User Guide: Costing Model for CD4 and Viral Load Transition

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Introduction

This tool allows you to model different scenarios of viral load and CD4 transition based on different testing algorithms and programmatic scale-up rates. It will estimate the costs of your testing program based on a projected number of tests, including the costs of commodities, equipment, changes in ARV use, sample transport, results delivery, human resources, training, and data management for viral load and the costs of commodities only for CD4. It allows you to scale-up VL testing for ART patients, while scaling-down CD4 for routine ART monitoring and maintaining other types of CD4 testing (baseline, Pre-ART, opportunistic infections, etc.).

The tool measures:	The tool does not measure:
• Viral load costs, including commodities, equipment, drugs, sample transport, results delivery, human resources, training, and data management	• Outline on current manufacture relabeling practices • Secondary/literature research on manufacturer barriers and decisions • Potential decreases in commodity costs associated with global scale-up of VL
• CD4 commodity costs	• Comprehensive CD4 costs, including equipment, drugs, sample transport, results delivery, human resources, training, and data management
• Changes in treatment costs	• The full costs of treatment

You will begin with the Data & Assumptions tabs (Patient & Dx and Systems). All user-entered required cells are in yellow. For some assumptions, the tool provides guidance to facilitate entry if the required data is unavailable for your program. After entering the necessary information on these tabs, the Summary tab provides an estimate of program costs based on your population and program scale-up specifications.

Before starting the exercise:

Before you begin, you will need to gather the necessary data and information on patient populations, instrument usage, sample collection, ARV regimens, and programmatic costs. Guidance is provided for some of the assumptions where data may be limited. A complete list of necessary data and assumptions and associated guidance is provided at the end.

Step One: Data & Assumptions – Patient & Dx

In this section, you will enter information on your patient populations, testing algorithms, scenario parameters, testing instruments, sample collection, and laboratory commodity costs. All yellow cells in sections 1-4 must be filled in order to project testing volumes over the period of the model. Each additional section is necessary in order to include the specific costs to which they pertain in the costing model.

1. Patient Population Data

Timeframe

The tool is designed to model costs for a period of 3 years into the future. Under "Timeframe for Scale-up," you should begin with the previous year, or the year prior to scale-up initiation (Year 0), and enter the following 3 years.

Patient population for ART and Pre-ART

This section should be based on your HIV/AIDS population forecasts for ART and Pre-ART. You will begin with the number of patients in each category (Adult, Pregnant Women, and Children) at the end of the year prior to the beginning of your modeling (Year 0).

For the ART population, you will enter the total number of Adults, Pregnant Women, and Children, which should include both 1st and 2nd line patients. In the following cells, you will enter the current (Year 0) number of patients on second line. Because the pregnant women category should encompass a transitory group where women will enter and leave this group within approximately 12 months, the tool considers all pregnant women entered for each year as "new" to the group and on first line.

2. Assumptions – patients on Pre-ART & ART Testing Flow

In this section you will enter assumptions on the testing and movement of patients in Pre-ART and ART, including Pre-ART to ART migration, loss-to-follow-up rates, suspected failure rates, and switch rates. It is separated into sections for Pre-ART and ART Adult, ART Pregnant Women, and ART Children. We have provided guidance next to these cells if data from your program is not available. Users should attempt to gather the necessary data from their program or tailor the assumptions as much as possible to their specific circumstances.

Pre-ART

Pre-ART to ART Migration Rate for Adults & Children

These rates pertain to the percent of the Pre-ART population that will initiate ART in a given year. The number who migrate from Pre-ART to ART differs from the total number

of new ART patients because the former does not include those who go directly from test-to-treatment.

$$\frac{\text{\# of Pre-ART patients who initiate ART in year}}{\text{\# of Pre-ART patients in year}}$$

Attrition Rate Adults & Children patients in Pre-ART

This is the percent of the Pre-ART populations who will be lost-to-follow-up over the course of one year. This does not include those who migrate from Pre-ART to ART.

