



USAID | **DELIVER PROJECT**
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ZAMBIA: NATIONAL LONG TERM FORECAST REPORT FOR ARV DRUGS (2008 – 2015)



APRIL 2009

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USAID | DELIVER PROJECT, Task Order 1

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Abstract

In October 2008, the Ministry of Health (MOH), with technical assistance from the USAID | DELIVER PROJECT, Task Order 1, with funds from the President's Emergency Plan for AIDS Relief (PEPFAR), conducted a national long term forecast of ARV drug for 2008 through 2015.

The quantification's overall objective was to calculate ARV drug requirements for each year of the forecast period and to use those requirements to mobilize resources for the country. The quantification was updated in April 2009. This report presents the findings of the forecast as well as the methodology used and assumptions made to arrive at those findings.

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ACRONYMS

3TC	lamivudine
ABC	abacavir
AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
ATV/r	atazanavir/ritonavir
AZT	zidovudine
CHAI	Clinton HIV/AIDS Initiative
CHAZ	Churches Health Association of Zambia
CIDRZ	Center for Infectious Disease Research in Zambia
D4T	stavudine
DDI	didanosine
EFV	efavirenz
EGPAF	Elizabeth Glazer Pediatric AIDS Foundation
FDA	Federal Drug Agency
GRZ	Government of the Republic of Zambia
HIV	human immunodeficiency virus
Kg	kilograms
LMU	Logistics Management Unit
LPV/r	lopinavir/ritonavir
MOH	Ministry of Health
NAC	National Aids and TB Council
NVP	nevirapine
PEPFAR	President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother to child transmission
PS	Permanent Secretary
SCMgr	Supply Chain Manager
SCMS	Supply Chain Management System
STG	standard treatment guidelines
TDF	tenofovir
FTC	emtricitabine
TB	tuberculosis
UNICEF	United Nations International Children's Emergency Fund.
USAID	United States Agency for International Development
WHO	World Health Organization

INTRODUCTION

The USAID | DELIVER PROJECT supports the Zambia Ministry of Health (MOH) in their mission to provide a reliable supply of ARV drugs to public sector facilities. The MOH sees the need for long-term planning to support the current and future patients on antiretroviral treatment (ART). In that effort, the MOH moved in 2008 to develop a long-term forecast to plan in the short-term for procurements and funding required, and in the long-term for resource mobilization.

The long-term quantification task was to forecast consumption, develop procurement plans for the coming years, quantify the funding requirements for the future, review funding commitments and identify funding gaps to present to stakeholders for decision making.

The quantification workshop took place from 8th – 10th October, 2008 to prepare a long term forecast covering the period 2008 – 2015. The meeting was chaired by the MOH and attended by other key stakeholders working in the area of HIV and AIDS, including clinicians running ART clinics at health facilities. The full list of attendees is located in Annex A.

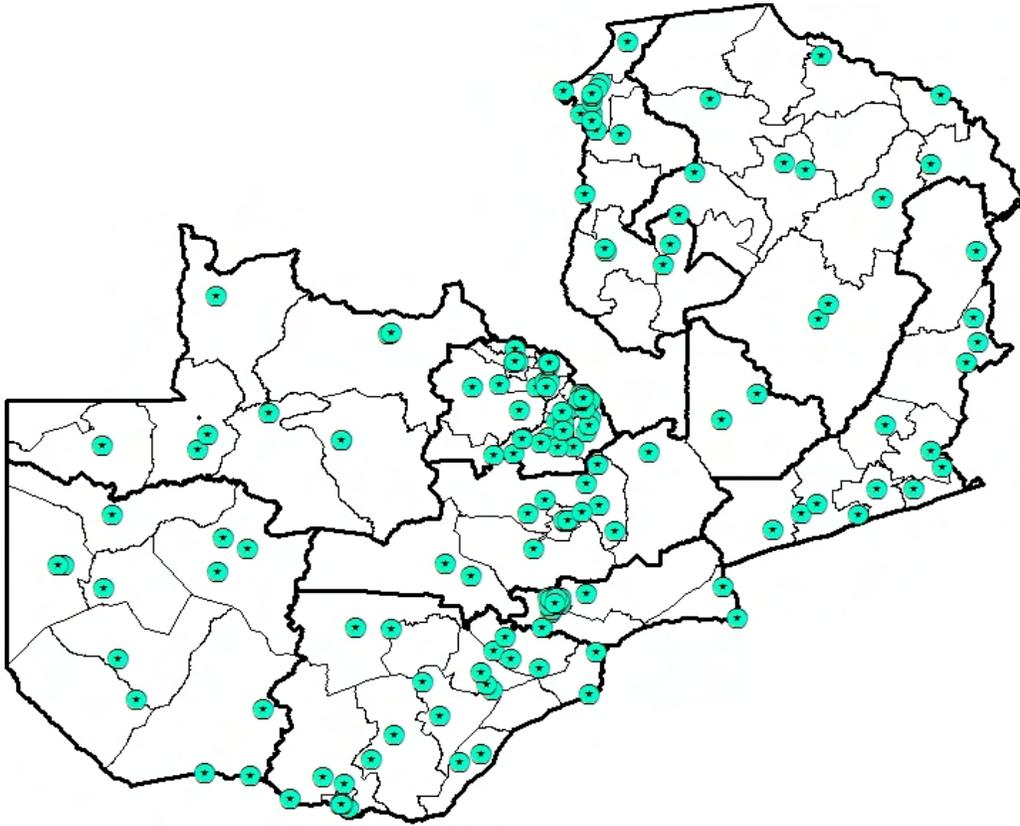
METHODOLOGY

The seven year quantification relied on assembling the best available data, and complementing gaps in data with information obtained from all program stakeholders in the form of key assumptions. The quantification process itself was both iterative and participatory in an effort to ensure stakeholder ownership and buy-in of both the process and the results.

The MOH representatives and cooperating partners brought key data points to the quantification workshop. These key data items include ART patient numbers by regimen, treatment trends, clinician preferences, and treatment and dosing protocols. The partners include Zambia Prevention, Counseling and Treatment Project (ZPCT), Centre for Infectious Disease Research in Zambia (CIDRZ), AIDSRelief, and Church Health Association of Zambia (CHAZ). The forecast used this morbidity data to estimate the commodity product requirements for the country using the *Quantimed* software.

The forecasted commodity requirements by year from *Quantimed* were then reviewed by using actual facility-level consumption data captured by *Supply Chain Manger Software* (SCMgr) at the MOH Logistics Management Unit. SCMgr captures data from 171 ART sites throughout Zambia, as shown in Figure 1. The SCMgr data was inputted into the *PipeLine* software to compare past consumption trends with projected future trends. The forecast for some products were adjusted based on this information and the final forecast was adopted by the team.

Figure I. National ARV Logistics System: 171 (Full ART) Sites Nationwide



Conducting a seven year quantification meant that the team had to rely on many assumptions about the scale-up of the ART program in the future. The current rate of scale-up has been about 7,000 new patients per month. Questions arose around the issue of constantly increasing access while there was a decreasing level of quality of care, length of partner support, and the sustainability of maintaining current scale-up rates. The concern was that if we continue at this pace and then some key partners phase-out, there would be an increased funding gap. It was therefore decided that two forecast scenarios be developed. The two scenarios are as follows.

1. The current scale up rate continues and resources mobilized to support this scale-up.
2. The country would have to begin to “cap” the number of new patients being put on treatment. The figure for capping the number of patients would come from the definition used by some for universal access targets: 80% of the number of people who need treatment will receive ART.

The MOH has chosen to advocate for resources based on the first scenario; this is the scenario presented in this report.

ASSUMPTIONS

The following detailed assumptions were made through the course of the Zambia National ARV Drug Quantification 2009-2015 workshop. These assumptions were updated in February 2009 at the quarterly ARV quantification review meeting.

GENERAL ASSUMPTIONS

1. The forecast for ARV drugs was prepared as a national level forecast, inclusive of MOH sites supplied through MSL and through CHAZ.
2. The forecast for ARV drugs does not include an estimate of requirements for those products used in special cases such as salvage therapy. These cases are considered to be very minimal and the MOH has funds set aside for facilities that require these special products.
3. There are new Standard Treatment Guidelines for Antiretroviral Therapy (STGs) in Zambia. It is assumed all new patients initiating ART will follow these new STGs. The forecasted requirements include existing patients who remain on the old STGs.
4. It is estimated that about 5,000 patient are covered using the private sector.

QUANTIFICATION PATIENT BREAKDOWNS

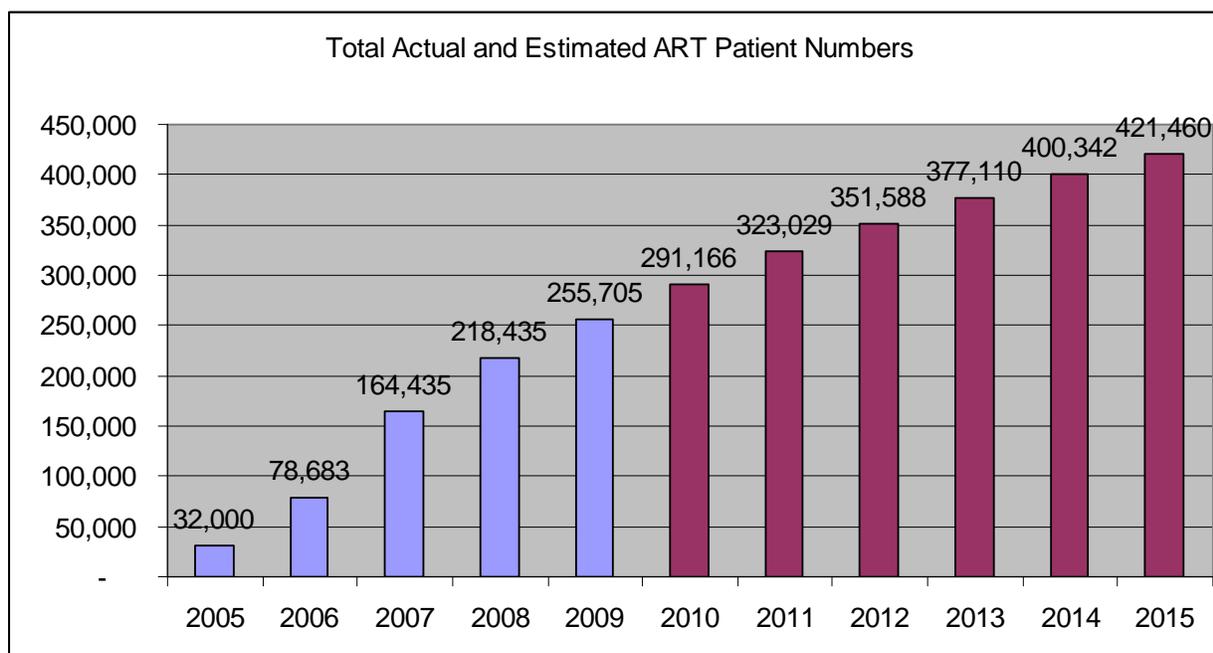
It was noted that the actual consumption trend in *Supply Chain Manager* and the *PipeLine* software showed an increasing scale up rate of approximately 4,000¹ new adult patient months per month. The numbers of patients who receive more than one month of ARVs and therefore do not come back the next month are less than 5%. Therefore, the actual number of patient months of consumption is very close to numbers of patients. The working ART patient estimates were therefore adjusted to reflect an increasing patient scale up rate of 4,000 patients (adults and pediatrics) per month and assumed fairly accurate. Table 1 lists the ART patient estimates by year of adults and pediatrics used for the purpose of quantification of ARV drug requirements. Figure 2 depicts the scale-up from 2005 through the expected patients on ART in 2015.

