

Healthcare Waste Management Cost Assessment

Launch of the Waste Cost Assessment Framework (WCAF) Tool for COP Planning



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February 8, 2022



Roche + CDC PPP HIV & TB Response:

Continuation & Expansion



Shared common goal of strengthening laboratory systems and diagnostic networks in countries severely affected by HIV and tuberculosis (TB)

CDC and Roche intend to focus on the following key objectives in alignment with mutual areas of interest and expertise, with the goal of substantially contributing to HIV and TB epidemic control.

- Increase laboratory human resource capacity building and training including laboratory quality management systems and continuous quality improvement programs
- Improve local and regional capacity for appropriate and cost-effective laboratory waste management and related biosafety approaches
- Optimize laboratory workflows for enhanced within-laboratory operational efficiency to support multi-pathogen integration of testing efforts
- Optimize integrated diagnostic network structure, capacity, and linkages for increased access, decreased result turnaround time, and improved responsiveness and adaptability

Memorandum of
Understanding to be signed
upon approval by CDC and
Roche
(2022-2027)

Tools created under the PPP



HIV Viral Load Laboratory: Waste Cost Assessment Framework (WCAF)

- Supports laboratories to develop a budget for waste disposal (across all platforms) for COP planning
- Functional assessment completed in 8 countries (*Ethiopia, Kenya, Uganda, Eswatini, Malawi, Nigeria, Zambia, Zimbabwe*)
- Excel based tool* to be launched via ASLM platform

HIV Laboratory [VL & EID] Waste Cost Analysis Framework (v10.0)

This HIV Laboratory Waste Cost Analysis Framework provides an easy-to-use, tool to support centralized Laboratories to accurately forecast liquid & solid waste volumes from their HIV Viral Load and Early Infant Diagnosis Programs, enabling the estimated cost of healthcare waste management and disposal to be included within COP planning in a standardized manner.

TO BE COMPLETED BY EACH CENTRALIZED LABORATORY DIRECTOR:
Please read the instructions for Use tab and then answer all questions shown in yellow in descending order, using the respective boxes and/or drop down menus. Where present, a red cell indicates an error in that answer, and a green cell, indicates that your inputs have been validated.

Section One
The first section of this tool enables you to provide key information regarding your laboratory and testing volumes, which will be used to generate the budget figure.

Please select the country in which your laboratory is based:

Please enter the name of the facility where your laboratory is based:

Please input your estimate of the number of each test you will deliver during the next COP cycle, into the yellow boxes below:

	Last 12 Months (Actual)	Next COP Cycle (Forecast)	Increase / Decrease	% Change
HIV EID tests run (incl. QC, repeats etc)	0	0	-	#DIV/0!
HIV VL tests run (incl. QC, repeats etc)	0	0	-	#DIV/0!

For each analyzer which will be deployed during the next COP cycle, please select the appropriate answers from each of the drop down menus below. If you have multiple analyzers please complete 1 column for each analyzer present for example, if you have 1 x Abbott m2000 and 2 x Roche c4800, complete 3 columns:

Centralized Laboratory Platform #	1	2	3	4	5	6	7
Select Manufacturer(s)	Select	Select	Select	Select	Select	Select	Select
Select Analyzer Model(s)	Select	Select	Select	Select	Select	Select	Select
Select Usage	Select	Select	Select	Select	Select	Select	Select
% of Total HIV EID Tests run each year	0%	0%	0%	0%	0%	0%	0%
Forecast HIV EID Tests run each year	-	-	-	-	-	-	-
Forecast HIV EID Tests run each month	-	-	-	-	-	-	-
% of Total HIV VL Tests run each year	0%	0%	0%	0%	0%	0%	0%
Forecast HIV VL Tests run each year	-	-	-	-	-	-	-
Forecast HIV VL Tests run each month	-	-	-	-	-	-	-

*Developed with the support of Roche Healthcare Consulting

Assay Verification Tool

- Streamlines the verification of new molecular assays for laboratories
- Web-based tool to be launched on ASLM platform
- Updated for use through collaboration with ILB's Viral Load team.