$$\frac{\text{\# of Pre-ART patients lost to follow-up in year}}{\text{\# of Pre-ART patients in year}}$$

Additional Pre-ART Adults & Children CD4 Provider-Initiated Testing

This pertains to the percent of Pre-ART patients who will receive an additional provider-initiated CD4 test during the year outside of the routine Pre-ART CD4 testing algorithm that is set in the given scenario (Section 8: Scenario Parameters). If users do not anticipate additional provider-initiated CD4 testing, this can be left blank.

$$\frac{\text{\# of provider-initiated Pre-ART CD4 tests in year}}{\text{\# of Pre-ART patients in year}}$$

ART

The user-entered required cells described below apply to Adults and Children and should be entered separately in the tool. User-entered assumptions are also required for pregnant women and are similar to the Adult and Children sections although briefer given that pregnant women should be considered as part of adults once breastfeeding is completed and the tool assumes all pregnant women will be on 1st line ARV.

2nd Line Switch Rate with CD4 Monitoring Only

This pertains to the percent of 1st line ART patients who will switch to 2nd line regimens over the course of a year following CD4 monitoring only (no viral load testing). If viral load testing has not begun in your program, the switch rate (# of new 2nd line patients/total 1st line patients) from the previous year (Year 0) can be used to approximate this rate.

$$\frac{\text{\# of 1st line patients who switch to 2nd line under CD4 monitoring in year}}{\text{\# of 1st line patients in year}}$$

2nd line Switch Rate with VL monitoring of suspected failure & 2nd line Switch Rate with Routine VL Monitoring

These rates will be automatically calculated based on the testing assumptions entered in the following two sections.

$$\frac{\text{\# of 1st line patients who switch to 2nd line after VL testing for suspected treatment failure in year}}{\text{\# of 1st line patients in year}}$$

$$\frac{\text{\# of 1st line patients who switch to 2nd line under routine VL testing in year}}{\text{\# of 1st line patients in year}}$$

Suspected Failure

The assumptions in this section should pertain to a scenario in which viral load testing is only used to confirm suspected failures as ordered by a healthcare provider. No routine viral load is assumed in these rates. If users are not including suspected failure testing in chosen scenarios (Section 8), this section can be left blank.

Patients on 1st Line Suspected to be Failing (1st VL Testing)

This pertains to the percent of patients on 1st line that will have a viral load test due to suspected virological failure in a given year. Suspected failure can be based on clinical or immunological monitoring. This is not the same as the number of viral load tests divided by the 1st line population, since patients could have more than one viral load test in a given year.

$$\frac{\text{\# of 1st line patients who receive a VL test due to suspected failure}}{\text{\# of 1st line patients in year}}$$

Patients retested after adherence and counseling (2nd VL Test)

This pertains to the percent of patients who received an initial suspected failure test who will receive a second viral load test. This involves the number of those who initially test above the viral load threshold, initiated adherence counseling, and then receive a second test after adherence counseling.

$$\frac{\text{\# of patients who receive a 2nd VL test following suspected failure}}{\text{\# of 1st line patients who received a VL test due to suspected failure}}$$

or

$$\frac{\text{\# 1st VL>threshold}}{\text{\# of received VL test due to suspected failure}} * \frac{\text{\# initiate adherence counseling}}{\text{\# 1st VL>threshold}} * \frac{\text{\# receive 2nd test}}{\text{\# initiate adherence counseling}}$$

Patients Virologically failed (2 VL>1000 copies) switched to 2nd line

This pertains to the percent of patients who were tested twice who are subsequently switched to a 2nd line regimen. This involves the number of twice-tested patients who will test above the viral load threshold and the percent of those patients who will ultimately be switched to 2nd line.

$$\frac{\text{\# of patients who switch to 2nd line under suspected failure testing}}{\text{\# of 1st line patients who received 2 suspected failure VL tests}}$$

or

$$\frac{\text{\# of patients with 2nd VL>threshold}}{\text{\# of patients who receive 2nd test}} * \frac{\text{\# of patients who switch to 2nd line}}{\text{\# of patients with 2nd VL>threshold}}$$