Table 1. National ART Patient Estimates for Quantification

	2008	2009	2010	2011	2012	2013	2014	2015
Adults	200,435	234,405	265,996	295,376	322,700	348,111	371,743	393,721
Peds	18,000	21,300	25,170	27,653	28,888	28,999	28,599	27,739
TOTAL	218,435	255,705	291,166	323,029	351,588	377,110	400,342	421,460

¹ The original Oct. 2008 Quantification estimated 7,000 patient scale-up per month. Upon review of the ART patient data, the MOH found that some of the patients were double-counted and reduced the scale-up figures.

Figure 2. Total Actual and Estimated ART Patients 2005 - 2015



These estimates were also compared with the Universal Access figures that were developed using the *Spectrum* software. The GRZ has a goal of treating 80% of the people who need ART by 2015. Comparing the figures of people in need of ART with the national ART estimates, Zambia is expected to reach this goal by 2014, but then fall slightly below in 2015. Table 2 below provides a comparison of the national adult ART patient estimates with the estimated need. In 2008, 66.3% of the need is met and by 2015 79.6% is estimated to be met.

Table 2. Adult ART Need vs. National ART Adult Patient Estimates for Quantification

	2008	2009	2010	2011	2012	2013	2014	2015
Adults in Need of ART	302,238	330,992	357,625	383,323	408,966	435,619	464,123	494,913
Adult ART Patient Estimates	200,435	234,405	265,996	295,376	322,700	348,111	371,743	393,721
% of Adult ART Need Met	66.3%	70.8%	74.4%	77.1%	78.9%	79.9%	80.1%	79.6%

The *Spectrum* model also provided an estimate of the number of pediatrics in need of ART. These figures are represented in Table 3. The original estimates from *Spectrum* are shown in the first line of the table. After discussion with those involved in pediatric care, the quantification team agreed that these numbers appear too low. The team adjusted the estimates of need, shown on the second row of the table. The *Spectrum* figures of children in need of ART will be reevaluated in March 2009 and this estimate of need met will be updated following that evaluation.

Table 3. Pediatric ART Need vs. National ART Pediatric Patient Estimates for Quantification

	2008	2009	2010	2011	2012	2013	2014	2015
Children in Need of ART	29,264	29,973	30,512	30,644	30,520	30,165	29,598	28,753
Adjusted Children in Need of ART	33,122	31,400	38,000	44,500	47,500	49,000	49,000	49,000
Children ART Patient Estimates	18,000	21,300	25,170	27,653	28,888	28,999	28,599	27,739

To estimate the number of children in need of ART, the impact of PMTCT interventions on the number of new pediatric patients was explored. This is depicted in Figure 3.

It is assumed that 80,000 HIV+ women were pregnant in 2008. Of those, 67,000 received PMTCT. When a woman receives PMTCT, the HIV transmission rate within the first year of the baby's life, including the breastfeeding period, is 15%. When a woman does not receive PMTCT, the transmission rate in the first year of the baby's life, including the breastfeeding period, is 40%. Given these two data points, in 2008, it is estimated that 15,250 babies were HIV positive after one year.

Of the 15,250 babies, it is estimated that 30% will die before one year without co-trimoxazole prophylaxis treatment. This means that 10,675 HIV+ babies will live to be one year of age. Of those babies, it is estimated that 50% will be brought to the clinic (5,338 babies) and a little more than half of these babies will be put on ART. The team agreed that approximately 3,300 new pediatric patients will be put on ART in 2009.

It was generally felt that many HIV positive women are still having their babies in the homes with limited PMTCT interventions. The MOH will ensure that the New PMTCT Protocol Guidelines are finalized and disseminated, and awareness campaigns are increased on using the recommended regimen: Zidovudine /Lamivudine and Nevirapine in mothers and Zidovudine and Nevirapine in babies. Table 4 lists the expected number of mother and babies to access PMTCT interventions during the forecast period².

It is assumed some mothers receiving PMTCT are on full ART (row 3 of Table 4). These figures are included in the total number of adults on ART.

² The number of mothers expected to access PMTCT services was increased in Feb. 2009 review. These increases are reflected in this table.

Figure 3. Impact of PMTCT on New Pediatrics in Need of ART

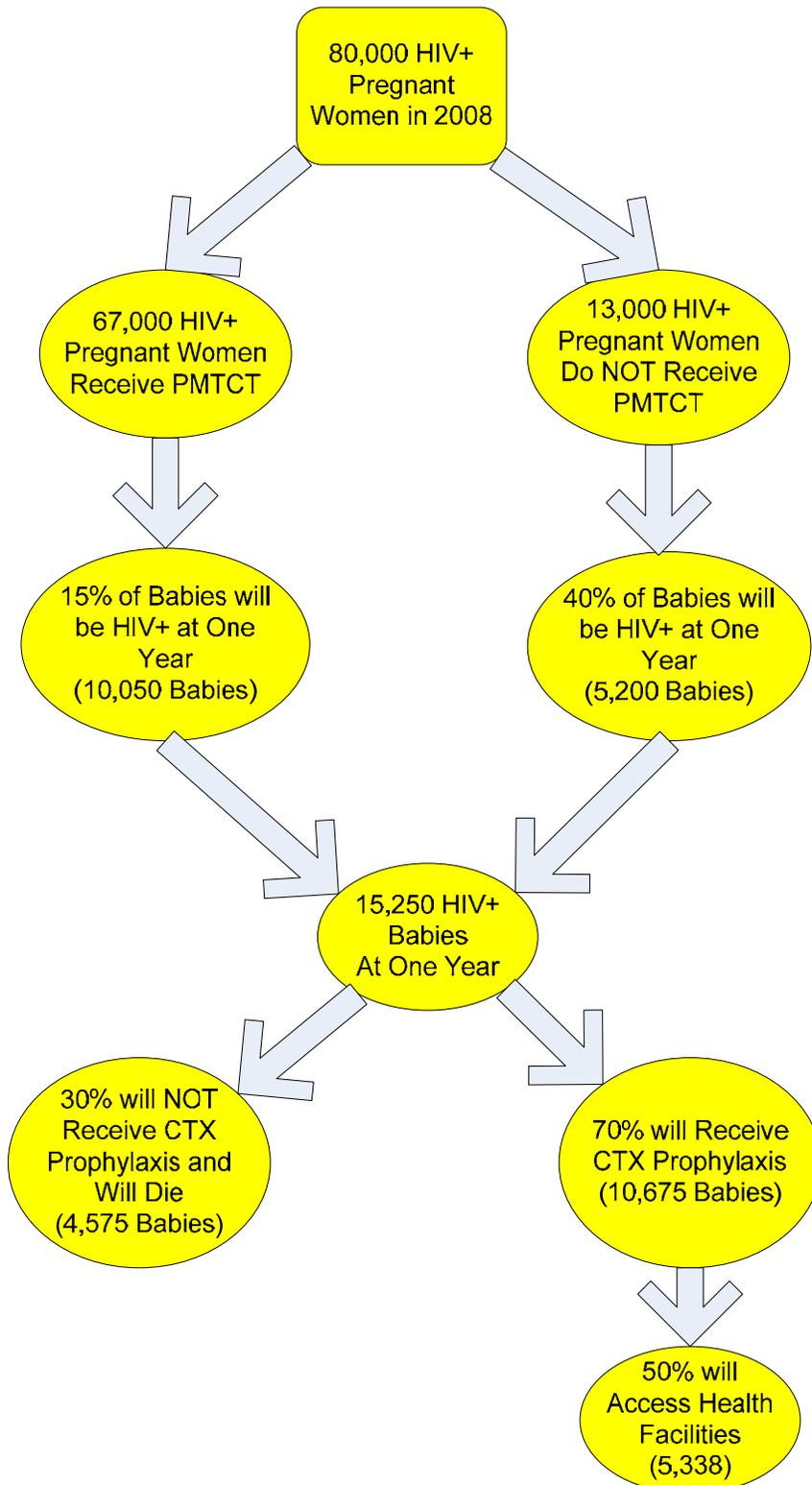


Table 4. PMTCT Patient Estimates

	2008	2009	2010	2011	2012	2013	2014	2015
Mothers in Need	84,568	86,042	87,698	88,195	88,776	89,696	90,871	91,825
Mothers Expected on PMTCT	62,526	68,554	68,161	67,769	68,192	69,614	71,037	73,460
Mothers Expected on ART	5,437	7,284	9,131	10,978	12,824	14,671	16,518	18,365
% of Need Met	80%	88%	88%	89%	91%	94%	96%	100%
Babies Expected on PMTCT	18,000	30,000	32,500	54,800	55,200	55,600	56,000	56,400

PATIENT CONDITIONS AND REGIMENS

To gather the different treatment regimens being used, the team defined ten conditions. These conditions matched the data available and allows for further detailed assumptions to be developed about the percentage of patients on each regimen by condition. Table 5 lists the different conditions that were considered in this exercise.

