World Health Organization

TECHNICAL REPORT

AIDS MEDICINES AND DIAGNOSTICS SERVICE

ANTIRETROVIRAL MEDICINES IN LOW-AND MIDDLE-INCOME COUNTRIES: FORECASTS OF GLOBAL AND REGIONAL DEMAND FOR 2014-2018

JULY 2015

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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
PFSCM	Partnership for Supply Chain Management
PI	protease inhibitor
SCMS	Supply Chain Management System
SL	second-line
TDF	tenofovir
TEE	tenofovir-emtricitabine-efavirenz
TLE	tenofovir-lamivudine-efavirenz
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund

EXECUTIVE SUMMARY

The number of people on treatment in low- and middle-income countries continues to show promising growth indicating that the global effort to scale up HIV treatment to reach 15 million people by the end of 2015 will be achieved. At the end of 2013, the number of people receiving antiretroviral therapy (ART) had reached 11.7 million, an increase of 1.8 million from the previous year (*1, 2*).

The goal of this report is to provide countries and suppliers with estimates of the global market for antiretroviral (ARV) medicines in low- and middle-income countries up to 2018. The report includes estimates of the global demand for both active pharmaceutical ingredients (APIs) and ARV formulations to enable suppliers to manage their manufacturing capacity accordingly.

In this report, three forecasting approaches are used to project the demand for ART expressed as the number of people on treatment from 2014–2018:

- the linear regression forecast extrapolates from the historical trends of the previous three years (2011, 2012 and 2013) 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; and

In addition, the above 3 projections and their average are compared to the Fast Track projection, which assumes that by 2020, 90% of all people living with HIV will know their status, 90% of people who know their status will receive treatment and 90% of people on treatment will achieve viral suppression.

The linear and the country target approaches use data from the 2013 WHO survey on ARV drug use, augmented in the CHAI model by 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 2014–2018 were developed through the work of the Technical Working Group Meeting on Global Antiretroviral Demand Forecast, which included staff from CHAI, Avenir Health (formerly Futures Institute), the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund),the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Office of the United States Global AIDS Coordinator, the Partnership for Supply Chain Management, the United Nations Children's Fund (UNICEF), the United States Agency for International Development (USAID) and the World Health Organization (WHO). The Technical Working Group coordinated several sources of data on ARV drugs, including the WHO survey on ARV drug use, the Global Price Reporting Mechanism (GPRM) data on procurement, Supply Chain Management System (SCMS) 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 depth of historical data to improve the accuracy of forecasting demand. As a result, the distribution of adults and children receiving ARV treatment was calculated based on the average of five sources of data: the 2014 WHO survey of ARV drug use, GPRM procurement data, the Global Fund projected procurement for 2015 and 2016, SCMS procurement data and CHAI's global ARV forecast.

For adult patients, individual ARV drugs were categorized under four market categories:

- Primary nucleoside reverse-transcriptase inhibitors (NRTIs) and nucleotide reverse-transcriptase inhibitors (NtRTIs): stavudine (d4T), zidovudine (AZT), tenofovir (TDF), abacavir (ABC) and didanosine (ddI).
- Secondary NRTIs: lamivudine (3TC) and emtricitabine (FTC).
- Non-nucleoside reverse-transcriptase inhibitors (NNRTIs): nevirapine (NVP) and efavirenz (EFV).
- Protease inhibitors (PIs): ritonavir-boosted lopinavir (LPV/r) and ritonavir-boosted atazanavir (ATV/r).

For paediatric patients, individual PIs were categorized under three market categories:

- NRTIs and NtRTIs: d4T, AZT, TDF and abacavir (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 Fig. 4–17.

In addition to providing estimated demand for APIs, this report includes estimated demand for ARV formulations (in person-years) based on projected procurement data from CHAI, the Global Fund and SCMS for 2014 to 2016 (Tableaux 13, 15-17).

The figures in this report are not meant to be definitive consumption of ARVs from 2014 to 2018; rather, they provide a range of possible demand if current trends continue. The linear regression approach projects 19.7 million people receiving treatment by 2018, the CHAI forecast estimates 19.7 million, the country target approach projects 30.7 million, while the Fast Track projection estimates 23.8 million. The average projection of the three approaches reaches 23.5 million by 2018. 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. Number of adults and children receiving treatment (average scenario), and number of women receiving ARV drugs for PMTCT, based on average of linear and country target projections (millions), 2014–2018

Number of people receiving ART or ARV drugs for PMTCT	2014	2015	2016	2017	2018
Number of adults receiving ART (millions)	13.1 [12.0–15.1][a]	15.6 [14.2–18.6]	17.5 [16.0–22.0]	19.9 [17.3–25.2]	22.1 [18.5–28.5]
Number of children receiving ART (millions)	0.89 [0.74–1.2]	1.0 [0.79–1.3]	1.1 [0.84–1.5]	1.2 [0.90–1.9]	1.4 [0.93–2.2]
Number of people receiving ART (millions)	14.0 [12.8–16.3]	16.6 [15.0–19.9]	18.6 [16.7–23.5]	21.1 [18.2–27.1]	23.5 [19.7–30.7]
Proportion of people receiving first-line ART (%)	94.8	94.6	94.5	94.3	94.1
Proportion of people receiving second-line ART (%)	5.2	5.4	5.5	5.7	5.9
Number of women receiving ARV drugs for PMTCT, based on average of linear and country target projections (millions)	1.6 [1.5–1.7]	1.8 [1.6–1.9]	2.0 [1.8–2.2]	2.2 [2.0–2.4]	2.4 [2.2–2.7]

[a] Numbers in brackets show the low and high estimates.

1. INTRODUCTION

The objectives of this report are to:

- provide information on the projected number of people who will be on antiretroviral therapy (ART) from 2014 to 2018;
- update the forecasts of global demand for antiretroviral (ARV) drugs prepared in 2013; and
- forecast the global and regional demand for individual ARV drugs from 2014 to 2018.

The data sources for this report are the:

- reported use of ARV drugs and country planning targets for the number of people on ART from the 2012 to 2014 annual WHO surveys on the use of ARV drugs.
- Global Price Reporting Mechanism (GPRM) of WHO;
- quantification of ARV drugs for selected countries to be procured for 2015 and 2016, by the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund);
- quantities of ARV drugs for 15 countries to be procured for 2014, 2015 and 2016, by the United States President's Emergency Plan for AIDS Relief (PEPFAR)-funded Supply Chain Management System (SCMS) project;
- volumes of ARVs reported in the projection of ARV drug demand by the Clinton Health Access Initiative (CHAI); and
- estimated number of people who need ART, from the Joint United Nations Programme on HIV/AIDS (UNAIDS);

All these data were compiled and used to project the demand for ARV drugs from 2014 to 2018. The number of people receiving ART for the projected years is forecast using three approaches:

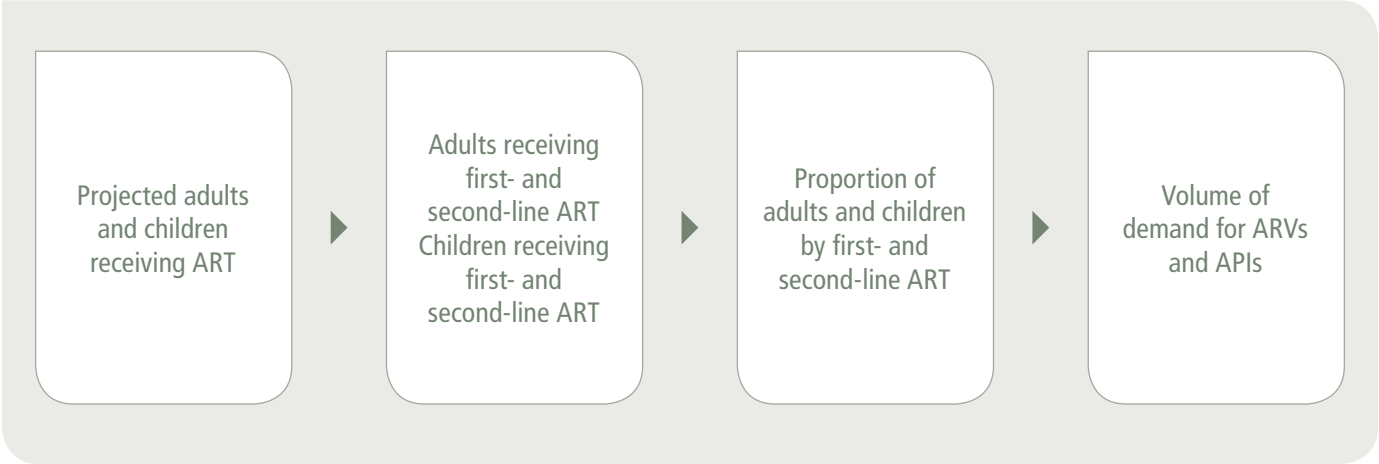
- linear projections of historical numbers of people receiving ART by country;
- country target projection, based on planning targets submitted by national programmes; and
- projections by CHAI.

These 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 World Health Organization (WHO) ARV use surveys conducted in 2012, 2013 and 2014, which assessed the use of ARV medicines at the end of 2011, 2012 and 2013 (2–6);
- linear extrapolation of the relative market share of protease inhibitors (PIs) for 2010–2014 from GPRM procurement data; and
- the CHAI projections for second-line therapy for 2013–2018.
- Determine the distribution of regimens for adults and children receiving first- and second-line therapy, using the average proportions from five sources of data – WHO ARV drug use survey, CHAI, SCMS, Global Fund and GPRM:
  - linear regression based on the WHO surveys of reported ARV use at the end of 2011, 2012 and 2013;
  - linear extrapolation of the relative market share of active pharmaceutical ingredients (APIs) for 2010–2013 and part of 2014 from GPRM procurement data;
  - CHAI ARV market share projections for 2013–2018;
  - Global Fund procurement forecast for 2015 and 2016; and
  - SCMS country forecasts of the number of persons on ART and the regimen breakdown for 2015 and 2016.
- Calculate the number of person-years of treatment for each ARV drug.
- Calculate the total API volumes required to meet the forecast demand for adults and children for each ARV drug.
- Calculate the number of adults and children on the most prescribed treatment regimens.

The model used for forecasting ARV drug demand in this report is illustrated 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 2014–2018

Fig. 1. Model used for forecasting ARV drug demand



2. METHODS FOR DETERMINING KEY FORECAST VARIABLES

2.1. Total number of people receiving treatment

The WHO global ARV drug use survey and the Global AIDS Response Progress Report (GARPR) use the same indicator for people on ART. Information in GARPR is exported into the WHO global ARV drug use survey; 146 countries provided this information. Table 2 summarizes the underlying assumptions and data sources of the three approaches to forecasting the number of people receiving ART to 2018.

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 2012 to 2014	Country targets for 2014–2018	Global progress reports published annually by WHO/ UNICEF/UNAIDS
Number of countries for which data are used	146 (WHO ARV drug use survey conducted in 2014)	47[1]	21 highest-burden countries[2]
Proportion of people in low- and middle-income countries receiving treatment represented in the data set	99%	53% (extrapolated to the remaining 47% of low- and middle-income countries)[3]	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 2011–2013, with the rate of increase limited by the number of people estimated to need treatment by 2018 using 2013 WHO consolidated eligibility criteria	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 2011–2013 and will plateau as universal access is achieved

[1] Belarus, Benin, Burkina Faso, Burundi, Cambodia, Cameroon, Cape 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.

[2] 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.

[3] 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 give the average estimated number of people on ART for all low- and middle-income countries.

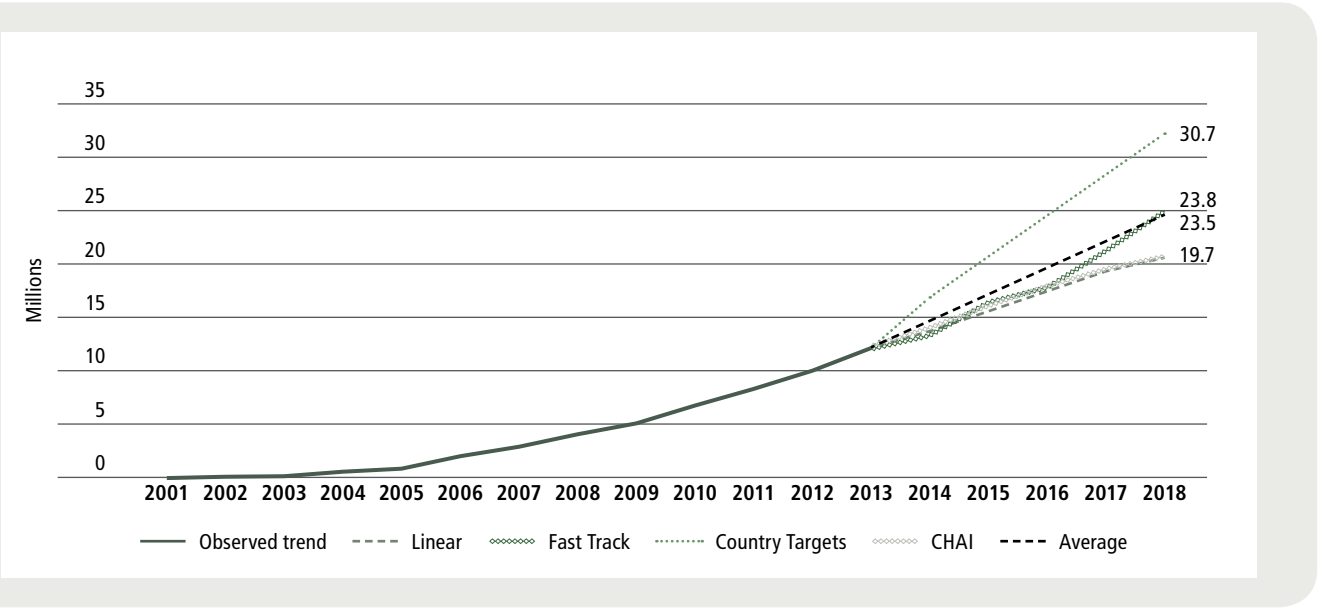
Table 3 and Fig. 2 present the three projection scenarios of the estimated number of people receiving ART from 2014 to 2018 and the average of the three projections. Table A1 provides the average number of people receiving treatment by region for the linear and country target projections.

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 projection 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.

