIV/AIDS
Department of Health and Human Services

Thomas Coburn, M.D.
Co-Chair, Secretary's Advisory Council on HIV/AIDS
Department of Health and Human Services

CLIA Update



Judith A. Yost
Director, Division of Laboratories

Status

- Waived Lab Survey Project
- 2001 Lab Registry
- New & Improved CLIA Website
- Rapid HIV CLIA Categorization
- DOD Lab Program Re-Approval & MOU
- Secretary's Regulatory Reform Initiative
- Final QC Regulation Clearance
- DAB/ALJ Hearing Master Index
- Criteria for Test Waiver Final Regulation

CLIA Statistics Jan. 2002

<u>Total Laboratories Enrolled</u>	174,504
-Certificate of Compliance	21,809(13%)
-Certificate of Waiver	93,129(55%)
-Certificate of PPM	37,755(22%)
-Certificate of Accreditation	16,312(10%)

<u>Exempt State Labs</u>	5499
-New York (Except POL's)	2747
-Washington	2752



CLIA Authority

- CMS has delegated authority for all CLIA regulations.
- CMS is working with Tri-Agencies to coordinate program policies & priorities.
- Regular Tri-Agency meetings are being convened.
- Progress has been made, communication enhanced & mutual priorities determined.

Waived Lab Project

- Studies by CMS & others indicated 50% of waived labs have quality problems.
 - Not following mfgs.’ instructions; not doing QC.
- Followup data of problem labs reflects compliance is maintained 75% of time using education.
- CMS compiling “Clearinghouse” of existing educational programs for CLIA Website.
- CMS initiated surveys of 2% of waived labs annually for 3 years in all states Apr. 15, 2002.
 - Comprehensive information collection including ”outcomes”.

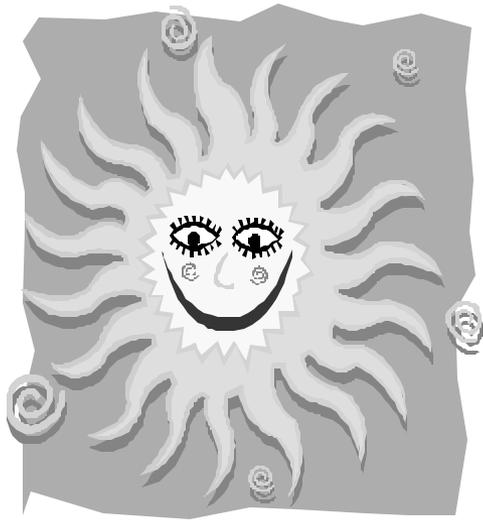
Waived Lab Project Cont'd.

- CMS working with manufacturers to enhance clarity of instructions.
- CMS, FDA & manufacturers on NCCLS workgroup to develop international labeling standards.
- Tri-Agencies working on final rule for waived criteria.
- CMS will evaluate survey findings annually & at 3 yrs. to determine appropriate oversight of waived labs.

2001 Lab Registry

- Can be found on CLIA web site.
- Lists 221 labs with sanctions completed.
 - 196 individual labs; some listed twice.
- Reflects more labs than previously(207); includes *repeat* offenders.
- Incorporates labs from exempt states, OIG & accrediting organizations in eight categories.





Successes

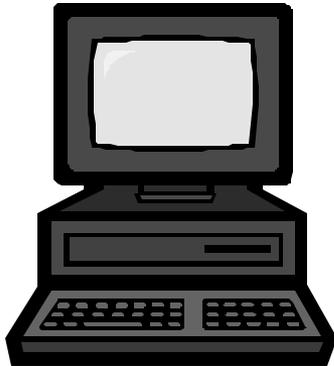
- Hearing Decisions Web Index
- CLIA Website Transition
- Department of Defense (DOD) MOU

Hearing Decision Master Index

- Decision, Synopsis, Summary Points.
- Basis for Sanctions.
- Arguments by both sides of case.
- Excerpts from the ruling & referenced cases.
- Complete actual hearing decision, applicable regulatory references.
- Updated annually.
- CLIA Web site:
www.cms.hhs.gov/clia/hearinggroup.asp.
- ***CLIA has never lost a case!!***

www.cms.hhs.gov/clia/

- News
- Special Alerts
- How to Apply
- Program Description/Projects
- Regulations & Federal Register Documents
- Test Categorizations
- Fee Schedule
- State Agency Contacts
- CMS Regional Office Contacts



www.cms.hhs.gov/clia/ (Cont)

- Approved Accrediting Organizations
- Exempt States
- State Lab Licensure Programs
- PT Providers
- Certification Boards
- FAQs
- Statistics
- Hearing Decisions
- Lab Registries
- Medicaid CLIA Releases
- OIG Reports

DOD Re-Approval

- Secretary DHHS & Secretary DOD MOU for approval of DOD lab oversight program.
 - AFIP works with DOD on standards.
 - Extended for 5 years.
- Most DOD labs accredited by CAP.
- DOD regulations are equivalent to CLIA.
- DOD labs may have unusual circumstances.



To Be Announced

- Secretary's Regulatory Reform Initiative
- Rapid HIV Test Categorization Status
- Final QC Regulation
- Waived Test Criteria Final Regulation

Regulatory Reform Initiative

Draft Recommendations (1)

- Simplify/clarify regulations.
- Provide information to POLs about training opportunities.
- Update website/ possible link to NLTN.
- Develop & disseminate basic laboratory practices document.
- Offer technical assistance in interpreting reg requirements.
- Modify the AQAS as an educational tool.

Regulatory Reform Initiative

Draft Recommendations (2)

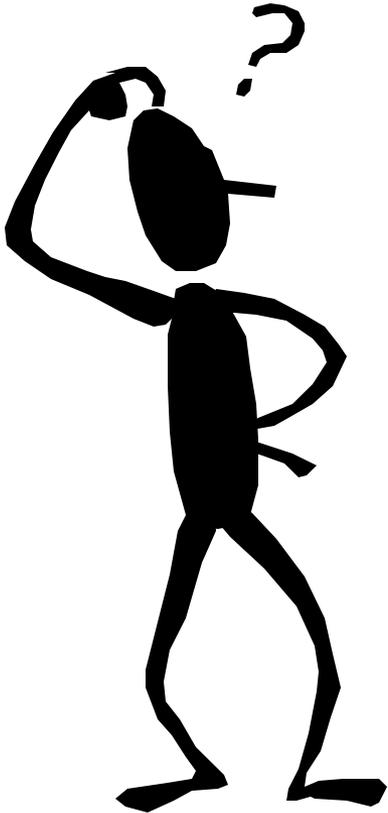
- Increase the number of POL reps on CLIAC.
- Conduct training at industry meetings.
- Design educational brochure for POLs.
- Solicit feedback at Open Forums.
- Place education clearinghouse on CLIA website.
- Promote self assessment tools for laboratories.

Final QC Regulation

- Finalizes QC, PTM & QA—due end 2002.
 - Most standards unchanged.
- Closes phase-ins that expire 12/31/2002.
 - Ph.D lab dir.; mod. comp. QC; FDA role.
- Reflects new technology; responds to comments.
- Incorporates basic Quality Systems concepts & CLIAC recommendations.
 - Follows lab workflow/prevents errors.
- Streamlines, simplifies & adds QC flexibility.
- Has 90 day effective date to educate & implement.
 - Guidance will be forthcoming.

Waived Test Criteria Regulation

- Revised criteria published by FDA in draft guidance to be withdrawn.
- FDA now using '95 proposed rule used by CDC for waiver reviews.
- Final rule including comments under development by Tri-Agencies.
- Issue 1: Movement to waive rapid HIV test.
 - Pre & post analytical considerations.
 - PACHA meeting conclusions.
- Issue 2: QC for waived tests—recommended or required when no failsafe is present.



THE END!!

THANK YOU!!

Questions???

Coordinating Council on the Clinical Laboratory Workforce (CCCLW)

Summit Meeting Report to CLIAC

September 11, 2002

Overview

- Meeting held on April 2, 2002 in Chicago
- Hosted by ASCLS
- Previously known as the Summit on Laboratory Workforce Shortage
- New name proposed: Coordinating Council on Clinical Laboratory Workforce (CCCLW)

Strategic Plan Update

Review of Current Status

- Data Collection – ASCP
- Recruitment – ASCLS
- Marketing – CLMA
- Financing Education - NAACLS

Data Collection

- Wage and Vacancy Survey
- Medical Technologist Prospective Study (in 9th year)
- Annual Survey of Programs (from Program Directors)
- Job task/Practice Analysis for MT, MLT, and PBT in progress

Recruitment

- Career brochure and CD video to promote laboratory careers
- Career Toolbox
- Career video for PBS (possible joint venture with Johnson and Johnson)

Marketing and Financing

- Not much progress on Field Guide for laboratory managers on addressing workforce shortage
- Discussion on available scholarships for clinical laboratory students

Other Opportunities

- Professional licensure - ASCLS
- National Preparedness for Bioterrorism – FDA Office of Science and Technology
- Loan Forgiveness – ASCP (HR 1948)
- Logo/Identity – ASCLS
- Career Ladders – ASCLS

Workgroup Summary for Strategic Plan Data Collection

- Enhance ASCP Wage and Vacancy survey questions to fill gaps (i.e. hiring trends, expand database of targeted individuals)
- Terminology – have glossary of definitions of categories for better correlation of answers
- Error rates – obtain tangible data
- Licensure – do labs in licensed states perform better on PT than those without licensure

Workgroup Summary

Recruitment

- Organize available materials; pool resources
- Develop consistent message for material packets along with dissemination plan
- Use career ladder/licensure information as positive recruitment tools

Workgroup Summary

Marketing

- Joint CLMA/Educator's Forum – schedule another? Proposed timeframe of March 2003
- Career pathways – how to form partnership with hospital HR departments
- Implementation strategy for Field Guide
- Improve recognition of problem – invite AHA, AMA, HRSA to CCCLW meetings

Workgroup Summary

Financing Education

- Expand base for soliciting scholarship funding (schools/universities, state societies)
- Establish CCCLW website for information
- Develop list of “local” resources
- Identify “free” training (i.e. military)
- Potential industry support of programs

Summary

- Joint support of subsequent meetings (estimated ~ \$250 each)
- Steering committee to set agenda and organize meetings (initial committee includes ASCP, ASCLS, CLMA, NAACLS)
- Keeping information flowing in between face-to-face meetings
- Distribute list of meeting participants and e-mail addresses
- Revise Strategic Plan; disseminate to all organizations

Coordinating Council on the Clinical Laboratory Workforce



CCCLW ACTIVITY

Update Since April 2002

Report to CLIAC

September 2002

Brenta G. Davis, Ed.D

Status of Manpower Shortage

- **Still exists because of lack of applicants to educational programs.**
 - We are producing about half the number of graduates we need each year
 - Programs that are open are only 77% full (July 2002)

Status of Shortage Cont.

- **Signs of hope**

- About half of programs report a modest increase in applicant pools and enrollments

- Overall, median salaries in US have increased approximately 19% since 2000

- Health care careers seem more attractive in current economic climate

CCCLW Since April 2002

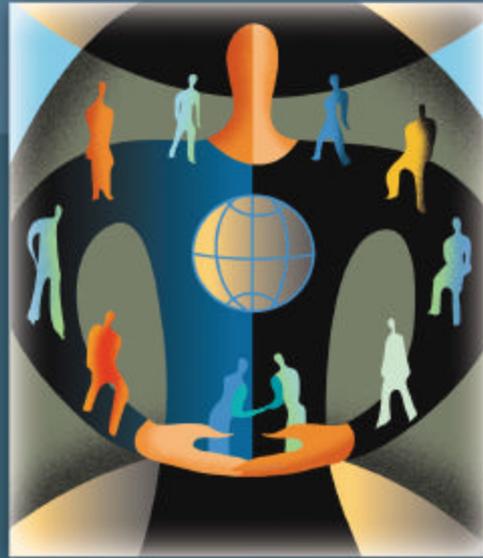
- **Recognition of CCCLW as focal point of information and action**
 - **AMA Health Professions e-letter article and web site item**
 - **Inclusion on program of G-2 Lab Institute in October**
 - **J&J/Ortho-Clinical Diagnostics(OCD) contact**

CCCLW since April, cont

- **J&J/OCD proposed project**
 - Special web site and targeted brochures for high school and college students
 - Turnkey Media Kit
 - Primary implementation by PR professionals to media outlets throughout the US
 - OCD will meet with CCCLW in fall before final decision to proceed

HOW CLIAC HELPS

- **Continued concern about the shortage signals its significance to healthcare community and government**
- **Continued participation in CCCLW**
- **Participation in other meetings and informational sessions about workforce issues**



In Our Hands

**HOW HOSPITAL LEADERS CAN BUILD
A THRIVING WORKFORCE**

Presentation Overview

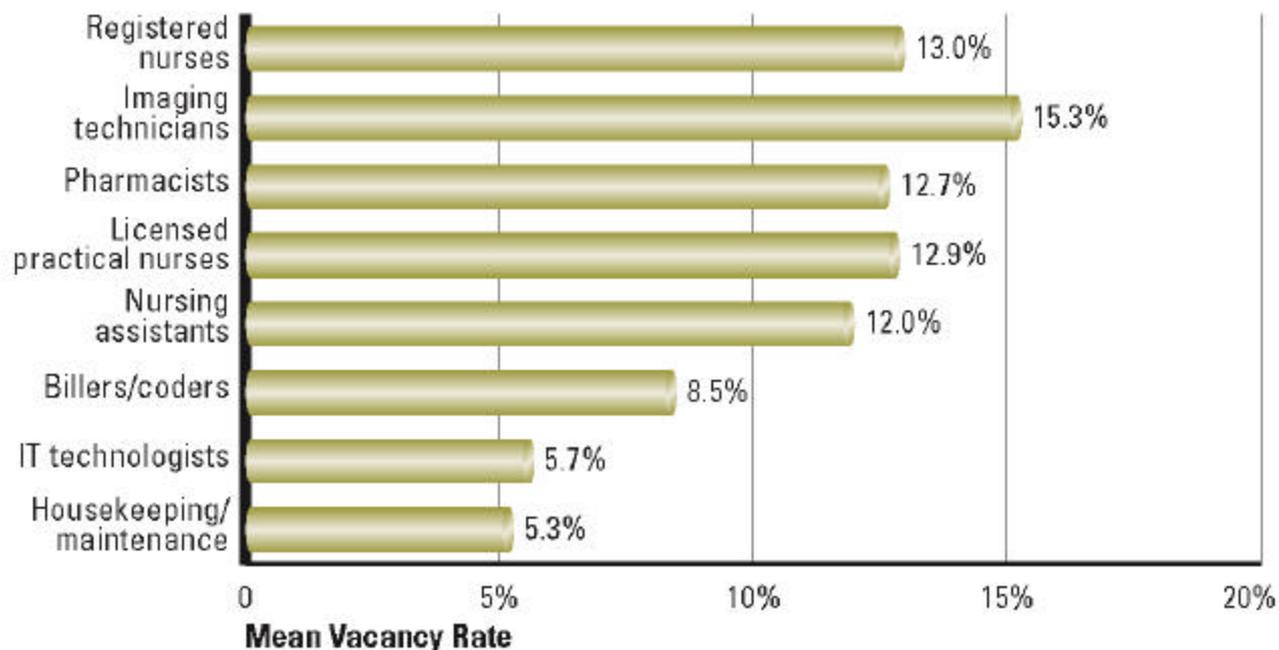
- **A Looming Crisis in Care**
- **AHA Workforce Commission**
- **Recommendations**
- **Commission Conclusions**

In Our Hands

The Current Situation:

A SHORTAGE OF ALL TYPES OF HOSPITAL WORKERS

Hospital Vacancy Rates — Fall 2001

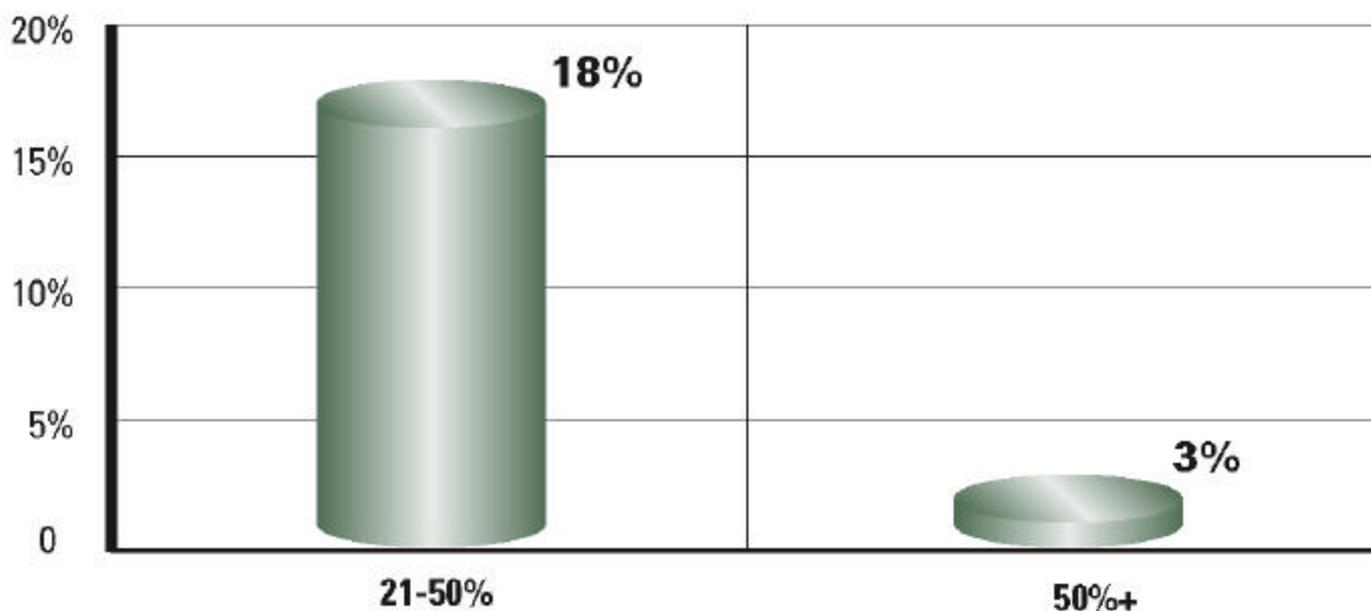


Source: First Consulting Group, Fall 2001.

The Current Situation:

**21% OF HOSPITALS REPORT SEVERE SHORTAGES
(OVER 20% VACANCY RATE) OF IMAGING TECHNICIANS.**

Percentage of Hospitals Showing Vacancy Rate Change

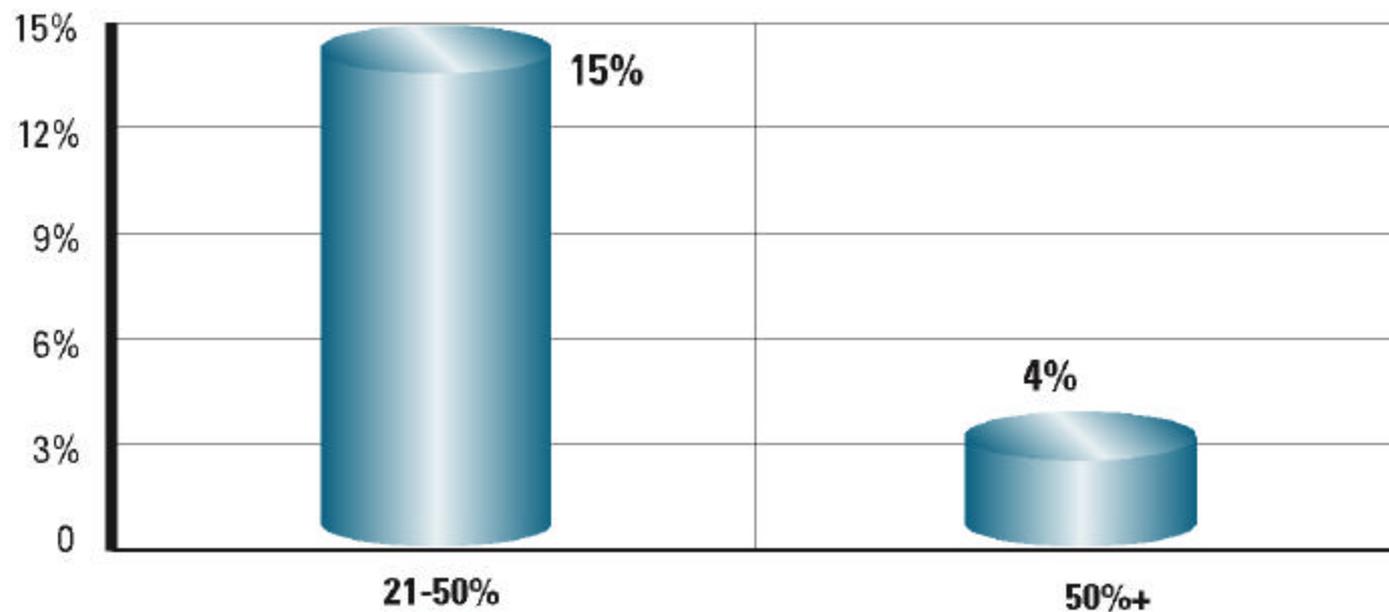


Source: First Consulting Group, Fall 2001.

