

TECHNICAL REPORT



AIDS MEDICINES AND DIAGNOSTICS SERVICE

**ANTIRETROVIRAL MEDICINES  
IN LOW-AND MIDDLE-INCOME  
COUNTRIES: FORECASTS OF  
GLOBAL AND REGIONAL DEMAND  
FOR 2013-2016**

MARCH 2014



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# ABBREVIATIONS AND ACRONYMS

3TC	lamivudine
ABC	abacavir
API	active pharmaceutical ingredient
ART	antiretroviral therapy
ARV	antiretroviral
ATV	atazanavir
ATV/r	ritonavir-boosted atazanavir
AZT	zidovudine (also known as ZDV)
CHAI	Clinton Health Access Initiative
d4T	stavudine
EFV	efavirenz
FTC	emtricitabine
FL	first-line
GF	Global Fund
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism
LPV	lopinavir
LPV/r	ritonavir-boosted lopinavir
NNRTI	non-nucleoside reverse-transcriptase inhibitor
NRTI	nucleoside reverse-transcriptase inhibitor
NtRTI	nucleotide reverse-transcriptase inhibitor
NVP	nevirapine
OGAC	Office of the US Global AIDS Coordinator
PFSCM	Partnership for Supply Chain Management
PI	protease inhibitor
SCMS	Supply Chain Management System
SL	second-line
TDF	tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

# EXECUTIVE SUMMARY

The global effort to scale-up HIV treatment in low- and middle-income countries continues to move closer towards achieving the goal of 15 million people receiving treatment by 2015. By the end of 2012, 9.7 million people in low- and middle-income countries were receiving antiretroviral therapy (ART), which represents an increase of 1.7 million from the previous year (1, 2).

The goal of this report is to provide countries and suppliers with a sense of how the global market for antiretroviral (ARV) medicines in low- and middle-income countries is likely to evolve from 2013 to 2016. The report also aims to provide suppliers with a global forecast of the estimated demand for active pharmaceutical ingredients (APIs) so that they can manage their manufacturing capacity accordingly.

Three forecasting approaches are used to project the demand for ART, expressed as the number of people on treatment from 2013 to 2016, in this report:

- the linear regression forecast extrapolates from historical trends in the number of people receiving ARV drugs;
- the country target model reflects the reported programme goals of national programmes;
- the approach of the Clinton Health Access Initiative (CHAI) focuses on the experience of countries with a high burden of HIV infection.

The three approaches use data from the 2012 WHO survey on ARV use, augmented in the CHAI model with data from the progress report towards universal access and country information (2, 4, 5, 6, 7).

The assumptions underlying the forecasts for demand for APIs for 2013–2016 were developed through the work of the Technical Working Group Meeting on Global Antiretroviral Demand Forecast, which included staff from CHAI; Futures Institute; Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); Joint United Nations Programme on HIV/AIDS (UNAIDS); Office of the United States Global AIDS Coordinator (OGAC); Partnership for Supply Chain Management (PFSCM); United Nations Children's Fund (UNICEF); United States Agency for International Development (USAID); and World Health Organization (WHO). The Technical Working Group coordinated several sources of data on ARV drugs, including the WHO survey on ARV use, the Global Price Reporting Mechanism (GPRM) data on procurement, Supply Chain Management System procurement, national guidelines and CHAI data on drug recipients, to consolidate key assumptions and generate the projected demand for APIs.

This year's report was able to build on the accumulation of data to improve the accuracy of forecasting demand. As a result, the distribution of adult and children receiving treatment by ARV drugs was calculated separately based on an average of five sources of data (four sources of data in the case of children): the 2013 WHO survey of ARV use; GPRM procurement data; Global Fund projected procurement for 2014 and 2015; Supply Chain Management System (SCMS) procurement data (for adults only); and CHAI's global ARV forecast. For adult patients, individual ARV drugs were categorized by four market categories:

- Primary nucleoside reverse-transcriptase inhibitors (NRTIs) and nucleotide reverse-transcriptase inhibitors (NtRTIs): (d4T, AZT and TDF).
- Secondary NRTIs (3TC and FTC).
- Non-nucleoside reverse-transcriptase inhibitors (NNRTIs) (NVP and EFV).
- Protease inhibitors (PIs) (LPV/r and ATV/r). For paediatric patients, individual PIs were categorized into three market categories:
  - NRTIs and NtRTIs (d4T, AZT, TDF and ABC)
  - secondary NRTIs (3TC and FTC)
  - NNRTIs and PIs (NVP, LPV/r and ATV/r).

The projections for the adult and paediatric API market are shown in Figs 4–15.

The figures in this report do not state what should be or will be accomplished by 2016. Rather, they estimate the likely demand if current trends continue. The linear regression approach projects 15.7 million people receiving treatment by 2016; the CHAI forecast is just under 16.1 million; and the country target approach projects 18.5 million. The average projection of the three approaches reaches 16.8 million by 2016. Table 1 shows the results for the number of people receiving ART, the proportion of people on first- and second-line therapy, and the number of HIV-infected women receiving ARVs for prevention of mother-to-child-transmission (PMTCT).

**Table 1. Summary of results, based on average of three forecasting approaches**

<b>Number of people receiving ART or ARV drugs for PMTCT</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
Number of adults receiving ART (millions)	10.7 [10.4–11.2] <sup>a</sup>	12.4 [11.9–13.2]	14.1 [13.3–15.3]	15.7 [14.7–17.3]
Number of children receiving ART (millions)	0.80 [0.72–0.94]	0.89 [0.80–1.0]	0.98 [0.88–1.2]	1.1 [0.96–1.2]
Number of people receiving ART (millions)	11.5 [11.5–11.5]	13.3 [12.7–14.2]	15.0 [14.2–16.4]	16.8 [15.7–18.5]
Proportion of people receiving first-line ART(%)	95.6	95.4	95.2	95.0
Proportion of people receiving second-line ART (%)	4.4	4.6	4.8	5.0
Number of women receiving ARV drugs for PMTCT, based on linear and country target projections (millions)	1.7 [1.1–2.2]	1.9 [1.3–2.6]	2.2 [1.4–3.0]	2.5 [1.5–3.4]

a Numbers in brackets show the low and high estimates.

# 1. INTRODUCTION

The objectives of this report are to:

- provide information about the projected number of people who will be on antiretroviral therapy (ART) for 2013–2016;
- update the forecasts of global demand for antiretroviral (ARV) drugs prepared in 2012;
- forecast the global and regional demand for ARV drugs from 2013 to 2016.

This report consolidates data compiled by the:

- Clinton Health Access Initiative (CHAI) on projection of ARV demand;
- Global Price Reporting Mechanism (GPRM);
- Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund);
- Joint United Nations Programme on HIV/AIDS (UNAIDS) on the estimated number of people who need ART;
- United States President's Emergency Plan for AIDS Relief (PEPFAR)-funded Supply Chain Management System (SCMS) Project on quantities of ARVs to be procured for 2014 and 2015;
- World Health Organization (WHO) survey on ARV use.

All these data were compiled and used to project the demand for ARV drugs from 2013 to 2016. The number of people receiving ART for the projected years is forecasted using three approaches:

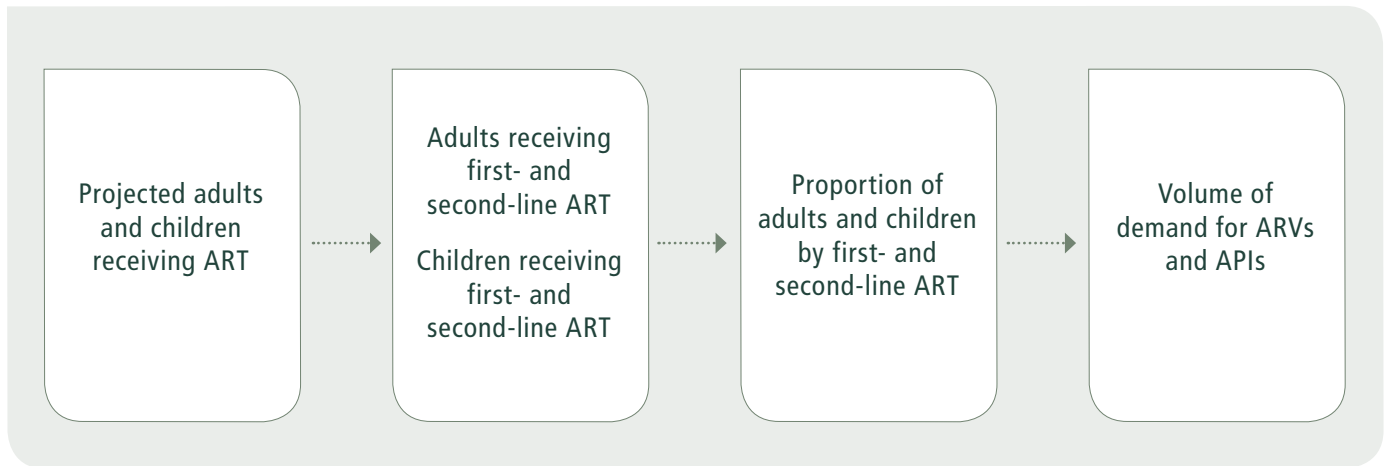
- linear projection of historical numbers of people receiving ART by country;
- country target projection, based on planning targets submitted by national programmes;
- projection by CHAI.

The three approaches are explained in detail in the following pages. In general, forecasting the global demand for ARVs involves the following steps:

- Project the total number of people receiving ART.
- Determine the number of people receiving first-line and second-line therapy, using the average of proportions from three sources of data:
  - linear regression based on the WHO ARV use surveys conducted in 2011, 2012 and 2013, which assessed the use of ARV medicines at the end of 2010, 2011 and 2012, respectively (2–6);
  - linear extrapolation of the relative market share of protease inhibitors (PIs) for 2009–2013 from GPRM procurement data;
  - the CHAI projections for second-line therapy for 2013–2016.
- Determine the distribution of regimens for adults and children receiving first- and second-line therapy, using the average proportions from five sources of data (four data sources for children):
  - linear regression based on the WHO surveys of reported ARV use at the end of 2010, 2011 and 2012;
  - linear extrapolation of the relative market share of APIs for 2009–2013 from GPRM procurement data;
  - CHAI ARV market share projections for 2013–2016;
  - Global Fund procurement forecasts for 2014 and 2015;
  - the fifth source for adults is based on SCMS procurement forecasts for 2014 and 2015.
- Calculate the number of person-years of treatment for each ARV drug.
- Calculate the total API volumes required to meet the forecasted demand for adults and children for each ARV drug.

The model used for forecasting ARV drug demand in this report is shown in Fig. 1. The calculated averages of the results of each step in terms of the numbers of people receiving ARV drugs, and the breakdown of first-line and second-line therapy and regimen use, were used as the basis to determine the final estimates of the demand for APIs for 2013–2016

**Fig. 1. Model used for forecasting ARV drug demand**



## 2. METHODS FOR DETERMINING KEY FORECAST VARIABLES

### 2.1. Total number of people receiving treatment

Table 2 summarizes the underlying assumptions and data sources of the three approaches to forecasting the number of people receiving ART to 2016.

**Table 2. Summary of assumptions made in the forecast scenarios**

	Forecasting method		
	Linear projection	Country target projection	CHAI projection
Data sources	WHO AIDS Medicines and Diagnostics Service surveys conducted from 2011 to 2013	Country targets for 2013–2016	Global progress reports published annually by WHO/ UNICEF/UNAIDS
Number of countries for which data are used	96 (WHO ARV use survey conducted in 2013)	46	21 highest burden countries <sup>a</sup>
Proportion of people in low- and middle-income countries receiving treatment represented in the data set	65%	47% (extrapolated to the remaining low- and middle-income countries) <sup>b</sup>	85% (extrapolated to the remaining 15% of patients in low- and middle-income countries)
Underlying assumption	Number of people receiving ARV drugs will increase linearly at the same rate as the linear trend observed in 2010–2012, with the rate of increase limited by the number of people estimated to need treatment by 2016	National programme planning targets will be achieved	Number of people receiving treatment will increase linearly at the same rate as the linear trend observed in 2010–2012 and will plateau at universal access

a Botswana, Brazil, Cameroon, China, Côte d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Thailand, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

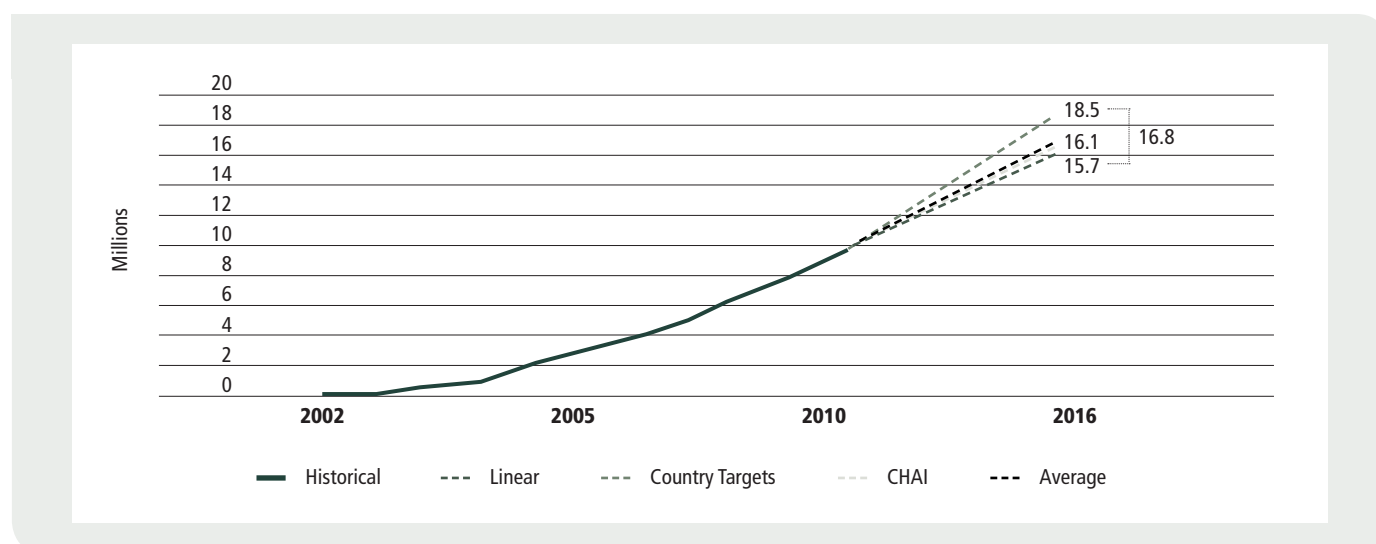
b For details of the composition of the geographical regions, see the explanatory notes for classification of low- and middle-income countries by income level, epidemic level and geographical, UNAIDS, UNICEF and WHO regions on page 152 in Global HIV/AIDS response: epidemic update and health sector progress towards universal access. Progress report 2011 (6).