Patients on 2nd line suspected to be failing

This pertains to the percent of second line patients who will receive a provider-initiated VL test for suspected failure (based on clinical or immunological monitoring).

$$\frac{\text{\# of 2nd line patients who receive a VL test due to suspected failure}}{\text{\# of 2nd line patients in year}}$$

Patients on 2nd line retested after adherence and counseling

This pertains to the percent of 2nd line patients who received a suspected viral load test who are then retested after adherence counseling. It includes both the percent of those tested with VL > 1000 copies and the percent of those patients who are subsequently retested.

$$\frac{\text{\# of 2nd line patients who receive a 2nd VL test following suspected failure}}{\text{\# of 2nd line patients who received a VL test due to suspected failure}}$$

or

$$\frac{\text{\# of 2L patients with 1 VL>threshold}}{\text{\# of 2L patients who received 1 VL test due to suspected failure}} * \frac{\text{\# of 2L patients who receive 2nd test}}{\text{\# of 2L patients with 1 VL>threshold}}$$

Patients switched to 2nd line after only 1 VL test > 1000 copies

This pertains to the percent of 1st line patients who switch to 2nd line after only 1 suspected failure viral load test above threshold. This is used in a scenario in which patients switch to 2nd line without adherence counseling following a VL > 1000 copies.

$$\frac{\text{\# of 1st line patients switched to 2nd line after 1 VL test due to suspected failure}}{\text{\# of 1st line patients who received a VL test due to suspected failure}}$$

or

$$\frac{\text{\# of patients with 1 VL>threshold}}{\text{\# of patients who receive 1st test}} * \frac{\text{\# of patients who switch to 2nd line after 1st test}}{\text{\# of patients with 1 VL>threshold}}$$

Routine Monitoring

The assumptions in this section should pertain to a scenario in which patients receive routine viral load monitoring based upon the testing algorithms entered in Section 4. If users are not including routine testing in chosen scenarios (Section 8), this section can be left blank.

Virological Failure on 1st Line because VL>1000 copies

This pertains to the percent of 1st line patients who will have a routine viral load test that is above the threshold in a given year.

$$\frac{\text{\# of 1L patients with first routine monitoring VL>threshold in year}}{\text{\# of 1st line patients in year}}$$

Patients retested after adherence and counseling (2nd VL Test)

This pertains to the percent of patients with an initial VL result above the threshold who will receive a second viral load test. This involves the number of those who initially test above the viral load threshold, initiated adherence counseling, and then receive a second test after adherence counseling.

$$\frac{\text{\# of patients who receive a 2nd VL test following adherence counseling}}{\text{\# of 1st line patients with routine VL>threshold}}$$

or

$$\frac{\text{\# of patients who initiate counseling}}{\text{\# of patients with 1 routine VL>threshold}} * \frac{\text{\# of patients retested following counseling}}{\text{\# of patients who initiate counseling}}$$

Patients Virologically failed (VL>1000 copies) switch to 2nd line

This pertains to the percent of patients who were tested twice who are subsequently switched to a 2nd line regimen under routine monitoring. This involves the number of twice-tested patients who will test above the viral load threshold and the percent of those patients who will ultimately be switched to 2nd line.

$$\frac{\text{\# of patients who switch to 2nd line under routine monitoring}}{\text{\# of 1st line patients who received 2 VL tests}}$$

or

$$\frac{\text{\# of patients with 2nd VL>threshold}}{\text{\# of patients who receive 2nd test}} * \frac{\text{\# of patients who switch to 2nd line}}{\text{\# of patients with 2nd VL>threshold}}$$

Virological Failure 2nd Line because VL > 1000 copies

This pertains to the percent of 2nd line patients who will test above the threshold during routine monitoring.

$$\frac{\text{\# of 2L patients with 1 routine VL>threshold}}{\text{\# of 2nd line patients in year}}$$

