World Health Organization

TECHNICAL REPORT

AIDS MEDICINES AND DIAGNOSTICS SERVICE

COMBINED GLOBAL DEMAND FORECASTS FOR ANTIRETROVIRAL MEDICINES AND HIV DIAGNOSTICS IN LOW- AND MIDDLE-INCOME COUNTRIES FROM 2015 TO 2020

SEPTEMBER 2016

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PART I. GLOBAL DEMAND FORECASTS FOR ANTIRETROVIRAL MEDICINES IN LOW- AND MIDDLE-INCOME COUNTRIES FROM 2015 TO 2020

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ABBREVIATIONS AND ACRONYMS

3TC	lamivudine
ABC	abacavir
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
ddI	didanosine
DRV	darunavir
EFV	efavirenz
ETV	etravirine
FTC	emtricitabine
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRM	Global Price Reporting Mechanism
IDV	indinavir
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
PI	protease inhibitor
RAL	raltegravir
RTV	ritonavir
SCMS	Supply Chain Management System
SQV	saquinavir
TDF	tenofovir
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund

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EXECUTIVE SUMMARY

The number of people receiving antiretroviral therapy (ART) in low- and middle-income countries continues to show promising growth, indicating that the global effort to scale up HIV treatment has exceeded 15 million people by the end of 2015. As of the end of 2015, the number of people receiving ART had reached 15.9 million in low- and middle-income countries, indicating a stable annual growth rate of 1.8 million per year since 2012.

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 for 2015–2020. The report includes estimates of the global demand for both active pharmaceutical ingredients and ARV formulations to enable suppliers to manage their manufacturing capacity accordingly.

This report uses three forecasting approaches to project the demand for ART, expressed as the number of people receiving treatment from 2015 to 2020:

- the linear regression forecast extrapolates from the historical trends of the previous three years (2012, 2013 and 2014) in the number of people receiving ARV drugs;
- the country target model reflects the reported programme goals of national programmes; and
- the approach of the Clinton Health Access Initiative (CHAI) focuses on the experience of countries with high ARV medicine use for treating and preventing HIV infection.

Like the previous year, the above three projections and their average are compared to the Fast-Track projection, which assumes that, by 2020, 90% of all people living with HIV know their HIV status, 90% of the people who know their HIV-positive status are accessing treatment and 90% of the people receiving treatment have suppressed viral loads.

All three projections methods are based on the 2015 WHO survey on ARV drug use, and for the CHAI model, augmented by data from data specific to each of the 21 countries with high ART use.

The assumptions underlying the forecasts for demand for active pharmaceutical ingredients for 2015–2020 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 and 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 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 active pharmaceutical ingredients.

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 drug treatment was calculated based on the average of five sources of data: the 2015 WHO survey of ARV drug use, Global Price Reporting Mechanism procurement data, the Global Fund projected procurement for 2015 and 2016, Supply Chain Management System procurement data and CHAI's global ARV drug forecast.

For adults, 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); and
- protease inhibitors (PIs): ritonavir-boosted lopinavir (LPV/r) and ritonavir-boosted atazanavir (ATV/r).

For children, individual PIs were categorized under three market categories:

- NRTIs and NtRTIs: d4T, AZT, TDF and ABC;
- secondary NRTIs: 3TC and FTC; and
- NNRTIs and PIs: NVP, LPV/r and ATV/r.

Fig. 4–17 show the projections for the market for active pharmaceutical ingredients for adults and children.

In addition to providing estimated demand for active pharmaceutical ingredients, this report includes estimated demand for ARV drug formulations (in person-years) based on projected procurement data from the Supply Chain Management System and the Government of South Africa for 2016 to 2019 (Table 12).

The figures in this report are not meant to be definitive consumption of ARV drugs from 2015 to 2020; rather, they provide a range of possible demand for ARV drugs if current trends continue. The linear regression approach projects 25.3 million people receiving treatment by 2020, the CHAI forecast estimates 24.9 million, the country target approach projects 27 million and the Fast-Track projection estimates 26.1 million. The average projection of the first three approaches reaches 25.7 million by 2020. The following table shows the results for the number of people receiving ART, the proportion of people receiving first- and second-line therapy and the number of women living with HIV receiving ARV drugs for preventing mother-to-child transmission.

