

EID and Viral Load Product and Site Selection Tool

May 2015



Background: Why is a product selection process necessary?

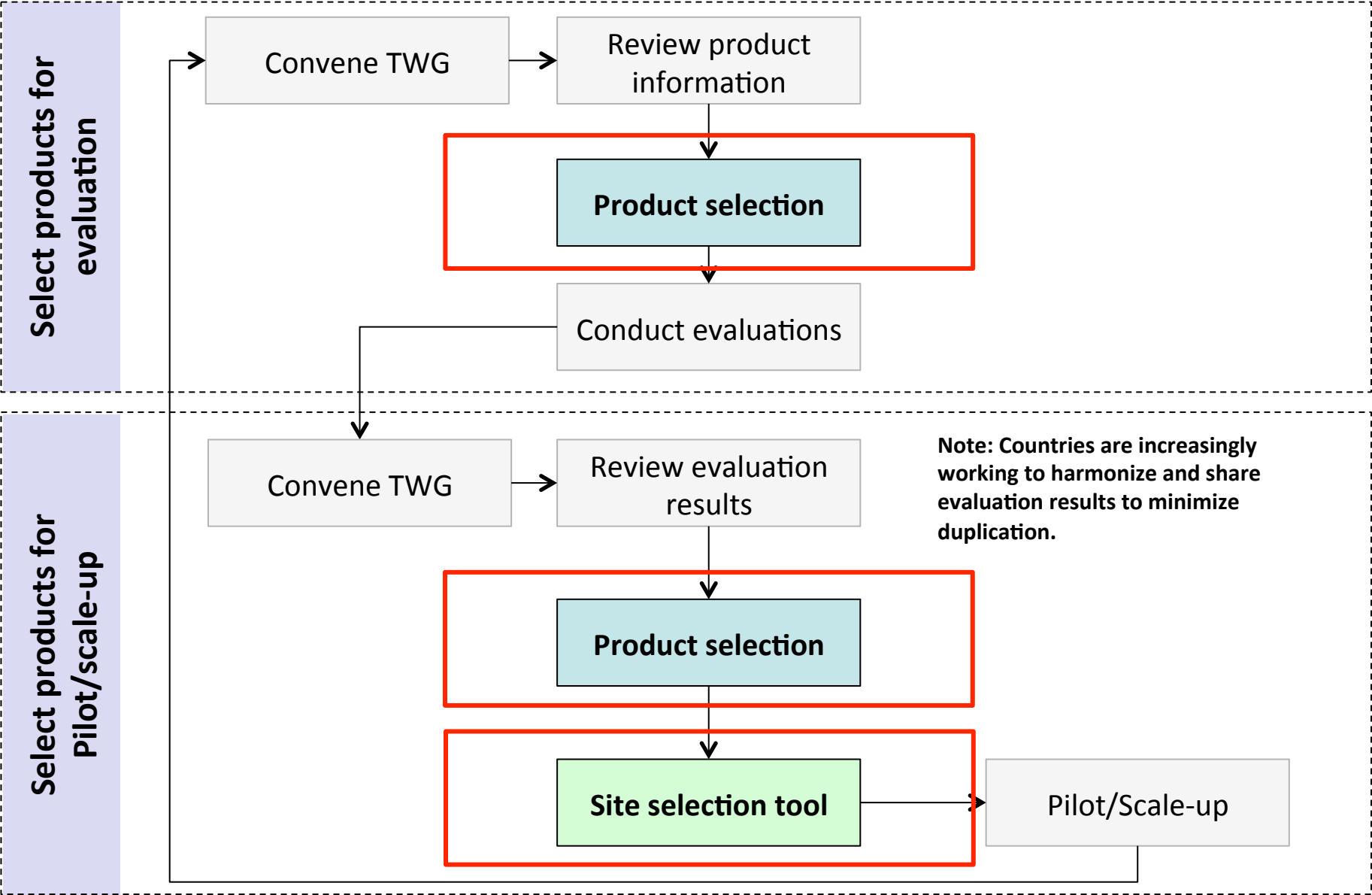
- Comprehensive product information
 - Historically, in the diagnostics sector, decision-makers have lacked sufficient information to make informed product selection decisions
 - Suppliers provide Ministries of Health (MOHs) with extensive marketing materials, but they lack comprehensive and unbiased information to pick the products that are most appropriate for their countries
- Public procurement principles
 - Public funding requires that public procurement principles be observed in the procurement of commodities. MOHs have an obligation to demonstrate that a rational and transparent process has been followed to select products for procurement.

There is a role to play for neutral 3rd parties to facilitate the development of a rational and transparent product selection process.

Key Principles of Product and Site Selection

1. It should be MOH-led and involve all key stakeholders to drive consensus
2. It should be rational, transparent, and well-documented
3. It should be driven by the country's unique diagnostic testing priorities, including such factors as:
 - a. Patient volumes
 - b. Clinical need (i.e., potential need for emergency EID testing in hospitals)
 - c. Access challenges (low-volume sites with long turnaround times and/or sites that are located far from centralized testing labs)
 - d. Cost efficiency
4. It should be an iterative process

Product and site selection tool are just part of a broader process



The product and site selection tool and accompanying guidance can be used to facilitate stakeholder discussions

Understand current testing landscape

- Understand the current gaps in testing coverage in the country:
 - What segments have the poorest access to testing?
 - At what level of the health system do most patients seek care?
 - Which segments of the health system would be best served by POC?