Patients on 2nd line retested after adherence and counseling

This pertains to the percent of 2nd line patients with virological failure who are retested. It includes both the percent of 2nd line patients with virological failure who initiate adherence counseling and the percent of those patients who are subsequently retested.

$$\frac{\text{\# of 2nd line patients who receive a 2nd VL test following adherence counseling}}{\text{\# of 2nd line patients with virologic failure}}$$

or

$$\frac{\text{\# of 2L patients who initiate adherence counseling}}{\text{\# of 2L patients with 1st VL>1000 copies}} * \frac{\text{\# of 2L patients who receive 2nd test}}{\text{\# of 2L patients who initiate adherence counseling}}$$

Patients switched to 2nd line after only 1 VL test > 1000 copies

This pertains to the percent of 1st line patients who switch to 2nd line after only 1 routine viral load monitoring test above threshold.

$$\frac{\text{\# of 1st line patients switched to 2nd line after 1 routine VL test above>threshold}}{\text{\# of 1st line patients who received a routine VL test}}$$

or

$$\frac{\text{\# of patients with 1st VL>threshold}}{\text{\# of patients who receive 1st test}} * \frac{\text{\# of patients who switch to 2nd line after 1st test}}{\text{\# of patients with 1st VL>threshold}}$$

Loss

Attrition Rate on 1st Line

This pertains to the percent of 1st line patients who are lost-to-follow-up over a year. It includes those who die, but not those who switch to a 2nd line regimen.

$$\frac{\text{\# of 1st line patients lost to follow-up in year}}{\text{\# of 1st line patients in year}}$$

Attrition Rate on 2nd Line

This pertains to the percent of 2nd line patients who are lost-to-follow-up over a year. It includes those who die, but not those who switch to a 3rd line regimen.

$$\frac{\text{\# of 2nd line patients lost to follow-up in year}}{\text{\# of 2nd line patients in year}}$$

3. Testing Algorithms

In this section, you will enter the desired testing algorithm for adults, children, and pregnant women under routine monitoring.

If your program is following the WHO recommended testing algorithm for viral load testing, you can select "Yes" and the algorithm will be prepopulated for you. If not, you must manually enter the algorithm below.

Viral Load

Tests First Year – This is the number of tests a patient who begins ART will receive in their first year on treatment, including baseline testing.

Tests Per Year – on-going – This is the number of yearly tests a patient who has been on ART for more than a year should receive, i.e. the number of yearly tests after 12 months.

Tests – on-going for 2nd line – This is the number of yearly tests a patient on 2nd line ART will receive.

CD4

ART

Tests First Year – This is the number of tests a patient who begins ART will receive in their first year on treatment, including baseline testing.

Tests Per Year – on-going – This is the number of yearly tests a patient who has been on ART for more than a year should receive, i.e. the number of yearly tests after 12 months.

Pre-ART

Tests at Diagnosis – This is the number of tests a patient receives at the time of diagnosis, regardless of whether the patients initiates treatment subsequently or enters Pre-ART care.

Tests First Year (excluding baseline) – This is the number of tests a patient who enters Pre-ART following diagnosis will receive in their first year in care, excluding the test at diagnosis.

Tests Per Year – on-going – This is the number of yearly tests a patient who has been in care for more than a year should receive, i.e. the number of yearly tests after 12 months.

4. Scenario Parameters

This section is where you set the testing scenario that you would like to cost. It involves designating what groups of patients (Adults, PW, Children) will be getting what kind of testing (routine VL, suspected failure, CD4).

Target Population

You can designate only certain groups to be eligible for each type of testing or for the entire population. Selecting "All Patients…" does not mean that 100% of the population will receive testing, but rather that all groups are eligible for testing. Actual service utilization will be determined by scale-up targets set for each type of testing.