Number of adults and children receiving treatment (average scenario) and number of women receiving ARV drugs for preventing mother-to-child transmission, based on average of linear and country target projections (millions), 2015–2020

	2015	2016	2017	2018	2019	2020
Number of adults receiving ART (millions)	14.9 [14.6–15.6][a]	17.0 [16.4–17.9]	19.0 [18.3–20.1]	20.9 [20.1–22.2]	22.6 [21.8–23.9]	24.3 [23.6–25.4]
Number of children receiving ART (millions)	0.95 [0.84–1.1]	1.1 [0.93–1.3]	1.2 [1.0–1.4]	1.25 [1.1–1.5]	1.33 [1.21–1.53]	1.39 [1.3–1.58]
Number of people receiving ART (millions)	15.9 [15.4–16.7]	18.1 [17.3–19.2]	20.2 [19.3–21.5]	22.1 [21.2–23.7]	24.0 [23.0–25.4]	25.7 [24.9–26.7]
Proportion of people receiving first-line ART (%)	94.5	94.3	94.1	93.8	93.5	93.2
Proportion of people receiving second-line ART (%)	5.5	5.7	5.9	6.2	6.5	6.8
Number of women receiving ARV drugs for preventing mother-to-child transmission, based on average of linear and country target projections (millions)	1.5 [1.4–1.6]	1.65 [1.5–1.8]	1.75 [1.6–1.9]	1.85 [1.7–2.0]	1.95 [1.8–2.1]	2.05 [0.9–2.2]

[a] The 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 living with HIV who will be receiving antiretroviral therapy (ART) from 2015 to 2020;
- update the forecasts of global demand for antiretroviral (ARV) drugs prepared in 2014; and
- forecast the global and regional demand for individual ARV drugs from 2015 to 2020.

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 2013 to 2015 annual WHO surveys on the use of ARV drugs;
- the Global Price Reporting Mechanism of WHO;
- the quantification of ARV drugs for selected countries to be procured for 2016 by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund);
- the quantities of ARV drugs for 15 countries to be procured for 2015, 2016 and 2017 by the United States President's Emergency Plan for AIDS Relief (PEPFAR)–funded Supply Chain Management System project;
- the volumes of ARV drugs reported in the projection of ARV drug demand by the Clinton Health Access Initiative (CHAI); and
- the estimated number of people who need ART from the Fast-Track projection made by UNAIDS.

All these data were compiled and used to project the demand for ARV drugs from 2015 to 2020. The number of people receiving ART for future years has been forecast using three approaches:

- linear projections of historical numbers of people receiving ART by country;
- country target projections, 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 ARV drugs 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 proportions from three sources of data:
    - linear regression based on the WHO ARV use surveys conducted in 2013, 2014 and 2015, which assessed the use of ARV medicines at the end of 2012, 2013 and 2014 *(1–6)*;
    - linear extrapolation of the relative market share of protease inhibitors (PIs) for 2010–2014 from Global Price Reporting Mechanism procurement data; and
    - the CHAI projections for second-line therapy for 2014–2020;
- determine the distribution of ARV 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, Supply Chain Management System, Global Fund and Global Price Reporting Mechanism:
    - linear regression based on the WHO surveys of reported ARV use at the end of 2012, 2013 and 2014;
    - linear extrapolation of the relative market share of active pharmaceutical ingredients for 2010–2014 and part of 2014