The Current Situation:

**19% OF HOSPITALS REPORT SEVERE SHORTAGES
(OVER 20% VACANCY RATE) OF PHARMACISTS.**

Percentage of Hospitals Showing Vacancy Rate Change

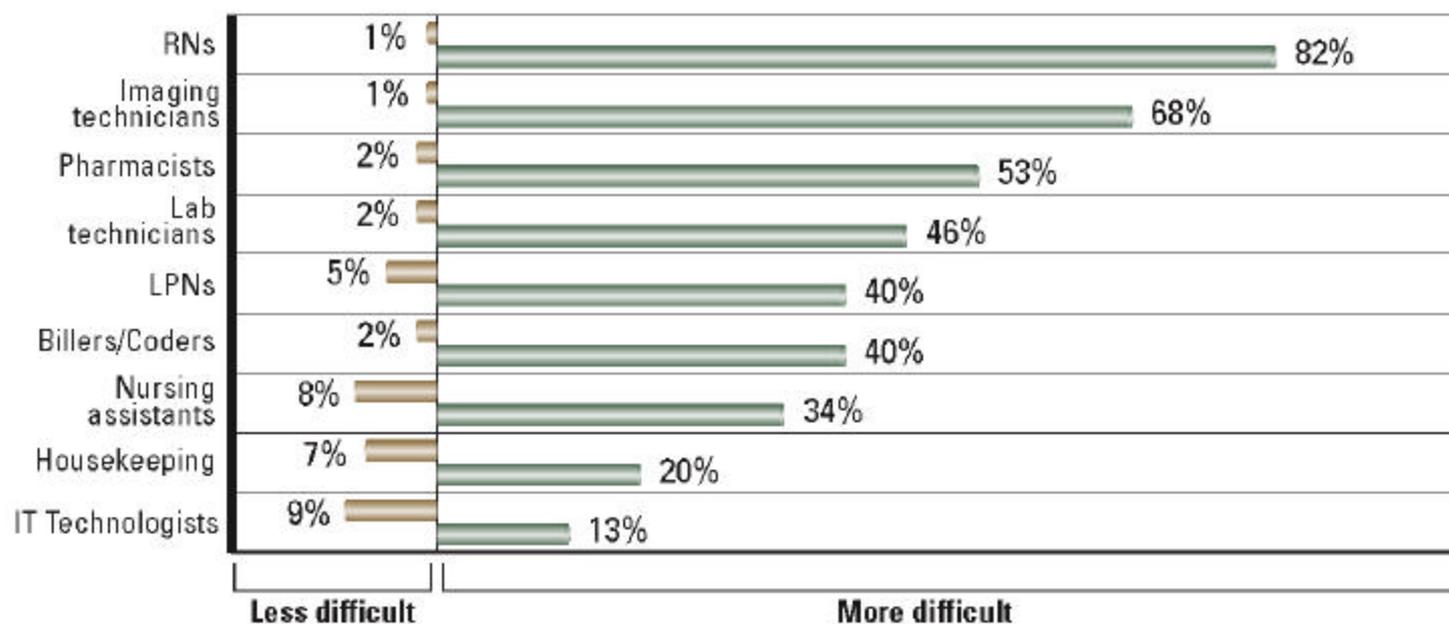


Source: First Consulting Group, Fall 2001.

The Current Situation:

HOSPITALS ARE FINDING THAT THE EFFORT REQUIRED TO RECRUIT WORKERS IS INCREASING

Percentage of Hospitals Reporting More or Less Difficulty Recruiting, 1999-2001

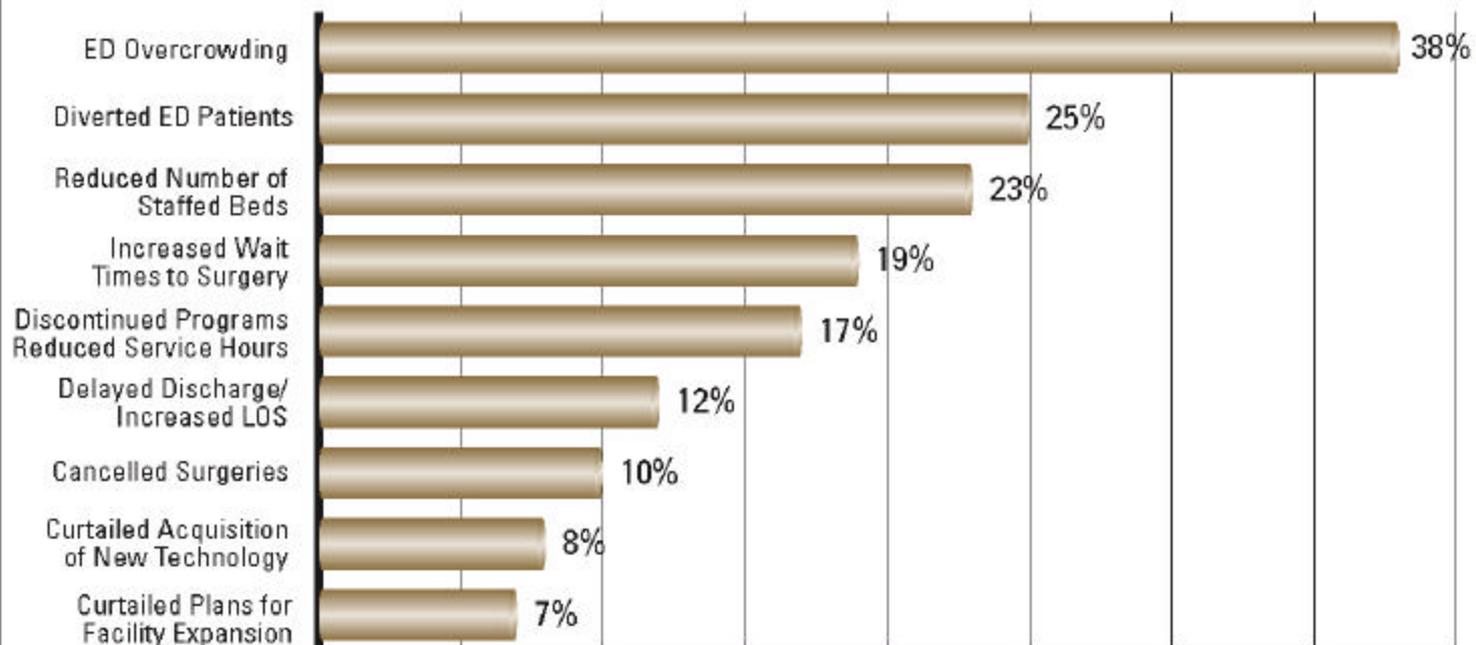


Source: First Consulting Group, Fall 2001.

The Current Situation:

THE SHORTAGE IS FORCING CHANGES IN HOSPITAL OPERATIONS AND PATIENT CARE.

Service Impacts of the Workforce Shortage



Source: First Consulting Group, Fall 2001.

A Looming Crisis in Care

This is not a short-term problem.

ON THE HORIZON:

**A long-term shortage that will
become worse with time**

In Our Hands

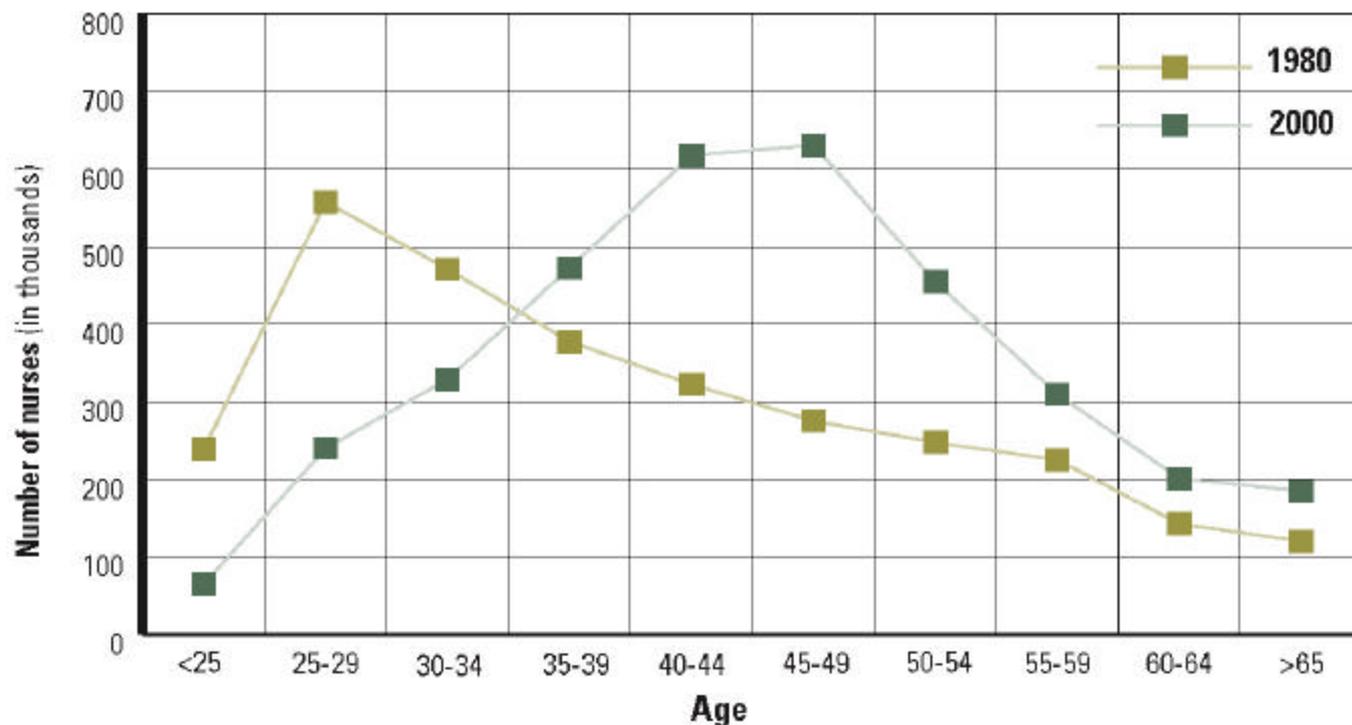
A Looming Crisis in Care

- **Workforce is aging**
- **Fewer potential workers following retiring baby boomers**
- **Fewer choosing health careers**
- **Employee dissatisfaction is high**

In Our Hands

The Workforce is Aging

Age Distribution of the Registered Nurse Population, 1980 and 2000



Source: HRSA, The Registered Nurse Population: National Sample Survey of Registered Nurses, March 2000.

Fewer Potential Workers Following Retiring Baby Boom Generation

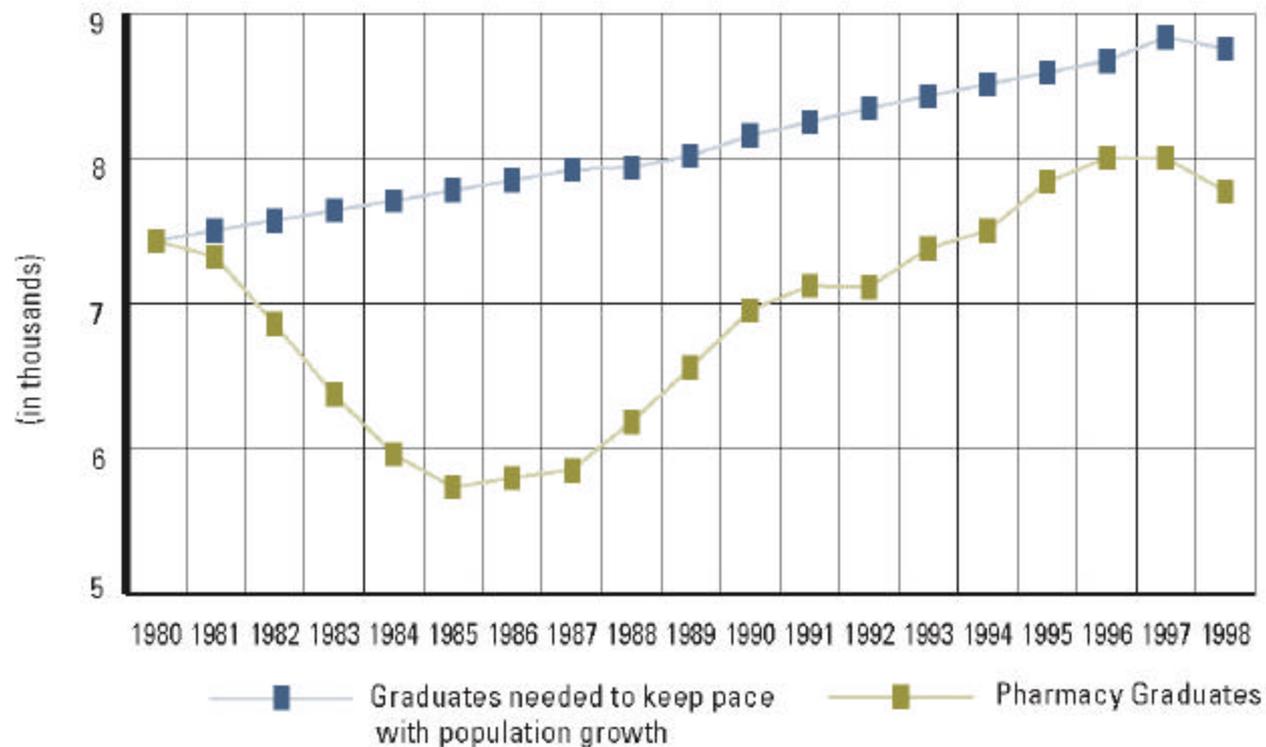
Annual Rates of Labor Force Growth, 1950-2025

Time Period	Labor Force Growth
1950-1960	1.1%
1960-1970	1.7%
1970-1980	2.6%
1980-1990	1.6%
1990-2000	1.2%
2000-2015	1.0%
2015-2025	0.2%

Source: U.S. Department of Labor, Working in the 21st Century. June 2001.

Fewer Choosing Health Care Careers

Pharmacy Graduates Versus Number of Graduates Needed to Keep Pace with Population Growth, 1980-1999



Source: Health Resources and Services Administration, *The Pharmacist Workforce*.
Washington, DC: Department of Health and Human Services, December 2000.

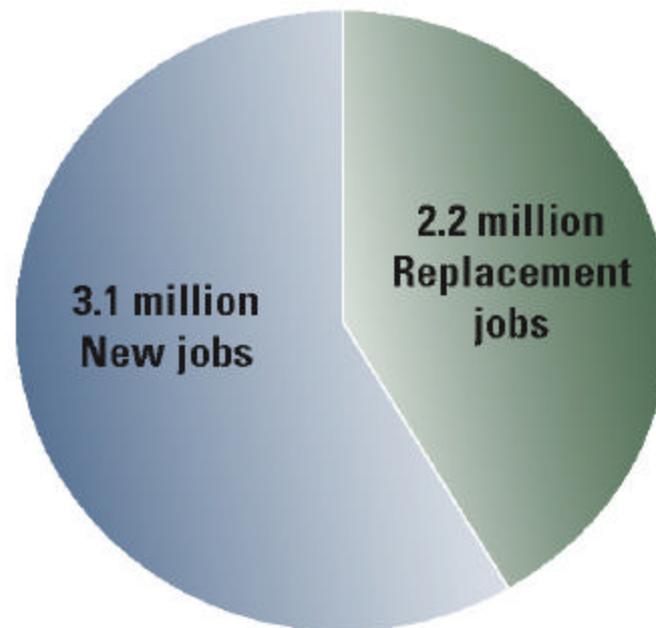
Dissatisfied Employees

- **Stressful environment**
- **Too much paperwork –
not enough caring**
- **Few opportunities to influence**
- **Loyalty to profession –
not employer**

In Our Hands

A Looming Crisis in Care

Number of New Health Workers Needed by 2010



Source: Bureau of Labor Statistics, Occupational Employment Projections to 2010
Monthly Labor Review November 2001

AHA
Commission on Workforce
for Hospitals
and Health Systems



Commission Charge:

DEVELOP BOLD GOALS AND ACTIONABLE RECOMMENDATIONS TO:

- **Fully value and invest in recruitment, development, and retention of workers**
- **Expand interest in health careers**
- **Make hospitals "employers of choice"**

In Our Hands

AHA *Workforce Commission*

27 COMMISSIONERS

- **Stakeholder representatives of the problem and the solutions**
- **Multiple disciplines: CEOs, MD, RNs, pharmacy, allied health, HR, education, labor, foundation, business**

ONE YEAR OF STUDY AND DELIBERATION

In Our Hands



In Our Hands

HOW HOSPITAL LEADERS CAN BUILD
A THRIVING WORKFORCE

AHA Commission on Workforce for Hospitals and Health Systems

April 2002



Report Organization

- **A Looming Crisis in Care**
- **5 Core Chapters**
 - ◆ *Foster Meaningful Work*
 - ◆ *Improve the Workplace Partnership*
 - ◆ *Broaden the Base*
 - ◆ *Collaborate with Others*
 - ◆ *Build Societal Support*
- **Workforce Strategy Map**

In Our Hands

Report Organization

- **5 Core Chapters**
 - ◆ *Foster Meaningful Work*
 - ◆ *Improve the Workplace Partnership*
 - ◆ *Broaden the Base*
 - ◆ *Collaborate with Others*
 - ◆ *Build Societal Support*

In Our Hands

Foster Meaningful Work

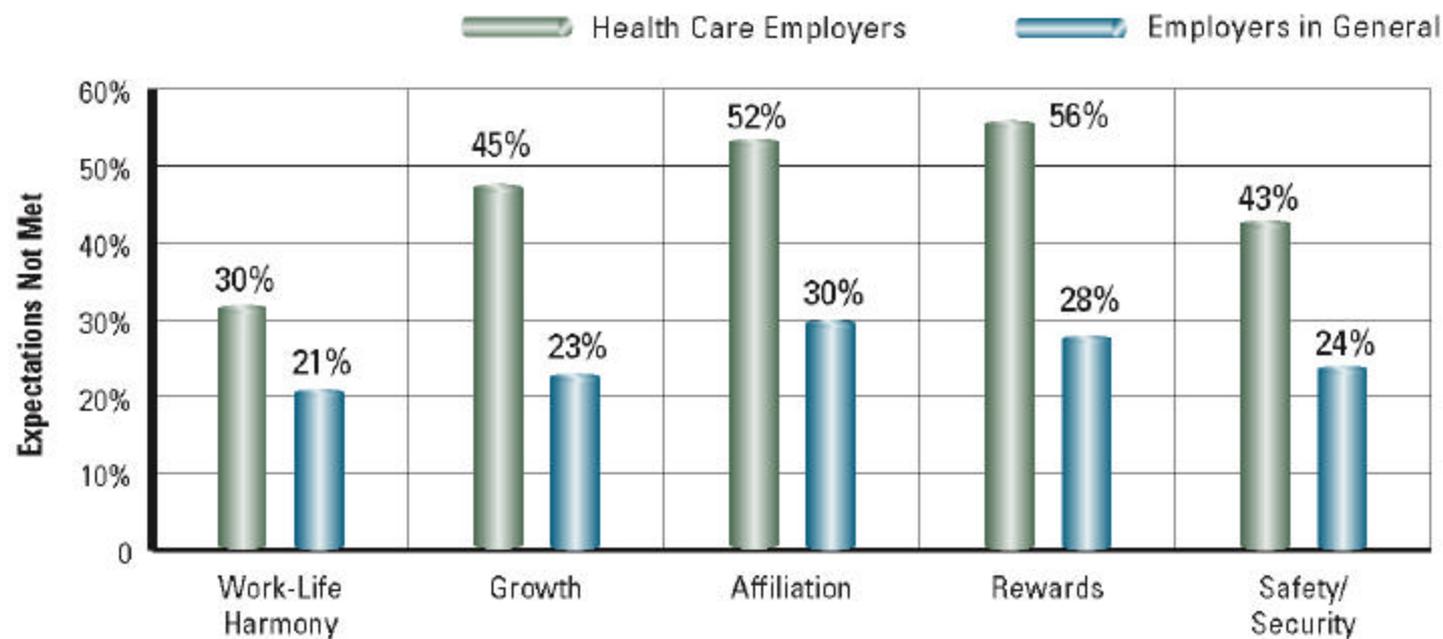


- **Work design an organizational priority and competence**
- **Enough qualified staff for safe, timely care**
- **Caregiver time in patient care**
- **Knowledge management**
- **Learn from business on work design and processes**

In Our Hands

Improve the Workplace Partnership

Percentage of Employees Whose Expectations Are Not Being Met



The Performance Pyramid™ Component

Source: Aon Loyalty Institute, Healthcare @Work. Ann Arbor, Michigan, 2001.

