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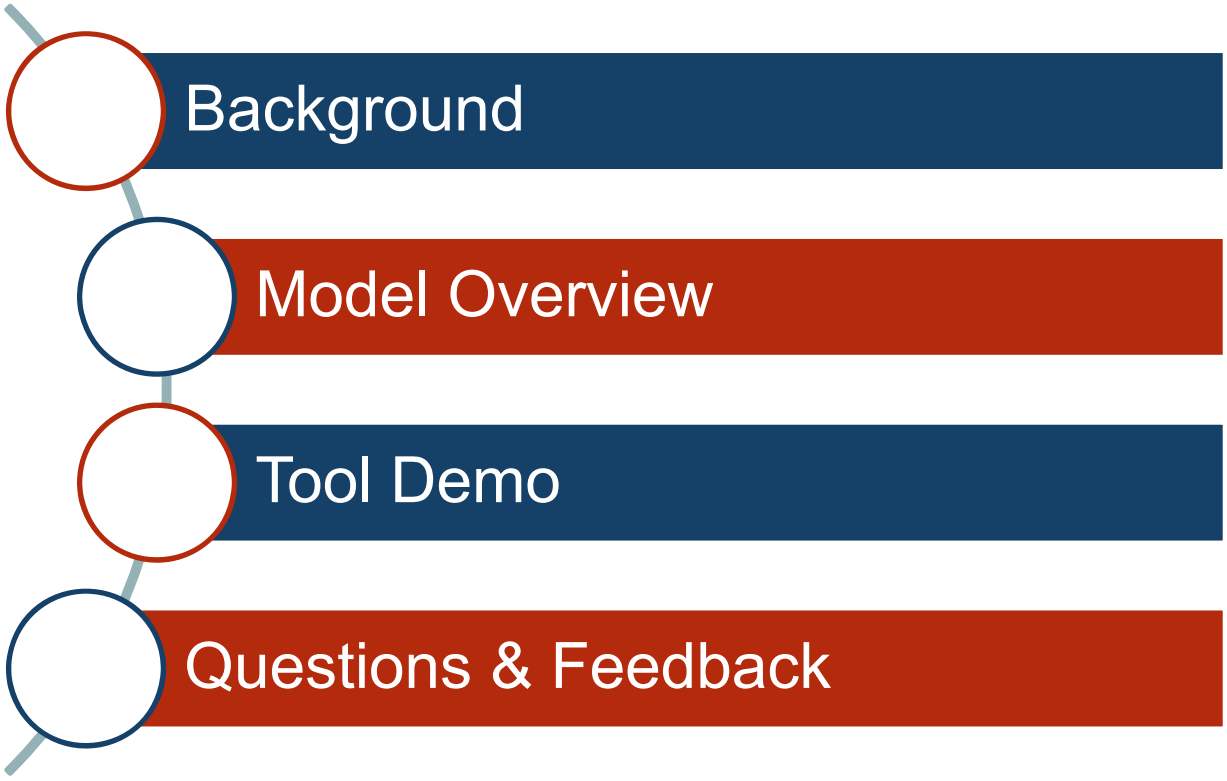
Costing Model for Viral Load and CD4 Testing Transition

September 2015

Webinar Outline



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VL Taskforce Group

- The Viral Load and Early Infant Diagnosis Implementation Task Force (VELITF) was launched at the ASLM 2014 Conference, and charged with leading the Diagnostics Access Initiative (DAI) implementation support.

- A few DAI partners (SCMS, CHAI, MSF, and USAID) have collaborated over Q1-Q3 2015 to develop a comprehensive VL costing model which also incorporates CD4 testing.

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Need for a Comprehensive Costing Tool

Countries need to understand the all-inclusive cost of VL testing to:

- Define their scale-up plans
- Apply for donor funding
- Calculate their funding gap to reach global goals such as UNAIDS 90-90-90
- Budget for CD4 testing despite the uptake of VL
- Inform supplier negotiations for lower costs based on testing volumes