Table 5. Patient Conditions

Adults	New Adults – First Line (New STGs)
	Existing Adults – First Line (New STGs)
	Existing Adults – First Line (Old STGs)
	Existing Adults – Second Line (New STGs)
	Existing Adults – Second Line (Old STGs)
Pediatrics	New Pediatrics – First Line
	Existing Pediatrics – First Line
	Existing Pediatrics –Second Line
PMTCT	PMTCT Mothers
	PMTCT Babies

The team used the patient numbers to agree on the percentage of patients that would constitute each of the ten patient conditions. Table 6 shows the percentage of existing patients in each condition over the seven years and Table 7 shows the actual number of patients this represents each year. It is assumed that all new patients are on the new STG first line regimens. There is no expectation that patients will be on alternative regimens, which are not in the national ART protocol. The MOH has a small fund set aside to assist clinicians who have patients on alternative regimens.

Table 6. Percentage of Existing Patients per Condition per Year

Distribution at the End of the Year	2007	2008	2009	2010	2011	2012	2013	2014	2015
Adults									
Percentage on Old STGs	88.00%	69.00%	50.00%	40.00%	34.00%	38.00%	22.00%	16.00%	10.00%
Percentage on 1 st Line	94.00%	92.50%	90.00%	88.50%	86.00%	83.00%	80.00%	77.50%	75.00%
Percentage on 2 nd Line	5.56%	7.50%	10.00%	11.50%	14.00%	17.00%	20.00%	22.50%	25.00%
Percentage on New STGs	12.00%	31.00%	50.00%	60.00%	66.00%	62.00%	78.00%	84.00%	90.00%
Percentage on 1 st Line	99.50%	99.85%	99.85%	99.77%	99.72%	99.85%	99.50%	99.00%	98.50%
Percentage on 2 nd Line	0.50%	0.15%	0.15%	0.23%	0.28%	0.35%	0.50%	1.00%	0.50%
Pediatrics									
Percentage on First Line	100.00 %	98.30%							
Percentage on Second Line	0.00%	1.70%							

Table 7. Number of Patients per Condition per Year

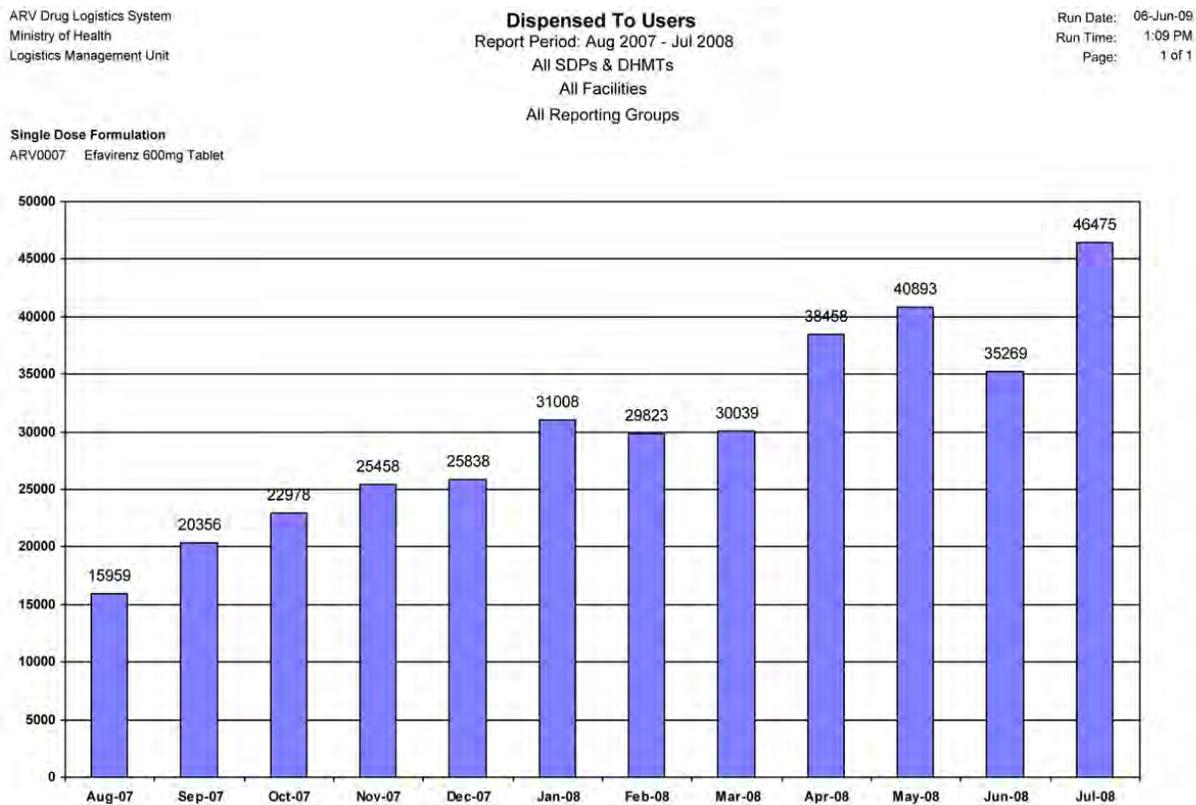
Distribution at the Start of the Year	2008	2009	2010	2011	2012	2013	2014	2015
Adults								
No. on Old STGs	135,023	118,673	105,694	97,324	90,281	83,915	78,258	72,984
No. on 1 st Line	126,921	108,518	93,537	83,212	74,661	67,148	60,986	55,396
No. on 2 nd Line	7,507	10,155	12,157	14,112	15,621	16,767	17,272	17,588
No. on New STGs	18,412	57,785	108,998	148,426	181,302	186,069	252,520	290,406
No. on 1 st Line	18,320	67,094	112,463	151,101	186,413	219,124	249,264	277,218
No. on 2 nd Line	92	86	128	359	574	773	1,194	1,825
Pediatrics								
No. on First Line	12,160	15,093	17,973	20,371	21,469	21,127	19,324	16,846
No. on Second Line	0	207	443	704	980	1,603	2,778	4,329

In July 2007, MOH of Zambia implemented new ART protocols for adults. Key to this change was the introduction of new adult first line ARV drug regimens in line with the WHO July 2005 recommendations for use of tenofovir-based regimens. Zambia began treating patients with tenofovir/emtricitabine (TDF/FTC), commonly known as Truvada, in September 2007.

As discussed below, TDF/FTC regimens are very expensive. Therefore, starting in mid-2009 the team agreed to introduce the tenofovir/lamivudine (TDF/3TC) fixed dose combination drugs to replace 50% of the TDF/FTC estimates. In 2010, 60% will be using TDF/3TC and 40% TDF/FTC. In 2011, this increases to 80% using TDF/3TC and in 2012, TDF/FTC is phased out and 100% of use is TDF/3TC.

The use of efavirenz (EFV) 600mg increased significantly throughout 2008. Figure 4 shows the actual consumption reported from ART sites throughout in the country from August 2007 through July 2008. The increased use of EFV 600mg tablets is due to increased cases of TB co-infection as well as patient preference over nevirapine (NVP) 200mg as the administration dose of EFV 600mg is once daily.

Figure 4. EFV 600mg Consumption Aug. 2007 – Jul. 2008



MOH, ZPCT, CIDRZ, CRS, and CHAZ provided information about the number of patients on each regimen. This information was used to extrapolate the percentage of patients expected to be on each regimen each year by patient condition. Table 8 shows the percentage of adult patients by condition and regimen. Table 9 shows the percentage of pediatric patients by condition and regimen. Annex B presents the total number of patients expected to be on each regimen each year.

Table 8. Percentage of Adult Patients by Regimen

Regimen	Percentage							
	2008	2009	2010	2011	2012	2013	2014	2015
Existing Adults - First Line (Old STGs)								
D4T + 3TC + NVP (30/150/200mg)	47.6%	52.1%	52.1%	52.1%	52.1%	52.1%	52.1%	52.1%
D4T + 3TC + NVP (40/150/200mg)	4.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AZT + 3TC + NVP (300/150/200mg)	12.9%	12.9%	12.9%	12.9%	12.9%	12.9%	12.9%	12.9%
AZT + 3TC + EFV (300/150/600mg)	23.9%	23.9%	23.9%	23.9%	23.9%	23.9%	23.9%	23.9%
D4T + 3TC + EFV (30/150/600mg)	10.6%	11.2%	11.2%	11.2%	11.2%	11.2%	11.2%	11.2%
D4T + 3TC + EFV (40/150/600mg)	0.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Existing Adults - Second Line (Old STGs)								
TDF + FTC + LPV/r	71.6%	71.6%	71.6%	71.6%	71.6%	71.6%	71.6%	71.6%
ABC + DDI + LPV/r	24.8%	24.8%	24.8%	24.8%	24.8%	24.8%	24.8%	24.8%
TDF + DDI + NFV	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ABC + DDI + NFV	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ABC + 3TC + LPV/r	3.6%	3.6%	3.6%	3.6%	3.6%	3.6%	3.6%	3.6%
TDF + 3TC + LPV/r	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
TDF + DDI + LPV/r	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Existing Adults - First Line (New STGs)								
TDF + FTC + EFV	48.1%	29.35%	23.48%	11.50%	0.0%	0.0%	0.0%	0.0%
TDF + FTC + NVP	48.1%	19.60%	15.65%	7.70%	0.0%	0.0%	0.0%	0.0%
TDF + 3TC + EFV	0.9%	29.35%	35.20%	46.10%	56.9%	56.3%	55.7%	55.1%
TDF + 3TC + NVP	0.9%	19.60%	23.47%	30.80%	37.9%	37.5%	37.1%	36.7%
ABC + 3TC + NVP	1.1%	1.10%	1.20%	2.00%	2.7%	3.2%	3.7%	4.2%
ABC + 3TC + EFV	1.0%	1.00%	1.00%	1.90%	2.5%	3.0%	3.5%	4.0%
Existing Adult - Second Line (New STGs)								
AZT + TDF/FTC + LPV/r	18.9%	18.9%	18.9%	18.9%	18.9%	18.9%	18.9%	18.9%
D4T + TDF/FTC + LPV/r	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%	0.3%
AZT + 3TC + LPV/r	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%	43.0%
D4T + 3TC + LPV/r	37.8%	37.8%	37.8%	37.8%	37.8%	37.8%	37.8%	37.8%
New Adults - First Line (New STGs)								
TDF + FTC + EFV	48.1%	29.35%	23.50%	11.8%	0.0%	0.0%	0.0%	0.0%
TDF + FTC + NVP	48.1%	19.60%	15.70%	7.8%	0.0%	0.0%	0.0%	0.0%
TDF + 3TC + EFV	0.9%	29.35%	35.30%	47.0%	58.8%	58.8%	58.8%	58.8%
TDF + 3TC + NVP	0.9%	19.60%	23.50%	31.4%	39.2%	39.2%	39.2%	39.2%
ABC + 3TC + EFV	1.1%	1.10%	1.10%	1.10%	1.10%	1.10%	1.10%	1.10%
ABC + 3TC + NVP	1.0%	1.00%	0.90%	0.90%	0.90%	0.90%	0.90%	0.90%