Improve the Workplace Partnership

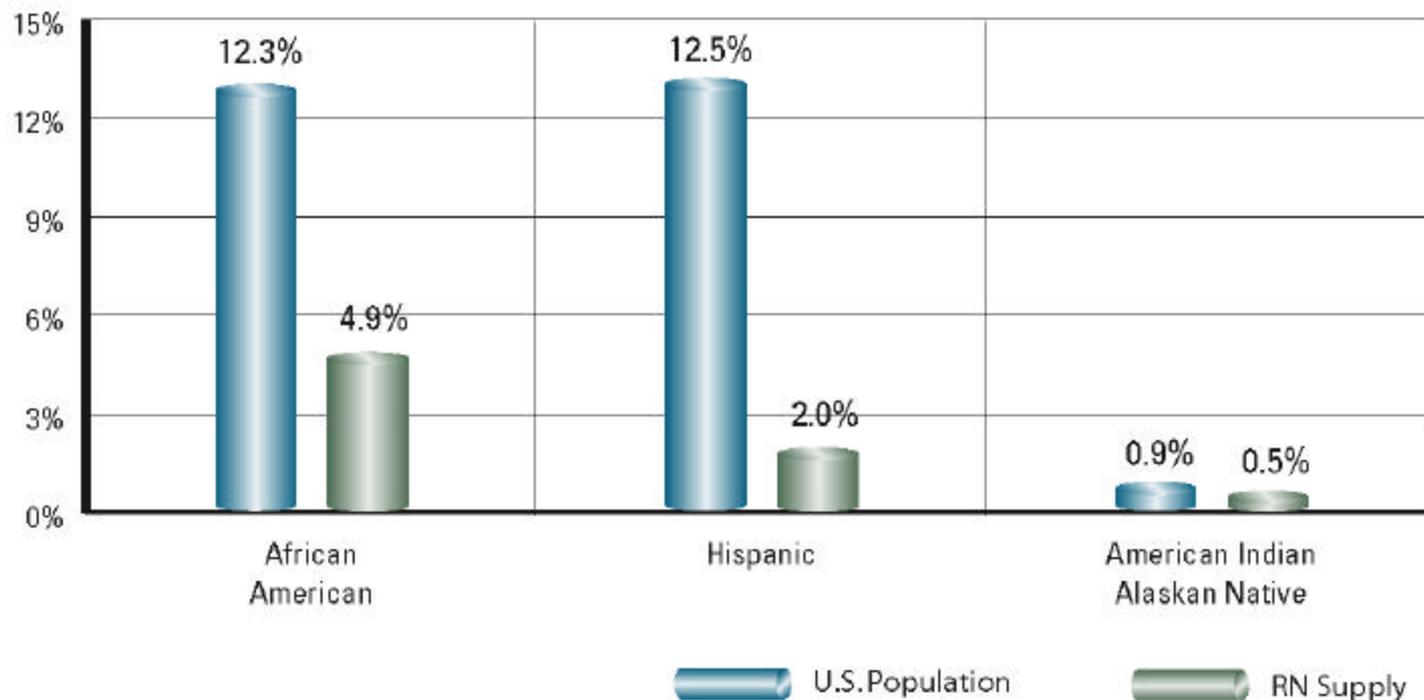


- **Culture that values workers**
- **Front-line managers**
- **Focus on retention and employee stability**
- **Comprehensive rewards strategy**
- **Continuous board/senior leadership attention**

In Our Hands

Broaden the Base

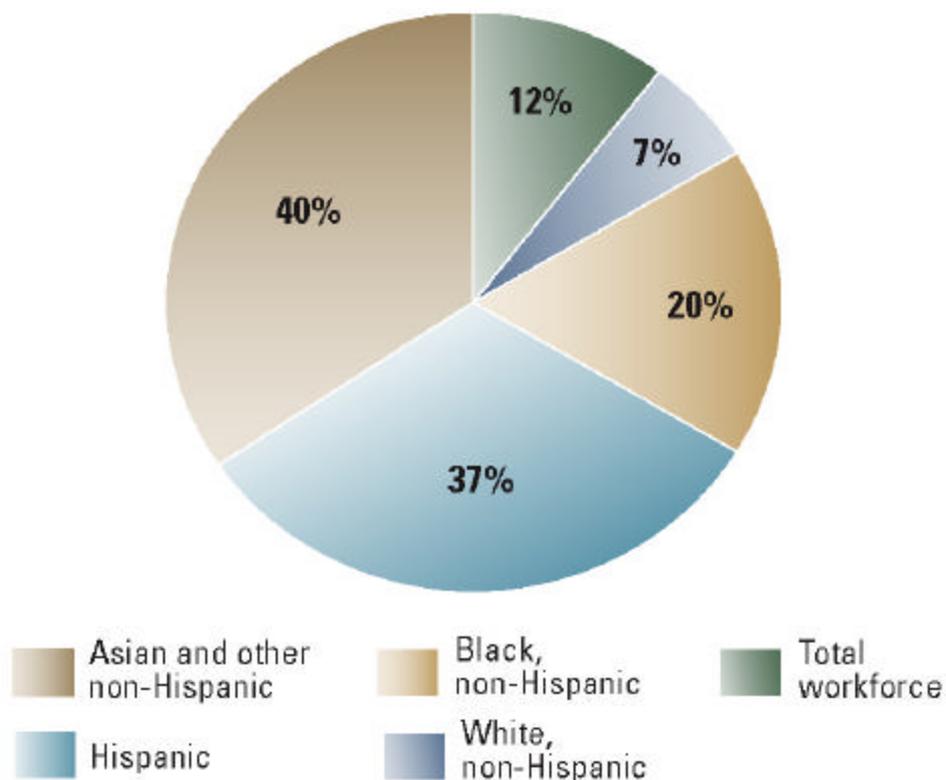
Racial Composition of U.S. Population and RNs, 2000



Source: U.S. Census Bureau, Internal Release Data April 2, 2001 and National Sample Survey of Registered Nurses 2000, HRSA, Bureau of Health Professions, Division of Nursing.

Broaden the Base

Percent Change in Labor Force, Projected 1998-2008



Source: Department of Labor. Workforce in the 21st Century. June 2001.

Broaden the Base



- **More diverse workforce**
 - ◆ *Both genders*
 - ◆ *Racial and ethnic minorities*
 - ◆ *Immigrants*
 - ◆ *All generations*
- **Compete with the economy at-large**
- **Image of health care careers**

In Our Hands

Collaborate with Others



- **Hospitals work together in local communities**
- **Use associations to broaden initiatives**
- **Education System**
 - ◆ *K-12 Schools*
 - ◆ *Colleges/Universities*
- **Community organizations, corporations, foundations**
- **Field retention**

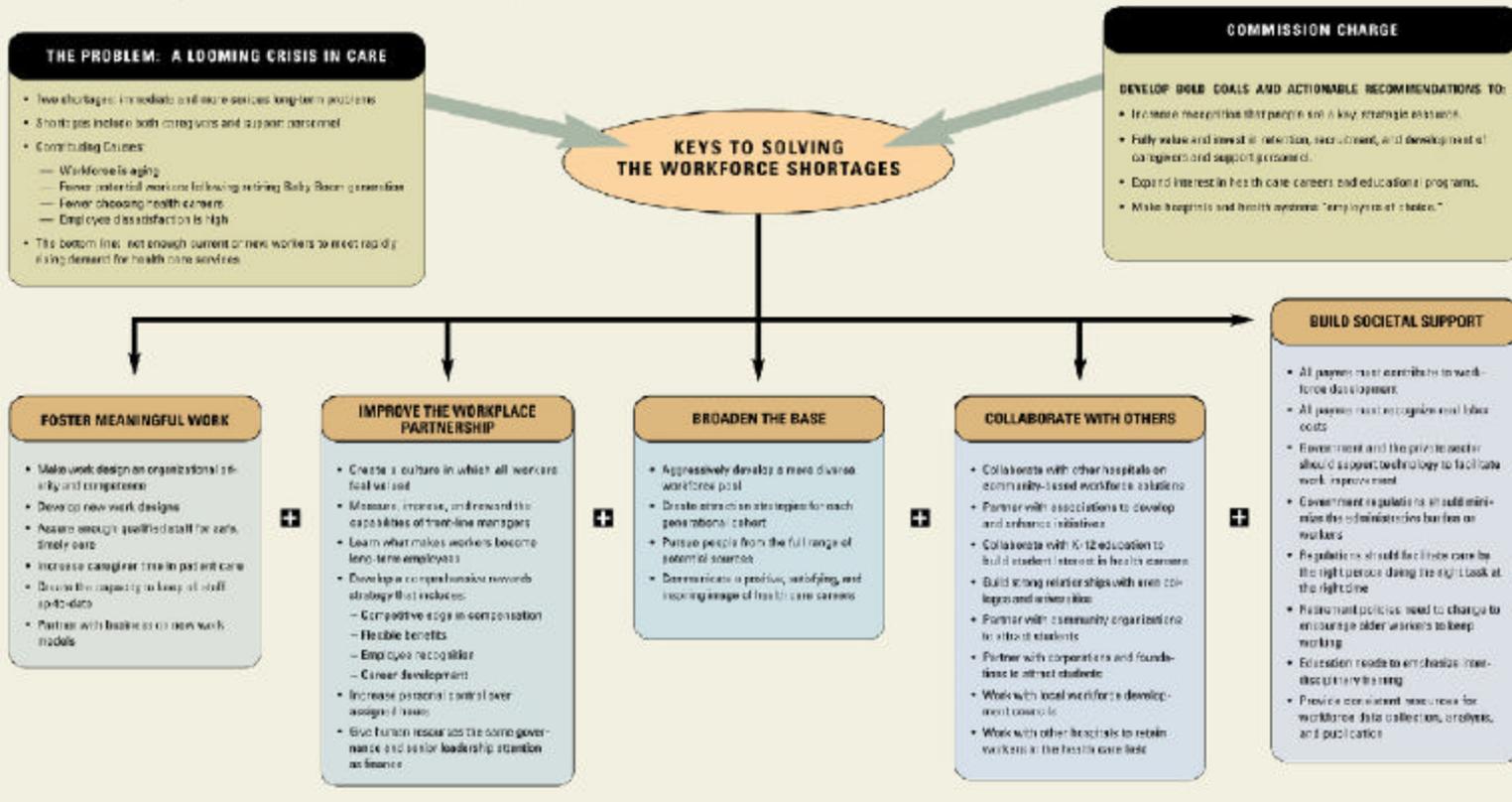
In Our Hands

Build Societal Support

- **Adequate payment**
- **Support for technology**
- **Reduce burdensome regulations**
- **Retirement policies**
- **Interdisciplinary educational approaches**
- **Workforce data collection/planning**

In Our Hands

The Workforce Strategy Map



Commission Conclusions

- **Immediate and sustained action by hospital leaders**
- **Human resources must become central to hospital strategy**
- **Recommendations are not a menu of choices**
- **Opportunity for fundamental health delivery improvements**
- **Recommendations are foundation for health care's future**

In Our Hands

Sentinel Event Data and Staffing Effectiveness

Joint Commission on Accreditation of
Healthcare Organizations

Joanne Born, Executive Director
Laboratory Program

Overview

- JCAHO accredits more than 17,000 healthcare organizations in the US and overseas
- 2500 laboratory organizations (4500) CLIA certificates
- Mission is to promote patient safety and performance improvement through accreditation survey
- Survey of compliance with professionally derived standards

Sentinel Events and JCAHO

- Any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof
- Thorough and credible root cause analysis, risk reduction strategies
- Leadership expectations standards-based
- Voluntary self-reporting
- Database

Sentinel Event Categories

Suicide, 17.1%

Operative/postoperative complications, 12.2%

Medication Error, 11.5%

Wrong-site surgery, 11.2%

Delay in treatment, 5.3%

Transfusion error, 2.6%

Equipment-related, 1.6%

12 other categories

Settings

- 82% in hospitals (general, psychiatric)
- 3.6% in emergency department
- 0.3% in clinical laboratory
- Remainder, varied settings

Categories of Root Causes

- Communication, 63% of all events
- Orientation/training, 58%
- Availability of information, 20%
- Staffing levels, 18%
- Competency/credentialing, 12%
- Procedural compliance, 12%
- Others

Orientation/Training, identified as root cause...

- 62% of inpatient suicides
- 80% of op/post-op events
- 60% of medication errors (number one)
- 38% wrong site surgery
- 28% delays in treatment
- 75% transfusion events

Staffing Levels, as root cause...

- 42% of op/post-op events
- 18% of medication errors
- 25% of delays in treatment
- 25% of transfusion events

Competency/Credentialing...

- 24% of op/post-op events
- 21% of medication errors
- 28% of delays in treatment

Lab Compliance Issues

- Staff competency (includes point of care)
- Proficiency testing performance, corrective action, regulated analytes
- Quality control performance Hematology and Chemistry, remedial action, review
- Waived testing quality control (non-lab) and staff training (incl. Manufacturer's instructions)
- Training of staff monitoring transfusions

JCAHO and Staffing Effectiveness

- Shortage of qualified professional personnel
- Identified linkages between staffing effectiveness and patient safety
- Legislation
- Develop approach for ALL types of organizations
- Link to clinical/service outcomes
- Engage field in development

Staffing Effectiveness:

“The number, competency, and skill mix of staff as related to the provision of needed services.

Development...

- National panel of over 100 experts, 2000
- Representatives from various settings and disciplines (20% providing direct care)
- Analyzed staffing models and sensitivity of screening indicators

Approach

- Multiple indicators in combination (human resource indicator and service indicator)
- Indicators as screening tool for staffing issues
- Allows flexibility
- Requires analysis of variation from expected
- Expects response if indicated
- No prescribed staffing levels

Under Consideration

Service Indicators

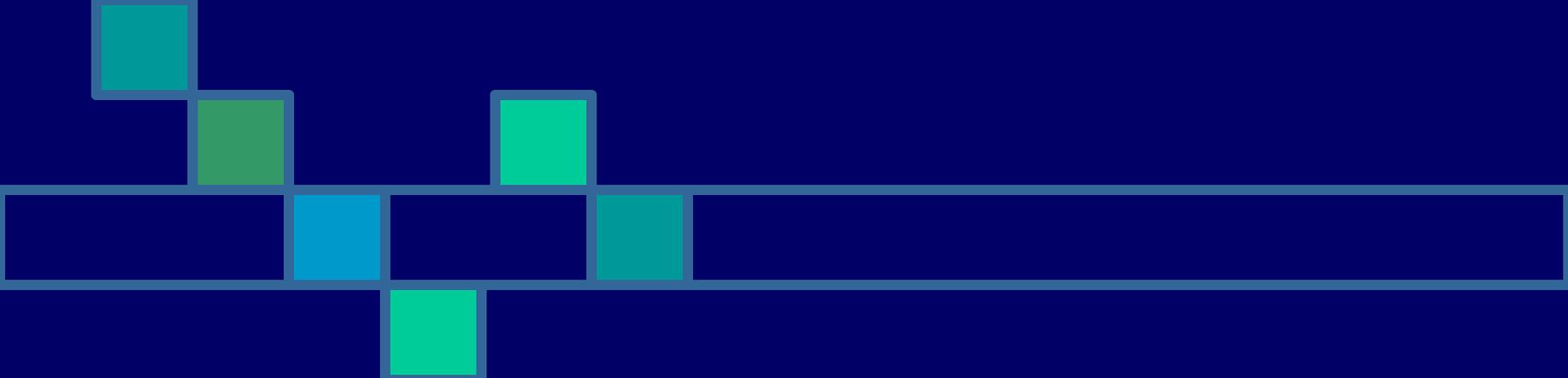
- Patient complaints
- TAT
- Delayed tests
- Repeat tests
- Mis-ID of specimens
- Left without being seen
- Increase in STAT orders (outside of rounds)

HR Indicators

- Staff turnover
- Staff injury
- Overtime
- Education hours
- Vacancy rate
- Sick time
- Satisfaction of staff
- Understaffed according to plan
- Agency use



Questions?...



Legislative Solutions
to the
Laboratory Workforce Shortage



By Robin E. Stompler
Vice President, Government Affairs
American Society for Clinical Pathology

Two Approaches



Laboratory Budget Issues



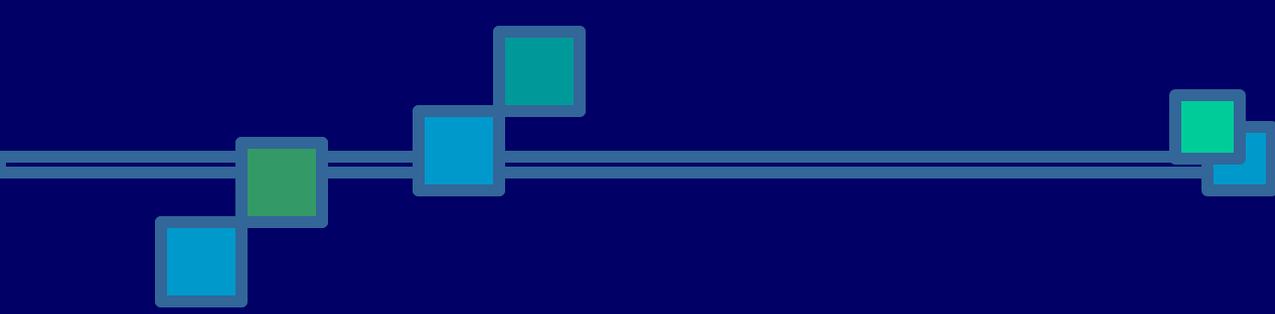
- CPI Update
- Copayments & Competitive Bidding
- Specimen Collection Fee
- Physician Payment Update
- Regulatory Reform

Focus on Education

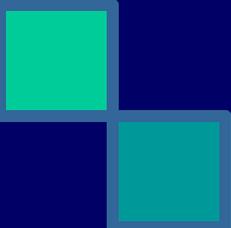


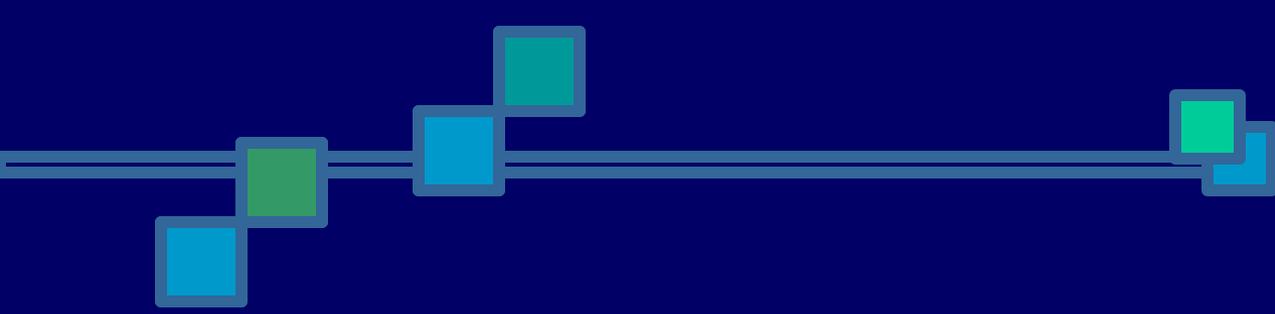
- Allied Health Project Grants

- Title VII, Public Health Service Act
- Attract professionals to field and underserved communities
- Proven success

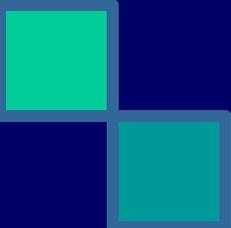


Allied Health Project Grants

- 
- “Such sums”
 - \$9.49 million - FY 2002
 - \$0 – FY 2003 ???
- 

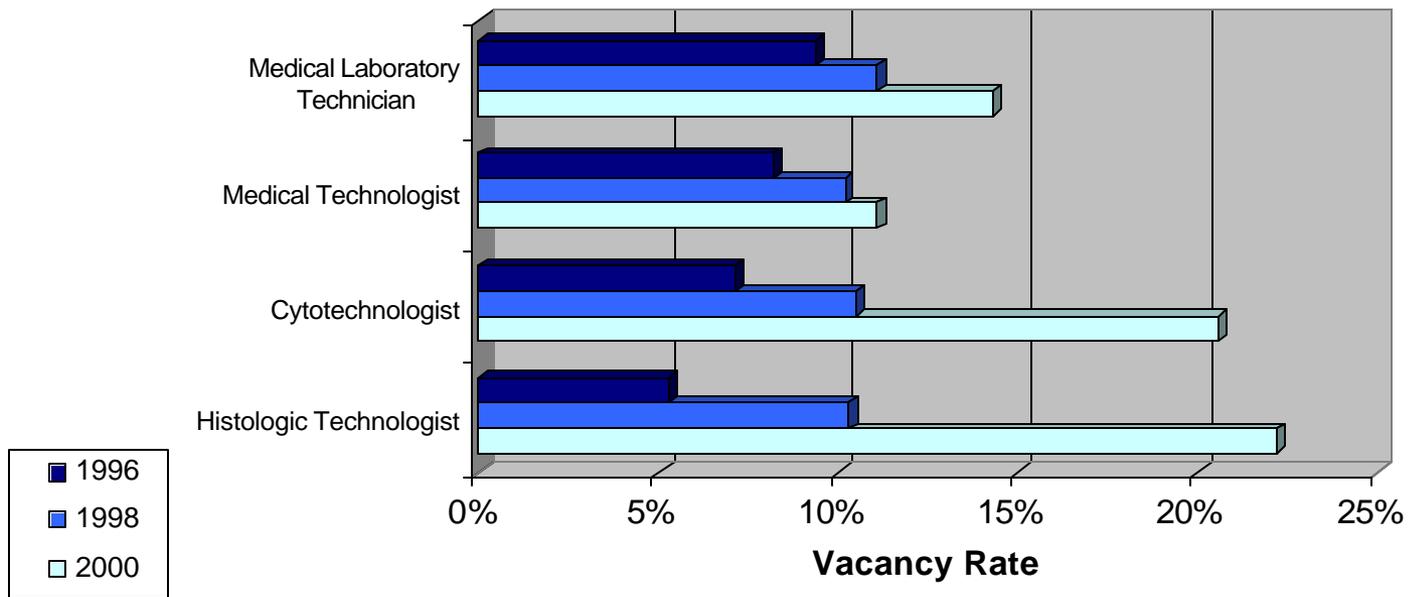


The Shortage

- 
- ASCP Board of Registry & MORPACE
Wage and Vacancy Survey March 2001
 - General Accounting Office Nov 2001
- 

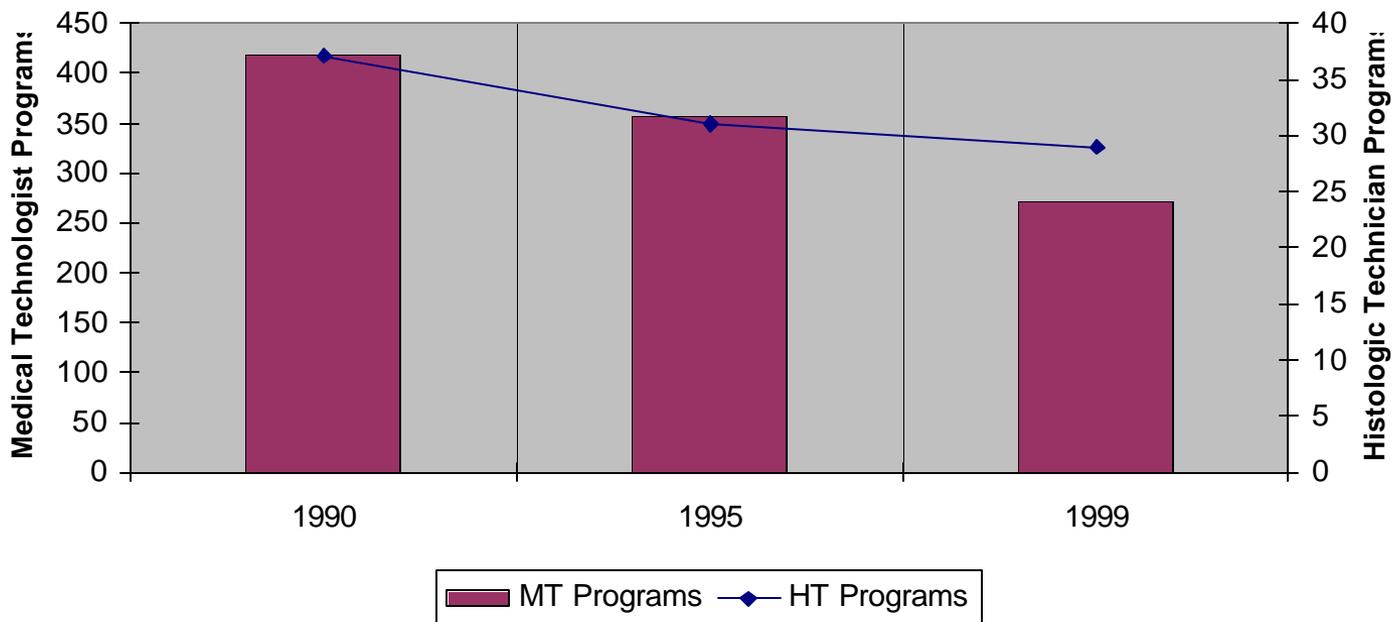
In wake of the decline of medical technology education program enrollees, GAO noted that the overall supply of workers may be affected in coming years. "While little is known about recent trends in the utilization of laboratory services, demand is expected to rise as the U.S. population ages," the agency contended.