Scale-Up Targets

This refers to the percent of the patients in each designated group who will receive testing for each year of scale-up. You do not have to set scale-up targets for groups who are not receiving a particular type of testing.

a. *VL used to confirm suspected failure for patients not receiving VL routine monitoring*
   If Yes, only those who are not receiving routine monitoring (based on the selection in part b) will be eligible for suspected failure VL testing.
   If No, no suspected failure testing will be assumed.
b. *VL used also/only for routine monitoring*
   If Yes, all patients in the designated groups will be eligible for routine VL testing, as determined by the VL testing algorithm set in Part 3.
c. *CD4 used for routine Pre-ART monitoring in addition to provider-initiated testing?*
   If Yes, all patients in the designated Pre-ART groups will be eligible for routine CD4 testing, as determined by the CD4 Pre-ART testing algorithm set in Part 3.
   If No, only provider-initiated CD4 testing for those in Pre-ART will be assumed.
   The number of provider-initiated CD4 tests will be determined by the rate set in Part 2 – "Additional Pre-ART CD4 Provider-Initiated Testing."
d. *CD4 used for routine monitoring of those receiving routine VL monitoring?*
   If Yes, those receiving routine VL testing will also be eligible for routine CD4 testing, as determined by the CD4 ART testing algorithm set in Part 3.
   If No, those receiving routine VL testing will not be eligible for additional CD4 testing.
e. *CD4 used for routine monitoring of those not receiving VL?*
   If Yes, those not receiving routine VL testing will be eligible for routine CD4 testing, as determined by the CD4 ART testing algorithm set in Part 3.
   If No, those not receiving routine VL testing will not receive any routine testing.

5. Testing in Lab

This section allows users to add extra tests that will be required for training, quality assurance, sample rejection, and wastage. These rates will apply both to the quantification of CD4 and VL testing commodities.

$$\frac{\text{\# of tests for training, EQA, sample rejection, or wastage}}{\text{\# of tests ordered}}$$

6. VL PCR Machines and CD4 Machines

In this section, you will enter the instrument distribution of CD4 and VL machines from your program as the percent of total tests performed by each type of machine. The sum of the percent must equal 100%.

$$\frac{\text{\# of tests performed by type of machine year}}{\text{total \# of tests in year}}$$

You must enter the expected instrument distribution for each year of your forecast. If you expect to replace certain machines with a different brand or to purchase additional machines that could change this distribution, this should be reflected in the yearly instrument distribution.

For each machine used, you must also enter the ratio of controls-to-tests. Even if an instrument is not being used, you must enter a non-zero figure for this ratio, though only instruments that are in use and have a non-zero distribution percent will affect the test calculations.

If you are using a type of machine that is not listed, you can replace the name of a machine you are not using in the left-hand column with this machine. For CD4 machines, there is also an "Other" row in which you can add a machine that is not already listed.

7. Sample Collection

This section pertains to the sample collection distribution of viral load tests you expect for your program. The options are DBS (Dried Blood Spot), PPT (Plasma Preparation Tubes), and EDTA (Ethylenediaminetetraacetic Acid Plasma). As with the instrument distribution, these figures must be entered for each year of the forecast and must sum to 100% for the year.

$$\frac{\text{\# of samples collected through method in year}}{\text{total \# of samples collected in year}}$$

8. Diagnostic products for costing

In this section, you will enter the cost per test for sample collection and laboratory testing. The labs costs should include both reagents and consumables, but not the cost of the machines. However, in the case of reagent rental agreements, the cost per test could also include the cost of the instrument and of service & maintenance.

You might also want to add the cost of shipment and distribution to the cost per test to ensure it is captured in the overall costs, as these costs are not included elsewhere in the tool.

Step Two: Data & Assumptions – Systems

In this tab, you will enter cost and distribution information as related to ARV commodities, viral load equipment, sample transportation and results delivery, human resources and training, and data management. If you do not wish to have some of these costs included in your budget projection, you can leave a section blank and the tool will exclude it from the estimation.

1. Drug Costs and Distribution

This section uses the distribution of 1st and 2nd line adult and children ARV regimens and their weighted costs to estimate the (potential) increase in 2nd line use costs following VL

scale-up. This section does not calculate the total treatment costs a country might incur, but only the difference in costs resulting from the introduction of VL testing.

