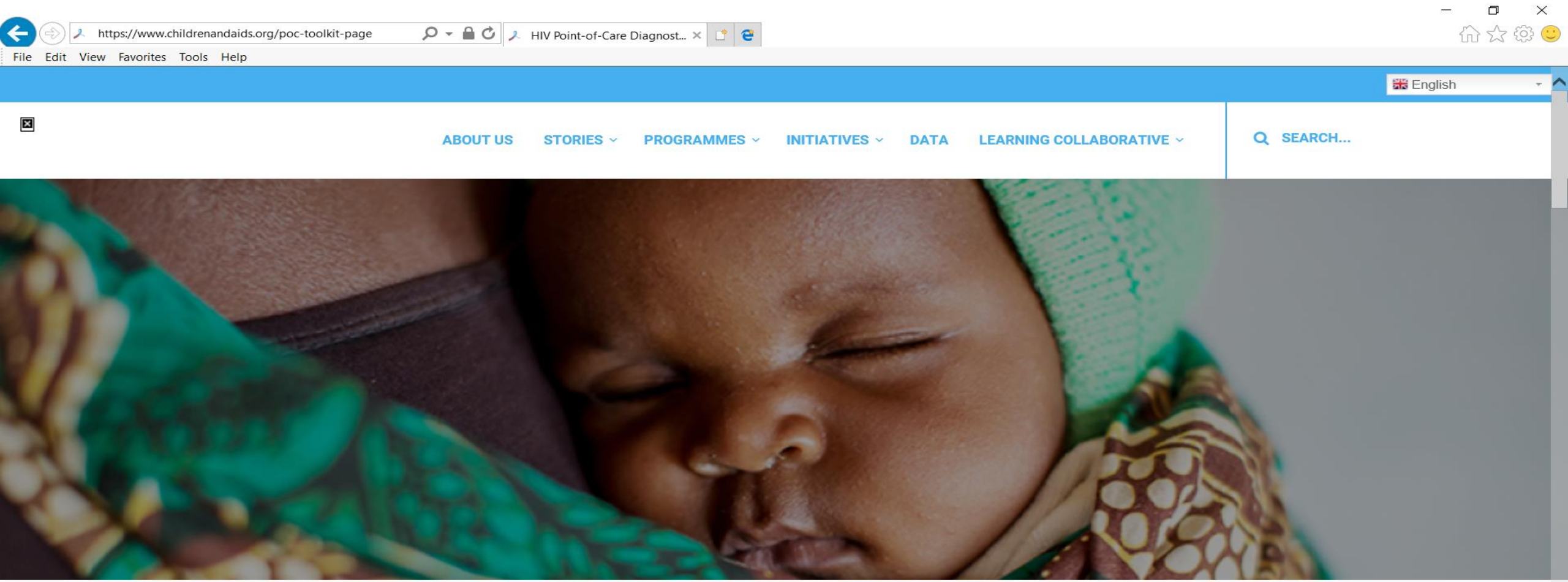

https://www.childrenandaids.org/poc-toolkit-page

- What is the HIV Point-of-Care Diagnostics Toolkit?
- Why was the Toolkit developed?
- How is the Toolkit organized?
- How was the Toolkit developed?
- Are there other useful resources available for countries to learn from?
- How can you provide feedback on the Toolkit?
  - To provide feedback on this Toolkit or to share tools from your country context, contact Alex Costa at UNICEF (alecosta@unicef.org).
  - To share your thoughts about these resources and additional modules you would find useful, please take the survey.

Product and Site Selection

Forecasting and Supply Planning

Regulations

Quality Assurance

This project is made possible thanks to Unitaid's support.

Unitaid accelerates access to innovation so that critical health products can reach the people who most need them.

Product and site selection	• **Global Fund's Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool (GF)** • **EID and VL Product and Site Selection Tool (CHAI)** • **Guidance Note on Product Selection, Facility Upgrades, and Sample Transportation (EGPAF)** • **Side-by-Side Analysis of POC EID Products** • **Guidance for Site Enrollment (EGPAF)** • **USAID's Laboratory Efficiency and Quality Improvement Planning tool (LabEQIP*) (USAID)**
Forecasting and supply planning	• **The primary tool in this module is ForLAB, a standardized, open-source quantification tool designed to help program managers forecast commodity needs for diagnostic services.** • **Forecasting and Supply Planning for the Scale-up of new POC EID/VL Technologies.**
Regulations	• **Regulatory processes and frameworks for medical devices** • **Product evaluations** • **National approval for use and** • **Post-market surveillance**
Quality assurance	• **The POC Quality Assurance Budgeting Tool (CHAI)** • **Stepwise Process for Improving the Quality of HIV-Related Point of Care Testing (SPI-POCT) Checklist** • **Site Monitoring Guidance (EGPAF)** • **Improving the Quality of HIV-Related Point of Care Testing: Insuring the Reliability and Accuracy of Test Results**

Product selection

The selection of POC products should be objective and transparent, deploying the most appropriate products to sites, complementing the existing laboratory network to maximize impact on patient access to testing. POC products should be selected in response to the specific needs, capacity, and limitations of selected sites and the laboratory-clinic network as a whole, as well as to ensure instruments are fit-for-purpose.