Vacancy Rate Percentages For Medical Laboratory Professions

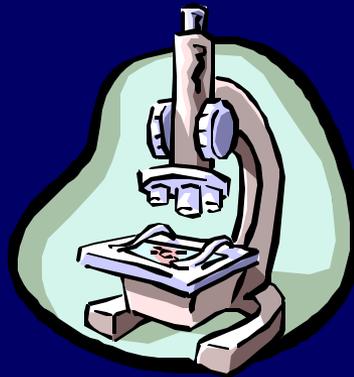


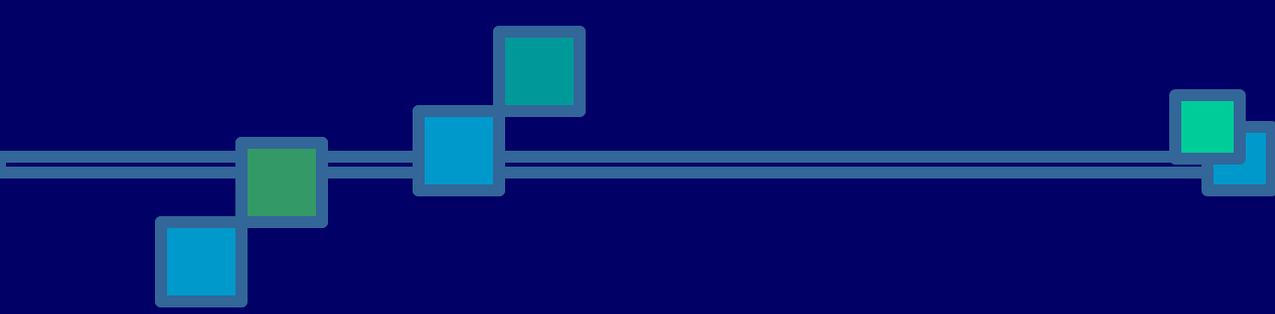
Source: 1996, 1998, 2000 Wage and Vacancy Survey. From ASCP Board of Registry, Chicago, IL, and Morpace International, Detroit, MI.

Accredited Medical Laboratory Technology Programs

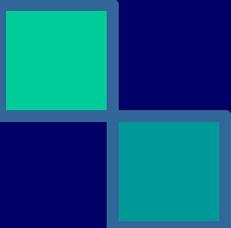


Additional Concerns

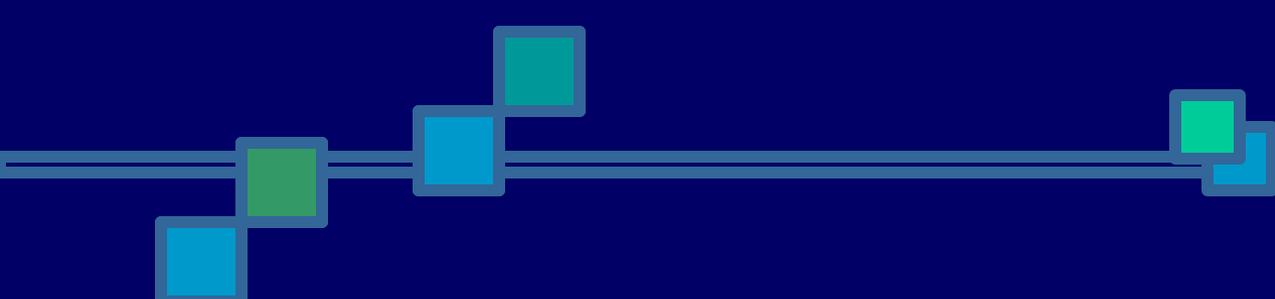




Seeking Solutions

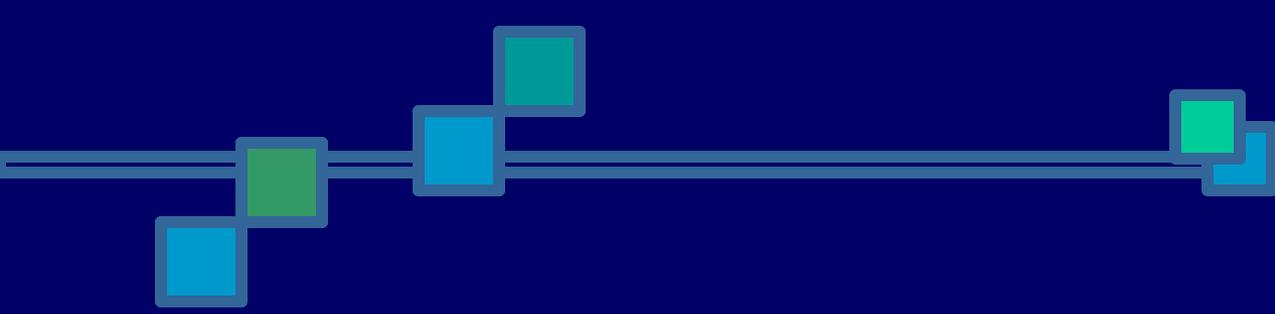
- 
- Fall 2000 – ASCP Proposal
 - Focus on Laboratory Personnel Needs
 - No new programs
 - Education
- 



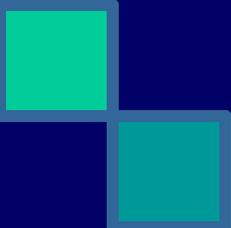


Medical Laboratory Personnel Shortage Act of 2001

- Reps. John Shimkus, Jesse Jackson, Jr., Michael Bilirakis, Sherrod Brown
 - HR 1948
 - Over 40 bipartisan cosponsors
 - Focus on laboratory personnel
- 



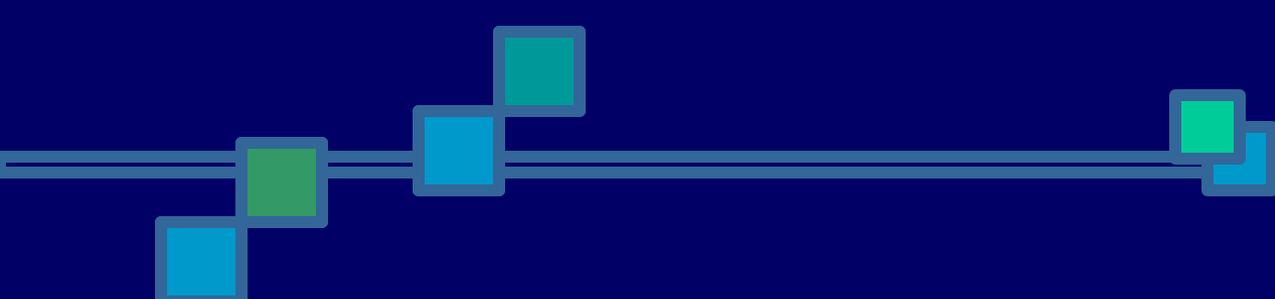
HR 1948

- 
- National Health Service Corps
 - Allied Health Project Grants
 - Breast and Cervical Cancer
 - Public Health Improvement Act
 - NHLBI
- 

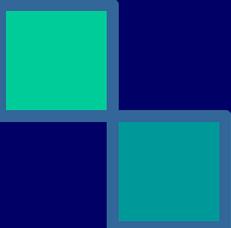
HR 1948 - Action

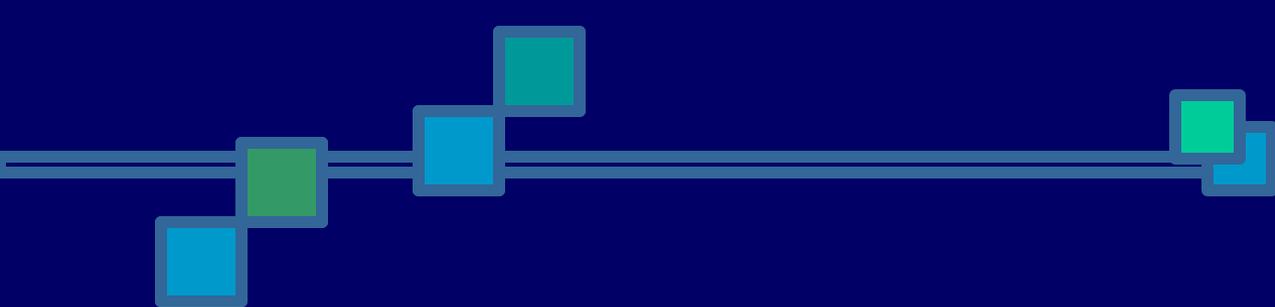
- Thousands of letters, phone calls, emails
- Joint letters to Congress
- Testimonies & statements
- Hundreds of visits



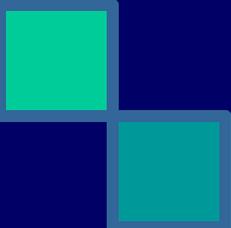


HR 1948 - Accomplishments

- 
- “Laboratory techs are on par with nurses”
 - Congressional recognition
 - Appropriations increase/recognition
 - Public Health Security and Bioterrorism Preparedness and Response Act
- 

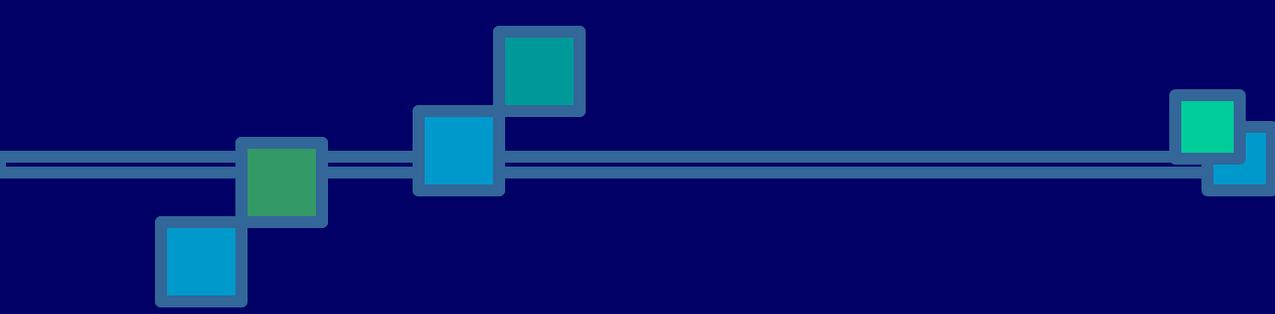


Bioterrorism Law

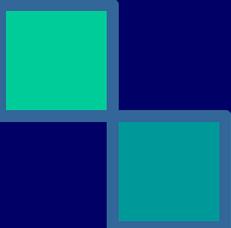


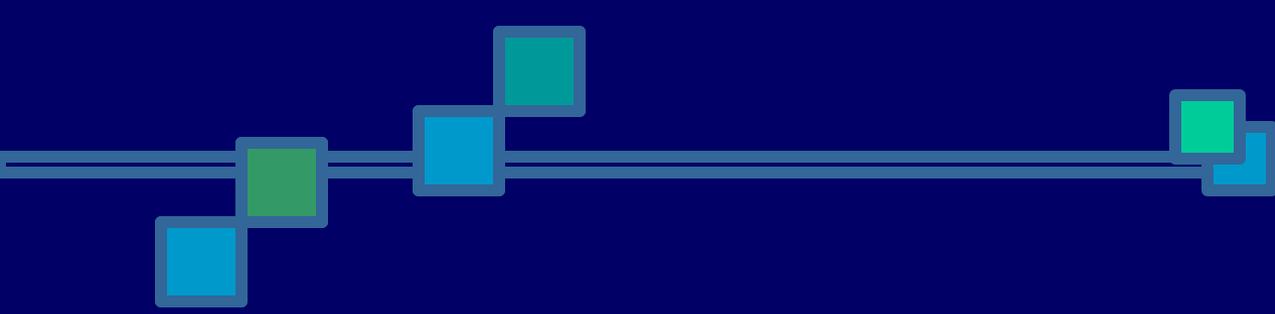
The Secretary may make awards of grants and cooperative agreements to appropriate public and nonprofit private health or educational entities, including health professions schools and programs as defined in section 799B, for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies.



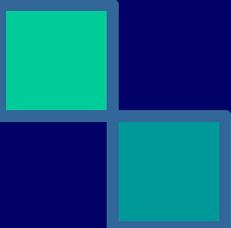


A State Approach

- 
- California SB 1809
 - MLTs able to practice
 - Governor signed!
- 



For CLIAC Consideration

- 
- HHS Strategic Plan
 - Importance of Education Funding
 - Patient Safety
- 



American Society for Clinical Pathology
1225 New York Avenue, NW
Suite 250
Washington, DC 20005

(202) 347-4450
www.ascp.org

Clinical Laboratory Workers CLIAC Meeting, September 12, 2002

Atul Grover

Chief Medical Officer

Agrover@hrsa.gov

National Center for Health Workforce Information and Analysis

Bureau of Health Professions

Health Resources and Services Administration

Bureau of Health Professions

Mission and Functions

Mission: To increase health care access by assuring a health professions workforce that meets the needs of the public.

Functions

- Develop the health professions workforce through research, analysis, and planning
- Improve distribution and diversity of health professionals to rural/urban underserved areas
- Improve the quality of health professions practice and education
- Focus on key 21st century health professions issues (geriatrics, genetics, diversity/distribution)

Assuring an Adequate Health Care Workforce Requires:

Workforce Planning and Analyses-----→ **To Train the Right People**

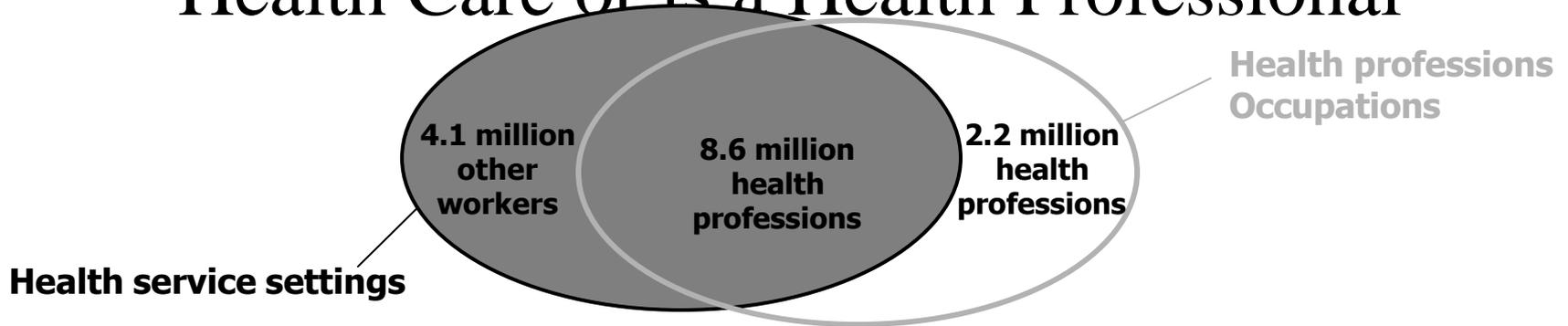
High Quality Education----→ **The Right Skills**

Equitable Distribution----→ **The Right places**

National Center for Health Workforce Information and Analysis

- **Mission: Collect, analyze, and disseminate health workforce information and facilitate national, State, and local workforce planning efforts.**
 - Collect health professions-related data
 - Assist State and local workforce planning efforts
 - Conduct issues-related analyses
 - Conduct evaluations of health professions training programs
 - Develop tools and conduct research on the health workforce

More Than 1 in 10 Americans Works in Health Care or is a Health Professional



	Health Professionals	Other Workers	Total
Health service setting	8,642,749	4,098,331	12,741,080
Other work settings	2,167,418	126,649,685	128,817,103
Total	10,810,167	130,748,016	141,558,183

Health professionals working in health service settings	8,642,749	6.1%
Health professionals working in other settings	2,167,418	1.5%
Other workers in health service settings	4,098,498	2.9%
US health workforce	14,908,498	10.5%
US civilian labor force	141,558,183	100.0%

National Center for Health Workforce Analysis

Recent Products

- ▶ *State Health Workforce Profiles*
- ▶ *Pharmacist Shortage Study*
- ▶ *GME Primer*
- ▶ *Comprehensive Health Workforce Profiles Pilot Project: 10 States*

National Center for Health Workforce Analysis

▶ Activities

- ▶ *State Health Workforce Profiles* 2nd Edition
- ▶ Health Workforce: Trends, Issues, and Supply and Demand Projections
- ▶ Supply, Demand, and Shortages of RNs
- ▶ Comprehensive Health Workforce Profiles
Pilot Project: 8 Additional States

National Center for Health Workforce Analysis

▶ Activities

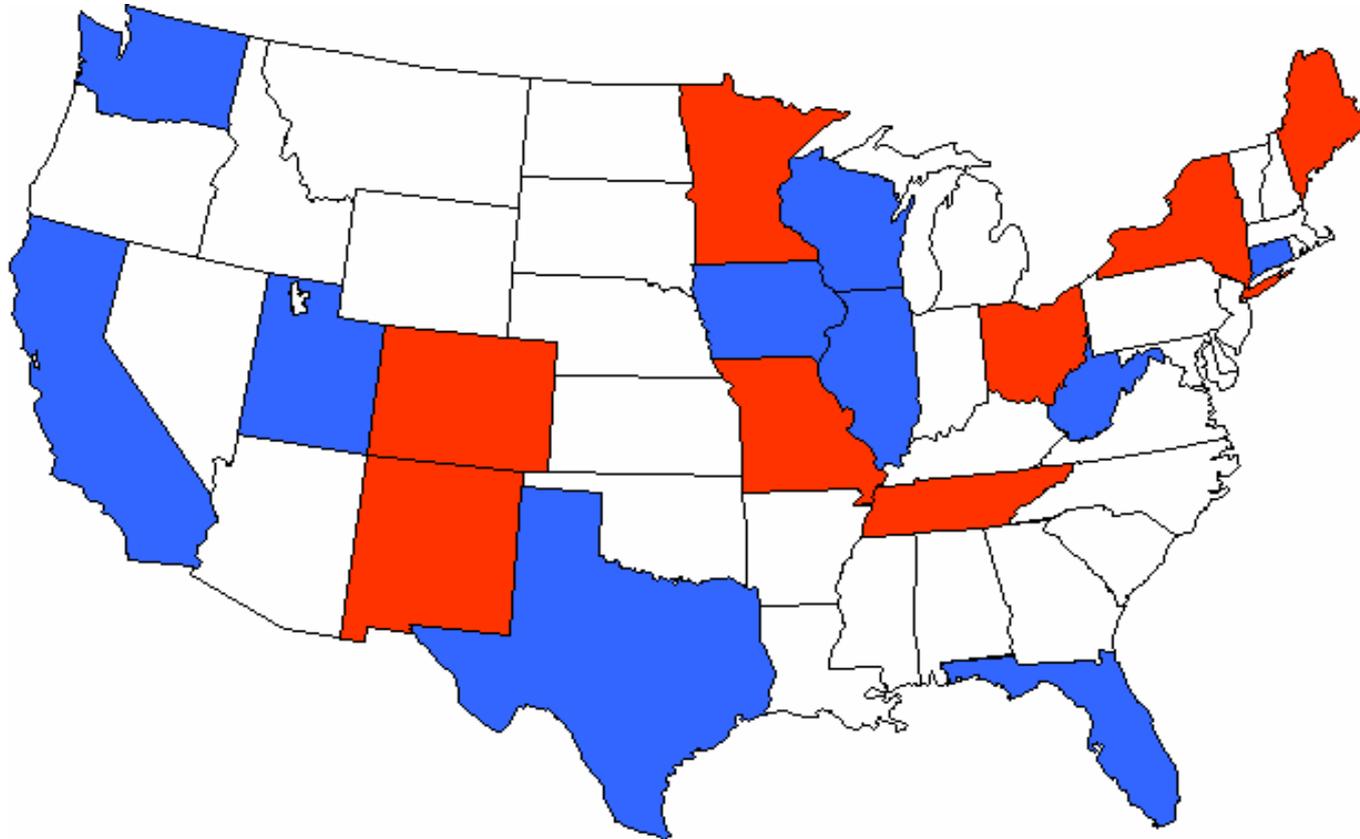
- ▶ Supply and Demand for Nursing Aides and Home Health Care Aides
- ▶ Scope of Practice Laws and Effect on Access
- ▶ State GME Financing and Health Workforce Goals
- ▶ The Impact of Changing Demographics on Requirements for Health Care Providers

National Center for Health Workforce Analysis

Regional Centers for Health Workforce Studies

- **University of California/San Francisco (UCSF)**
(<http://futurehealth.ucsf.edu/cchws.html>)
- **State University of NY Albany (SUNY/Albany)**
(<http://chws.albany.edu>)
- **University of Illinois Chicago (UIC)**
(<http://www.uic.edu/sph/ichws>)
- **University of Washington Seattle (UW)**
(<http://www.fammed.washington.edu/CHWS/index.html>)
- **University of Texas Health Sciences Center at San Antonio** (Coming Soon!)