The results for each of the three methods were summed and divided by three to get the average estimated number of people on ART for all low- and middle-income countries. Table 3 and Fig. 2 present the three projection scenarios of the estimated number of people receiving ART from 2013 to 2016 and the average of the three projections. Table A1 provides the average number of people receiving treatment by region for the linear and country target projections.

The linear projection and CHAI projection are similar, except for the addition of women starting on ART through option B+ for prevention of mother-to-child-transmission (PMTCT) in the linear projection. The country target scenario varies from these two scenarios because the estimates are informed by the aspirations of each reporting country to reach the goal of universal access to treatment by 2015, thus surpassing 15 million on treatment by 2016.

**Table 3. Number of adults and children receiving treatment by scenario and average, 2013–2016**

Forecasting method	Age group	2013	2014	2015	2016
Linear projection	Adults	10 400 000	11 900 000	13 300 000	14 700 000
	Children	730 000	830 000	920 000	1 000 000
	Total	11 200 000	12 700 000	14 200 000	15 700 000
Country target projection	Adults	11 200 000	13 200 000	15 300 000	17 300 000
	Children	940 000	1 000 000	1 200 000	1 200 000
	Total	12 100 000	14 200 000	16 400 000	18 500 000
CHAI projection	Adults	10 600 000	12 100 000	13 600 000	15 100 000
	Children	720 000	800 000	880 000	960 000
	Total	11 330 000	12 900 000	14 500 000	15 700 000
Average	Adults	10 700 000	12 400 000	14 100 000	15 700 000
	Children	800 000	890 000	980 000	1 070 000
	Total	11 500 000	13 300 000	15 000 000	16 800 000

**Fig. 2. Comparison of projections of the number of people receiving ART, 2013–2016**

### 2.1.1 Linear projection

The linear projection estimates the annual increase in the number of people receiving treatment for 154 countries from a linear regression line fitted to the number of adults and children receiving ART from the past 3 years (2010, 2011 and 2012), as reported in the WHO/UNAIDS/UNICEF reports on universal access to HIV prevention, treatment, care and support (4–6). The regression fit uses the actual

month and year of each report and the results of applying linear regression were constrained by the UNAIDS estimated total need for ART (from Spectrum projections for each country prepared in cooperation with UNAIDS).

The total need for ARV drugs is defined as everyone currently receiving ART, plus those who meet the eligibility criteria but are not receiving ART. With the 2013 update in WHO treatment guidelines on the use of ARV

drugs recommending a higher CD4 threshold for initiating treatment, the scale-up of treatment for prevention and option B+ for PMTCT, the total number of people who need treatment has increased from previous estimates (7). The linear approach is constrained by the estimated number of people who need ART projected for 2016 based on WHO 2013 treatment recommendations.

Since option B+ for PMTCT<sup>1</sup> is already being scaled-up or being considered for scale-up, we have added the number of women initiating ART through option B+ to the linear and country target projections of the number of adults receiving ART. The number and proportion of pregnant women receiving various options for PMTCT, including lifelong ART (option B+), is shown in Table 7 in Section 2.4.

### 2.1.2 Country target projection

Most countries have their own targets for the number of people they expect to be receiving ART during the next 3–5 years. These targets consider the realities in each country and their goals for increasing coverage. For the 2013–2016 country targets, 46 countries<sup>2</sup> provided projections, accounting for about half the people receiving ART in low- and middle-income countries. For countries that did not define targets, it is assumed that the total number of people receiving ART will grow at the same rate as the aggregate projection for these 46 countries. This equates to an average annual growth of nearly 2 million people per year. We assume that the number of people receiving ART and the country target projections account for the pregnant women who initiate ART for life through option B+.

### 2.1.3 CHAI projection

Each year, CHAI derives a 5-year forecast for the total number of patients on ART in low- and middle-income countries. CHAI compiles historic data on the number of patients on ART in the 21 highest burden countries from the global progress reports published annually by UNAIDS, UNICEF and WHO, then linearly extrapolates the previous 3 years of data to estimate future patient growth in each of those countries, allowing growth to plateau as countries approach universal access. CHAI then aggregates the patient estimates across the 21 countries,

which represent 85% of patients in low- and middle-income countries, and extrapolates the results to the remaining 15%.

## 2.2. Number of people receiving first- and second-line therapy

Three data sources were used to determine the proportion of people receiving second-line therapy:

- Linear regression of the proportion of people receiving second-line therapy reported in the 2010, 2011, 2012 and 2013 WHO surveys. As with the previous year, we assumed that the percentage of people receiving second-line therapy would not exceed 5.5% by 2016 because, unless viral load testing is expanded, identifying everyone needing to transition to second-line therapy in this time frame is unlikely.
- Linear regression of the proportion of the people receiving protease inhibitors (PIs) reported by the GPRM for 2009, 2010, 2011 and 2012 (8). The projection for each year is calculated by adding the annual increment determined by the regression analysis to the proportion of people receiving second-line therapy in the previous year.
- CHAI collects data on second-line patient numbers in the 21 highest burden countries from country teams and published literature. CHAI then estimates future second-line patient numbers in each country by considering factors such as treatment failure rates and attrition rates. CHAI then aggregates second-line estimates across the 21 countries and extrapolates these results to patients in the remainder of low- and middle-income countries. The proportion of people receiving second-line therapy is calculated by dividing this figure by the total number of patients on treatment.

Table 4 shows the projected proportion of people receiving second-line therapy for each of the three data sources, which are within 1.5 percentage points of each other, as well as the average, which was used in estimating the demand for APIs.

1 PMTCT option B+ is an ARV treatment in which pregnant women living with HIV initiate ART regardless of CD4 count.

2 Belarus, Benin, Burkina Faso, Burundi, Cambodia, Cameroon, Cabo Verde, Central African Republic, Côte d'Ivoire, Cuba, Democratic Republic of the Congo, Ecuador, Egypt, El Salvador, Ethiopia, Gabon, Guinea, Guyana, Iran, Islamic Republic of, Iraq, Kenya, Lao People's Democratic Republic, Liberia, Malawi, Malaysia, Mali, Morocco, Myanmar, Nicaragua, Nigeria, Oman, Paraguay, Peru, Philippines, Republic of Moldova, Senegal, Seychelles, Syrian Arab Republic, Thailand, Togo, Tunisia, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

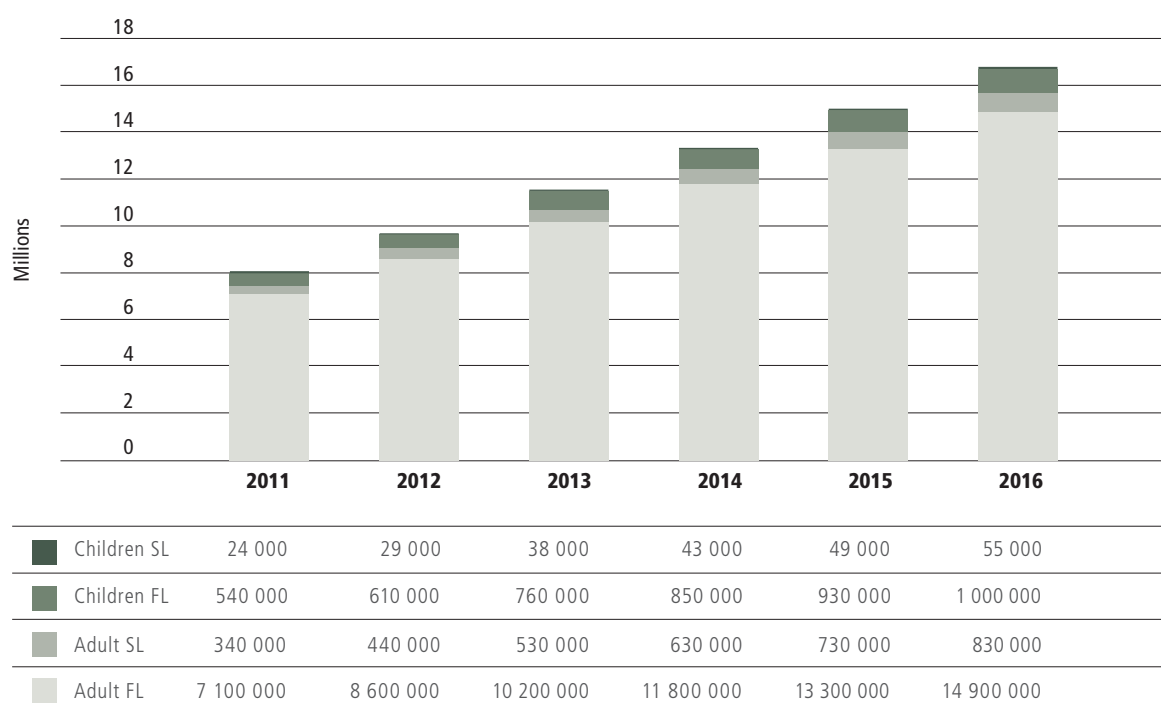


**Table 4. Proportion of people receiving second-line ART, 2013–2016**

Data source	Proportion of people receiving second-line ART 2013 2016 (%)			
	2013	2014	2015	2016
WHO AIDS Medicines and Diagnostics Service survey	5.1	5.2	5.3	5.4
GPRM	3.6	3.9	4.2	4.5
CHAI	4.4	4.6	4.8	5.0
Average	4.4	4.6	4.8	5.0

The average proportions of people receiving second-line therapy are then applied to the average number of adults and children receiving treatment as forecast for 2013–2016 (see Table 3). Figure 3 shows the number of adults and children receiving first- and second-line therapy. The number of adults and children on first- and second-line

therapy for the linear, CHAI and country target scenarios are shown in Figs A1–A3. The average number of adults and children on first- and second-line therapy, based on the linear and country target projections for each region, are shown in Figs A4–A9.

**Figure 3. Number of adults and children receiving first- and second-line ART, 2013–2016, based on an average of three projections. FL, first-line; SL, second-line.**

## 2.3. Proportion of adults and children receiving treatment by ARV drug

The distribution of adults and children receiving treatment by ARV drug was calculated separately using an average of five data sources: CHAI's global ARV forecast; Global Fund projected procurement for 2014 and 2015; GPRM procurement data; SCMS procurement data; and the 2013 WHO survey of ARV use. With the availability of more detailed data, each forecast scenario was divided into two: regimen distributions for adult patients and for paediatric patients.

- For adult patients, individual ARV drugs were categorized by the following market categories:
  - primary nucleoside reverse-transcriptase inhibitors (NRTIs) and nucleotide reverse-transcriptase inhibitors (NtRTIs): stavudine (d4T), zidovudine (AZT) and tenofovir (TDF);
  - secondary NRTIs: lamivudine (3TC) and emtricitabine (FTC);
  - non-nucleoside reverse-transcriptase inhibitors (NNRTIs): nevirapine (NVP) and efavirenz (EFV);
  - PIs: primarily ritonavir-boosted lopinavir (LPV/r) and ritonavir-boosted atazanavir ATV/r.
- For paediatric patients, individual drugs were categorized by the following market categories:
  - primary NRTIs and NtRTIs: stavudine (d4T), zidovudine (AZT), tenofovir (TDF) and abacavir (ABC);
  - secondary NRTIs: lamivudine (3TC);
  - NVP, EFV and LPV/r.

### 2.3.1 Observed trend in regimens based on a survey of ARV drug use

This projection method was based on observed trends in regimen use, as reported in the WHO surveys of ARV drug use from 2010 to 2012. For the countries that responded, the reported proportions of adults and children receiving each regimen were disaggregated into the percentage of adults and paediatric patients receiving each individual ARV drug. For countries that did not respond to the survey, the average regional distribution was used. To forecast the ARV drug distribution from 2013 to 2016 by country, a linear regression line was fitted to the reported ARV drug distribution from 2010 to 2012 projected to 2016 but constrained to be between 0% and 100%.

Note that the PIs indinavir, saquinavir and nelfinavir were calculated differently. It was assumed that since all three ARV drugs will no longer be marketed, no one will receive these by the end of 2013 and that people formerly using all three ARV drugs will be transitioned to LPV/r and ATV/r

in a ratio of nine to one, based on current GPRM data (i.e. 90% are transitioned to LPV/r and 10% to ATV/r).

### 2.3.2 Observed procurement trend from the GPRM database

Global procurement data reported in the GPRM database were available for 2011, 2012 and the first three quarters of 2013. The total volume procured for each category was aggregated from the annual procurement quantity for all ARV drugs in the group. The annual market share for each ARV drug was then calculated as its procurement volume proportional to the total annual volume for all ARV drugs in the same category. The annual ARV drug market share was then logged for a year, with the assumption that countries were procuring about 1 year ahead of actual consumption.

### 2.3.3 Regimen distribution forecast by SCMS

SCMS supports or collaborates with PEPFAR country ministries of health and implementing partners to prepare annual forecasts of ARV medicines for national ART programmes. These forecasts are based on:

- data current at the time of the forecast;
- distribution of patients by first- and second-line regimens;
- assumptions about the evolution of this distribution over a 2–3-year forecast period as national treatment guidelines address developments such as WHO recommendations and formulation options.

