Planning and budgeting tool for TB and drug resistant TB testing

User guide

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ISBN 978-92-4-003813-4 (electronic version)
ISBN 978-92-4-003814-1 (print version)

Suggested citation. Planning and budgeting tool for TB and drug resistant TB testing: user guide. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

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Background

The TB diagnostics planning and budgeting tool facilitates systematic calculation of the quantities and costs of products for countries planning to order diagnostic products and laboratory supplies from the Global Drug Facility catalogue. The tool calculates the quantities of products required from past consumption or morbidity-based forecasting methods for all WHO-endorsed TB diagnostic products to set targets for scaling up according to the country's epidemiology and from algorithms.

The product prices and descriptions used in this tool are from the 2021 GDF Diagnostics Catalogue.

The tool is an updated version of a forecasting tool used in the EXPAND-TB project, developed by FIND, the Global Laboratory Initiative, the Global Drug Facility and partners.

The tool consists of a set of Excel spreadsheets providing preliminary instructions, epidemiology and algorithms, diagnostic testing methods, biosafety and cleaning, equipment maintenance, repair and a budget summary.

Users should fill out only the values in red on all sheets.

1. Information and introduction

This section comprises four steps.

- ✓ **Step 1:** The user should select "Yes" or "No" from the drop-down menu to configure the diagnostic tests and consumables to be forecasted and procured; the default is Yes for all. Each of the listed diagnostic testing methods has a corresponding sheet. According to the input, the corresponding sheets are visible on the navigation bar (bottom of Excel sheets)
- ✓ **Step 2: Enter the year for which you want a forecast of consumables.**
- ✓ **Step 3:** The user defines the forecasting period in months.
- ✓ **Step 4:** The user clicks on "epidemiology" to enter national epidemiological data and assumptions (refer to the next point).
- ✓ **Step 5:** The user clicks on visible diagnostic tests sheets through the Excel navigation bar on the bottom.

2. Epidemiology

Values in red should be entered or adjusted according to actual country data and practices, when possible. Some default values are included under programmatic assumptions, but these should be refined when possible. These data automatically link to all diagnostic test sheets for the morbidity-based forecasting method.

3. Lipoarabinomannan (LAM) assay

The user can use one of two methods proposed for calculating the items and costs of LAM.

- ✓ Method 1: This method is based on the average number of LAM tests performed per month, in the past or expected. Users enter the number of tests performed per month, and the total number of LAM tests will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The patient populaton "PLHIV seriously ill or with CD4 < 200" includes patients with a CD4 count < 100. The user should enter the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

the total number of LAM tests during the period, calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

4. Truenat

The user can use one of the two methods proposed for calculating the items and costs for Truenat:

- ✓ Method 1: This method is based on the average daily use of a Truelab analyser, either past or expected. Users should enter information on the Truelab analyser (uno, duo, quattro) in the country and the average number of Truenat chip ports per day. The total amounts and items will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the total number of Truenat tests for the period, calculated with method 1 or 2, and the average percentage. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) error, invalid or no result (3% is the default value when there was no past consumption).

5. Loop-mediated isothermal amplification for detection of *M. tuberculosis* (TB-LAMP)

Two methods are proposed for calculating the items and costs for TB-LAMP.

- ✓ Method 1: This method is based on the average number of TB-LAMP tests performed per month, either in the past or expected. Users should enter the number of tests performed per month, and the total number of TB-LAMP tests will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

the number of batches per day, the number of specimens and controls per batch and the total number of TB-LAMP tests during the period, calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

6. Xpert MTB/RIF Ultra

The user can use one of two methods proposed for calculating the items and costs for Xpert MTB/RIF Ultra.

- ✓ Method 1: This method is based on the average daily use per module, either past or expected. Users should enter the number of modules in the country and the

average number of Xpert MTB/RIF Ultra tests performed per module per day; the total amounts and items will be calculated automatically

- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the total number of Xpert MTB/RIF Ultra tests required for the period calculated with the method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) the average percentage of error/invalid/no result (3% is the default value when there is no historical consumption).

Notes:

If sputum containers are used, the user should enter "0" on the quantity of packs to be ordered on the line "Sterile plastic centrifuge tube 50 mL".

If "sterile plastic centrifuge tube 50 mL" are used, the user should divide the value in the cell "total number of Xpert MTB/RIF Ultra cartridges required for the period (C20)" by the corresponding unit pack (C24).