Comprehensive Health Workforce Profiles Pilot Project: 18 States



In 2001 = CA, CT, FL, IL, IA, TX, UT, WA, WV, WI

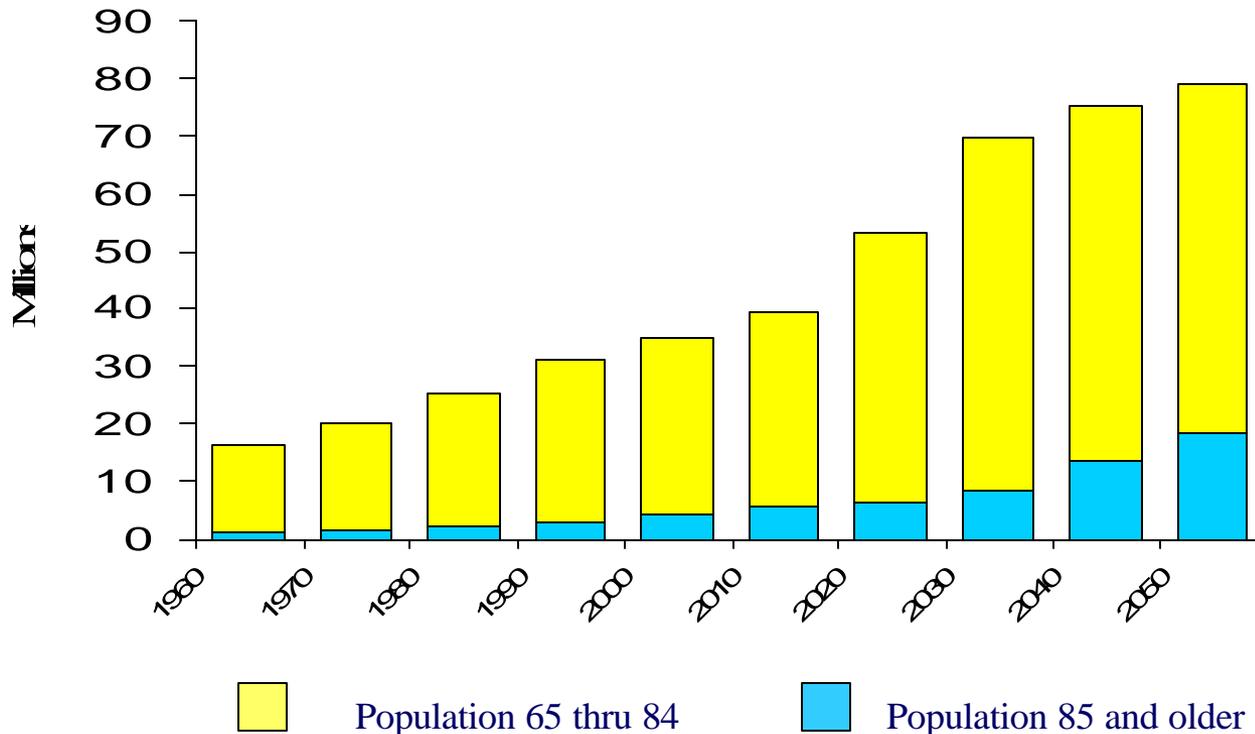
In 2002 = CO, ME, MO, MN, NM, NY, OH, TN

Demand for Health Professionals Will Grow at Twice the Rate of All Occupations Between 2000-2010

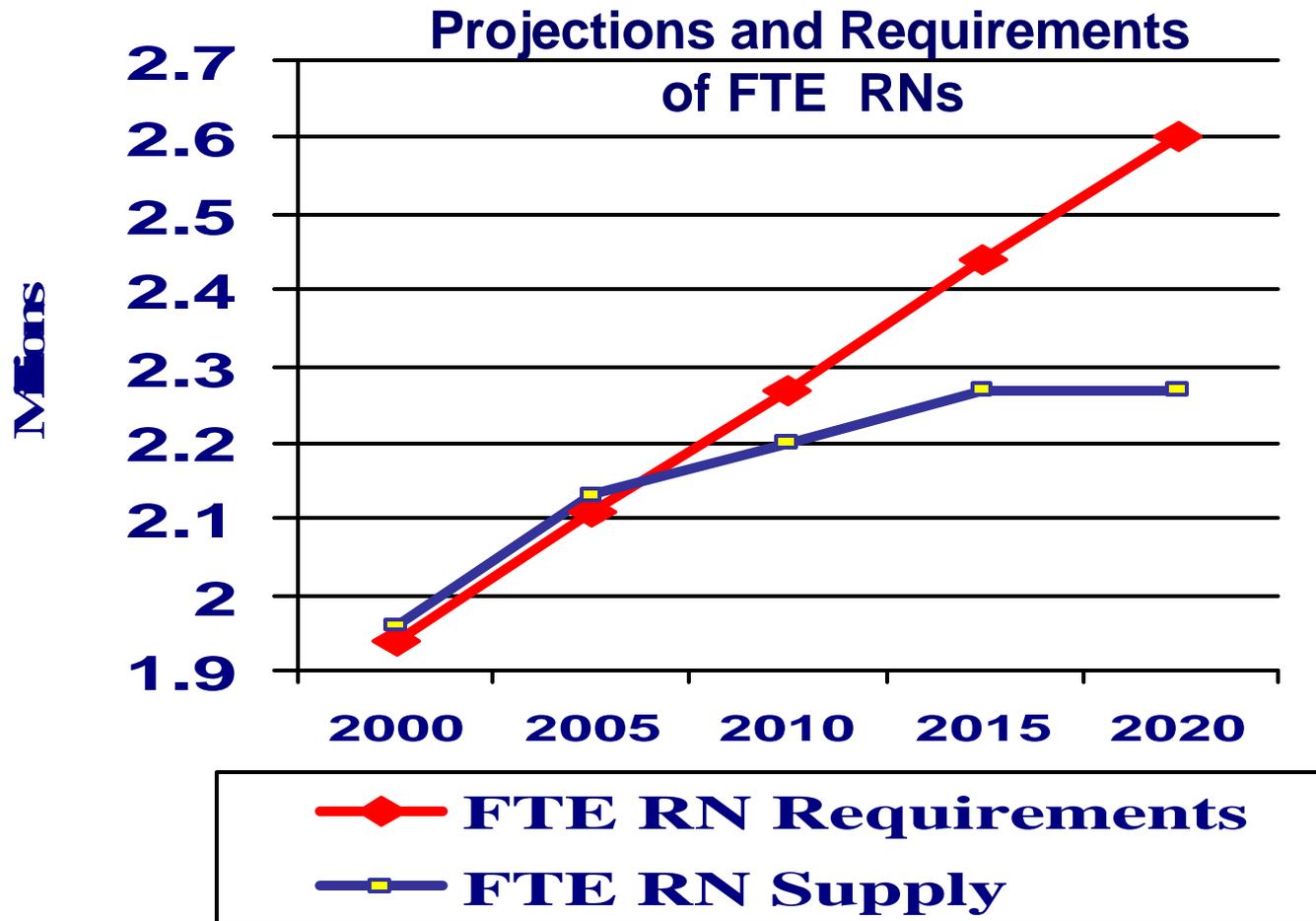
	2000 (000's)	2010 (000's)	Percent Change
Total U.S Employment	145,594	167,754	15%
Total Health Occupations	10,984	14,186	29%
Physicians	598	705	18%
Dentists	152	161	6%
Pharmacists	217	270	24%
Registered Nurses	2,194	2,755	26%
Mental and Behavioral Health Occupations	518	657	27%
Therapists	479	639	33%
Public and Environmental Health	241	302	25%
Health Technicians and Technologists	2,459	3,090	26%
Health Service Occupations	3,197	4,264	33%

The Growth in the Number of Elderly Citizens Will Increase Requirements for Health Care Providers

The Number of Elderly Citizens is Growing Steadily in the United States

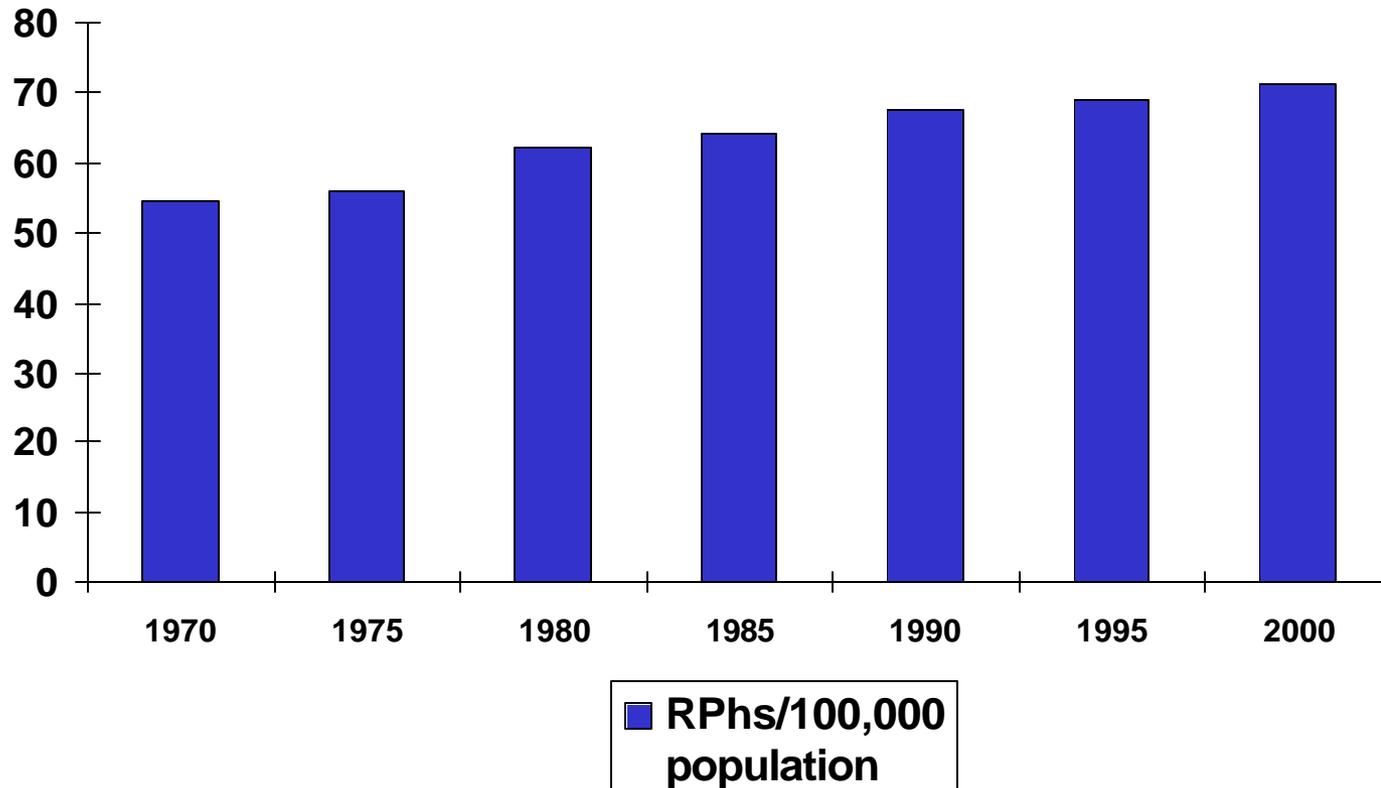


The Health Workforce: Trends, Issues, and Supply and Demand Projections



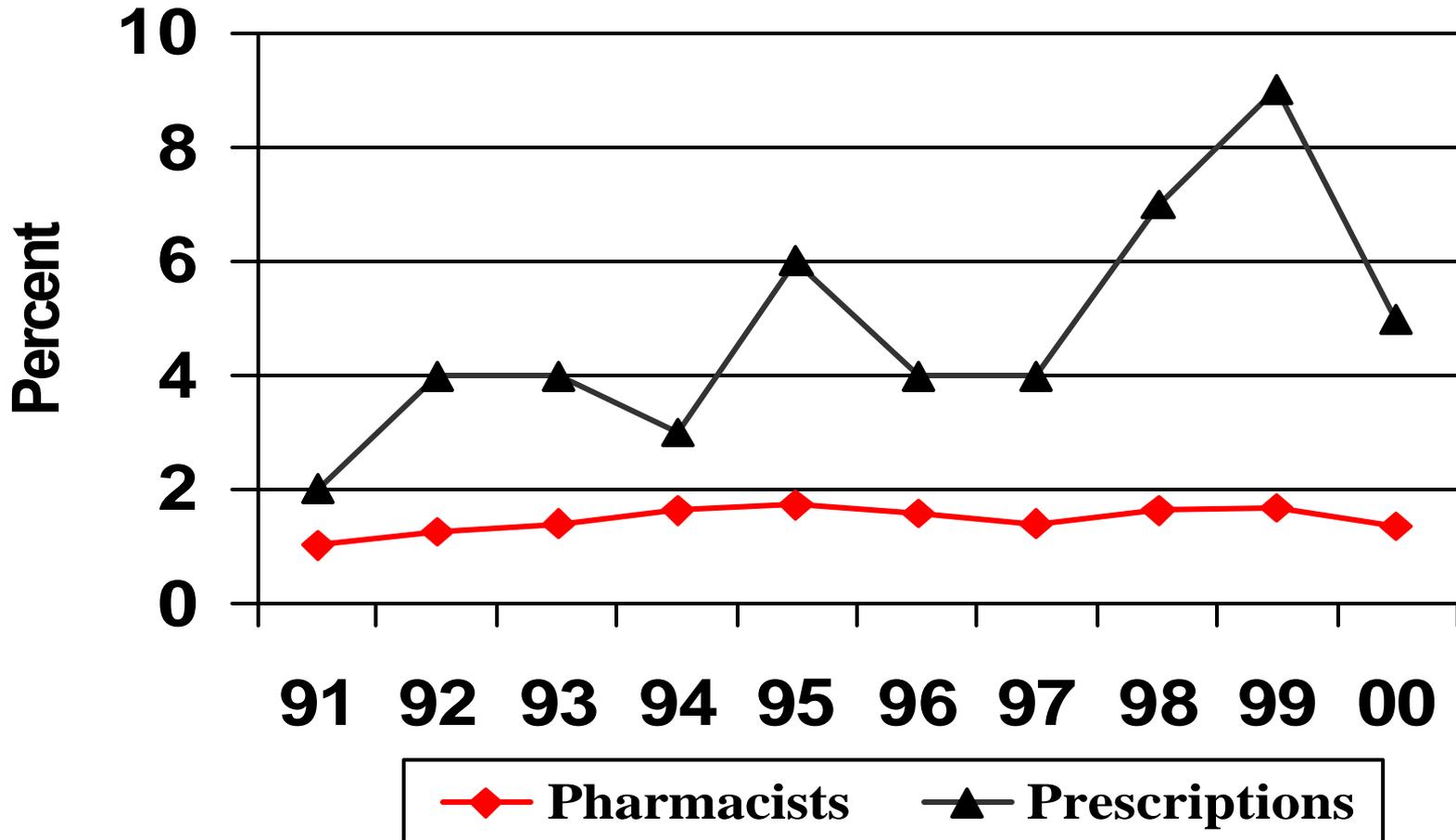
Pharmacists--Shortage?

Pharmacists per 100,000 Population: 1970-2000



Source: Bureau of the Census

Pharmacist Shortage—Rx Growth Rate



Health Care Worker Shortages

- Registered nurses
- Direct care workers
- Clinical lab technologists and technicians
- Radiology techs
- Pharmacists
- Dentists
- Information system specialists
- Medical coders

Clinical Laboratory Workers

- Generally, clinical laboratory *technologists* hold a bachelor's degree with a major in medical technology or in a life science
- Clinical laboratory *technicians* generally hold an associate's degree or certificate
- Employment for both categories expected to grow

Clinical Lab Worker Job Growth

- Lab technologists and technicians held 295,000 jobs in 2000
- Half working in hospitals, remainder in labs, offices, physician clinics (some in blood banks, research and testing)
- Employment expected to grow 15% through 2010 (equal to other occupations)

Job Growth Factors

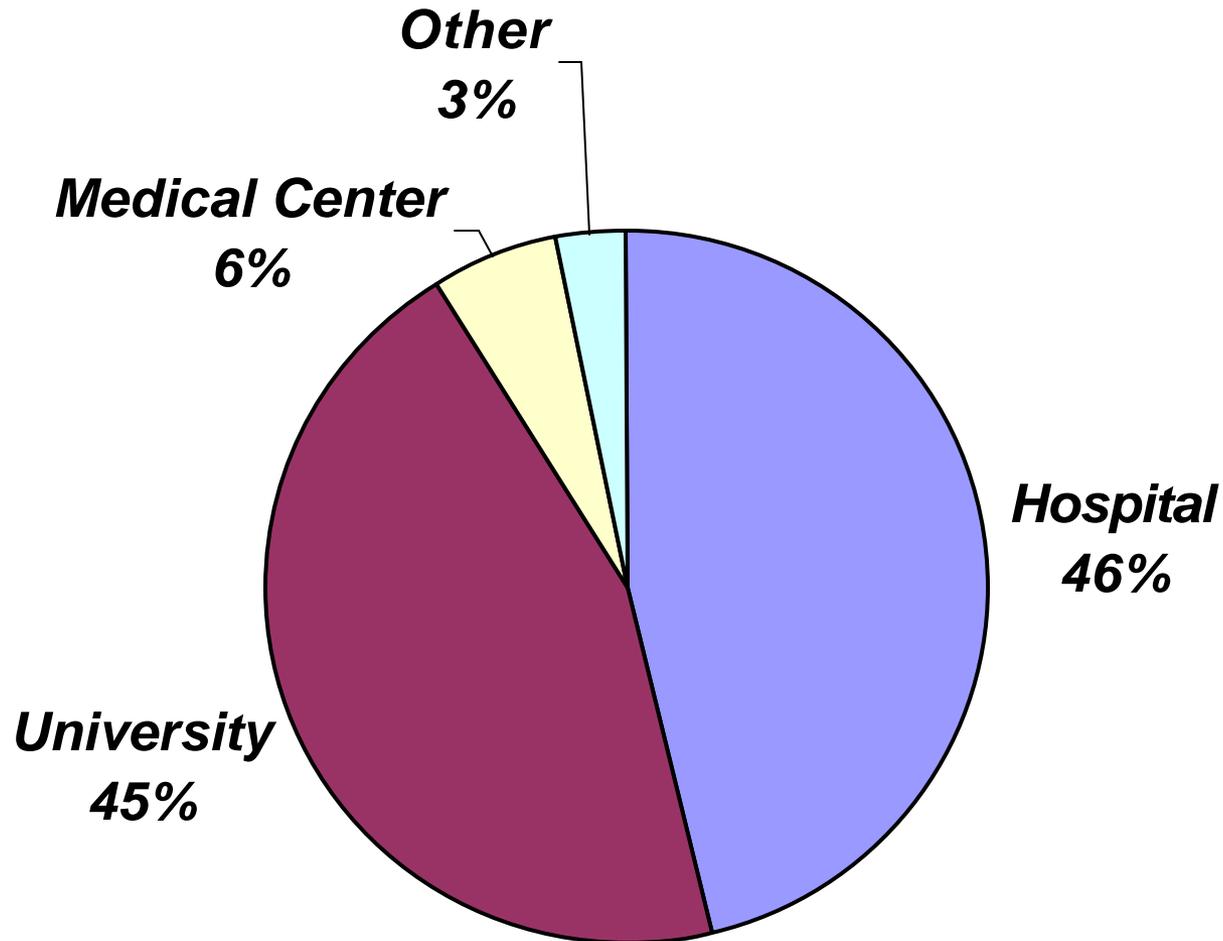
- Technological advances: Dual effects
 - Additional diagnostic tests developed to increase demand
 - R&D simplifying routine testing, allowing for movement out of the laboratory setting
- Aging population with increased needs
- Need to replace workers who retire, transition to other fields

Tasks of Medical Technologists

- Collect and prepare specimens
- Perform routine & specialized lab tests
- Recognize QC, instrument, data problems
- Train other lab personnel
- Communicate results to technical/lay people
- Participate in continuing education
- Recognize normal and abnormal values
- Correlate abnormal values with disease status

Training: Medical Technologists (MT)