Table 9. Percentage of Pediatric Patients by Regimen

Regimen	Percentage							
	2008	2009	2010	2011	2012	2013	2014	2015
Existing Pediatrics - First Line								
D4T + 3TC + NVP	60.6%	60.6%	50.6%	50.6%	50.6%	50.6%	50.6%	50.6%
D4T + 3TC + EFV	12.5%	12.5%	12.5%	2.5%	2.5%	2.5%	2.5%	2.5%
AZT + 3TC + NVP	21.8%	21.8%	31.8%	31.8%	31.8%	31.8%	31.8%	31.8%
AZT + 3TC + EFV	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%
AZT + 3TC + ABC	0.2%	0.2%	0.2%	5.2%	5.2%	5.2%	5.2%	5.2%
D4T + 3TC + ABC	0.9%	0.9%	0.9%	5.9%	5.9%	5.9%	5.9%	5.9%
New Pediatrics - First Line								
D4T + 3TC + NVP	60.6%	60.6%	50.6%	50.6%	50.6%	50.6%	50.6%	50.6%
D4T + 3TC + EFV	12.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%	2.5%
AZT + 3TC + NVP	21.8%	21.8%	31.8%	31.8%	31.8%	31.8%	31.8%	31.8%
AZT + 3TC + EFV	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%
AZT + 3TC + ABC	0.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%	5.2%
D4T + 3TC + ABC	0.9%	5.9%	5.9%	5.9%	5.9%	5.9%	5.9%	5.9%
Existing Pediatrics - Second Line								
ABC + DDI + NFV	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
ABC + DDI + LPV/r	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%	96.0%
AZT + DDI + LPV/r	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%
DDI + EFV + LPV/r	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

The quantification included assumptions about requirements for PMTCT mothers and babies. Table 10 shows a change over the years from single dose treatments of nevirapine in mothers and babies to more double and triple drug treatments for mothers and double drug treatments for babies.

Table 10. Percentage of PMTCT Mothers and Babies by Regimen

Regimen	Percentage							
	2008	2009	2010	2011	2012	2013	2014	2015
PMTCT (Mothers)								
AZT + NVP	45.0%	30.0%	25.0%	30.0%	30.0%	30.0%	30.0%	30.0%
NVP (Single Dose)	50.0%	30.0%	15.0%	0.0%	0.0%	0.0%	0.0%	0.0%
AZT+3TC+NVP	5.0%	40.0%	60.0%	70.0%	70.0%	70.0%	70.0%	70.0%
PMTCT (Babies)								
NVP (Single Dose)	50.0%	30.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
AZT+NVP	50.0%	70.0%	80.0%	80.0%	80.0%	80.0%	80.0%	80.0%

REGIMEN SWITCHES

Key clinicians practicing at UTH and other ART health facilities in Lusaka provided most of the data on switch rates for ART clients resulting from treatment failure, toxicity, and lost to follow up or death. Adult patients are expected to switch to new second line regimens or old second line regimens with 5%-10% target of new patients failing to start on the new first line due to renal function insufficiency or lack of lab testing facilities to determine renal function. The renal function test is mandatory in the new guidelines in order to begin the TDF-based regimen.

Salvage therapy will be considered on a case by case basis by an HIV specialist. Some patients are expected to switch from the old first line to the new first line due to clinical failure and toxicity.

It was assumed that the majority of the pediatric ART patients on second line regimens will be older children. Many of the pediatric patients that started treatment early are expected to start switching from pediatric regimens to adult regimen at around 10 years. In 2007, many new patients were initiated on ART at about 5 years of age, meaning that these patients will reach 10 years of age in 2012. An estimated 5% of pediatric patients switch to adult regimens each year (see Table 11).

Table 11. Switch Rates

From (Condition)	To (Condition)	Percentage Switch							
		2008	2009	2010	2011	2012	2013	2014	2015
Existing Adult First Line (Old STGs)	Existing Adult Second Line (Old STGs)	2.5%	2.5%	3.0%	3.0%	3.0%	2.5%	2.5%	2.5%
	Existing Adult First Line (New STGs)	5.0%	5.0%	2.0%	1.0%	1.5%	1.3%	1.3%	1.3%
New Adult First Line (New STGs)	New Adult Second Line (New STGs)	0.0%	0.1%	0.5%	0.5%	0.5%	0.5%	0.5%	0.5%
Existing Pediatrics First Line	Existing Pediatrics Second Line	1.7%	1.7%	1.7%	1.7%	1.7%	1.7%	1.7%	1.7%
Existing Pediatrics First Line	Adult first line old STGs	N/A	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%	5.0%

PRODUCT AND DOSING ASSUMPTIONS

Current product and dosing assumptions were developed based on what most clinicians and pharmacists have experienced in the field. There are a number of expected product changes during the forecast period that were included in the quantification process. Annex C shows the actual product breakdowns per regimen.

ADULTS

- In view of the change in treatment protocols, Triomune 40 is expected to be phased-out by December 2008.

- Questions arose about how soon production of generic TDF/FTC would be available in Zambia. The product is now FDA approved and is reported by the Zambia Pharmaceutical Regulatory Authority (PRA) as a registered product.
- Considerations about introducing ATV/r in place of LPV/r for second line treatment were explored. ATV/r does not have as many side effects as LPV/r, such as the diarrhea effect in patients taking LPV/r. The cost of ATV/r is also much less than LPV/r. The team was informed that ATV/r produced by Matrix or Strides should be submitted by Q1 2009 to WHO and FDA. The benefit was noted that ATV/r in the formulation could boost the efficacy of TDF/FTC as second line (old STGs). Until the product is submitted to WHO/FDA, the team agreed not to include it in the quantification process.
- The use of EFV with TDF/FTC was noted to have increased in the last months of 2008. The increased use of EFV 600mg tablets was due to increased cases of TB co-infection and patient preference as the administration dose is once daily.

PEDIATRICS

- Zidovudine/lamivudine/nevirapine fixed dosed combination will be introduced in 2010 and increase the percentage use each year.
- Pediatrics currently on second line regimens are taking LPV/r solution 80/20mg. A decision was made that Alluvia half strength tab 80/20mg and sprinkles 80mg be introduced after they receive FDA approval by Feb/Mar 2009. This is currently not included in the quantification, but will be updated throughout the 2009 year.
- Didanosine 25mg tabs will be introduced for use in January 2009.
- It is recommended that dispensers must be advised to ensure stavudine 1mg/ml solution is stored in the refrigerator. All dispensers must have appropriate storage conditions before this drug is ordered for their facility.
- Efavirenz 50mg caps are available for use in children on first line pediatric regimens weighing below 35 kg. Its use will be promoted along side 200mg tablets in pediatrics as it avoids high volume solutions and ensures a more correct dosing.
- The use of stavudine 20mg caps is very low as compared to stavudine 15mg caps. The decision was made to phase out stavudine 20mg from the national system in 2009 and promote the use of stavudine 15mg for continued use in pediatrics above 13 kg.
- For pediatrics on zidovudine-based regimens, a proportion of 100mg caps has been allocated to those weighing 13 kg and above. This avoids high volume solutions and ensures a more correct dosing is available for use in children on both first line and second line pediatric regimens.
- Nevirapine 10mg/ml, 25 ml bottle is recommended for use in PMTCT for babies as it is in ideal package size and avoids excessive wastage as compared to 240ml bottles.
- MOH and partners presented promised to enhance campaign to increase product options for pediatrics, making use of national events like child health week.

FINDINGS

After assembling the best available data and developing the key assumptions discussed earlier, the information gathered through the quantification workshop was compiled for input into *Quantimed*. In order for *Quantimed* to analyze the data and estimate ARV drug requirements, three data points were required for each of the defined conditions (Table 5): the number of starting patients, the number of patients to be added over the course of each forecast year (addition) and the number of patients to be subtracted over the course of the forecast year (attrition). Table 12 summarizes these three data items for each condition by year, based on the assumptions presented in the previous section.

Table 12. Inputs into Quantimed by Condition

	2008	2009	2010	2011	2012	2013	2014	2015
<i>Existing Adults - First Line (Old STGs)</i>								
Starting Patients	126,921	108,518	93,537	83,212	74,661	67,148	60,986	55,396
Addition	0	755	899	1,019	1,073	1,056	966	842
Attrition	18,404	15,735	11,224	9,569	8,586	7,218	6,556	5,955
<i>Existing Adults - First Line (New STGs)</i>								
Starting Patients	18,320	67,094	112,463	151,101	186,413	219,124	249,264	277,218
Addition	6,346	5,426	1,871	1,248	1,120	839	762	692
Attrition	1,282	4,697	7,872	10,577	13,049	15,339	17,448	19,405
<i>New Adults - First Line (New STGs)</i>								
Starting Patients	0	0	0	0	0	0	0	0
Addition	47,000	48,000	48,000	48,000	48,000	48,000	48,000	48,000
Attrition	3,290	3,360	3,360	3,360	3,360	3,360	3,360	3,360
<i>Existing Adults - Second Line (Old STGs)</i>								
Starting Patients	7,507	10,155	12,157	14,112	15,621	16,767	17,272	17,588
Addition	3,173	2,713	2,806	2,496	2,240	1,679	1,525	1,385
Attrition	526	711	851	988	1,093	1,174	1,209	1,231
<i>Existing Adults - Second Line (New STGs)</i>								
Starting Patients	92	86	128	359	574	773	1,194	1,825
Addition	0	48	240	240	240	475	714	951
Attrition	6	6	9	25	40	54	84	128
<i>Existing Pediatrics - First Line</i>								
Starting Patients	12,160	15,093	17,973	20,371	21,469	21,127	19,324	16,846
Addition	0	0	0	0	0	0	0	0
Attrition	2,031	2,521	3,001	3,402	3,942	4,504	4,728	4,525

	2008	2009	2010	2011	2012	2013	2014	2015
<i>New Pediatrics - First Line</i>								
Starting Patients	0	0	0	0	0	0	0	0
Addition	5,840	6,000	6,000	5,000	4,000	3,000	2,500	2,000
Attrition	876	600	600	500	400	300	250	200
<i>Existing Pediatrics - Second Line</i>								
Starting Patients	0	207	443	704	980	1,603	2,778	4,329
Addition	207	257	306	346	722	1,334	1,830	1,998
Attrition	0	21	44	70	98	160	278	433
<i>PMTCT (Mother)</i>								
Starting Patients	0	0	0	0	0	0	0	0
Addition	67,000	67,500	68,000	68,500	69,000	69,500	70,000	70,500
Attrition	0	0	0	0	0	0	0	0
<i>PMTCT (Child)</i>								
Starting Patients	0	0	0	0	0	0	0	0
Addition	18,000	30,000	32,500	54,800	55,200	55,600	56,000	56,400
Attrition	0	0	0	0	0	0	0	0

ESTIMATE OF REQUIREMENTS

Using the *Quantimed* software, the data was compiled into a database made up of individual data subsets for each year of the forecast period (2009 – 2015). Within these subsets, individual ARV drug requirements were calculated and reported for each of the respective years. Table 13 represents the forecasted ARV drug requirements, in bottles, for each year of the forecast period.