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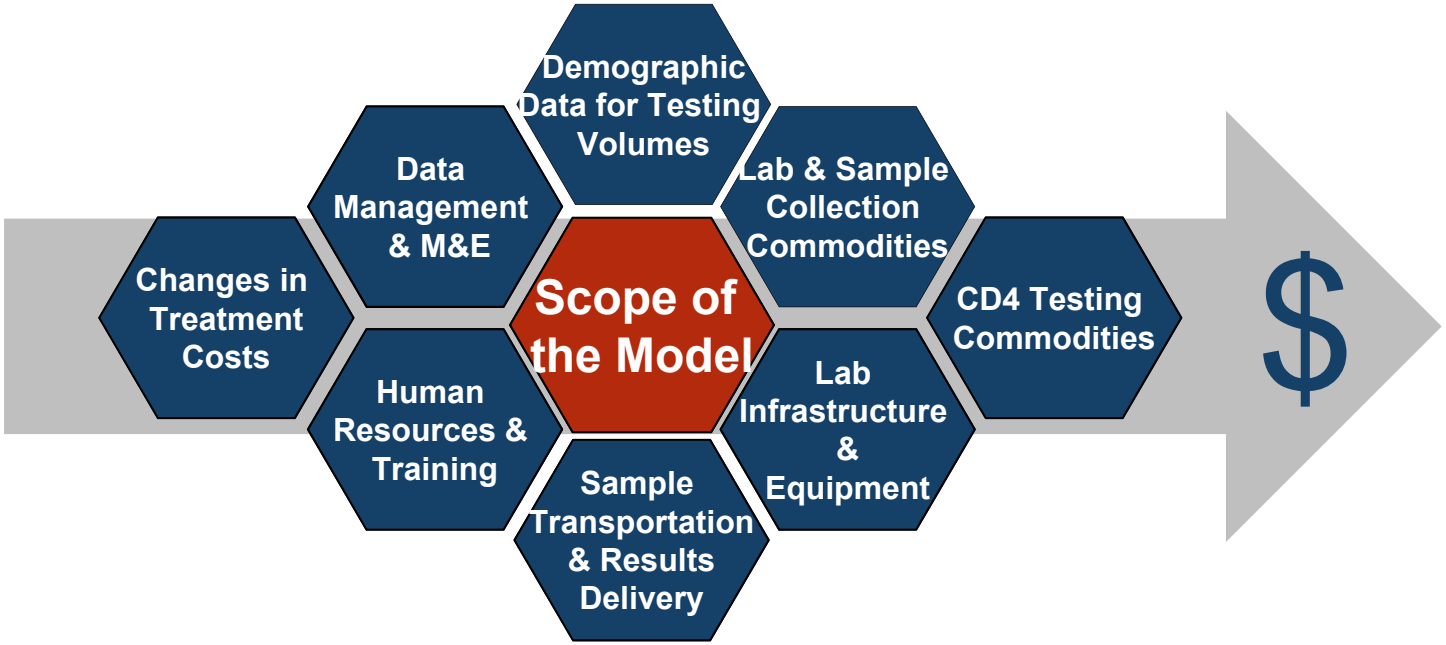
Scope & Concept



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Model Overview

Excel-based

3 Year Scale-up

User-guided scenario building

VL scale-up for ART monitoring
Maintains CD4 for other purposes

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What this tool does and does not do

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	× Potential decreases in commodity costs associated with global scale-up of VL × Secondary/literature research on manufacturer barriers and decisions
✓ CD4 commodity costs **only** ✓ CD4 testing volumes following VL scale-up	× Comprehensive CD4 costs, including equipment, drugs, sample transport, results delivery, human resources, training, and data management × Impact of test-and-treat model on CD4
✓ **Changes** in 1st/2nd line distribution and associated treatment costs	× The full costs of treatment × Change in patient population due to 90-90-90 or test-and-treat implementation
✓ **Instrument capacity and need**	× **Staff need and capacity** (in version 1.0) × Transport network requirements

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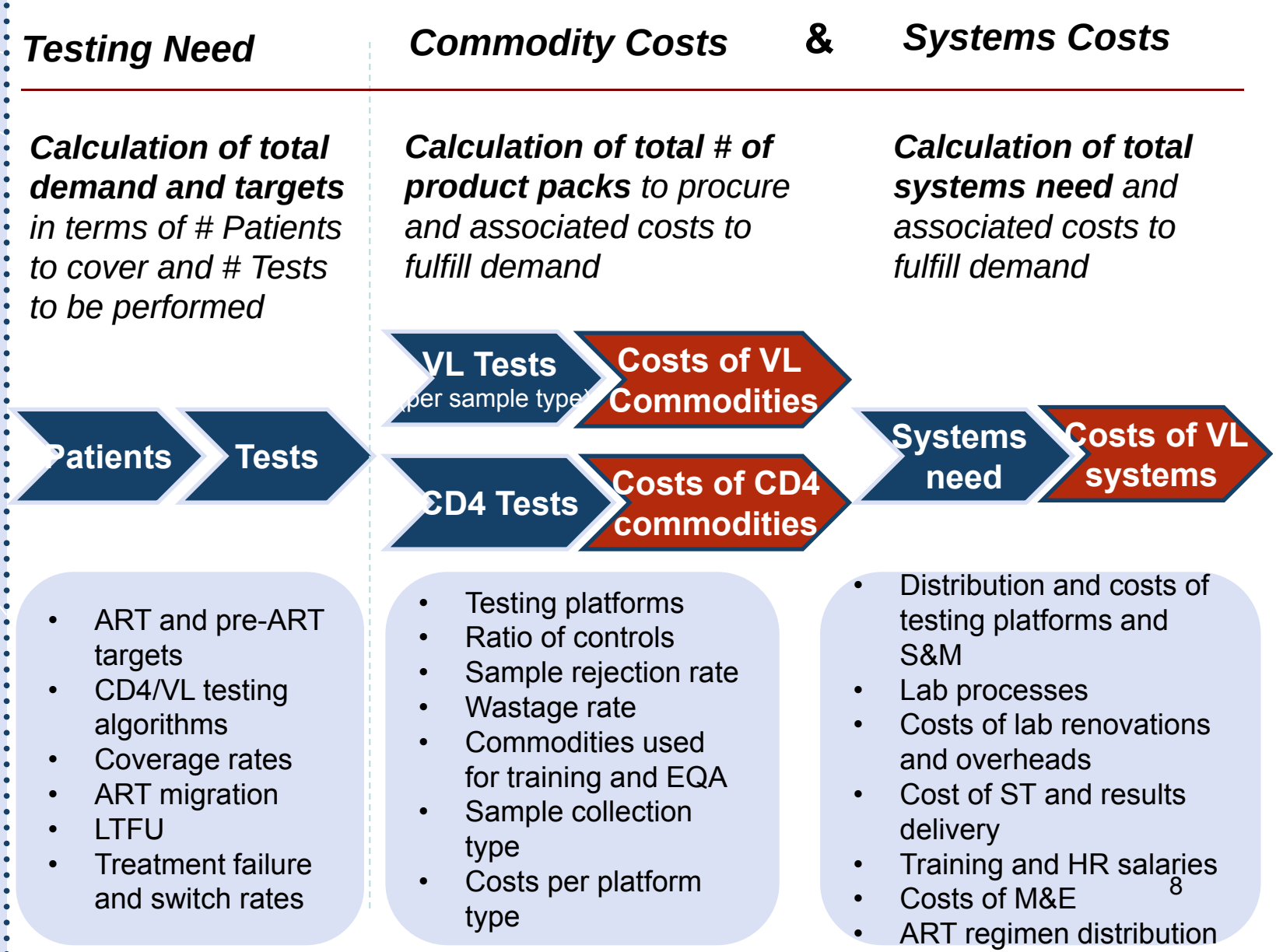
Model Logic Flow