Baccalaureate Degree in MT or Biological Sciences with Training

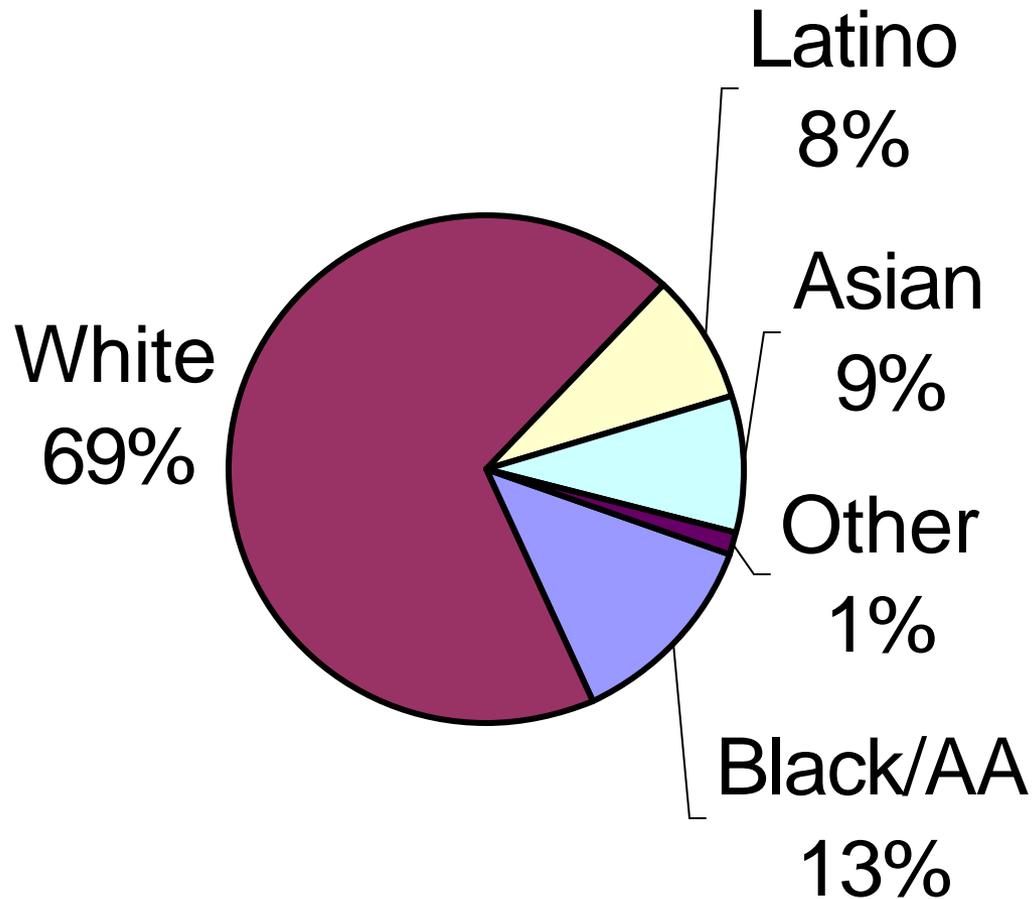


Demographics: Medical Technologists

- 76% Female
- 97% Baccalaureate degrees (3% Grad/other)
- 58% Urban, 24% Suburban, 18% Rural
- 46% Married

Survey data from certified MT (ASCP) Lab Medicine, 31(7), July 2000

Demographics: Medical Technologists



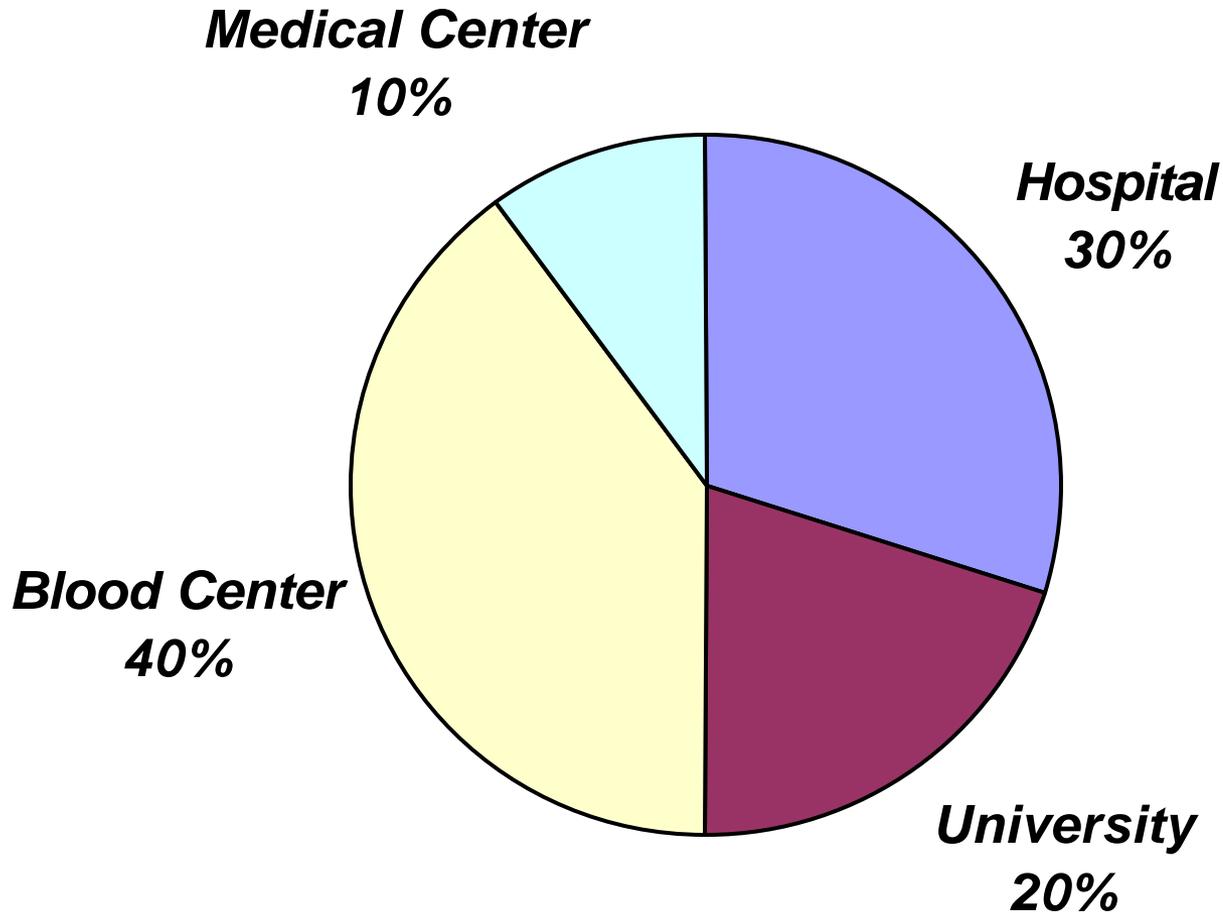
Survey data from certified MT (ASCP) Lab Medicine, 31(7), July 2000

Medical Technologists: Specialization

- Clinical chemistry technologists
- Microbiology technologists
- Blood bank (immunohematology) technologists
- Immunology technologists
- Cytotechnologists
- Molecular biology technologists

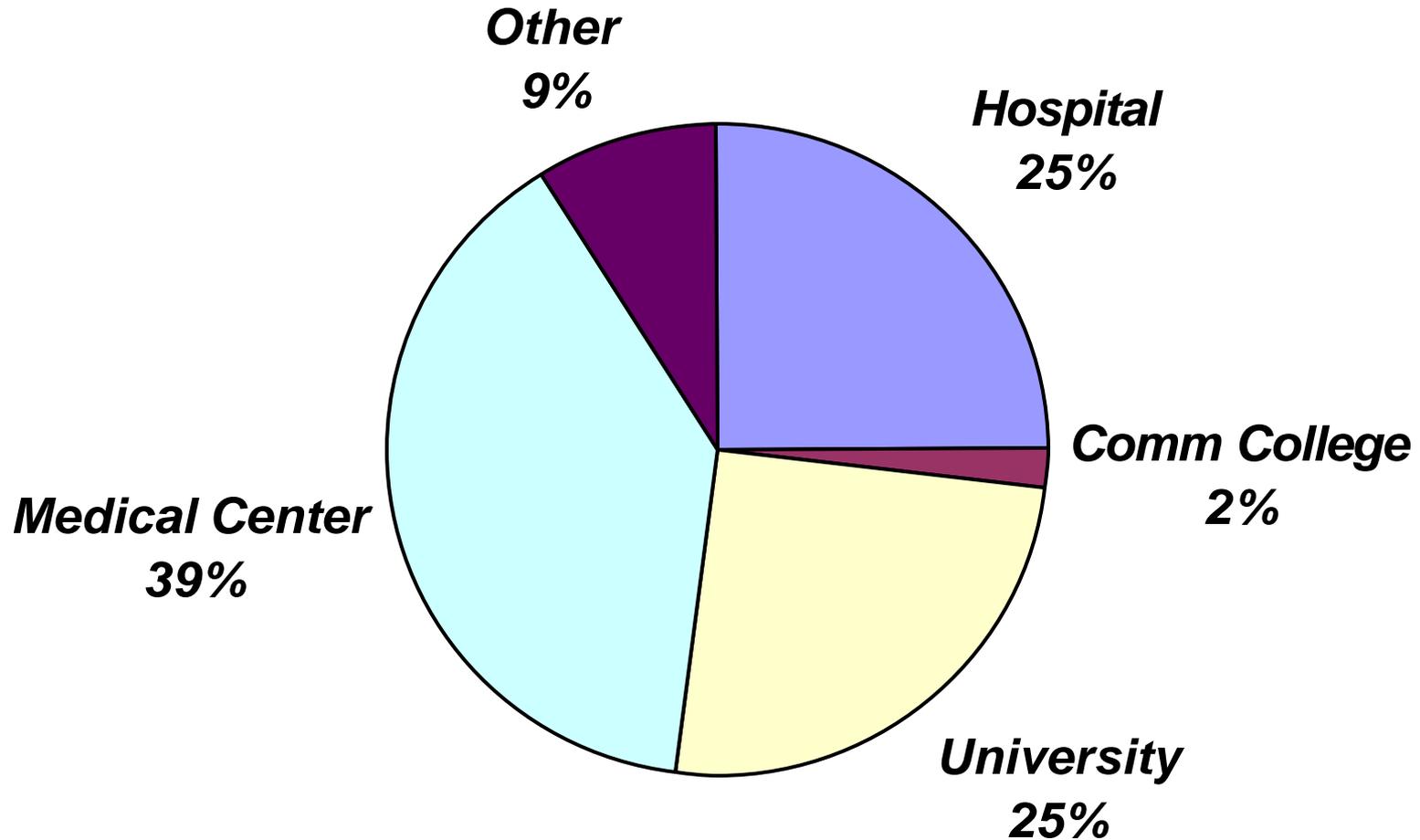
Training: Specialists in Blood Banking (SBB)

Baccalaureate Degree in Health Sciences, One Year Training Program



Training: Cytotechnologists (CT)

Baccalaureate Degree and Completion of Accredited CT Program

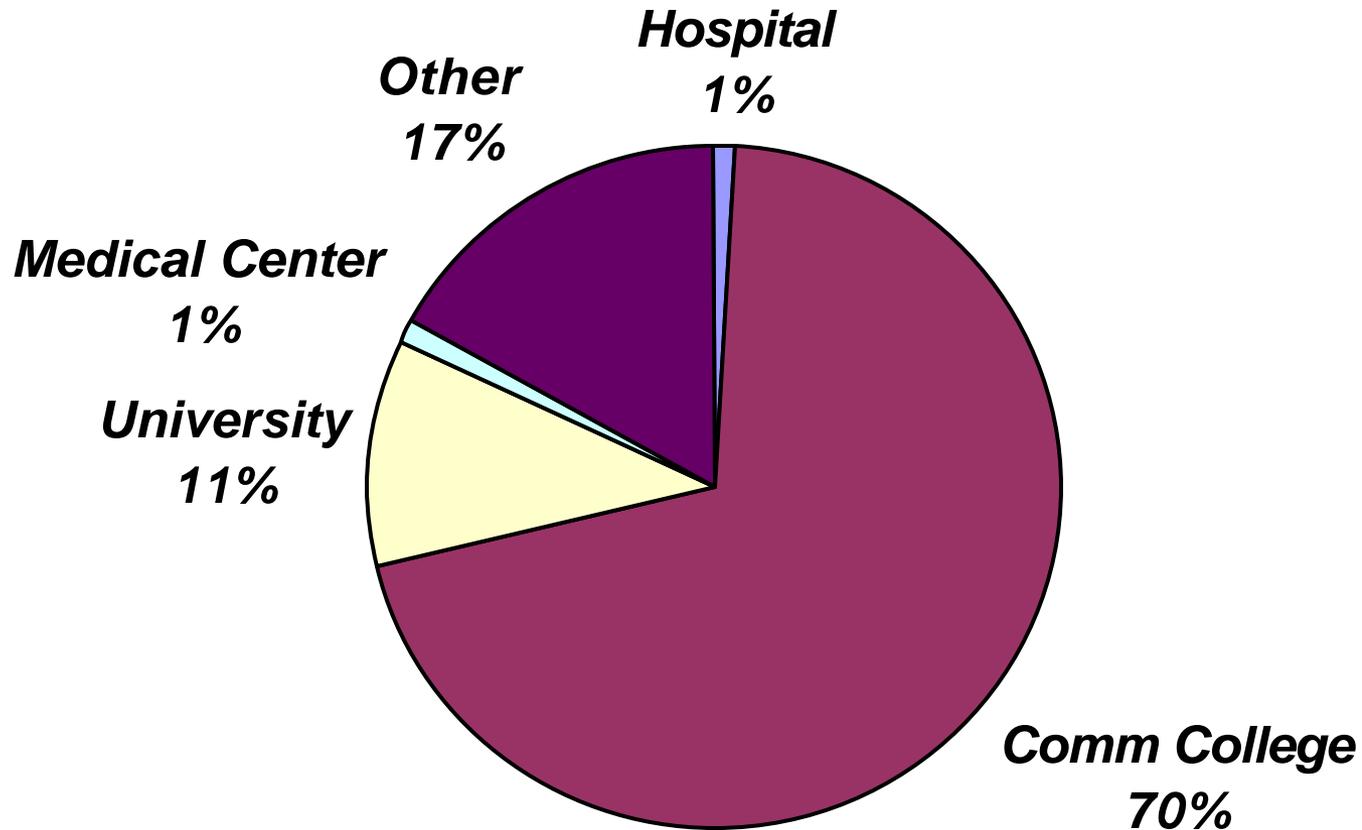


Medical and Clinical Laboratory Technicians

- Perform less complex tests than technologists
- May prepare specimens and operate automated analyzers
- May also specialize
 - Histology technicians
 - Phlebotomists

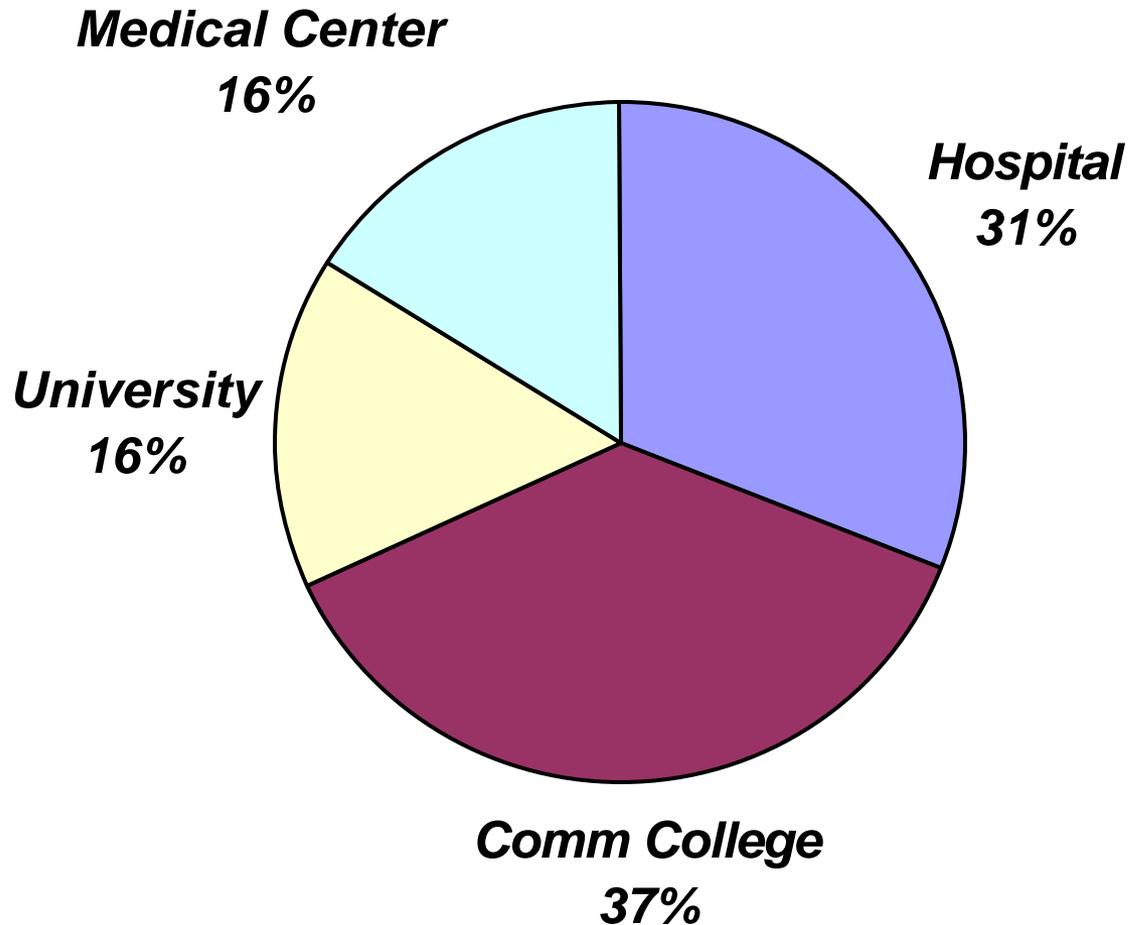
Training: Medical Laboratory Technicians (MLT)

Associate Degree, Completion of Accredited CLT/MLT or Certificate Program

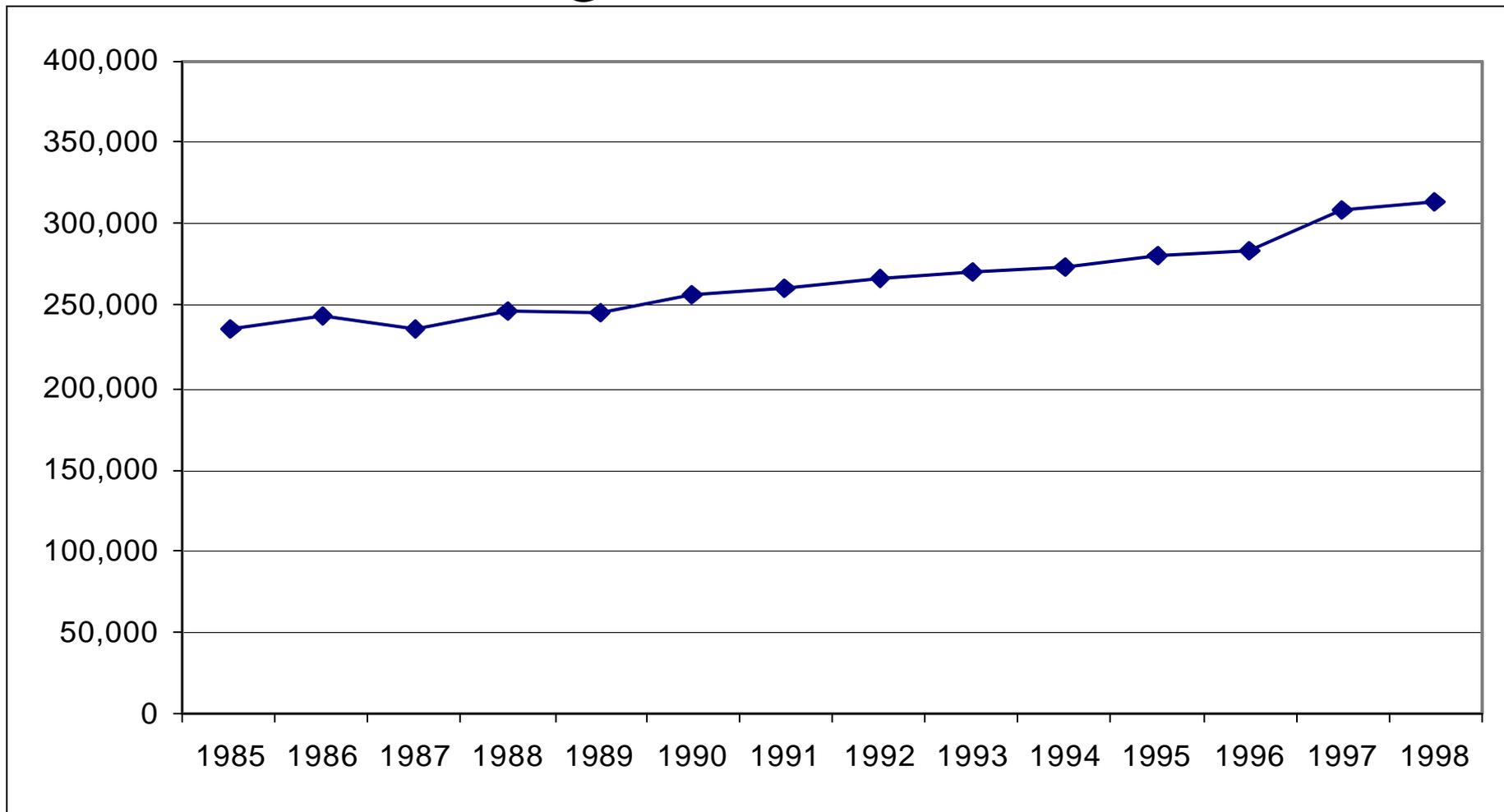


Training: Histologic Technician (HT)