Determine key criteria

- Determine the most important ~5 – 10 criteria when selecting POC products
- Discuss how these criteria should be weighted against each other in each segment
- Determine balance between patient numbers, access, and price to be used in site selection

Review product pipeline and assign scores to products

- Review all available information for each product
- Assign scores for each of the products for the criteria determined in step 2

Select POC products and sites

- Review scores for each product in the various segments
- Hold discussions across all stakeholders to consider scores and other relevant factors
- Select products for evaluation and/or scale-up and match to appropriate sites
- Repeat process periodically to include new products and new information

EID and VL Site and Product Selection Tool Overview (1 of 5)

Goal: Help countries determine optimal deployment of POC and conventional equipment at a site level to maximize patient impact while maintaining cost efficiency

1

Define country and site-level information

- Enter details regarding country guidelines, existing equipment, lab operations, sample transportation, costs, and site-level patient data, including but not limited to:
 - ART patients
 - PMTCT patients OR historical EID test numbers
 - Existing access to testing (EID or VL)
 - Distance from lab or turnaround time in days
 - Presence of pediatric or nutrition ward

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Assign site selection criteria

- Weight most important criteria for site selection, including minimizing cost, improving on-site access to testing, or maximizing patient coverage
- Choose maximum number of devices to be deployed per site

Site Name	ART Patients	EID patients	Existing Access to VL	Existing Access to EID	Distance (or time in days) from lab

EID and VL Site and Product Selection Tool Overview (2 of 5)

3

Assess existing coverage through conventional systems and role of POC

- Outputs of site-level data used to define access to on-site testing
- User can test various scenarios shifting balance from conventional to POC at national level to determine potential patient and cost impact
- This will help inform the overall balance between POC and conventional testing in country

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Step 1: Market Segmentation

1.1 Review the segmentation of the testing demand by throughput volume in the table below. Note which segments have the greatest unmet need

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!	-

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	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
% Sites covered by conventional	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!
% Sites not covered	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!

Choose the % of sites for POC vs Conventional:

POC
100%

Selecting POC sites: Choose the balance between prioritizing # of patients covered

Patients covered
80%

Cost analysis

Average cost per test

#DIV/0!

Public Health impact

of cases of elevated VL detected per year

0

of treatment failures detected per year

0

of HIV exposed infants getting EID results

0

EID and VL Site and Product Selection Tool Overview (3 of 5)

4

Determine key criteria for new product selection

- Identify all the factors that should be considered when selecting new product
- Identify percentage weights to be given to each criteria

Performance Criteria	>0 and <=5	>5 and <=10	>10 and <=20	>20
Tests Offered (EID or VL)			5%	10%
Quantitative/Semi-Quantitative				5%
Device/Device-Free	5%	5%		
Throughput			15%	25%
Power Source	20%	20%	10%	10%
Connectivity	10%	10%	20%	15%
Device Cost	20%	20%	10%	5%
Reagent Cost	10%	10%	10%	10%
Ease of Use	15%	15%	15%	5%
After-Sale Support	20%	20%	15%	15%

5

Review product pipeline and assign scores to products

6

Select new products to deploy

EID and VL Site and Product Selection Tool Overview (4 of 5)

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Score and select sites and assign products

- Sort sites to rank from highest to lowest based on EID, VL, or both
- Select which sites will be chosen for new product deployment
- Designate product for all chosen sites

This sheet allows the user to weigh the 4 criteria for site selection (step 1) and select sites for a POC device (step 4).

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#	Site Name	Segmentation	Current VL coverage	Current EID coverage	Best Score (Both)	Best Score (VL)	Best Score (EID)	Selected?
1					0.00	0.00	0.00	
2					0.00	0.00	0.00	
3					0.00	0.00	0.00	
4					0.00	0.00	0.00	
5					0.00	0.00	0.00	
6					0.00	0.00	0.00	
7					0.00	0.00	0.00	
8					0.00	0.00	0.00	
9					0.00	0.00	0.00	
10					0.00	0.00	0.00	

3 {

Sort by
VL+EID Score

Sort by VL
only Score

Sort by EID
only Score

4

Undo Sort

EID and VL Site and Product Selection Tool Overview (5 of 5)

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Review outputs and adjust as necessary

- Review model outputs, including:
 - Distribution of on-site access to testing by facility size
 - List of sites and devices selected
 - Required budget
 - Average cost per test
 - Public health impact
- Adjust model outputs based on findings

2

Budget

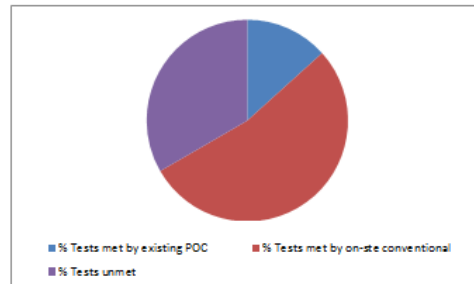
Estimated costs	
Average cost per year	\$ 195,000
Average cost per test	\$ 5.97
1st year Equipment cost	\$ 60,000
1st year Reagent cost	\$ 165,000
1st year Total cost	\$ 225,000

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Final List of sites/devices selected

SITES SELECTED	DEVICES SELECTED
A	BD Facs Presto
B	BD Facs Presto
C	BD Facs Presto
D	BD Facs Presto
E	BD Facs Presto

BEFORE SITE/PRODUCT SELECTION



AFTER SITE/PRODUCT SELECTION