7. Ziehl-Neelsen-stained and fluorescent light-emitting diode (ZN-LED) microscopy

On this sheet, only consumption-based forecasting is proposed. The user should enter the number of smears procured in the past year for diagnosis, treatment monitoring and from culture. The number of smears should reflect the current algorithm and any replacement of smear microscopy with rapid molecular tests.

Note: The user should use the dropdown menu to indicate whether a kit or separate consumables are preferred.

8. Xpert MTB XDR

The user can use one of the two methods proposed for calculating the items and costs for Xpert MTB XDR.

- ✓ Method 1: This method is based on the average daily use per module, either past or expected. Users should enter the number of modules in the country and the average number of Xpert MTB XDR tests used per module per day; the total amounts and items will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the total number of Xpert MTB XDR tests used during the period, calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) the average percentage of error, invalid, no result (3% is the default value when there is no past consumption).

Notes:

If sputum containers are used, the user should enter "0" on the quantity of packs to be ordered on the line "Sterile plastic centrifuge tube, 50 mL".

If "sterile plastic centrifuge tube, 50 mL" are used, the user should divide the value in the cell "total number of Xpert MTB/RIF Ultra cartridges for the period (C20)" by the corresponding unit pack (C24).

9. Line probe assay (LPA) 1st line

The user can use one of two methods proposed for calculating the items and costs for LPA 1st line.

- ✓ Method 1: This method is based on the average number of LPA 1st-line tests performed per month, either past or expected. Users should enter the number of tests performed per month; the total number of LPA 1st-line tests will be calculated automatically
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the type of LPA 1st-line test, "Genotype MTBDR plus" or "Genoscholar NTM+MDRTB II", from the drop-down menu;

ii) the number of batches per week, the number of specimens and controls per batch and the total number of LPA 1st-line tests used during the period calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered;

iii) the type of LPA 1st-line equipment, "MULTIBLOT NS-4800" or "GT-BLOT 48" or "TWINCUBATOR", selected from the drop-down menu;

iv) whether "Genolyse kit" and 1.5-mL or 2-mL tubes are used; and

v) whether "1 vial per batch" or" aliquot" and "Combitips" are used.

10. Line probe assay (LPA) 2nd line

The user can use one of two methods for calculating the items and costs for LPA 2nd line.

- ✓ Method 1: This method is based on the average number of LPA 2nd-line tests performed per month, either past or expected. Users should enter the number

of tests performed per month, and the total number of LPA 2nd-line tests will be calculated automatically

- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the number of batches per week, the number of specimens and controls per batch and the total number of LPA 2nd-line tests used during the period calculated with method 1 or 2. If the user used both methods, enter a value between methods 1 and 2.

ii) the type of LPA 2nd-line equipment, "TWINCUBATOR" or "GT-BLOT 48", selected on the drop-down menu;

iii) whether the "Genolyse kit" and 1.5-mL or 2-mL tubes are used; and

iv) whether "1 vial per batch" or "aliquot" and "Combitips" are used.

11. MAX multi-drug-resistant (MDR)-TB

The user can use one of two methods for calculating the items and costs for MAX MDR-TB.

- ✓ Method 1: This method is based on the average number of MAX MDR-TB tests performed per month, either past or expected. Users should enter the number of tests performed per month, and the total number of MAX MDR-TB tests will be calculated automatically
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the number of specimens and controls per batch and the total number of MAX MDR-TB tests during the period calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) the percentage of tests repeated (3% is the default value when there is no past consumption) and the number of extra tests used per batch because of a pipetting error (1 additional sample as a default value).

12. FluoroType MTBDR Ver 2.0

The user can use one of two methods for calculating the items and costs for FluoroType MTBDR Ver 2.0.

- ✓ Method 1: This method is based on the average number of FluoroType MTBDR Ver 2.0 tests performed per month, either past or expected. Users should enter

the number of tests performed per month, and the total number of FluoroType MTBDR Ver 2.0 tests will be calculated automatically.

- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the number of specimens and controls per batch and the total number of FluoroType MTBDR Ver 2.0 tests used during the period with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) the percentage of tests repeated (3% is the default value when there is no past consumption), the number of extra tests used per batch because of a pipetting error (1 additional sample as a default value) and the extraction kit used, "Fluorolyse Extraction kit" or GXT DNA/RNA extraction kit".