Validation Verification Parameters

Please select parameters for test.
For a definition of test, please mouse over the test name.

- ☒ Linearity
- ☐ Precision
- ☐ Accuracy
- ☐ Limit of Detection
- ☐ Method Correlation

Limit of Detection
Definition:
• The lowest concentration of analyte that can be consistently detected (typically, in $\geq 95\%$ of samples tested under routine clinical laboratory conditions) in a defined type of sample.²

How LOD will be performed:
• A panel member will be chosen from the linearity panel and 20 replicates will be run to generate results for comparison to the manufacturer's reported limit of detection (LOD).⁴

How LOD will be assessed:

Accuracy Results
Accuracy of test results obtained for the assay can be assessed based on tolerance limits for quantitative assays

Accuracy is defined as the closeness of the agreement between the average value obtained from a large series of test results and laboratory accepted reference value.

The tolerance limit for quantitative assays is the sum of biological variation in the quantitation and the intra-assay impression; biological variation is approximately $0.3 \log_{10}$ and intra-assay variation is approximately $0.2 \log_{10}$ or a total of $0.5 \log_{10}$.

As per CLSI document EP15-A2, data from precision runs can also be utilized to test for trueness (accuracy).¹

Accuracy Assessment - cobas® HIV-1 for use on the cobas® 6800 System

Difference Log₁₀

*ASLM: African Society for Laboratory Medicine

Background – Waste Management



As a consequence of Viral load (VL) scale-up, volumes of associated Healthcare and Laboratory Waste have grown exponentially

By 2030, more than 30m HIV VL tests will be performed globally¹



Improper management of waste from HIV VL testing poses a significant threat to Public Health & the environment including GTC², other chemicals, plastics/consumable



Countries require assistance to quantify & sustainably address waste resulting from VL programs



¹Habiyambere V, Dongmo Nguimfack B, Vojnov L, Ford N, Stover J, Hasek L, et al. (2018) Forecasting the global demand for HIV monitoring and diagnostic tests: A 2016-2021 Analysis. PLoS ONE 13(9): e0201341. <https://doi.org/10.1371/Journal.pone.0201341>

² Guanidinium Thiocyanate

Our goals from this collaboration¹

CDC, ASLM and Roche



Assessing the waste generated across all manufacturers for centralized diagnostics platforms in VL & EID Laboratories²

Developing a new tool to support VL & EID Laboratories in budgeting for appropriate waste management as part of COP submissions

Collaboration with ASLM for monitoring and evaluation of the impact of the tool for program waste management

¹ This initiative is contained under the CDC-Roche Public Private Partnership Memorandum of Understanding and the workplan for 2020

² Phase 1 Wave 1 work focused on VL & EID Laboratories in Kenya to deliver an initial fact base. Wave 2 (initiated in Feb 2021) validated this fact base through the inclusion of VL & EID Laboratories in Zambia and Nigeria.

Creation of a Tool for Waste Management

Will deliver a tool to support country VL & EID waste management programs



HIV Laboratory Waste Cost Assessment Framework (WCAF)

An easy to use tool to support laboratories in communicating waste disposal costs (across all platforms) to country level program managers for COP planning.