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Sources of Necessary Data

ART Forecast and Quantification	ForLab Template	Care and Treatment data	Publically Available Data
ART Patient Population	Existing laboratories and platforms	Patient Attrition and Migration	Reagent and consumable costs
Regimen distribution and costs	Current machines distribution and capacity	Adherence counseling, retesting, and switch rates	Testing cascade from pilot VL programs
1st/2nd line split	Testing algorithms	Human resources headcount	Platform prices

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Tool Demo

Costing Model for CD4 and Viral Load Transition

Date: May 2015 *Version Control: 1.0*

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CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

World Health Organization

Cover page | Introduction | Summary | Data&Assumptions - Patient & Dx | Data&Assumptions - Systems | Testing Data Calculations | Systems Data Calculations

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Patient Population

1. Patient Data

		Timeframe for Scale-Up			
		Baseline	Expected		
	Year	2014	2015	2016	2017
	Total Patients in Pre-ART	790,020	958,161	1,206,064	1,329,068
	Total Patients on ART	596,622	763,902	956,458	1,202,996
	Pre-ART				
Specific Groups	Adults	762,853	910,253	1,145,761	1,262,614
Specific Groups	Children	27,167	47,908	60,303	66,453
	ART				
Specific Groups	Adults	476,783	610,282	781,162	999,887
Specific Groups	Pregnant Women	97,200	126,000	141,600	162,000
Specific Groups	Children	22,639	27,620	33,696	41,109
	Total Patients on 2° line	21,337			
Specific Groups	Adults	20,430			
Specific Groups	Children	907			

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Pre-ART Patient Flows

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

Pre-ART		*Guidance:*
Adults Pre-ART to ART Migration Rate	20%	
Children Pre-ART to ART Migration Rate	10%	
Attrition Rate Adult patients in Pre-ART	10%	
Attrition Rate Children patients in Pre-ART	10%	
Additional Pre-ART Adults CD4 Provider-Initiated Testing	5%	*5%*
Additional Pre-ART Children CD4 Provider-Initiated Testing	5%	*5%*

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ART Patient Flows & Testing Cascade

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

ART		Guidance:
2° line Adult switch rate with CD4 monitoring only	0.90%	
2° line Adult switch rate with VL monitoring of suspected failure	2.88%	
2° line Adult switch rate with routine VL monitoring	3.78%	
Suspected Failure Testing		
Patients on 1° line suspected to be failing (1st VL test)	12%	*10-14%*
Patients retested after adherence and counseling (2nd VL test)	60%	*60%*
Patients virologically failed (2 VL > 1000 copies) switched to 2°line	40%	
Patients on 2° line suspected to be failing (3rd VL test)	27%	*27-38%*
Patients on 2° line retested after adherence and counseling (4th VL test)	35%	
Patients switched to 2°line after only 1 VL test > 1000 copies	10%	
Routine Monitoring		
Virological Failure on 1°line because VL > 1000 copies	18%	*10-20%*
Patients retested after adherence and counseling (2nd VL test)	60%	*23%*
Patients virologically failed (2 VL > 1000 copies) switched to 2°line	35%	*17-53%*
Virological Failure on 2°line because VL > 1000 copies (3rd VL test)	15%	
Patients on 2° line retested after adherence and counseling (4th VL test)	30%	
Patients switched to 2°line after only 1 VL test > 1000 copies	5%	
Attrition		
Attrition rate Adult patients on 1°line (%)	6%	
Attrition rate Adult patients on 2° line (%)	12%	