For countries receiving Global Fund grants, the **Global Fund's Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool** is designed to guide countries receiving Global Fund grants with the selection and procurement of viral load (VL) and early infant diagnosis (EID) technologies, including POC diagnostic technologies approved by the Global Fund. It is advised that countries using Global Fund funding to purchase POC diagnostic products discuss their needs with Global Fund procurement as part of the product selection process.

Clinton Health Access Initiative's (CHAI) **EID and VL Product and Site Selection Tool** is an excel-based decision-making tool designed to help countries with:

- Selecting the most appropriate EID and VL products and sites for piloting and scaling up EID and VL point of care testing.
- Determining the optimal deployment of POC devices and conventional equipment to maximize patient impact while maintaining cost efficiency.

It is intended to help technical working groups (TWGS) and stakeholders better understand the current gaps in testing coverage in the country; identify the key country-specific criteria for selecting sites and POC products; and score those criteria to determine the balance between patient volume, access, and price when making decisions about site and product selection. It has been implemented in Cameroon, Malawi and Zimbabwe.

For **guidance** on how to use the CHAI EID and VL Product and Selection Tool, click here. For a version of the tool with sample data **click here**.

It is important to note that accurately completing the tool requires gathering site-level data, national programmatic indicators, and evaluating the relative importance of device performance characteristics. Assembling and cleaning the data can require significant time and sometimes, dedicated resources.

CHAI and the African Society of Laboratory Medicine are available to support use of the tool with technical assistance. For additional information, please contact Seth McGovern at CHAI (**sethmcgovern@clintonhealthaccess.org**).

Focusing more specifically on EID, the Elizabeth Glaser Pediatric AIDS Foundation's (EGPAF) guidance notes (below) are collectively designed to help countries select the most appropriate products and sites to support the piloting and scale up of POC EID technologies, including within the context of a hub and spoke model.

Introduction

The Early Infant Diagnosis (EID) and Viral Load Product and Site Selection Tool is designed to assist countries in selecting the most appropriate EID and VL products and sites for piloting and scale-up of POC diagnostic technologies.Currently, site selection options include the Alere Q, Cepheid GeneXpert, Cepheid Omni, and Diagnostics for the Real World's Samba II. The tool will be expanded as other products receive regulatory approval through WHO-PQ, FDA, or CE-marking for HIV 1-2 viral load and EID testing. Omni is expected to be on the market in 2017, and Alere Q's viral load assay cartridge is in development.

Contact

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Note: Use of tool requires Microsoft Excel 2007 or later.

3. Insert inputs and assumptions

Country Guidelines		
# of VL for ART patient per year		<---- *The WHO guidelines recommend at least one test per year for all patients on ART, beginning six months after initiating treatment. Patients with high viraemia should be retested within 3-6 months.*
Percent of patients requiring second viral load test due to treatment failure or non-adherence		<---- *This figure should come from national program records and will vary by country.*
Number of EID tests per exposed infant		<---- *The WHO guidelines recommend one test at 4-6 weeks for all infants and a serological test at 9 months followed by an EID test for infants with confirmed HIV exposure. Countries with high facility delivery rates should also consider testing at birth.*
Positivity rate in HIV-exposed infants		<---- *This figure should come from national program records and will vary by country.*
Lab Infrastructure and Operations		*Note: Only the maximum number of POC devices per site dictates product and site selection. The remaining metrics only affect the gap analysis and can be estimates.*
# of PCR instruments in country		<---- *Total number of instruments in public sector in country available for use or ready for installation*
Average throughput of PCR instrument		<---- *What is the average number of tests that can be run on the DNA-PCR instruments available in country?*
# of centralized testing labs		<---- *# of centralized testing labs*
Maximum number of POC devices per site		<---- *What is the maximum number of devices that can be deployed to a given site? If a technology cannot meet the total need of the site with the maximum number of devices per site, it will not be considered.*
# of working hours per work day in health facility		
# of working days per year in health facility		
Sample transport costs		*Note: Ensure that any costs below are not duplicative.*
Fixed central costs ($/per year)		<---- *Any national-level costs for orchestrating sample transport. These should be fixed costs such as program management or overhead. They should not overlap with lab overhead costs (row 63).*
Number of sites accessing sample transport		
Frequency of ST per week		<---- *Estimate of number of times sample is dropped off/picked up per week*
Variable costs per test ($/test)		<---- *Additional cost incurred per test*
Variable costs per km ($/km)		<---- *Additional cost incurred per km travelled*
Variable costs per site ($/route drop off)		<---- *Additional cost incurred per site*
ensure that these costs are mutually exclusive i.e. a cost (e.g. HR, fuel) is taken into account in only one of these rows		
Cost of running centralized lab		
Cost per PCR machine ($)		<---- *Estimated cost of new DNA PCR instrument (only include if instruments are procured or purchased through reagent rental, not placed)*
Lifespan of device (# of years)		<---- *How many years should equipment cost be distributed over?*
Cost per centralized lab ($/year)		<---- *Cost of running a centralized testing lab e.g. electricity, internet, rent etc.*
Cost per test ($/per test for all testing commodities)		<---- *Cost of testing one sample using conventional instruments, including reagents, consumables, sample collection materials, etc.*
Lab technician salary per hour		<---- *Salary of lab technician responsible for operating PCR instrument*
Number of lab technicians required per PCR device		<---- *Number of staff required to operate 1 PCR device for 8 hrs. per day*
Annual cost per PCR machine for service and maintenance ($/machine)		<---- *Cost of running one PCR machines per year e.g. Service and Maintenance, Electricity*
Cost of running POC		
Avg. cost per POC machine ($/machine)		<---- *Avg. cost of POC device + accessories*
Lifespan of device (# of years)		<---- *How many years should equipment cost be distributed over?*
Avg. cost per test ($/per test for all testing commodities)		<---- *Cost of testing one sample using cartridge, reagents, consumables, and sample collection materials*
Phlebotomist or lab technician salary per hour		<---- *Salary of lab technician responsible for operating POC instrument*
Number of lab technicians required per POC device		<---- *Number of staff required to operate 1 PCR device for 8 hrs. per day*
Overhead cost per POC site ($/per site/per year)		<---- *Additional cost per POC test e.g. HR, electricity*
Health impact		*Note: Given limited data availability, the below figures can be estimates based on experience with POC CD4 scale-up and conventional testing. Over time, these should be sourced from available research.*
EID LTFU with Sample Transport (%)		<---- *% of HIV+ infants lost with conventional EID system*