WCAF Tool

- considers all key variables in the disposal of waste from a VL & EID instrument
- including but not limited to Roche platforms
- supports laboratories to accurately forecast liquid & solid waste volumes
- thereby enabling the true cost of waste disposal to be aggregated across country program labs for COP planning in a robust and standardized manner

HIV Laboratory Waste Cost Assessment Framework (WCAF)



Overview of tool and key attributes

Purpose

Section One - To provide key information regarding your laboratory and your HIV Viral Load (VL) & Early Infant Diagnosis (EID) testing volumes.
Section Two - To estimate the combined quantities of liquid waste produced as a result of VL & EID testing.
Section Three - To estimate the combined quantities of solid waste produced as a result of VL & EID testing.
Section Four - To gather information about your laboratory's existing & proposed waste management practices and the anticipated cost of operating these.
Section Five - To provide the information required as part of your laboratory's next Country Operational Plan (COP) cycle submission.
Section Six - To provide the Laboratory Director completing the HIV Laboratory Waste Cost Analysis Framework (WCAF), space to add any notes they may wish to make in relation to the WCAF.
Extraction Table - To provide information to the Centers for Disease Control and Prevention (CDC) International Laboratory Branch (ILB) for research and statistical purposes.

Instructions for Laboratory Directors

- Familiarize yourself with the HIV Laboratory WCAF and the related guidance issued by the CDC ILB in regards to HIV VL & EID Healthcare Waste Management (HWM) in PEPFAR supported Labs.
- Allow plenty of time to gather the information required to complete the HIV Laboratory WCAF. A list of the information required can be found in Part A below. You will need all of this information to successfully complete the WCAF.
- Explain the purpose of the HIV Laboratory WCAF to the Laboratory Manager, Quality Officer, Logistician or others from who you will require information. Remember to include in your explanation why this is important to the program, to the Laboratory and to your local community.
- Complete the HIV Laboratory WCAF by going through all of the sections, in descending order, completing the boxes marked in yellow. Should you wish to add a note in respect of any of your answers, a notes box (Section Six - which is marked in yellow) may be found at the bottom of the HIV Laboratory WCAF. **Please do not enter information into any box that is not highlighted in yellow.**
- Attach your completed HIV Laboratory WCAF form saved as an Excel file, to your COP planning submission and retain a copy for your official records.
- If you have any queries about how to complete the WCAF, please contact: xxx@cdc.gov

Part A: Data required to complete the HIV Laboratory WCAF

Section One

- Number of HIV EID tests run (including Quality Control [QC], repeats etc) in the past 12 months
- Number of HIV VL tests run (including QC, repeats etc) in the past 12 months
- Forecast number of HIV EID tests to be run (including QC, repeats etc) in the 12 months covered by the next COP cycle
- Forecast number of HIV VL tests to be run (including QC, repeats etc) in the 12 months covered by the next COP cycle
- Details of the number of analyzers you will utilise during the next COP cycle - for each analyzer including manufacturer & platform name e.g. Abbott m2000
- Forecast of the % of HIV EID tests that will be run on each analyzer during the next COP cycle
- Forecast of the % of HIV VL tests that will be run on each analyzer during the next COP cycle

Section Two

- No additional information required

Section Three

- Estimated % of packaging waste by weight recycled by an external contractor at no cost to the Laboratory
- Estimated % of packaging waste by weight removed by Laboratory staff for re-use elsewhere e.g. cardboard boxes for storage or animal bedding
- Estimated % of packaging waste by weight not currently recycled but suitable for recycling by an external contractor, if a fee was paid for its collection.

HIGHLIGHTS

- Excel based tool
- Comprehensive instructions for use
- Care taken in design to use base data that labs have or can access and calculate the rest
- Expectation is that lab manager/director would complete the tool (with help from their operational teams)

HIV Laboratory Waste Cost Assessment Framework (WCAF)



Overview of tool and key attributes

6 Sections:

1. Key information regarding the laboratory and testing volumes, which will be used to generate the budget figure
2. Automatically estimates the combined quantities of liquid waste created based upon the key inputs into Section One
3. Enables you to estimate the combined quantities of solid waste created based upon the key information & testing volumes input into Section One
4. Enables you to input data in relation to your local HWM practices and costs
5. Contains the information generated by this Waste Cost Assessment Framework, for countries' next COP Cycle submission (in USD)
6. Blank for you to add any notes in relation to your completion of the WCAF