Table 3. Number of adults and children receiving treatment by scenario and average, 2014–2018

Forecasting method	Age group	2014	2015	2016	2017	2018
Linear projection	Adults	12 500 000	14 200 000	15 900 000	17 300 000	18 800 000
	Children	740 000	790 000	840 000	890 000	930 000
	Total	13 200 000	15 000 000	16 700 000	18 200 000	19 700 000
Country target projection	Adults	15 100 000	18 600 000	22 000 000	25 200 000	28 500 000
	Children	1 200 000	1 300 000	1 500 000	1 900 000	2 200 000
	Total	16 300 000	19 900 000	23 500 000	27 100 000	30 700 000
CHAI projection	Adults	12 700 000	14 500 000	16 200 000	17 600 000	18 500 000
	Children	820 000	910 000	1 000 000	1 100 000	1 200 000
	Total	13 500 000	15 400 000	17 200 000	18 700 000	19 700 000
Fast Track	Adults	12 000 000	14 900 000	16 000 000	19 400 000	22 600 000
	Children	800 000	900 000	1 000 000	1 100 000	1 200 000
	Total	12 800 000	15 800 000	17 000 000	20 500 000	23 800 000
Average	Adults	13 100 000	15 600 000	17 500 000	19 900 000	22 100 000
	Children	900 000	1 000 000	1 100 000	1 200 000	1 400 000
	Total	14 000 000	16 600 000	18 600 000	21 100 000	23 500 000

Fig. 2. Comparison of projections of the number of people receiving ART, 2001–2018



2.1.1 Linear projection

This forecast estimates the annual increase in the number of people receiving treatment based on responses from the 146 countries mentioned under Section 2.1, representing approximately 99% of the number of people receiving treatment in all 154 low- and middle-income countries. The survey data are then used to plot a linear regression line fitted to the number of adults and children receiving ART over the past three years (2011, 2012 and 2013), 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 to the WHO treatment guidelines on the use of ARV drugs recommending a higher CD4 threshold for initiating treatment, and 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*) of 15.7 million by 2016 to 16.7 million. The linear approach is constrained by the estimated number of people who need ART projected for 2018 based on WHO 2013 treatment recommendations.

Since option B+ for PMTCT[1] 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. This may overestimate the number of people on ART if some women on ART discontinue treatment when they stop breastfeeding.

2.1.2 Country target projection

Most countries set their own targets for the number of people they expect to be receiving ART during the next three to five years. These targets consider the realities in each country and their goals for increasing coverage. For the 2014–2018 country target projections, 47 country projections in successive global WHO ARV drug use surveys were used, 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 47 countries. This equates to an average annual growth of nearly 4 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 five-year forecast of global demand for ARVs in low- and middle-income countries. The forecast is broken down into demand by regimen,

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

country, first line versus second line, adults versus children, and generic accessible versus inaccessible countries. The data inputs use the total patient numbers in the *Towards universal access progress report*, published annually by WHO/UNAIDS, as the baseline. The forecast assumes that the number of people on ART will increase at the same rate as the linear trend observed over the previous three years, but plateauing as countries approach universal coverage under the 2013 WHO guidelines. The ratio of patients by regimen is evaluated based on data collected from CHAI country teams, national guidelines and historic uptake rates.

To arrive at a global forecast, CHAI applies this methodology to the 21 highest-burden countries, and then extrapolates to the rest of the world. The 21 countries are: 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.

2.1.4 Fast Track projection

For comparison purposes the Fast Track projection from UNAIDS is also shown in Table 2 and Fig. 2[1]. This projection assumes that by 2020, 90% of all people living with HIV will know their status, 90% of people who know their status will receive treatment and 90% of people on treatment will achieve viral suppression. The Fast-Track projections were made using the Spectrum/Goals model applied to 28 high burden countries, which account for over 85% of all new infections, and the results scaled up to represent all low- and middle-income countries. The model tracks new infections over time by CD4 count, age and sex. It estimates survival on ART as a function of CD4 count at treatment initiation and includes the effect of ART on viral suppression and reductions in infectivity.

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.
- Linear regression of the proportion of the people receiving PIs reported by the GPRM for 2011, 2012 and 2013 (*8*) and extrapolated using a linear regression to 2014 to 2018.
- 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 remaining 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.

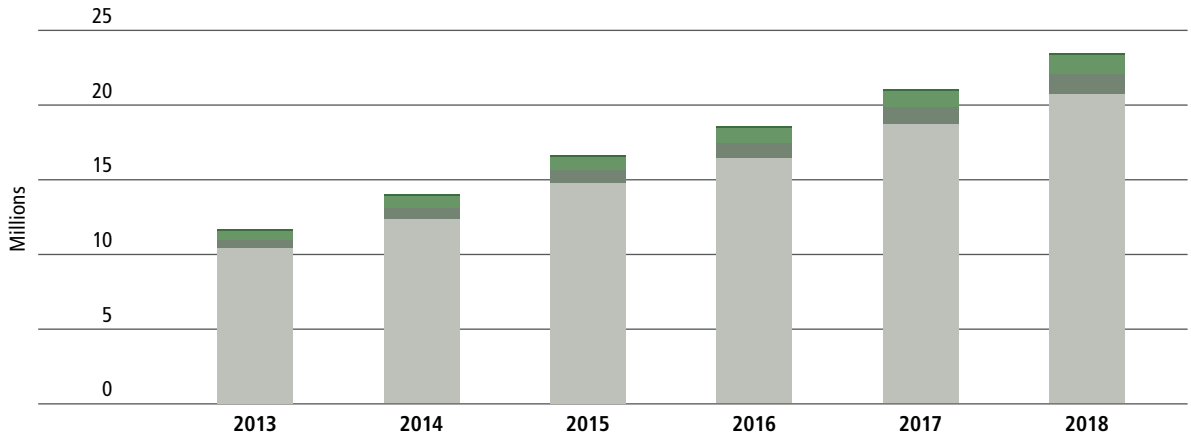
Table 4. Proportion of people receiving second-line ART, 2013–2018

	Proportion of people receiving second-line ART 2014–2018 (%)					
Data source	2013	2014	2015	2016	2017	2018
WHO AIDS Medicines and Diagnostics Service survey	5.6	5.9	6.0	6.1	6.1	6.2
GPRM	4.5	4.8	5.2	5.6	5.9	6.3
CHAI	5.0	4.9	4.9	4.9	5.1	5.3
Average	5.0	5.2	5.4	5.5	5.7	5.9

[1] UNAIDS. Fast-Track: ending the AIDS epidemic by 2030. November 2014.

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 2014–2018 (see Table 3). Fig. 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 Fig. 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 Fig. A4–A9.

Fig. 3. Number of adults and children receiving first- and second-line ART, 2013–2018, based on the average of three projections



	2013	2014	2015	2016	2017	2018
Children SL	37 000	46 000	54 000	61 000	69 000	83 000
Children FL	700 000	840 000	950 000	1 040 000	1 130 000	1 320 000
Adult SL	550 000	680 000	840 000	970 000	1 100 000	1 300 000
Adult FL	10 400 000	12 400 000	14 800 000	16 500 000	18 800 000	20 800 000

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 transaction data; SCMS procurement data; and the 2014 WHO survey of ARV drug 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), tenofovir (TDF), abacavir (ABC) and didanosine (ddI).
- 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: d4T, AZT, TDF and ABC.
- Secondary NRTIs: ddI and 3TC.
- NNRTIs and PIs: 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 2013. For the countries that responded, the reported proportions of adults and children receiving each regimen were disaggregated into the percentage of adults and children 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 2014 to 2018 by country, a linear regression line was fitted to the reported ARV drug distribution from 2010 to 2013 projected to 2018 but constrained to be between 0% and 100%.

This methodology was applied to all PIs except indinavir, saquinavir and nelfinavir. It was assumed that since these three ARV drugs will no longer be marketed, no one will receive these by the end of 2014 and that people formerly using these three drugs will be transitioned to LPV/r and ATV/r in a ratio of 9:1, based on current GPRM data (that is, 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 2010, 2011, 2012, 2013 and partial data for 2014 (the first three quarters of 2014). 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 was then calculated as its procurement volume proportional to the total annual volume for all ARVs in the same category.

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; and
- assumptions about the evolution of this distribution over a two to three-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[1] and 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 these data and an internally developed forecasting model to project ARV drug demand by drug and by regimen in each country over the next five years. CHAI then aggregates estimates across the 21 countries and extrapolates these results to patients in the remaining low- and middle-income countries.

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)[2] and 30 countries (2015 and 2016 projection).[3]

Fig. 4–17 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 children.

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[1] Botswana, Burundi, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Mozambique, Namibia, Nigeria, Rwanda, Tanzania, Uganda, Viet Nam, Zambia and Zimbabwe.

[2] Afghanistan, Angola, Bolivia, Burundi, Cambodia, Cameroon, Cape Verde, Chad, Comoros, Democratic Republic of the Congo, Côte d'Ivoire, 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, Palestine, Paraguay, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Sri Lanka, Thailand, Timor-Leste, Uganda, United Republic of Tanzania, Viet Nam, Yemen and Zambia.

[3] Armenia; Burundi; Cape Verde; Comoros; Democratic Republic of the Congo; Côte d'Ivoire; Georgia; Ghana; Honduras; Indonesia; Lao People's Democratic Republic; Lesotho; Malawi; Mauritania; Mozambique; Nepal; Niger; Nigeria; Philippines; Sri Lanka; United Republic of Tanzania; Timor-Leste; Uganda; Viet Nam.

Fig. 4. Projected adult market share (%) of d4T as a proportion of the adult volume of primary NRTIs, 2011–2018

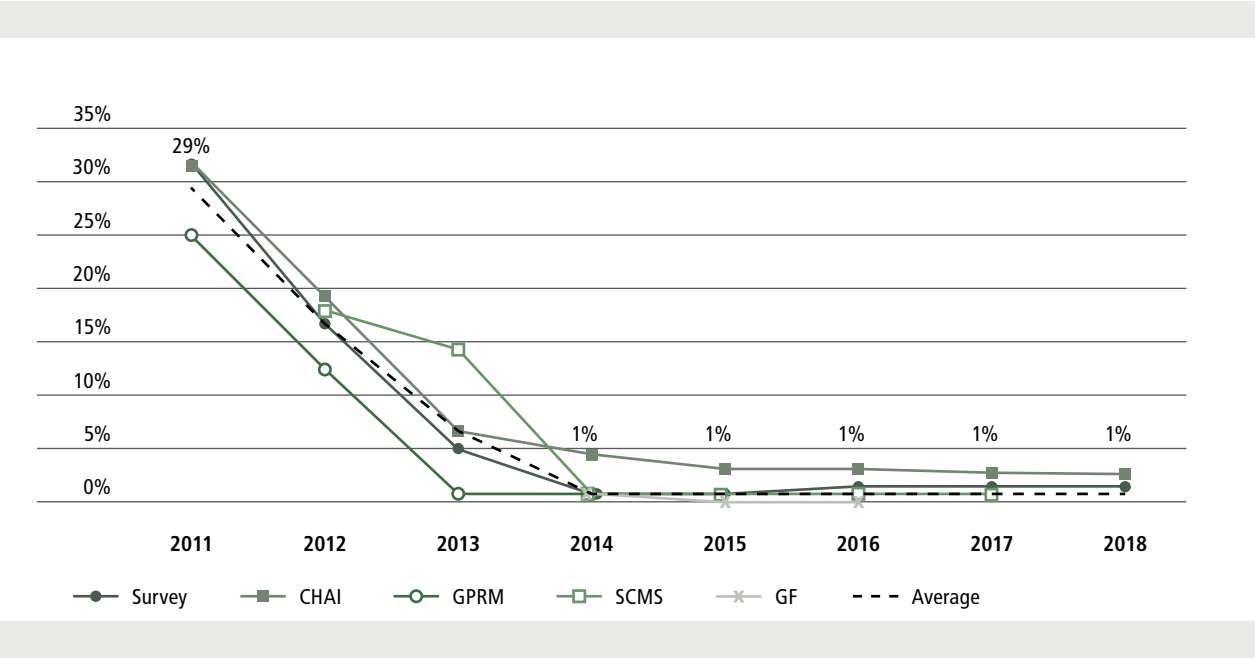


Fig. 5. Projected paediatric market share (%) of d4T as a proportion of the paediatric volume of primary NRTIs, 2011–2018

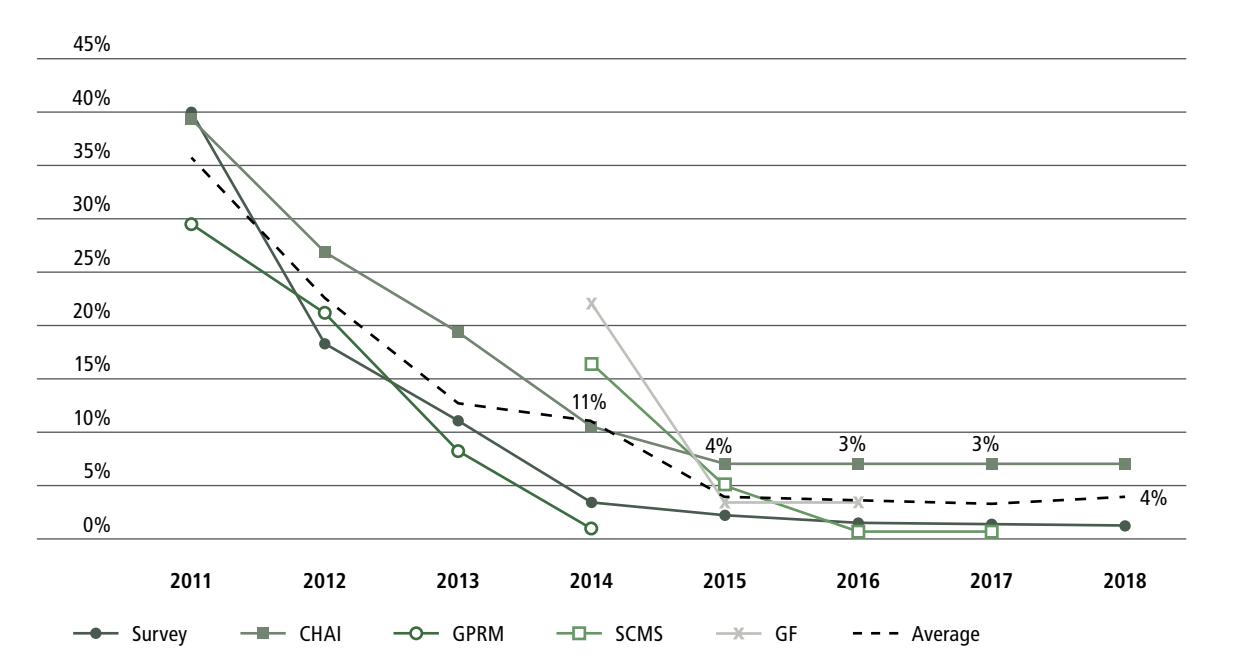


Fig. 6. Projected adult market share (%) of TDF as a proportion of the adult volume of primary NRTIs, 2011–2018