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VL Testing Algorithm

3. Testing Algorithms

VL Testing Algorithm

Does the country follow the WHO recommended testing algorithm (as per the 2013 consolidated guidelines)? No

WHO recommended testing algorithm	- Year 1 - # tests First year	- Following Years - # tests per year - on-going	- Following Years - # tests - on-going for patients on 2° line
Adults - # VL Tests per year	1	2	2
Pregnant Women - # VL Test per year	1	-	n/a
Children - # VL Tests per year	1	2	2

CD4 Testing Algorithm

	# tests First year	# tests per year – on-going
ART Adults	1	2
ART Pregnant Women	1	-
ART Children	1	2

	# tests at Diagnosis	# tests First year	# tests per year on-going
Pre-ART Adults	1	1	1
Pre-ART PW	-	n/a	n/a
Pre-ART Children	1	1	1

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Scenario Building 1

4. Scenario Parameters

a) VL used to confirm suspected failure for patients not receiving VL routine monitoring?

	Yes
Target population	Only specific groups

	Adults	Pregnant Women	Children
Groups	Yes	No	No

Scale-Up Targets for VL suspected failure testing (% of target population)	2015	2016	2017
Adults	25%	50%	75%
Pregnant Women	25%	50%	75%
Children	25%	50%	75%

b) VL used also/only for routine monitoring?

	Yes
Target population	All patients on ART

	Adults	Pregnant Women	Children
Groups	No	Yes	Yes

Scale-Up Targets for routine VL testing (% of target population)	2015	2016	2017
Adults	0%	0%	25%
Pregnant Women	50%	75%	90%
Children	25%	40%	60%

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Scenario Building 2

4. Scenario Parameters

c) CD4 used for routine Pre-ART monitoring in addition to provider-initiated testing? Yes

Target population All patients in Pre-ART

Groups	Adults	Children
	Yes	Yes

Coverage Targets for routine CD4 testing for Pre-ART (% of target population)

	2015	2016	2017
Adults	20%	20%	20%
Children	5%	5%	5%

d) CD4 used for routine monitoring of those receiving VL? No

Target population All patients on ART

Groups	Adults	Pregnant Women	Children
	No	Yes	Yes

Scale-Up Targets for routine VL testing (% of target population)

	2015	2016	2017
Adults	0%	0%	25%
Pregnant Women	50%	75%	90%
Children	25%	40%	50%

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Scenario Building 3

4. Scenario Parameters

e) CD4 used for routine ART monitoring of those not receiving VL?	Yes
Target population	Only specific groups

	Adults	Pregnant Women	Children
Groups	Yes	Yes	No

Coverage Targets for routine CD4 testing for ART (% of target population)	2015	2016	2017
Adults	10%	10%	10%
Pregnant Women	10%	10%	10%
Children			

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Additional Testing Requirements

5. Testing in Lab

	% Total Test	*Guidance*
Training and EQA	1%	1%
Sample Rejection Rate (%)	10%	10%
Wastage	5%	5%

6. Sample Collection

VL Sample Collection Types

	2015	2016	2017
% Samples collected through DBS	0%	15%	30%
% Samples collected through PPT Tubes			
% Samples collected through EDTA	100%	85%	70%
	100%	100%	100%

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Machine Distribution

7. VL PCR machines and CD4 machines

VL PCR machine Types (% Tests):	2015	2016	2017	Ratio of controls			
Roche 48	58%	60%	80%	1	controls out of	28	tests
Abbott m2000	0%	5%	10%	1	controls out of	96	tests
Roche 96	41%	35%	10%	1	controls out of	58	tests
Siemens Versant					controls out of	1	tests
Biocentric					controls out of	1	tests
Cepheid GeneXpert					controls out of	1	tests
Alere Q					controls out of	1	tests
	100%	100%	100%				

CD4 machine Types	2015	2016	2017	Ratio of controls			
FACSCount	35%	35%	35%	2	controls out of	75	tests
FACSCalibur					controls out of	90	tests
Partec	64%	64%	64%	1	controls out of	90	tests
Guava					controls out of	1	tests
PIMA	1%	1%	1%	1	controls out of	10	tests
BD FACSPresto					controls out of	1	tests
Other					controls out of	1	tests
Error: the sum must be 100%	100%	100%	100%				

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Commodity Costs

8. Diagnostic products for costing

Item	Cost per Test	*Guidance*
Sample Collection		
DBS Bundles	$2.20	$2.20
EDTA Tubes	$0.50	$0.50
PPT Tubes	$1.75	$1.75
Labs VL		
Reagents and Consumables Roche 48	$9.40	$9.40
Reagents and Consumables Abbott m2000	$11.50	
Reagents and Consumables Roche 96	$9.40	
Reagents and Consumables Siemens Versant		
Reagents and Consumables Biocentric		
Reagents and Consumables Cepheid GeneXpert		
Reagents and Consumables Alere Q		
Labs CD4		
Reagents and Consumables FACSCount	$6.94	$6.94
Reagents and Consumables FACSCalibur	$7.51	$7.51
Reagents and Consumables Partec	$4.71	$4.71
Reagents and Consumables Guava	$15.28	$15.28
Reagents and Consumables PIMA	$12.30	$12.30
Reagents and Consumables BD FACSPresto		
Reagents and Consumables Other		