The regimen distribution data were aggregated across the 15 PEPFAR countries analysed to contribute towards the assessment of trends presented in this report.

### 2.3.4 Regimen distribution forecast by CHAI

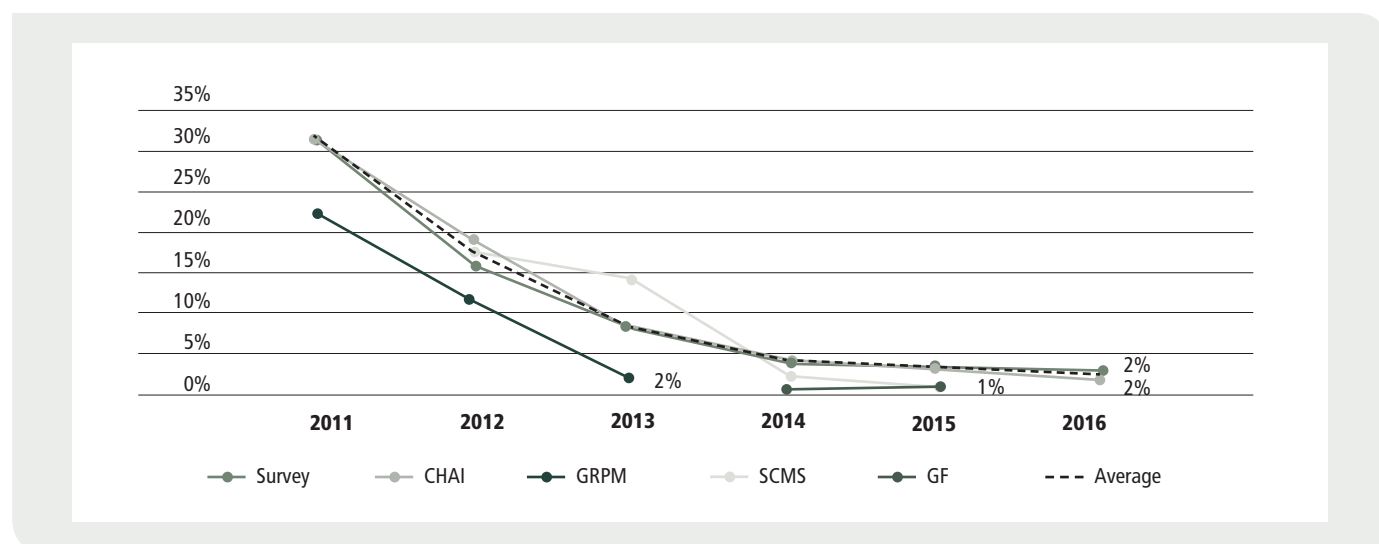
Each year, CHAI derives a global ARV forecast for adults and children in low- and middle-income countries. CHAI collects data from country teams and published literature on patient regimens, national guidelines, attrition rates, failure rates, toxicity rates, future ARV trends and other key factors in the 21 highest burden countries. CHAI then uses the data and an internally developed forecasting model to project ARV demand by drug and by regimen in each country over the next 5 years. CHAI then aggregates estimates across the 21 countries and extrapolates these results to patients in the remaining low- and middle-income countries. It is important to note that the CHAI forecast was finalized in May 2013, before the release of the new WHO guidelines, and thus it reflects a baseline perspective on how the market will evolve in the absence of major policy shifts. The extent to which the new guidelines impact ARV trends will become clearer as countries review the guidelines and determine if, and how, to implement each recommendation. Subsequent forecasts will begin to reflect these shifts.

### 2.3.5 Regimen distribution forecast by the Global Fund

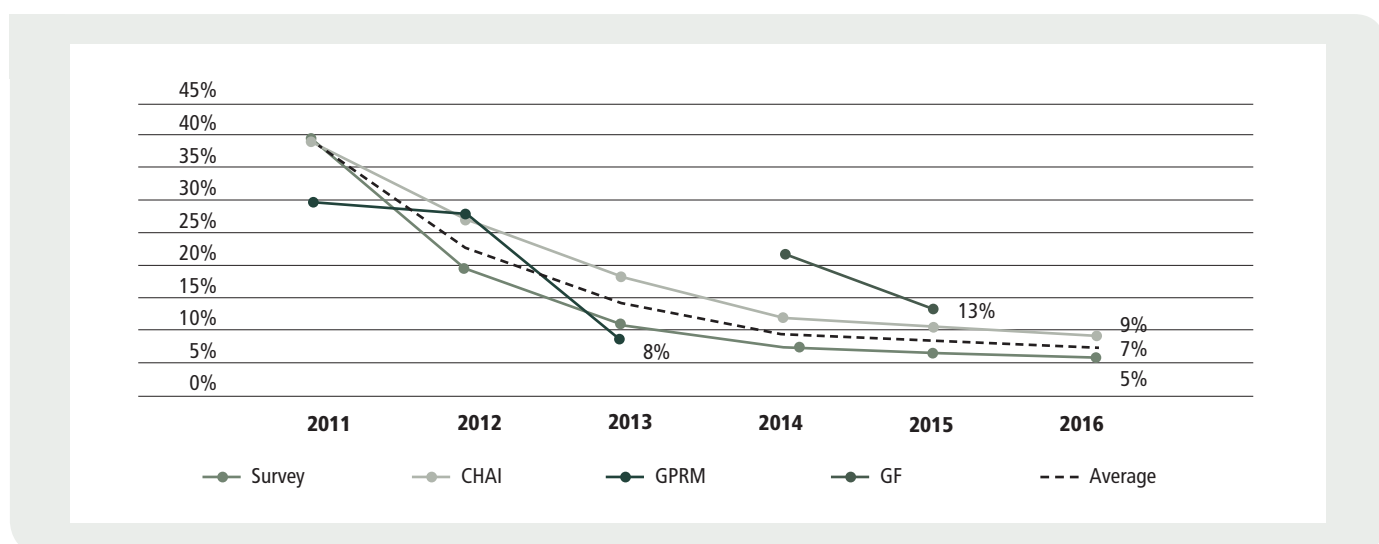
Global Fund regimen distribution data were based on a procurement forecast based on procurement plans for approved grants in 54 countries (2014 projection)<sup>1</sup> and

30 countries (2015 projection)<sup>2</sup>. Figures 4–15 show the trends for all five approaches plus the average for each ARV drug for adults as well as the four approaches plus the average for paediatric patients.

**Fig. 4. Projected adult market share (%) of d4T as a proportion of the adult volume of primary NRTIs, 2011–2016**



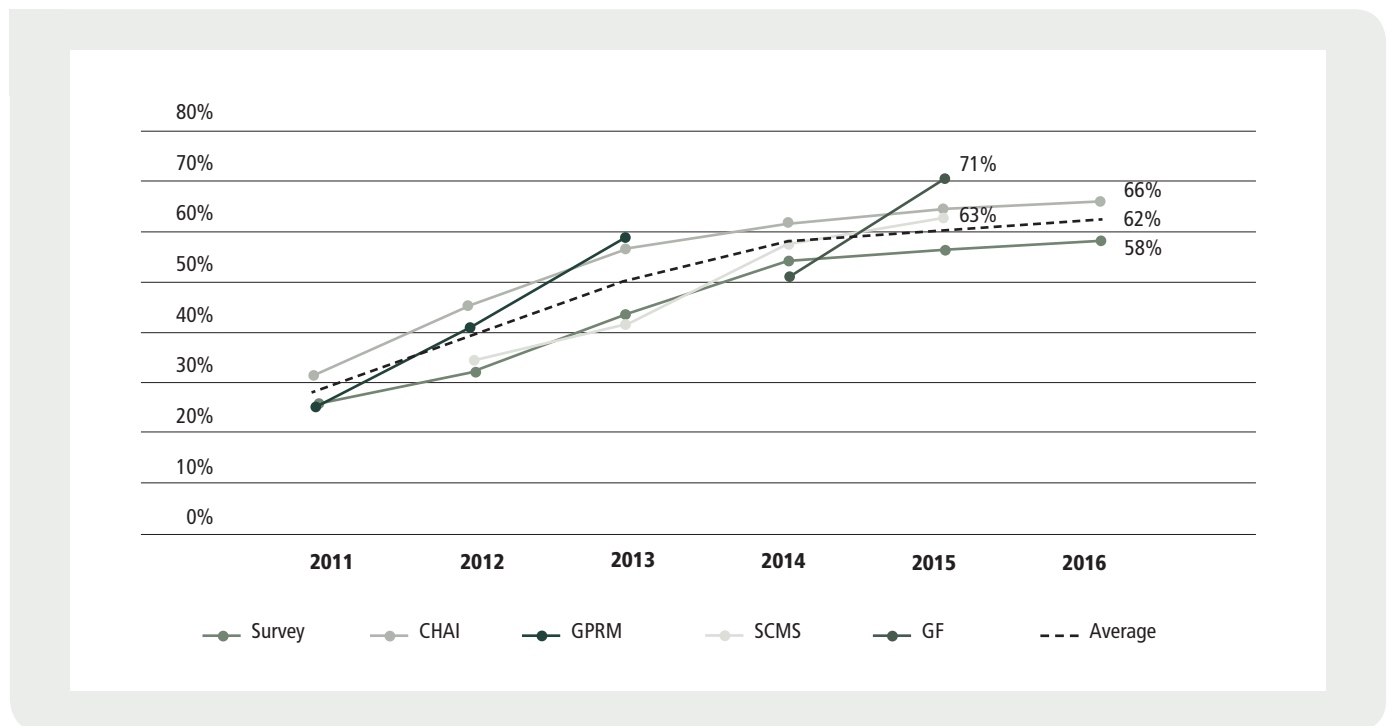
**Fig. 5. Projected paediatric market share (%) of d4T as a proportion of the paediatric volume of primary NRTIs, 2011–2016**



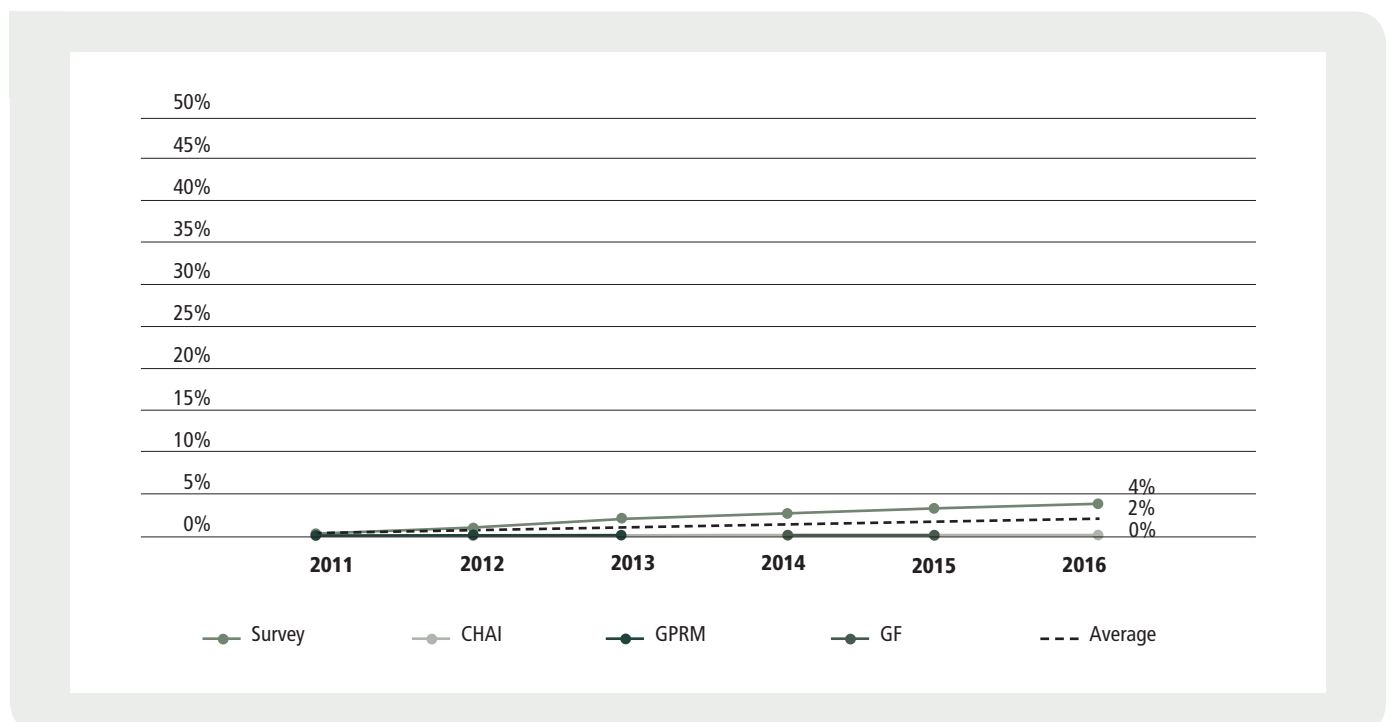
1 Afghanistan, Angola, Bolivia, Burundi, Cambodia, Cameroon, Cabo Verde, Chad, Comoros, Côte d'Ivoire, Democratic Republic of the Congo, Djibouti, Egypt, El Salvador, Ethiopia, Gambia, Georgia, Ghana, Guinea, Haiti, Honduras, India, Indonesia, Iran (Islamic Republic of), Kenya, Kyrgyzstan, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Mali, Mauritania, Mauritius, Morocco, Multicountry Americas (CARICOM/PANCAP), Myanmar, Nepal, Niger, Nigeria, occupied Palestinian territory, Paraguay, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Sri Lanka, Thailand, Timor-Leste, Uganda, United Republic of Tanzania, Viet Nam, Yemen and Zambia.