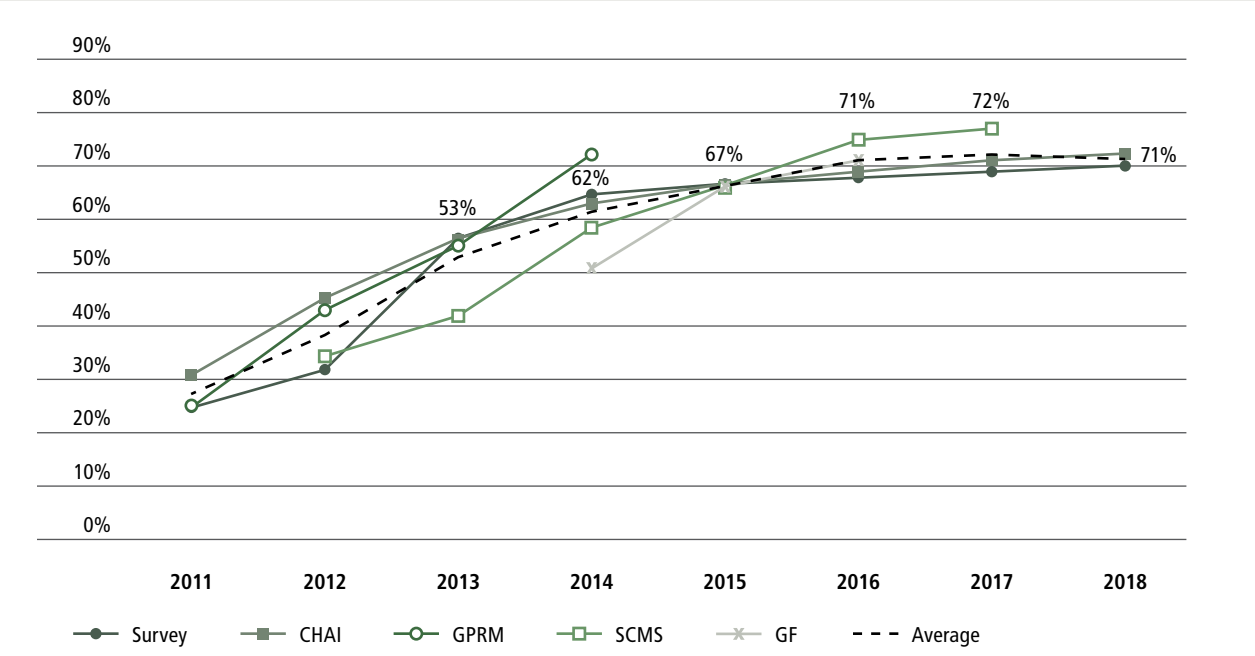


Fig. 7. Projected paediatric market share (%) of TDF as a proportion of the paediatric volume of primary NRTIs, 2011–2018

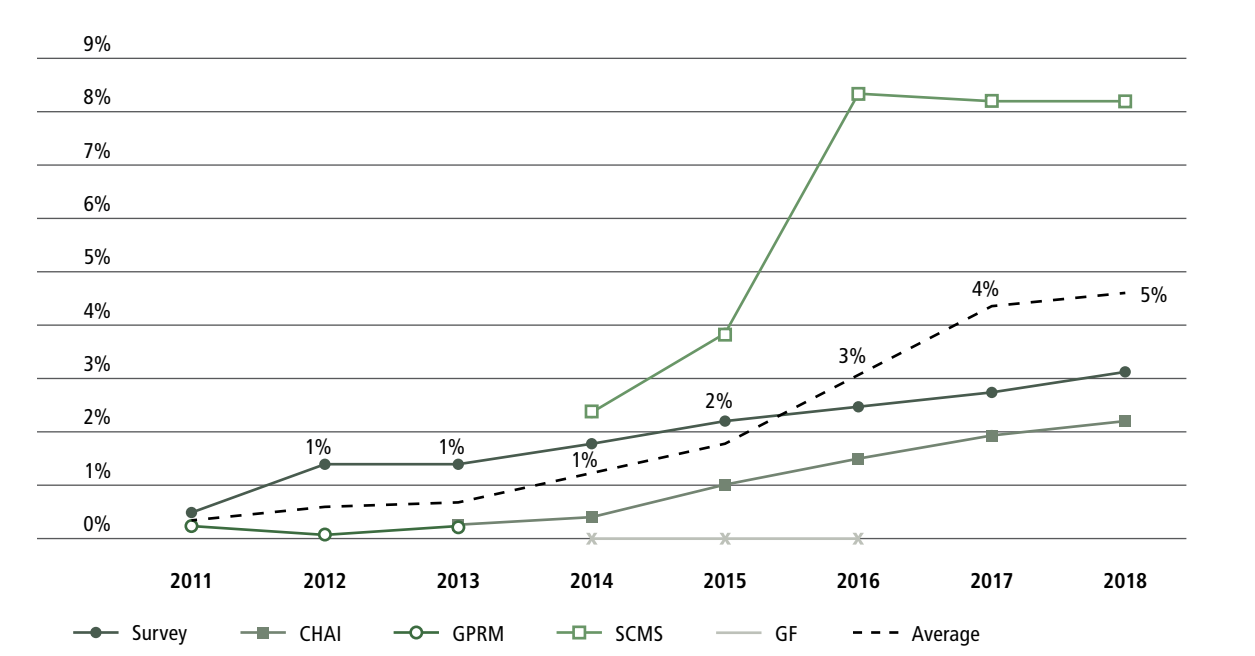


Fig. 8. Projected adult market share (%) of AZT as a proportion of the adult volume of primary NRTIs, 2011–2018

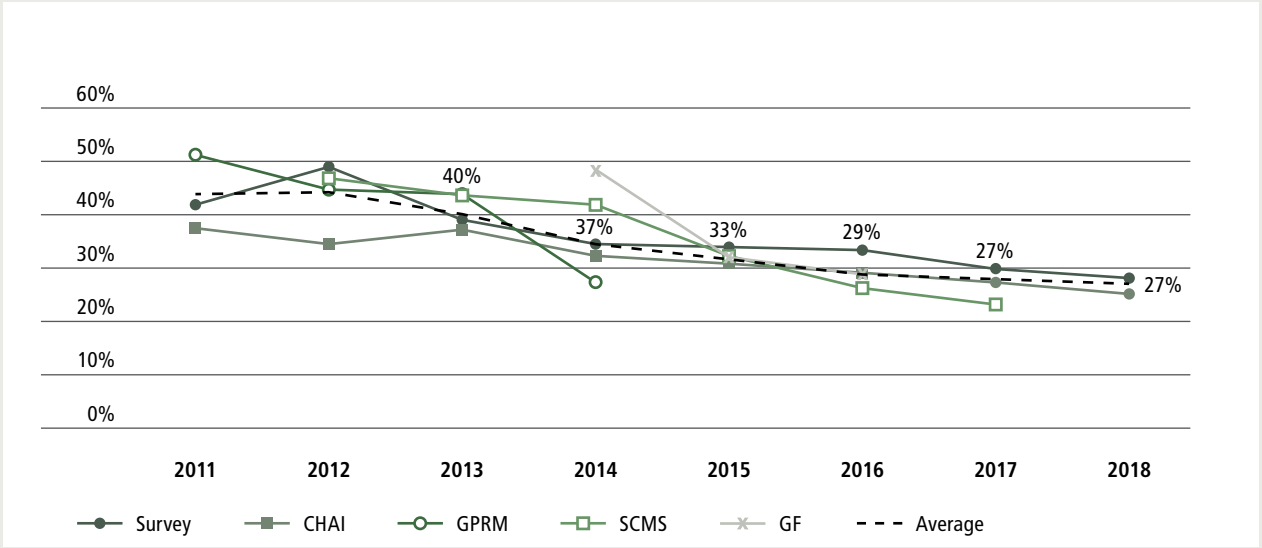


Fig. 9. Projected paediatric market share (%) of AZT as a proportion of the paediatric volume of primary NRTIs, 2011–2018

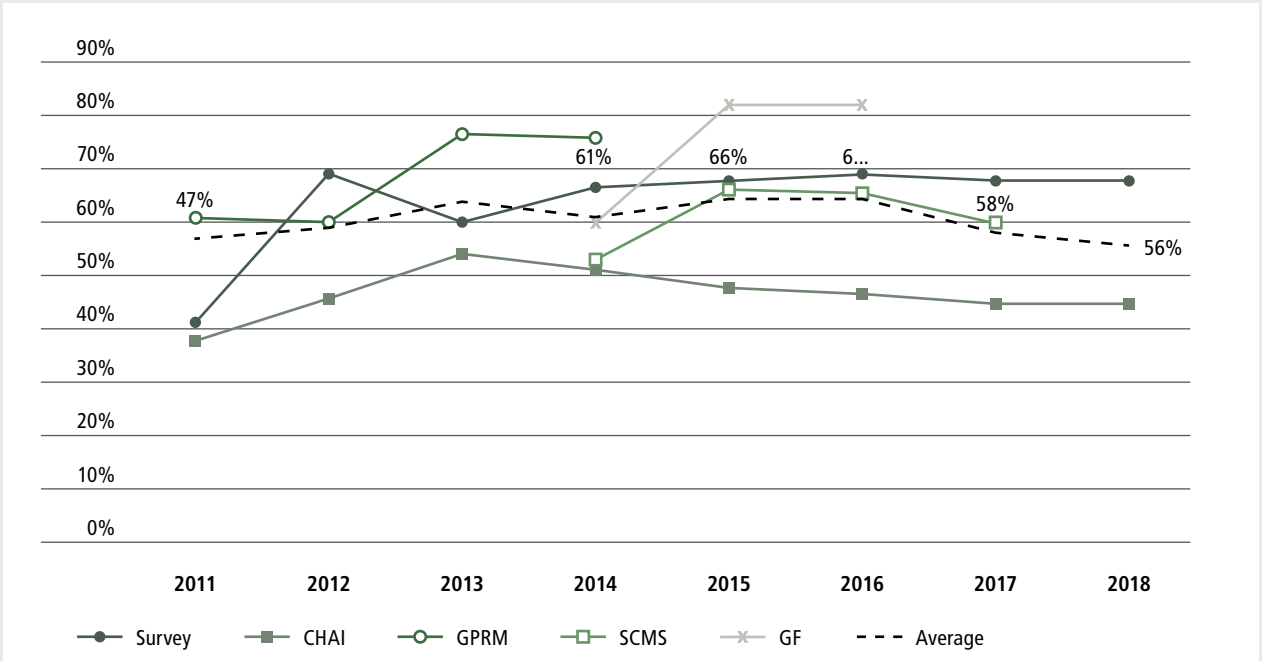


Fig. 10. Projected market share (%) of ABC as a proportion of the adult volume of primary NRTIs, 2011–2018

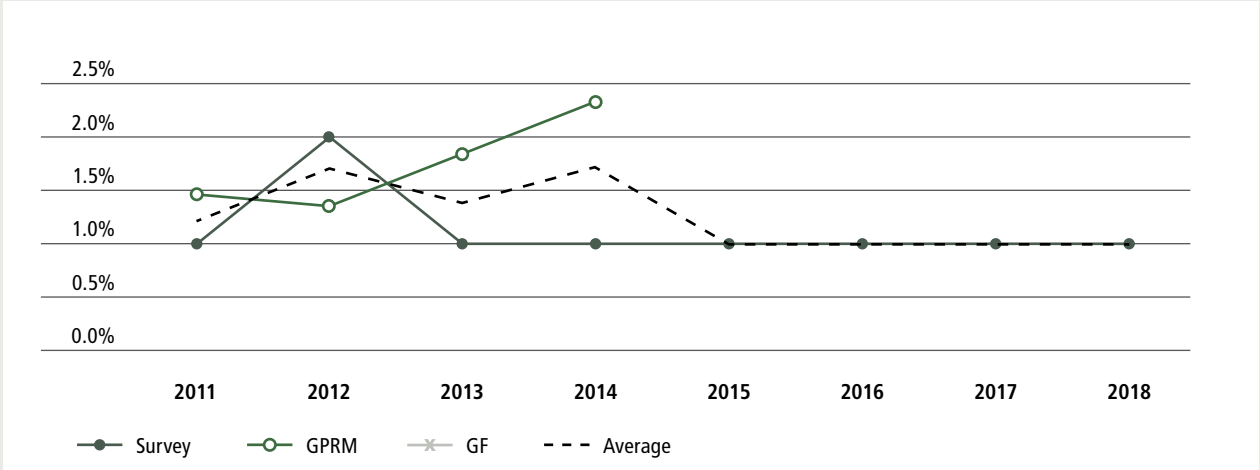


Fig. 11. Projected paediatric market share (%) of ABC as a proportion of the paediatric volume of primary NRTIs, 2011–2018