1st and 2nd Line Drug Annual Costs
In this section, you will enter the average cost for each ARV regimen for one year of treatment. The most common regimens are listed, but users can change these or add additional regimens in the "other" cells.

Information on ARV drug prices is available from these sources:

WHO Global Price Reporting Mechanism:
http://apps.who.int/hiv/amds/price/hdd/
MSH International Drug Price Indicator Guide:
http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English
SCMS e-catalog:
http://scms.pfscm.org/scms/ecatalog/arvs

1st and 2nd Line Drug Distribution
In this section, you will enter the regimen distribution for your adult and child ART populations for each year of scale-up, which will be used to calculated a weighted cost of ARV commodities. Each column must sum to 100%.

$$\frac{\text{\# of patients on given regimen}}{\text{total adult or child ART population}}$$

For some regimens, dual (e.g. TDF/3TC + EFV) and triple (TDF/3TC/EFV) formulations are available and may both be used in a program. This situation can be handled in one of two ways: the formulations can be listed separately in this section, with separate prices and distributions or the formulations can be listed as one regimen with a weighted cost.

Original and Updated Prevalence Rates
This section allows for a comparison of 1st and 2nd line ARV drug costs with and without VL scale-up.

For the Original 1st and 2nd Line Prevalence Rates, you will enter what the distribution of 1st and 2nd line ART patients was estimated to be without VL monitoring scale-up. If no forecast is available, your program's current 1st/2nd line split can be used.

$$\frac{\text{\# of patients on specific line}}{\text{total adult or child ART population}}$$

The Updated 1st and 2nd Line Prevalence Rates are calculated figures from the patient and dx assumptions in the previous tab and should not be manually entered.

2. Lab and VL Equipment Costs

Conventional Platforms

Lab Name & Testing Platform
In this section, you will enter information on each lab that is or will be performing viral load testing. First you will enter the name of the lab and the testing platform it uses. If a lab is using multiple platforms, please fill in one line for each kind.

# of Testing Platforms
Next you will enter the number of machines the lab will have in each year of scale-up. The initial cost of existing machines will not be included in the overall cost estimate, but the cost of new platforms will.

Reagent Rental
This pertains to whether platforms are being procured on a rental basis. In some reagent agreement plans, the cost of the machine may already be included in the reagent rental. If "Yes" is selected, it is assumed that the cost of the instrument and service and maintenance is included in the cost of reagents and consumables entered in section 8 of the Data & Assumptions - Patient & Dx Tab.

Daily Throughput
Here you will enter the daily capacity of a single platform at each lab, i.e. that number of tests that can be performed on one machine at each lab on an average day. This is used to determine whether testing platform capacity is sufficient for the estimated number of yearly tested to be performed. If platforms are used for both VL and EID testing or other types of tests, the daily throughput should reflect what daily capacity is available for VL testing alone.

Cost of the Platform
Here you will enter the cost of a new testing platform. This will only be applied to new platforms that are to be purchased in year 1, 2, or 3 and not to existing platforms as long as "Reagent Rental" is not selected.

Annual S&M Cost per Platform
This pertains to the yearly maintenance costs for a testing platform. It is assumed that new platforms will be covered under warranty for the first year, and so this is only applied to platforms in their second year of use.

Lab Upgrade Costs

Here you can enter any costs related to the renovations or upgrades to the laboratories themselves to accommodate the installation of viral load testing platforms. If you do not anticipate any additional renovation costs, this can be left blank.

Annual Lab Overhead Costs
Here you can enter any additional overhead costs that labs will incur due to viral load testing.

POC Testing Labs

This section pertains to point-of-care testing and the associated costs.

Name of Testing Platform and # of Platforms
Here you will enter a line for each type of POC testing platform in your program and the number of each type in each year of the costing.

