TB Elimination Cooperative Agreements
Laboratory Upgrade Component

Post-Conference Workshop
August 13, 2008
Agenda

- History of laboratory upgrade component of TB cooperative agreements
- TB LAB Formula Working Group FY2010 - 2014 Cooperative Agreements
- Proposed formula and formula elements
- Performance and data elements for application and progress reports
- Cooperative agreement administration
- Comments from APHL
- Q&A
TB LAB Formula Working Group
FY2010 - 2014 Cooperative Agreements

Beverly Metchock, DrPH, D(ABMM)
Team Leader, Reference Laboratory
Mycobacteriology Laboratory Branch
Division of TB Elimination
TB Lab Formula Working Group

- Parallel to Prevention and Control (P&C) working group
- Purpose: review existing formula and recommend whether there are modifications or revisions required for the FY2010-2014 allocation
- Expectations: weekly meetings beginning 6/5/2008
- Timeline: draft plan with narrative to DTBE by ~10/1/2008; final plan for CDC review ~11/1/2008
TB Lab Formula Working Group

• Group members
  – Represent labs from low, medium, and high TB incidence states
  – Represent labs with low, medium, and high testing volumes
  – Include Lab Directors, Section Directors, Lab Supervisors, Lab Managers (some “outside the box”)
Issues for the Working Group

• FORMULA
• Distribution schedule
• If time permits,
  – Guidance document – instructions, clarification, definitions
  – Data to include in progress reports
  – Definitions of terms
TB Lab Formula Working Group

- **Public Health Laboratories**
  - Jane Bush (GA)
  - Debra Horensky (NM)
  - Billie Juni (MN)
  - Samuel Merritt (NC)
  - Max Salfinger (FL)
  - Kevin Sohner (OH)
  - Julie Tans-Kersten (WI)
  - Cindy Vanner (RI)
  - Daphne Ware (MS)
  - Susie Zanto (MT)

- **CDC – Laboratory**
  - Beverly Metchock
  - Angela Starks
  - Dave Wilson
  - Thomas Shinnick

- **CDC – Program**
  - Greg Andrews

- **NTCA**
  - Phil Griffin (KS)

- **APHL**
  - Kelly Wroblewski
  - Rosemary Humes
Proposed Formula and Redistribution Schedule

Angela Starks, Ph.D.
Senior Service Fellow
Reference Laboratory Team
Mycobacteriology Laboratory Branch
Division of TB Elimination
How will funding be calculated for FY2010?

• Anticipate same total amount of funds will be available in FY2010 as in FY2009

• Funds will be allocated to each lab using the current formula with a change in distribution
  - Parallels Prevention & Control redistribution
    - 55% distributed based on prior funding
    - 45% distributed based on workload

• Goal of redistribution is progression towards 100% formula-based funding to better reflect changing epidemiology
How will funding be calculated for FY2011 & FY2012 (proposed)?

• Funds allocated using a **newly proposed** formula
  - 55% distributed based on prior funding
  - 45% distributed based on proposed formula

• Proposed formula reflective of laboratory workload

• Proposed formula implemented in FY2011 to:
  1) allow reported data from FY2008 and FY2009 to be used for calculating award (2 year average)
  2) avoid redistribution and implementation of new formula in the same year
Proposed Elements For Calculating Formula-based Funding Amount

1) Total number of clinical specimens processed.
   - reflects total workload

2) Number of individual patients for whom a clinical specimen was processed and a TB culture inoculated.