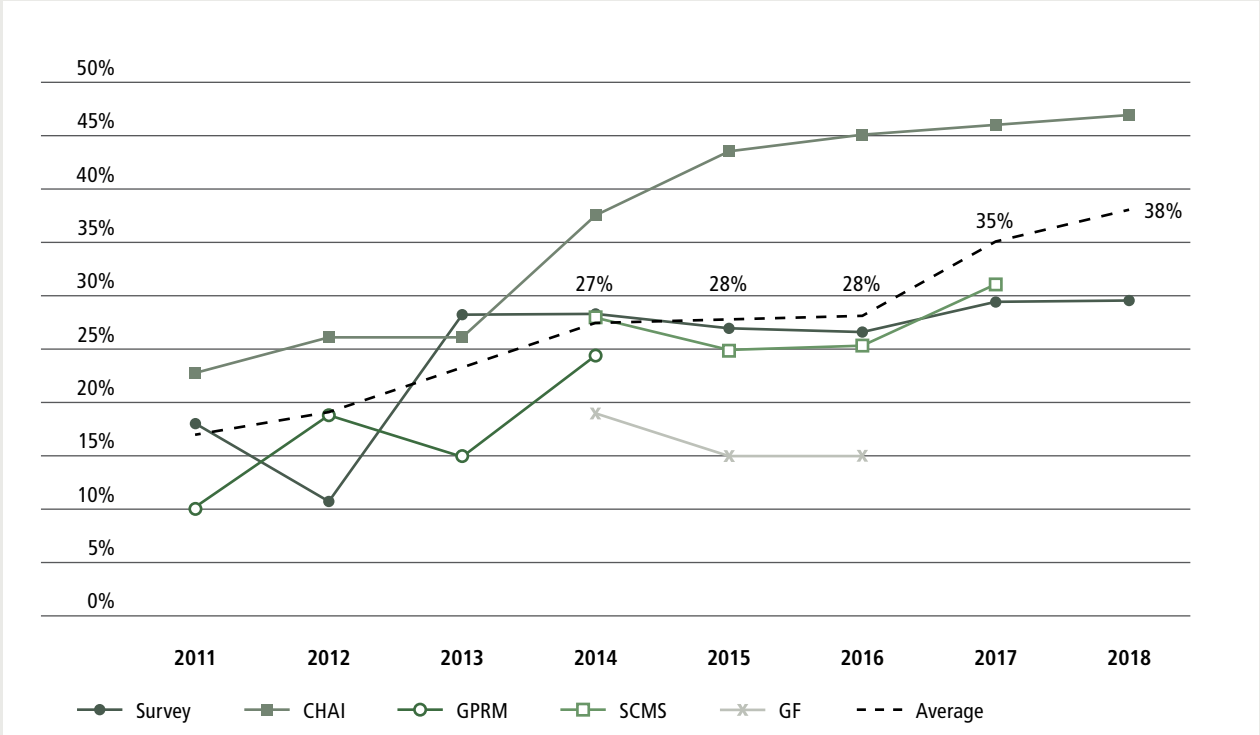


Fig. 12. Projected market share (%) of ddI as a proportion of the adult volume of primary NRTIs, 2011–2018

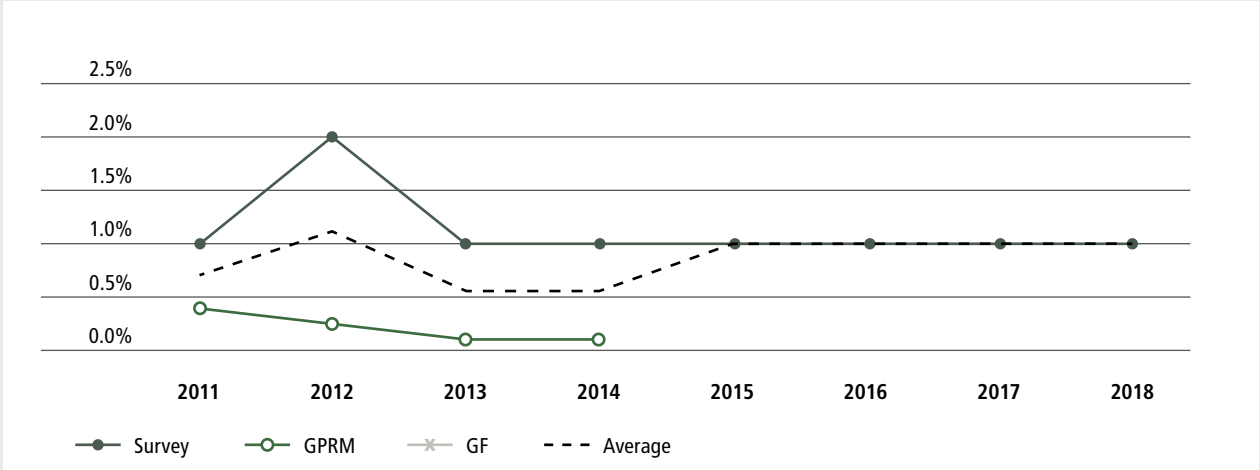


Fig. 13. Projected adult market share (%) of 3TC and FTC as a proportion of the adult volume of secondary NRTIs, 2011–2018

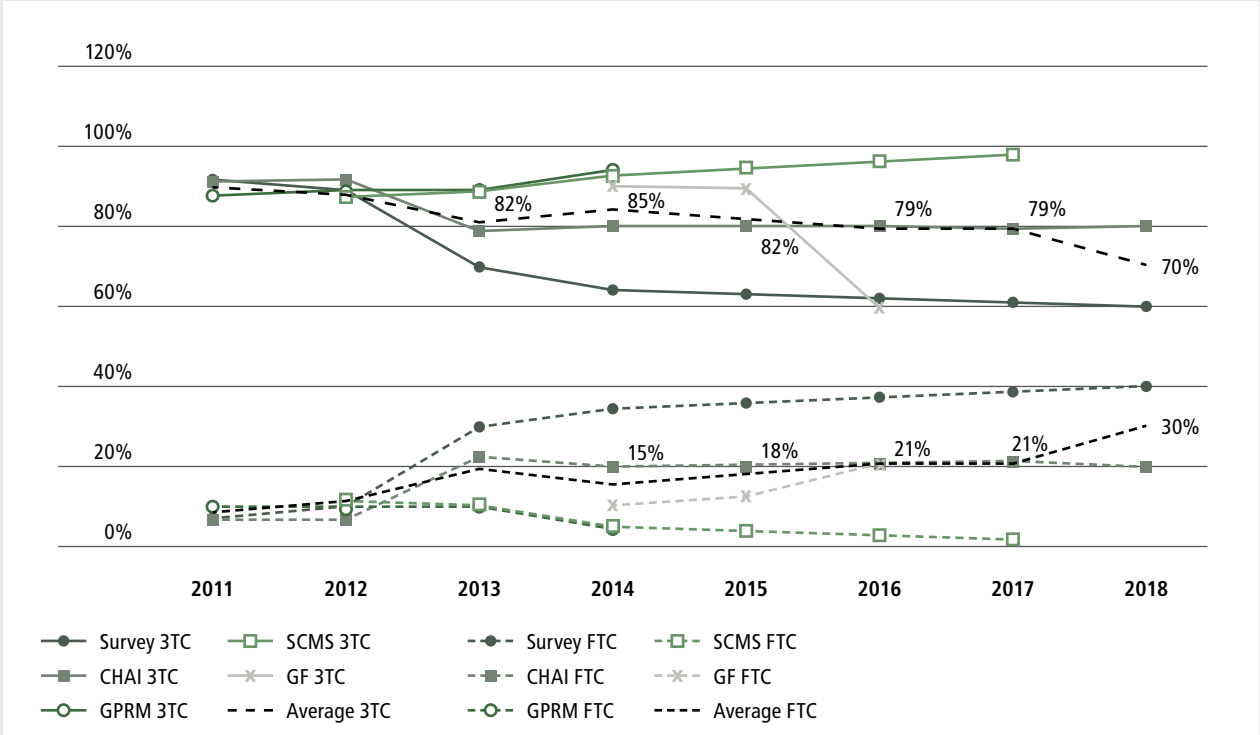


Fig. 14. Projected paediatric market share (%) of 3TC as a proportion of the paediatric volume of secondary NRTIs, 2011–2018

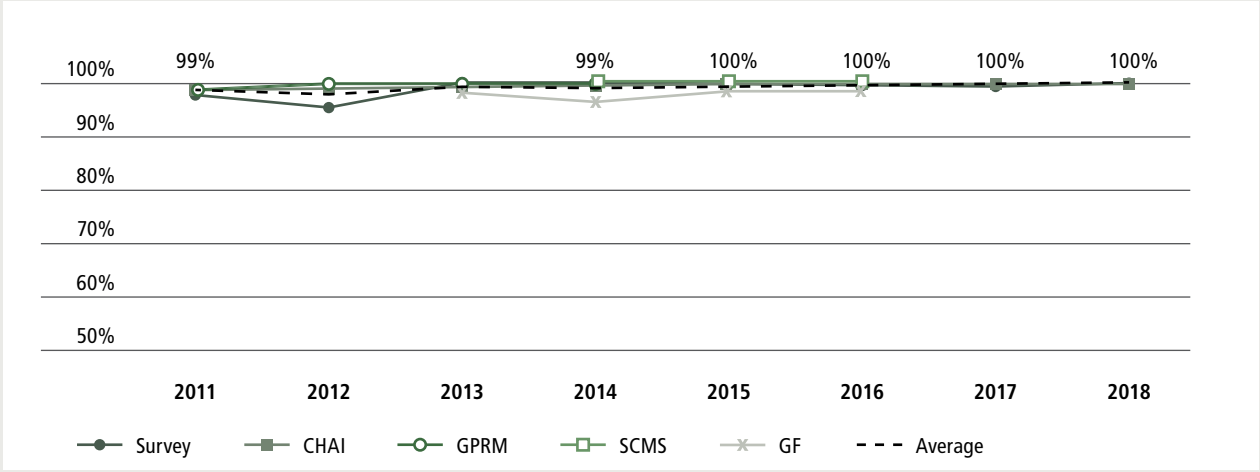


Fig. 15. Projected adult market share (%) of NVP and EFV as proportions of the adult volume of NNRTIs, 2011–2018

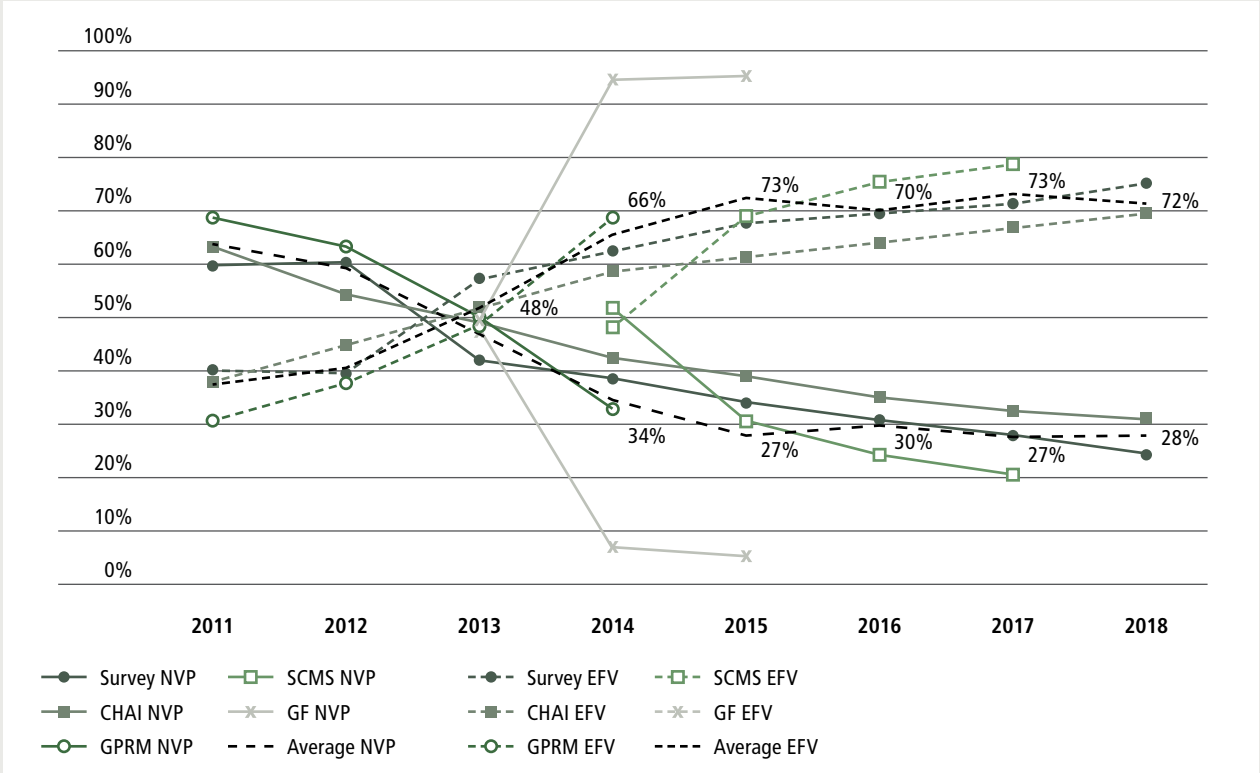


Fig. 16. Projected paediatric market share (%) of NVP, EFV and LPV as proportions of the paediatric volume of NNRTIs and PIs, 2011–2018