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ARV Costs

1. Drug Costs and Distribution

Annual Costs

Adult 1st Line	2015	2016	2017
TDF / 3TC / EFV	$125.80	$115.58	$109.50
TDF / 3TC / NVP			
ABC / 3TC / EFV	$198.32	$198.32	$198.32
AZT / 3TC / EFV			
AZT / 3TC / NVP	$98.67	$98.67	$98.67
Other			
Weighted cost:	$112.31	$111.25	$107.09

Distribution

	2015	2016	2017
	49%	72%	75%
	1%	1%	1%
	50%	27%	25%
Sum:	*100%*	*100%*	*100%*

Adult 2nd Line	2015	2016	2017
TDF / 3TC / LPV/r	$282.63	$282.63	$282.63
TDF / 3TC / ATV/r	$299.18	$287.01	$274.85
AZT / 3TC / ATV/r	$322.66	$310.49	$298.33
ABC / 3TC / LPV/r	$386.29	$386.29	$386.29
TDF/3TC/AZT+ATV/r	$364.03	$351.86	$339.69
Weighted cost:	$280.14	$254.14	$246.02

	2015	2016	2017
	40%	34%	29%
	19%	22%	22%
	18%	26%	34%
	14%	4%	0%
	9%	14%	14%
Sum:	*100%*	*100%*	*100%*

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ARV Costs – 1st/2nd Line

Comparison

	ART Population		
	2015	**2016**	**2017**
Original 1st Line Prevalence Rate:	95.72%	95.72%	95.72%
Original 2nd Line Prevalence Rate:	4.28%	4.28%	4.28%
Updated 1st Line Prevalence Rate:	95.62%	94.79%	93.35%
Updated 2nd Line Prevalence Rate:	4.38%	5.21%	6.65%

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Equipment & Lab Costs

2. Lab and VL Equipment Costs

		# of Platforms								Lab Upgrade Costs		
		2014	2015	2016	2017					2015	2016	2017
Lab Name	Testing Platform					Reagent Rental	Daily throughput	Cost of the platform	Annual S&M /platform			
Facility A1	Roche 48	4	4	4	4	No	84	$113,000	$3,000			
Facility A2	Roche 96	2	2	2	2	No	168	$113,000	$3,000			
Facility B	Roche 48	2	2	2	2	No	84	$113,000	$3,000			
Facility C	Roche 48	1	1	1	1	No	84	$113,000	$3,000			
Facility D	Roche 48	1	1	1	1	No	84	$113,000	$3,000			
Facility E1	Roche 96	3	3	3	3	No	168	$113,000	$3,000			
Facility E2	Roche 48	3	3	4	4	No	84	$113,000	$3,000		$2000	
Facility F1	Roche 48	5	5	5	5	No	84	$113,000	$3,000			
Facility F3	Abbott m2000	2	2	2	2	No	184	$160,000	$3,000			
Facility G	Abbott m2000	0	0	1	1	No	184	$160,000	$3,000		$10,000	

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Transport & Data Management

3. Sample Transportation and Results Delivery

Cost per Sample	2015	2016	2017
DBS / Paper			
DBS / Electronic		$ 0.10	$ 0.10
PPT / Paper			
PPT / Electronic			
Plasma (EDTA) / Paper			
Plasma (EDTA) / Electronic	$ 1.20	$ 1.20	$ 1.20
Weighted cost:	$1.20	$1.04	$.087

Distribution	2015	2016	2017
		15%	30%
	100%	85%	70%
Sum:	*100%*	*100%*	*100%*

4. Data Management Costs

Cost per VL Test

	2015	2016	2017
Reporting Activities	$0.05	$0.04	$0.03
M&E Activities	$0.10	$0.08	$0.07

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Personnel

5. Human Resource and Training Costs

		Headcount in Country			% allocated to VL			
Lab Technicians	**Monthly Salary**	**2015**	**2016**	**2017**	**2015**	**2016**	**2017**	**Annual Training**
Senior laboratory technician	$100	20	35	40	20%	30%	40%	$200.00
Junior laboratory technician	$80	30	50	60	10%	20%	50%	$100.00

		Headcount in Country (dedicated to VL)					
Clinicians & Other Health Workers	**Monthly Salary**	**2015**	**2016**	**2017**	**Time Spent per VL test**	**Intro Training**	**Refresher Training**
Doctor							
Nurse							
Primary counselor							
Receptionist							

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Summary

VL Scale-Up and CD4 Transition Costing Summary

Key Assumptions

VL Testing Algorithm follows WHO 2013 guidelines	No		
	Adults	**Pregnant Women**	**Children**
VL testing used to confirm suspected treatment failures for patients not on VL routine monitoring	Yes	No	No
	Adults	**Pregnant Women**	**Children**
VL testing used for routine monitoring	Yes	Yes	Yes
	Adults	**Pregnant Women**	**Children**
CD4 testing used for routine monitoring of patients on ART	Yes	Yes	No
	Adults	**Pregnant Women**	**Children**
CD4 testing used for routine monitoring of pre-ART patients	Yes	Yes	Yes