Table 13. Forecasted ARV Drug Requirements (Bottles)

Product	2009	2010	2011	2012	2013	2014	2015
ABC 20mg/ml, 240ml	10,518*	20,037	58,913	69,292	85,366	94,550*	103,734
ABC 300mg/tab, 60 Tabs	37,600*	78,845	118,343	150,579	189,205	221,075**	252,846
DDI 100mg/tab, 60 Tabs	18,268*	44,109	51,801	60,241	70,493	87,239**	103,985
DDI 25mg/tab, 60 Tabs	2,100*	42,699	48,686	53,827	59,591	62,880**	66,168
EFV 200mg/cap, 90 Caps	12,447	14,638	13,000*	12,000*	11,000**	10,000**	9,000**
EFV 50mg/tab, 30 Tabs	14,197*	8,783	4,145	4,209	3,991	3,515*	3,038
EFV 600mg/tab, 30 Tabs	1,094,317	1,291,632	1,439,476	1,582,094*	1,638,163	1,699,152	1,738,501

Product	2009	2010	2011	2012	2013	2014	2015
3TC 10mg/ml, 240ml	44,685*	74,356*	108,992	99,660	99,122	72,323	61,808
3TC 150mg/tab, 60 Tabs	54,265	78,134	92,760**	101,563	137,790	161,873	199,284
3TC/d4T 150/30mg/tab, 60 Tabs	157,335**	120,990	108,317	97,094	90,474	85,127	80,359
3TC/d4T/NVP 150/30/200mg/tab, 60 Tabs	636,457	557,440	498,131	447,430	404,462	367,421	333,594
3TC/d4T/NVP 30/6/50mg/tab, 60 Tabs	17,743**	19,193**	6,660	5,328	4,085	3,339	2,664
3TC/d4T/NVP 60/12/100mg/tab, 60 Tabs	28,559*	86,110	107,970	111,403	106,821	95,550	82,034
3TC/AZT 150/300mg/tab, 60 Tabs	494,955*	496,800	576,277	491,926	513,312	442,204	422,484
3TC/AZT/NVP 30/60/50mg/tab, 60 Tabs	NA	9,720	45,550	54,288	63,054	62,626	53,499
LPV/r 100/25mg/tab, 120 Tabs	NA	338	1,038	2,405	5,451	11,000	18,909
LPV/r 80/20mg/tab, 120 Tabs (Sprinkles)	NA	338	519	802	1,363	2,200	3,152
LPV/r 200/50mg/tab, 120 Tabs	57,160*	163,861	187,452	202,326	218,702	228,776**	238,850
LPV/r 80/20mg/ml, 300ml	1,367	1,856	2,388	2,591	4,438*	5,720	6,303
NVP 10mg/ml, 240ml	47,491*	84,248*	94,914	81,118	82,074	46,858	40,849
NVP 10mg/ml, 25ml	3,500	6,499	9,600	9,679	9,762	9,840	10,001
NVP 200mg/tab, 60 Tabs	738,500**	836,134**	884,830	1,009,938**	1,048,869	1,098,163	1,136,536
d4T 15mg/tab, 60 Tabs	13,387	12,497	9,963	10,006	9,413	8,364	3,516
d4T 1mg/ml, 200ml	50,367*	75,441*	71,943	73,060	69,279	61,730	54,854

Product	2009	2010	2011	2012	2013	2014	2015
TDF/FTC 300/200mg/tab, 30 Tabs	840,799	626,178	383,865	NA	NA	NA	NA
TDF/3TC 300/300mg/tab, 30 Tabs	315,508	939,267	1,535,459	1,870,102	2,177,473	2,442,961	2,525,431
AZT 100mg/cap, 100 Caps	16,358	23,061	17,952	16,420	14,973	10,723	9,936
AZT 10mg/ml, 240ml	36,600**	59,303	48,843	41,563	39,979	32,889	25,372
AZT 300mg/tab, 60 Tabs	47,987	86,905	135,538	136,384	139,228	142,074	146,920

*Forecast decreased based on consumption trends

**Forecast increased based on consumption trends

These requirements were then inputted into the *PipeLine* software and compared with the actual consumption reported from ART facilities nationwide. Adjustments were made to the forecast for products whose forecast trend was significantly different to the consumption trends.

ESTIMATED FORECAST COST

The key funding sources for ARV drug procurement in Zambia are Government of Zambia (GRZ), USG (SCMS funded by PEPFAR through USAID), Global Fund, and Clinton Foundation and UNICEF funding through UNITAID. The last funding commitment from UNITAID/CHAI is for pediatric ARV drugs up to 1st Quarter 2011. The cost of each ARV drug was determined by averaging the prices of these suppliers. Annex D presents the average cost per product per year. Table 14 represents the cost of the ARV procurement for each year, including an analysis for 2009 of what is already in the country and estimating for 2010-2015 the cost plus a 6 month buffer stock.

Table 14. Funding Required per Year

Year	Feb. 2009 Update	Oct. 2008 Estimate
2009	\$70,035,530	\$84,460,586
2010	\$62,736,637	\$112,556,730
2011	\$69,603,404	\$123,549,733
2012	\$73,115,246	\$132,445,913
2013	\$79,977,434	\$161,350,854
2014	\$83,636,640	\$169,829,328
2015	\$86,333,130	\$190,688,800

FUNDING SOURCES FOR PROCUREMENT OF ARV DRUGS

The following tables show the funding commitments that are currently known by funder and supplier.

Table 15. UNITAID Funding Estimate per Year

Year	Supplier Funding Port	Amount	Total Funding Per Year
2009	Clinton Foundation	\$20,481,892	\$23,147,082
	UNICEF	\$2,665,190	
2010	Clinton Foundation	\$6,509,124	\$6,509,124
	UNICEF	\$0	
2011	Clinton Foundation	\$2,000,000	\$2,000,000
	UNICEF	\$0	

UNITAID/Clinton Foundation funding commitment for pediatric ARV drugs lasts up to 1st Quarter 2011.

UNITAID/UNICEF funding commitment is not defined after 2009.

Table 16. Global Fund Funding Estimate per Year

Global Funding Estimate			
Specific Global Fund	Funding Recipient/ Procurement Supplier	GFR4P2 & GFR8	Total Funding Per Year
2007-2008 (Year 3)			
GFR4P2	MOH	\$4,834,526	\$9,540,294
	CHAZ	\$3,980,280	
	ZNAN	\$725,488	
2009-2010			
			\$2,019,220
2009-2010 (Year 4)			
GFRIP2 Savings	MOH	\$2,019,220	\$14,862,945
GFR4P2	MOH	\$10,375,207	
	CHAZ*	\$7,256,333	
	ZNAN*	\$1,030,560	
2009-2010 (Year 5)			
GFR4P2	MOH	\$18,964,798	\$27,519,730
	CHAZ**	\$7,524,372	
	ZNAN**	\$1,030,560	
2010-2011			
GFR8***		\$20,752,253	\$20,752,253

*Although \$8.2 million was allocated to CHAZ/ZNAN, only \$2,432,518 is allocated by CHAZ. **Currently these funds are included in the national funding for the country. ***GF Round 8 will be split over 2010 and 2011 as needed.

Table 17. Government of Zambia Funding Estimate per Year

Year	Supplier	Amount	Total Funding Per Year
2008	MOH	\$5,158,393	\$5,158,393
2009*	MOH	\$3,200,000	\$3,200,000
2010**	MOH	\$5,000,000	\$5,000,000
2011**	MOH	\$20,000,000	\$20,000,000
2012***	MOH	\$20,000,000	\$20,000,000
2013***	MOH	\$20,000,000	\$20,000,000
2014***	MOH	\$20,000,000	\$20,000,000
2015***	MOH	\$20,000,000	\$20,000,000

*MOH verbally committed to US\$10,000,000 in 2009, but only \$3,200,000 has been secured.

**Originally MOH committed to \$5 million in 2010, but this has been reduced based on the experience from 2009.

***based on verbal communication from ART Coordinator for MOH. Official funding commitment still to be confirmed.

Table 18. US Government Funding Estimate per Year

Year	Supplier Funding Port	Amount	Funding Per Year
2009	SCMS COP 08*	\$5,265,056	\$23,465,056
	SCMS COP 09	\$18,200,000	
2010	SCMS COP 09*	\$5,300,000	\$23,500,000
	SCMS COP 10	\$18,200,000	
2011	SCMS COP 10*	\$5,300,000	\$23,500,000
	SCMS COP 11	\$18,200,000	
2012	SCMS COP 11*	\$5,300,000	\$23,500,000
	SCMS COP 12	\$18,200,000	
2013	SCMS COP 12*	\$5,300,000	\$23,500,000
	SCMS COP 13	\$18,200,000	
2014	SCMS COP 13*	\$5,300,000	\$23,500,000
	SCMS COP 14	\$18,200,000	
2015	SCMS COP 14*	\$5,300,000	\$23,500,000
	SCMS COP 15	\$18,200,000	

* Carry over funds from previous years Country Operation Plan (COP)

GAP ANALYSIS

Table 19 below shows the ARV drug cost estimates & gap analysis expected based on the ARV drugs required and the funding currently available.