Baccalaureate Degree, Completion of Accredited HLT Program



Total Number of US Medical Laboratory Technologists and Technicians



Source: BLS

Accreditation

- National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)
 - Medical/clinical technologists, technicians, histologic technologists/technicians, pathologists assistants
 - Programs in phlebotomy, cytogenetic technology, molecular biology, clinical assisting
- Commission on Accreditation of Allied Health Education Programs (CAAHEP)
- Accrediting Bureau of Health Education Schools (ABHES)

Licensure

- Licensure requirements vary by state
- Certification is voluntary, though required by many employers
 - American Society of Clinical Pathologists Board of Registry
 - American Medical Technologists
 - National Credentialing Agency for Laboratory Personnel
 - Board of Registry of the American Association of Bioanalysts

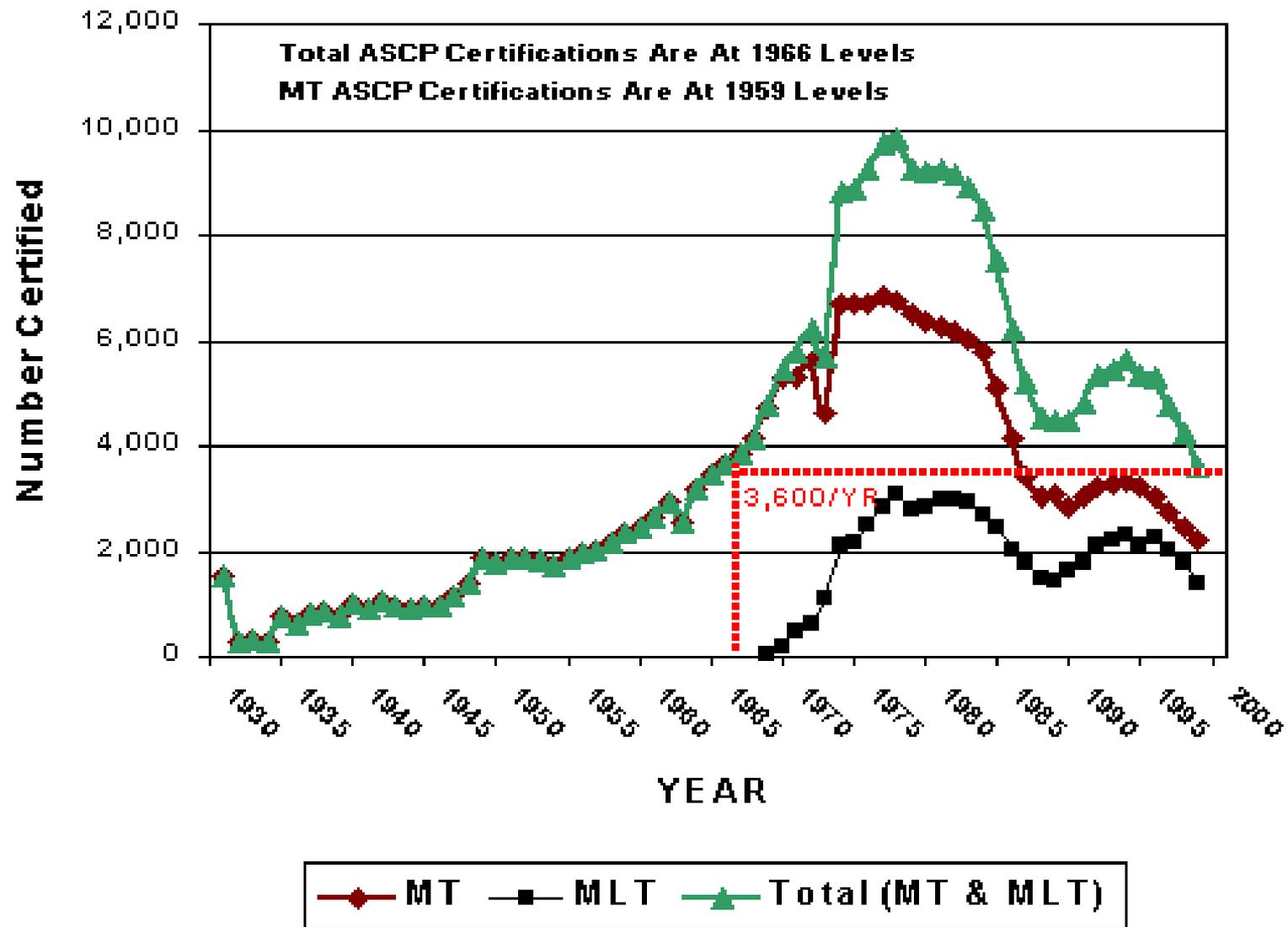
ASCP Certification--- Technicians and Technologists

	Medical Technologists	Medical Laboratory Technicians
1980	6,340	2,865
1985	5,085	2,447
1990	2,849	1,647
1995	3,217	2,120
1996	3,051	2,263
1997	2,760	2,001
1998	2,476	1,766
1999	2,216	1,395

What Has Happened to All the Techs ? *Pennell C. Painter, Ph.D .*

<http://www.ivdtrials.com/TechStaff.htm>

ASCP MT & MLT Certifications Per Year



What Has Happened to All the Techs ? *Pennell C. Painter, Ph.D.*

34

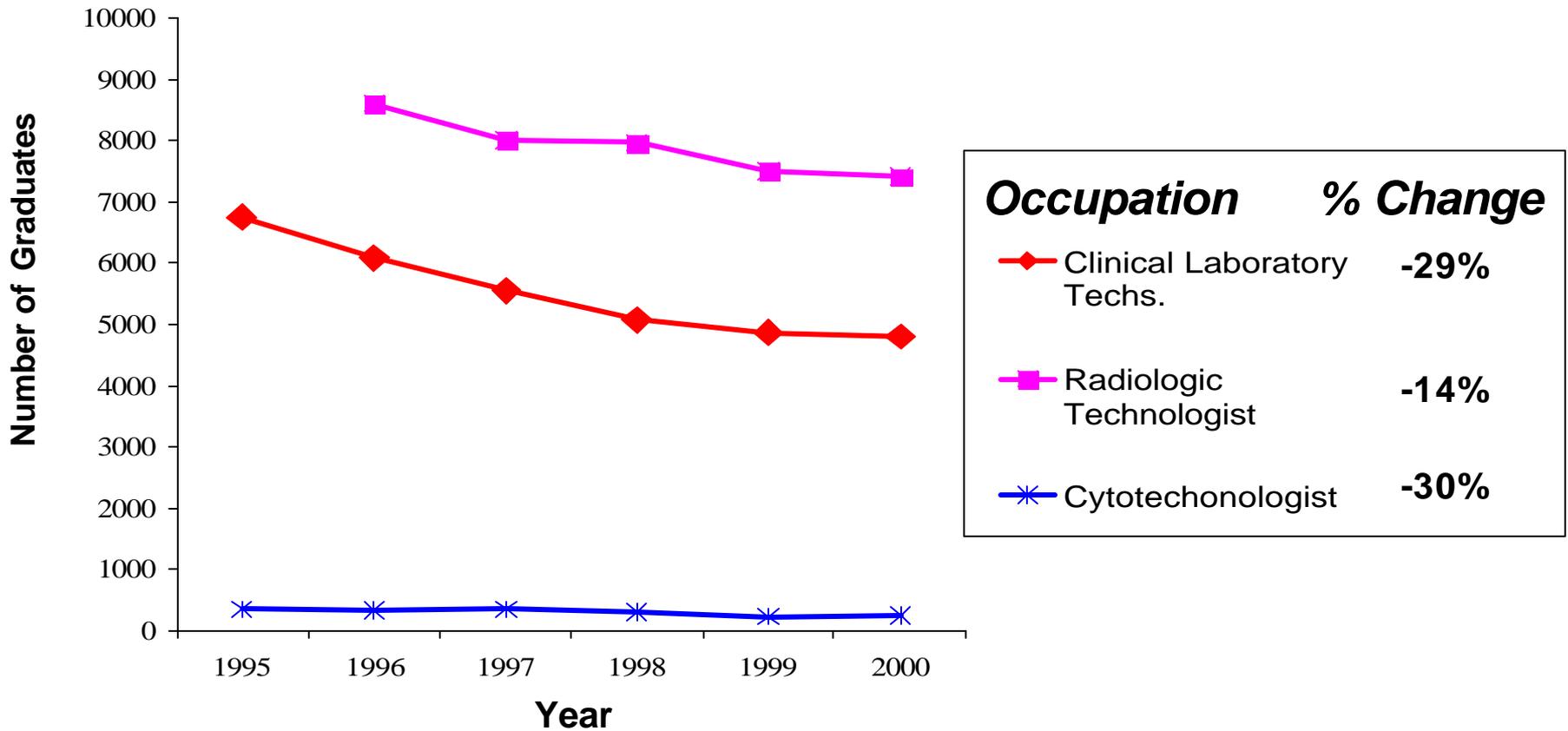
<http://www.ivdtrials.com/TechStaff.htm>

Medical Laboratory Technician and Techologist Training Program Declines.

Health Professions Education Programs: 1985-2000

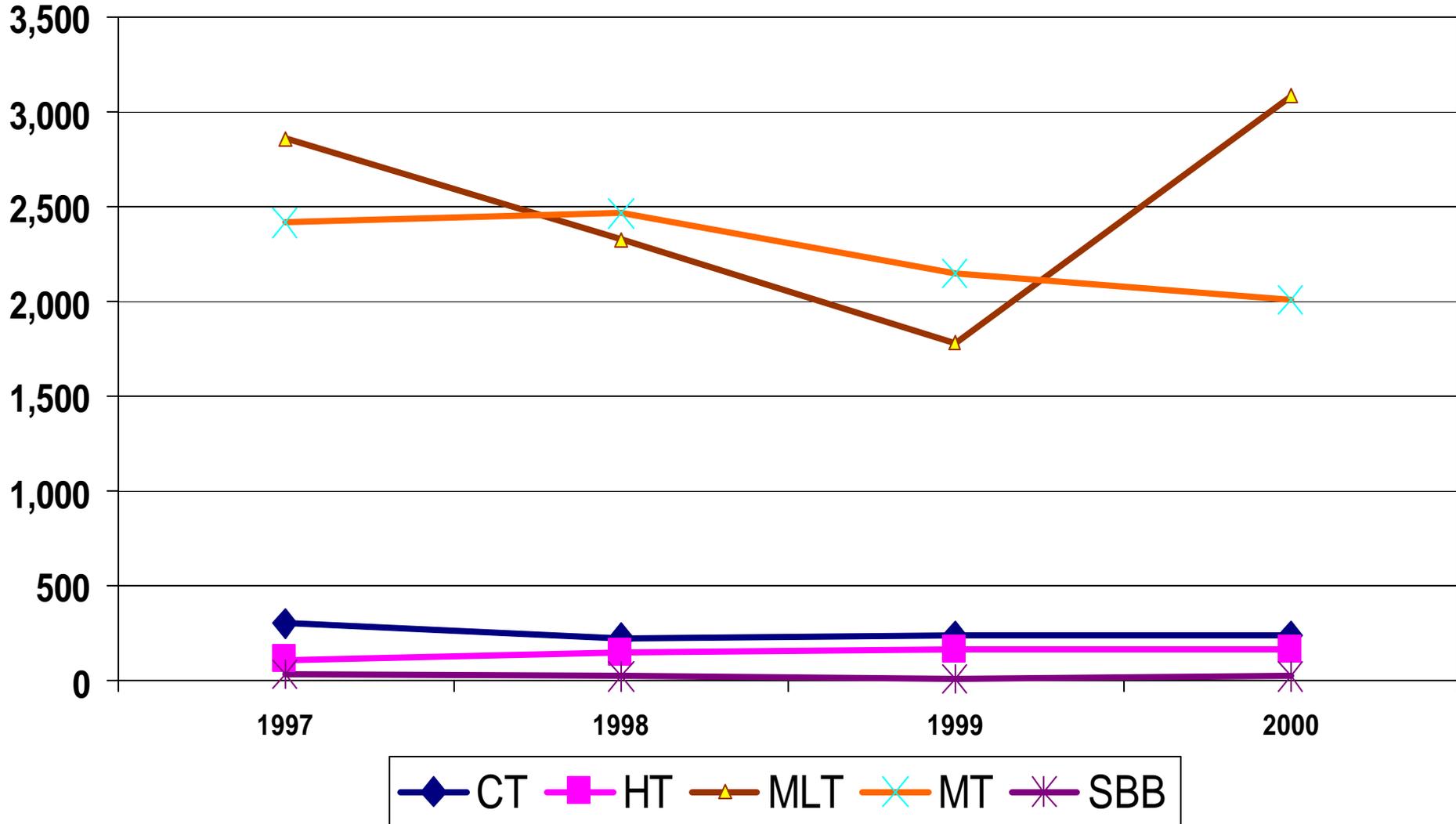
	1985	1990	1995	2000	Change 1985-2000
Medical Laboratory Technologists	584	420	357	255	-56.3%
Medical Laboratory Technicians	281	256	260	242	-13.9%
Total	865	676	617	497	-42.5%

Number of Graduates Declining



Source: AMA, *Health Professions Career and Education Directory* (various eds.)

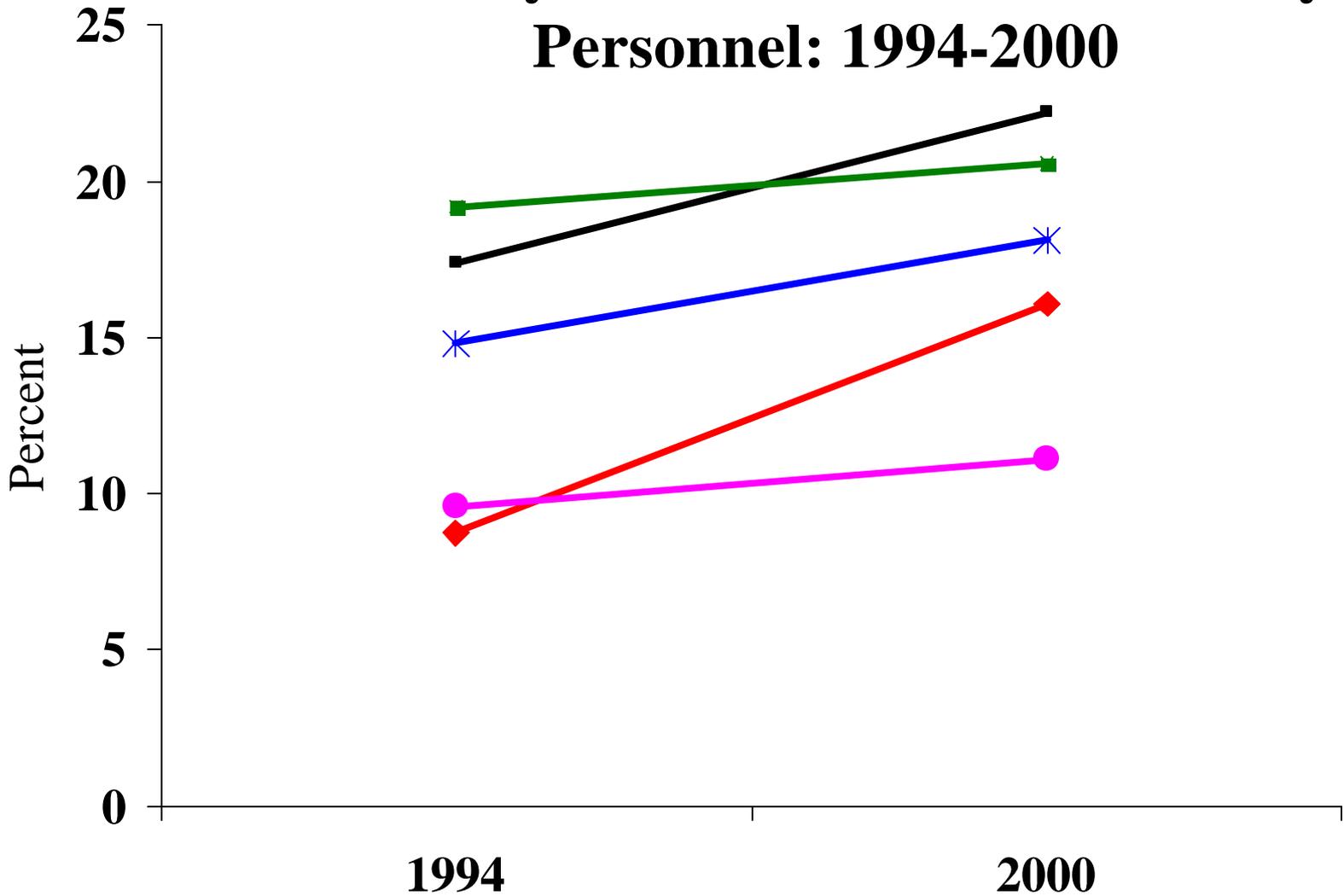
Total Enrollment in NAACLS and CAAHEP Accredited Programs



Vacancy rates—a good measure of shortages

- In 2000, the vacancy rates for these disciplines exceed the average unemployment rate—typically about 5% -- by two- to four-fold.
- Conversely, very high employment for new grads
 - **Cytotechnologists 98%**
 - **Histologic Technicians 96%**
 - **Medical Laboratory Technicians 96%**
 - **Medical Technologists 96%**
 - **Specialists in Blood Banking 100%**

Vacancy Rates for Select Laboratory Personnel: 1994-2000

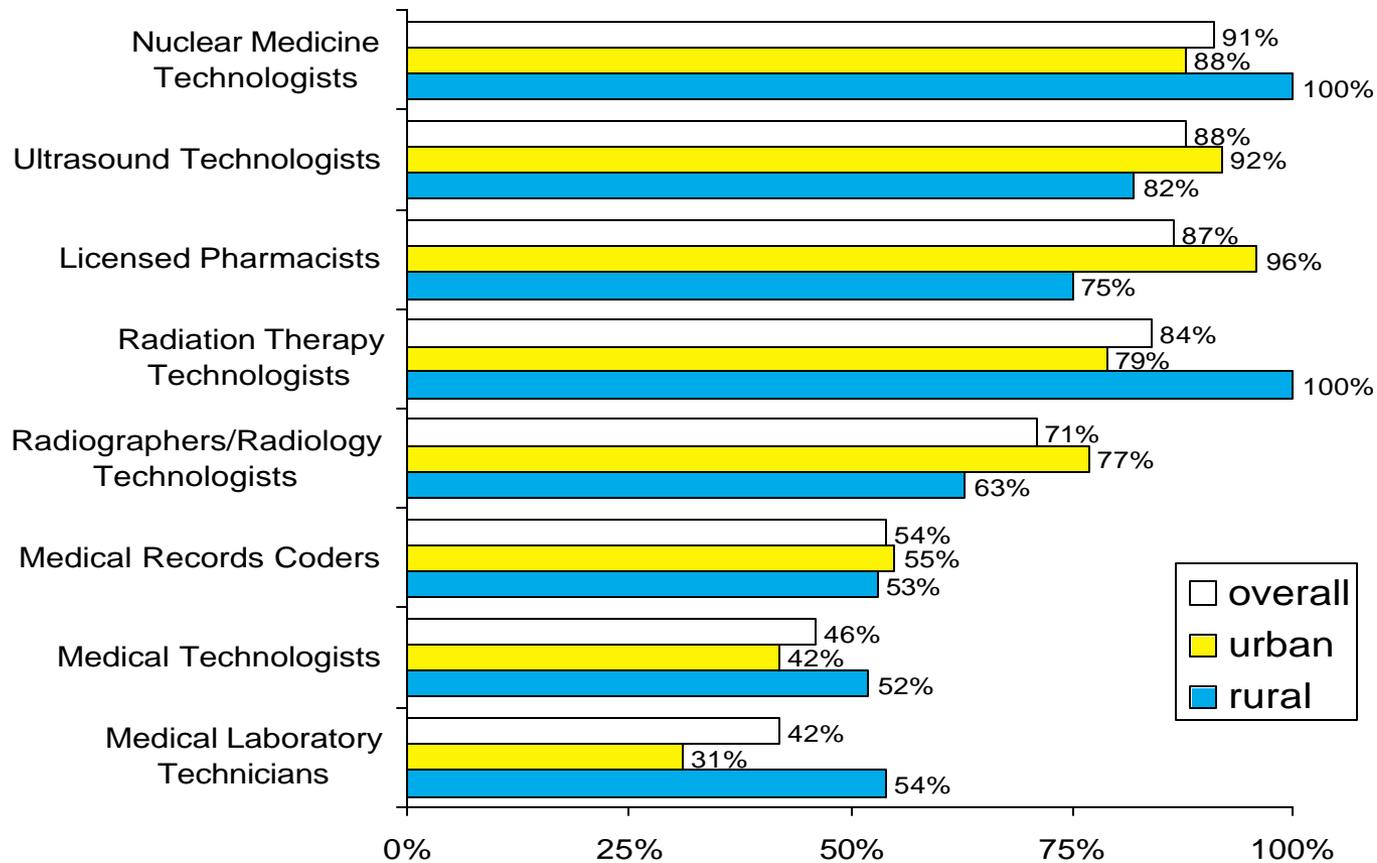


- ◆ Histo. Technicians
- Cytotechnologist
- Medical Technologists

- Histotechnologist
- * Phlebotomizes

Washington State—Example of Shortages

Percent of Hospitals Reporting Difficulty Recruiting Personnel for Select Occupations



