National Quantification of HIV/AIDS Program Pharmaceutical Needs ForJuly2019–June2021

April 2019

Addis Ababa, Ethiopia

Acknowledgments

The Federal Ministry of Health (FMoH) and the Ethiopian Pharmaceutical Supply Agency (EPSA) would like to express appreciation to the United States Agency for International Development (USAID) Global Health Supply Chain Program - Procurement and Supply Management (GHSC-PSM) project in Ethiopia and Clinton Health Access Initiative (CHAI) for the comprehensive support on the national quantification of HIV program pharmaceuticals (2019-2021).FMoH and EPSA would also like to acknowledge JSI/AIDSFreefor their significant technical support throughout the process. Special acknowledgement also goes to the technical team (Annex I) and workshop participants (Annex II) for their valuable contributions.

Contents

List of Tables

Acronyms

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
ATV	Atazanavir
ATV/r	Atazanivar/ritonavir
AZT	Zidovudine
BMI	Body Mass Index
CD4	Cluster of Differentiation 4
CDC	Centers for Disease Control
CHAI	Clinton Health Access Initiative
CSA	Central Statistics agency
CTX	Co-Trimoxazole
DBS	Dried Blood Spot
DRV	Darunavir
DRV/r	Darunavir/ritonavir
DTG	Dolutegravir
EDHS	Ethiopia Demographic and Health Survey
EFV	Efavirenz
EFY	Ethiopian Fiscal Year
EPHI	Ethiopian Public Health Institute
FANTA	Food and Nutrition Technical Assistance
FBP	Food by Prescription
FHAPCO	Federal HIV/AIDS Prevention and Control Office
GF	Global Fund
GHSC-PSM	Global Health Supply Chain-Procurement and Supply Management
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HEI	HIV-Exposed Infant
HMIS	Health Management Information System

L&D	Labor and Delivery
LPV/r	Lopinavir/ritonavir
NGO	Nongovernmental Organization
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NVP	Nevirapine
OI	Opportunistic Infection
PEPFAR	President's Emergency Plan for AIDS Relief
EPSA	Ethiopian Pharmaceuticals Supply Agency
PI	Protease Inhibitor
PLHIV	People Living with HIV/AIDS
PMTCT	Prevention of Mother-To-Child Transmission
Pr-EP	Pre-Exposure Prophylaxis
PPT	Plasma Preparation Tube
PPM	Pulled Procurement Mechanism
RAL	Raltegravir
RHB	Regional Health Bureau
RPR	Rapid Plasma Reagin
RTV	Ritonavir
STI	Sexually Transmitted Infection
TB	Tuberculosis
TDF	Tenofovir
TLD	Tenofovir Lamivudine Dolutegravir
TLE	Tenofovir Lamivudine Efavirenz
USD	U.S. Dollars
USAID	United States Agency for International Development
VDRL	Venereal Disease Research Laboratory
WHO	World Health Organization

Executive Summary

As part of a comprehensive and effective response to HIV/AIDS, the process of securing and sustaining the continuity of pharmaceutical supplies in rapidly growing programs requires considerable financial and human resources, strong supply chain management, and close coordination. The Federal Ministry of Health, Ethiopian Pharmaceuticals Supply Agency (EPSA), Federal HIV/AIDS Prevention and Control Office (FHAPCO), Ethiopian Public Health Institute (EPHI), and partners consider the routine and comprehensive quantification of HIV/AIDS pharmaceuticals to be a critical step in implementing an effective program. To quantify health commodity demands, stakeholders considered several current developments in the HIV/AIDS prevention and control program:Revision of the national guidelines for comprehensive HIV prevention, care, and treatment; introduction of dolutegravir based regimen; NVP based regimen shift; optimization of pediatrics regimen; introduction of third-line treatment; change in test protocol; introduction of new laboratory testing equipment and pediatrics accelerated plan. The objective of the workshop was to review currently assessed data on program performance and reach consensus on the data and other key assumptions required to forecast HIV/AIDS commodity needs from July 2019 to June 2021. The scope includes:ARVs for all pediatric and adult clients; medicines for prevention of mother-to-child transmission (PMTCT); medicines for pre-exposure prophylaxis (PrEP); medicines for prevention and treatment of opportunistic infection; HIV diagnostic rapid test kits; Early infant diagnosis (EID) pharmaceuticals; Viral load (VL) monitoring and other ART monitoring laboratory pharmaceuticals; medicines for treating sexually transmitted infections (STIs) and condoms for HIV prevention. Forecast results are shown in detail in different sections of this document. Costs of the different subcategories of products are summarized in Table1. Costs include product and procurement and supply management-related costs.

Table 1: Cost Summary of forecasted HIV/AIDS pharmaceuticals, July 2019–June 2021

S.No.	Product Category	Estimated Cost (USD)	
		July 2019 - June 2020	**July 2020 - June 2021**
1	ARVs	**53,320,789.77**	**56,088,319.52**
2	Medicines for opportunistic infections	**$3,271,279.25**	**$2,994,771.41**
3	Medicines for sexually transmitted infections	**$889,553.38**	**$936,052.40**
4	Condom requirements	**$4,128,407.45**	**$4,246,548.82**
5	HIV diagnostic rapid test kits	**$ 9,525,864**	**$ 9,525,864**
7	EID pharmaceuticals and Viral load monitoring pharmaceuticals	**$11,728,692.00**	**$13,551,348.00**
8	CD4 reagents	**$3,484,175.78**	**$3,760,782.87**
9	Hematology reagents	**$2,109,444.41**	**$2,111,420.26**
10	Chemistry reagents	**$154,092.79**	**$168,230.92**
11	Lab consumables	**$548,933.14**	**$627,240.31**
	Total	**$89,161,231.97**	**$94,010.578.51**

Background

The mission of the Federal Democratic Republic of Ethiopia, Ministry of Health, is to reduce morbidity, mortality, and disability and improve the health status of the Ethiopian people through providing and regulating a comprehensive package of promotional, preventive, curative, and rehabilitative health services througha decentralized health system. HIV prevention and control is one of the critical health agenda for the Ethiopian government. The prevalence ofHIV has been declined substantially among all age groups in the past years. The overall trend of national HIV prevalence has remarkably declined from 4.4 percent in 2003 (FHAPCO, 2006) to 0.96 percent in the 2018 (EPHI Projection 2018).

Cognizant of the challenges of the previous efforts and building on lessons learned, the current strategic plan is developed to guide the 2015–2020 national response to achieve the "90-90-90" targets: 90 percent of all people living with HIV will know their HIV status, 90 percent of all people diagnosed with HIV will receive antiretroviral treatment (ART), and 90 percent of all people receiving ARTwill achieve viral suppression. The strategic plan aims to pave a path to end the AIDS epidemic in the country by 2030 through four strategic objectives:implementing a high-impact and targeted prevention program, intensifying targeted HIV testing and counseling services, virtually eliminating mother-to-child transmission and sustaining quality care and treatment

To realize the targets, consistent supply of HIV pharmaceuticalsto health system end users is indispensable. EPSA is committed toensuring the sustainable availability of HIV and other medicines and supplies throughout the country.

As part of the effort, national forecasts of pharmaceuticals demand for the HIV prevention and control program were being conducted as appropriate by EPSA in collaboration with its partners for fund mobilization and supply planning. In the past years, the quantification exercise results were able to guide differentprocurement orders of Antiretroviral (ARVs) medicines and other HIV pharmaceuticals for the program. This 2019 exercise need to address the recent initiatives and treatment recommendations of the HIV which have implications in the supply management program pharmaceuticals. The program is going to phase out ARV regimens containing NVP and Efavirenz 600mg while introducing different new ARV regimens containing DTG 50gm, EFV400mg, DRV and RAL. The program plans to place all eligible ART clients on TLD and other regimens containing DTG 50mg in 2019. Pediatrics ART optimization and third line ART are among the new initiatives being implemented by the program.

Pre-Exposure Prophylaxis (Pr-EP) is being piloted with the potential of scale up implementation in2019 and will have supply implication.

The forecastedpharmaceuticals requirement was developed to address the needs of expandingand emerging services of the HIV program. Product procurement, however, will be guided by the program assumptions for the new items, consumption reports from health facilities every two months and/or financial feasibility as appropriate. This approach will enable to closely monitor the stock status of ARVs medicines and other HIV pharmaceuticals, thus facilitating decision-making on appropriate modifications of supply plans to ensure continuity of the supply of ARVs medicines and others product categories.
This report presents the processes followed, data used for quantification, and forecasted quantities and estimated costs of the pharmaceuticals.

Scope of the Quantification

This quantification exercise aims to address the national level demands of program interventions by covering a range products including:

- ARVs for all pediatric and adult clients
- Medicines for Prevention of mother-to-child transmission (PMTCT)
- Medicines for prevention and treatment of opportunistic infection
- HIV diagnostic rapid test kits
- Early infant diagnosis (EID)pharmaceuticals
- Viral load (VL) monitoringand other ART monitoring laboratory pharmaceuticals
- Medicines for treating sexually transmitted infections (STIs)
- Condoms for HIV prevention

Objective

The objective of this quantification is to determine the national requirements of HIV pharmaceuticals included in the scope to assist fund mobilization and procurement decision-making for July 2019–June 2021.

Methodology

A variety of resources were referred to extract inputs and develop assumptions for this quantification exercise. This includes:

- Appropriate national strategic documents, such as the Health Sector Transformation Plan and FHAPCO's 2015–2020 HIV investment case for Ethiopia
- The most recent spectrum projection for number of clients on ARVs
- Federal Ministry of Health program update report on ART
- The Federal Ministry of Healthprovided national targets
- National strategic plan for eliminatingmother-to-child transmission of HIV and syphilis
- National ConsolidatedGuidelines for Comprehensive HIV Prevention, Care, and Treatment (August 2018)
- Implementation manual for DTG rollout and ART optimization in Ethiopia (January 2019)
- EDHS 2016 and 2018

To see the current program performance, EPSA in collaboration with Global Health Supply Chain-Procurement and Supply Management (GHSC-PSM) and Clinton Health Access Initiative (CHAI) conducted several assessments that are used as input for the quantification. These include:

- Assessments of the most recent ART utilization practice in all public and private ART sites receiving HIV pharmaceuticals
- Current pediatrics age and weight distribution

In addition to assessments, the quantification team gathered recent publications to validate assessment results.

The two-day event,National ARVs and Other HIV Supplies Need Quantification Workshop,was held in Adama on April 8 and 9, 2019 (see Annex II). It was organized by the Federal Ministry of Health, EPSA, and FHAPCO in collaboration with GHSC-PSM and CHAI and included representativesand technical experts from government organizations and stakeholders.

Several presentations were made to the larger audience, including:

- Data extracted from national reference documents
- Assessment results and recent literature
- Trends of ARV regimen changes over time
- Timelines for the implementation of new initiatives

After general discussion, detailed technical discussions were heldin small groups, and final agreed-upon inputs were presented back to the larger group. Subsequently, a technical team includingthe Federal Ministry of Health, EPSA, FHAPCO, EPHI, GHSC-PSM, CHAI, and AIDSFree generated the forecasted requirement of all pharmaceuticals in the scope using the morbidity scale-up-based quantification method as the program was still expanding.

The team used Quantimed®, the medicines forecasting software package,to forecast ARVs andMs-Microsoft Excelspread sheet to forecast medicines for treating and preventing OIs, laboratory and other pharmaceuticals. Unit costs of each product were taken from EPSA recent purchase orders prices for ARVs, medicines, and RTKs. The GHSC-PSM unit cost was also used for laboratory products, and these unit costs were assumed as a median price to serve over the forecast period.

