

Guide for Using the GDF Spreadsheet for Calculating TB Drugs

GDF is pleased to present an improved spreadsheet for calculating TB drug requirements during GDF missions. This spreadsheet replaces all former versions. The tables relating to drug quantities in the Mission Checklists Guidelines will be filled with the data from this spreadsheet.

Purpose

The spreadsheet has been specially developed for use by GDF consultants during country missions to calculate (with the NTP staff) the anti-TB drug quantities to be ordered as part of the next GDF Grant or Technical Agreement. The spreadsheet can also be used for other purposes, including to:

- Calculate the "rational" stock of a particular medicine
- Compare the costs of different regimens
- Calculate the cost per patient treatment and develop different "what-if" scenarios

The spreadsheet is a Microsoft Excel Template (*.xlt), so it will always open as a new sheet and it is impossible to accidentally write over the original version.

When saving a copy of the spreadsheet for a specific country, please follow the standard GDF naming format: "YYYYMMDD Country Adult/Paed Term Year DCS.xls". The date for the title should correspond to the most recent date you work on the spreadsheet (today's date), not the original date the calculation was done. This naming system allows you to easily keep track of different drafts.

For example, possible names could include:

- 20090815 Uganda Adult T1Y3 DCS.xls
- 20091225 Peru Paeds T1Y1 DCS.xls

The GDF TB Drug Calculation Spreadsheet has 7 worksheets, each with a separate tab:

- **Country and Date:** Enter the country name and date. The date should be from the most recent stock levels available.
- **Dosages Adult:** Enter the number of adult patients to be treated with Patient Kits and/or by the different treatment regimens.
- **Dosages Paeds:** Enter the number of paediatric patients to be treated by the different drug regimens.
- **Useable Stock Level Calculation:** Enter all data on stock levels and expiration dates. This sheet allows you to determine whether a country can realistically use the stock it has before it expires.
- **Quantities:** This sheet calculates the quantities required for each product, given the annual rate of consumption, stock level, and pending deliveries. It shows the estimated date of arrival for the regular order and the latest an accelerated order must arrive to prevent stockouts.
- **Order:** The order sheet translates the calculated quantities into an accelerated and regular order. This worksheet provides estimations of the total cost of the order, including related costs such as quality assurance, freight, and insurance. Please note the DCS is only an estimate and should not be considered as an official invoice. The exact costs of an order will be communicated to a country by GDF's procurement agent through an official proforma once all suppliers and sub-contractors have provided confirmed quotations.
- **Prices:** These prices are the lowest possible prices per product that GDF is able to provide under its current agreement with its suppliers. In some circumstances (capacity of supplier, urgency of

order, or registration requirements in-country), the primary supplier may not be selected, which could result in slightly higher prices.

The DCS is designed to be simple to use and very few entries are required. All cells where data from the consultant is needed are shaded in yellow. **CHANGING ANYTHING NON-SHADED CAN RESULT IN ERRORS. PLEASE MAKE SURE YOU ALWAYS SAVE A BACKUP COPY BEFORE EXPERIMENTING WITH THE CELLS THAT CONTAIN FORMULAS.**

STEP BY STEP GUIDE TO COMPLETING THE CALCULATION SPREADSHEET

Sheet 1: Country and Date

In cell **C4**, enter the name of the country and the type of calculation (Adult, Paeds).

In cells **A7**, **B7** and **C7**, click on each of the cells' drop down menus to choose the date, month and year that correspond with the stock levels you are using for the DCS. This date is used to calculate rational stock levels, delivery lead times, and the dates drugs are required. It should correspond to the stock levels you are entering. For example, countries often collect data on actual stock levels at the regional and district level on a quarterly basis. In these cases, if you are using stock data from the close of Q2 for your calculation (even if the mission takes place in September), enter the date as 30 June 2009 in Line 23.

Sheet 2: Dosages Adult

(Skip the table of Rows 3-17, which serves as a control and will be used later in the process)

Patient Kits

Complete the number of patients that will be treated with patient Kits of each category in cells **D21-D23** and **E21-E23** for Category I + III patients respectively and in cells **D27-30** for Category II patients. Leave all cells that are not applicable blank.