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Summary Outputs

Summary Outputs

	2015	2016	2017	TOTAL
Total ART Patients	763,902	956,458	1,202,996	**2,923,356**
Total Pre-ART Patients	958,161	1,206,064	1,329,068	**3,493,292**
Total VL Tests	105,705	198,198	715,342	**1,019,245**
Total CD4 Tests	730,248	936,571	922,911	**2,589,730**
VL Testing Capacity	Sufficient	Sufficient	Insufficient	

Note: If VL testing capacity is insufficient, additional platforms need to be placed to meet the testing need.

	2015	2016	2017	TOTAL
Total VL Costs	$ 1,518,986	$ 4,310,081	$ 13,798,095	$ **19,627,162**
Diagnostic commodities Costs	$ 1,142,404	$ 2,204,029	$ 8,251,951	$ **11,598,384**
Change in Treatment Costs	$ 127,173	$ 1,454,163	$ 4,615,910	$ **6,197,247**
Lab and VL Equipment	$ 73,000	$ 358,000	$ 81,000	$ **512,000**
Sample Transportation and Results Delivery	$ 145,873	$ 235,905	$ 715,700	$ **1,097,478**
Human Resource and Training	$ 14,680	$ 34,200	$ 62,000	$ **110,880**
Data Management	$ 15,856	$ 23,784	$ 71,534	$ **111,174**
Total CD4 Commodity Costs	$ 4,790,154	$ 6,143,556	$ 6,053,953	$ **16,987,664**

	2015	2016	2017
Cost of VL Testing per ART Patient	$18.00	$27.42	$30.58
Cost per VL Test	$14.37	$21.75	$19.29

Testing volumes

Equipment Capacity

Total VL Costs

CD4 commodity costs only

Comprehensive Cost per Test

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Adding New Equipment

2. Lab and VL Equipment Costs

Lab Name	Testing Platform	# of Platforms 2014	2015	2016	2017	Reagent Rental	Daily throughput	Cost of the platform	Annual S&M /platform	Lab Upgrade Costs 2015	2016	2017
Facility A1	Roche 48	4	4	4	4	No	84	$113,000	$3,000			
Facility A2	Roche 96	2	2	2	2	No	168	$113,000	$3,000			
Facility B	Roche 48	2	2	2	2	No	84	$113,000	$3,000			
Facility C	Roche 48	1	1	1	1	No	84	$113,000	$3,000			
Facility D	Roche 48	1	1	1	1	No	84	$113,000	$3,000			
Facility E1	Roche 96	3	3	3	3	No	168	$113,000	$3,000			
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Facility B	Roche 48	2	2	2	2	No	84	$113,000	$3,000			
Facility C	Roche 48	1	1	2	2	No	84	$113,000	$3,000		$2000	
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Facility E1	Roche 96	3	3	3	3	No	168	$113,000	$3,000			
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Cost of VL Testing per ART Patient	$18.00	$28.15	$30.59	
Cost per VL Test	$14.37	$22.33	$19.29	