2 Afghanistan, Comoros, Côte d'Ivoire, Democratic Republic of the Congo, El Salvador, Georgia, Ghana, Haiti, Honduras, India, Indonesia, Kyrgyzstan, Lao People's Democratic Republic, Malawi, Mali, Mauritania, Morocco, Multicountry Americas (CARICOM/PANCAP), Myanmar, Niger, Nigeria, Philippines, Rwanda, Senegal, Sierra Leone, South Africa, Sri Lanka, Timor-Leste, Viet Nam and Zambia.

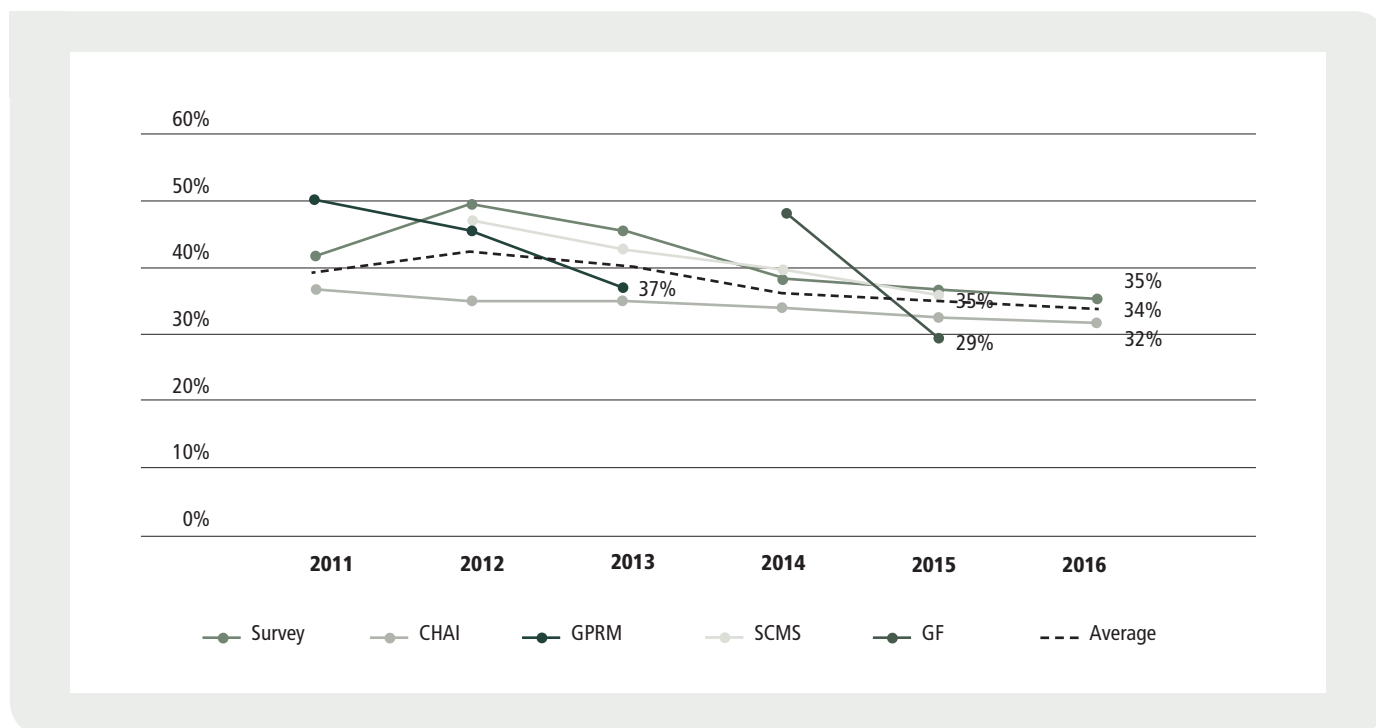
**Fig. 6. Projected adult market share (%) of TDF as a proportion of the adult volume of primary NRTIs, 2011–2016**



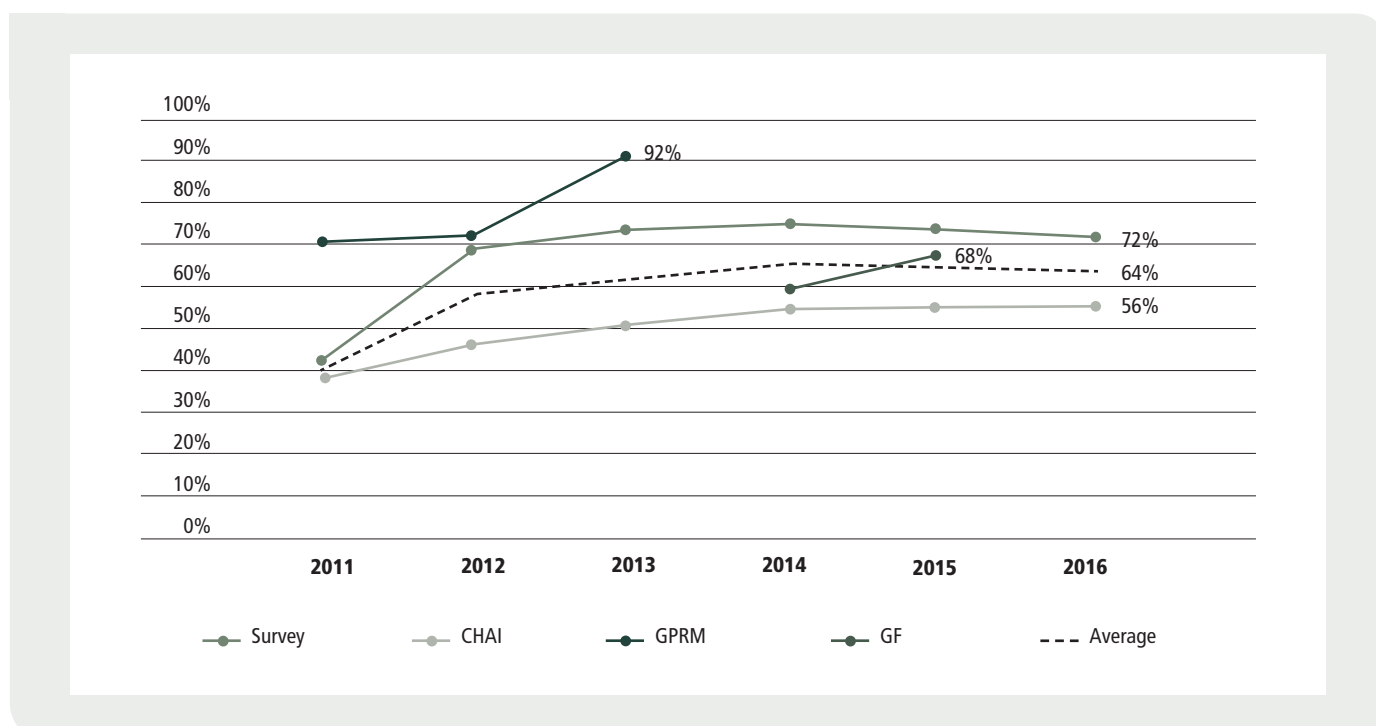
**Fig. 7. Projected paediatric market share (%) of TDF as a proportion of the paediatric volume of primary NRTIs, 2011–2016**



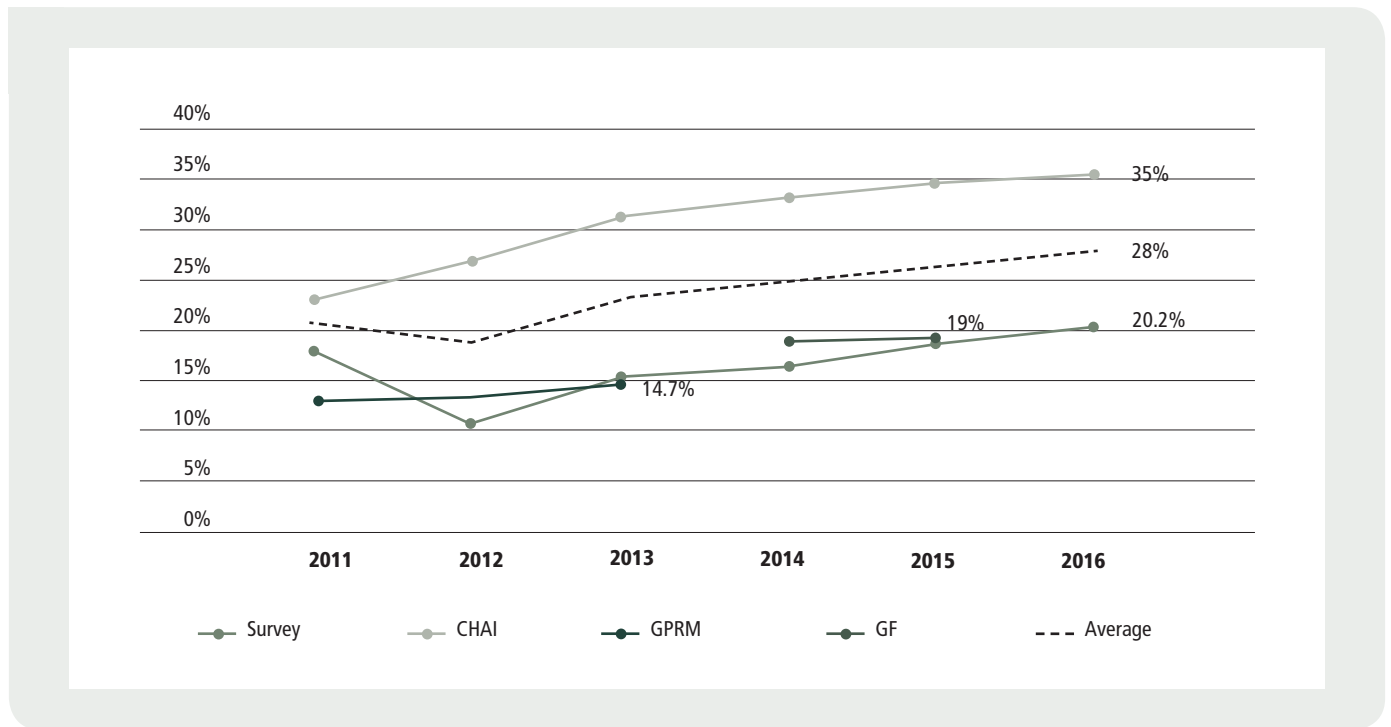
**Fig. 8.** Projected adult market share (%) of AZT as a proportion of the adult volume of primary NRTIs, 2011–2016



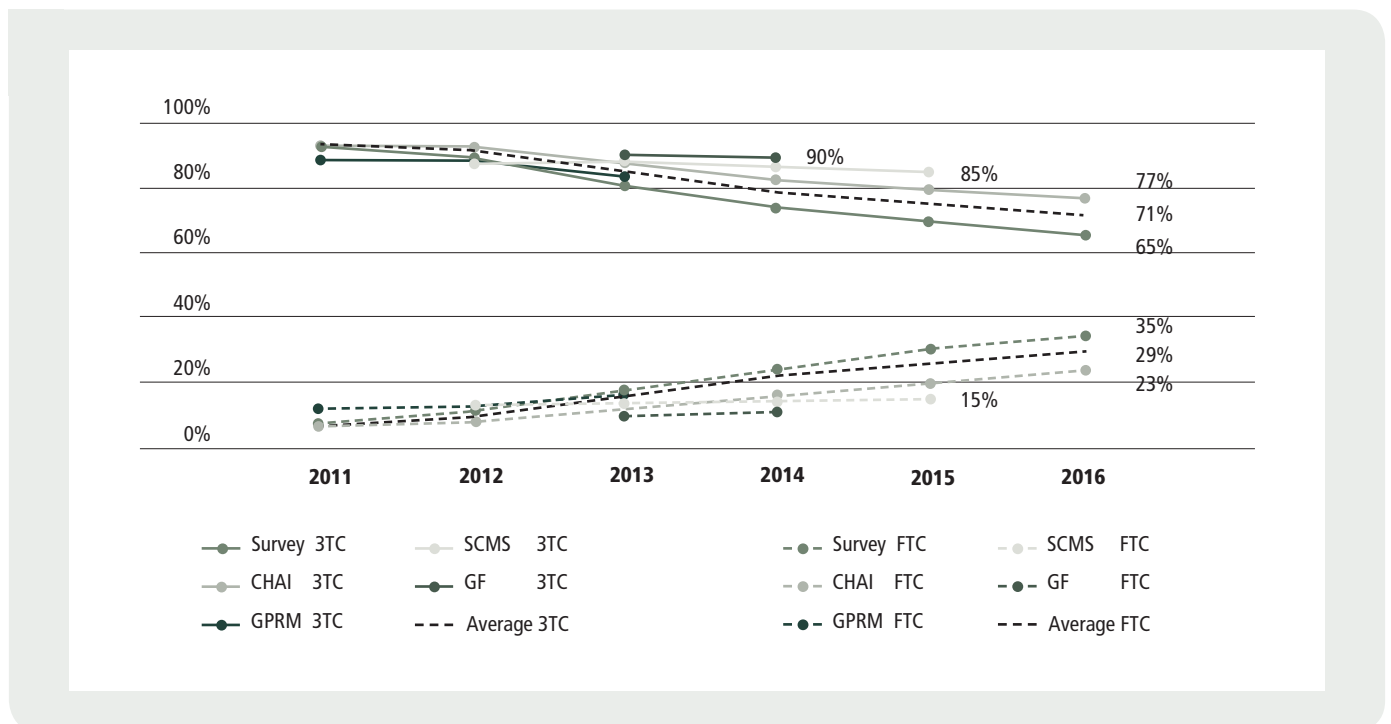
**Fig. 9.** Projected paediatric market share (%) of AZT as a proportion of the paediatric volume of primary NRTIs, 2011–2016