SECTION 1: ANTIRETROVIRAL MEDICINES

1.1. Projected Number of Clients on ART

The quantification team reviewed PEPFAR, EPSA and FMOH servicedata sources regarding total number of clients on ART. The total number of clients on ART from FMOH service data as of December 2018 was 468,417 which was projected to 491,266 as of June 2019 after triangulating the monthly enrollment rate of three data sources.

According to the assessment conducted in 1291 ART sites by EPSA in March 2019 indicates that about 95.8% of the total ART clients are adults while the rest are in pediatric age groups as of February 2019. The same proportion was used for June 2019. However, considering the improvement plan for accelerated HIV care plan in children the proportion of ART clients on pediatrics age group was taken as 6% and 8% for 2020 and 2021respectively.

The number of clients on ART is further stratified to allow for applying different growth rates in each group, to accommodate variations in treatment options according to patient characteristics and the use of various ARV formulations (Table 2)

Table 2: Projected net number of adults and pediatric clients on ART, July 2019–June2021

Clients on ART	Feb-19	Jun-19	Jun-20	Sep-20	Jun-21
Total Adult and Pedi [DHIS 2]	**474,081**	**491,266**	**542,820**	**555,709**	**607,264**
Total Adult	**454,170**	**470,633**	**510,251**	**511,252**	**558,682**
Adult first line	439,947	455,894	494,272	495,242	541,186
Adult second line	14,223	14,616	15,458	15,477	16,913
Adult third line	0	123	521	534	583
Total Pediatrics	**19,911**	**20,633**	**32,569**	**33,343**	**36,436**
Pediatric 1st line	18,896	19,581	30,909	31,642	34,578
Pediatric 2nd line	1,015	989	1,544	1,500	1,622
Pediatric 3rd line	0	63	116	113	141

1.2. Adult ART

1.2.1. Adult first line

The national site-level assessment conducted by EPSA showed that 96.87%of adult ART clients are on first-line regimens as of Feb 2019.The workshop participants agreed to take the same proportion of adult first line clients throughout the quantification periods assuming that the rate of first line treatment failure will not increase in the coming three years due to the introduction of new ARVs.

1.2.1.1. Proportion of Existing Adults on First-line ART regimens

Based on EPSA site level assessment in March 2019, about 61.2% of existing adult clients are on TDF/3TC/EFV while 20.09%,9.77% and 8.60% are on AZT/3TC/NVP, AZT/3TC/EFV and TDF/3TC/NVP respectively. The same proportion was assumed to continue for existing adult clients until end of May 2019.

Table 3: Proportion of existing adult first line ART clients, February 2019

ARV Regimens	Proportion
TDF/3TC/EFV	61.18%
AZT/3TC/NVP	20.09%
TDF/3TC/NVP	8.60%
AZT/3TC/EFV	9.77%
ABC/3TC/EFV	0.24%
ABC/3TC/NVP	0.10%
Total Adult First Line	100.00%

FMOH plans to phase out the use of Nevirapine /NVP/ containing ARV regimens starting June 2019. All existing adult clients who are on NVP end-lock will be switched to DTG or EFV based on indication by the end of September 2019.

It was also assumed that eligible existing adult clients will be switched to Dolutegravir (DTG) containing regimens from June 2019 and the shift ends by the end of September 2019. Average proportion was taken for the transition periods, between June and September 2019.
Since there is no national data on prevalence of contraceptive use among women on ART, the contraceptive prevalence rateprojection of 44.7%, 49.6% and 55% for 2018/19, 2019/20 and 2020/21,respectively,taken from the national contraceptive pharmaceuticals need quantification 2019-2021 document,was used to determine women of reproductive age eligible for DTG.
Most (94%) of clients on AZT/3TC backbone can be shifted to TDF/3TC backbone while 6% of the clients who can't tolerate TDF due to renal insufficiency will remain on AZT based regimens.
Regarding the use of TDF/3TC/EFV, based on the recommendation on the recent guideline TLE400 will be used in all client groups except pregnant women and TB/HIV co-infection cases.
See table below for average proportion of existing adult clients by first-line ART regimen before, during and after the shift to DTG containing regimens. (Table 4)

Table 4: Distribution of existing clients on adult first-line ART regimens, May 30, 2019–September 30, 2019

ARV Regimens	Median proportion	September 30 2019
TDF/3TC/DTG	34.30%	68.60%
TDF/3TC/EFV	45.26%	29.33%
AZT/3TC/DTG	0.63%	1.26%
AZT/3TC/EFV	5.15%	0.54%
ABC/3TC/EFV	0.16%	0.08%
ABC/3TC/DTG	0.10%	0.20%
AZT/3TC/NVP	10.05%	0.00%
TDF/3TC/NVP	4.30%	0.00%
ABC/3TC/NVP	0.05%	0.00%

1.2.1.2. Proportion of treatment-naïve adults on first-line ART regimens

At the national quantification workshop, consensus was reached that TDF-based regimens will be prescribed starting from April 2019 for 94 percent of treatment-naïve adults while AZT-based regimens will be prescribed for 5.5 percent of adult clients who can't tolerate TDF due to renal dysfunction. ABC-based regimen will be prescribed for 0.5 percent who can't tolerate the two regimens during the three years.

Similarly, about 70.05 percent of treatment naïve adult clients will take DTG while 29.95 percent will take EFV containing regimens.

As per the current WHO recommendation, adult client with TB co-infection who are on DTG containing regimens will take additional DTG 50mg.

Table 5: Proportion of treatment naive clients on adult first-line ART regimens, April 2019-June 2021

Regimens	Proportion
TDF/3TC/DTG	65.85%
TDF/3TC/EFV	28.15%
AZT/3TC/DTG	3.85%
AZT/3TC/EFV	1.65%
ABC/3TC/DTG	0.35%
ABC/3TC/EFV	0.15%

1.2.2. Adult Second-line ART Regimen

The recent site-level assessment of total clients on ART conducted by EPSA in March 2019 shows that of the total adult clients on ART, 3.13 percent are on second-line treatment regimens. Even though, the capacity of diagnosing treatment failure increases by routine viral load testing, the workshop participants agreed that the rate of first line ART failure will not show increment due to the

introduction of new ARVs, like DTG. Thus, the proportion of adult clients on second line ART was assumed to remain the same throughout the quantification period.

1.2.2.1. Proportion of existing Adults on Second-line ART Regimens

The result of EPSA assessment conducted in March 2019 shows that the proportion of ATV/r to LPV/r is 84.1 percent to 15.9percent. The proportion of second line ART adult clients on TDF, AZT and ABC back bones are 54 percent, 30.6 percent and 15.4 percent respectively. The assessment result also shows that some second line clients are on suboptimal regimens which are not recommended by the guideline. One of the reasons explained for these suboptimal four drug-based regimens was failure of clients on second-line treatment. Regardless of the practice, the ARVs will be quantified according to the standard recommended regimens indicated in the guideline.Health facilities with suboptimal regimens will be advised to shift clients to a recommended regimen, which now includes third-line options.

Clients on ABC-based regimens, even though not recommended by the guideline, are assumed to continue because as explained by clinicians, most adults on the ABC-based second-line regimen are clients from the AZT-based first-line regime who cannot take the TDF-based second-line regimen due to renal impairment. These clients also require a loose 3TC for dosage adjustment. Hence, the proportion of existing clients on second-line ART regimens was reconstructed based on findings of the assumptions(Table 6)

Table 6: Proportion of existing adult clients on second-line ART, March 2019

Regimen	Proportion
TDF/3TC/ATV/r	45.13%
AZT/3TC/ATV/r	26.06%
TDF/3TC/LPV/r	5.75%
ABC/3TC/ATV/r	10.94%
AZT/3TC/LPV/r	4.21%
ABC/3TC/LPV/r	4.41%
TDF/3TC/ABC/LPV/r	1.40%
TDF/3TC/ABC/ATV/r	1.25%
Total Adult Second Line	100.00%

1.2.2.2. Proportion of New Adults on Second-line ART Regimens

For new second-line ART starting clients, the TDF-based regimen is recommended as the preferred second-line regimen for AZT-based regimen failure, while the AZT-based regimen is recommended as a preferred second-line regimen for TDF-based regimen failure. Also, when clients fail from AZT-

based first-line regimen and can't be shifted to a TDF-based regimen because of renal impairment, then ABC will be the option for the second-line shift. Adult clients on second line with TB co-infection (8 percent) will be on LPV/r end-lock while the rest (92 percent) will be on ATV/r. The proportion of nucleoside reverse transcriptase inhibitors(NRTIs) for each year is shown in Table 7.

Table 7: Assumptions on regimen proportion of NRTIs for new second-line ART, July 2020–June2021

Regimen back-bone	June 2020	June 2021
TDF	4.75%	4.75%
AZT	92.75%	92.75%
ABC	2.5%	2.5%

1.2.3. Adult Third-line ART Regimen

It was assumed that 3.2 percent of adult clients on secondline ART will have treatment failure and start third line ART throughout the quantification period. About 92.75 percent, 4.75 percent and 2.5 percent adult client on third line ART will be on TDF/3TC, AZT/3TC and ABC/3TC NRTI backbones respectively. Since all existing adult second line clients have been exposed to either EFV or NVP containing regimens their third line regimen will have DTG end lock

1.2.4. Adult ARV Regimen Medicines, Forecasted Quantities, and Estimated costs

According to the above assumptions adult ARV regimen medicines, forecasted quantities and estimated costs areshown in Table 8below.

Table 8: Adult ARV regimen medicines, forecast quantities July2019–June 2021

Product	Units	July 2019 - June 2020	
		Quantity	Total Cost
abacavir 300MG/tab	60	50,008	398,567.34
Atazanavir-Ritonavir 300+100MG/tab	30	155,619	1,864,319.94
Darunavir 600MG/tab	60	5,274	274,266.20
Dolutegravir 50MG/tab	30	377,174	1,320,109.35
Efavirenz 600MG/tab	60	51,919	231,558.82
Lamivudine 150MG/tab	60	45,260	73,774.53
Lamivudine-Dolutegravir-Tenofovir DF 300+50+300MG/tab	30	2,103,823	12,307,361.42

Lamivudine-Dolutegravir-Tenofovir DF 300+50+300MG/tab	90	467,516	7,971,150.07
Lamivudine-Efavirenz-Tenofovir DF 300+400+300MG/tab	30	1,915,972	11,495,830.40
Lamivudine-Efavirenz-Tenofovir DF 300+600+300MG/tab	30	263460	1,449,030.00
Lamivudine-Tenofovir DF 300+300MG/tab	30	159,799	455,426.85
Lamivudine-Zidovudine 150+300MG/tab	60	232,229	1,096,118.63
Lopinavir-Ritonavir 200+50MG/tab	120	57,604	940,678.08
Ritonavir 100MG/tab	60	5,274	36,129.30

1.3. Pediatric ART

In February 2019, EPSA through its branches assessed the weight and age proportions of pediatric clients on ART in 1291 health facilities. The weight and age proportion of pediatric clients is depicted in Table 9 and 10. These proportions isused to determine the appropriate quantities of each pediatric formulation required for the next two Ethiopian fiscal years (EFYs) in accordance with the regimen and dosing recommendations for each age and weight band.For weight and age distribution, the team reached consensus to keep the assessment data constant for the next two-year period.

