Guidelines for Multi-Month Prescribing and Treat All Calculator

I.   Summary Description

ART programing adopted two new global initiatives in 2016: 1) "Treat all" (also known as test and start, or treat and treat), whereby anyone who tests positive for HIV, is immediately eligible for receiving ARVs; and 2) "Multi-month prescribing ," whereby depending on the HIV treatment and patient eligibility guidelines in a country, ART patients may receive several months of ART regimens at one time, and will not need to return to health facilities and/or clinics monthly to receive their ARV supply.   Both goals will aim to assure improved adherence to ART, quicker and better control of HIV for new patients, and contributing to cost savings for health care systems (by limiting patient visits), and for patients (by decreasing the number of visits to health facilities to obtain ARVs).

However, implementation of multi-month prescribing and treat all are likely to increase the quantity of ARVs needed within a health system.   Treat all will bring more new patients into ART quicker, and multi-month prescribing will require an initial scale-up and pre-positioning of ARVs, to assure that any eligible patient could receive several months of ARVs during an upcoming visit to a health facility/clinic.

Therefore, USAID's Supply Chain for Health team has put together a multi-month prescribing/treat all ARV Planning Tool to help countries consider their ARV procurement and supply chain planning for implementing the two initiatives. The tool allows countries to input the total number of stable patients (eligible for multi-month prescribing , and newly identified HIV positive patients starting ART (new patients to be enrolled in ART via Treat All) and determine the number of ART treatments (1 treatment=1 ART patient), needed to start and implement multi-month prescribing and treat all over a three year period. This should help countries identify the initial "bump" of additional ARV treatments needed to implement multi-month prescribing and treat all in year one, and note how many additional ARV treatments are needed in years 2 and 3, as new HIV positive patients become stable and eligible for multi-month prescribing, while new patients are enrolled in ART via Treat All. Finally, the tool also provides countries an estimate of the number of ARVs needed to transition a country's care and treatment programs from monthly prescribing to 2-, 3-, 4-, or 6-months multi-month prescribing programs.

II.   Abbreviations

MMP- Multi-month prescribing
PLWHIV- People living with HIV/AIDS
ART- Antiretroviral treatment
ARV- Antiretroviral drugs

III.   Objectives

1)   This tool intends to help country governments, donors, and other stakeholders consider the total amount of ARV treatments (1 ARV treatment=1 ART patient) needed to implement multi-month prescribing (MMP) and treat all programs.

2) The tool aims for countries to explore the additional amount of ARV treatments needed, and the time period needed to shift a care and treatment program from monthly prescribing to a 2-, 3-, 4-, or 6-month multi-month prescribing.

3) The tool helps countries understand the impact of treat all (test and start) programs; particularly how new patients will impact future needs for ARV treatments, and as the new patients become identified as "stable" and eligible for MMP.

4) The tool also provides stakeholders an opportunity to model and note the total number of extra ART treatments needed to "jump-start" multi-month prescribing and treat all.

IV.   Data Needed for Using Tool

Anyone using the tool needs two data points:

1) Number of Existing (Stable) Patients on ART- This will feed into calculations on the different models for MMP (2-, 3-, 4-, or 6-months), and note when these patients will receive ART, and how many additional ARV treatments are needed each year (as compared to the baseline of current monthly-MMP) to implement MMP.

2) Total Number of New HIV+ Patients- This will feed into calculations for the number of people that will be identified as HIV+, and starting ART due to treat all, and the number of additional ARV treatments needed to assure ARVs are available for the new patients.   Further, this model assumes individuals will become eligible for MMP one-year after starting ART, and will increase the total number of ARVs needed for MMP in subsequent years.

Since this tool can be used for modeling and exploratory purposes, users of the tool can enter any number of existing stable patients on ART, and of new HIV+ patients. The data entered in this tool does not have to be the exact or current data found in HIV care and treatment programs.

Further, the tool allows for estimating the number of ARV treatments needed for MMP and Treat All, for three years. This requires the number of existing (stable) patients on ART, or total number of new HIV+ patients to be entered for years 1, 2, and 3.

Yet, the tool could be used for only identifying ARV needs for year 1 (and not entering the needed date for years 2 and 3), or years 1 and 2 (and not entering the needed data for year 3).

Additionally, the tool could be used for only identifying ARV treatments needed for MMP (and not entering data regarding the new HIV+ patients); or for only identifying ARV treatments needed for Treat all (and not entering data regarding the number of existing (stable) patients on ART).

V.   Data/Tool Considerations

1) This tool should be used for modeling purposes-only, and the results of the tool should not be the basis for actual program implementation, procurement, or other program management activities, as further discussion, analysis, and decision-making with various stakeholders is needed.