This HIV Laboratory Waste Cost Analysis Framework provides an easy to use, tool to support centralized Laboratories to accurately forecast liquid & solid waste volumes from their HIV Viral Load and Early Infant Diagnostic Programme, within the estimated cost of healthcare waste management and disposal to be included within COP planning in a standardized manner.
Forecast HIV VL Tests run each month

Please read the Instruction

Section One

The first section of this tool

Please select the country
Please enter the name of laboratory is based:

Please input your estim

HIV EID tests run (incl. QI
HIV VL tests run (incl. QC

For each analyzer which
analyzers please compl

Centralized Laboratory P

Select Manufacturer(s)

Select Analyzer Model(s)

Select Usage

% of Total HIV EID Tests r

Forecast HIV EID Tests ru

Forecast HIV EID Tests ru

% of Total HIV VL Tests ru

Forecast HIV VL Tests ru

Section Two

The second section of this tool automatically estimates the combined quantities of liquid waste created based upon the key information & testing volumes input into Section One.

Non-Dilute Liquid Waste Generated (Litres)
Volume of which is suitable without further pre-treatment for discharge to mains sewerage (Litres)
Total Liquid Waste for Treatment & Disposal (Litres)
Total Liquid Waste for Treatment & Disposal (Litres) per test performed

Section Three

The third section of this tool enables you

Packaging Waste Generated (kg)
% of packaging waste formally recycled (at no charge) by weight
% of packaging informally re-used by weight
Packaging waste for disposal (kg)
% of packaging waste recycled & re-used at no cost
% of packaging waste for disposal suitable for paid recycling (if available) by weight
Packaging waste for disposal suitable for recycling (if available) (kg)
Residual packaging waste for disposal (kg) not suitable for recycling
Solid waste generated from platforms incl. ALL discarded samples (kg)
Personal Protective Equipment (PPE) waste generated (kg)

Total solid waste for disposal (kg)
Total solid waste for disposal (kg) per

Section Four

The fourth section of this tool enables you to input data in relation to your local HWM practices and costs. Please enter all amounts to the nearest whole unit.

Cost of Waste Disposal Permits / Licences each year
HWM Administration (Hours per month)
Average hourly cost of staff administering HWM
Total Waste Administration Costs

Waste Handling (Hours per week)
Average hourly cost of staff handling healthcare waste
Total Waste Handling Costs
Is there an Autoclave On-Site?
Cost of Electricity (KWH)
Cost of Water (per cubic Metre)
Cost of Autoclave Maintenance each year
Total Autoclave Costs

Waste Containers cost each year
Waste Management option selected for Liquid Waste Disposal & Treatment
Cost of disposal & treatment (litre)
Consignment Cost
of Consignments each year
Total Liquid Waste Disposal & Treatment Costs

Cost of recycling service for packaging waste suitable for recycling (kg)
Consignment Cost
of Consignments each year
Total Cost of Recycling Service

Waste Management option selected for Solid Waste Disposal
Cost of disposal & treatment (kg)

Section Five

The fifth section contains the information generated by this Waste Cost Assessment Framework, which you will require as part of your next COP Cycle submission.

Budget required with Next COP cycle for disposal of program waste in a standardized manner as per CDC ILB guidance

Exchange Rate 0.0000 FALSE to USD

Budget required with Next COP cycle for disposal of program waste in a standardized manner as per CDC ILB guidance

\$0 US Dollars

Please enter this figure in your COP cycle budget submission

Section Six

This sixth section is intentionally blank for you to add any notes in relation to your completion of the WCAF.

Insert notes here

Notes:

- i) This model - HIV Laboratory Waste Cost Analysis Framework v0.9 is a DRAFT work in progress prepared by Roche Healthcare Consulting for the Centers for Disease Control and Prevention, International Laboratory Branch, April 15 2021.
- ii) For Kenya, OEM export packaging is removed by KEMSA prior to onward supply to Laboratories and KEMSA utilizes non-standardized exterior packaging for the onward supply of consumables to Laboratories
- iii) Model excludes any CAPEX required to establish sustainable disposal solutions and follows a zero-based budget approach.

