Justification for Change Request

Purpose

CDC is requesting OMB approval for a non-substantial change request to OMB 0920-0600 Model Performance Evaluation Program for Mycobacterium tuberculosis/non-tuberculosis Mycobacteria Drug Susceptibility Testing Program. These are minor changes to questions on the MTBC Results Worksheet that accompanies the *M. tuberculosis* (TB) isolates for the TB portion of the Model Performance Evaluation Program (MPEP).

The reasons for changing the questions are: (1) to clarify some of the questions; (2) to make answer choices consistent in expression and order; (3) to delete questions that no longer need to be asked because there is already sufficient information; and (4) to add a one-time-only question to get feedback from participants about whether the program should include evaluation of NTM strains.

In addition, there is a change to a note to participants to emphasize in the instructions that participants should test isolates for susceptibility of second-line drugs, if they perform this testing on patients (some labs were already doing this, but others weren't.) Ensuring consistency in responses will provide more reliable data, and will improve assessment of testing for susceptibility to second-line drugs.

Modified Questions

The first two questions were changed to make answer choices between the questions consistent in the way they are described, and to make them consistent in the order in which they appear. An additional choice for molecular method was added because more labs are adopting this technology. The highlighted phrases in Questions 2 and 3 were added to enhance clarity.

1. What method(s) was used in your laboratory to perform drug susceptibility testing on the MTBC isolates in this shipment? (Please blacken all that apply.)

   O Agar Proportion (Middlebrook 7H10)

   O Agar Proportion (Middlebrook 7H11)

   O Radiometric (BACTEC)

   O VersaTREK Myco

   O MGIT System

   O Lowenstein Jensen (LJ) proportion method

O Molecular Method (please specify): _____

O Other (please specify): _____

2. If your laboratory uses more than one method for testing **this shipment's isolates** for first-line drugs for MTBC susceptibility, please indicate the primary method **(NOT confirmatory method)** that is used. (Please blacken only one circle.)

O Agar Proportion (Middlebrook 7H10)

O Agar Proportion (Middlebrook 7H11)

O Radiometric (BACTEC)

O VersaTREK Myco

O MGIT System

O Lowenstein Jensen (LJ) proportion method

O Molecular Method (please specify): _____

O Other (please specify): _____

3. If you use Middlebrook 7H10 or 7H11 media **as either a primary or secondary method** of MTBC drug susceptibility testing, your media is: (Please blacken all that apply.)

O purchased "commercially-prepared" containing anti-tuberculosis drugs

O prepared in-house with disks containing anti-tuberculosis drugs

O prepared in-house by reconstituting and adding anti-tuberculosis drugs

O Not Applicable

Deleted Questions

The questions deleted are listed below. The first question has been asked numerous times in the past, and participant laboratories have sufficiently been made aware of recommended guidelines regarding biosafety levels. The last two questions were initially meant to be asked only on a temporary basis, and are no longer needed.

1. Please indicate what level of biosafety practices your mycobacteriological laboratory follows for *M. tuberculosis* cultures. (Please blacken only one circle.)

   O Biosafety Level 1

   O Biosafety Level 2

   O Biosafety Level 3

   O Biosafety Level 2 for facilities with Level 3 containment equipment

   O Do not know

2. Does your laboratory perform on-site susceptibility testing of non-tuberculous mycobacteria? (Please blacken only one circle.)

   O Yes

   O No

3. For the species of NTM that you do not test in-house, do you refer (send out) these to another laboratory for drug susceptibility testing? (Please blacken only one circle.)

   O Yes

   O No

   O Not Applicable

New Question

The following question is intended to be asked one time only, to gather information from participants on the need for MPEP to offer additional isolates for performance evaluation.

1. a. In your opinion, is there a need for offering performance evaluation of NTM strains?

   O Yes

   O No

1. b. If yes - For your laboratory, would it be more advantageous to offer evaluation of:

   O Rapidly growing NTM

   O Slowly growing NTM

Modified Instructions

CDC revised the instructional note to participants that appears on the worksheet to clarify test results that need to be submitted. Previously, some labs submitted data for testing second-line drugs for susceptibility, whereas others did not, even though they might perform this testing on patients. Practice guidelines recommend that if first-line drugs are susceptible to TB, they should be used; hence testing second-line drugs for susceptibility is not necessary. This is advisable for patient testing, but following this reasoning with MPEP TB isolates does not allow for evaluation of testing second-line drugs. For consistency between results received from labs, and to enhance test performance evaluation of second-line drugs, CDC modified the instructional note as follows (highlights show how the note was modified):

"***Please note:*** Treat these cultures in the same manner that you routinely treat MTBC isolates, with the following exception:

If you test second-line drugs in your laboratory, test these isolates (regardless of results from testing first-line drugs) using those second-line drugs normally used to test patient isolates. This will provide you with an opportunity to evaluate your performance for testing second-line drugs."