Reagent Rental
This pertains to whether platforms are being procured on a rental basis. If "Yes" is selected, it is assumed that the cost of the instrument and service and maintenance is included in the cost of reagents and consumables entered in section 8 of the Data & Assumptions - Patient & Dx Tab.

Daily Throughput
Here you will enter the daily capacity of a single platform at each lab, i.e. that number of tests that can be performed on one machine at each lab on an average day. This is used to determine whether testing platform capacity is sufficient for the estimated number of yearly tests to be performed. If platforms are used for multiple types of tests, the daily throughput should reflect what daily capacity is available for VL testing alone.

Cost of the Platform
Here you will enter the cost of a new testing platform. This will only be applied to new platforms that are to be purchased in year 1, 2, or 3 and not to existing platforms.

Annual S&M Cost per Platform
This pertains to the yearly maintenance costs for a testing platform. It is assumed that new platforms will be covered under warranty for the first year, and so this is only applied to platforms in their second year of use.

3. Sample Transportation and Results Delivery Costs for VL Testing

This section pertains to the costs associated with sample transportation and results delivery for viral load testing. Here you will enter the cost associated with each kind of sample collection (DBS, PPT, and plasma) for paper and electronic results delivery for viral load only. You will also enter the estimated distribution of each type of sample transportation and results delivery, which must sum to 100% for each sample type. Any methods that your program does not use can be left blank.

4. Human Resource and Training Costs

This section pertains to the total cost of human resources, including monthly salary, training costs, and time allocated to viral load testing, for workers directly related to VL testing.

Lab Technicians

Here you will enter the monthly salary, the number working in your program, the percent of their time to be allocated to viral load testing, and the per worker annual training costs associated with viral load testing for senior and junior laboratory technicians.

Clinicians & Other Health Workers

This section refers only to those doctors, nurses, primary counselors, and receptionists who will be working at least in part in your viral load monitoring program. Here you will enter the monthly salary, the number working in your program, the time spent per viral load test, the initial per person training cost for viral load testing, and the annual refresher training cost per worker. The "training cost for VL per person" refers to initial training for new health workers in the viral load testing algorithm, results interpretation, adherence counseling, patient education, sample reception, and other relevant aspects as applied to each cadre of worker.

5. Data Management Costs

In this section, you will enter a cost per test for reporting and for monitoring and evaluation activities.

Step Three: Summary

After you have entered all the necessary information in the two Data & Assumptions tabs, the Summary tab will provide the estimated yearly testing totals and cost outputs of the tool for each component of your programs.

Key Assumptions

The Key Assumptions box provides a summary of the scenario you have chosen to model based on the assumptions in Section 4 of the Data & Assumptions – Patient & Dx tab.

Summary Outputs

This provides an overall summary of total patients, testing volumes, VL testing capacity, total VL costs, total CD4 commodity costs, and cost per viral load test and per ART patient.

A. Output in # Tests and Patient Coverage

This table breaks down the projected total number of CD4 and VL tests per year by type of testing based on the information entered in Data & Assumptions – Patient & Dx.

B. Output in Commodity Costs
This provides an estimate of the commodity costs associated with projected VL and CD4 testing.

C. Output in Change in Treatment Costs

This provides an estimate of the change in ART commodity costs associated with VL scale-up as compared to a scenario where VL scale-up was not introduced.

D. Output in Lab and Equipment Costs (viral load testing only)

This provides the estimated costs of viral load laboratory and equipment costs for both conventional and point-of-care platforms.

E. Output in Sample Transportation and Results Delivery Costs (viral load testing only)

This provides the total estimated costs of sample transportation and results delivery based on your program's collection and reporting methods.

F. Output in Human Resource and Training Costs (viral load testing only)

This provides the total estimated cost of human resources and training that are directly related to viral load testing.

G. Output in Data Management Costs (viral load testing only)

This provides an estimate of data management costs associated with your VL program.