Stop TB Patient Kits contain a complete supply of the appropriate drugs to treat one (1) patient per Kit. The quantities of drugs in the Kits are based on the average weight band of 40-54 Kg. The Kits are available for the following regimens:

Category I + III Patients:

Kit A: 2(RHZE)/4(RH)

Kit B: 2(RHZE)/6(EH)

Kit C: 2(RHZE)/4(RH)₃

All Cat I+III Kits contain 6 blisters (RHZE) of 28 tabs =168 tabs (56 doses of 3 tabs) for the intensive phase. For the continuation phase:

Kit A: 12 blisters of R150/H75 of 28 tabs = 336 tabs (112 doses of 3 tabs)

Kit B: 12 blisters of E 400/H150 of 28 tabs = 336 tabs (168 doses of 2 tabs)

Kit C: 6 blisters of R150/H150 of 28 tabs = 168 tabs (56 doses of 3 tabs)

Category II Patients:

Kit A1: 2S(RHZE)/1(RHZE)/5(RHE) with Auto Disabling (AD) syringes

Kit A2: 2S(RHZE)/1(RHZE)/5(RHE) with standard syringes

Kit B1: 2S(RHZE)/1(RHZE)/5(RH)E with AD syringes

Kit B2: 2S(RHZE)/1(RHZE)/5(RH)E with standard syringes

All Kits contain 9 blisters (RHZE) of 28 tablets = 252 tabs (84 doses of 3 tabs) and 60 units each of Streptomycin 1g, Water for Injection 5ml, and syringes (AD in Kit A1 and B1; standard in Kit A2 and B2) for the intensive phase. For the continuation phase:

Kit A1 and A2: 15 blisters of R150/H75/E275 = 420 tabs (140 doses of 3 tabs)

Kit B1 and B2: 15 blisters of R150/H75 = 420 tabs (140 doses of 3 tabs)

10 blisters of E400 = 280 tabs (140 doses of 2 tabs)

NB: All calculations in the spreadsheet are based on an assumed average weight band of 40-54 kg for all patients and on 28 doses per month for daily and 12 doses per month for intermittent regimens.

Separate drugs

Next, determine how many patients will be treated by the NTP during the period for which the drugs are calculated (usually the next 12 months). Choose which treatment regimens will be used and the number of patients for each regimen by entering patient numbers into the two separate tables for Intensive and Continuation Phases (D38-D87). Please note Cells D66 and D88 are calculated automatically. For the purposes of this calculation Stop TB Patient Kits are calculated separately and the patients should not be included in the cells mentioned above.

These entries should be the number of patients anticipated to be treated in the following 12 month period. The numbers should be based on historical data that is adjusted to anticipate future changes.

It is possible to combine different regimens and/or patient Kits for different patients within the same category. Take care to ensure the total number of patients entered per category, regardless of regimen, corresponds to the total number of patients to be treated in that category. Also, be sure the number of patients in each category of treatment is the same for the Intensive and Continuation Phases.

The small table at the top of the page (A5 to F9) serves as a check to ensure that these two conditions are satisfied. The table calculates the total number of patients in each phase and category from the data entered in all the yellow shaded cells. If you have entered different numbers of patients within the categories or between the Intensive and Continuation Phases, this table will give an error message. The patient numbers for the different categories, regimens, and phases should be reviewed and adjusted to match the total number of patients intended for treatment.

In many cases Category I and III patients are treated with same regimens, especially when using patient Kits. However, if information is available regarding the numbers of patients in each of these categories, it should be entered separately in the treatment regimen and patient kits table. If this information is not available, for purposes of drug requirements, all patients should be entered under Category I (with an accompanying note stating that Category III patients are included with Category I patients¹.)

The dosages for each regimen can be adjusted in the table to the right of the regimens. **In general, as these dosages are based on WHO Treatment Standards, it is not recommended to make adjustments.** However, it may be useful to adjust the number of tablets per day to better reflect the average weight of the population served or the total number of days per treatment month (28 vs 30 days). If this is done, **please shade the changes in green so that the GDF Secretariat and the Technical Review Committee (TRC) can better evaluate the appropriateness of this choice.** Also indicate in a separate note or in the mission report checklist what changes were made and for what reasons.