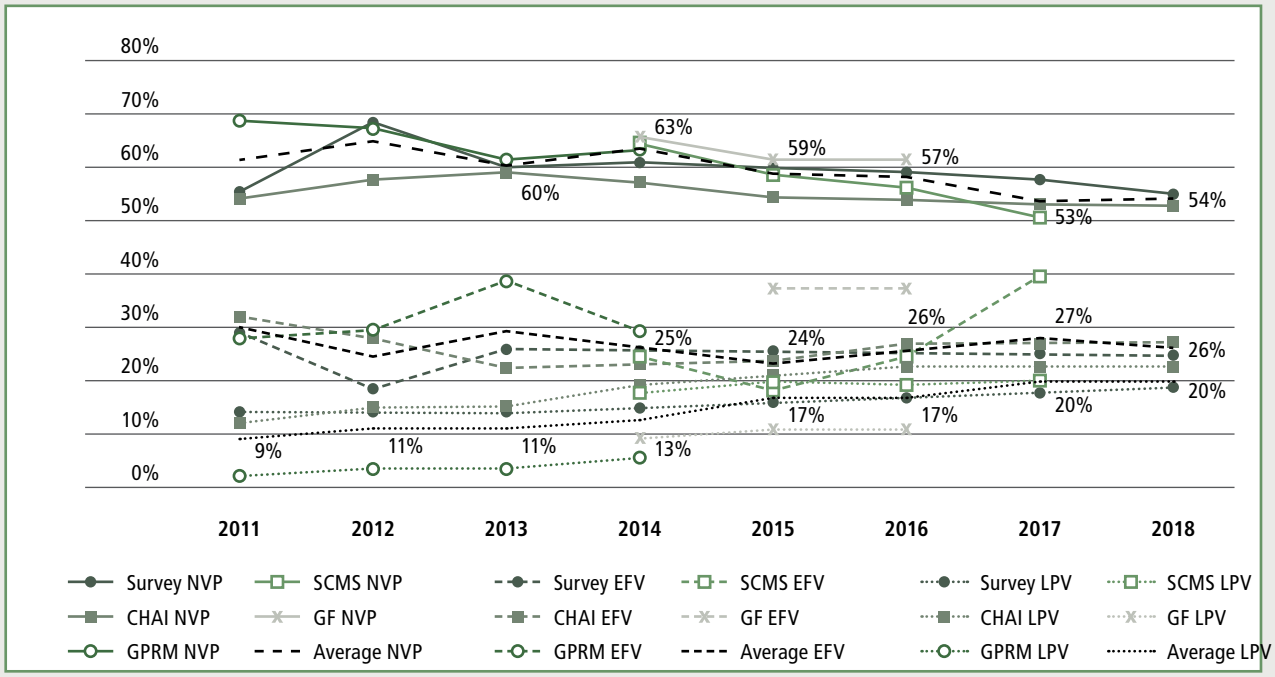
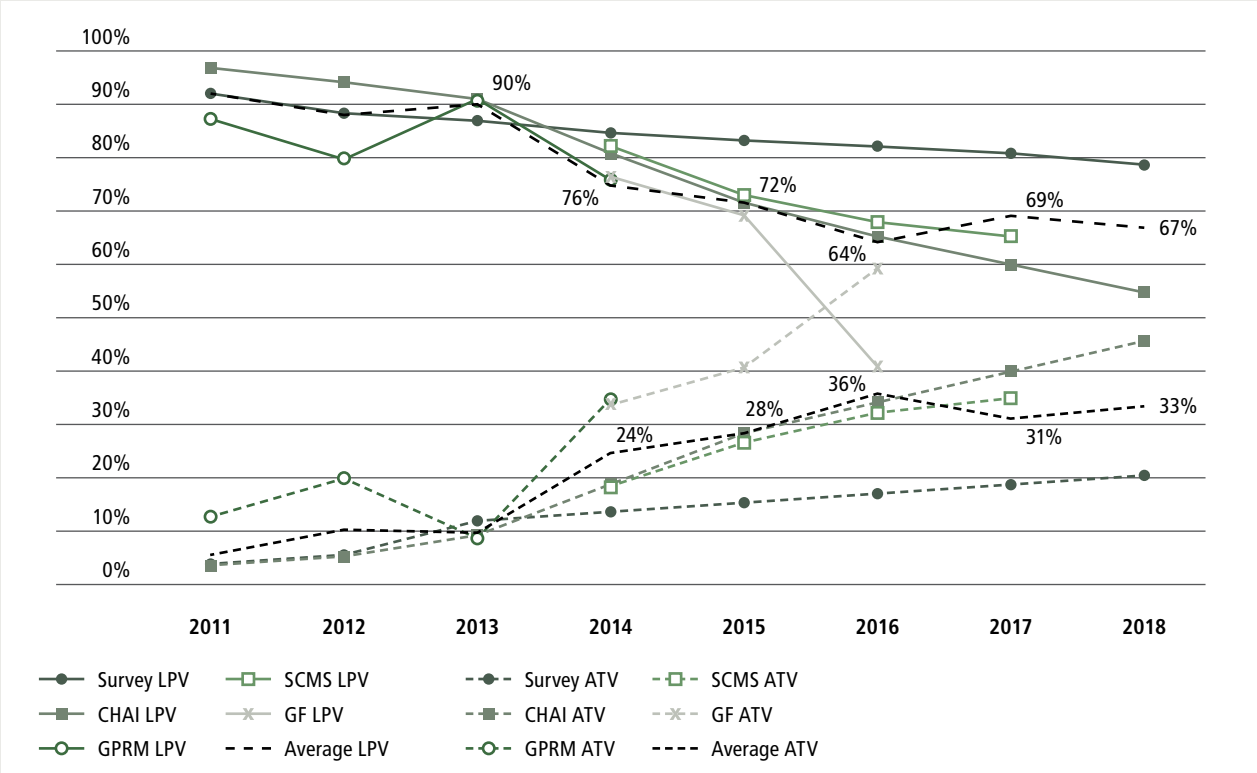


Fig. 17. Projected adult market share (%) of LPV and ATV as proportions of the adult PI volume, 2011–2018



As Fig. 4–17 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 for each ARV for adult and paediatric patients separately.

Table 5. Average market share for adult ARV drugs

ARV drug	Average market share (%)				
	2014	2015	2016	2017	2018
d4T, TDF and AZT share of primary NRTIs					
d4T	1	1	1	1	1
TDF	62	67	70	72	71
AZT	37	33	30	27	27
3TC and FTC share of secondary NRTIs					
3TC	85	84	84	79	70
FTC	15	16	16	21	30
ABC[1]	2	1	1	1	1
ddI9[1]	1	1	1	1	1
NVP and EFV share of NNRTIs					
NVP	38	33	30	27	28
EFV	61	67	70	73	72
LPV/r and ATV/r share of PIs					
LPV	60	52	52	58	67
ATV	27	36	39	31	33

[1] Average market share based on WHO Survey and GPRM data.

Table 6. Average market share for paediatric ARV drugs

ARV drug	Average market share (%)				
	2014	2015	2016	2017	2018
d4T, TDF, AZT and ABC share of primary NRTIs					
d4T	11	4	3	3	4
TDF	1	2	3	4	3
AZT	61	66	66	58	56
ABC	27	28	28	35	38
3TC and ddI share of secondary NRTIs					
3TC	99	100	100	100	100
ddI	1	1	1	1	1
NVP, EFV and LPV share					
NVP	63	59	57	53	54
EFV	23	24	26	27	26
LPV	13	17	17	20	20

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 projections – linear and country target. The linear projection is based on linear regression of data on PMTCT from 2011 to 2013, whereas the country targets are based on the goals set by 47 countries. Table 7 shows the projected number of women receiving ARV drugs for PMTCT for each projection, as well as the average of the two projections. 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, 2014–2018

Forecasting method	No. of women receiving ARV drugs for PMTCT				
	2014	2015	2016	2017	2018
Linear projection	1 500 000	1 600 000	1 800 000	2 000 000	2 200 000
Country target projection	1 700 000	1 900 000	2 200 000	2 400 000	2 700 000
Average	1 600 000	1 800 000	2 000 000	2 200 000	2 400 000
Annual rate of increase (%)	–	13	11	10	9

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 (Table 7) – WHO 2006 AZT, option A, option B and option B+ – was determined through the WHO ARV drug use survey and the global ART access progress report, *Global AIDS response progress reporting* (*9*). Most country programmes are rapidly scaling down option A and 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 – WHO 2006 AZT regimens, Option A – would be discontinued by 2018 and that the use of Option B and 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 2018

Regimen	Projected regimen mix for women receiving ARV drugs for PMTCT	
	2013[a]	2018
Single-dose NVP (%)[b]	0	0
WHO 2006 AZT (other) (%)[c]	0	0
Option A (%)[d]	0	0
Option B (%)[e]	53	30
Triple ART (%)[f]	47	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 person-years and 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 API person-years

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 API volume in person-years for each ARV drug based on the average of the three projections – linear, country target and CHAI.

Table 9. API demand volume in person-years, based on the average of three projections

Drug	Demand for APIs (person-years) based on the average of linear, CHAI and country target projected number of patients and API market share				
	2014	2015	2016	2017	2018
d4T	437 000	355 000	285 000	327 000	396 000
AZT	4 800 000	5 400 000	5 800 000	6 200 000	7 000 000
TDF	6 700 000	9 200 000	11 800 000	14 100 000	15 900 000
ABC	333 000	443 000	537 000	742 000	902 000
ddI	142 000	179 000	227 000	282 000	326 000
3TC	9 800 000	11 800 000	13 800 000	14 900 000	15 100 000
FTC	2 200 000	2 500 000	2 800 000	3 700 000	5 300 000
NVP	5 200 000	5 400 000	5 400 000	5 600 000	6 200 000
EFV	6 200 000	8 400 000	10 500 000	12 400 000	13 700 000
LPV	427 000	529 000	597 000	799 000	935 000
ATV	237 000	312 000	393 000	384 000	431 000
RTV[a]	665 000	800 000	1 000 000	1 200 000	1 400 000

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

3.2. 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.

Table 10 shows the recommended daily doses for adult and paediatric patients.

Table 10. Adult and paediatric daily doses for ARV drugs, based on WHO recommendations

Drug	Adult daily dose (mg/day)	Paediatric doses (mg/day) 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	–	–	–	–	–	–

3.3. Forecast demand for APIs for 2014–2018

Table 11 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 (Fig. 4–17). 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 converted into person-years and then multiplied by the ARV distribution and finally multiplied by the recommended dosage for each ARV drug. Table 12 shows the volume of AZT, 3TC, NVP and LPV demand for PMTCT: single-dose NVP, dual ARV drugs, option A and option B based on the average of the linear and country target projections of the number of mothers needing PMTCT (Table 8).

Table 11. Volume of demand for APIs in metric tonnes based on the average of linear, CHAI and country target projections, 2013–2018

Drug	Demand for APIs (metric tonnes) based on the average of linear, CHAI and country target projections				
	2014	2015	2016	2017	2018
d4T	9	7	6	7	8
AZT	929	1085	1203	1296	1380
TDF	726	997	1276	1524	1711
ABC[a]	40	53	66	87	103
ddI[a]	14	19	24	29	34
3TC	1017	1227	1433	1551	1571
FTC	160	183	199	266	384
NVP	707	731	719	743	817
EFV	1320	1787	2239	2626	2908
LPV	134	146	157	194	216
ATV	14	23	34	35	42
RTV[a]	38	46	54	67	77

Table 12. Volume of demand for APIs in metric tonnes for women on PMTCT based on the average of linear and country target projections, 2013–2018

Drug	Demand for APIs (metric tonnes) for women on PMTCT based on the average of linear and country target projections[1]				
	2014	2015	2016	2017	2018
NVP	7	7	7	7	7
AZT	264	274	277	273	261
3TC	132	137	139	137	131
LPV	351	366	370	364	348
RTV	88	91	92	91	87

[a] Volume of demand is based on the averages for linear and country target projections.
[1] Note: The forecast volume demand for PMTCT does not include women on triple ART for their health or Option B+. This has been included in ARV for adult HIV treatment.

3.4. ARV formulations

Projections of ARV formulation requirements were compiled from three major sources – CHAI, the Global Fund and SCMS. Formulation requirement data from CHAI and SCMS were projected for 2014, 2015 and 2016 while data from the Global Fund were projected for 2015 and 2016. Data from CHAI were based on the projected number of people on each ARV formulation from 21 countries extrapolated to the rest of the world. Quantification data from SCMS and the Global Fund were converted from quantities of each ARV formulation to patient-years by multiplying the number of bottles/packages by the smallest units in each bottle/package and dividing total quantity of smallest units of each ARV formulation by the daily dose times the number of days in one year (365 days) to obtain the number of patient-years of each formulation in both datasets, the number of patient-years from both datasets were added but not extrapolated to estimate the LMIC demand of ARV formulations. The ARV formulation data from SCMS and Global Fund are aggregated and then compared to CHAI projected formulations. It is important to note that the CHAI dataset includes South Africa while Global Fund and SCMS do not have data from South Africa. This explains the significant differences in the uptake of FTC and of the ARV paediatric formulations. Table 13 shows the CHAI projected ARV formulation data with the aggregated SCMS and Global Fund ARV formulation quantification data, side by side. ARV formulation data from each source (CHAI, the Global Fund and SCMS) are shown in Tables A15, A16 and A17 in Annex 1.

Table 13. Comparison of ARV formulation forecast between CHAI projected procurement and aggregation of SCMS and Global Fund procurement data in person-years, 2014–2016

Product	SCMS and Global Fund ARV formulation data (person-years)			CHAI ARV formulation data (person-years)		
	2014	2015	2016	2014	2015	2016
3TC 10 mg/ml	1221	3521	3510	76 644	74 082	74 780
3TC 150	40 714	54 081	83 927	694 472	706 521	732 020
3TC 300	–	–	–	696 191	746 490	766 654
ABC 20 mg/ml	769	930	921	82 061	99 955	111 113
ABC 300	30 191	42 218	60 098	48 254	43 852	43 406
ABC 300 3TC 150 AZT 300	805	4683	4792	–	–	–
ABC 300 3TC 300	–	–	–	–	–	–
ABC 60	2294	5199	5563	16 000	3000	4000
ABC 60 3TC 30	32 616	36 519	52 428	–	–	–
ABC 60 3TC 30 dispersible	11 925	68 308	93 776	37 000	32 000	30 000
ABC 600 3TC300	49 869	70 037	84 809	17 302	15 641	13 622
ATV 150	12	1672	1675	–	–	–
ATV 200	157	5253	5292	–	–	–

Product	SCMS and Global Fund ARV formulation data (person-years)			CHAI ARV formulation data (person-years)		
	2014	2015	2016	2014	2015	2016
ATV 300	–	4932	4932	–	–	–
ATV/r 300/100	29 996	139 464	183 890	71 000	131 000	197 000
AZT 10 mg/ml	548	7147	7153	–	–	–
AZT 100	97	5601	5597	–	–	–
AZT 300	24 379	32 210	31 334	266 000	277 000	294 000
AZT 300 3TC 150	539 283	915 205	950 389	967 000	1 072 000	1 176 000
AZT 300 3TC 150 EFV 600	–	8219	8219	–	–	–
AZT 300 3TC 150 NVP 200	1 113 290	2 065 197	2 065 505	1 979 000	1 919 000	1 859 000
AZT 60 3TC 30	30 971	94 266	99 578	6000	2000	5000
AZT 60 3TC 30 NVP 50	99 994	278 556	286 615	41 000	49 000	36 000
d4T 12 3TC 60	331	225	228	–	–	–
d4T 12 3TC 60 NVP 100	1935	1280	1196	–	–	–
d4T 15	1	–	–	–	–	–
d4T 20	5	3	3	–	–	–
d4T 30	608	612	611	152 000	119 000	94 000
d4t 30 3TC 150 (60 tab)	5 441	4 800	4 246	54 000	51 000	46 000
d4t 30 3TC 150 NVP 200	25 637	15 375	3 671	181 000	134 000	137 000
d4T 6 3TC 30	1741	4951	5018	30 000	12 000	5000
d4T 6 3TC 30 NVP 50	6173	2315	2298	11 000	–	8000
ddI 125	14	100	103	12 000	1000	1000
ddI 200	88	723	728	27 000	8000	–
ddI 25	11	1341	1338	12 000	2000	1000
ddI EC 250	256	1903	1899	3000	3000	2000
ddI EC 400	348	2778	2772	3000	3000	3000
DRV 300	863	13 956	14 771	–	–	–
DRV 600	24	601	236	–	–	–
EFV 200	50 434	165 775	206 295	429 000	436 000	447 000