List of Necessary Data or Assumptions

**those in italics are optional*

Patient & Dx

Population Data

1. Number of Adult and Children in Pre-ART projected for the next 3 years
2. Number of Adult, Children, and Pregnant Women on ART for the next 3 years
3. Current 2L ART population of Adults and Children

Testing Flow

1. Migration rates: Pre-ART to ART migration rate for Adults and Children
2. Attrition rates: Adults and Children in Pre-ART and ART
3. *CD4 Provider-Initiated Testing rate outside routine CD4 monitoring*
4. Switch rate from 1st to 2nd line under CD4 monitoring only
5. Suspected failure testing:
   **necessary only if suspected failure testing is part of desired scenario*
   - % of 1st line patients who will receive 1st suspected failure test
   - % of those tested once who will receive a 2nd test
   - % of those with 2 VL tests who will switch to 2nd line
   - % of 2nd line patients who will receive suspected failure test
   - % of those 2nd line patients tested who will be retested
   - *% of patients who will switch to 2nd line following only 1 VL test>threshold*
6. Routine Monitoring:
   **necessary only if suspected failure testing is part of desired scenario*
   - % of 1st line patients who will have 1 routine VL test above threshold
   - % of those tested once who will receive a 2nd test
   - % of those with 2 VL tests who will switch to 2nd line
   - % of 2nd line patients who will receive suspected failure test
   - % of those 2nd line patients tested who will be retested
   - *% of patients who will switch to 2nd line following only 1 VL test>threshold*

National Testing Algorithm

1. # of VL tests for Adults, Children, and Pregnant Women on 1st line ART during their 1st year on ART and subsequent years
2. # of VL tests for Adults and Children on 2nd line ART
3. # of CD4 tests for Adults, Children, and Pregnant Women on ART during their 1st year on ART and subsequent years
4. # of CD4 tests for Adults, Children, and Pregnant Women at time of diagnosis

5. # of CD4 tests for Adults and Children in Pre-ART during their 1st year on ART and subsequent years

Scenario Parameters

*these are user-driven assumptions or targets

1. Type of VL testing (routine, suspected) failure to be used for Adults, Children, and Pregnant Women on ART
2. VL scale-up targets for each type of testing
3. CD4 coverage targets for Pre-ART and ART

Laboratory Testing

% of total tests that used for:

1. Training and Quality Assurance
2. Sample Rejection
3. Wastage

Instruments

1. Number of each type of VL and CD4 to be used in country
2. % of tests that will be performed through each kind of machine
3. Ratio of controls per tests for each type of machine used

Sample Collection

1. % of samples that will be collected through DBS, PPT, and EDTA

Diagnostic Product Costs

Cost per test for (necessary only for kinds to be used in program):

*see guidance for sample prices

1. DBS Bundles
2. EDTA Tubes
3. PPT Tubes
4. Reagents and consumables for each VL and CD4 machine

Systems

**Each of the following data are only necessary if including these elements in the costing*

Drug Costs and Distribution

1. Distribution of 1st and 2nd line ARV regimens for adults and children
2. Annual cost of each regimen used
3. Current 1st and 2nd line prevalence under no VL scale-up scenario

Lab and VL Equipment

1. # of tradition and POC testing platforms at each laboratory
2. Whether the laboratory has a reagent rental scheme
3. Daily throughput of each laboratory or POC testing platform
4. Cost of each type of platform used
5. Annual maintenance cost for each platform used
6. Predicted laboratory upgrade costs per site, if any
7. Annual overhead costs for each laboratory

Sample Transport and Results Delivery

1. Distribution of type of sample transportation and results delivery
2. Cost of each type of sample transportation and results delivery used

Human Resources

1. Monthly salary of lab technicians, clinicians, counselors, and receptionists
2. Headcount of lab technicians, clinicians, counselors, and receptionists dedicated to VL
3. % of lab technicians time allocated to VL testing
4. Time spent per VL test for clinicians, counselors, and receptionists
5. Annual training costs for each cadre
6. Training cost for clinicians, counselors, and receptionists

Data Management

1. Cost per VL test for reporting and monitoring and evaluating activities