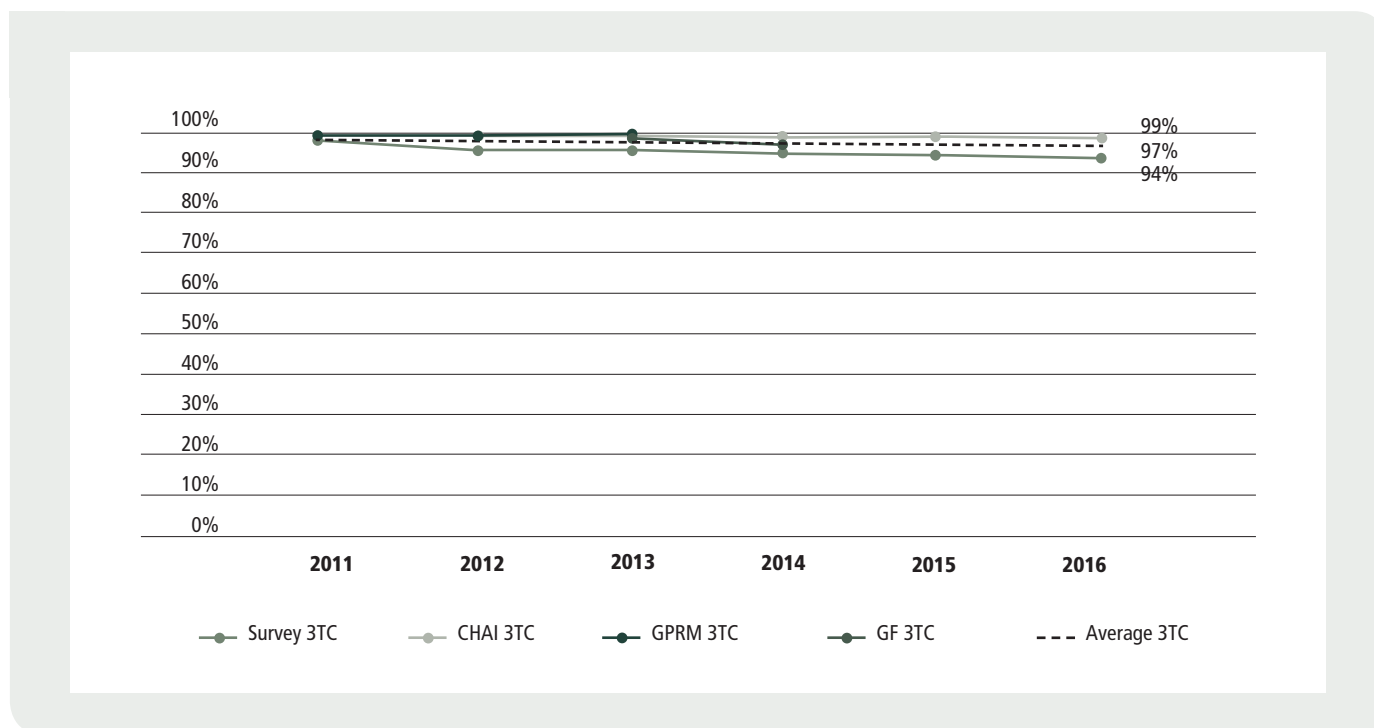
**Fig. 10. Projected paediatric market share (%) of ABC as a proportion of the paediatric volume of primary NRTIs, 2011–2016**



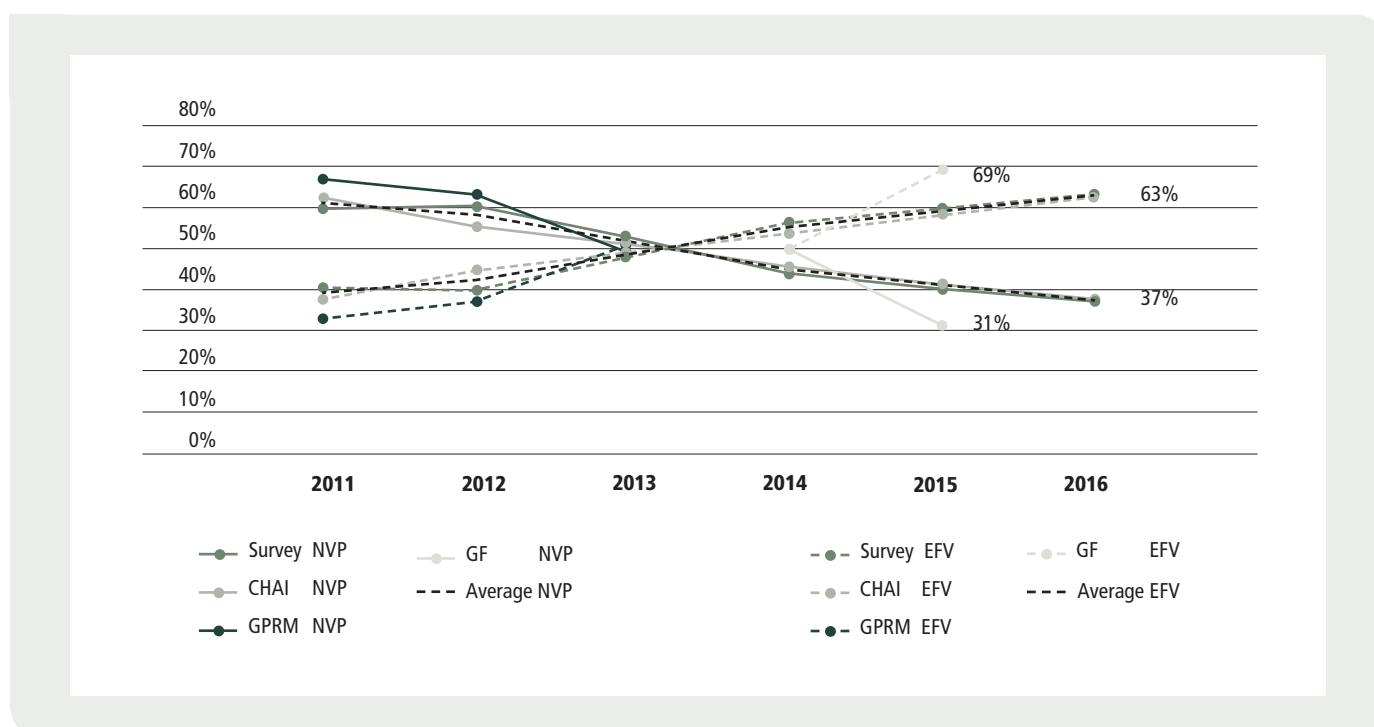
**Fig. 11. Projected adult market share (%) of 3TC and FTC as a proportion of the adult volume of secondary NRTIs, 2011–2016**



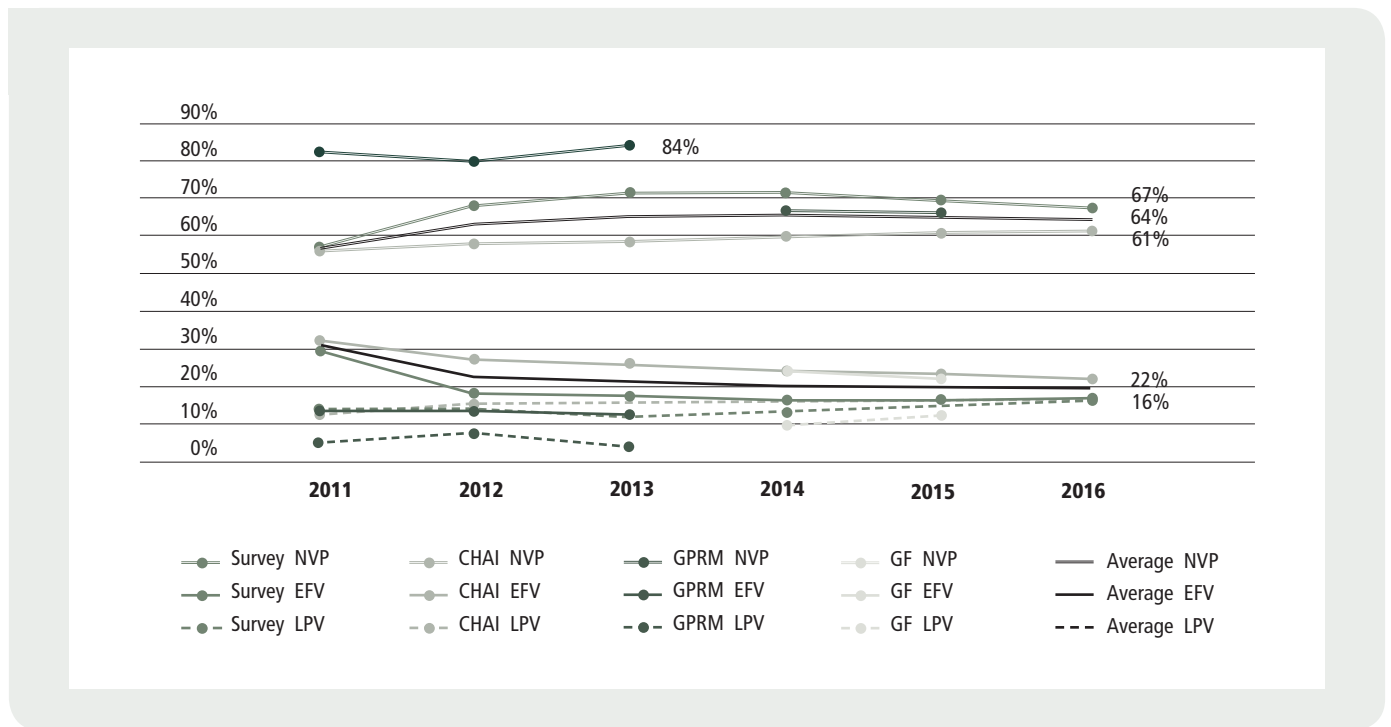
**Fig. 12.** Projected paediatric market share (%) of ABC as a proportion of the paediatric volume of primary NRTIs, 2011–2016



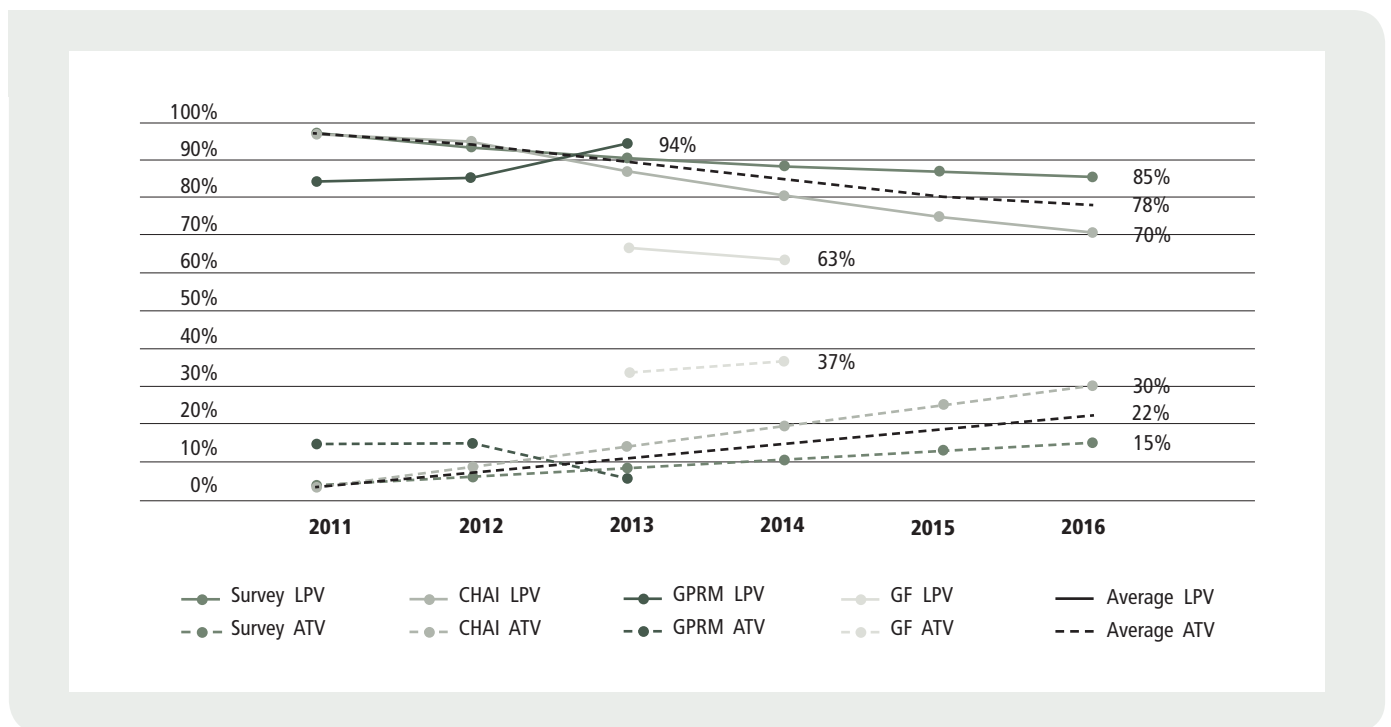
**Fig. 13.** Projected adult market share (%) of NVP and EFV as proportions of the adult volume of NNRTIs, 2011–2016



**Fig. 14. Projected paediatric market share (%) of NVP, EFV and LPV as proportions of the paediatric volume of NNRTIs and PIs, 2011–2016**



**Fig. 15. Projected adult market share (%) of LPV and ATV as proportions of the adult PI volume, 2011–2016**





As Figs 4–15 show, the market share projections for adult and paediatric patients were within a 10% range, indicating fairly similar estimates. Tables 5 and 6 show the annual

average market share of the projections (five projections for adult patients and four for paediatric patients) for each ARV for adults and paediatric patients separately.