2) Anyone using this tool, should feel free to adjust the number of existing (stable patients) and total number of new patients for years 1, 2, and 3, as needed to reflect the reality of their country, current and future HIV treatment target, and/or for modeling out scenarios regarding MMP and treat all.

3) The definition of stable patients (the basis for determining multi-month prescribing) is up to the user to define. There is no set definition for this tool, adjust as needed. This tool assumes all stable patients in year 1, will remain stable patients in years 2 and 3; and stable patients in year 2 will remain stable patients in year 3.

4) This tool considers all "new" patients (part of treat all) to become "stable" patients and eligible for multi-month prescribing, after 1 year. However for the first year after a patient begins ART, they will receive their ARVs on a monthly basis, and transition to multi-monthly prescribing, exactly 1 year after starting ART.

   For example, a new patient that begins ART in month 3 of year 1, will receive monthly ARV prescribing for the remainder of year 1 (months 4-12), and the beginning of year 2 (months 1 and 2); however, starting in month 3 of year 2, this patient would be considered stable (and eligible for MMP) and will start receiving multi-month prescribing for the remainder of year 2 and all of year 3.

   This tool determined a 1 year period was appropriate for moving new patients from monthly prescribing to multi-month prescribing,   as a new patient will have likely gone through two viral load tests, and there will be a lengthy record to note patient adherence to ART, or reaction to different regimens.

5) The number of new HIV+ patients, is defined as the forecasted number of patients who will test positive for HIV in the upcoming year, and become eligible to receive ART; or the number of current PLWHIV that are now eligible for ART, given that their CD4 count is >500 (from when they were last tested). This is completely open to edit and adjustment as needed, based on the forecasted testing, and positivity rates in a country, the population of PLWHIV with CD4 above 500, or other scenarios the user would like to model.

6) Additionally, the number of new HIV+ patients is not "dynamic", instead we are assuming new HIV+ patients will enroll into treatment uniformly across each of the 12 months in the tool. Thereby, the number of new HIV+ patients for each year is a compound rate. Seasonality of HIVE testing and ART enrollment is not considered in this tool.

7) This model assumes a "symmetrical" implementation of multi-month prescribing across a "group" of patients that is a factor of 12. It is possible to adjust the number of patient groups to

reflect the reality of a country (such as the implementation of multi-month prescribing would take place over 10 regions, or 30 health centers, etc).

8) This tool can only model multi-month prescribing and treat all either nationally (all levels of a country's health system/supply chain), or across one-level of a health system/supply chain (i.e. provincial/regional, district, health facility, etc). The tool is unable to differentiate between and/or link the various levels of a health system/supply chain.

   This means if:
   - The tool is used at a national level, one would observe how multi-month prescribing and treat all would affect all PLWHIV in the country.
   - The tool is applied at the provincial/regional level, the tool is noting the number of ARV treatments needed for all PLWHIV within a province/region;
   - The tool is applied at the district level, the tool is noting the number of ARV treatments needed for all PLWHIV within a district; etc.
   - The tool is applied at the health facility/clinic level, the tool is noting the number of ARV treatments needed for all PLWHIV that receive their ARVs from that health facility/clinic.

9) This tool does not account for any stock-on-hand in country, or for future procurement via supply plans. Essentially, this tool provides the number of ARV treatments needed each month for ART patients (stable, new, and patients from the previous year becoming stable). Essentially the tool acts as though there is zero ARVs in-country as of month 1, year 1. Further the tool assumes 100% consumption each month, and there is no extra ARVs remaining from the previous month that could be applied for the treatment of patients in future months.

10) For each MMP scenario spreadsheet, there is an area in year 1, surrounded by a doted red line. This represented the phase-in period for starting multi-month prescribing. The tool assumes an even phase-in period of:

- 2 months for 2-month multi-month prescribing;
- 3 months for 3-month multi-month prescribing;
- 4 months for 4-month multi-month prescribing; and
- 6-months for 6-month multi-month prescribing.

It's possible to phase-in multi-month prescribing during other time periods (all at once, or over several months to years).   However, the purpose of this tool is to only consider the ARV treatments needed for implementing multi-month prescribing and treat-all under 2-, 3-, 4-, or 6-month multi-month prescribing scenarios.

Overall, PEPFAR has noted that a shorter phase-in period would mean the system would require less ARV treatments cumulatively for the entire year, but more ARV treatments at the start of implementation. A longer phase-in period requires more ARV treatments cumulatively for the year, but less ARV treatments at the beginning of implementation. PEPFAR is also testing a tool to model 3-month multi-month prescribing from implementing all at-once through a slow phase-in over 12 months. A similar model is being developed for moving from 3-month multi-month prescribing to 6-month multi-month prescribing.