Table 9: Proportion of Pediatrics Weight Band

Weight in kilograms	**Proportion in percent (Feb 2019 EPSA assessment)**	**Proportion in percent (July 2019–June 2021)**
3–5.9	0.5%	0.5%
6–9.9	3.1%	3.1%
10–13.9	7.2%	7.2%
14–19.9	17.6%	17.6%
20–24.9	20.6%	20.6%
25–29.9	18.2%	18.2%
30–34.9	12.3%	12.3%
≥35	20.5%	20.5%
Total	100%	100%

Table 10: Proportion of Pediatric Clients by Age Group

Age group (years)	**Proportion in percent (Feb 2019 EPSA assessment)**	**July 2019–June 2021**
Less than ten years &<20kg	25.4%	25.4%
Less than 10 years &≥20kg	22.4%	22.4%

10–15 years, and weight <30kg	24.9%	24.9%
10–15 years, and weight≥30kg	27.3%	27.3%
Total	100.00%	100.00%

1.3.1. Pediatric First-line ART Regimen

1.3.1.1. Distribution of Preexisting Pediatric Clients on First-line ART Regimen

As shown in Table 11, the regimen proportion for existing pediatric clients on first-line ART was assumed to be in line with the February 2019 EPSA national assessment.

Table 11: Proportion of existing pediatric clients on first-line ART

Serial no.	Regimen	Proportion in percent (February 2019 EPSA assessment)
1	ABC/3TC/EFV	2.5%
2	ABC/3TC/Lop/r	2.2%
3	ABC/3TC/NVP	2%
4	AZT/3TC/EFV	15%
5	AZT/3TC/LOP/r	2.1%
6	AZT/3TC/NVP	70.3%
7	TDF/3TC/EFV	4.9%
8	TDF/3TC/NVP	1%
Total		100.00%

Pediatrics ART Optimizations

Pediatrics ART optimization will start as of June 2019 and will be completed end of September 2019. The proportion of regimen from June 2019 to September 2019 for existing clients is depicted in Table 12 below.After the shift is completed, the proportion at the end of September 2019 will continue till June 2021.
The Implementation manual for DTG rollout and ART optimization in Ethiopia (January 2019),recommend that for children younger than ten years and less than 20kg, an ABC + 3TC + LPV/r regimen should be used as the preferred first-line ART. ABC +3TC+EFV, AZT + 3TC + LPV or AZT + 3TC + LPV can be used in special circumstances.

The preferred NRTI for children less than 10 years and greater than 20kg is ABC + 3TC and AZT+3TC can be used for special circumstances. For this age and weight category, DTG is the preferred end lock for first-line treatment and LPV is the alternative.

The preferred regimen for children older than 10 years or for 30kg & above TDF + 3TC +DTG and TDF+3TC +EFV, AZT+3TC+EFV & ABC+3TC+EFV can be used as alternate regimen.

The distribution of existing clients on the optimized regimen depicted in table 12 below as per the above recommendations.

Table 12: Distribution of existing clients on Pediatrics first-line ART regimen June 2019– September 2019

Regimen	<10 yrs&<20kg			<10 yrs&>20kg			>10 yrs&>30kg		
	June 2019	**Median Proportion**	**Sep 2019**	**June 2019**	**Median Proportion**	**Sep 2019**	**June 2019**	**Median Proportion**	**Proportion end of Sep 2019**
ABC/3TC/EFV	2.7%	3.8%	4.75%	2.6%	1.3%	0.0%	2.2%	1.1%	0.02%
ABC/3TC/Lop/r	4.8%	48.7%	90.25 %	2.4%	2.6%	2.85%	1.9%	0.9%	0.00%
ABC/3TC/NVP	2.1%	1.0%	0.00%	2.1%	1.0%	0.00%	1.8%	0.8%	0.00%
AZT/3TC/EFV	15.5 %	7.7%	0.25%	15.5%	7.5%	0.00%	13.4%	8.7%	4.52%
AZT/3TC/LOP/r	2.3%	3.6%	4.75%	2.3%	3.7%	5.00%	1.9%	0.9%	0.00%
AZT/3TC/NVP	72.6 %	35.3%	0.0%	72.6%	35.3%	0.00%	62.2%	29.4%	0.00%
TDF/3TC/EFV	0.0%	0.0%	0.0%	0.0%	0.0%	0.00%	12.0%	7.2%	2.86%
TDF/3TC/NVP	0.0%	0.0%	0.0%	0.0%	0.0%	0.00%	2.4%	1.2%	0.00%
ABC/3TC/DTG	0.0%	0.0%	0.0%	2.6%	48.6%	92.15%	0.0%	0.03%	0.06%
TDF/3TC/DTG	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	2.2%	49.8%	92.54%
	100.0%	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %	100.00 %

1.3.1.2. Distribution of New Pediatrics on First-line ART Regimen

For treatment-naïve pediatrics the proportion of Back bones & end locks varies depending on their age and weight:

For children younger than ten years and less than 20kg,

- 95 percent of these clients will take ABC based regimen while 5 percent will take AZT based regimens.
- All clients less than 3yrs in this group will take LPV/r. For clients 3yrs to 10 years will take LPV/r and EFV in 95% and 5% proportion respectively.

For children younger than ten years and for 20kg &above,

- 95 percent of these clients will take ABC based regimen while 5 percent will take AZT based regimens.
- 97 percent of these clients will take DTG as an end lock and 3% will take EFV.

For children older than 10 years or for 30kg & above,

- 95 percent of these clients will take TDF based regimen, 4.5 percent will take AZT based regimen and the rest 0.5 percent will take ABC based regimens.
- 97 percent of these clients will take DTG as an end lock and 3% will take EFV.

Based on the above assumptions, the distribution of new children on first line ART is shown in Table 13.

Table 13: Proportion of new pediatrics on first-line ART, July 2019– June 2021

	July 2019 to June 2021		
Regimen	**<10 yrs&<20kg**	**<10 yrs&≥20kg**	**>10 yrs or≥30kg**
ABC/3TC/EFV	4.75%	0.00%	0.02%
ABC/3TC/Lop/r	90.25%	2.85%	0.00%
ABC/3TC/DTG	0.00%	92.15%	0.49%
AZT/3TC/EFV	0.25%	0.00%	4.50%
AZT/3TC/Lop/r	4.75%	5.00%	0.00%
TDF/3TC/DTG	0.00%	0.00%	92.15%
TDF/3TC/EFV	0.00%	0.00%	2.85%
AZT/3TC/DTG	0.00%	0.00%	0.00%
Total	100.00%	100.00%	100.00%

1.3.2. Pediatric second-line ART regimen

1.3.2.1. Distribution of existing pediatric clients on second-line ART regimens

The regimen proportion obtained from the EPSA February 2019 national assessment was taken for existing pediatric clients for the coming two-years period (July 2019–June 2021), as shown in Table 14.

Table 14: Proportion of existing pediatric clients on second-line ART for July 2019–June 2021

Regimens	Proportion in percent (February 2019 EPSA assessment)	July 2019–June 2021
ABC/3TC/LPV/r	27.80%	27.80%
AZT/3TC/ATV/r	5.10%	5.10%
AZT/3TC/LPV/r	16.40%	16.40%
TDF/3TC/ATV/r	22.10%	22.10%
TDF/3TC/LPV/r	18.70%	18.70%
ABC/3TC/ATV/r	9.90%	9.90%
Total	100.00%	100.00%

1.3.2.2. Distribution of new pediatric on second-line ART regimen

It was assumed that 5% and 4% of children on ART will be on second- line in 2020 and 2021,

respectively.

The Implementation manual for DTG rollout and ART optimization in Ethiopia (January 2019), recommend that children younger than ten years and less than 20kg on ABC+3TC+LPV/ will be switched to RAL +AZT + 3TC whereas those on AZT + 3TC + LPV will be switched to RAL +ABC + 3TC. For children less than 10 years and greater than 20kg ABC + 3TC +DTG and AZT+3TC +DTG recommended as a second line regimens and AZT+3TC+ATV/r or LPV/r recommended for children older than 10 years or for 30kg & above. Proportion of new pediatric client's on second-line depicted in the table 15 below.

Table 15: Proportion of new pediatric client's second-line ART, July 2019 to June 2021

	June 19 to June 20			June 20 to June 21		
Regimen	**<10 yrs&<20kg**	**<10 yrs&>20kg**	**>10 yrs or >30kg**	**<10 yrs&<20kg**	**<10 yrs&>20kg**	**>10 yrs or >30kg**
ABC/3TC/Ral	**92.50%**	**0.00%**	**0.00%**	**5.00%**	**0.00%**	**0.00%**
ABC/3TC/LPV/r	**0.00%**	**2.78%**	**0.04%**	**0.00%**	**89.73%**	**0.04%**
ABC/3TC/ATV/r	**0.00%**	**0.00%**	**0.46%**	**0.00%**	**0.00%**	**0.46%**
ABC/3TC/DTG	**0.00%**	**89.73%**	**0.00%**	**0.00%**	**2.78%**	**0.00%**
AZT/3TC/Ral	**7.50%**	**0.00%**	**0.00%**	**95.00%**	**0.00%**	**0.00%**
AZT/3TC/LPV/r	**0.00%**	**7.50%**	**1.00%**	**0.00%**	**7.50%**	**7.60%**
AZT/3TC/ATV/r	**0.00%**	**0.00%**	**11.50%**	**0.00%**	**0.00%**	**87.40%**
TDF/3TC/LPV/r	**0.00%**	**0.00%**	**6.96%**	**0.00%**	**0.00%**	**0.36%**
TDF/3TC/ATV/r	**0.00%**	**0.00%**	**80.04%**	**0.00%**	**0.00%**	**4.14%**
Total	**100.00%**	**100.00%**	**100.00 %**	**100.00%**	**100.00%**	**100.00%**

1.3.3. Pediatric Third-line ART Regimen

About 116 clients in June 2020 & 138 clients in June 2021 from second line ART will be swiched to pediatric third-line regimens.
The Implementation manual for DTG rollout and ART optimization in Ethiopia (January 2019), recommend that children younger than ten years and less than 20kg will be maintained on their second line regimen until they become 20kg or approved DTG dosing available. Children less than 10 years and greater than 20kg will be shifted to DRV/r + ABC + 3TC +DTG or DRV/r + AZT + 3TC +DTG.Children older than 10 years or 30kg and above who are on AZT/3TC back bone will be shifted to DRV/r + ABC + 3TC +EFV third line regimen. The assumption for the pediatric third-line regimen proportion is shown in Table 16.

Table 16: Regimen proportion of pediatric third-line clients, July 2019–June2021

Regimen	**June 19 to June 21**		
	<10 yrs&<20kg	**<10 yrs&≥20kg**	**>10 yrs or >30kg**
ABC/3TC/Ral	**63.79%**	**0.00%**	**0.00%**
ABC/3TC/DRV/DTG	**0.00%**	**63.79%**	**0.00%**
ABC/3TC/DRV/EFV	**0.00%**	**0.00%**	**100.00%**

AZT/3TC/Ral	**36.21%**	**0.00%**	**0.00%**
AZT/3TC/DRV/DTG	**0.00%**	**36.21%**	**0.00%**
Total	**100.00%**	**100.00%**	**100.00%**

1.3.4. Pediatrics ARV Regimen Medicines, Forecasted Quantities, and Estimate Cost

As per the above assumptions Pediatrics ARV regimen medicines, forecasted quantities and estimated costs are shown in Table 17 below.