D96 is an automatic calculation of single drug formulations for patients who experience adverse reactions to one or more of the drugs in the standard regimens. Enter a percentage (between .5% and 2%) and the sheet will automatically calculate the separate drugs needed to treat the few patients with adverse reactions.

Sheet 3: Dosages Paeds

(Skip the table of Rows 2-19, which serves as a control and will be used later in the process)

¹ Nevertheless, an effort should be made to insure the availability of such data in the future (it is essential to know the number of patients in all categories of treatments including Cat I and Cat III. This is to establish whether the programme is following the principles of the DOTS strategy for method of diagnosis, e.g. a high proportion of Cat III may indicate over reliance on x-ray or less emphasis on sputum smear microscopy).

Paediatric Prophylaxis

Complete the number of paediatric patients that will be provided prophylaxis in cells **D25** and **D26**. In absence of country-specific data, estimate 2/3 of paediatric cases as 0-35 months and 1/3 as 36-60 months. Leave all cells that are not applicable blank.

You can estimate the number of paediatric cases as a percentage of the adult smear positive and smear negative cases in **D36** and **D37** - WHO estimates paediatric cases to be (on average) between 10% and 20%, however this percentage can vary depending on local circumstances. Enter the actual number of paediatric patients to be treated in **D39**.

Separate drugs

The GDF DCS allows for the quantification to be based on the Interim WHO Guidelines for the Treatment of TB in Children and the Previous WHO Guidelines for the Treatment of TB in Children. During the transition period, GDF will supply drugs according to either guideline. If a country has not yet shifted to the Interim Guidelines, please skip the area highlighted in green and enter data only in the area highlighted in blue.

In the relevant section, enter the number of patients that will be treated by the NTP during the period for which the drugs are calculated (usually the next 12 months). Choose which treatment regimens will be used and the number of patients for each regimen by entering patient numbers into the two separate tables for Intensive and Continuation Phases:

- Interim WHO Guidelines: **D62-D92**. Please note Cells D79 and D92 are calculated automatically.
- Previous WHO Guidelines: **D102-135**. Please note Cells D122 and D136 are calculated automatically.

These entries should be the number of patients anticipated to be treated in the following 12 month period. The numbers should be based on historical data that is adjusted to anticipate future changes.

It is possible to combine different regimens for different patients within the same category. Take care to ensure the total number of patients entered per category, regardless of regimen, corresponds to the total number of patients to be treated in that category. Also, be sure the number of patients in each category of treatment is the same for the Intensive and Continuation Phases.

The small table at the top of the page (A25 to G13) serves as a check to ensure that these two conditions are satisfied. The table calculates the total number of patients in each phase and category from the data entered in all the yellow shaded cells. If you have entered different numbers of patients within the categories or between the Intensive and Continuation Phases, this table will give an error message. The patient numbers for the different categories, regimens, and phases should be reviewed and adjusted to match the total number of patients intended for treatment.

In many cases Category I and III (previous WHO Guidelines for the Treatment of TB in Children) paediatric patients are treated with same regimens. However, if information is available regarding the numbers of patients in each of these categories, it should be entered separately in the treatment regimen and patient kits table. If this information is not available, for purposes of drug requirements, all patients should be entered under Category I (with an accompanying note stating that Category III patients are included with Category I patients².)

² Nevertheless, an effort should be made to insure the availability of such data in the future (it is essential to know the number of patients in all categories of treatments including Cat I and Cat III. This is to establish whether the programme is following the principles of the DOTS strategy for method of diagnosis, e.g. a high proportion of Cat III may indicate over reliance on x-ray or less emphasis on sputum smear microscopy).

The dosages for each regimen can be adjusted in the table to the right of the regimens. **In general, as these dosages are based on WHO Treatment Standards, it is not recommended to make adjustments.** However, if you do adjust the number of tablets per day to better reflect the local circumstances or national guidelines (number of tablets, days per treatment month), **please shade the changes in green** so that the **GDF Secretariat and the Technical Review Committee (TRC) can better evaluate the appropriateness of this choice.** Also indicate in a separate note or in the mission report checklist what changes were made and for what reasons.