Product	SCMS and Global Fund ARV formulation data (person-years)			CHAI ARV formulation data (person-years)		
	2014	2015	2016	2014	2015	2016
EFV 600	505 292	796 823	819 935	1 541 000	1 774 000	1 899 000
ETV 100	18	1403	1331	–	–	–
ETV 200	11	–	16	–	–	–
IDV 400	9	13	15	–	–	–
LPV/r 100/25	10 432	43 514	46 934	70 000	58 000	49 000
LPV/r 200/50	138 845	343 781	314 764	288 000	302 000	315 000
LPV/r(80/20mg/ml) 60ml	37 015	36 367	34 290	14 000	17 000	10 000
NVP 10mg/ml 100ml	4 004	28 342	28 387	–	–	–
NVP 10mg/ml 240ml	3978	6573	6380	–	–	–
NVP 200	629 754	533 298	543 943	2 066 000	2 246 000	2 346 000
NVP 50	5734	20 016	22 726	72 000	6000	6000
RAL 400	437	668	881	–	–	–
RTV 100 (60 tab)	1779	6407	7217	–	–	–
SQV 200	184	184	184	–	–	–
SQV 500	85	190	370	–	–	–
TDF 150	3515	6021	4498	–	–	–
TDF 200	3 847	3 983	23 384	–	–	–
TDF 250	–	–	–	–	–	–
TDF 300	10 841	28 858	35 448	935 000	1 023 000	1 077 000
TDF 300 3TC 300	741 249	562 279	592 534	1 711 000	2 047 000	2 196 000
TDF 300 3TC 300 + ATV/r copack	1568	2566	1752	–	–	–
TDF 300 3TC 300 EFV 600	1 501 213	5 412 014	6 248 452	1 754 000	2 705 000	3 625 000
TDF 300 3TC 300 NVP 600	–	–	–	–	–	–
TDF 300 FTC 200	740 466	498 791	528 771	221 000	199 000	208 000
TDF 300 FTC 200 EFV 600	74 310	439 488	950 135	2 141 000	2 383 000	2 753 000
TDF 300 3TC 300 NVP 200	–	12 329	12 329	–	–	–

While the discrepancies between the two datasets are obvious. We believe that, where trends in the uptake of different formulations go in the same direction, it provides assurance that their demand will increase in the near future. Both datasets concur in their assessment that demand for TLE, TEE, EFV 600mg and ATV/r 300/100mg will grow quickly and that demand for d4T containing products will decrease further.

4. DISCUSSION

The approach outlined in this report builds on previous annual forecasts by providing an average of projections, API market share and formulations from multiple sources that include the WHO ARV survey, ministries of health, procurement data and regional estimates. This process improves on the methodologies to estimate the number of adults and children on treatment, the proportion of people on first- and second-line therapies, and the distribution of adult and paediatric patients on different ARV medicines, as well as on demand projections for adult and paediatric formulations. More importantly, the trend in the number of people on treatment continues to grow annually despite flat-lined or reduced international funding with the likelihood that the target of 15million people on treatment by 2015 will be met or exceeded. However, it is important to note that the annual growth rate for paediatric patients continues to lag behind that of adult patients. As new initiatives, such as WHO's 2013 consolidated treatment guidelines and PEPFAR's Accelerating Children's HIV/AIDS Treatment (ACT) are being adopted or scaled up, the expectation is that there will be an increase in the growth rate of paediatric ARVs.

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ANNEX 1

Table A1. Projected number of people receiving ART by region based on the average of linear and country target projections, 2014–2018

Region	Age group	Projected number of people receiving ART by region based on the average of linear and country target projections				
		2014	2015	2016	2017	2018
Sub-Saharan Africa	Adults	10 800 000	12 900 000	15 000 000	17 000 000	18 900 000
	Children	820 000	900 000	1 000 000	1 220 000	1 350 000
Latin America and Caribbean	Adults	1 000 000	1 200 000	1 400 000	1 400 000	1 500 000
	Children	30 000	32 000	35 000	41 000	44 000
Eastern Mediterranean	Adults	42 000	53 000	61 000	69 000	77 000
	Children	1 800	2 000	2 400	2 800	3 100
Europe	Adults	350 000	420 000	500 000	560 000	640 000
	Children	13 000	14 000	16 000	19 000	21 000
South and South-East Asia	Adults	1 100 000	1 300 000	1 500 000	1 600 000	1 800 000
	Children	63 000	72 000	81 000	94 000	100 000
Western Pacific	Adults	800 000	930 000	1 000 000	1 100 000	1 300 000
	Children	37 000	41 000	45 000	52 000	57 000

Table A2. Number of women receiving ARV drugs for PMTCT by region, based on the average of linear and country target projections, 2014–2018

Region	Projected number of women receiving drugs for PMTCT based on the average of linear and country target projections				
	2014	2015	2016	2017	2018
Sub-Saharan Africa	1 400 000	1 600 000	1 800 000	2 000 000	2 200 000
Latin America and Caribbean	34 000	40 000	46 000	52 000	59 000
Eastern Mediterranean	8 000	10 000	12 000	14 000	16 000
Europe	20 000	22 000	23 000	25 000	27 000
South and South-East Asia	57 000	69 000	82 000	94 000	106 000
Western Pacific	13 000	15 000	17 000	20 000	22 000

Table A3. Volume of demand for APIs in person-years: linear projection, 2014–2018

Drug	Demand for APIs (person-years) based on the linear projection				
	2014	2015	2016	2017	2018
d4T	357 000	269 000	181 000	230 000	322 000
AZT	4 900 000	5 200 000	5 400 000	5 600 000	6 300 000
TDF	6 200 000	8 400 000	10 700 000	12 600 000	13 900 000
ABC	296 000	359 000	420 000	537 000	616 000
ddI	132 000	155 000	188 000	219 000	246 000
3TC	9 500 000	10 900 000	12 400 000	13 000 000	12 400 000
FTC	2 000 000	2 200 000	2 200 000	3 200 000	5 000 000
NVP	4 900 000	4 800 000	4 500 000	4 600 000	5 100 000
EFV	5 900 000	7 800 000	9 600 000	11 000 000	11 900 000
LPV	560 000	619 000	653 000	828 000	918 000
ATV	144 000	224 000	309 000	278 000	317 000
RTV	704 000	800 000	1 000 000	1 100 000	1 200 000

Table A4. Volume of demand for APIs in person-years: country target projection, 2014–2018

Drug	Demand for APIs (person-years) based on the country target projection				
	2014	2015	2016	2017	2018
d4T	418 000	354 000	257 000	347 000	514 000
AZT	5 600 000	6 800 000	7 600 000	8 400 000	10 000 000
TDF	7 000 000	10 700 000	14 700 000	18 400 000	21 300 000
ABC	371 000	527 000	653 000	947 000	1 188 000
ddI	151 000	204 000	267 000	346 000	406 000
3TC	10 700 000	14 000 000	17 000 000	18 800 000	18 900 000
FTC	2 300 000	2 800 000	3 000 000	4 500 000	7 500 000
NVP	5 600 000	6 300 000	6 300 000	6 800 000	8 000 000
EFV	6 700 000	9 900 000	13 000 000	15 700 000	17 800 000
LPV	650 000	834 000	934 000	1 287 000	1 527 000
ATV	163 000	288 000	422 000	407 000	496 000
RTV	813 000	1 100 000	1 400 000	1 700 000	2 000 000

Table A5. Volume of demand for APIs in person-years: CHAI projection, 2014–2018

Drug	Demand for APIs (person-years) based on CHAI patient projection				
	2014	2015	2016	2017	2018
d4T	537 000	441 000	418 000	405 000	351 000
AZT	4 000 000	4 200 000	4 400 000	4 500 000	4 700 000
TDF	6 900 000	8 600 000	10 100 000	11 500 000	12 400 000
ABC	9 121 000	10 607 000	11 924 000	13 051 000	13 941 000
ddI	2 371 000	2 610 000	3 009 000	3 376 000	3 538 000
3TC	5 000 000	5 100 000	5 200 000	5 300 000	5 300 000
FTC	6 000 000	7 600 000	9 100 000	10 400 000	11 400 000
NVP	100 000	100 000	200 000	300 000	400 000
EFV	400 000	400 000	400 000	500 000	500 000
LPV	477 000	561 000	653 000	749 000	843 000
ATV	537 000	441 000	418 000	405 000	351 000
RTV	4 000 000	4 200 000	4 400 000	4 500 000	4 700 000

Table A6. Volume of demand for APIs in metric tonnes: linear projection, 2014–2018

Drug	Demand for APIs (metric tonnes) based on the linear projection				
	2014	2015	2016	2017	2018
d4T	7	5	4	5	6
AZT	961	1094	1150	1201	1243
TDF	674	908	1150	1356	1498
ABC	37	45	54	65	74
ddI	13	16	20	23	26
3TC	975	1116	1278	1337	1288
FTC	147	159	161	230	362
NVP	660	641	596	603	675
EFV	1254	1645	2023	2327	2524
LPV	133	138	144	183	204
ATV	16	24	33	30	34
RTV	39	45	52	63	71

Table A7. Volume of demand for APIs in metric tonnes: country target projection, 2014–2018

Drug	Demand for APIs (metric tonnes) based on country target projection				
	2014	2015	2016	2017	2018
d4T	8	7	5	7	10
AZT	968	1259	1515	1706	1886
TDF	756	1159	1585	1980	2295
ABC	44	62	79	108	131
ddI	15	21	28	36	42
3TC	1092	1420	1733	1907	1920
FTC	164	201	218	325	536
NVP	740	816	810	866	1016
EFV	1401	2084	2733	3304	3745
LPV	151	178	196	264	306
ATV	18	31	45	44	53
RTV	44	58	71	93	112

Table A8. Volume of demand for APIs in metric tonnes based on CHAI projection, 2014–2018

Drug	Volume of demand for APIs metric (tonnes): CHAI based on patient projection				
	2014	2015	2016	2017	2018
d4T	12	10	9	9	8
ZDV	857	902	944	981	1010
TDF	747	925	1093	1237	1341
3TC	852	985	1146	1288	1410
FTC	107	171	188	217	243
NVP	719	736	751	761	760
EFV	1303	1632	1961	2247	2454
LPV	117	123	129	135	139
ATV	8	15	22	30	39
RTV	32	36	40	44	48

Table A9. Volume of demand for APIs in metric tonnes in sub-Saharan Africa based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in sub-Saharan Africa				
	2014	2015	2016	2017	2018
d4T	6	5	3	5	7
AZT	703	951	1082	1177	1267
TDF	573	831	1099	1339	1517
ABC	20	26	31	42	50
ddI	5	6	7	9	10
3TC	831	1035	1240	1342	1330
FTC	125	147	156	230	372
NVP	573	602	583	610	702
EFV	1085	1539	1968	2334	2597
LPV	82	91	97	126	146
ATV	9	15	20	18	20
RTV	24	28	32	39	45

Table A10. Volume of demand for APIs in metric tonnes in Latin America and the Caribbean based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in Latin America and the Caribbean				
	2014	2015	2016	2017	2018
d4T	0.3	0.3	0.2	0.3	0.4
AZT	44	54	60	65	68
TDF	34	50	65	77	88
ABC	13	17	22	27	31
ddI	6	8	11	13	15
3TC	49	52	56	63	65
FTC	8	7	7	11	19
NVP	28	29	29	31	38
EFV	52	73	99	120	139
LPV	27	31	32	41	42
ATV	5	7	10	11	14
RTV	8	12	15	20	23

Table A11. Volume of demand for APIs in metric tonnes in the Eastern Mediterranean based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in the Eastern Mediterranean				
	2014	2015	2016	2017	2018
d4T	0	0	0	0	0
AZT	13	4	4	5	5
TDF	2	4	5	6	7
ABC	1	1	2	2	2
ddI	0.3	0.4	0.6	0.7	0.8
3TC	3	4	5	6	6
FTC	1	1	1	1	2
NVP	2	2	3	3	3
EFV	4	6	8	9	10
LPV	1	1	1	2	2
ATV	0	0	0	0	0
RTV	0	0	0	0.5	0.5

Table A12. Volume of demand for APIs in metric tonnes in Europe based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in Europe				
	2014	2015	2016	2017	2018
d4T	0.2	0.1	0.1	0.1	0.2
AZT	38	26	30	32	35
TDF	16	24	31	38	43
ABC	6	8	11	13	16
ddI	3	4	5	6	7
3TC	23	28	32	34	33
FTC	4	4	5	6	9
NVP	12	13	13	13	16
EFV	24	32	42	51	58
LPV	14	18	22	31	39
ATV	2	3	5	5	5
RTV	4	6	8	12	15

Table A13. Volume of demand for APIs in metric tonnes in South and South-East Asia based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in South and South-East Asia				
	2014	2015	2016	2017	2018
d4T	0.6	0.5	0.4	0.6	0.8
AZT	132	104	114	127	139
TDF	65	90	121	150	174
ABC	1	1	2	3	3
ddI	0.1	0.1	0.1	0.1	0.1
3TC	93	105	120	125	120
FTC	14	15	16	22	34
NVP	64	61	56	56	64
EFV	122	156	192	219	239
LPV	8	9	9	11	11
ATV	1	2	3	3	3
RTV	3	3	3	3	4

Table A14. Volume of demand for APIs in metric tonnes in the Western Pacific based on the average of linear and country target projections, 2014–2018

Drug	Volume of demand for APIs (metric tonnes) in the Western Pacific				
	2014	2015	2016	2017	2018
d4T	0.3	0.3	0.2	0.2	0.3
AZT	43	36	42	47	51
TDF	23	35	48	59	68
ABC	1	1	1	2	2
ddI	0.2	0.3	0.4	0.5	0.6
3TC	33	41	48	52	51
FTC	5	6	6	9	15
NVP	21	22	20	21	25
EFV	40	56	70	81	92
LPV	9	10	11	15	17
ATV	1	2	3	3	3
RTV	3	3	4	4	5