Table 17: Forecast Results and Estimated Cost of Pediatric ARVs, July 2019–June 2021

Product	Units	July 2019 - June 2020 Quantity	July 2020 - June 2021 Quantity
Abacavir 300MG/tab	60	42,516	57,425
Abacavir-Lamivudine 120+60MG/tab	60	180,259	248,866
Atazanavir-Ritonavir 300+100MG/tab	30	3,008	3,909
Darunavir 75MG/tab	480	16	34
Darunavir 150MG/tab	240	126	275
Darunavir 600MG/tab	60	428	906
Dolutegravir 50MG/tab	30	94,046	131,601
Efavirenz 200mg/tab	90	4,540	3,870
Efavirenz 50MG/tab	30	11,032	9,550
Efavirenz 600MG/tab	30	4,252	4,734
Lamivudine 150MG/tab	60	42,516	57,425
Lamivudine-Dolutegravir-Tenofovir DF 300+50+300MG/tab	30	95,885	132,775
Lamivudine-Efavirenz-Tenofovir DF 300+400+300MG/tab	30		4,105

		4,190	
Lamivudine-Tenofovir DF 300+300MG/tab	30	2,964	3,946
Lamivudine-Zidovudine 150+300MG/tab	60	9,239	9,598
Lamivudine-Zidovudine 30+60MG/tab	60	24,600	25,946
Lopinavir-Ritonavir 100+25MG/tab	120	18,284	25,116
Lopinavir-Ritonavir 200+50MG/tab	120	38,447	50,953
Lopinavir-Ritonavir 40+10MG/caps	120	37,012	52,021
Raltegravir 100MG/tab	60	1,498	3,001
Ritonavir 100MG/tab	60	428	906
Ritonavir 25MG/tab	60	252	549

1.4. Pre-Exposure prophylaxis

Oral pre-exposure prophylaxis (PrEP) of HIV is the use of ARV drugs by people who are not infected with HIV but at a substantial risk to block the acquisition of HIV. Oral pre-exposure prophylaxis (PrEP) TDF/3TC should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches.

Pre exposure prophylaxis (PrEP) is one of the new innovative approaches for prevention of HIV and will be piloted in selected target groups in Ethiopia. For the 2019/20 and 2020/21, 3000 target group which consists of female sex workers (FSWs) and discordant couples will take TDF/3TC as a prophylaxis. See table 18 for the forecasted quantity and Cost.

Table 18: Forecast results and estimated cost of pre-exposure prophylaxis (PrEP), July 2019–June 2021

Product	Units	July 2019 - June 2020 Quantity	July 2020 - June 2021 Quantity
Lamivudine-Tenofovir DF 300+300MG/tab	30	28,500	28,500

1.5. ARVs for Prophylaxis of Mother-to-Child Transmission of HIV

The national strategic plan for elimination of mother-to-child transmission of HIV reports that PMTCT option B+ has been implemented nationwide. A once-daily fixed-dose combination of TDF + 3TC + EFV is recommended as first-line ART in all pregnant, laboring, and lactating women living with HIV, including pregnant women in the first trimester of pregnancy and women of childbearing age. All infants born from mothers living with HIV will receive NVP and AZT prophylaxis daily for six weeks and continue NVP prophylaxis for another six weeks and considering the dosage and bottle size an average of 2bottles for each suspension is used considering wastage. The requirement of the ARVs for mothers was considered and included under adult first-line regimen. For HIV-exposed infants (HEIs) the target for infant prophylaxis is shown in Table 19.

Table 19: Infant HIV Prophylaxis Target, July 2019–June 2021

Target Group	2019	2020	2021
Mothers Needing PMTCT	23,433	21,955	20,663
Women Receiving ART	23,433	21,955	20,663
No. of HIV exposed infants	23,433	21,955	20,663
Infants receiving NVP & AZT Prophylaxis	23,433	21,955	20,663

1.5.1. Forecast Results

The final list ofinfant HIV prophylaxis medicines, forecasted quantities, and costs is shown in Table

20.

Table 20: Forecast results of infant HIV prophylaxis July 2019–June 2021

product	Unit	Quantity July 19-June 20	Quantity July 20-June 21
Nevirapine 10MG/ml	100ml	43,910	41,326
Zidovudine 10MG/ml	100ml	43,910	41,326

1.6. Summarized Forecasted ARV Requirements

The forecasted number of packs and estimated costs for July 2019 –June 2021 are shown in Table 21.

Table 21: ForecastedQuantities of ARVs for July 2019 –June 2021

Product	Units	July 2019 - June 2020 Quantity	July 2020 - June 2021 Quantity
Abacavir 300MG/tab	60	92,524	107,835
Abacavir-Lamivudine 120+60MG/tab	60	180,259	248,866
Atazanavir-Ritonavir 300+100MG/tab	30	158,627	169,129
Darunavir 600MG/tab	60	5,702	7,569
Dolutegravir 50MG/tab	30	471,220	561,237
Efavirenz 200mg/tab	90	4,540	3,870
Efavirenz 50MG/tab	30	11,032	9,550
Efavirenz 600MG/tab	30	108,090	48,234
Lamivudine 150MG/tab	60	87,776	103,087
Lamivudine-Dolutegravir-Tenofovir DF 300+50+300MG/tab	30	2,199,707	2,471,236
Lamivudine-Dolutegravir-Tenofovir DF 300+50+300MG/tab	90	467,516	519,658
Lamivudine-Efavirenz-Tenofovir DF 300+400+300MG/tab	30	1,920,161	1,670,427
Lamivudine-Efavirenz-Tenofovir DF 300+600+300MG/tab	30	263,460	247,956

Lamivudine-Tenofovir DF 300+300MG/tab	30	162,763	106,945
Lamivudine-Zidovudine 150+300MG/tab	60	241,468	208,734
Lamivudine-Zidovudine 30+60MG/tab	60	24,600	25,946
Lopinavir-Ritonavir 100+25MG/tab	120	18,284	25,116
Lopinavir-Ritonavir 200+50MG/tab	120	96,051	110,227
Lopinavir-Ritonavir 40+10MG/caps	120	37,012	52,021
Raltegravir 100MG/tab	60	1,498	3,001
Ritonavir 100MG/tab	60	5,702	7,569
Ritonavir 25MG/tab	60	252	549
Zidovudine 10MG/ml	100	43,910	41,326
Nevirapine 10MG/ml	100	43,910	41,326
Darunavir 150MG/tab	240	126	275
Darunavir 75MG/tab	480	16	34

SECTION 2: MEDICINES FOR OPPORTUNISTIC INFECTIONS

Opportunistic infections are the predominant causes of morbidity and mortality among HIV-infected clients. Most occur at lower CD4; however, they are preventable and treatable. In today's test-and-treat era, the argument that OIs are less common than they were in the early days of HIV/AIDS seems true but still, screening, prevention, and treatment of OIs and other co morbidities are a critical component of the HIV control program. A major focus of this quantification was co-trimoxazole (CTX) prophylactic therapy, among treating or preventing other OIs and treating cryptococcal meningitis.

2.1. Method and Key Assumptions, OIs

CTX is quantified for prophylaxis of Pneumocystis jirovecii pneumonia, toxoplasmosis, and bacterial infections, diarrhea caused by Isospora belli or Cyclospora species, and malaria in adults, adolescents, pregnant women, and children with HIV who seek comprehensive HIV prevention, care, and treatment service. CTX prophylaxis is recommended for adults (including pregnant women) with severe or advanced HIV clinical disease (WHO stage 3 or 4) and/or with a CD4 count ≤350 cells/mm^3 (strong recommendation, moderate-quality evidence). CTX prophylaxis may be discontinued in adults (including pregnant women) with HIV who are clinically stable on ART, with evidence of immune recovery and viral suppression (conditional recommendation, low-quality evidence).

Consumption method quantification was used to quantify CTX for prophylaxis for adult HIV positive clients with 10 percent decrement annually and morbidity method was used for children taking CTX for prophylaxis and treatment forecast. According to the national guidelines for comprehensive HIV prevention, care, and treatment (February 2018), the following assumption is considered for children taking CTX for prophylaxis and treatment.

- All HIV exposed infants from 0 to 2 years old will take CPT
- 5 percent of those infants will continue taking CPT until 5 years of age
- From the 5 percent, 70percent of them will continue taking the CPT until 10 years of age
- All the children switching from first line to second line will take CPT
- 10 percent of children on ART will take CTX treatment for pneumocystis pneumonia

Preventing occurrence of cryptococcal meningitis and treating confirmed cases were another OI focus. Since cryptococcal meningitis is a major contributor to high mortality before and after ART is initiated; medicines for preventing and treating cryptococcal meningitis must be availed to prevent death. Based on the new comprehensive HIV prevention, care, and treatment guidelines (February 2018), fluconazole is forecasted for HIV-positive clients with CD4<100/ml and testing positive for cryptococcal antigen. According to a pilot study conducted in Ethiopia from June 2015 to July 2016, in 22 high-caseload facilities in all regions, the proportion of newly enrolled clients with CD4 count less than 100 cells/mm3 was 25.88 percent. In the same study the prevalence of clients who screened positive for cryptococcalantigenemia was high (9.9 percent).

Based on these assumptions the quantity and cost of CTX and fluconazole were determined, as shown in Table 22.

2.2 Forecast Results, OIs

Table 22: Forecast quantity of CTXand fluconazole, July 2019–June2021

S.No	Item description	Pack size	July 2019–June 2019	July 2020–June 2021
			Forecasted quantity	Forecasted quantity
1	Sulphamethozazole + trimethoprim,200mg+40mg/5 ml mixture	100ml	686,634	689,566
2	Sulphamethoxazole + trimethoprim,400mg+80mg–tablet	10x100	1854	2453
3	Sulphamethoxazole + trimethoprim, 800 mg + 160 mg–tablet	10x100	135,462	121,916
4	Fluconazole, 100mg –tablet	100	151	1,532
5	Fluconazole, 200mg –tablet	100	4,687	5,192

SECTION 3: CONDOM REQUIREMENTS FOR PREVENTION OF STIs

Unprotected sex is the leading cause of HIV transmission, accounting for more than 80 percent of the total number of infections. The national condom demand is covered by the government, NGOs, and a few profit-making organizations. Most of the national demand is supplied through social marketing.

3.1. Method and Key Assumptions, Condoms

Quantification was conducted using a demographic method that determines the forecasted quantity of condoms based on the assumption of prevalence of condom use during risky sexual practice. Most of the data were obtained from government strategic documents, EDHS11, EDHS16, Ethiopia HIV Investment case for 2015-2020 and published research articles.

A total 68 percent of the national demand for condoms is supplied through social marketing based on the investment case and Population Services International Ethiopia reports. Population groups targeted for condom quantification are men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them (EDHS11) and commercial sex workers.

The reproductive age group of men is 15 to 49 years based on Ethiopia HIV Investment case for 2015-2020. The population has been taken from Central Statistics Agency (CSA) reports, and population growth is expected to be the same as the general population (2.26 percent). As per EDHS 2016 data, the percentage of men aged 15–49 years men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them was 6.9 percent, 0.8 percent of men who paid for sexual intercourse in the past 12 months was subtracted from to exclude double counting with commercial sex workers and condom use in this category was 51 percent with 0.78 percent annual increment. As USAID condom CYP conversion factor, the number of condoms required per person per year is 120.

It was assumed that 99 percent of the female sex workers use a condom with an average of nine sexual acts per week. Based on the investment case document target percent of sex workers using condom

becomes 100% by 2020. The number of commercial sex workers has been taken from the HIV 2015–2020 investment case document, and it was assumed that one condom is used per one sexual act.