Table 19. Gap Analysis 2009 - 2015

	2009	2010	2011	2012	2013	2014	2015
Funds Required	\$70,035,530	\$62,736,637*	\$69,603,404	\$73,115,246	\$79,977,434	\$83,636,640	\$86,333,130
GRZ	\$3,200,000	\$5,000,000	\$10,000,000	\$15,000,000	\$20,000,000	\$20,000,000	\$20,000,000
UNITAID	\$23,147,082	\$6,509,124	\$2,000,000				
USG	\$23,465,056	\$23,500,000	\$23,500,000	\$23,500,000	\$23,500,000	\$23,500,000	\$23,500,000
Global Fund	\$14,862,945	\$27,519,730	\$20,752,253				
Total	\$64,675,083	\$62,528,854	\$56,252,253	\$38,500,000	\$43,500,000	\$43,500,000	\$43,500,000
Gap	(\$5,360,447)	(\$207,783)	(\$13,351,151)	(\$34,615,246)	(\$36,477,434)	(\$40,136,640)	(\$42,833,130)

*Please note, that the current estimates show that CHAZ has more funding than its current patient numbers require; if the extra funding is not available for procurements that can go through MSL, then the funding gap would increase as the MOH would need more funding to meet the patient needs supported through the MSL distribution system.

The GRZ verbally committed to \$10,000,000 in 2009. To date, only \$3,200,000 has been allocated and therefore reflected in Table. 18. The result is a shortage in 2009 of \$2.8 million. Additionally, the GRZ verbally committed to \$15,000,000 in 2010 and \$20,000,000 in subsequent years. This was reduced as shown in Table 18 and the resulting expected gap grows each year.

Global Fund Round 8 is shown in 2011. The funds are available in 2010, but are expected to be spent in 2011.

RECOMMENDATIONS

1. The ARV quantification team needs to agree on a way forward to reduce the cost of ARVs. The team has agreed to phase TDF/FTC out for the less expensive drug TDF/3TC. Additionally, new products should be available soon, such as APV/r, which could drastically reduce some of these costs.
2. The MOH and partners must ensure that all health facilities using stavudine 1mg/ml solution have proper refrigeration or appropriate storage conditions.
3. Key members of the ARV quantification team should work with the National TB and AIDS Council (NAC) to confirm the expected number of pediatric patients needing ART.

ANNEX A

CONTACT LIST OF ATTENDEES

#	Name	Position	Organization	Email Add.	Physical Address	Contact #	Fax #	Mobile
1	Dr A. Mwango	ARV Coordinator	MoH	mwangoaj@yahoo.co.uk	MoH, Ndeke House, Lusaka	0211-253180/2	0211-253344	0955 857052
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3	Caroline Yeta	Director, Licensing & Inspectorate	PRA	cyeta@pra.gov.zm , pharmacy@pra.gov.zm	PRA Offices, Lsk	0211-220429	0211-238458	0966 763708
4	J. Johannsen	Program Manager	CHAI	jjohannesen@clintonfoundatoin.org	331 Independence Ave, Lsk	0211 250646	0211 256902	0979 068269
5	Dr C. Shumba		ZPCT/FHI	cshumba@zpct.org	Plot 2055 Nasser Road, Lsk	0211 257331-7	0211 - 257329	0976 978383
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7	Billy Mweetwa	Senior Pharmacist	CIDRZ	billy.mweetwa@cidrz.org	Thabo Mbeki Road, Counting Hse, Lsk	0211-293773	0211-293766	0977 697551
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9	Dr Mwangelwa Mubiana – Mbewe	Paediatrician	CIDRZ	mwangelwa.mbewe@cidrz.org	P.O. Box 50016, Lsk	0211-293772	0211-293766	0955 883075
10	Dr Eric Sattin	ART Treatment Advisor	NAC	esattin@nacsec.org.zm	315 Independence Ave, Lsk	0211-255092	0211-253881	0979 259235
11	Dr Suba Lungu	HIV/AIDS TB Specialist	ZNAN	znan@zamnet.zm , subalun@yahoo.com	Plot 7450, Katopolo Rd, Rhodespark	0211-256792	0211-256790	0977 775261

#	Name	Position	Organization	Email Add.	Physical Address	Contact #	Fax #	Mobile
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13	Richard Osmanski	Snr. HIV/AIDS Technical Advisor	USAID - Zambia	rosmanski@yahoo.com rosmanski@usaid.gov	351 Independence Ave, Lsk	0211-254303	0211-254532	0978 790228
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ANNEX B

CUMMULATIVE NUMBER OF PATIENTS PER REGIMEN PER YEAR

Note this is the cumulative number of patients that were on each regimen at any time during the year. One patient may be listed in more than one regimen if they switched regimens during the year.

Adults - First Line (Old STGs)							
	2009	2010	2011	2012	2013	2014	2015
D4T + 3TC + NVP (30/150/200mg)	60,415	56,909	49,201	43,884	39,458	35,535	32,277
D4T + 3TC + NVP (40/150/200mg)	5,686	-	-	-	-	-	-
AZT + 3TC + NVP (300/150/200mg)	16,309	14,042	12,182	10,866	9,770	8,798	7,992
AZT + 3TC + EFV (300/150/600mg)	30,322	26,105	22,570	20,131	18,100	16,301	14,807
D4T + 3TC + EFV (30/150/600mg)	13,504	12,217	10,577	9,434	8,482	7,639	6,939
D4T + 3TC + EFV (40/150/600mg)	685	-	-	-	-	-	-
TOTAL	126,921	109,272	94,530	84,314	75,810	68,273	62,014
Adults - Second Line (Old STGs)							
	2009	2010	2011	2012	2013	2014	2015
TDF + FTC + LPV/r	7,650	9,217	10,718	11,897	12,793	13,213	13,464
ABC + DDI + LPV/r	2,652	3,195	3,715	4,124	4,435	4,580	4,667
TDF + DDI + NFV	-	-	-	-	-	-	-
ABC + DDI + NFV	-	-	-	-	-	-	-
ABC + 3TC + LPV/r	389	468	545	605	650	671	684
TDF + 3TC + LPV/r	--	-	-	-	-	-	-
TDF + DDI + LPV/r	-	-	-	-	-	-	-
TOTAL	10,691	12,881	14,978	16,625	17,878	18,464	18,815
Adults - First Line (New STGs)							
	2009	2010	2011	2012	2013	2014	2015
TDF + FTC + EFV	34,471	35,373	51,526	23,184	-	-	-

TDF + FTC + NVP	34,471	23,622	34,370	15,475	-	-	-
TDF + 3TC + EFV	609	35,373	57,190	92,793	134,930	152,063	167,489
TDF + 3TC + NVP	616	23,622	38,114	61,996	89,891	101,302	111,576
ABC + 3TC +NVP	752	1,326	1,900	3,575	5,591	7,567	9,779
ABC + 3TC +EFV	709	1,205	1,575	3,327	5,120	7,031	9,183
TOTAL	71,630	120,520	184,675	200,350	235,532	267,963	298,027

Adult - Second Line (New STGs)

	2009	2010	2011	2012	2013	2014	2015
AZT + TDF/FTC + LPV/r	17	25	69	113	154	236	361
D4T + TDF/FTC + LPV/r	0	0	1	2	2	4	6
AZT + 3TC + LPV/r	40	57	158	257	350	537	820
D4T + 3TC + LPV/r	35	51	139	226	308	472	721
TOTAL	92	134	368	599	814	1,248	1,908

Pediatrics - First Line

	2009	2010	2011	2012	2013	2014	2015
D4T + 3TC + NVP	10,908	12,783	12,130	12,838	12,887	12,208	11,043
D4T + 3TC + EFV	2,250	2,037	2,397	634	637	603	546
AZT + 3TC + NVP	3,924	4,598	7,623	8,068	8,099	7,672	6,940
AZT + 3TC + EFV	720	844	959	1,015	1,019	965	873
AZT + 3TC + ABC	36	342	348	1,319	1,324	1,255	1,135
D4T + 3TC + ABC	162	490	516	1,497	1,503	1,424	1,288
TOTAL	18,000	21,093	23,973	25,371	25,469	24,127	21,824

Pediatrics - Second Line

	2009	2010	2011	2012	2013	2014	2015
ABC + DDI + NFV	-	-	-	-	-	-	-
ABC + DDI + LPV/r	198	425	676	941	1,539	2,666	4,156
AZT + DDI + LPV/r	8	18	28	39	64	111	173
DDI + EFV + LPV/r	-	-	-	-	-	-	-
TOTAL	207	443	704	980	1,603	2,778	4,329

PMTCT (Mother)

	2009	2010	2011	2012	2013	2014	2015
AZT + NVP	22,780	13,500	13,600	13,700	13,800	13,900	14,000
NVP (Single Dose)	40,870	27,000	13,600	6,850	6,900	6,950	7,000
AZT+3TC+NVP	3,350	27,000	40,800	47,950	48,300	48,650	49,000
TOTAL	67,000	67,500	68,000	68,500	69,000	69,500	70,000

PMTCT (Child)

	2009	2010	2011	2012	2013	2014	2015
AZT + NVP	28,665	38,080	38,400	38,720	39,040	39,360	40,000
NVP (Single Dose)	12,285	9,520	9,600	9,680	9,760	9,840	10,000
Total	40,950	47,600	48,000	48,400	48,800	49,200	50,000