13. Cobas MTB and MTB-RIF-INH and Abbott RT MTB and MTB RIF-INH

The user can use one of two methods for calculating the items and costs for both tests.

- ✓ Method 1: This method is based on the average number of tests performed per month, either past or expected. Users should enter the number of tests performed per month, and the total number of tests will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

the number of specimens and controls per batch and the total number of tests used during the period, calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

14. Processing and solid/liquid culture

The user can use one of two methods for calculating the items and costs for both tests.

- ✓ Method 1: This method is based on the average number of cultures performed per month, either past or expected. Users should enter the number of cultures processed per month, and the total number of processed cultures will be calculated automatically
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with to the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the type of medium used for culture (i.e., Lowenstein–Jensen (LJ) medium or mycobacteria growth indicator tube (MGIT)).

ii) for LJ, the number of cultures processed during the period calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered. In addition, the user should enter the following parameters of the workload: number of slants used per sample, repetition rate, contamination rate and average specimen volume (in mL) to be decontaminated.

iii) for MGIT culture, the number of cultures processed during the period calculated with method 1 or 2. If the user used both methods, a value between that found with method 1 and 2 is entered.

iv) the following parameters of the workload: repetition rate, contamination rate and percentage MTB-positive culture.

15. Rapid MTB identification

On this sheet, only forecasting of consumption is proposed. The user should enter the number of samples tested for rapid MTB identification per month and whether a Capilia or an MPT63 test kit is preferred. The quantity of items and costs for rapid MTB identification will be calculated automatically.

16. Lowenstein–Jensen (LJ) 1st- and 2nd-line drug-resistance testing

The user can use one of two methods for calculating the items and costs for the two tests:

- ✓ Method 1: This method is based on the average number of LJ cultures performed per month, either past or expected. Users should enter the number of LJ cultures per month, and the total number of processed cultures will be calculated automatically
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the total number of 1st- and 2nd-line LJ cultures performed during the period calculated with method 1 or 2 and the repeat rate. If the user used both methods, a value between that found with method 1 and 2 is entered.

ii) all the values in the column "Needs per test" according to the laboratory's standard operating procedure (SOP). The table includes default values that should be modified according to the user's laboratory SOP.

17. Mycobacteria growth indicator tube (MGIT) 1st-line drug-resistance testing (DST)

The user can use one of two methods for calculating the items and costs for MGIT 1st-line DST and for pyrazinamide DST.

- ✓ Method 1: This method is based on the average number of tests performed per month, either past or expected. Users should enter the number of tests performed per month, and the total number of tests will be calculated automatically.
- ✓ In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

the total number of MGIT 1st line (SIRE kit) and pyrazinamide DST used during the period calculated with method 1 or 2 and the repeat rate. If the user used both methods, a value between that found with method 1 and 2 is entered.

18. Mycobacteria growth indicator tube (MGIT) 2nd-line drug-resistance testing (DST)

The user can use one of two methods for calculating the items and costs for MGIT 2nd-line DST.

- ✓ Method 1: This method is based on the average number of tests performed per month, either past or expected. Users should enter the number of tests performed per month, and the total number of tests will be calculated automatically.
- ✓ Method 2: In this method, the epidemiological data entered on the "Epidemiology" sheet are used. The user enters the percentage value in accordance with the algorithm implemented or to be implemented.

Once method 1 and/or 2 are completed, the following information must be entered:

i) the drug formula in the drop-down menu, "Lyophilized vials" or "Pure drug substances"; and

ii) the total number of MGIT 2nd-line DST used during the period calculated with method 1 or 2 and the repeat rate. If the user used both methods, a value between that found with method 1 and 2 is entered.

19. Biosafety and cleaning

The user should enter the number of staff and number of biosafety cabinets. The system will calculate and display an itemized list of all the biosafety and cleaning items required for a given period.

20. Maintenance and repair

This sheet provides two separate lists of commonly used laboratory equipment: one for equipment for which there are annual service and maintenance contracts and one for equipment for which there are no such contracts. For the latter, the cost of repair is estimated to be 10% of the equipment price.

Users should enter the number of units of all equipment. Blank cells are provided for users to enter additional equipment not listed on the Excel sheet. A €/US$ converter is provided at the top of the sheet for items priced in € on the Global Drug Facility sheet.

21. Budget summary

This sheet is filled in automatically once all the data have been entered on the sheets “Biosafety and cleaning” and “Maintenance and repair” .

World Health Organization

For further information, please contact:

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9789240038134