3) Number of individual patients for whom an isolate was received by the PHL to rule out or confirm the ID of Mtb complex.
4) Number of individual patients for whom *M. tuberculosis* DSTs were performed for first line drugs. (includes isolates referred to another lab)

5) Number of individual patients from your jurisdiction for whom a clinical specimen was tested with a NAA test or other rapid tests such as direct HPLC. (includes in house and referred testing)
   - Formula elements #2-#5 reflect laboratory workload on a per patient basis- ensures equitable distribution

6) Development of integrated laboratory system.
   - Funds for this element distributed on a per program basis (equal amount)
### Proposed Element Weights

<table>
<thead>
<tr>
<th>Per patient basis</th>
<th>Total # specimens</th>
<th>TB culture inoculated</th>
<th>Isolates received for ID</th>
<th>NAA testing of clinical specimen</th>
<th>DST for first-line drugs</th>
<th>Lab system-equal amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5%</td>
<td>15%</td>
<td>15%</td>
<td>25%</td>
<td>25%</td>
<td>15%</td>
</tr>
</tbody>
</table>

- Data provided by the labs will be used to determine the funding amount for each element.
- The amounts for the individual elements will be added together to determine the formula-based portion of the award.
Base: % of prior year funding

Total Award

Formula-based amount

- Total # specimens processed (5%)
- # pts. TB cultures inoculated (15%)
- # pts. isolates received for ID (15%)
- # pts. DST for FLDs (25%)
- # pts. NAA test (25%)
- Development of lab system (15%)
How will funding be calculated for FY2011 & FY2012 (proposed)?

• An “incentivized approach” is proposed for formula element #5 – Number of patients for whom a clinical specimen was tested with a NAA test.

• Funding for NAA element calculated using the number of patients for whom DST is performed as a surrogate of the # of TB cases the lab has confirmed.
Why use an incentivized approach for the NAA formula element?

- Goal of cooperative agreement funding is enhancement of laboratory services
- Some labs do not currently perform test or have referral strategy for NAA testing
- Incentivized approach allows all laboratories a window of opportunity to establish access either in house or referred
How will funding be calculated for FY2013 & FY2014 (proposed)?

- Funds will be allocated to each lab using the proposed formula with a change in distribution
  - Parallels Prevention & Control redistribution
    - 40% distributed based on prior funding
    - 60% distributed based on formula

- Funding for NAA testing element will be calculated using actual reported data from previous fiscal year
## Summary of FY2010-FY2014 Funding Plan

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Distribution (base/formula)</th>
<th>Formula</th>
<th>NAA element incentivized?</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2010</td>
<td>55% / 45%</td>
<td>Current</td>
<td>Not applicable</td>
</tr>
<tr>
<td>FY2011</td>
<td>55% / 45%</td>
<td>Proposed</td>
<td>Yes</td>
</tr>
<tr>
<td>FY2012</td>
<td>55% / 45%</td>
<td>Proposed</td>
<td>Yes</td>
</tr>
<tr>
<td>FY2013</td>
<td>40% / 60%</td>
<td>Proposed</td>
<td>No</td>
</tr>
<tr>
<td>FY2014</td>
<td>40% / 60%</td>
<td>Proposed</td>
<td>No</td>
</tr>
</tbody>
</table>
FY2010 Application and Progress Reports

Beverly Metchock, DrPH, D(ABMM)
Team Leader, Reference Laboratory
Mycobacteriology Laboratory Branch
Division of TB Elimination
CDC Activities

• Include:
  – Technical assistance including site visits
  – Work with partners to address training needs, develop best practice guidelines, testing algorithms
  – Consultation on QA and performance indicators
  – Provide aggregate annual report of TATs and performance measures from funded laboratories for peer group comparison
Awardee Activities

• Include the following for both the application and the interim and annual progress reports:
  – Providing all workload data requested (both data for formula and other workload-related data)
  – Providing all data requested regarding meeting CDC recommended turnaround times and Healthy People 2010 goal

• Formula is independent of the activities
Note on TAT Data

• Report percentages for each recommendation
  – NOT mean or average
  – NOT “met” or “not met”

• For example, for ID TAT within 21 days
  – Data shows that 49 of the 78 Mtb isolates recovered from clinical specimens processed in your lab were ID’d as Mtb in $\leq 21$ day;
  – $49/78 = 68.2\%$
  – Report 68.2% identified with 21 days
2 Components

• 1: Meeting CDC recommended turnaround times and Healthy People 2010 goal
• 2: Developing an integrated system that ensures timely laboratory testing and timely flow of information
Addressing the Components