ANNEX C

PRODUCTS PER REGIMEN

Regimen	Products
Adults - First Line (Old STGs)	
D4T (30) + 3TC + NVP	d4T30/3TC/NVP (Triomune 30) 1 tab twice daily
D4T (40) + 3TC + NVP	NA
AZT + 3TC + NVP	AZT/3TC 1 tab twice daily, NVP 200mg 1 tab twice daily
AZT + 3TC + EFV	AZT/3TC 1 tab twice daily, EFV 600mg 1 tab once daily
D4T (30) + 3TC + EFV	d4T30/3TC 1 tab twice daily, EFV 600mg 1 tab once daily
	NA
Adults - First Line (New STGs)	
TDF + FTC + EFV	TDF/FTC 1 tab daily, EFV 600 mg 1 tab daily
TDF + FTC + NVP	TDF/FTC 1 tab daily, NVP 1 tab twice daily
TDF + 3TC + EFV	TDF/3TC 1 tab daily, EFV 600 mg 1 tab daily
TDF + 3TC + NVP	TDF/3TC 1 tab daily, NVP 1 tab twice daily
ABC + 3TC +NVP	ABC 300mg tabs (1 tab twice daily), 1 3TC tab 2 times daily, NVP 200mg 1 tab twice daily
ABC + 3TC +EFV	ABC 300mg tabs (1 tab twice daily), 1 3TC tab 2 times daily, EFV 600 mg 1 tab once daily
Adults - Second Line (Old STGs)	
TDF + FTC + LPV/r	TDF/FTC 1 tab twice daily, LPV/r 2 tabs twice daily
ABC + DDI + LPV/r	ABC 300mg 1 tab twice daily, DDI 100mg 2 tabs twice daily, DDI 25mg 1 tab twice daily, LPV/r 2 tabs twice daily
TDF + DDI + NFV	NA
ABC + DDI + NFV	NA
ABC + 3TC + LPV/r	ABC 300 mg 1 tab twice daily, 3TC 150 mg 1 tab twice daily, LPV/r 2 tabs twice daily
TDF + 3TC + LPV/r	NA
TDF + DDI + LPV/r	NA
Adults - Second Line (New STGs)	
AZT + TDF/FTC + LPV/r	TDF/FTC 1 tab once daily, AZT 300mg 1 tab twice daily, LPV/r 2 tabs twice daily
D4T + TDF/FTC + LPV/r	d4T30 1 tab twice daily, TDF/FTC 1 tab once daily, LPV/r 2 tabs twice daily
AZT + 3TC + LPV/r	AZT/3TC 1 tab twice daily, LPV/r 2 tabs twice daily
D4T + 3TC + LPV/r	d4T30/3TC 1 tab twice daily, LPV/r 2 tabs twice daily

Regimen Abbreviation	Description	Dosing Options	2008	2009	2010	2011	2012	2013	2014	2015
Existing Pediatrics First Line										
d4T + 3TC + NVP	Stavudine / Lamivudine / Nevirapine	Triumune Junior 1 tab twice daily	35%	65%	80%	90%	90%	90%	90%	90%
		3TC Solution, 60 mg twice daily; NVP solution, 100mg twice daily	30%	15%	10%	5%	5%	5%	5%	5%
		3TC Solution, 30 mg twice daily, NVP solution, 50mg twice daily	35%	20%	10%	5%	5%	5%	5%	5%
		d4T solution, 10mg twice daily	50%	25%	15%	7.50%	7.50%	7.50%	7.50%	7.50%
		d4T 15mg 1 cap twice daily	15%	10%	5%	2.50%	2.50%	2.50%	2.50%	2.50%
d4T + 3TC + EFV	Stavudine / Lamivudine / Efavirenz	d4T solution 6mg twice daily;	35%	35%	35%	35%	35%	35%	35%	35%
		d4T solution, 10mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		d4T 15mg 1 cap twice daily	15%	15%	15%	15%	15%	15%	15%	15%
		3TC solution 30mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		EFV 200mg 1 tab once daily								
		3TC solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		EFV 200mg tab 2 tabs once daily								
AZT + 3TC + NVP	Zidovudine / Lamivudine / Nevirapine	AZT 100mg one tab twice daily	50%	50%	45%	25%	20%	20%	10%	10%
		3TC solution 60mg twice daily								
		NVP solution 100mg twice daily								
		FDC – AZT/3TC/NVP			10%	55%	65%	80%	90%	90%
		AZT solution 60mg twice daily	50%	50%	45%	20%	15%	20%	10%	10%
		3TC solution 30mg twice daily								
		NVP solution 50mg twice daily								
AZT + 3TC + EFV	Zidovudine / Lamivudine / Efavirenz	AZT 100mg one tab twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 60mg twice daily								

Regimen Abbreviation	Description	Dosing Options	2008	2009	2010	2011	2012	2013	2014	2015
		EFV 200mg tab 2 tabs once daily								
		AZT solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 30mg twice daily								
		EFV 200mg tab 1 tab once daily								
AZT + 3TC + ABC	Zidovudine / Lamivudine / Abacavir	AZT 100mg one tab twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 60mg twice daily								
		ABC solution 160mg twice daily								
		AZT solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 30mg twice daily								
		ABC solution 80mg twice daily								
d4T + 3TC + ABC	Stavudine / Lamivudine / Abacavir	d4T solution 6mg twice daily	65%	65%	65%	65%	65%	65%	65%	65%
		d4T solution, 10mg twice daily	35%	35%	35%	35%	35%	35%	35%	35%
		3TC solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		ABC solution 160mg twice daily								
		3TC solution 30mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		ABC solution 80mg twice daily								

New Pediatrics First Line

d4T + 3TC + NVP	Stavudine / Lamivudine / Nevirapine	Triomune Jr. 1 tab twice daily, 324 days	40%	45%	35%	40%	40%	40%	40%	40%
		3TC Solution, 60 mg twice daily, 30 days								
		NVP solution, 100mg twice daily, 30 days								
		d4T solution 12mg twice daily for 30 days	30%	30%	45%	50%	50%	50%	50%	50%
		Triomune Baby 1 tab twice daily, 324 days								
		3TC Solution, 30 mg twice daily, 30 days								

Regimen Abbreviation	Description	Dosing Options	2008	2009	2010	2011	2012	2013	2014	2015	
		NVP solution, 50mg twice daily, 30 days									
		d4T solution 6mg twice daily for 30 days									
		NVP solution 100mg twice daily, 324 days	30%	25%	20%	10%	10%	10%	10%	10%	
		NVP solution 100mg for 30 days									
		d4T 15mg 1 cap twice daily									
		3TC solution 60mg twice daily									
d4T + 3TC + EFV	Stavudine / Lamivudine / Efavirenz	d4T solution 6mg twice daily;	35%	35%	35%	35%	35%	35%	35%	35%	
		d4T solution, 10mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%	
		d4T 15mg 1 cap twice daily	15%	15%	15%	15%	15%	15%	15%	15%	
		3TC solution 30mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%	
		EFV 200mg 1 tab once daily									
		3TC solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%	
		EFV 200mg tab 2 tabs once daily									
AZT + 3TC + NVP	Zidovudine / Lamivudine / Nevirapine	AZT 100mg one tab twice daily	50%	50%	35%	20%	15%	10%	10%	10%	
		3TC solution 60mg twice daily									
		NVP solution 100mg twice daily			30%	65%	75%	90%	90%	90%	
		FDC – AZT/3TC/NVP									
		AZT solution 60mg twice daily	50%	50%	35%	15%	10%	10%	10%	10%	
		3TC solution 30mg twice daily									
		NVP solution 50mg twice daily									
AZT + 3TC + EFV	Zidovudine / Lamivudine / Efavirenz	AZT 100mg one tab twice daily	50%	50%	50%	50%	50%	50%	50%	50%	
		3TC solution 60mg twice daily									
		EFV 200mg tab 2 tabs once daily									

Regimen Abbreviation	Description	Dosing Options	2008	2009	2010	2011	2012	2013	2014	2015
		AZT solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 30mg twice daily								
		EFV 200mg tab 1 tab once daily								
AZT + 3TC + ABC	Zidovudine / Lamivudine / Abacavir	AZT 100mg one tab twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 60mg twice daily								
		ABC solution 160mg twice daily								
		AZT solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		3TC solution 30mg twice daily								
		ABC solution 80mg twice daily								
d4T + 3TC + ABC	Stavudine / Lamivudine / Abacavir	d4T solution 6mg twice daily	65%	65%	65%	65%	65%	65%	65%	65%
		d4T solution, 10mg twice daily	35%	35%	35%	35%	35%	35%	35%	35%
		3TC solution 60mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		ABC solution 160mg twice daily								
		3TC solution 30mg twice daily	50%	50%	50%	50%	50%	50%	50%	50%
		ABC solution 80mg twice daily								

Pediatric Second Line

ABC + DDI + LPV/r	Abacavir / Didanosine/ Lopinavir/ Ritonavir	ABC solution 80mg twice daily	30%	30%	30%	25%	20%	20%	15%	10%		
		DDI 25mg 1 tab twice daily										
		LPV/r solution 80mg twice daily										
				ABC solution 160 mg twice daily	70%	70%	50%	45%	40%	30%	25%	20%
				DDI 100mg 1 tab twice daily								
				LPV/r solution 160mg twice daily								
				ABC solution 80mg twice daily			10%	10%	10%	10%	10%	10%

Regimen Abbreviation	Description	Dosing Options	2008	2009	2010	2011	2012	2013	2014	2015
		DDI 25mg 1 tab twice daily								
		LPV/r sprinkles 80mg twice daily (feb/mar 2009 FDA approval)								
		ABC solution 160 mg twice daily								
		DDI 100mg 1 tab twice daily			10%	20%	30%	40%	50%	60%
		LPV/r (half) tab 80/20mg twice daily (feb/mar 2009 FDA approval)								
AZT + DDI + LPV/r	Zidovudine / Didanosine/ Lopinavir/ Ritonavir	AZT solution 80mg twice daily								
		DDI 25mg 1 tab twice daily	30%	30%	30%	25%	20%	20%	15%	10%
		LPV/r solution 80mg twice daily								
		AZT 100mg one tab twice daily								
		DDI 100mg 1 tab twice daily	70%	70%	50%	45%	40%	30%	25%	20%
		LPV/r solution 160mg twice daily								
		AZT solution 80mg twice daily								
		DDI 25mg 1 tab twice daily			10%	10%	10%	10%	10%	10%
		LPV/r sprinkles 80mg twice daily (feb/mar 2009 FDA approval)								
		AZT 100mg one tab twice daily								
		DDI 100mg 1 tab twice daily			10%	20%	30%	40%	50%	60%
		LPV/r (half) tab 80/20mg twice daily (feb/mar 2009 FDA approval)								

APPENDIX D

AVERAGE PRICE³ PER PRODUCT (IN BOTTLES) PER YEAR

Product	2009	2010	2011	2012	2013	2014	2015
ABC 20mg/ml, 240ml	\$16.49	\$16.49	\$18.65	\$19.6	\$19.6	\$19.6	\$19.6
ABC 300mg/tab, 60 Tabs	\$27.99	\$28.80	\$29.45	\$29.45	\$29.45	\$29.45	\$29.45
DDI 100mg/tab, 60 Tabs	\$8.46	\$8.61	\$8.66	\$8.68	\$8.68	\$8.68	\$8.68
DDI 25mg/tab, 60 Tabs	\$7.68	\$7.84	\$7.84	\$7.84	\$7.84	\$7.84	\$7.84
EFV 200mg/cap, 90 Caps	\$15.95	\$15.95	\$16.32	\$16.80	\$16.80	\$16.80	\$16.80
EFV 50mg/tab, 30 Tabs	\$2.88	\$2.72	\$2.72	\$2.72	\$2.72	\$2.72	\$2.72
EFV 600mg/tab, 30 Tabs	\$11.52	\$8.96	\$8.96	\$8.96	\$8.96	\$8.96	\$8.96
3TC 10mg/ml, 240ml	\$1.98	\$2.02	\$2.02	\$2.02	\$2.02	\$2.02	\$2.02
3TC 150mg/tab, 60 Tabs	\$3.98	\$3.98	\$4.05	\$4.05	\$4.05	\$4.05	\$4.05
3TC/d4T 150/30mg/tab, 60 Tabs	\$4.46	\$4.95	\$5.04	\$5.04	\$5.04	\$5.04	\$5.04
3TC/d4T/NVP 150/30/200mg/tab, 60 Tabs	\$7.64	\$7.64	\$7.64	\$7.64	\$7.64	\$7.64	\$7.64
3TC/d4T/NVP 30/6/50mg/tab, 60 Tabs	\$2.70	\$2.75	\$2.75	\$2.75	\$2.75	\$2.75	\$2.75

³ This price is inclusive of estimated freight costs.