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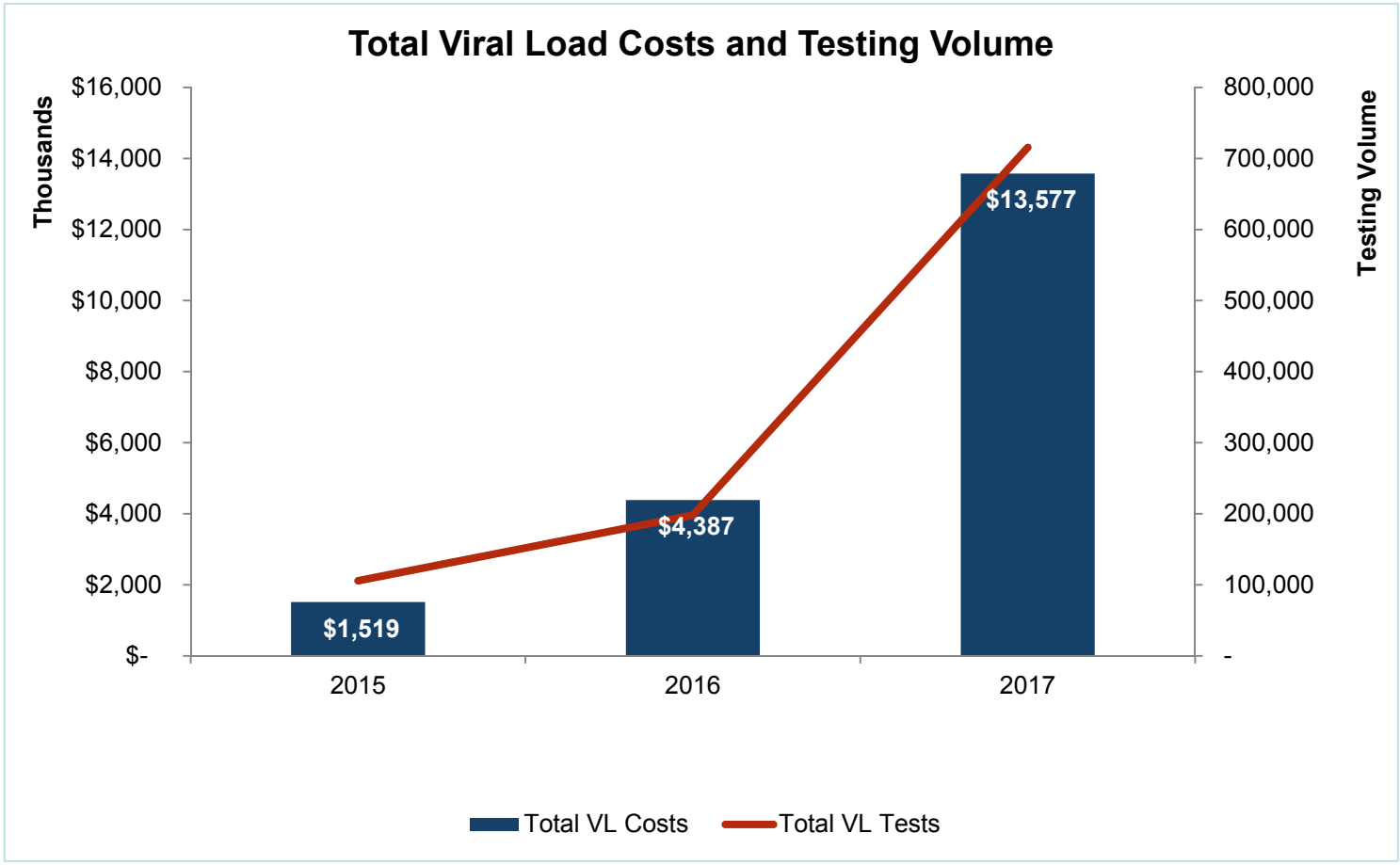
Output Graphs 1 - VL



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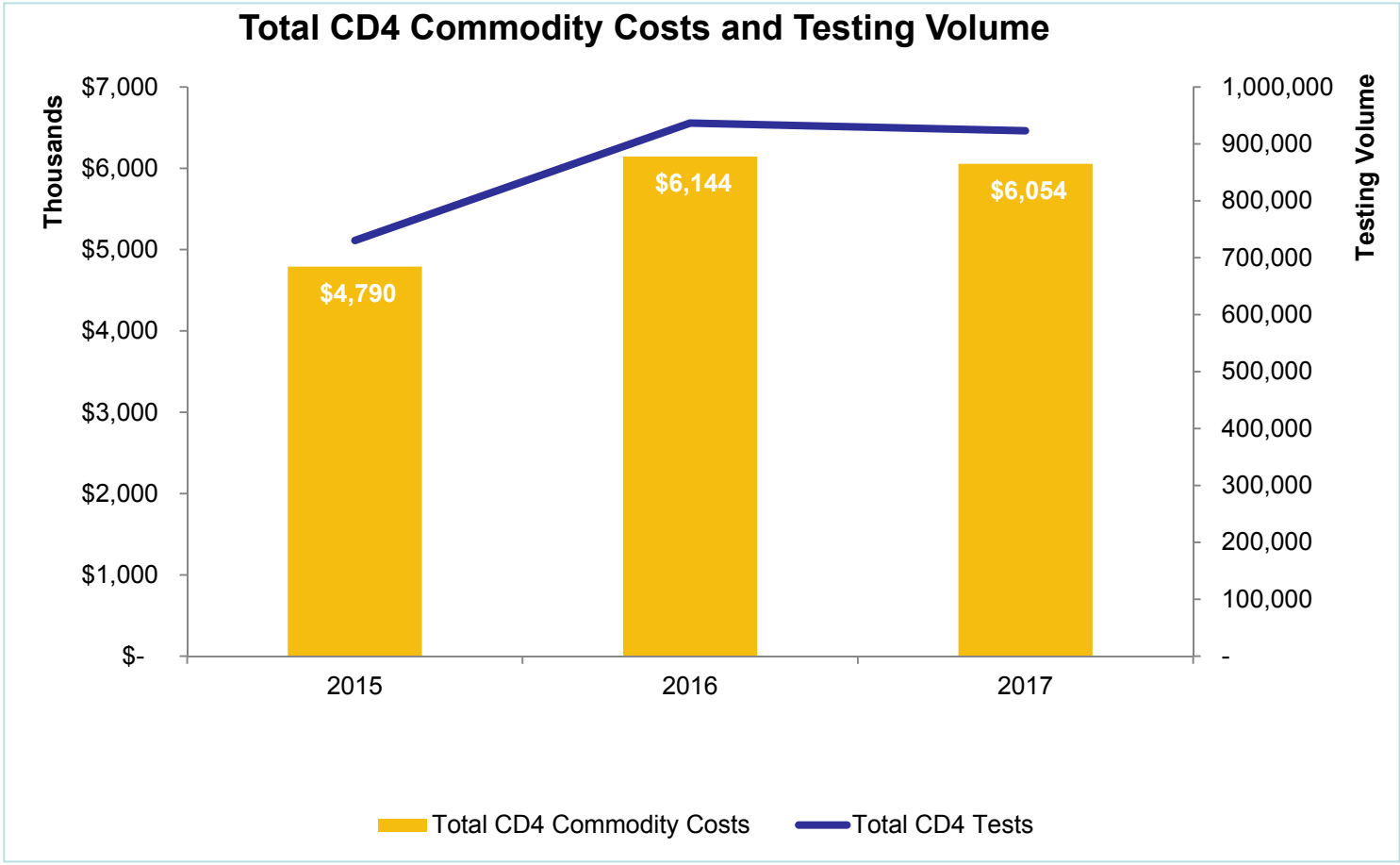
Output Graphs 2 – CD4