Disclaimer:

This Waste Calculator Tool ("Tool") has been developed by Roche Healthcare Consulting ("Roche") in collaboration with the Centers for Disease Control and Prevention ("CDC") and is intended to assist laboratories that perform HIV/EID diagnostic testing in estimating the cost of waste disposal for budgeting purposes.

The laboratories use of this Tool and/or any data collected by the Tool should not be considered a substitute for the laboratory's own independent cost calculations and data set across compliance with applicable laws, regulations

HIV Laboratory Waste Cost Assessment Framework (WCAF)



Overview of tool and key attributes

Extraction Table	
Country	Select
Facility	0
# of HIV EID Tests Forecast (per year)	-
# of HIV VL Tests Forecast (per year)	-
Total Liquid Waste for Treatment & Disposal (per year in litres)	0
Total Solid Waste for Disposal (per year in kilograms)	0
% of all Solid Waste Recycled (per year in kilograms)	#DIV/0!
Waste Management option selected for Liquid Waste Disposal & Treatment	Select
Waste Management option selected for Solid Waste Disposal & Treatment	Select
Budget Requested (per year in US Dollar)	\$0

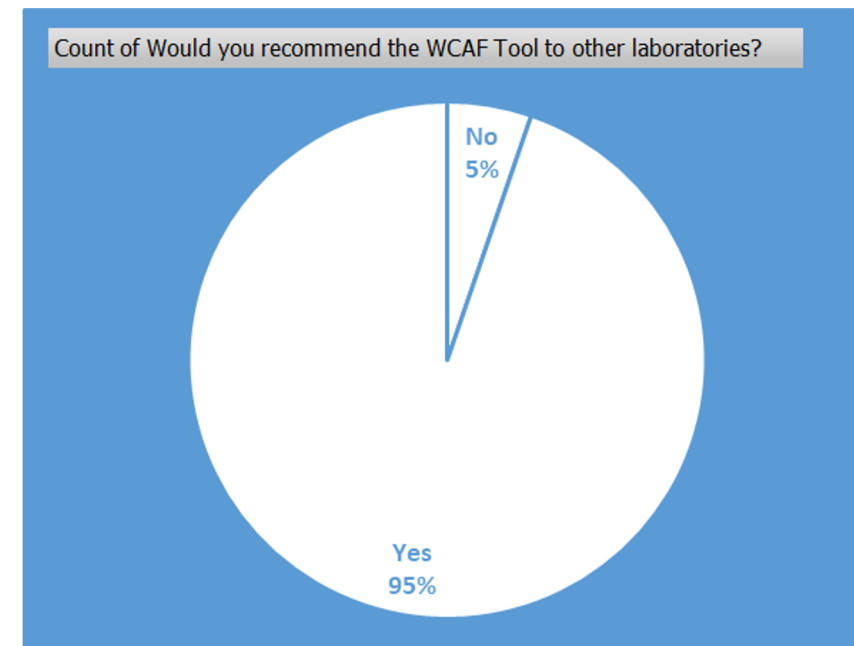
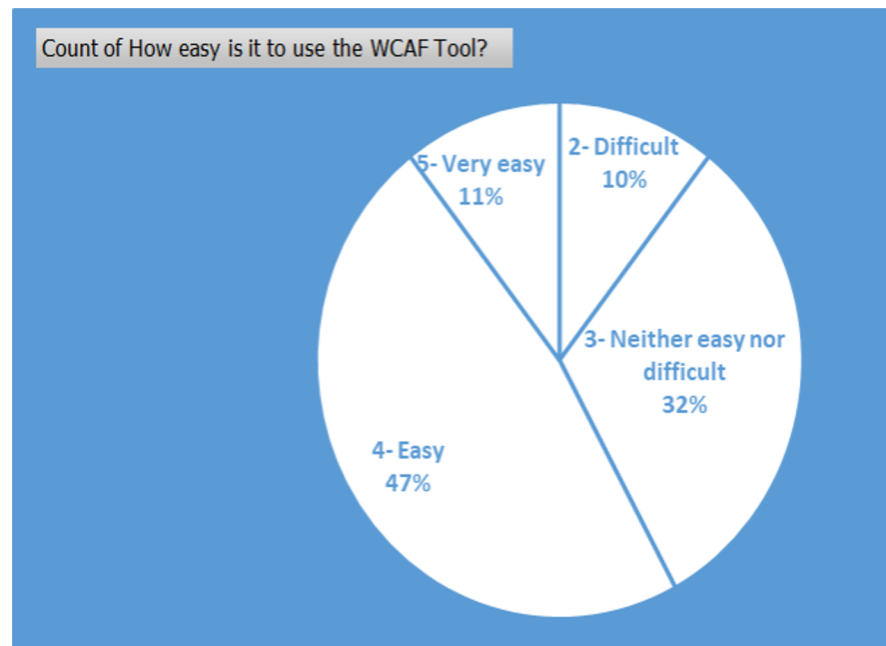
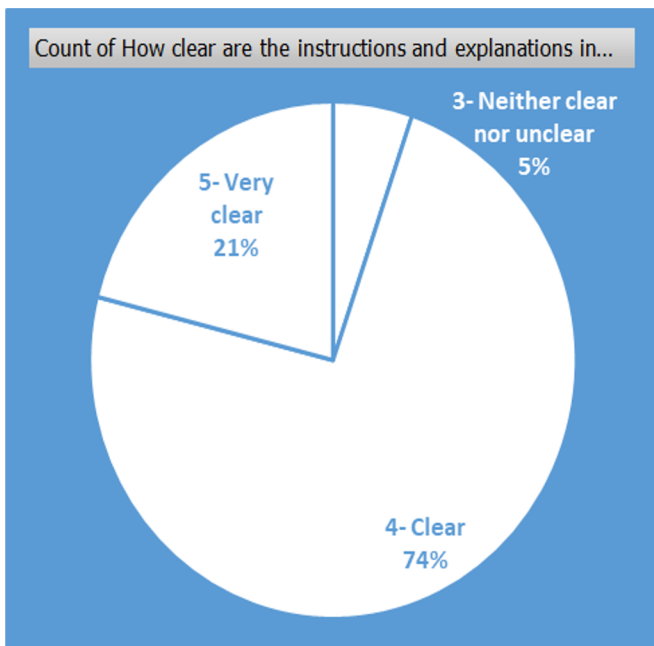
HIGHLIGHTS

- Summary of background data behind the budget figure
- Aid for consolidating multi-lab data for county/region and country-level planning

Functional Assessment Feedback



We asked to 19 sites about the draft version of the tool*



*Countries included: Kenya, Uganda, Eswatini, Nigeria, Zambia, Zimbabwe

Functional Assessment Feedback



We asked to 19 sites about the draft version of the tool*

What did you like about the WCAF Tool?

- Easy to follow and implement
- Covers both solid and liquid waste
- Easy to understand and with required inputs, it is also easy to use
- It is user friendly and saves time by automatically calculating some parameters
- it captures key concepts in waste management
- helps in budget preparation
- STEP TO STEP APPROACH

How would you describe your overall experience with the WCAF Tool?