11) It is possible to complete 5-, 7-, 9-, 10-, or 11-month multi-month prescribing. However, after modeling this, PEPFAR noted that this would mean patients would receive their ARVs during different months from year to year. This could lead to issues with adherence, and thereby PEPFAR decided to not continue modeling multi-month prescribing for these scenarios.

12) Since 1 ARV Treatment= 1 ART Patient, by noting the total number of ARV treatments needed resulting from this model; a country could apply their treatment guidelines and care and treatment data (% of patients on first-, second-, or third-line; % of adult-, pediatric-, adolescent-, PMTCT-patients; % of patients on different formulations, etc), to determine the quantity of actual ARV formulations used for care and treatment programming.

VI. Instructions

1) Fill-In All Cells Marked in Green on the "Start- Input and Assumptions" spread sheet.

The information noted in the green cells will pre-populate cells in the 2 month-, 3-month, 4-month, 6-month, and "total" spreadsheets, to provide an idea of how many ARV treatments are needed for implementing multi-month prescribing and treat all over a 3 year period.

VII. Results/Outputs

The tool provides several results/outputs for countries to consider as they plan their implementation of multi-month prescribing and treat all. This includes:

- Number of Additional ARV Treatments Needed (founded on the far right columns at the end of year's table, in each multi-month prescribing model spreadsheet):
  - Extra ARV Treatment Stock needed to Assure Month Multi-Month Prescribing under this model:
    - The results found in this cell notes the additional ARV Treatments needed under the multi-month prescribing scenario (2-, 3-, 4-, or 6-months) as compared to the number of ARV Treatments needed for monthly prescribing.
  - Extra Months of ARV Treatment Stock Needed to Implement 2 Month Multi-Month Prescribing from beginning of the year:

- - - The results found in this cell notes the additional ARV Treatments needed under the multi-month prescribing scenario (2-, 3-, 4-, or 6-months) as compared ot monthly prescribing, and expressed in months of ARV Treatments.
    - o Extra ARV Treatment Stock Needed for New Patients under Treat All:
      - - The results found in these cells notes the additional ARV Treatments needed for adding new patients via Treat all (test and start).
    - o Extra Months of ARV Treatment Stock Needed to Implement Multi-Month Prescribing and Treat All:
      - - The results found in this cell notes the additional ARV Treatment needed for implementing multi-month prescribing scenario (2-, 3-, 4-, or 6 months) and the additional ARV Treatments needed for all new patients added via Treat All, as compared to monthly prescribing, and expressed in months of ARV Treatments.

- Graphs charting the volume of ARV treatments (MMP vs. Treat All) needed for each year of implementation:
  - o These graphs provide a visualization of the total volume of ARV treatments needed under each model, highlighting the total amount of ARV treatments needed for MMP versus Treat All.
    - - The graphs include:
      - - A dotted line noting the total number of ARV treatments needed for both Multi-Month Prescribing and Treat All
      - - The total volume of ARV Treatment needed for Multi-Month Prescribing
      - - The total volume of ARV Treatment needed for New Patients starting on ART (and receiving monthly prescribing)- *only found next to the tables for years 1, 2, and 3*
      - - The total volume of ARV Treatments for new patients transitioning from monthly prescribing on Treat All, to multi-month prescribing- *only found next to the tables for year 1, 2, and 3*
      - - Total volume of all ARV Treatments from Treat All (New Patients on monthly prescribing plus the New Patients still on monthly prescribing before transferring to multi-month prescribing after one-year on ART*)- only found under the grand total table*

- Totals Spreadsheet:
  - o Graph 1: Comparison of Model Results Across MMS and Treat All Scenarios
    - - The table includes the number of ARV Treatments needed (for both multi-month prescribing and Treat All) across all three years of the model for each of the multi-month prescribing scenarios.
    - - The graph, expresses the total number of ARV Treatments needed in the table. It's key to highlight that by the end of each multi-month prescribing period (2-, 3-, 4-, or 6-months) the number of ARV Treatments needed is exactly the same.

- o Graph 2: Number of Extra Months of ARV Stock Needed to Implement MMP and Treat All
    - ▪ The table and graph note the total number of ARV Treatment stock needed (expressed in months of treatment) for each of the multi-month prescribing scenarios over the three years period measured in the model.
        - For most scenarios, the highest amount of ARV Treatments needed is in year 1, when extra ARV treatments will need to be available for starting multi-month prescribing.
        - In subsequent years, the number of extra ARV Treatments needed is driven by the number of new patients starting monthly prescribing during Treat All.