* Of hospitals employing the position

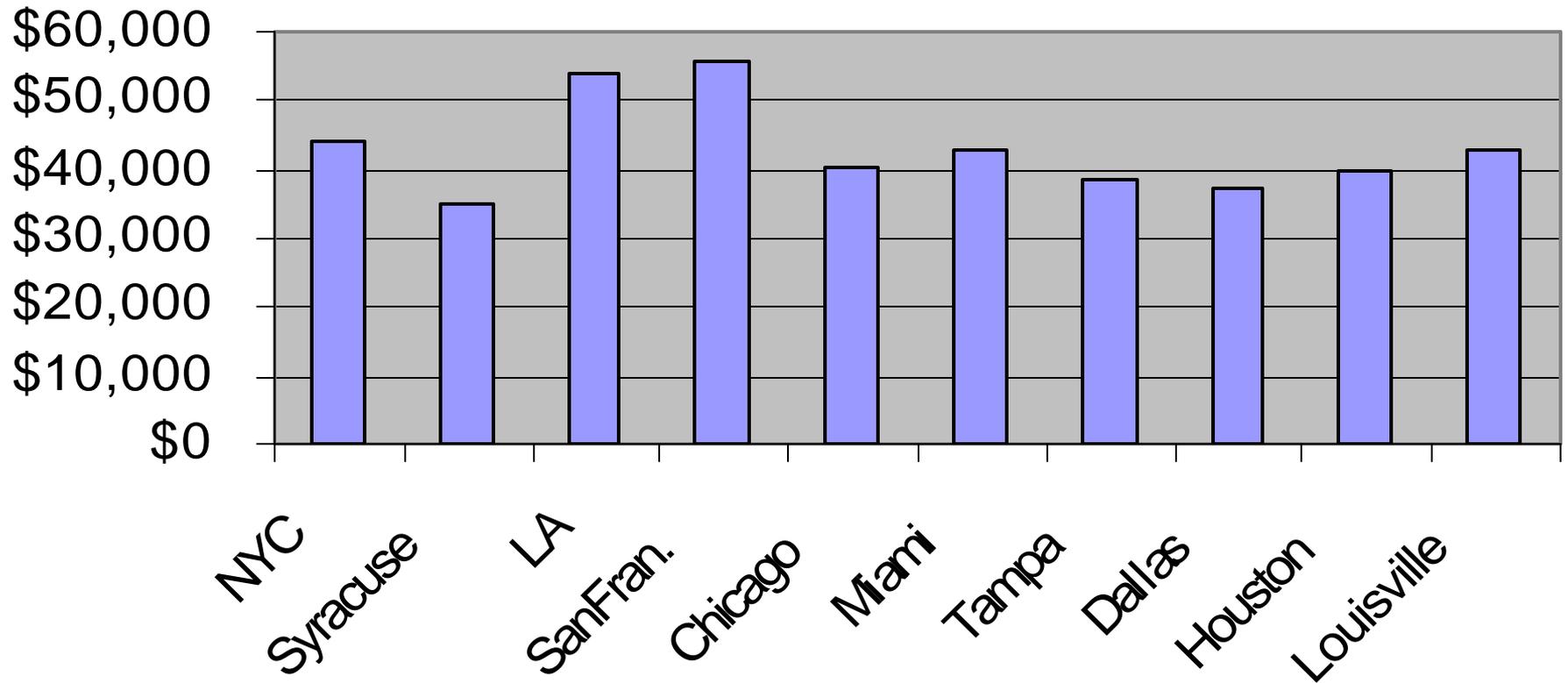
Medical Technologists and Medical Laboratory Technicians

Median Annual Salaries, 2000^[1]

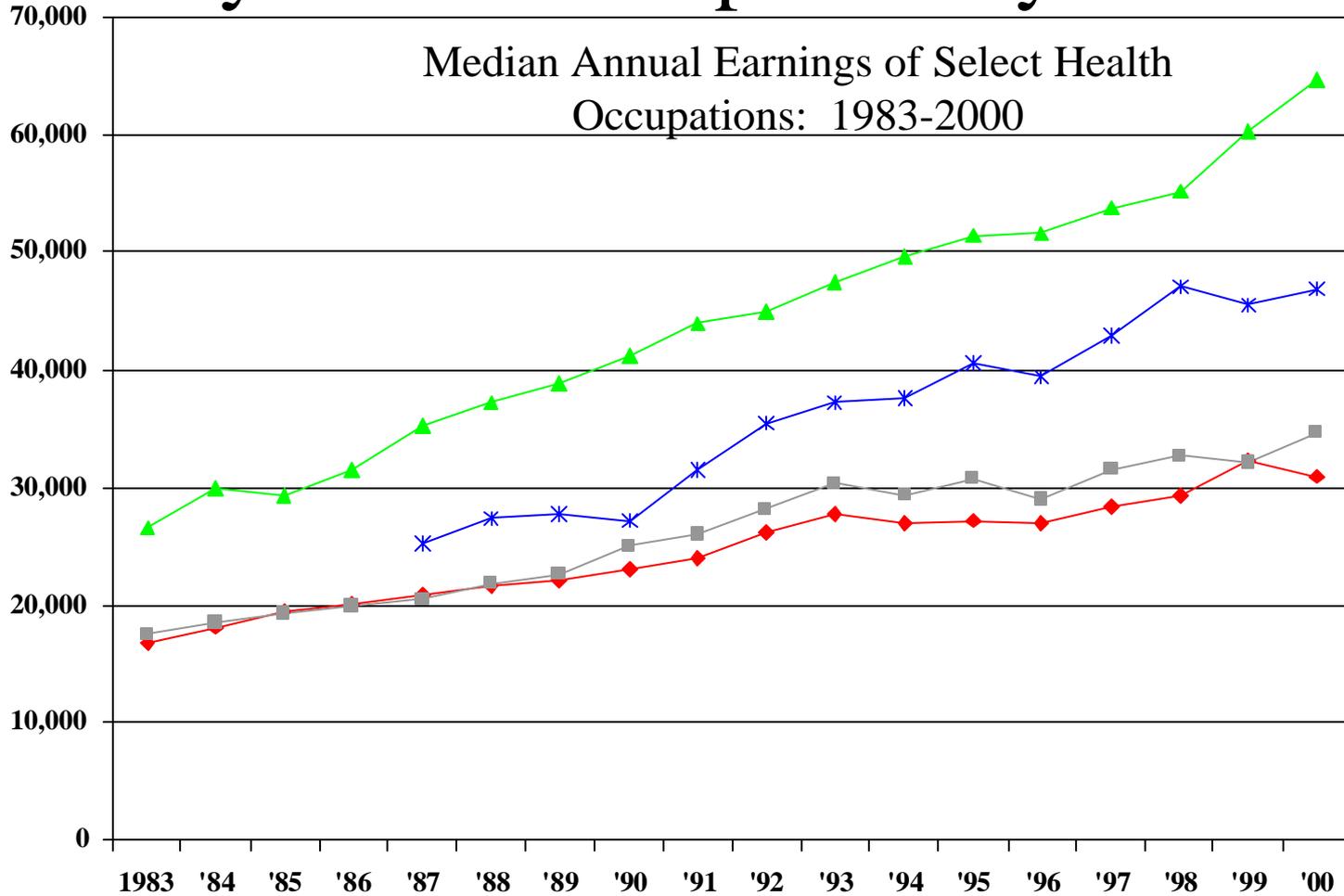
	Medical Technologists	Medical Laboratory Technicians
All Settings	\$40,518	\$27,539
Office and Clinics of Medical Doctors	\$38,854	\$27,186
Hospitals	\$40,851	\$28,870
Medical and Dental Laboratories	\$39,790	\$25,251

^[1] Occupational Employment Statistics, Bureau of Labor Statistics.

Mean Annual Salaries, Medical and Clinical Lab Technologists (2000)



Salary data can help identify a shortage.



Source: Bureau of Labor Statistics, Current Population Survey

Factors Affecting Labor Market

BLS predicts need for 120,000 new technicians and technologists between 2000-2010

Supply factors include

- Retirement of a large number of clinical laboratory technicians
- Individuals choosing more lucrative technical careers over clinical laboratory sciences
- Like nursing, which is also heavily a women dominated field, women now have more career opportunities and can choose better paying jobs

Increased Demand for Laboratorians

- Volume of tests expected to increase with population growth and the aging of population
- Technological advances and new tests
- Need to replace transitioning workers

Laboratorian Shortages: Reported Factors

- Salary levels
- Few opportunities for advancement
- Stressful working conditions
- Lack of visibility on the health care team
- Lack of a professional image
- Risk of infectious diseases
- Increased legal liabilities

Barriers to Addressing Lab Worker Shortages

- Diversity of professions and professional training, including training sites
- Lack of data on all laboratorians
- Difficulty in predicting technological changes
- Unknown usage of alternate workers (and ability to substitute)



Clinical Laboratory Sciences Personnel Shortage Study

2003

- Employment of clinical lab workers estimated at 295,000 in 2000
- Vacancies reported from 10% to 22%
- Employment projected to grow to 348,000 by 2010
- Study to assess supply, demand, and shortages of
 - Clinical Laboratory Scientists & Medical Laboratory Technologists
 - Histotechnologists
 - Histologic Technicians
 - Cytotechnologists
 - Pathologist Assistants

Key Questions to be Addressed

- How many lab workers will be needed, and where?
- How many will be formally trained?
- How many will come from alternate career paths/training?
- How are responsibilities affected by education/training?

Key Questions to be Addressed

- Where will supply fall short of demand?
- What are key factors influencing supply/demand now and in the future?
- What is the impact of a clinical lab worker shortage on the health care system?
- What are the recommendations of the clinical lab worker professions to address workforce?

Report To CLIAC on SACGT

Patricia Charache, M.D.

September, 12, 2002

SACGT Report

September 12, 2002

The Charter for SACGT expired in August.

- **DHHS has decided not to renew the charter of SACGT**

Format of This Presentation

- **Summarize the premise and outputs of SACGT in areas in which its activities relate to issues that impact directly on quality of patient care laboratory practices.**
- **(The body of SACGT's activities involved areas not in CLIAC's purview.)**

Background Premise

- Over 800 genetic tests now exist, (577 in CLIA approved labs, 368 in research labs). Most target rare genetic disorders; others are being developed.
- These tests have multiple uses, e.g. newborn screening, carrier screening, predictive testing, disease diagnosis or prognosis, pharmacogenetics.
- Some, especially predictive tests, raise sensitive medical, social, ethical, and legal issues.

SACGT Charter

- **Advise the Secretary on all aspects of the development and use of genetic tests. Includes**
 - **safe and effective incorporation of genetic technologies into health care**
 - **assessing the effectiveness of existing and future measures for oversight of genetic tests, and**
 - **identifying research needs related to the Committee's purview.**

Accomplishments

- **Recommendations By SACGT (7/00)**

There is a need:

- **To improve the oversight of genetic tests**
- **For Federal legislation to prevent discrimination in insurance and employment**
- **Study the effect of gene patents and licensure**
- **Study further the issue of informed consent of third parties in human research subjects.**

Recommendations Pertaining to Adequacy of Oversight of Genetic Tests (Continued)

- **The FDA should regulate laboratory developed genetic tests (“home brews”), using an innovative, flexible approach**
- **CLIA should be augmented to incorporate specific provisions for genetic testing laboratories**
- **Private-public collaborations are needed to ensure continued analysis of post market data**

Definitions: (PC痴)

- Analytical Validity: Primarily concerned with ability to accurately measure a given analyte.
- Clinical validity: Ability to separate clinical disease from no disease or risk of disease through measuring that analyte.
- Clinical utility: Clinical validity plus full knowledge of test , including gene penetrance, etc.significance in populations to be tested.

Ongoing SACGT Considerations: Oversight

Who is responsible

<u>Activity</u>	<u>IRB</u>	<u>CLIA</u>	<u>FDA</u>
Research (development)	X		
Research, (validated analytically, clinically) limited patient reports	X	X	
Wide use patient reports, fully validated, +/--continued research	+/-	X	X

Ongoing SACGT Activities: Work Groups and Task Forces

- **Pursued recommendation issues**
- **Established work groups for additional issues related to other aspects of testing**
 - **Education**
 - **IRB/Consent**
 - **Rare Diseases**
 - **Access**
 - **Data collection, clinical utility information**

Education Work Group

- Assess the adequacy of current efforts to advance genetics education of health professionals
- Year-long data gathering and fact finding; educational summit in Baltimore, May, 2002.

Issues: *For appropriate pre- and post-analytical aspects of testing, educated users are required. Laboratory Directors, IRB's, clinicians, others need knowledge base.*

Consent/IRB Work Group

- A brochure was developed to explain genetic testing and informed consent to the public
 - White paper was under development on principles of informed consent, defining levels of consent, and consent recommendations for various types of genetic tests
-

Laboratory Issues: Who decides level of consent What is the laboratory's role in assuring patient consent?

Rare Disease Testing Work Group

- **Definition of a rare genetic disease**
 - **Developmental and practice incentives**
 - **Special access issues**
 - **Quality assurance and validation assistance for research laboratories testing for rare diseases.**
-

*Issues: Limited test sites, mainly research labs ,
home brew tests if limited industrial interest, no
proficiency tests, patent issues*

Access Work Group Discussions

- **Reimbursement for:**
 - **Test cost**
 - **Genetic education and counseling**
 - **Other professional services**
 - **Non-reimbursed laboratory costs**
- **Health care disparities**
- **Gene patents and licensing:**
 - **Value for industrial interest in development**
 - **Issue for access and quality assurance**

Data Work Group

Goal: To improve knowledge of the disease and the clinical validity and utility of a test

- **Needs:** Improved post market data collection, access to data, resources for data organization, and analysis. Both clinical and laboratory data are required
- **Survey of HHS activities to advance knowledge of clinical validity and utility (translational research)**

Lab Issues: *Who is to provide the data and how? Privacy? Cost? Definitions of a test, etc.*

Additional Concerns Supportive of CLIAC's Reports

- **Waived tests (of major concern as they apply to genetic testing because of pre- and post analytical considerations)**
- **CMS study of laboratories performing waived tests**

Summary

SACGT recommendations and considerations:

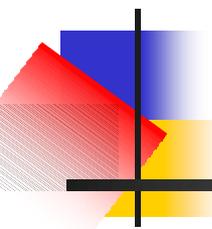
- **Oversight functions, including FDA review of tests, template approach and enhanced CLIA**
- **Additional subject matter covered by work groups and task forces: Education, IRB/Consent, Rare Diseases, Access, Data Work Group**
- **Other issues: Patent issues; (Waived tests, CMS findings of Waived testing laboratories)**

Outstanding Issues

- **Classification of laboratory oversight responsibilities, clarifying when CLIA applies to research facilities**
- **Provision of education/guidance documents for IRB's, and/or research laboratories interested in patient care**
- **Oversight of laboratory developed tests: CMS and deemed status organization feasible assessment instruments for analytical and clinical validation (not full clinical utility).**

Outstanding Issues

- Informed consent issues, (check off box on lab requests?)
- Reimbursement for laboratory expenses associated with clinical user discussions.
- Education of Laboratory Directors and Technical Supervisors specific to genetic testing
- Consideration of result implications in test categorization decisions, e.g. waived vs. other .

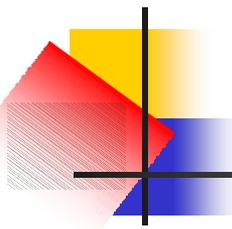


Molecular genetic test orders

Kathy LaBeau, Network Director

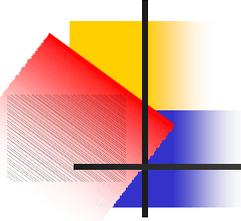
Pacific Northwest Laboratory Medicine Sentinel Monitoring Network

Presentation to CLIAC – September 12, 2002



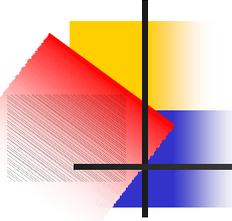
Genetic testing in Washington and the Pacific Northwest

- Snapshot of testing in 2001/2002
 - What tests are being ordered?
 - Where are tests being performed?
 - How is the genetic testing laboratory chosen?



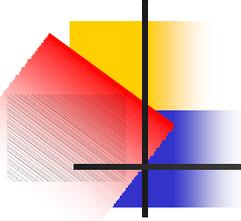
Washington State database

- WA Medical Test Site (MTS) Program
 - CLIA-exempt state program
 - More detail about genetic tests than CLIA database
 - Molecular
 - Biochemical
 - Cytogenetic
 - Maternal serum AFP



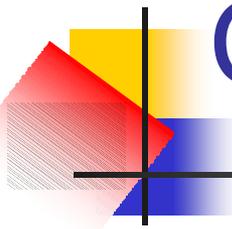
Genetic testing in Washington

- 13 of 716 moderate/high complexity labs (1.8%) perform genetic testing
 - 12/13 molecular
 - 6/13 cytogenetic
 - 2/13 biochemical



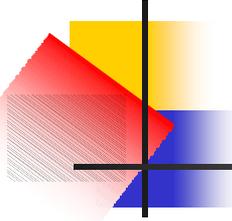
Genetic testing in Washington

- 6 research labs
 - Providing results for patient care
- 4 hospitals (university & children's)
- 2 independent labs (1 hospital-based)
- 1 State public health lab (newborn screening)
- 85% are accredited by private organization
 - CAP, AABB, ASHI



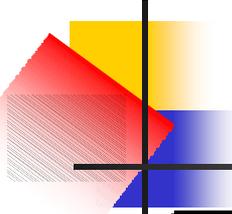
Genetic testing in Washington

- 11 of 716 moderate/high complexity labs (1.5%) perform maternal serum AFP
- Genetic testing accounts for 0.4% of total volume of testing in Washington's moderate/high complexity labs
- 0.37% of which is newborn screening



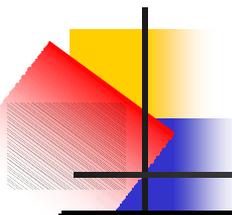
Data from Pacific NW network

- Lab Medicine Sentinel Monitoring Network
 - Voluntary participation by 600+ laboratories
 - Waived, PPMP, moderate, high complexity
 - POL, hospital, independent labs
 - Alaska, Idaho, Oregon, Washington
 - Questionnaire sent to 330 moderate & high complexity labs in January 2002
 - 204 respondents - Genetic testing orders



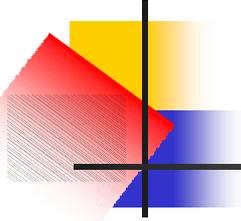
Questionnaire respondents

	Questionnaire respondents N = 204	All network participants N = 330	All labs in Pacific NW N = 1539
AK (%)	9	9	6
ID (%)	19	19	16
OR (%)	22	22	32
WA (%)	50	49	46



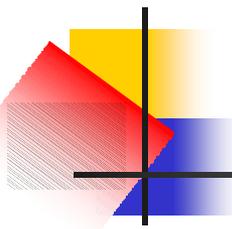
Questionnaire respondents

	Questionnaire respondents N = 204	All network participants N = 330	All labs in Pacific NW N = 1539
Urban/Rural (%)	54/46	56/44	68/32
POL/Hosp/IL (%)	59/31/9	59/31/10	73/17/10
Accredited (%)	32	33	30



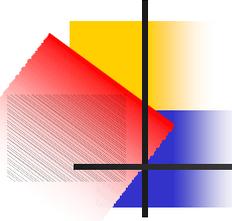
Network questionnaire results

- 53% of respondents handled orders for molecular genetic tests in previous 3 months (October - December 2001)
 - 66% of hospitals
 - 58% of independent (reference) labs
 - 46% of physician office labs



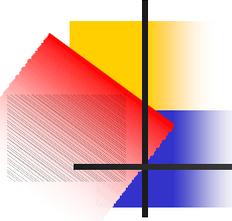
What tests are most commonly ordered?

- 1) Factor V Leiden Thrombophilia
- 2) Fragile X Syndrome
- 3) Hemochromatosis
- 4) Cystic Fibrosis
- 5) Hemoglobin S
- 6) BCR/ABL Translocation
- 7) BRCA-1 or BRCA-2
- 8) Huntington Disease
- 9) Prader-Willi Syndrome
- 10) Y Chromosome Detection



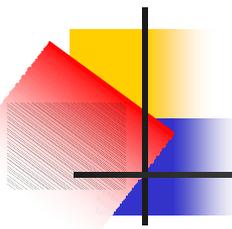
On-site testing

- 2% of the network respondents performed molecular genetic testing on-site
 - 3 independent, 1 hospital
 - All urban
 - All accredited



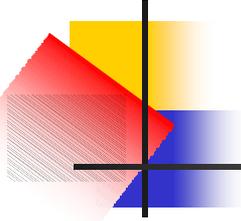
Send-out testing

- 62% sent orders to their reference lab, who in turn decided where the test would be performed
- 7% sent orders directly to the genetic testing lab
- 31% did some combination of these



How is the genetic testing laboratory chosen?

- Of 95 responses:
 - 39 % Information from reference lab (37%) or Internet resource about reference labs (2%)
 - 39 % Information from health care provider
 - Genetic counselor (12%)
 - Patient's provider (12%)
 - Medical geneticist (10%)
 - Neurologist, oncologist, pathologist, etc (5%)
 - 8 % Do not know
 - 4 % Mandated by managed care contract agreement



Where does testing go?

- 52% stays within the Pacific NW region
- 48% is sent out of the region
 - 15% to large national reference labs
 - Quest/Nichols Institute - California
 - Lab Corp - North Carolina
 - 33% to other genetic testing labs