**Table 5. Average market share for adult ARV drugs**

ARV drug	Average market share (%)			
	2013	2014	2015	2016
<b>d4T, TDF and AZT share of primary NRTIs</b>				
d4T	8	4	3	2
TDF	50	58	61	62
AZT	40	36	35	34
<b>3TC and FTC share of secondary NRTIs</b>				
3TC	85	79	74	71
FTC	15	21	26	29
<b>NVP and EFV share of NNRTIs</b>				
NVP	52	45	41	37
EFV	48	55	59	63
<b>LPV/r and ATV/r share of PIs</b>				
LPV	89	84	81	78
ATV	11	16	19	22

**Table 6. Average market share for paediatric ARV drugs**

ARV drug	Average market share (%)			
	2013	2014	2015	2016
<b>d4T, TDF, AZT and ABC share of primary NRTIs</b>				
d4T	14	9	8	7
TDF	1	2	2	2
AZT	62	65	65	64
ABC	23	25	26	28
<b>3TC share of secondary NRTIs</b>				
3TC	98	98	97	97
<b>NVP, EFV and LPV share</b>				
NVP	65	66	65	64
EFV	21	20	20	20
LPV	14	14	15	16

## 2.4. Calculating the number of women receiving ARV drugs for PMTCT

The number of women receiving ARV drugs for PMTCT was based on two projection scenarios: linear and country target. The linear projection is based on linear regression of data on PMTCT from 2010 to 2012, whereas the country targets are based on the goals set by 46 countries. Table 7

shows the projected number of women receiving ARV drugs for PMTCT for each scenario, as well as the average of the two scenarios. Table A2 shows the estimated average number of women receiving ARV drugs for PMTCT by region, based on linear and country target projections.

**Table 7. Total and average number of women receiving ARV drugs for PMTCT, 2013–2016**

Forecasting method	No. of women receiving ARV drugs for PMTCT			
	2013	2014	2015	2016
<b>d4T, TDF, AZT and ABC share of primary NRTIs</b>				
Linear projection	1 170 000	1 300 000	1 420 000	1 550 000
Country target projection	2 220 000	2 590 000	3 010 000	3 440 000
Average	1 690 000	1 940 000	2 220 000	2 500 000
Annual rate of increase (%)	-	15	14	13

As the average of the two projections shows, the number of women receiving ARV drugs for PMTCT is expected to increase, mostly because of expanded coverage of services for PMTCT. To project the demand for ARV drugs for women receiving ARV drugs for PMTCT, the total number of women receiving current WHO-recommended regimens as shown in Table 8 (WHO 2006 AZT, option A, option B and option B+) was determined through the WHO ARV drug use survey and the global ART access report progress (Global AIDS Response Progress Reporting) (9). Most country programmes are rapidly scaling down option A and option B and a number of countries with a high burden of PMTCT, including Malawi and Uganda, are now using option B+,

while others, like Zambia, are considering it. As a result, we expect the distribution of regimens for PMTCT to change dramatically in the next few years. We have assumed that single-dose NVP and WHO 2006 AZT regimens would be discontinued by 2016 and that the use of ART would rise substantially, as shown in Table 8.

The number of women receiving each regimen is determined by multiplying the number of women receiving services for PMTCT by the regimen mix in that year. The volume of ARV drugs required is calculated by multiplying the number of women receiving each regimen by the recommended doses.

**Table 8. Projected regimen mix for women receiving ARV drugs for PMTCT, 2012 and 2016**

Regimen	Projected regimen mix for women receiving ARV drugs for PMTCT	
	2012 <sup>a</sup>	2016
<b>d4T, TDF, AZT and ABC share of primary NRTIs</b>		
Single-dose NVP (%) <sup>b</sup>	5	0
WHO 2006 AZT (other) (%) <sup>c</sup>	2	0
Option A (%) <sup>d</sup>	44	10
Option B (%) <sup>e</sup>	8	20
Triple ART (%) <sup>f</sup>	41	70

a Proportion of various PMTCT options developed by WHO and UNAIDS and provided by the Strategic Information Planning Unit, HIV/AIDS Department, WHO.

b Single-dose NVP. One or two courses of single-dose NVP during and after labour.

c WHO 2006 AZT. Starting at 28 weeks of pregnancy, this treatment recommends a regimen of twice-daily AZT, single-dose NVP at the onset of labour and AZT + 3TC during delivery and 1 week postpartum.

d Option A. Starting at 14 weeks of pregnancy or soon thereafter, recommending twice-daily AZT for the mother and infant prophylaxis with either AZT or NVP for 6 weeks after birth for infants not breastfeeding.

e Option B. Triple-therapy regimen, usually AZT + 3TC + NVP during pregnancy and breastfeeding.

f Triple ART. Lifelong triple therapy for the mother's health based on each country's eligibility criteria. This includes option B+, which is lifelong treatment for mothers regardless of CD4 count.

## 3. FORECASTING THE DEMAND FOR ACTIVE PHARMACEUTICAL INGREDIENTS

This section provides details of the forecast for API volumes in metric tonnes. Its objective is to assist suppliers in ensuring that adequate manufacturing capacity is available to meet the demand for ARV drugs.

### 3.1. Calculating the total volumes of APIs required for each ARV drug

The volumes required for each ARV drug are calculated as the product of the number of person-years of use, the recommended daily dose and 365 days per year. The number of person-years is estimated as the number of people who continue on that ARV drug from the previous year plus half the number of people who start on that ARV drug during the year. This assumes that

the starting dates for those initiating ART that year are evenly distributed throughout the year. These calculations are summed across all countries and types of treatment (first- and second-line therapy for adults and children) to calculate the total demand in person-years. Table 9 shows the recommended daily doses for adult and paediatric patients.

**Table 9. Adult and paediatric daily doses for ARV drugs, based on WHO recommendations**

Drug	Adult daily dose (mg/day)	Paediatric doses by weight band (kg)					
		3.0–5.9	6.0–9.9	10.0–13.9	14.0–19.9	20.0–24.9	25 (adult)
d4T	60	1	1	15	20	20	30
AZT	600	10	10	10	300	300	300
TDF	300	6	6	6	6	6	200
3TC	300	10	10	10	150	150	150
FTC	200	-	-	-	-	-	-
ABC	600	20	20	20	300	300	300
NVP	400	10	10	10	200	200	200
EFV	600	-	-	200	200	200	200
LPV	800	80	80	80	80	80	80
ATV	300	-	-	-	-	-	-
RTV (with LPV/r)	200	-	-	-	-	-	-
RTV (with ATV/r)	100	-	-	-	-	-	-

### 3.2. Forecast demand for APIs for 2013–2016

Table 10 shows the volume of API in metric tonnes required for each ARV drug based on the average estimates of the numbers on treatment (see Table 3), the proportion receiving first- and second-line therapy (Table 4) and the distribution of ARV drug regimens (Figs 4–15). Tables A3–A5 show the detailed volume demand for each of the three projections individually. Tables A6–A11 show the volume of demand in metric tonnes based on the average of the

linear and country target projections for each region.

The API need in metric tonnes was calculated using the average projection of number of people receiving treatment (including pregnant women receiving lifelong ART for their health as well as those on option B+) converted into person-years and then multiplied by the ARV distribution and finally multiplied by the

recommended dosage for each ARV drug. Table 11 shows the volume of AZT, 3TC, NVP and LPV demand for PMTCT: single-dose nevirapine, dual ARV drugs, option A and option B based on the average of the linear and country target projections.

**Table 10. Volume of demand for APIs in metric tonnes based on the average of linear, CHAI and country target projections, 2013–2016**

Drug	Demand for APIs (tonnes) based on the average of linear, CHAI and country target projections			
	2013	2014	2015	2016
d4T <sup>a</sup>	19	13	11	9
AZT	844	958	1099	1232
TDF	509	725	903	1065
3TC <sup>a</sup>	943	1041	1200	1320
FTC <sup>a</sup>	102	169	241	304
NVP	707	738	777	798
EFV	922	1273	1692	2082
LPV	174	215	262	311
ATV	8	15	22	32
RTV	47	62	79	97

a Volume of demand is based on averages for linear and country target projections.

**Table 11. Volume of demand for APIs in metric tonnes for women on PMTCT based on average of linear and country target projections, 2013–2016**

Drug	Demand for APIs (tonnes) for women on PMTCT based on average of linear and country target projections <sup>a</sup>			
	2013	2014	2015	2016
NVP	46	41	33	22
AZT	128	147	169	191
3TC	31	45	62	82
LPV	81	119	165	218
RTV	20	30	41	55

a The forecasted volume demand for PMTCT does not include women on triple ART for their health or option B+. It has been included in ARV for adult HIV treatment.

## 4. DISCUSSION

This report shows that despite flat-lined or reduced international funding, the number of people on treatment continues to grow annually. The forecasting process outlined here builds on previous annual forecasting exercises to improve the forecasting result by using an average of scenarios to generate the number of people on treatment, the proportion on first- and second-line therapy and the distribution of adult and paediatric patients on the different ARV drugs. The strength of this approach is to offer a range of projections that are more accurate in the short term, but as previous results have shown, conservative in the long term.

One key difference in this year's report is the disaggregation of ARV distribution into adult and

paediatric markets. The goal of this endeavour was to improve the accuracy of the ARV demand forecast in light of available historical data and trend analysis. As the results show and as expected, there are consistent differences in the annual rate of increase and ARV demand for adults and paediatric patients. Overall, we expect the target of 15 million people on ART by 2015 to be achieved and even exceeded. However, the annual growth rate for paediatric patients continues to lag behind the annual growth rate for adults. It is expected that the growth rate for paediatric ARV demand will increase with the 2013 consolidated WHO treatment guidelines, which recommend ART for all HIV-positive children under the age of 5 years as well as the scale-up of programmes targeting the virtual elimination of mother-to-child-transmission.

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# ANNEX 1.

**Table A1. Projected number of people receiving ART by region based on average of linear and country target projections, 2013–2016**

Region	Age Group	Projected number of people receiving ART by region based on average of linear and country target projections			
		2013	2014	2015	2016
Sub-Saharan Africa	Adults	7 000 000	8 300 000	9 700 000	11 200 000
	Children	550 000	700 000	780 000	860 000
Latin America and Caribbean	Adults	690 000	860 000	930 000	1 060 000
	Children	27 000	37 000	40 000	43 000
Eastern Mediterranean	Adults	23 000	28 000	33 000	38 000
	Children	1 000	1000	2 000	2 000
Europe	Adults	192 000	250 000	290 000	330 000
	Children	9 000	11 000	12 000	13 000
South and South-East Asia	Adults	840 000	970 000	1 100 000	1 220 000
	Children	45 000	52 000	59 000	64 000
Western Pacific	Adults	150 000	190 000	210 000	240 000
	Children	6 000	18 000	19 000	20 000

**Table A2. Number of women receiving ARV drugs for PMTCT by region, based on average of linear and country target projections, 2013–2016**

Region	No. of women receiving drugs for PMTCT based on average of linear and country target projections			
	2013	2014	2015	2016
Sub-Saharan Africa	1 600 000	1 800 000	2 100 000	2 100 000
Latin America and Caribbean	33 000	39 000	44 000	50 000
Eastern Mediterranean	3 000	3 000	4 000	4 000
Europe	29 000	33 000	38 000	42 000
South and South-East Asia	28 000	31 000	34 000	37 000
Western Pacific	9 000	10 000	11 000	12 000
Global	1 700 000	1 900 000	2 200 000	2 500 000



**Table A3. Volume of demand for APIs in metric tonnes: linear projection, 2013–2016**

Drug	Volume of demand for APIs (tonnes): linear projection			
	2013	2014	2015	2016
d4T	18	12	10	8
AZT	895	1008	1156	1295
TDF	505	724	897	1051
3TC	921	989	1051	1128
FTC	100	161	226	281
NVP	707	716	751	766
EFV	925	1216	1490	1784
LPV	205	250	306	363
ATV	9	17	25	36
RTV	55	72	91	112

**Table A4. Volume of demand for APIs in metric tonnes: country target projection, 2013–2016**

Drug	Volume of demand for APIs (tonnes): country target projection			
	2013	2014	2015	2016
d4T	19	13	12	10
AZT	946	1127	1331	1526
TDF	526	794	1021	1230
3TC	965	1092	1200	1320
FTC	104	176	256	327
NVP	739	792	859	899
EFV	961	1330	1692	2082
LPV	222	283	356	432
ATV	10	19	29	42
RTV	60	85	111	139

**Table A5. Volume of demand for APIs in metric tonnes: CHAI projection, 2013–2016**

Drug	Volume of demand for APIs (tonnes): linear projection			
	2013	2014	2015	2016
TDF	496	658	791	913
AZT	691	788	866	938
NVP	674	706	720	729
EFV	879	1113	1371	1636
ATV	4	8	12	18
LPV	95	111	125	139
RTV	25	30	35	41

**Table A6. Volume of demand for APIs in metric tonnes in sub-Saharan Africa based on an average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs (tonnes) in sub-Saharan Africa based on an average of linear and country target projections			
	2013	2014	2015	2016
d4T	13	10	9	8
AZT	715	835	972	1096
TDF	397	588	742	876
3TC	736	813	884	965
FTC	79	131	188	238
NVP	570	592	632	653
EFV	740	995	1243	1508
LPV	135	172	216	263
ATV	6	12	18	26
RTV	35	47	60	75

**Table A7. Volume of demand for APIs in metric tonnes in Latin America and the Caribbean based on an average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs (tonnes) in Latin America and the Caribbean based on an average of linear and country projections			
	2013	2014	2015	2016
d4T	2	1	1	1
AZT	71	79	90	104
TDF	42	60	74	89
3TC	71	77	82	90
FTC	8	13	18	24
NVP	50	57	64	70
EFV	67	99	131	170
LPV	41	48	58	67
ATV	2	4	5	7
RTV	12	16	21	25

**Table A8. Volume of demand for APIs in metric tonnes in the Eastern Mediterranean based on an average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs in metric tonnes in the Eastern Mediterranean based on an average of linear and country target projections			
	2013	2014	2015	2016
d4T	0	0	0	0
AZT	2	3	3	4
TDF	1	2	3	3
3TC	2	3	3	4
FTC	0	0	1	1
NVP	2	2	2	2
EFV	2	3	4	5
LPV	1	1	1	2
ATV	0	0	0	0
RTV	0	0	1	1