Product	2009	2010	2011	2012	2013	2014	2015
3TC/d4T/NVP 60/12/100mg/tab, 60 Tabs	\$5.43	\$5.53	\$5.53	\$5.53	\$5.53	\$5.53	\$5.53
3TC/AZT 150/300mg/tab, 60 Tabs	\$10.30	\$9.81	\$9.81	\$9.81	\$9.81	\$9.81	\$9.81
3TC/AZT/NVP 30/60/50mg/tab, 60 Tabs	NA	\$6.16	\$6.99	\$7.55	\$7.55	\$7.55	\$7.55
LPV/r 100/25mg/tab, 120 Tabs	NA	\$35.70	\$36.34	\$36.34	\$36.34	\$36.34	\$36.34
LPV/r 80/20mg/tab,120 Tabs (Sprinkles)	NA	\$36.34	\$36.34	\$36.34	\$36.34	\$36.34	\$36.34
LPV/r 200/50mg/tab, 120 Tabs	\$50.14	\$47.80	\$46.03	\$46.03	\$46.03	\$46.03	\$46.03
LPV/r 80/20mg/ml, 300ml	\$45.21	\$46.03	\$46.03	\$46.03	\$46.03	\$46.03	\$46.03
NVP 10mg/ml, 240ml	\$1.96	\$4.03	\$4.03	\$4.03	\$4.03	\$4.03	\$4.03
NVP 10mg/ml, 25ml	\$1.43	\$1.46	\$1.46	\$1.46	\$1.46	\$1.46	\$1.46
NVP 200mg/tab, 60 Tabs	\$3.96	\$3.80	\$3.36	\$3.36	\$3.36	\$3.36	\$3.36
d4T 15mg/tab, 60 Tabs	\$1.65	\$1.68	\$1.68	\$1.68	\$1.68	\$1.68	\$1.68
d4T 1mg/ml, 200ml	\$1.65	\$1.68	\$1.68	\$1.68	\$1.68	\$1.68	\$1.68
TDF/FTC 300/200mg/tab, 30 Tabs	\$22.12	\$13.44	\$13.44	NA	NA	NA	NA
TDF/3TC 300/300mg/tab, 30 Tabs	\$12.25	\$11.94	\$11.94	\$11.94	\$11.94	\$11.94	\$11.94
AZT 100mg/cap, 100 Caps	\$5.50	\$5.50	\$5.60	\$5.60	\$5.60	\$5.60	\$5.60
AZT 10mg/ml, 240ml	\$2.37	\$2.41	\$2.41	\$2.41	\$2.41	\$2.41	\$2.41
AZT 300mg/tab, 60 Tabs	\$8.88	\$9.81	\$9.81	\$9.81	\$9.81	\$9.81	\$9.81

APPENDIX E

SUMMARY OF UPDATES FROM 27 FEB. 2009 QUANTIFICATION REVIEW MEETING

PATIENT ESTIMATES

ADULTS

Adult patient numbers were overestimated for 2008 in Oct. by 28,000 patients. The MOH feels that this was due to double counting. The same patient was counted by multiple facilities most likely due to patient referral. The patient is seen at the large facility initially and then referred to a closer health centre for follow up. This patient was counted twice – once by each facility.

The table below shows the original estimates vs. the updated estimates from the Feb. meeting.

Year	Oct. 2008 Patient Estimates	Feb. 2009 Patient Estimates	Percent Reduction
2008	228,435	200,435	-12.3%
2009	284,445	234,405	-17.6%
2010	330,533	265,996	-19.5%
2011	373,396	295,376	-20.9%
2012	407,258	322,700	-20.8%
2013	433,750	348,111	-19.7%
2014	463,388	371,743	-19.8%
2015	492,951	393,721	-20.1%

The number of new patients per year was also adjusted down after reviewing the scale-up figures from 2008. The team originally estimated 63,678 new patients in 2009, but this was reduced to 48,000 patients each year. The table below shows the change in the estimated number of new adult patients per year.

Year	Oct. 2008 New Patient Estimates	Feb. 2009 New Patient Estimates	Percent Reduction
2008	75,000	47,000	-37%
2009	72,000	48,000	-33%
2010	66,000	48,000	-27%
2011	66,000	48,000	-27%
2012	60,000	48,000	-20%
2013	55,000	48,000	-13%
2014	60,000	48,000	-20%
2015	62,000	48,000	-23%

PEDIATRICS

Pediatric patients were also overestimated at the Oct. 2008 Quantification. In 2009, the estimate was 2,000 more than the actual after reviewing the data. The rate of scale up has also been adjusted over the years. The original forecast had estimated 8,000 new patients in 2009 and decreasing this to 4,000 new patients in 2015. The updated quantification now estimates the scale-up to go from 6,000 in 2009 to 2,000 in 2015. The change was agreed due to impact of PMTCT as well as difficulty in reaching some of the children in need.

Year	Oct. 2008 Patient Estimates	Feb. 2009 Patient Estimates	Percent Reduction
2008	20,000	18,000	-10.0%
2009	25,000	21,300	-14.8%
2010	30,500	25,170	-17.5%
2011	35,450	27,653	-22.0%
2012	37,905	28,888	-23.8%
2013	39,115	28,999	-25.9%
2014	39,203	28,599	-27.0%
2015	39,283	27,739	-29.4%

PMTCT MOTHERS

The number of mothers receiving PMTCT was underestimated at the Oct. meeting. Dr. Bweupe emailed the updated estimates (through Dr. Sattin) on 3/3/2009.

Year	Oct. 2008 Patient Estimates	Feb. 2009 Patient Estimates	Percent Increase
2008	54,000	62,526	+15.8%
2009	58,400	68,554	+17.4%
2010	59,000	68,161	+15.5%
2011	60,000	67,769	+12.9%
2012	60,500	68,192	+12.7%
2013	61,000	69,614	+14.1%
2014	61,500	71,037	+15.5%
2015	62,500	73,460	+17.5%

PMTCT BABIES

The number of babies seen for PMTCT was reduced in 2008 and 2009 based on the 2008 adjusted figures. In 2010, the number of babies seen is linked to the number of HIV+ mothers expected to deliver at the health facility. Since the number of HIV+ mothers expected to receive PMTCT increased, the number of babies also increased.

Year	Oct. 2008 Patient Estimates	Feb. 2009 Patient Estimates	Percent Reduction/Increase
2008	27,000	18,000	-33.3%
2009	40,950	32,500	-20.6%
2010	47,600	54,215	+13.9%
2011	48,000	54,553	+13.7%
2012	48,400	55,691	+15.1%
2013	48,800	56,830	+16.5%
2014	49,200	58,768	+19.4%
2015	50,000	58,768	+17.5%

PRODUCT CHANGES

TDF/FTC AND TDF/3TC

The original quantification assumed that from 2010 – 2015 50% of patients would use TDF/FTC and 50% would use TDF/3TC. After discussing the transition of this drug, the fact that TDF/3TC is significantly less expensive and the fact that TDF/3TC is now FDA-approved, the team agreed to

transition over 3 years to 100% use of TDF/3TC for first line patients. In 2009, there will be 50/50 use of the drugs with effect from July 2009. In 2010, there will be an estimated split of 60/40 (TDF/3TC to TDF/FTC). In 2011, this will increase to 80/20 and by 2012, 100% will be using TDF/3TC. The rationale for the slower transition is to ensure that since there is only one supplier of the TDF/3TC, the country does not run into a situation where the supplier is not able to meet the demand.

PMTCT DOSING FOR MOTHERS

The team discussed the rapid scale-up of AZT 300mg tablets from the original forecast. The team agreed that of the mothers receiving three drugs for PMTCT in 2009 and 2010, 50% will receive the single dose of AZT and single 3TC instead of the combination drug (AZT/3TC – Combivir) as originally forecasted. In 2011 onwards, it is expected that 100% of the mothers will receive the fixed-dose combination drug AZT/3TC.

PRICING CHANGES

TDF/FTC

The price of the branded TDF/FTC is approximately \$28/bottle. The generic TDF/FTC is expected to be FDA-approved by mid-2009. The estimate of this product is currently \$17/bottle. Matrix provided information that their price will reduce further to \$12/bottle when the product is FDA approved. This price was used for all procurements from 2010 – 2015.

NOTE: This reduction in price in 2010 is one of the reasons for the reduced funding requirement from 2009 to 2010.

TDF/3TC

Originally, the generic TDF/3TC was estimated to be \$13/bottle. Since the meeting, the price estimate has been reduced to \$10-11.50/bottle.

EFV 600 MG

Efavirenz 600mg originally was quantified at approximately \$12/bottle. Several manufacturers have developed a new manufacturing process to make the API for EFV using less costly and more efficient chemical processes. Thus, several of the manufactures have provided newer and lower prices. The average price for EFV 600mg is now between \$7.50 and \$8 per bottle.

NOTE: This reduction in price in 2010 is one of the reasons for the reduced funding requirement from 2009 to 2010.

ARV'S QUANTIFICATION WORKSHOP HELD AT BLUE NILE LODGE ON 27TH FEBRUARY 2009.

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