- Great! Good for HWM cost assessment and forecasting.
- Relatively easy but data should be as reliable as possible
- Generally it is reminder of good practice in waste management in relation to workload
- it is not easy to capture expenses as all payments and budgets are done by hospital administration
- it's a good tool that will help local government and labs to do their budgets on waste management so its excellent


**Countries included: Kenya, Uganda, Eswatini, Nigeria, Zambia, Zimbabwe*

Accessing the WCAF Tool

Located on the ASLM website in the Resource Centre




Who We AreWhat We DoMembership OpportunitiesResource CentreCOVID-19ASLM2021



Special ECHO Session Dec 2021: The Diagnostic Evidence Hub's Role in Accelerating Uptake of Diagnostic Innovations

February 7, 2022 | e-Learning, Video, ECHO Session

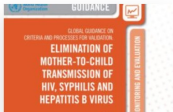
On 8 December 2021 this special ECHO session was held to focus on the role of the Diagnostic Evidence Hub in accelerating uptake of diagnostic innovations. The Diagnostic Evidence Hub, launched in 2020 by the FASTER Project and hosted on the ASLM website, provides easy access to consolidated regulatory and performance data for test methods... [Read More](#)



The HIV Laboratory Waste Cost Assessment Framework (WCAF)

February 5, 2022 | Tool


The HIV Laboratory Waste Cost Assessment Framework (WCAF) is a tool to support laboratories with a standardised format for forecasting waste disposal costs for HIV viral load (VL) and early infant diagnosis (EID) to country level program managers for country operational plan (COP) planning. This tool was co-developed by US CDC and Roche Diagnostics under... [Read More](#)




WHO Global Guidance on Criteria and Processes for Validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus 2021

January 4, 2022 | Guidelines

Mother-to-child transmission (MTCT), or 'vertical transmission' is a significant contributor to the acquisition of HIV with an estimated 150 000 new HIV infections among children reported in 2020, and other infectious diseases including syphilis and hepatitis B (HBV). The 2021 World Health Organization global guidance on criteria and processes for validation: elimination of mother-to-child transmission... [Read More](#)





WHO Global Tuberculosis Report 2021


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The HIV Laboratory Waste Cost Assessment Framework (WCAF)


February 5, 2022

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The HIV Laboratory Waste Cost Assessment Framework (WCAF) is a tool to support laboratories with a standardised format for forecasting waste disposal costs for HIV viral load (VL) and early infant diagnosis (EID) to country level program managers for country operational plan (COP) planning. This tool was co-developed by US CDC and Roche Diagnostics under a public-private partnership for the waste generated by the VL/EID kits used in PEPFAR-supported countries. It is supplier agnostic, making it useful to calculate volumes of solid and liquid waste across VL/EID centralised platforms used in the country. Thanks to the country teams who supported the development and assessment of the tool: Kenya, Zambia, Nigeria, Uganda, Eswatini, Zimbabwe, Ethiopia, and Malawi. A short instructional video is available to help navigate the tool [here](#). For any questions around the use of the tool please contact Monte D. Martin [here](#) and David Bressler [here](#).



Related Files

 CDC WCF V14

<https://aslm.org/resource/the-hiv-laboratory-waste-cost-assessment-framework-wcaf/>

Acknowledgments



Thank you to the many contributors to the creation of this tool

CDC International Laboratory Branch (ILB)

Monte Martin
Dave Bressler
Ritu Shrivastava
Shirley Lecher
Clement Zeh
Heather Alexander

Country Teams

CDC Country Offices/Ministries of Health/Implementing Partners
Kenya, Zambia, Nigeria, Uganda, Eswatini, Zimbabwe, Ethiopia, and
Malawi

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Desmond Ikebude
Venkatraman Rathinam
Tobias Omollo Bunde
Faith Mathai
Martin Maina
Emma Maina
John Abwao
Nico Gunter

Healthcare Waste Management Cost Assessment

A background image showing two healthcare workers in blue scrubs shaking hands. The image is split diagonally: the left side is a faded, light blue version of the handshake, and the right side is a solid, medium blue version. The text 'Q&A' is centered over the diagonal split.

Q&A