Table 23: Major assumptions used for condom requirement forecast, July 2019–June2021

Parameter	July 2019–June 20	July 2020–June 21
Men with high risk Sexual behaviors		
Projected number of men aged 15-49 years (2.26% projection each year)	22,550,548	23,121,418
Percentage of men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them	6.90%	6.90%
Percentage men aged 15-49 who paid for sexual intercourse in the past 12 months	0.80%	0.80%
Percentage of men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them excluding men who paid for sexual intercourse in the past 12 months	6.10%	6.10%
Number of men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them	1,375,583	1,410,407
Percentage of men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them anduse condom during sexual act	53.3%	54.1%
Number of men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them and need condom	733,736	763,312
Estimated number of condom required per person per year	120	120
Estimated annual demand of condom for men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them	**88,048,345**	**91,597,440**
Commercial sex workers		
Total population of commercial sex workers	120,000	120,000
Average number of sex acts per week	9	9
Estimated number of sexual acts in a year	468	468
% of sex workers using condom	99%	100%
Number of sex workers using condom	118,800	120,000
Estimated quantity of condom required	**55,598,400**	**56,160,000**
Total Condom Requirement (men who had intercourse in the past 12 months with a person who was neither their wife nor lived with them and FCSWs	143,646,745	147,757,440

3.2 Forecast Results

Based on these assumptions, national condom requirements were calculated. The quantity and cost of condoms required for the forecast period are summarized in Table 24.

Table 24: Forecasted quantity and cost of condoms, July 2019–June 2021

Item Description	July 2019 - June 2020	July 2020- June 2021
	Forecasted Quantity	Forecasted Quantity
Condom - Male, Latex	143,646,745	147,757,440

SECTION 4: MEDICINES FOR STIS

In response to the country's need, sexually transmitted infection (STI) drugs have been quantified. EPSA is responsible for procuring and distributing these drugs using different funding sources. The use of these drugs will be managed according to the National STI Guideline.

4.1 Methodology and Key Assumptions, STIs

Quantification was conducted using the morbidity method. Assumptions for quantification of STI drug requirements were obtained from several sources, including:

- EDHS 2011 and 2016
- The current STI Treatment Guideline
- STI case reports from health management information system (HMIS)
- EPHI sentinel site surveillance reports
- Research publications
- Expert opinions offered in quantification discussions

The population segment of reproductive age (15–49 years for men and women) was considered as being vulnerable to contracting STIs based on HIV investment case report. The population estimation for both reproductive age groups has been taken from CSA reports, and population growth is expected to be the same as the general population (2.26 percent). The prevalence of STI stated on EDHS 2016 was 3.6 percent for men and 3.9 percent for women. These percentages were applied to the male and female vulnerable populations to estimate the number of STI cases and were further modified for health-seeking behavior.

Health-seeking behavior among STI-infected people was taken from EDHS 2016: 34 percent in men and 33 percent in women and an annual 2 percent increment in health-seeking behavior has been assumed based on expert opinion.

Table 25: Health-seeking behavior among STI-infected people, July 2019–June 2021

	July 2019–June 2020	**July 2020–June 2021**
Men	40%	42%
Women	39%	41%

Using data obtained from a sentinel sites surveillance study, HMIS report, EDHS 2016, EDHS 2011, and various research publications, the proportion of STI syndromes was determined:

- Except for neonatal conjunctivitis and neonatal herpes, EDHS 2011 considered that the reproductive age population is vulnerable to STIs.
- The number of cases of neonatal conjunctivitis and herpes was estimated to be 5,000 in 2018, with an annual decline of 500 based on the HMIS report and expert opinion reaching 4,500 in 2019, 4,000 in 2020 and 3500 in 2021 was assumed to continue.

Based on the data obtained from various research publications and expert opinions, the following assumptions were used:

- Prevalence of STI among pregnant women: 3.6 percent
- Prevalence of penicillin allergy: 5 percent
- Prevalence of vulvovaginal candidiasis among women who acquired STIs: 10 percent

Table 26: Proportion of STI syndromes, July 2019–June 2021

STI syndrome	**Proportion**
Adult	
Vaginal discharge	41.6%
Urethral discharge	25.3%
Lower abdominal pain (pelvic inflammatory disease)	13.9%
Genital ulcer	12.0%
Scrotal swelling	4.3%
Inguinal bubo swelling (swollen glands)	2.9%
Neonate	
Neonatal conjunctivitis	50%
Neonatal herpes	50%

4.2 Forecast Results

Based on these assumptions the STI medicine requirements were calculated. The quantity and value of

STI medicines required for the forecast period are summarized in Table 27.

Table 27: Forecasted quantity and cost of STI medicines, July 2019–June 2021

S. No	Item Description	Unit	July 2019 - June 2020	July 2020 - June 2021
			Forecasted Quantity	Forecasted Quantity
1	Ceftriaxone - 250mg - Powder for injection	Vial	354,972	382,012
2	Azithromycin - 1gm - Tablet	Tablet	705,444	760,023
3	Metronidazole - 250mg - Capsule	Capsule	9,399,242	10,128,077
4	Penicillin G, Benzanthin - 2.4 MIU - Injection	Vial	77,332	83,307
5	Ciprofloxacin - 250mg - Tablet	Tablet	606,444	653,301
6	Acyclovir - 400mg - Tablet	Tablet	2,442,055	2,630,744
7	Doxycycline - 100mg - Tablet	Tablet	659,868	710,854
12	Clotrimazole - 200mg - Tablet (Vaginal)	Pessary	882,638	951,391
8	Erythromycin - 125mg/5 ml - Oral Suspension	100ml	2,250	2,000
9	Acyclovir - 250mg - Powder for injection	Vial	47,250	42,000
10	Water For Injection - 10ml - Injection	Vial	432,304	465,319
11	Syringe 5ml	Piece	432,304	465,319
13	Erythromycin - 500mg - Tablet	Tablet	84,036	90,529
14	Condom	Piece	2,604,742	2,806,218

SECTION 5: LABORATORY PHARMACEUTICALS

5.1. HIV Rapid Test Kits

5.1.1 Key assumptions, HIV RTKs

- The HIV rapid test kit forecast was based on the national targets for HIV testing: 8 million in each of the forecast years.
- Based on the new algorithm, the three tests are:
  - Assay 1, screening test: HIV1/2 STAT-PAK™ assay
  - Assay 2: ABON™ HIV 1/2/O Tri-Line Human Immunodeficiency Virus Rapid Test Device
  - Assay 3: SD BIOLINE HIV-1/2

  HIV-positive identification will be achieved only when the three tests are reactive.
- An average positive yield of 2 percent, targeted testing with identification of the priority population, has been considered to determine quantities of second-line and third-line assays in both forecast years (2019/20 and 2020/21).
- For estimation of repeat tests, tests due to assay 1 and assay 2 discrepancies, a negative predictive value of the screening test considered as 99.5 percent (i.e., classified only 0.5 percent HIV-negative test as positive and these require repeat testing because most likely these will be negative at the assay 2 level). Thus, 0.5 percent of all the total negative tests are considered for repeat testing.
- Retesting will be conducted before starting ART for verification after the same testing algorithm.
- If variation happens between results of testing point and verification at ART, tiebreaker test will be done at regional laboratory to resolve this inconclusive result.
- 5 percent considered for quality control test
- 2 percent was considered for wastage and training

5.1.2 Results, RTKs

Based on these assumptions, the required items for HIV testing are shown in the tables below.

Table 28: Forecasted quantity and cost for the targeted HIV testing and counseling, 2019/20 to 2020/21

Product list	Unit of measurement	Quantity 2019/20	Quantity 2020/21
Assay 1(STAT-PAK)	20	438,658	438,658
Assay 2(ABON)	40	10,658	10,658
Assay 3 (SD BIOLINE)	25	13,696	13,696
EDTA capillary tube	100	175,463	175,463
Examination glove, medium	100	176,302	176,302
Test for inconclusive result	20	30	30
Total product cost			
PSM cost (24.75%)			
Total product cost with 24.75% PSM cost			

5.2. EID and ART Monitoring Laboratory Pharmaceuticals

Laboratory testing plays a crucial role in the detection and follow-up of disease progression after treatment starts. ART laboratory testing therefore helps the clinician in evaluating HIV-infected patients upon initiation of ART drug and subsequent follow-up; to assess the virologic and immunologic efficacy of treatment and to monitor abnormalities associated with ARV

drugs. The forecast in this quantification considers lab products for EID, VL, CD4, hematology, and clinical chemistry tests. In all lab areas, the forecast method used is morbidity method.

The target number of patients for VL, CD4, hematology, and clinical chemistry tests is:

- 491,266 by June 2019
- 542,820 by June 2020
- 607,264 by June 2021

The target number for EID is:

- 23,433 by 2019
- 21,955 by 2020
- 20,663 by 2021

5.2.1. EID|VL reagents and supplies

To increase access for detecting HIV-positive infants born of HIV-positive mothers and to achieve the national suppression target by 2020, the government of Ethiopia designs strategies, such as adopting point-of-care instruments that can be accessible to people at remote areas, increasing the number of VL testing sites by adding instruments of exiting platforms to the system, and making use of dried blood spot (DBS) sample collection for selected VL testing sites to make smooth the sample referral for people at far distance from testing facilities. Four types of instruments are available in Ethiopia currently for VL and EID testing; ABBOTT m2000 RealTime, COBAS TaqMan, COBAS 4800 and GeneXpert near point-of-care instruments. The number of COBAS TaqMan instrument is 6, COBAS 4800 8, ABBOTT m2000 instrument 16 and GeneXpert EID 69. The plan for GeneXpert scale up for the forecast period (2019/20 to 2020/21) is to add 50 instruments, making a total of 119 GeneXpert sites and there is plan to add 1 Abbott m2000 to make its total number 17. The percentage of EID tests to be performed by GeneXpert is 30% of the annual EID target in the forecast periods (2019/20 to 2020/21).

Table 29: Number of instruments for VL and EID testing

Type of instrument	Number of instruments	Type of service	Remark
COBAS TaqMan	6	VL & EID	
COBAS 4800	8	VL	
ABBOTT m2000	17	VL & EID	
GeneXpert EID	119	EID	69 sites currently testing EID (2018/19) and 50 additional sites will be scaled up

5.2.2. Key assumptions, EID/VL

The number of viral load tests per run including controls was assumed to be 72 for COBAS AmpliprepTaqMan, 96 for COBAS 4800 and 96 for M2000 RealTime. The number of EID tests per run assumed in both machines, COBAS TaqMan and M2000 RealTime, is 24. Viral load and EID reagents and consumables utilization rate (quantity required per test) for ABBOTT M2000 RealTime, COBAS 4800 and COBAS TaqMan machines were found from different testing facilities and expert opinion; they were used to calculate the required quantity of reagents and consumables. GeneXpert machine will be in use for EID testing during the forecast period. This is a cartridge-based amplification test that is used to help expand EID tests coverage in the country. The functionality rate of all machine types was assumed to be the same, 100 percent, in all the forecast years.

The guideline recommends viral load at six months and 12 months and every 12 months thereafter for adult non pregnant groups of patients receiving antiretroviral therapy. Viral load testing for pregnant mothers will be done after 3 months of ART initiation followed by every six months until the MTC (mother to child) transmission risk ends. Assumptions include 90 percent coverage of the VL test for 2019/20 and 92.5 percent for 2020/21. According to the national guideline and expert opinion, the viral load test will be repeated for suspected virology treatment failure (VL>1000 copies/ml) for 11.4 percent (suppression rate 88.6 percent) of viral load tests after three months of intensive adherence counseling and support. Other assumptions considered for VL based on assessment conducted at testing facilities and expert opinion are:

- Wastage, Abbott sites: 10%
- Wastage, COBAS TaqMan sites: 5%
- Wastage, COBAS 4800: 10%
- Reagent to run controls, Abbott sites: 3.12%
- Reagent to run controls, COBAS sites: 12.5%
- Training purpose: 2%

Based on the assumptions, the total viral load test by all types of instruments was estimated to be 716,707 in 2019/20 and 828,719in 2020/21 Table 30 provides details.