For each component, Lab/Program will
• Set short-term and long-term realistic achievable goals
• Describe a plan for achieving goals
• Set outcome or performance measures to monitor progress
Addressing the Components (2)

In addition:

• Component 1
  • Provide update using outcome or performance measures to describe progress
  • Describe obstacles encountered and/or reasons for failing to meet goals
  • Describe future plans

• Component 2
  • Describe progress
  • Describe obstacles encountered and/or reasons for failing to meet goals
  • Describe future plans
Component 1
Turnaround Times

Overall Goal:
• Use methods and attain or maintain the TATs cited in Tenover et al (1993) and CDC/APHL recommendations and HP2010
Component 1 – Example

- **Laboratory-Specific Goal**: Decrease specimen transport time from 3 days to 1 day
- **Plan**: Institute a state-wide courier service
- **Measure**: % of specimens received within 1 day of collection
Component 1 – Example

- **Laboratory-Specific Goal:** Increase % isolates meeting TAT of 28 d for drug testing from 60% to 70% within two years
- **Plan:** Have already incorporated automatic growth detection system DST; set up DST 2X instead of 1X week
- **Measure:** % of isolates meeting TAT
Component 1 – Example

- **Laboratory-Specific Goal**: Increase number of patients for whom NAA testing is performed

- **Plan**: Perform NAA testing on smear-positive specimens and high priority specimens identified by the TB program

- **Measure**: % of patients with culture-confirmed TB that had NAA testing performed
Component 1 – Example

- **Laboratory-Specific Goal**: Decrease TAT for NAA testing results from 1 week to 72 hours
- **Plan**: Perform NAA testing 2X per week instead of 1X per week
- **Measure**: % meeting TAT
Component 2
Laboratory System

Goal:

• Improve TB Control through optimal use of laboratory services and effective reporting and tracking of information
Component 2 – Example

- **Laboratory-Specific Goal**: Determine what TB laboratory services are available in your jurisdiction
- **Plan**: Identify and survey laboratories in your state that do mycobacteriology testing
- **Measure**: met vs. not met
Component 2 – Example

- **Laboratory-Specific Goal:** Establish better communication between laboratory and its clients
- **Plan:** Conduct a ‘Mycobacteriology 101’ course for TB Controllers and clinicians
- **Measure:** met vs. not met
Evaluation Criteria for Each Component

- **Program needs (20%)**
  - demonstrates need for upgrading lab activities

- **Objectives (35%)**
  - proposes measurable, specific, time-phased, relevant objectives

- **Plans (30%)**
  - proposes appropriate feasible activities

- **Program evaluation (15%)**
  - describes specific performance measures and milestones
Budget (not scored)

Provide two budgets that include the costs of accomplishing the 2 components

– budget based on projected award for the laboratory component of the TB CoAg

– budget reflecting additional costs not reflected in the budget based on projected award for the laboratory component of the TB CoAg
Laboratory Upgrade Program
Cooperative Agreements
Administration

David A. Wilson, M.Ed
Public Health Analyst
Mycobacteriology Laboratory Branch
Division of TB Elimination

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Role and Responsibilities

• Provide coordination and responsive service to internal/external customers.

• Collect, review and process applications for funding.

• Maintain State laboratories files.

• Approve Carryover and Rebudgeting Requests.
Interest Items

• Carryovers
  – Funds can be carried forward from any budget year.
  – Funds must be used in the year they were carried forward to.

• Redirection (Rebudgeting) of funds
  – Redirecting more than 25% of your total budget requires prior approval.
  – Redirect funds between budget categories only!

• Commingling of funds
  – Laboratory Upgrade funds must remain separate.

• Supplanting of funds
  – Laboratory Upgrade funds may not be used to replace State or local program funds.
Guidance

http://pgo.cdc.gov
CDC laboratory contacts

Beverly Metchock  
404-639-1285  
bem1@cdc.gov

Angela Starks  
404-639-3205  
eog0@cdc.gov

Dave Wilson  
404-639-4859  
zbu1@cdc.gov

Thomas Shinnick  
404-639-1474  
tms1@cdc.gov