Table A15. CHAI ARV formulation projections in person-years, 2014–2016

Product	2014	2015	2016
3TC 10 mg/ml	76 644	74 082	74 780
3TC 150	694 472	706 521	732 020
3TC 300	696 191	746 490	766 654
ABC 20 mg/ml	82 061	99 955	111 113
ABC 300	48 254	43 852	43 406
ABC 300 3TC 150 AZT 300	–	–	–
ABC 300 3TC 300	–	–	–
ABC 60	16 000	3000	4000
ABC 60 3TC 30	–	–	–
ABC 60 3TC 30 dispersible	37 000	32 000	30 000
ABC 600 3TC 300	17 302	15 641	13 622
ATV 150	–	–	–
ATV 200	–	–	–
ATV 300	–	–	–
ATV/r 300/100	71 000	131 000	197 000

AZT 10 mg/ml	–	–	–
AZT 100	–	–	–
AZT 300	266 000	277 000	294 000
AZT 300 3TC 150	967 000	1 072 000	1 176 000
AZT 300 3TC 150 EFV 600	–	–	–
AZT 300 3TC 150 NVP 200	1 979 000	1 919 000	1 859 000
AZT 60 3TC 30	6000	2000	5000
AZT 60 3TC 30 NVP 50	41 000	49 000	36 000
d4T 12 3TC 60	–	–	–
d4T 12 3TC 60 NVP 100	–	–	–
d4T 15	–	–	–
d4T 20	–	–	–
d4T 30	152 000	119 000	94 000
d4t 30 3TC 150 (60 tab)	54 000	51 000	46 000
d4t 30 3TC 150 NVP 200	181 000	134 000	137 000
d4T 6 3TC 30	30 000	12 000	5000
d4T 6 3TC 30 NVP 50	11 000	–	8000
ddI 125	12 000	1000	1000
ddI 200	27 000	8000	–
ddI 25	12 000	2000	1000
ddI EC 250	3000	3000	2000
ddI EC 400	3000	3000	3000
DRV 300	–	–	–
DRV 600	–	–	–
EFV 200	429 000	436 000	447 000
EFV 50	–	–	–
EFV 600	1 541 000	1 774 000	1 899 000
ETV 100	–	–	–
ETV 200	–	–	–
IDV 400	–	–	–
LPV/r 100/25	70 000	58 000	49 000
LPV/r 200/50	288 000	302 000	315 000
LPV/r(80/20mg/ml) 60ml	14 000	17 000	10 000
NVP 10mg/ml 100ml	–	–	–
NVP 10mg/ml 240ml	–	–	–
NVP 200	2 066 000	2 246 000	2 346 000

NVP 50	72 000	6000	6000
RAL 400	–	–	–
RTV 100 (60 tab)	–	–	–
SQV 200	–	–	–
SQV 500	–	–	–
TDF 150	–	–	–
TDF 200	–	–	–
TDF 250	–	–	–
TDF 300	935 000	1 023 000	1 077 000
TDF 300 3TC 300	1 711 000	2 047 000	2 196 000
TDF 300 3TC 300 + ATV/r copack	–	–	–
TDF 300 3TC 300 EFV 600	1 754 000	2 705 000	3 625 000
TDF 300 3TC 300 NVP 600	–	–	–
TDF 300 FTC 200	221 000	199 000	208 000
TDF 300 FTC 200 EFV 600	2 141 000	2 383 000	2 753 000
TDF 300 3TC 300 NVP 200			

Table A16. Global Fund ARV formulation projections in person-years, 2015–2016

Product	2015	2016
3TC 10 mg/ml	2283	2283
3TC 150	12 329	12 329
3TC 300	–	–
ABC 20 mg/ml	178	178
ABC 300	16 438	16 438
ABC 300 3TC 150 AZT 300	3699	3699
ABC 300 3TC 300	–	–
ABC 60	2466	2466
ABC 60 3TC 30	–	–
ABC 60 3TC 30 dispersible	32 877	32 877
ABC 600 3TC 300	–	–
ATV 150	1644	1644
ATV 200	4932	4932
ATV 300	4932	4932
ATV/r 300/100	80 548	100 685
AZT 10 mg/ml	6575	6575

AZT 100	5479	5479
AZT 300	12 329	12 329
AZT 300 3TC 150	410 959	410 959
AZT 300 3TC 150 EFV 600	8219	8219
AZT 300 3TC 150 NVP 200	863 014	863 014
AZT 60 3TC 30	45 205	45 205
AZT 60 3TC 30 NVP 50	133 562	133 562
d4T 12 3TC 60	–	–
d4T 12 3TC 60 NVP 100	–	–
d4T 15	–	–
d4T 20	–	–
d4T 30	–	–
d4t 30 3TC 150 (60 tab)	1849	1849
d4t 30 3TC 150 NVP 200	1233	1233
d4T 6 3TC 30	4110	4110
d4T 6 3TC 30 NVP 50	2055	2055
ddI 125	82	82
ddI 200	658	658
ddI 25	1315	1315
ddI EC 250	1644	1644
ddI EC 400	2466	2466
DRV 300	13 151	13 151
DRV 600	82	82
EFV 200	73 973	73 973
EFV 50	3082	3082
EFV 600	394 521	394 521
ETV 100	1233	1233
ETV 200	–	–
IDV 400	–	–
LPV/r 100/25	27 397	27 397
LPV/r 200/50	120 822	100 685
LPV/r(80/20mg/ml) 60ml	3082	3082
NVP 10mg/ml 100ml	23 014	23 014
NVP 10mg/ml 240ml	–	–
NVP 200	164 384	164 384
NVP 50	12 329	12 329

RAL 400	–	–
RTV 100 (60 tab)	4110	4110
SQV 200	–	–
SQV 500	–	–
TDF 150	–	–
TDF 200	–	–
TDF 250	–	–
TDF 300	16 438	16 438
TDF 300 3TC 300	139 726	139 726
TDF 300 3TC 300 + ATV/r copack	–	–
TDF 300 3TC 300 EFV 600	2 057 466	2 033 260
TDF 300 3TC 300 NVP 600	–	–
TDF 300 FTC 200	82 192	82 192
TDF 300 FTC 200 EFV 600	363 082	871 397
TDF 300 3TC 300 NVP 200	12 329	12 329

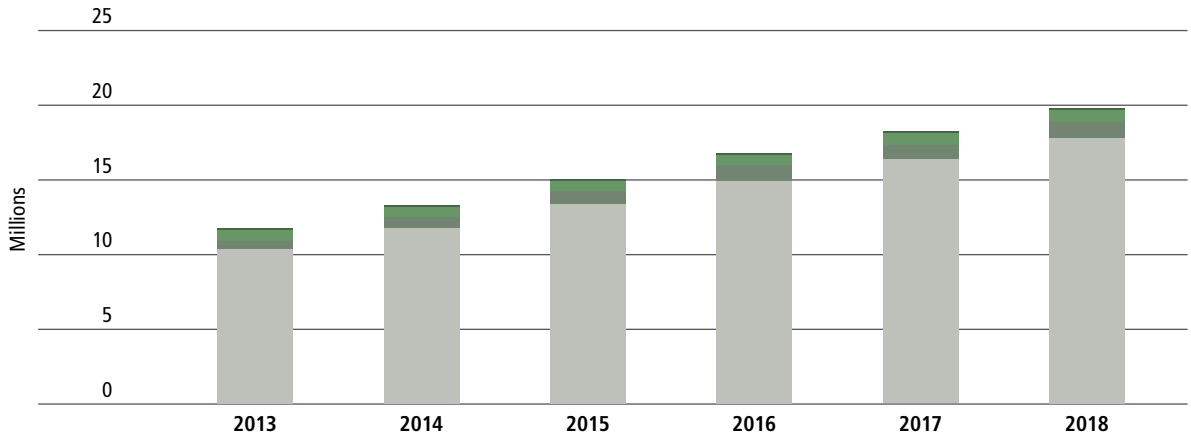
Table A17. SCMS ARV formulation projections in person-years, 2015–2016

Product	2014	2015	2016
3TC 10 mg/ml	1221	1238	1227
3TC 150	40 714	41 752	71 598
3TC 300	–	–	–
ABC 20 mg/ml	769	752	743
ABC 300	30 191	25 780	43 660
ABC 300 3TC 150 AZT 300	805	984	1 093
ABC 300 3TC 300	–	–	–
ABC 60	2294	2733	3097
ABC 60 3TC 30	32 616	36 519	52 428
ABC 60 3TC 30 dispersible	11 925	35 431	60 899
ABC 600 3TC300	49 869	70 037	84 809
ATV 150	12	28	31
ATV 200	157	321	360
ATV 300			
ATV/r 300/100	29 996	58 916	83 205
AZT 10 mg/ml	548	572	578
AZT 100	97	122	118

AZT 300	24 379	19 881	19 005
AZT 300 3TC 150	539 283	504 246	539 430
AZT 300 3TC 150 EFV 600	–	–	–
AZT 300 3TC 150 NVP 200	1 113 290	1 202 183	1 202 491
AZT 60 3TC 30	30 971	49 061	54 373
AZT 60 3TC 30 NVP 50	99 994	144 994	153 053
d4T 12 3TC 60	331	225	228
d4T 12 3TC 60 NVP 100	1935	1280	1196
d4T 15	1	–	–
d4T 20	5	3	3
d4T 30	608	612	611
d4t 30 3TC 150 (60 tab)	5441	2951	2397
d4t 30 3TC 150 NVP 200	25 637	14 142	2438
d4T 6 3TC 30	1741	841	908
d4T 6 3TC 30 NVP 50	6173	260	243
ddI 125	14	18	21
ddI 200	88	65	70
ddI 25	11	26	23
ddI EC 250	256	259	255
ddl EC 400	348	312	306
DRV 300	863	805	1620
DRV 600	24	519	154
EFV 200	50 434	91 802	132 322
EFV 50	1532	2562	5001
EFV 600	505 292	402 302	425 414
ETV 100	18	170	98
ETV 200	11	–	16
IDV 400	9	13	15
LPV/r 100/25	10 432	16 117	19 537
LPV/r 200/50	138 845	222 959	214 079
LPV/r(80/20mg/ml) 60ml	37 015	33 285	31 208
NVP 10mg/ml 100ml	4004	5328	5373
NVP 10mg/ml 240ml	3978	6573	6380
NVP 200	629 754	368 914	379 559
NVP 50	5734	7687	10 397
RAL 400	437	668	881

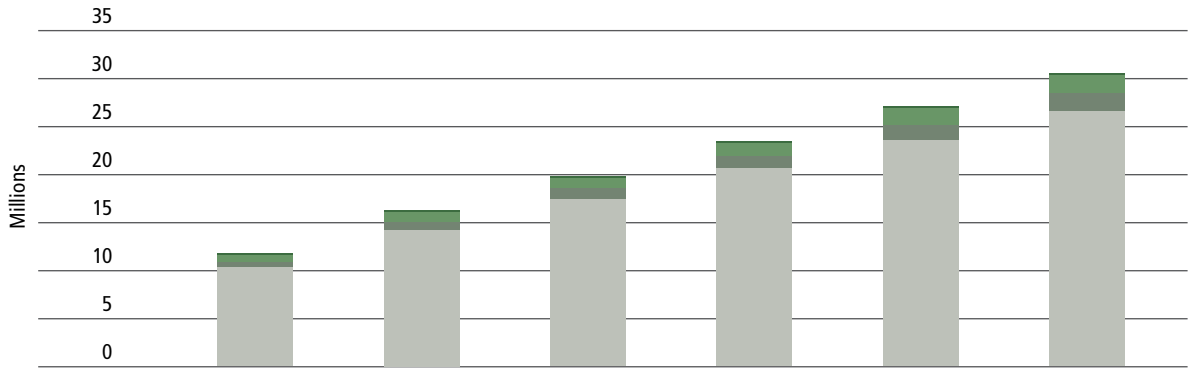
RTV 100 (60 tab)	1779	2297	3107
SQV 200	184	184	184
SQV 500	85	190	370
TDF 150	3515	6021	4498
TDF 200	3847	3983	23 384
TDF 250			
TDF 300	10 841	12 420	19 010
TDF 300 3TC 300	741 249	422 553	452 808
TDF 300 3TC 300 + ATV/r copack	1568	2566	1752
TDF 300 3TC 300 EFV 600	1 501 213	3 354 548	4 215 192
TDF 300 3TC 300 NVP 600	–	–	–
TDF 300 FTC 200	740 466	416 599	446 579
TDF 300 FTC 200 EFV 600	74 310	76 406	78 738
TDF 300 3TC 300 NVP 200	–	–	–

Fig. A1. Number of people receiving first- and second-line ART based on linear projection, 2013–2018



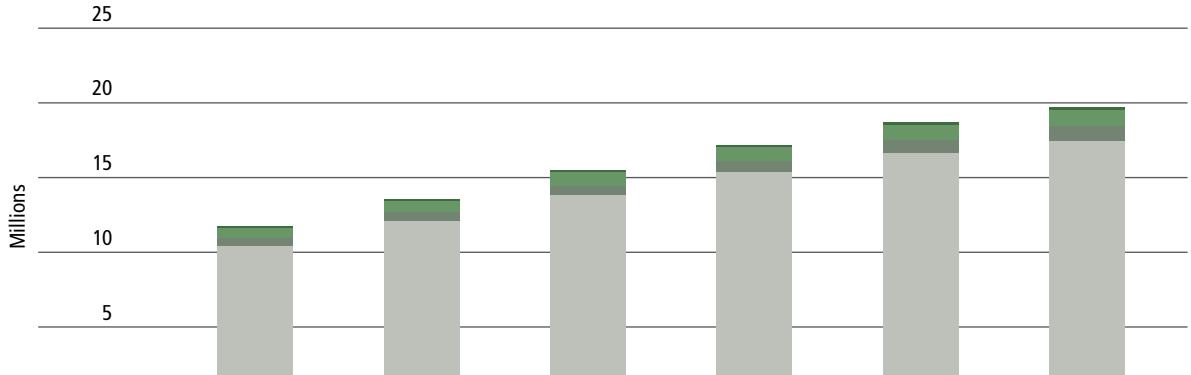
	2013	2014	2015	2016	2017	2018
Children SL	30 000	40 000	40 000	40 000	50 000	50 000
Children FL	710 000	700 000	750 000	800 000	840 000	880 000
Adult SL	560 000	740 000	860 000	980 000	970 000	1 100 000
Adult FL	10 400 000	11 800 000	13 400 000	15 000 000	16 400 000	17 800 000