Table 30: Number of viral load tests by each machine during the forecast period

Machine type	2019/20	2020/21
COBAS TaqMan	114,256	132,113
COBAS 4800	203,188	234,944
ABBOTT M2000 RT	399,263	461,662
Total	**716,707**	**828,719**

Viral load samples will be collected by two methods, plasma preparation tube (PPT) and dried blood spot (DBS). Blood samples in PPT should reach the testing site within six hours after collection. Sample referring facilities far from testing sites do not have the opportunity to comply with this protocol. Therefore, these facilities will use DBS cards to transport VL sample to testing sites. Only testing sites with ABBOTT m2000 RealTime instrument will receive DBS samples for VL testing. Referring facilities that use DBS cards to transport blood sample to testing sites will be mapped by EPHI and communicated to EPSA central, EPSA hubs, and their respective testing sites for product distribution and for optimum use of resources. PPT and DBS are therefore quantified based on the stated assumptions: 90 percent of tests at ABBOTT sites by PPT and 10% by DBS for 2019/20 and for 2020/21 85% of VL samples at Abbott sites will be collected by PPT and 15% by DBS. For COBAS sites 100 percent blood collection is by PPT.

According to national guidelines for comprehensive HIV prevention, care, and treatment 2018, HIV-exposed infants (HEIs) will be tested by DNA PCR at six weeks or at the earliest opportunity after six weeks. Consequently, HEIs including 18 percent repeat test were calculated. The test will be repeated if the infant:

- is positive for DNA PCR test
- gets sick after the first PCR-negative test and <12months
- is positive to rapid HIV test at $\geq$ 12 months of age or at least six weeks after completely stopping breastfeeding

Other assumptions for EID based on assessment conducted and expert opinion include:

- Wastage, Abbott sites: 10%
- Wastage, COBAS TaqMan sites: 2.5%
- Wastage, for GeneXpert: 4.6%
- Reagent to run controls, Abbott sites: 4.17%
- Reagent to run controls, COBAS sites: 8.33%
- Training purpose: 2%

Total EID test for 2019/20 and 2020/21 is 30,591and 28,791 respectively. Table 31 provides details. The test will be repeated if the infant:

Table 31: Number of EID tests by each machine during the forecast period

Machine type	2019/20	2020/21
COBAS TaqMan	5336	5022
ABBOTT M2000 RT	15571	14655
GeneXpert	9684	9114
Total	**30,591**	**28,791**

5.2.3. Results, EID/VL

Table 32: Viral load test commodity requirements using COBAS AmpliPrepTaqMan, 2019/20 to 2020/21

Ser #	Product name	Unit	Qty,2019/ 20	Qty, 2020/21
1	COBAS TaqMan, HIV-1Quantitative Test, 48 Tests	48	2,380	2,752
2	COBAS TaqManAmpliPrep, Wash Reagent, 5.1 L	100	1,143	1,321
3	Buffers in a box, premixed PBS Solution (10x)	1	6	6
4	COBAS TaqMan, K-Tubes, 12 Racks of 96, 1 Pack	1,152	99	115
5	COBAS TaqManAmpliPrep, Input Tubes With Barcode Clips (S Tubes), 12 Bags of 24 Tubes	288	397	459
6	COBAS TaqManAmpliPrep, Flapless Sample Processing Unit, 12 Racks of 24	288	397	459
7	COBAS TaqManAmpliPrep, Pipette K-Tips, 1.2 mm, 12 Racks of 36 K-Tips	432	264	306
8	Plasma preparation tube (PPT)	1,000	114	132
9	Bleach (10 times dilution of 5% - 0.5% NAHOCl) - in 500ml spray bottle	500	476	550
10	Disposable coat, blue	30	82	95

11	Disposable coat, white	30	82	95
12	Aerosol Barrier Tips, 1000 µl , Sterile, of 1000	1,000	114	132
13	Ethanol, Absolute	1000	238	275
14	Disposable, Powder-free nitrile gloves - Medium	50	258	298
15	Disposable, Powder-free nitrile gloves – Large	50	111	128
16	Shoe Covers, Non-Skid, of 100	100	25	28
17	Lint free cloth	50	74	85
18	Biohazard bag, 32 x 34in, Orange, 27 Gallon,	100	32	37
19	Absorbent pad with plastic Backing (blue diapers), 17x24 inches	250	15	17
20	Needle, Multi-Sample, Blood Collection, 21G, 1.25 in, Luer, Attached Tube Holder, 100 Needles	100	1143	1321

Table 33: EID test commodity requirements using COBAS AmpliPrepTaqMan, 2019/20 to 2020/21

Ser #	Product name	Unit	Qty,2019/ 20	Qty, 2020/21
1	COBAS TaqManAmpliPrep, HIV-1 Qualitative Test, 48 Tests	48	111	105
2	COBAS TaqManAmpliPrep, Wash Reagent, 5.1 L	100	53	50
3	COBAS TaqManAmpliPrep, Specimen Pre-Extraction Reagent, 5 x 78 mL, 1 Kit	468	14	13
4	COBAS TaqMan, K-Tubes, 12 Racks of 96, 1 Pack	1152	5	4
5	COBAS TaqManAmpliPrep, Input Tubes With Barcode Clips (S Tubes), 12 Bags of 24 Tubes	288	19	17
6	COBAS TaqManAmpliPrep, Flapless Sample Processing Unit, 12 Racks of 24	288	19	17
7	COBAS TaqManAmpliPrep, Pipette K-Tips, 1.2 mm, 12 Racks of 36 K-Tips	432	12	12
8	DBS collection kit of 20 test	1	267	251

Ser #	Product name	Unit	Qty,2019/ 20	Qty, 2020/21
9	Bleach (10 times dilution of 5% - 0.5% NAHOCl)	500	67	63
10	Disposable coat, blue	30	15	14
11	Disposable coat, white	30	15	14
12	Aerosol Barrier Tips, 1000 µl , Sterile	960	17	16
13	Ethanol, Absolute	1000	33	31
14	Lint-free cloth,	50	3	3
15	Disposable, Powder-free nitrile gloves - Medium	50	47	44
16	Disposable, Powder-free nitrile gloves – Large	50	20	19
17	Shoe Covers, Non-Skid, of 100	100	4	4
18	Biohazard bag, 32 x 34in, Orange, 27 Gallon	100	4	6
19	Absorbent pad with plastic Backing (blue diapers), 17x24 inches	250	6	6

Table 34: Viral Load commodity requirements using COBAS 4800, 2018/19 to 2020/21

Ser No	Product specification VL reagents	Unit	Total qty,2019/20	Total qty,2020/21
1	KIT COBAS 4800 SAMPLE PREP 2 960T CE-IVD	960	212	245
2	KIT COBAS 4800 LYSIS 2 960T CE-IVD	960	212	245
3	KIT COBAS 4800 HXV CONTROLS 10T CE-IVD	10 sets	212	245
4	KIT COBAS 4800 HIV-1 120T CE-IVD	120	1,752	2,025
5	MWP Microwell Plate (AD-plate 0.3ml)	50 sets	44	51
6	Reagent reservoir 200ml	100 sets	44	51
7	Reagent reservoir 50ml	200 sets	22	25
8	Tip CORE TIPS with Filter,1ml	3840	788	911
9	AD Plate (2.0ml)	40 sets	55	63
10	KIT COBAS 4800 SYS WASH BUFFER 960T IVD	960	212	245
11	Waste Bag Biohazard (small, role, placed on board)	25 sets	44	51
12	Plasma preparation tube (PPT)	1000	203	235
13	Bleach (10 times dilution of 5% - 0.5% NAHOCl) - in 500ml spray bottle	500 ml	847	979
14	Disposable coat, blue	30	146	168
15	Disposable coat, white	30		

			146	168
16	Aerosol Barrier Tips, 1000 µl , Sterile, of 1000	1000	203	235
17	Ethanol, Absolute	1000 ml	423	489
18	Disposable, Powder-free nitrile gloves - Medium	50 pair	459	531
19	Disposable, Powder-free nitrile gloves – Large	50 pair	197	227
20	Shoe Covers, Non-Skid, of 100	100	44	51
21	Lint free cloth	50	131	152
22	Absorbent pad with plastic Backing (blue diapers), 17x24 inches	250	17	20
23	Needle, Multi-Sample, Blood Collection, 21G, 1.25 in, Luer, Attached Tube Holder, 100 Needles	100	2032	2349

Table 35: Viral Load commodity requirements using ABBOTT M2000 RT, 2018/19to 2020/21

Ser #	Product specification VL reagents	Unit	Qty, 2019/20	Qty, 2020/21
1	Molecular, m2000 RealTime PCR, HIV-1 Amplification Reagent Kit, Quantitative, 1 kit = 96 tests, 4 x 24 test/pack; single use	96	4,159	4,809
2	Molecular, m2000 RealTime PCR, mSample Preparation Reagent RNA, (ROW), 1 kit =96 tests,4 x 24 Preps	96	4,159	4,809
3	Molecular, m2000 RealTime PCR, Control Kit,1 Kit =3 levels of control,24 total (8 Low Pos; 8 High Pos; 8 Neg)	Kit	537	621
4	Molecular, m2000 RealTime PCR, Calibrator Kit 12 Cal A, 12 Cal B, 4 Complete Calibration Sets	Kit	51	51
5	Molecular, m2000 RealTime PCR, mSample Preparation System Bulk Lysis Buffer, 4 x 46ml Lysis Buffer (184mL for DBS based VL test)	96	541	938
6	DBS collection kit, of 20 test/kit	Kit	1,996	3,462
7	Plasma Preparation Tube, K2- EDTA, 5 mL, Plastic, White Top, 1000 Tubes	1000	359	392
8	Molecular, m2000 RealTime PCR, Optical Calibration Kit	Kit	17	17
9	Molecular, m2000 RealTime PCR, Pipet Tips (DiTis), Disposable, with Filter, 1000µL,	2304	1560	1,803
10	Molecular, m2000 RealTime PCR, Pipet Tips (DiTis), Disposable, with Filter, 200µL,	2304	173	200
11	Molecular, m2000 RealTime PCR, Reaction Vessel, 5mL, Plastic,	2000	273	304
12	Molecular, m2000 RealTime PCR, Reagent Vessel, 200mL, Plastic,	90	277	321
13	Molecular, m2000 RealTime PCR, PCR Plate, Plastic, 96-Well, Deep,	32	390	451
14	Biohazard bag, 32 x 34in, Orange, 27 Gallon,	50	166	192
15	Molecular, m2000 RealTime PCR, Master Mix Tubes/caps, Plastic, 10ml,	150	286	479
16	Molecular, m2000 RealTime PCR, PCR Plate Optical Reaction Plate,	20	208	240
17	Molecular, m2000 RealTime PCR, Optical Adhesive Covers	100	42	48
18	Aerosol Barrier Tips, 1000 µl, Sterile, of 1000	960	45	52

19	Absolute Ethanol, 1000 mL	1000	457	529
20	Pasteur Transfer Pipets, STERILE, Packed, pack of 500	500	799	923
21	Disposable, Powder-free nitrile gloves – Medium	50	1202	1,390
22	Disposable, Powder-free nitrile gloves – Large	50	515	596
23	Shoe Covers, Non-Skid, of 100	100	86	99
24	Disposable coat, blue	30	286	331
25	Disposable coat, white	30	286	331
26	Absorbent pad with plastic Backing (blue diapers), 17x24 inches ,250 /case/5/pack	250	34	40
27	Lint free cloth	50	515	596
28	Vial, Cryogenic, 1.8mL, Self-Standing, Round Bottom, External Thread, Sterile, 450 Pcs	450	887	1,026
29	Needle, Multi-Sample, Blood Collection, 21G, 1.25 in, Luer, Attached Tube Holder, 100 Needles	100	3993	4,617
30	Halogen lamp	1	34	34