**Table A9. Volume of demand for APIs in metric tonnes in Europe based on an average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs (tonnes) in Latin America and the Caribbean based on an average of linear and country projections			
	2013	2014	2015	2016
d4T	0	0	0	0
AZT	21	25	29	35
TDF	12	18	24	29
3TC	20	23	25	28
FTC	2	4	6	8
NVP	10	11	11	12
EFV	13	17	22	26
LPV	19	27	36	45
ATV	1	2	3	5
RTV	6	10	13	17

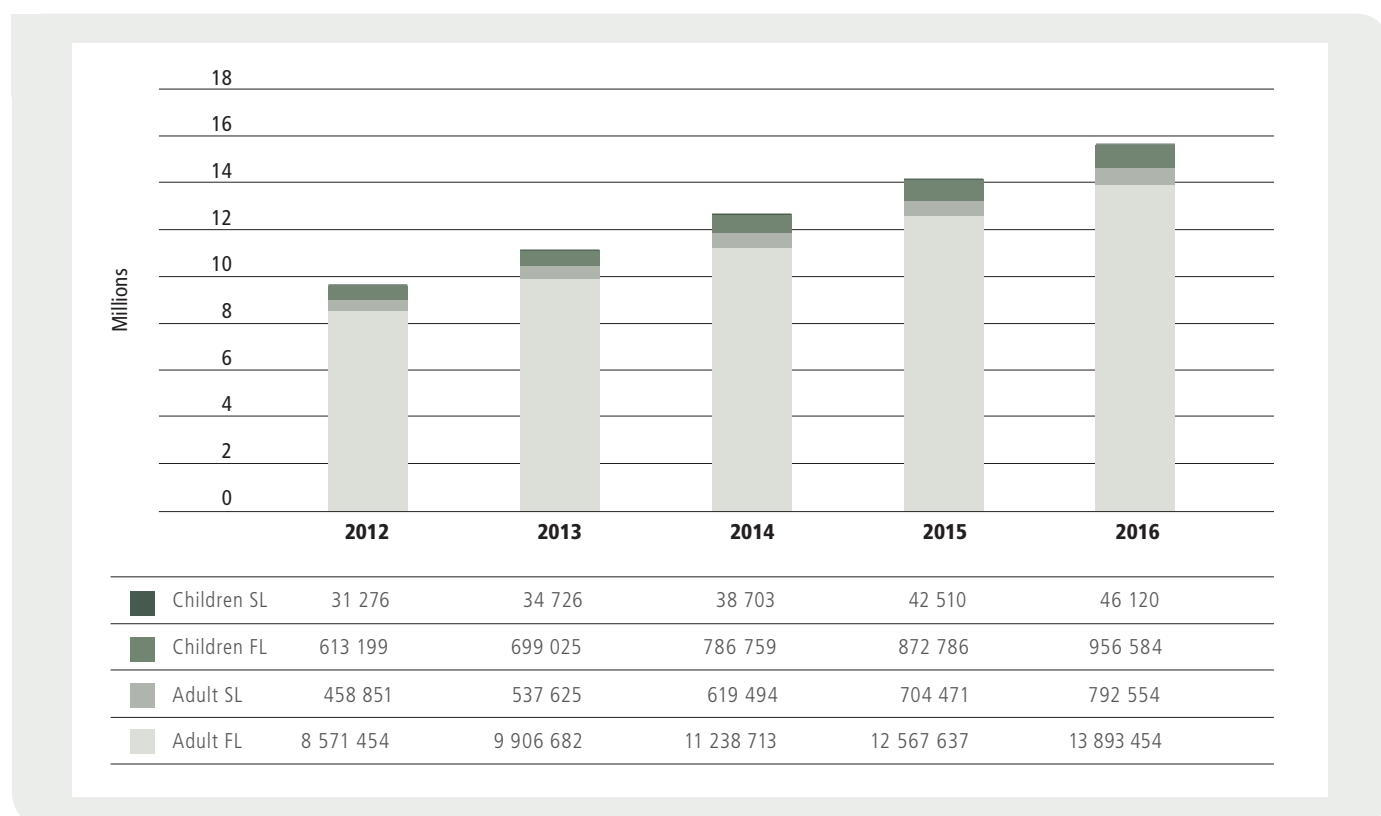
**Table A10. Volume of demand for APIs in metric tonnes in South and South-East Asia based on average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs in metric tonnes in the Eastern Mediterranean based on an average of linear and country target projections			
	2013	2014	2015	2016
d4T	2	1	1	1
AZT	81	90	106	123
TDF	47	66	85	104
3TC	84	89	93	98
FTC	10	15	21	25
NVP	67	67	69	69
EFV	89	117	140	164
LPV	10	11	11	11
ATV	0	1	1	1
RTV	3	4	5	5

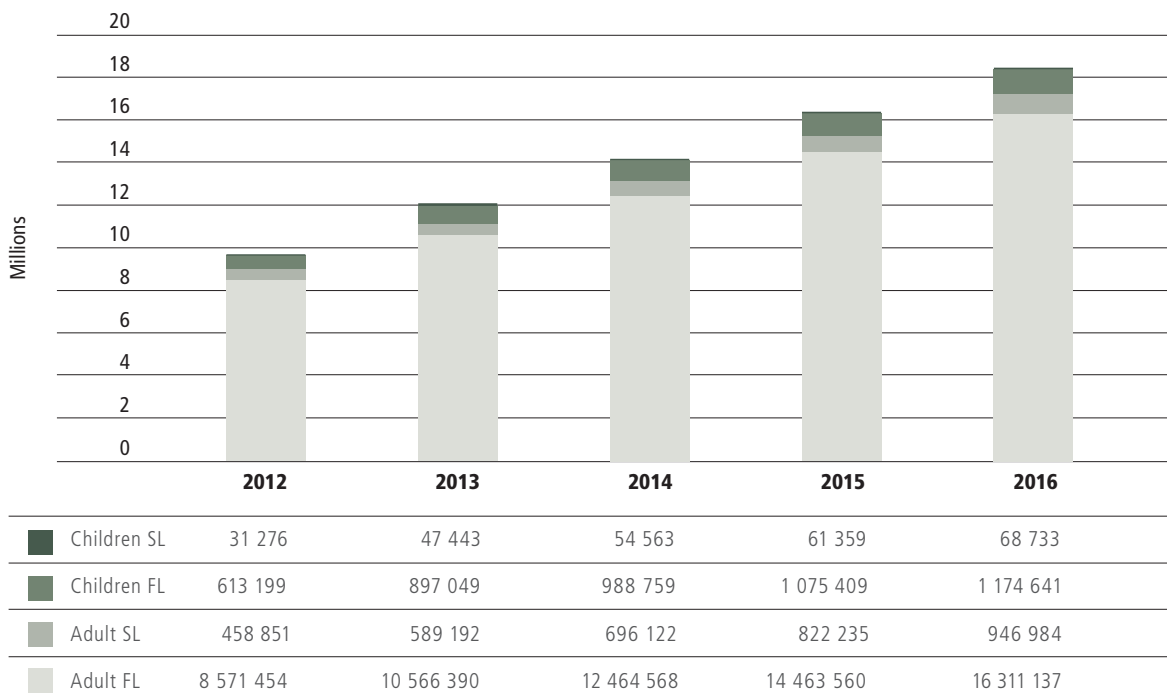
**Table A11. Volume of demand for APIs in metric tonnes in Europe based on an average of linear and country target projections, 2013–2016**

Drug	Volume of demand for APIs (tonnes) in the Western Pacific based on an average of linear and country target projections			
	2013	2014	2015	2016
d4T	1	0	0	0
AZT	30	36	43	51
TDF	17	25	33	41
3TC	32	37	39	41
FTC	4	6	8	10
NVP	24	26	27	27
EFV	32	43	52	61
LPV	8	10	11	12
ATV	0	1	1	1
RTV	3	3	4	4

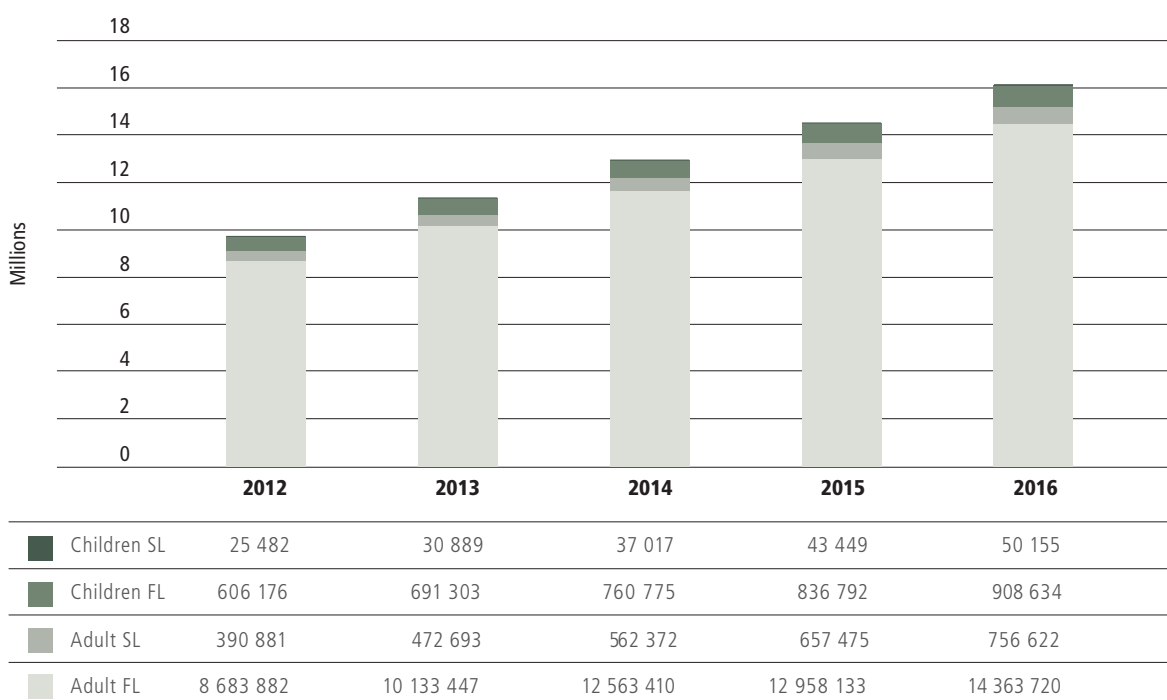
**Fig. A1. Number of people receiving first- and second-line ART based on linear projection, 2012–2016**



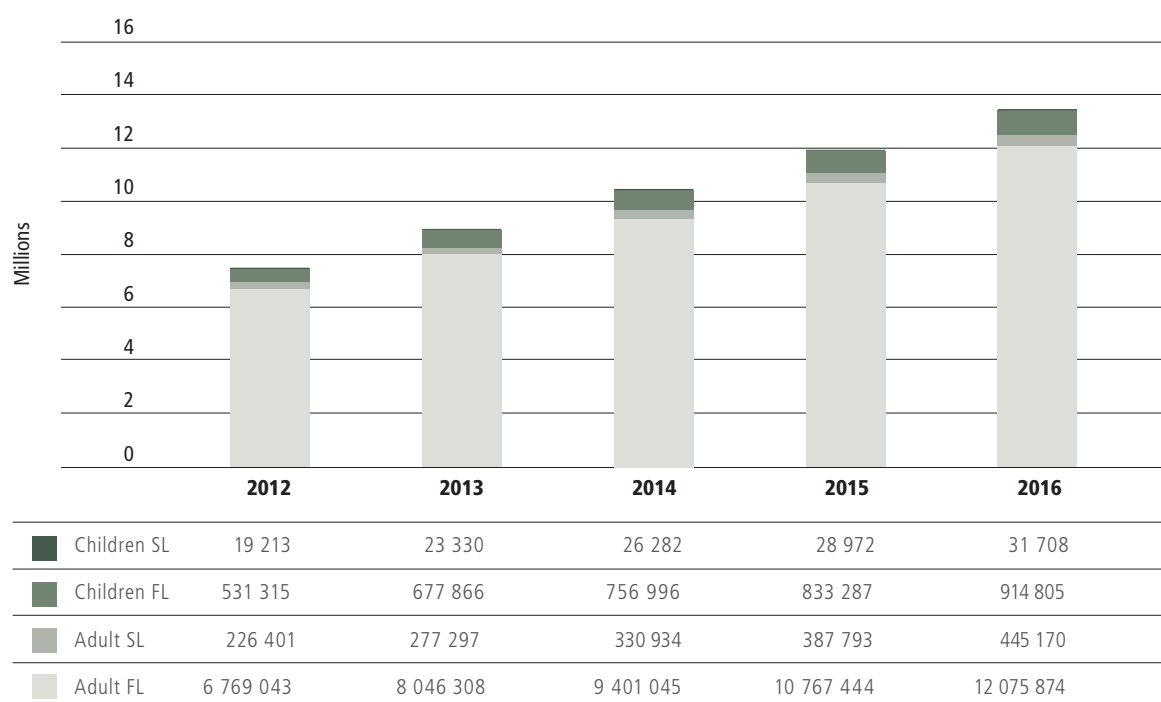
**Fig. A2. Number of people receiving first- and second-line ART based on country target projection, 2012–2016**