Fig. A2. Number of people receiving first- and second-line ART based on country target projection, 2013–2018



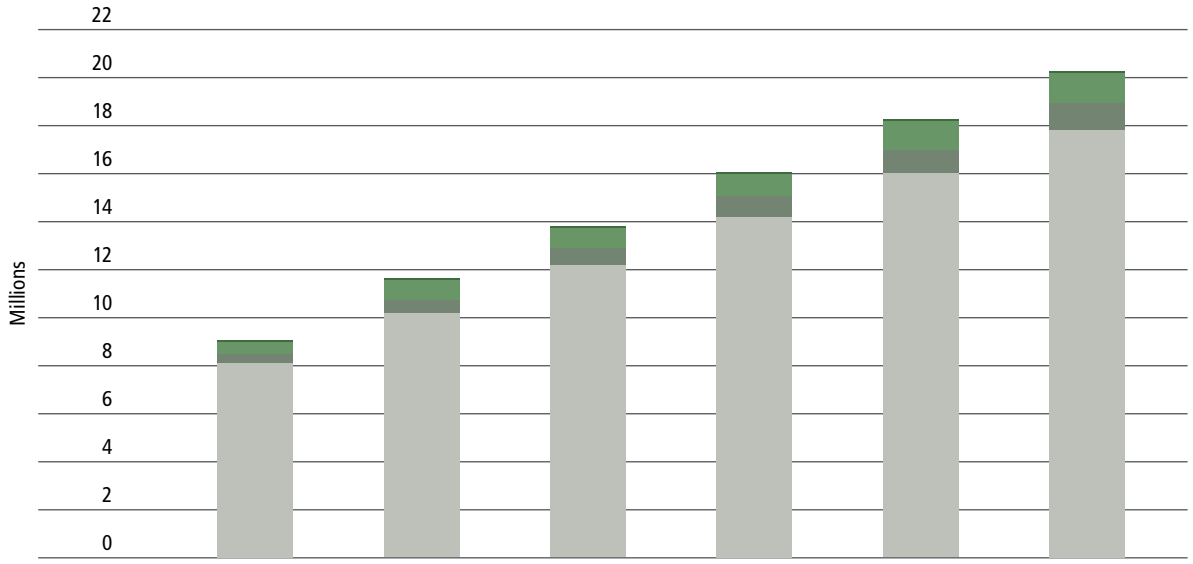
	2013	2014	2015	2016	2017	2018
Children SL	30 000	60 000	70 000	80 000	100 000	100 000
Children FL	700 000	1 100 000	1 200 000	1 400 000	1 800 000	2 000 000
Adult SL	560 000	90 000	1 100 000	1 300 000	1 600 000	1 800 000
Adult FL	10 400 000	14 200 000	17 500 000	20 700 000	23 600 000	26 700 000

Fig. A3. Number of people receiving first- and second-line ART based on CHAI data, 2013–2018



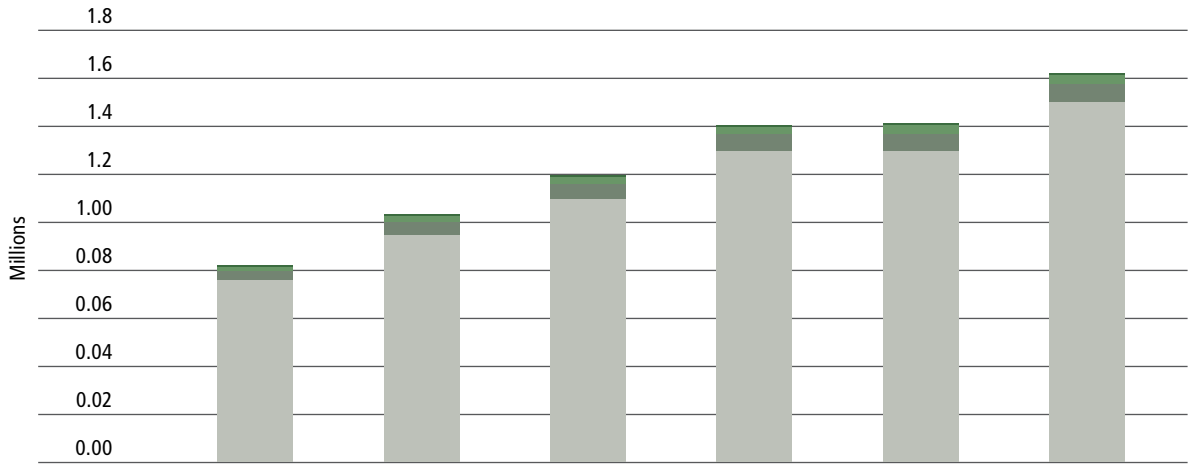
	2013	2014	2015	2016	2017	2018
Children SL	30 000	40 000	40 000	50 000	60 000	60 000
Children FL	700 000	800 000	900 000	900 000	1 000 000	1 100 000
Adult SL	600 000	600 000	700 000	800 000	900 000	1 000 000
Adult FL	10 400 000	12 100 000	13 800 000	15 400 000	16 700 000	17 500 000

Fig. A4. Number of people receiving first- and second-line ART in sub-Saharan Africa based on the average of linear and country target projections, 2013–2018



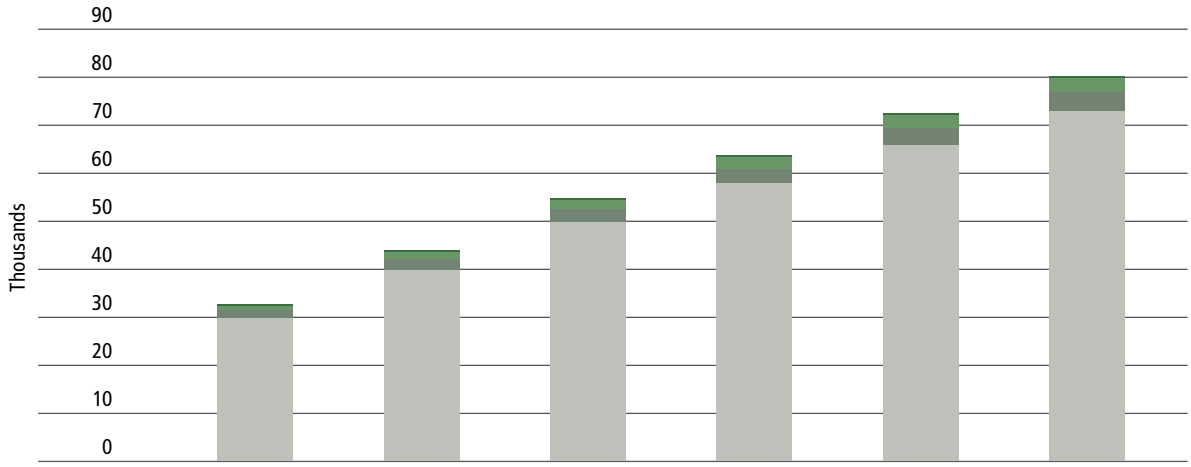
	2013	2014	2015	2016	2017	2018
Children SL	30 000	40 000	50 000	60 000	70 000	80 000
Children FL	490 000	780 000	850 000	940 000	1 200 000	1 300 000
Adult SL	430 000	560 000	690 000	830 000	970 000	1 100 000
Adult FL	8 100 000	10 200 000	12 200 000	14 200 000	16 000 000	17 800 000

Fig. A5. Number of people receiving first- and second-line ART in Latin America and the Caribbean based on the average of linear and country target projections, 2013–2018



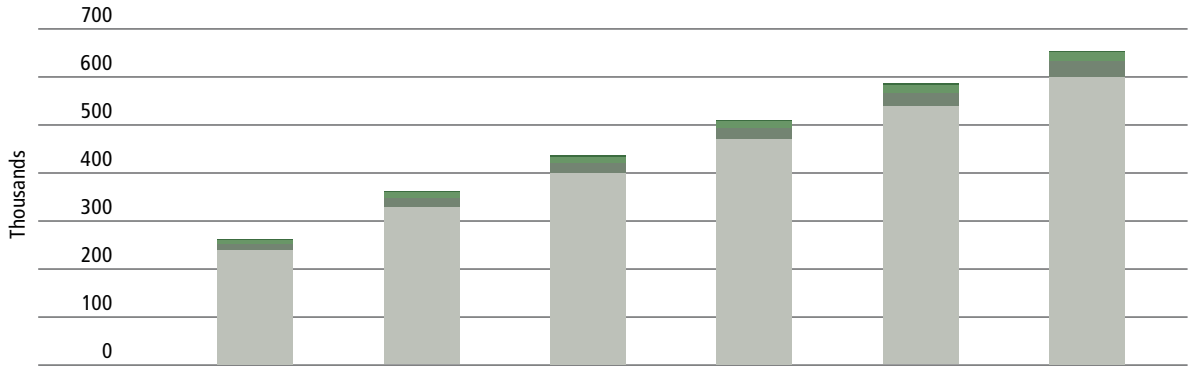
	2013	2014	2015	2016	2017	2018
Children SL	1 000	1 500	1 600	1 800	2 100	2 200
Children FL	19 000	29 000	30 000	33 000	39 000	42 000
Adult SL	40 000	50 000	60 000	68 000	70 000	77 000
Adult FL	760 000	950 000	1 100 000	1 300 000	1 300 000	1 500 000

Fig. A6. Number of people receiving first- and second-line ART in the Eastern Mediterranean based on the average of linear and country target projections, 2013–2018



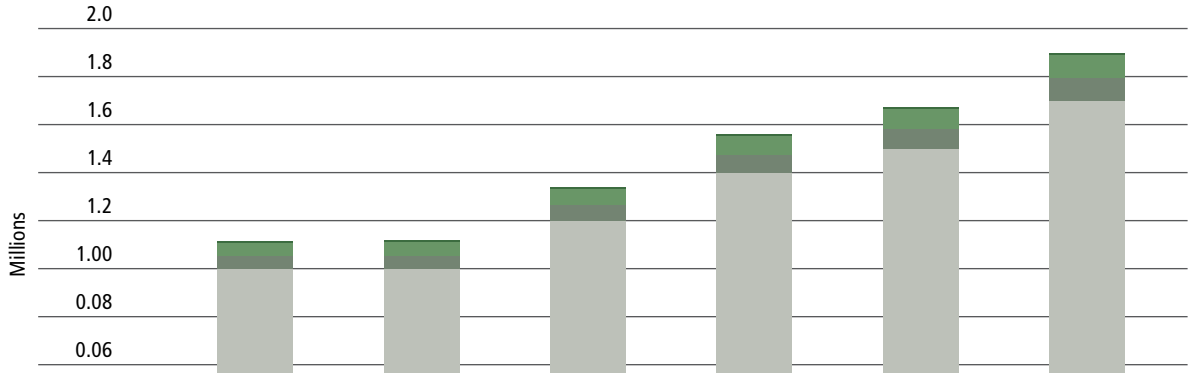
	2013	2014	2015	2016	2017	2018
Children SL	50	90	100	120	140	160
Children FL	1 000	1 700	1 900	2 300	2 700	2 900
Adult SL	1 600	2 100	2 700	3 100	3 500	3 900
Adult FL	30 000	40 000	50 000	58 000	66 000	73 000

Fig. A7. Number of people receiving first- and second-line ART in Europe based on the average of linear and country target projections, 2013–2018



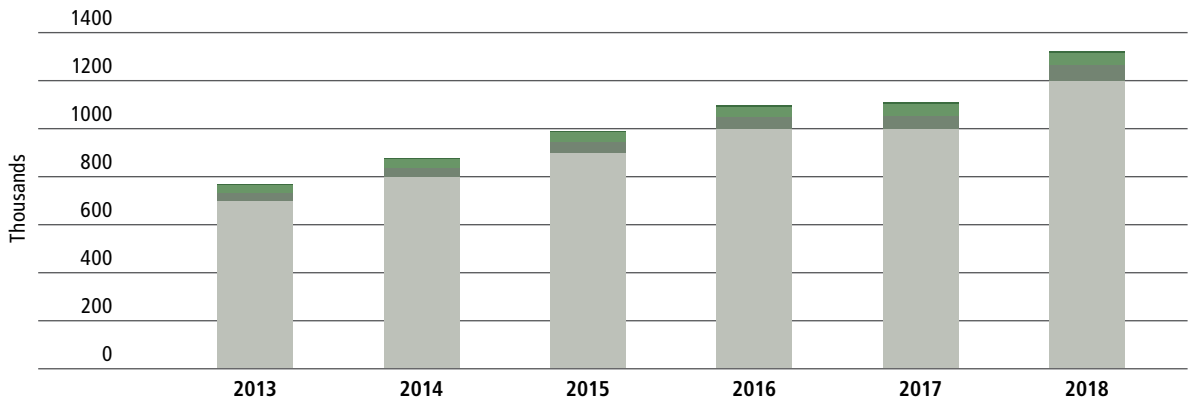
	2013	2014	2015	2016	2017	2018
Children SL	450	650	700	800	960	1 100
Children FL	8 600	12 000	13 000	15 000	18 000	20 000
Adult SL	13 000	18 000	21 000	25 000	28 000	32 000
Adult FL	240 000	330 000	400 000	470 000	540 000	600 000

Fig. A8. Number of people receiving first- and second-line ART in South and South-East Asia based on the average of linear and country target projections, 2013–2018



	2013	2014	2015	2016	2017	2018
Children SL	2 800	3 200	3 600	4 100	4 700	5 200
Children FL	52 000	60 000	68 000	77 000	89 000	99 000
Adult SL	55 000	55 000	65 000	75 000	80 000	90 000
Adult FL	1 000 000	1 000 000	1 200 000	1 400 000	1 500 000	1 700 000

Fig. A9. Number of people receiving first- and second-line ART in the Western Pacific based on the average of linear and country target projections, 2013–2018



	2013	2014	2015	2016	2017	2018
Children SL	1 700	1 900	2 100	2 300	2 600	2 900
Children FL	31 000	35 000	39 000	43 000	49 000	54 000
Adult SL	35 000	40 000	47 000	50 000	55 000	65 000
Adult FL	790 000	800 000	900 000	1 000 000	1 000 000	1 200 000

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