Table 36: EID commodity requirements using ABBOTT M2000 RT, 2019/20 to 2020/21

Ser #	Product specification VL reagents	Unit	Qty,2019/ 20	Qty, 2020/21
1	Molecular, m2000 RealTime PCR, HIV-1 Qualitative Amplification Reagent Kit,	96	162	153
2	Molecular, m2000 RealTime PCR, mSample Preparation Systems DNA,	96	162	153
3	Abbott RealTime HIV-1 Qual Control Kit,1 Kit =2 levels of control 24 total (12 Pos; 12 Neg)	Kit	59	55

4	Molecular, m2000 RealTime PCR, mSample Preparation System Bulk Lysis Buffer, 1 kit =96 tests (3 x 70ml Lysis Buffer)	96	162	153
5	DBS collection kit, of 20 test/kit	Kit	779	733
6	Molecular, m2000 RealTime PCR, Pipet Tips (DiTis), Disposable, with Filter, 1000µL,	2304	81	76
7	Molecular, m2000 RealTime PCR, Pipet Tips (DiTis), Disposable, with Filter, 200µL,	2304	54	51
8	Molecular, m2000 RealTime PCR, Reaction Vessel, 5mL, Plastic,	2000	8	7
9	Molecular, m2000 RealTime PCR, Reagent Vessel, 200mL, Plastic,	90	43	41
10	Molecular, m2000 RealTime PCR, PCR Plate, Plastic, 96-Well, Deep,	32	61	57
11	Biohazard bag, 32 x 34in, Orange, 27 Gallon,	100	26	24
12	Molecular, m2000 RealTime PCR, Master Mix Tubes/caps, Plastic, 10ml,	150	4	4
13	Molecular, m2000 RealTime PCR, PCR Plate Optical Reaction Plate,	20	32	31
14	Molecular, m2000 RealTime PCR, Optical Adhesive Covers	100	6	6
15	Tube, Centrifuge, 50mL, PP, Conical, Sterile, Screw Cap, Falcon 100 Pcs	500	162	153
16	Aerosol Barrier Tips, 1000 µl , Sterile	960	49	46
17	Pasteur Transfer Pipets, STERILE, Packed, pack of 500	500	31	29
18	Ethanol, Absolute	1000	130	122
19	Disposable, Powder-free nitrile gloves of 50 pairs - Medium	50	198	149
20	Disposable, Powder-free nitrile gloves of 50 pairs- Large	50	85	64

21	Shoe Covers, Non-Skid, of 100	100	18	17
22	Disposable coat, blue	30	43	41
23	Disposable coat, white	30	43	41
24	Absorbent pad with plastic Backing (blue diapers), 17x24 inches ,250 /case/5/pack	250	5	5
25	Lint free cloth	50	10	9

Table 37: EID commodity requirements using GeneXpert, 2018/19to 2020/21

Ser Nº	Product specification EID reagent	Unit	Qty, 2019-2020	Qty, 2020-2021
1	GeneXpert HIV 1 Qualitative Assay Cartridge	10	968	911
2	BD Micritainer Tube	200	48	46
3	Quikheel Lancet	200	48	46

5.3. CD4 Reagents

Routine CD4 monitoring has been central to the ART monitoring method in Ethiopia to aid clinical decision-making. After the adoption of routine viral load monitoring, however, routine CD4 testing will be slowly phased down, and costs saved from this process support the viral load scale-up plan.CD4 counts will continue to play an important role in baseline assessment, monitoring of OI prophylaxis, and other clinical assessments.

5.3.1 Key assumptions, CD4 reagents

The quantification team agreed to forecast CD4 reagents based on the following assumptions for estimated number of clients

- Baseline CD4 cell count will be done for all new clients.
- For 2019/20, clients on ART who cannot be covered by routine VL test will be monitored by CD4 cell count. It is agreed that 10 percent of patients on ART will be monitored by CD4, and 90 percent VLduring 2019/20. For 2020/21, CD4 is considered for 7.5 percent (92.5% covered by VL) of people on ART.
- Clients developing OI (31 percent) will be monitored by CD4 twice a year.
- About 5.5 percent of the CD4 count tests will mark up for repeat test due to clinician request, wastage, invalid test results, and training purposes.

Based on these assumptions, the total number of CD4 tests will be 421,247 for 2019/20, 501,637 for 2020/21,

Three platforms, BD FACScalibur-Multitest, BD FACSPresto, and PIMA, will be used to complete the CD4 count in the forecast period. Test proportion is allocated based on machine capacity and number of machines, as shown in Table 38.

Table 38: CD4 test proportion and test per year per machine

Types of machine	Number of machines	Machine throughput	Test proportion	Total number of tests	
				2019/20	2020/21
BD FACSPresto	290	80	82.3%	344,876	410,692
BD FACSCalibur-Multitest	7	150	3.6%	14,828	17,658
PIMA	207	20	14.1%	61,543	73,287
Total				**421,247**	**501,637**

5.3.2. Results, CD4 counting reagents

Table 39: CD4 commodity requirements using FACSCaliburMultitestmachine,2019/20 through 2020/21

Item	Unit	No. of packs, 2019/20	No. of packs, 2020/21
Flow Cytometry, BD FACS, Clean Solution	5000 ml	15	18
Flow Cytometry, BD FACS,	5000 ml	15	18

Rinse Solution			
Flow Cytometry, BD FACS, FACS Flow Sheath Fluid	20000 ml	15	18
Flow Cytometry, BD FACS, Lysing Solution	100 ml	7	7
Test Tube, Plastic, 12 x 75mm, Round Bottom, Sterile, With Snap Cap, 1000 Pcs	1000ml	7	7
Flow Cytometry, BD FACS, MultiTest CD3/CD4/CD8/CD45 with TruCOUNT tubes	50tests	297	353
Flow Cytometry, BD FACSCalibur, Calibrite 3 Color	25 tests	84	84
Flow Cytometry, BD Calibrite APC Beads	25 tests	84	84
Flow Cytometry, BD Multi-Check CD4 Normal Control 1 x 2.5 ml	Kit	84	84
Flow Cytometry, BD Multi-Check CD4 Low Control 1 x 2,5 ml,Normal	Kit	84	84
Flow Cytometry, BD FACS, Trucount Controls	Kit	84	84

Table 40: CD4 commodity requirements using FACSPresto machine, 2019/20 through 2020/21

Item	**Pack size**	**No. of packs, 2019/20**	**No. of packs, 2020/21**
BD FACSPresto Cartridge Kit, includes Finger Stick Sample Collection Kit, 100 Tests	100tests	3449	4,107
FACSPresto, Thermal Paper Roll, 6cm Core x 12m, 10 Rolls	10roll	345	411

Table 41:CD4 commodity requirement using PIMA machine, 2019/20 through 2020/21

Item	Pack size	No. of packs, 2019/20	No.of packs, 2020/21
Alere Pima RM CD4 Test Cartridge	100test	615	733
Alere Pima RM Printer Paper, 10rolls	10roll	206	206
Pima Analyzer Finger Stick Sample Collection Kit	100tests	615	733
Alere Pima RM CD4 Bead Standard Cartridge	1 low, 1 high	414	414

5.4 Hematology Reagents

Drug related side effects and response to ART must be monitored by the clinician. It is known that the number of total expected tests come from the national target and from national treatment and testing guideline.The guideline recommends hematology tests for baseline assessment, and subsequent number and frequency of tests needed per year vary according to clients' drug regimen. Based on this information, the total number of hematology tests is summed up as follows.

Table 42: Hematology number of tests per year for all the forecast years

Period	No. of tests
2019/20	**692,225**
2020/21	**812,708**

5.4.1. Machine assessment

About eight types of closed-type hematology platforms with a total 384 instruments (according to the GHSC-PSM assessment report) exist in the country.The number and maximum daily throughput of instruments is shown in Table 43. In forecasting hematology reagents 95 percent of the machines are considered functional during the forecast period.

Table 43: Hematology instrument, type, and number in the country

Instrument name	Max throughput	No. of machines
Mindray BC 5800	100	51
Sysmex KX 21N	80	40
Mindray 5000/5150	40	12
Mindray BC 3200/3000	80	83
Ruby	250	40
Emerald 18	150	20
Dcells 60	80	18
Emrald 22	75	60
Total		324

5.4.2. Assumptions

Based on the national target, national guidelines, and experts' opinion, the number of hematologic tests required during the forecast period was estimated based on the following assumptions:

- Baseline and one additional test will be conducted for all new ART clients.

- About 2761 for 2019/20 and 3591for 2020/21 of new ART clients on AZT-based regimen will have additional hematology tests
- For existing clients on ART that are on AZT based regimen: 97,851 clients for 2019/20 and 141,000 clients for 2020/2019 will have hematology tests 3 times a year
- All existing clients will have at least one test per year.
- About 8 percent was assumed for waste/loss, training, and quality control.
- Based on the manufacturer's guidelines, hematology analyzers normal, high, and low controls will run once daily and calibrators every six months.

5.4.3. Hematology results

Table 44: Hematology commodity requirement, 2019/20 to 2020/21

Sysmex KX21 Machine			
Product list	***Pack size***	***Total quantity 2019/20***	***Total quantity, 2020/21***
Sysmex, Cell Clean	*50ml*	320	*320*
Sysmex, Cellpack	*20000ml*	541	*541*
Sysmex, Stromatolyser WH	*3x500ml*	127	*127*
Sysmex, Thermal Printer Paper	*5roll*	320	*320*
SysmexEightcheck - Lowcontrol	*1.5mlx12*	160	160
SysmexEightcheck - High control	*1.5mlx12*	160	160
SysmexEightcheck - Normal control	*1.5mlx12*	160	160
Sysmex SCS -1000 Calibrator	*3x2ml*	20	20
Mindray 5800			
Mindray 5800 CBC + DIFF, Diluent	*20000ml*	*214*	
Mindray 5800 CBC + DIFF, LH Lyse	*200ml*	*348*	*214*
Mindray 5800 CBC + DIFF, LEO (I) Lyse	*200ml*	*554*	*348*
Mindray 5800 CBC + DIFF, LEO (II) Lyse	*200ml*	*113*	*554*
Mindray 5800 CBC + DIFF, LBA Lyse	*200ml*	*544*	*113*
Mindray 5800 CBC + DIFF, Probe cleanser	*100ml*	*60*	*544*
Mindray 5800 CBC + DIFF, Control Low	*5ml*	120	*60*
Mindray 5800BC + DIFF, Control Normal	*5ml*	120	120

Mindray 5800 CBC + DIFF, Control High	*5ml*	120	120
Mindray 5800 CBC + DIFF, Calibrator 2x3 ml	*3ml*	30	120
Mindray BC3000/3200 Machine			
Mindray BC3000, E-Z Cleaner, 100mL			
Mindray BC3000, M-30 L Lyse, 500mL	*500ml*	332	
Mindray BC3000, M-30 R Rinse, 20L	*20000ml*	996	166
Mindray BC3000, M-30 D Diluent, 20L	*20000ml*	498	332
Mindray BC3000, M-30P Probe cleanser, Bottle 12 x 17mL	*12x17ml*	72	996
Mindray BC3000, B-30 Control, Low, 6x3ml	*6x3ml*	344	498
Mindray BC3000, B-30 Control, Normal, 6x3ml	*6x3ml*	344	72
Mindray BC3000, B-30 Control, High, 6x3ml	*6x3ml*	344	344
Mindray BC3000, B-30, Calibrator	*3 ml*	86	344
Total with 19.75% PSM cost	**$100,683.00**	**$100,683.00**	344
Mindray 5150/5200			86
20L	*$ 25.50*	32	
Mindray 5150/5200 CBC, DIFF Lyse	4x500ml	24	**24**
Mindray 5150/5200 CBC LH Lyse	4X100ml	24	37
Mindray 5150 /5200 Probe cleanser	50ml	21	24
Mindray B55 Trilevel Low control	3ml	48	24
Mindray B55 Trilevel Normal control	3ml	48	24
Mindray B55 Trilevel High control	3ml	48	48
Mindray S 50 Calibrator	2x3ml	12	48
Dcells 60			
20000ml	*$ 18.37*	114	
Dcells 60, Dia-Rinse-	*20000ml*	46	**12**	**12**	