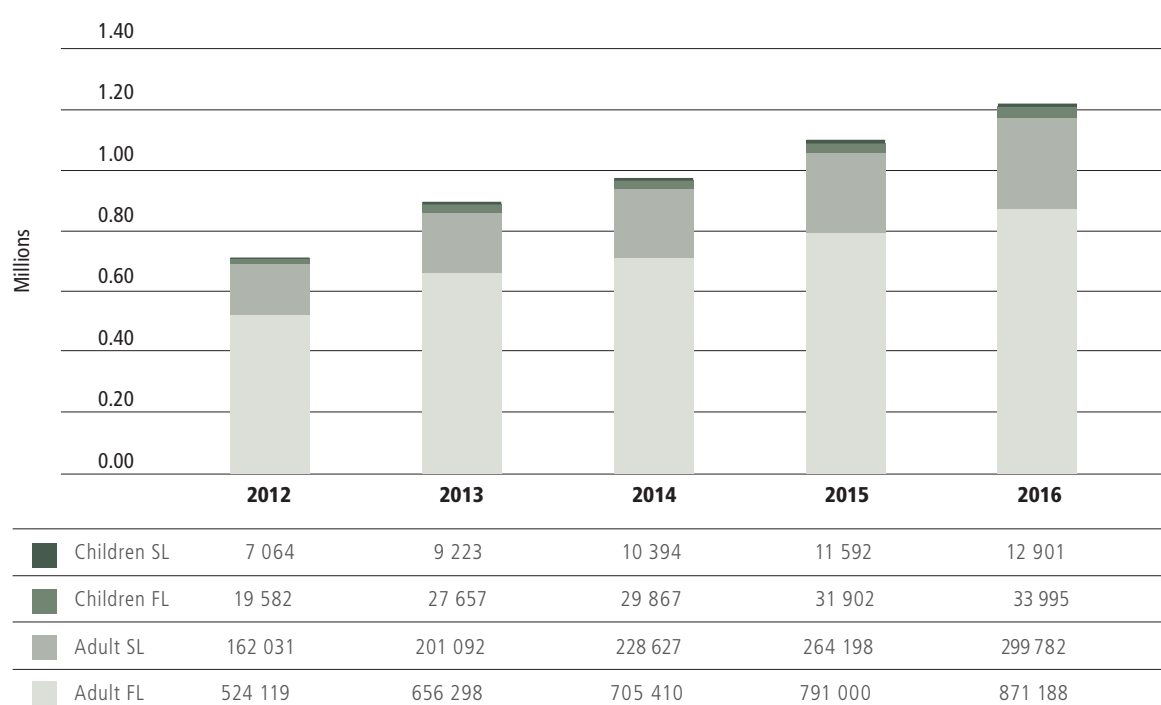
**Fig. A3. Number of people receiving first- and second-line ART, CHAI data, 2012–2016**



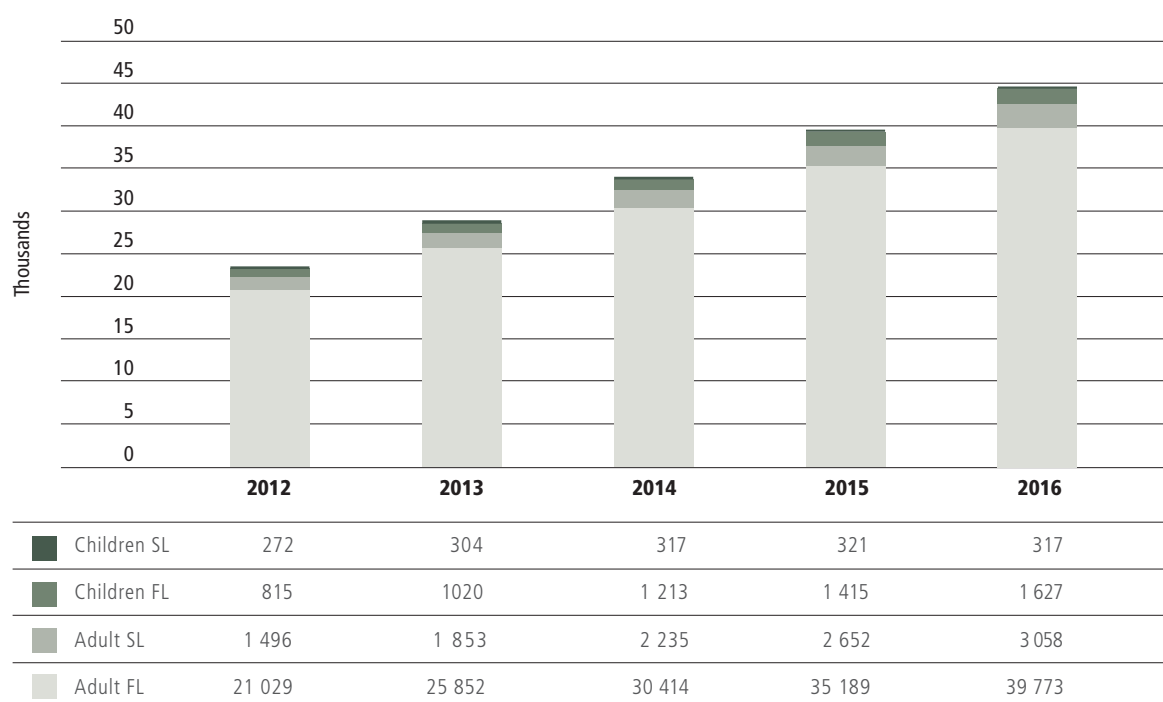
**Fig. A4. Number of people receiving first- and second-line ART in sub-Saharan Africa based on average of linear and country target projections, 2012–2016**



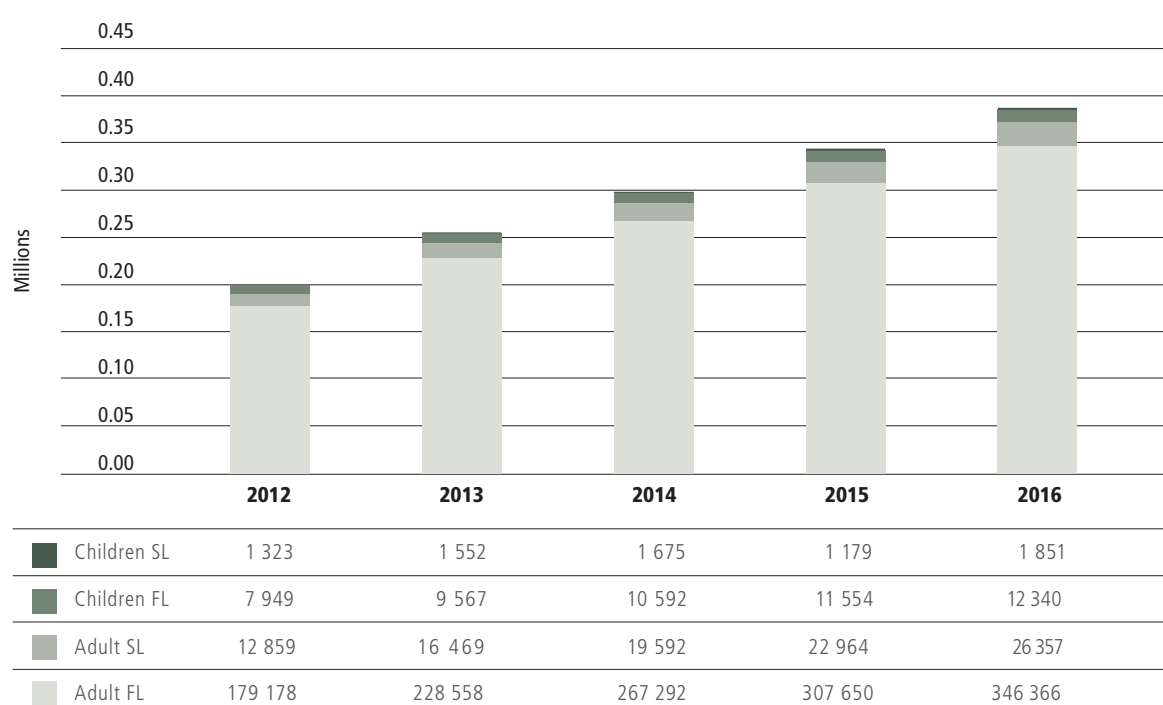
**Fig. A5. Number of people receiving first- and second-line ART in Latin America and the Caribbean based on average of linear and country target projections, 2012–2016**



**Fig. A6. Number of people receiving first- and second-line ART in the Eastern Mediterranean based on average of linear and country target projections, 2012–2016**

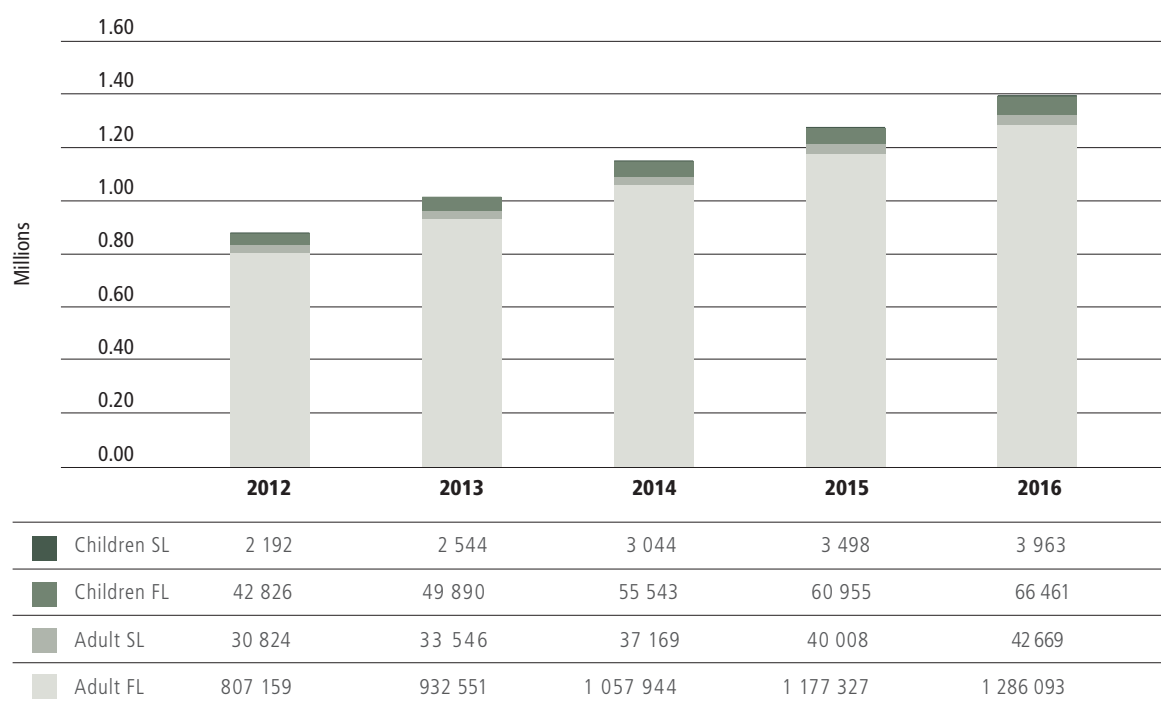


**Fig. A7. Number of people receiving first- and second-line ART in Europe based on average of linear and country target projections, 2012–2016**

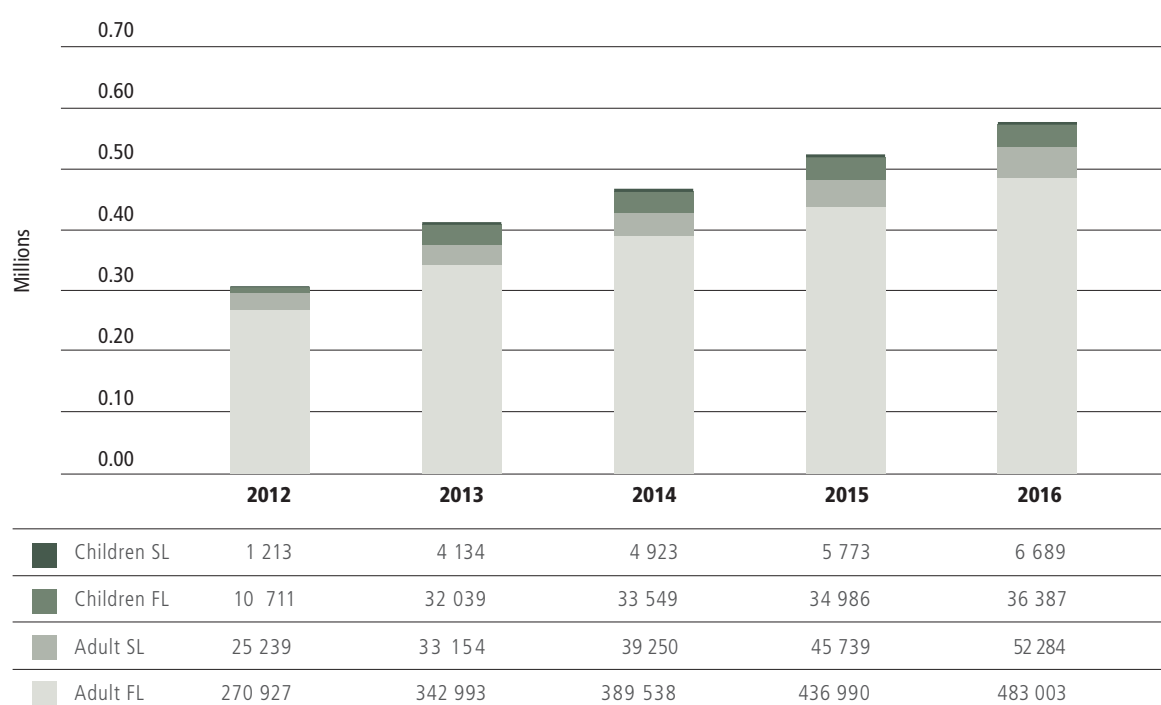




**Fig. A8. Number of people receiving first- and second-line ART in South and South-East Asia based on average of linear and country target projections, 2012–2016**



**Fig. A9. Number of people receiving first- and second-line ART in the Western Pacific based on average of linear and country target projections, 2012–2016**





**For more information, contact:**

World Health Organization  
Department of HIV/AIDS  
20, avenue Appia  
1211 Geneva 27  
Switzerland

E-mail: [hiv-aids@who.int](mailto:hiv-aids@who.int)

[www.who.int/hiv](http://www.who.int/hiv)

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