Integrated EID-VL Product and Site Selection Analysis Tool 102015_v3 [Read-Only] - Excel

Geoffrey Chipungu

File Home Insert Draw Page Layout Formulas Data Review View Tell me what you want to do Share

Cut Copy Format Painter Paste

Times New Roma 11 Wrap Text General

Conditional Formatting Format as Table

Heading ... Normal 14 Normal 2 Normal Bad
Good Neutral Calculation Check Cell Explanatory ...

Insert Delete Format

AutoSum Fill Clear Sort & Filter Find & Select

Clipboard Font Alignment Number Styles Cells Editing

BC13

Site Profiles

INSTRUCTIONS: Enter the site level information in all yellow columns for all facilities. In addition to helping with product selection, this data will also be critical in driving site selection after POC products have been selected. For EID, only the PMTCT patient numbers by site or the number of EID tests per year need be recorded, however both should be if they are available. The model will use the maximum of the two values to model the testing need. For Columns C, D, E, and F, values must be numerical. If no data is available, leave the cells blank. It is preferable to use the average TAT of conventional test results in column G. However if average TAT is not available you may use the distance to the conventional testing hub as a proxy. However, if you do so, be sure to use exclusively distance, rather than mixing distance and average TAT measurements. If neither data is unavailable, leave all cells blank. Do not assume uniform values for distance. Values for distance can be estimates, but they must not be equivalent across all sites or the score will generate an error.

Note, if seasonality factors significantly into turnaround time, a weighted average between rainy and dry season turnaround time in days could be used to best approximate the difficulty of conventional sample transportation.

Site Name	District	# of ART Pa	# PMTCT Pa	# of EID tests pe	Avg TAT in Day	Existing Access	Existing Access t	ART Si	Pediatric ART	e?

Title 0. Instructions 1. Inputs 2. Site profiles 3. Gap Analysis 4. Product Selection 5. Site selection 6. Product assignment 7. Output Appendix - Product Information Device profiles

Gap Analysis

INSTRUCTIONS: This worksheet presents data regarding existing coverage for conventional and POC testing and allows users to determine the impact of POC on cost and patient outcomes. The outcomes of this sheet do not factor into the outcomes of product and site selection but afford users further analysis for advocacy efforts in country as they extend access to diagnostics. After viewing the tables and graphs on existing coverage, drag the slider back and forth to manipulate how sites should be selected for POC. View the impact of changes to the distribution of POC and conventional testing sites below. Note both the cost and public health outputs, as both should be considered for program performance.

Step 1: Market Segmentation

VL – Market Segmentation by # of tests required per day

	>0 and <=5	>5 and <=10	>10 and <=20	>20	Total
# Sites in segment	-	-	-	-	-
% Sites in segment	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
# Tests per year	-	-	-	-	-
% Testing volume	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	

EID – Market Segmentation by # of tests required per day

	>0 and <=1	>1 and <=2	>2 and <=5	>5	Total
# Sites in segment	-	-	-	-	-
% Sites in segment	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
# Tests per year	-	-	-	-	-
% Testing volume	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	

VL – % Unmet need by # of tests required per day

	>0 and <=5	>5 and <=10	>10 and <=20	>20	Total
% Sites covered by existing POC					
% Sites covered by conventional					
% Sites not covered					
% Tests covered by existing POC					
% Tests covered by conventional					
% Tests unmet					

EID – % Unmet need by # of tests required per day

	>0 and <=1	>1 and <=2	>2 and <=5	>5	Total
% Sites covered by existing POC					
% Sites covered by conventional					
% Sites not covered					
% Tests covered by existing POC					
% Tests covered by conventional					
% Tests unmet