D						
Dcells 60, Dia-Lyse-Diff-D-CF	*500ml*	138	*133*			
Dcells 60, Dia-EZ cleanser D	*50ml*	349	*54*			
Dcells 60, Dia probe cleaner D	*50ml*	58	*162*			
Dcells 60, D-check low	*2ml*	72	*410*			
Dcells 60, D-check normal	*2ml*	72	*68*			
Dcells 60, D-check high	*2ml*	72	72			
Dcells 60, D-calibrator plus	*2ml*	12	72			
Cell-Dyn Ruby			12			
3800ml	*$ 148.00*	*572*				
Cell-Dyn Ruby, Diluent/Sheath Reagent	*20000ml*	*907*				
Cell-Dyn Ruby, Cyan-Free HGB NOC Lyse	*3800ml*	*286*	$ 84,656.00			
Cell-Dyn Ruby, CD26 Tri-Level-Control	*6x2.5ml*	240	572			
Cell-Dyn Ruby, HemCal Plus Calibrator	*2x3ml*	20	907			
Total with 19.75% PSM cost	**$454,039.00**	**$454,039.00**	286			
CD8 Emerald 22				240		
CD8 Emerald 22 Diluent	*1000ml*	720		20		
CD Emerald 22 Lyse	*1000ml*	360				
CD Emerald 22 E-Z Cleaner				*1000ml*		240
Cell-Dyn Emerald, 18 Plus Tri-Level-Controls, Half Pack, 6 x 2.5 ml	*6x2.5ml*	720	720			
Cell-Dyn Emerald, 18 Plus, Calibrator, 2 x 3 ml	*2x3ml*	60	360			
Total with 19.75% PSM cost	**$488,077.00**		**$488,077.00**	240		
CD8 Emerald 18				720		
Cell-Dyn Emerald 18, Cleaner, 1L	*1000ml*	80	60			
Cell-Dyn Emerald 18, Diluent, 10L	*10000ml*	240				
Cell-Dyn Emerald 18, Lyse Reagent, 1L				*1000ml*	80	

Cell-Dyn Emerald, 18 Plus Tri-Level-Controls, full Pack, 6 x 2.5 ml	*12x2.5ml*	720	80
Cell-Dyn Emerald, 18 Plus, Calibrator, 2 x 3 ml	*2X3ml*	60	240

5.5. Clinical Chemistry Reagents

The national guideline recommends clinical chemistry tests for evaluating ART clients upon initiation and subsequent follow-up to assess chemistry-related laboratory abnormalities that might be associated with antiretroviral drugs. Although clinical chemistry tests differ, the guideline recommends a few selected important tests for ART monitoring, such as liver function, renal function, lipid profile, and glucose tests. The proportion of ART regimen on which ART clients are served and the drug's tendency to develop toxicity were the reasons behind the need for clinical chemistry reagents forecast. Also, the following assumptions agreed to by participating experts were used.

5.5.1. Key assumptions, clinical chemistry reagents

- All new clients on ART will have all types of clinical chemistry tests as a baseline.
- Each chemistry test needed for diagnosing abnormalities was taken from regimen data assessment result of EPSA.
- Except for glucose and creatinine tests (considered twice a year), one test per year for existing and new clients due to regimen-induced specific toxicity was considered.
- From the working characteristics of the reagents, 5 percent for wastage, 5 percent for repeat test and EQA tests, and 1percent for training were considered.
- The laboratory machine inventory assessment report in 2017 indicates functionality status of chemistry machines as 51 percent. But considering the current focus on equipment management, machine functionality was taken as 70 percent.

5.5.2. Results, chemistry reagents

Based on these assumptions, the required clinical chemistry tests and budget requirement are indicated in Table 45.

Table 45: Clinical chemistry reagents requirements, 2019/20 to 2020/21

Item	Unit	No. of packs, 2019/20	No.of packs, 2020/21
GPT/ALT-reagent kit	200ml	3104	3728
GOT/AST reagent kit	*200ml*	3104	3728
Alkaline Phosphatase reagent kit	200ml	3104	3728
Auto Bilirubin D Liquicolor	375ml	1505	1808
Auto Bilirubin T Liquicolor	200ml	2822	3389
Creatinine reagent kit	200ml	2100	2100
Urea reagent kit	200ml	1512	1833
Cholesterol reagent kit	*200ml*	1400	1400
Triglycerides reagent kit	*200ml*	1400	1400
Glucose reagent kit	200ml	1626	1976
Alpha Amylase reagent kit	*6x25*	1400	1400
Multi-Calibrator, 4x5ml	4X5	350	350
Control N 5x5ml	5x5	350	350
Control P 5x5ml	5x5	350	350

5.6. Consumables

Consumables for hematology, CD4, and clinical chemistry services are forecasted considering common consumables for respective applicable lab areas. Consumables specific to one lab area are considered separately.

Table 46: Consumables requirement for hematology, CD4, and clinical chemistry tests

Consumables			
Product list	***Pack size***	***Total quantity 2019/20***	***Total quantity, 2020/21***
Alcohol, Ethanol/Ethyl, Denatured	1000ml	363	427
Bag, Biohazard, 37 x 48in (94 x 122cm)	100pcs	327	327
Blood Collection Tube, K2-EDTA, 4mL, Plastic, Lavender Top	100pcs	7052	8191
Blood Collection Tube, Pediatric, K2-EDTA, Lavender Top	200pcs	108	171
Sodium Hypochlorite Solution 5%	800ml	454	533
Gloves, Exam, Latex, Powdered, Non-Sterile, Large	100pcs	4532	4532
Gloves, Exam, Latex, Powdered, Non-Sterile, Med,	100pcs	9064	9064

Tourniquet	6pcs	687	687
Blood Collection Needle, Multi-Sample, 21G x 1.25in	100pcs	7052	8191
Blood Collection Set, 23G x 0.75in, Winged, with adapter, 7in Tube, Light Blue, Safety	50 pcs	433	684
Blood Collection Needle holder	1000 pcs	705	819
Sharps Container, Paperboard, 5L, Yellow	25 pcs	165	165
Rack, Test Tube, Epoxy Coated Wire, 36 Place, 10-13mm Tubes	each	1030	1030
Cotton Roll, Absorbent, Non-Sterile	100gm	3634	4267
blood collecting tub-serum separator ,5ml with clot activator gel 5ml	100pcs	15128	17802

Annex I: List of Technical Team Members

No.	Name	Organization
1	AbiyKiflom	EPSA
2	AlemworkTilahun	GHSC-PSM/ EPSA
3	AlexyvGizachew	GHSC-PSM
4	AsmamawSileshi	CHAI
5	Daniel Demissie	EPHI
6	DawitChalla	EPHI
7	Dr.ZerihunHika	FMOH
8	Esubalew Belayneh	EPSA
9	Genet Alemu	EPSA
10	Kassahun Endalew	EPSA
11	LulitHailu	EPHI
12	MaruMergia	CHAI
13	MuluLegesse	FMOH/GHSC-PSM
14	NigussuGudeta	GHSC-PSM
15	RaeyYohannes	GHSC-PSM/EPSA
16	TeferiFlatie	FHAPCO
17	Tigist Kassahun	EPSA
18	Tsion Tsegaye	EPSA
19	WelelawNecho	JSI/AIDSFree
20	YalemsewDerib	GHSC-PSM
21	ZeamanuelTesfahunegn	GHSC-PSM
22	ZelalemMesselle	CHAI
23	ZerihunFekade	EPSA

AnnexII: List of Workshop Participants

S.NO.	**FULL NAME**	**Work Place**	Organization
1	Abdu Ebrahim	Addis Ababa	DKT
2	AbiyKiflom	Addis Ababa	EPSA
3	Adnew W/Tensay	Addis Ababa	EPSA-AA
4	AlemworkTilahun	Addis Ababa	EPSA/GHSC-PSM
5	AlexyvGizachew	Addis Ababa	GHSC-PSM
6	Ahmed Kedir	Addis Ababa	EPSA-HO
7	AsmamawSileshi	Addis Ababa	CHAI
8	AzizaKassaye	Hawassa	Hawassa-RPHI
9	BaiysaBulcha	Addis Ababa	FHAPCO
10	BekeleAshagrie	Addis Ababa	USAID
11	Biruk Tadesse	Addis Ababa	EPSA
12	Daniel Demissie	Addis Ababa	EPHI
13	DawitChalla	Addis Ababa	EPHI
14	DrZerihunHika	Addis Ababa	FMOH
15	Dr. RozaNuri	Addis Ababa	ALERT
16	Dr.AsterShewamare	Addis Ababa	ZMD
17	Dr.GezahenDegefu	Dire Dawa	DD Ref.Hosp.
18	Dr.MirajShemisu	Addis Ababa	ZMD
19	Dr.SemereYohannes	Addis Ababa	SPMMMC
20	EmiamrewSisay	Addis Ababa	FMOH
21	Esubalew Belayneh	Addis Ababa	EPSA
22	FarisChiksa	Dire Dawa	DD-EPSA
23	FekaduAbebe	Addis Ababa	GHSC-PSM
24	FetiyaLalla Ahmed	Hawassa	EPSA
25	G/Mariam Wondie	B/Dar	FelegeHiwot GSH
26	Genet Alemu	Addis Ababa	EPSA
27	GhionTirsite	Addis Ababa	WHO
28	GiotomGigar	Addis Ababa	EPSA
29	Hailu Berta	Addis Ababa	EPSA-HO
30	HayelomAssefa	Addis Ababa	FHAPCO
31	Helen Fikru	Addis Ababa	GF
32	Henok Tadesse	E/Shoa	Adama-Reg Lab.
33	Kassahun Endalew	Addis Ababa	EPSA
34	Kefale Merera	Addis Ababa	EPSA
35	KibruyisfaTesfaye	Addis Ababa	AAHB
36	LulitHailu	Addis Ababa	EPHI
37	MaruMergie	Addis Ababa	CHAI
38	Mastewal Ezezew	Bahir Dar	B/Dar-EPSA
39	MengistuLegesse	Addis Ababa	EFMHACA
40	MuluLegesse	Addis Ababa	FMOH/GHSC-PSM
41	NegeseSewagegn	BahirDar	APHI-B/Dar
42	NigussuGudeta	Addis Ababa	GHSC-PSM
43	Patrick Githendu	Geneva	Global Fund
44	RaeyYohannes	Addis Ababa	EPSA/GHSC-PSM
45	Ruth Mulgeta	Addis Ababa	EPSA

46	TeferiFlatie	Addis Ababa	FHAPCO
47	Tigist Kassahun	Addis Ababa	EPSA
48	Tsion Tsegaye	Addis Ababa	EPSA
49	WelelawNecho	Addis Ababa	AIDS Free
50	WondiyfrawKifle	Addis Ababa	EPSA-HO
51	YalemsewDerib	Addis Ababa	GHSC-PSM
52	YayalNegash (Dr)	Addis Ababa	UNICEF
53	YinebebSileshi	Jimma	EPSA-Jimma
54	ZeamanualTesfahunegn	Addis Ababa	GHSC-PSM
55	ZelalemMessele	Addis Ababa	CHAI
56	ZerihunFakade	Addis Ababa	EPSA