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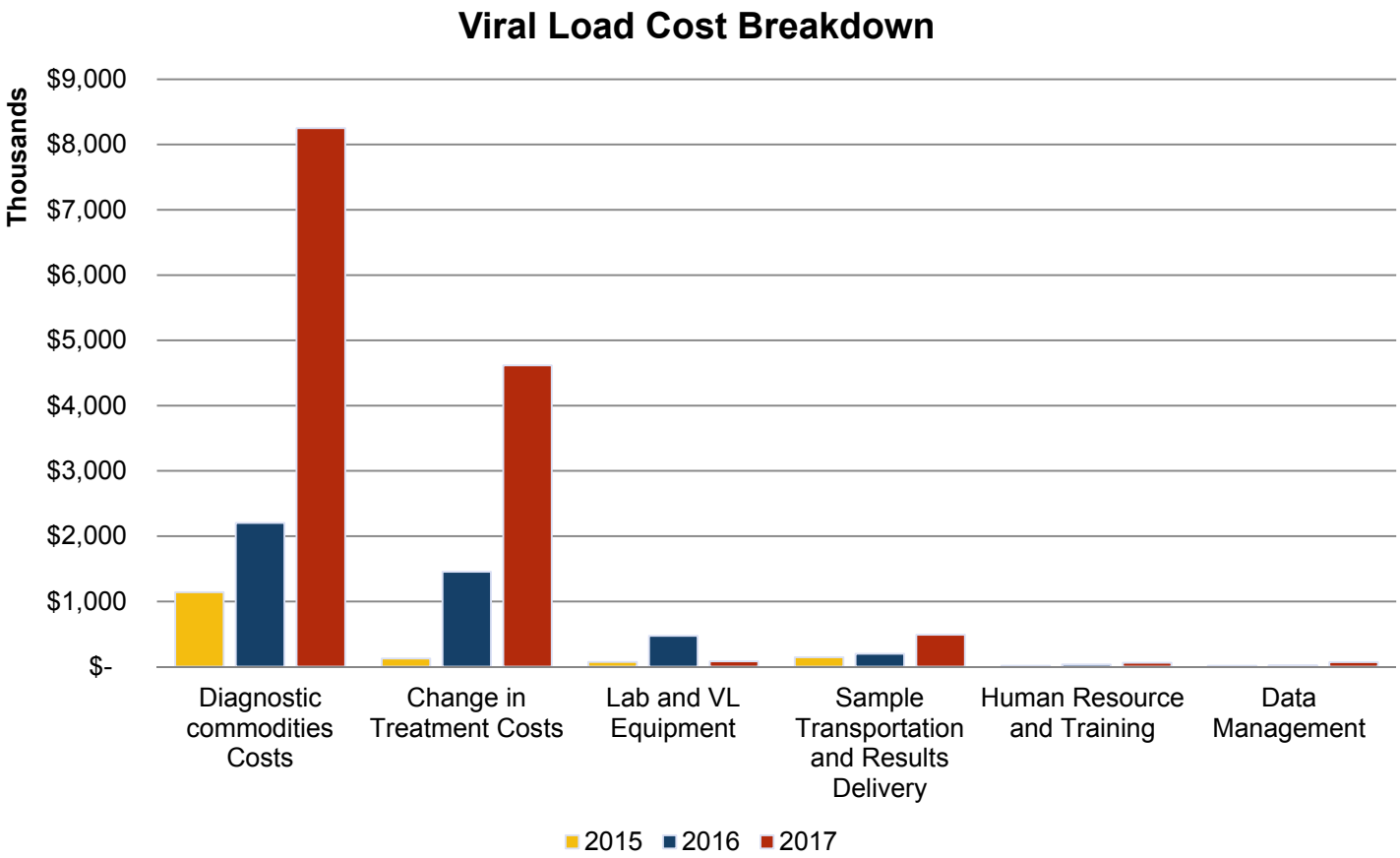
Output Graphs 3



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Questions?

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Next Steps

- Pilot tool with existing program data to ensure accuracy

Test

- Disseminate to countries to assist country plans and provide technical assistance for use

Utilize

- Continuously refine tool to ensure user-friendliness and usefulness of outputs

Refine

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Thank you!

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