The Mycobacteriology Laboratory of the Future

5th National Conference On Laboratory Aspects of Tuberculosis
11-13 August 2008
San Diego, CA

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13 August 2008
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Context
- Global Health Issues
- Laboratory Roles
- Future Directions of Technology

What Will It Look Like?
What Is Needed?
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Context: Global Health Issues: 2006

- Stable TB Prevalence
  - 9.8 M New Cases
  - 1.7 M Deaths

- No Evidence of Declining TB Drug Resistance
  - 490,000 MDR-TB Cases
  - 4.8% of All TB Cases
  - ~30,000 XDR-TB Cases
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Context: Global Health Issues

– Increased Opportunity for Spread
  • HIV > 6,800 New Infections Daily
  • 33.2 Million HIV-Infected Persons Globally
  • 22.5 Million HIV-Infected Persons in Sub-Saharan Africa
    – Social Disruption
    – Travel/Migration
    – Poor Health Care Infrastructure

– Global Economy/Travel
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Estimated Incidence of Tuberculosis per 100,000 Population in African Countries in 1990 and 2005.

Data are from the World Health Organization. ND denotes no data.
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Context: Global Health Issues

– Better Awareness of Magnitude of Problem
– Global Funding
  • Much Better Today
  • Varies by Region
  • Waxes and Wanes
– A Number of Global TB Control Initiatives
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Context: Global Health Issues
- Limited Data on Global Prevalence of Other Mycobacterial Infections
- WHO: Sustained Progress Against Leprosy
- WHO: Program Aimed at Buruli Ulcer
- ?? Others
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Context: Laboratory Roles

– Patient Care
  • Direct Care of Infected Patients
  • Care of Patient Contacts

– Public Health
  • Immediate Level: Contact Investigation
  • Community/Regional Level: Disease Control
  • National Level: TB Elimination
  • Global Level: Reduction of TB Burden
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Context: Laboratory Roles

- Scope of Services
- Methods & Technology
- Informatics
- Quality & Training
- Cost
- Effectiveness
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Context: Laboratory Roles

– Resource Limited Areas
  • Clinic/Health Post
  • Peripheral Laboratory
  • District Laboratory

– Developed Regions
  • Clinical/Hospital
  • Public Health
  • Specialized
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Context: Future Directions of Technology

– New Technology in Dichotomous Pathways
  • Rapid, Inexpensive Point-of-Care Tests
  • Gene Sequencing for Identification, Molecular Epidemiology, Genetic Antimicrobial Susceptibility Tests, Pharmacogenomics, Etc.

– Few New Diagnostic Tests for Clinical/Hospital Laboratories
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What Will It Look Like?
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It Depends
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What Will It Look Like?

- Resource Limited Areas
  - Infrastructure Inadequate
  - Shortages/Absence of Trained Staff
  - Increasing Demand for Testing
  - ? Rapid Diagnostic Tests
  - Newer Diagnostic Tests Unaffordable
  - For Many Regions, Future is Likely to Look Much as it Does Today
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What Will It Look Like?

– Developed Regions - Clinical Laboratories
  • Still A Need to Improve Basic Laboratory Practices
  • Increase in Molecular/Genetic Assays
  • ? Rapid Diagnostic Tests
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What Will It Look Like?

– Developed Regions - Public Health Laboratories
  • Still A Need to Improve Basic Laboratory Practices
  • Increasing Emphasis on Molecular/Genetic Assays
    – NAAT for Identification/Susceptibility Testing
    – ? Sequencing for Identification/Susceptibility Testing
    – Molecular Epidemiology
  • Information Technology
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What Will It Look Like?

– Developed Regions - Specialized Laboratories
  • Increasing Emphasis on Molecular/Genetic Assays
    – NAAT for Identification/Susceptibility Testing
    – Sequencing for Identification/Susceptibility Testing
    – Molecular Epidemiology
    – Pharmacogenomics
  • Information Technology
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What is Needed?

– Tiered Laboratory System
  • Part of a Broader Public System for TB Control
  • Coordinated by Role/Type of Testing
  • Rigid and Sustained Emphasis on Quality
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What is Needed?

– Tiered Laboratory System
  • Many Basic Research Laboratories
  • A Few Laboratories Performing Translational Research
  • A Few Cutting-Edge Reference Laboratories
  • Many Hospital/Clinical Laboratories
  • Many, Many Testing Sites in Developed World
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What is Needed?

– Public Policy and Funding
  • Increased Awareness of the Growing Dichotomy Between Laboratories in Developed and Resource-Limited Areas
  • Infrastructure and Sustainability Issues are Crucial
  • Must Minimize Future Swings in Funding
  • Strategic Goals
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What is Needed?

– Public Policy and Funding
  • No Single Technology/Test Will Solve All Issues
  • *Different Tests Yield Different Information*
  • Many Different Technologies/Tests Will Be Needed
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What is Needed?

– Public Policy and Funding
  • Work Force Issues at National Level
  • Thoughtful Funding Increases
  • National Coordination of Tiered Laboratory System
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What is Needed?

– Public Policy and Funding
  • Better System for Bringing Tests to FDA
  • Issues Meeting for Microbiology Devices Panel
  • Need Global Harmonization of Marketing Approval/Clearance Standards (Reciprocity)
What is Needed?

- Realistic Technology Assessments
  - Not Every Test Will Work Out
  - Laboratories Will Need to Choose Between Alternative Technologies/Methods/Tests
  - Laboratories Increasingly Will Need Technical Guidance
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What is Needed?

– Realistic Cost-Effectiveness Assessments

• Much of New Technology is Expensive
• Adding Tests But Not Dropping Very Many
• Need Better Cost Accounting Systems
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Facts Do Not Cease To Exist
Because They Are Ignored
- Aldous Huxley