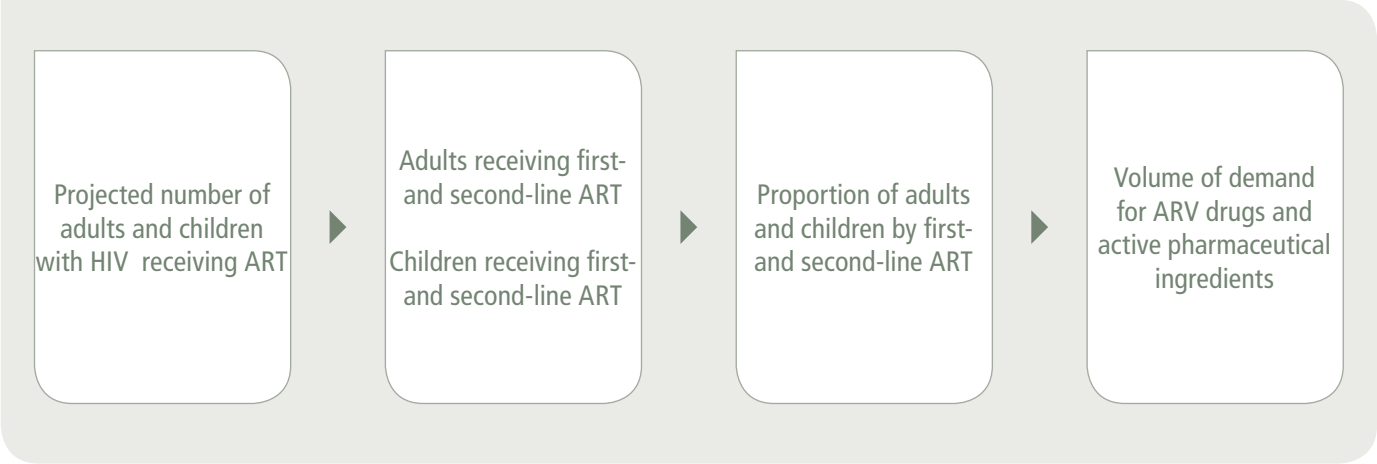
from Global Price Reporting Mechanism procurement data;

- CHAI projections of ARV drug market shares for 2015–2020;
- Global Fund procurement forecast for 2016; and
- Supply Chain Management System country forecasts of the number of people receiving ART and the regimen breakdown for 2015–2019;

- calculate the number of person-years of treatment for each ARV drug;
- calculate the total active pharmaceutical ingredient volumes required to meet the forecast demand for adults and children for each ARV drug; and
- calculate the number of adults and children receiving the most prescribed treatment regimens.

Fig. 1 illustrates the model used for forecasting ARV drug demand in this report. 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 active pharmaceutical ingredients for 2015–2020.

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 Reporting use the same indicator for the number of people receiving ART. Information in Global AIDS Response Progress Reporting is exported into the WHO global ARV drug use survey; 146 countries provided this information. Table 1 summarizes the underlying assumptions and data sources of the three approaches to forecasting the number of people receiving ART to 2020.

Table 1. 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 2015–2020	Global progress reports published annually by WHO, UNICEF and UNAIDS
Number of countries for which data are used	146 (WHO ARV drug use survey conducted in 2014)	35[a]	21 countries with high ART use[b]
Proportion of people living with HIV in low- and middle-income countries receiving treatment represented in the data set	99%	32% (extrapolated to the remaining 68% of low- and middle-income countries)[c]	Approximately 85% (extrapolated to the remaining 15% of people living with HIV in low- and middle-income countries)
Underlying assumption	The number of people living with HIV receiving ARV drugs will increase linearly at the same rate as the linear trend observed in 2012–2014, with the rate of increase limited by the number of people estimated to need treatment by 2020 using the 2015 WHO eligibility criteria	National programme planning targets will be achieved	The number of people living with HIV 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

[a] Argentina, Benin, Burkina Faso, Cambodia, Cabo Verde, Côte d'Ivoire, Cuba, Eritrea, Gabon, Georgia, Ghana, Honduras, Indonesia, Lao People's Democratic Republic, Lesotho, Madagascar, Malawi, Mali, Mozambique, Myanmar, Nicaragua, Niger, Oman, Panama, Poland, Republic of Moldova, Sierra Leone, Sri Lanka, Swaziland, Syrian Arab Republic, Uganda, Viet Nam, Zambia and Zimbabwe.

[b] Botswana, Brazil, Cameroon, China, Côte d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

[c] 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 living with HIV receiving ART for all low- and middle-income countries.

Table 2 and Fig. 2 present the three projection scenarios of the estimated number of people living with HIV receiving ART from 2015 to 2020 and the average of the three projections, together with the Fast-Track projection (see below). Table A1 (Annex 1) 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 in approach, except for the addition of women starting on ART through option B+ for preventing mother-to-child transmission 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 HIV treatment by 2020.

2.1.1 Linear projection

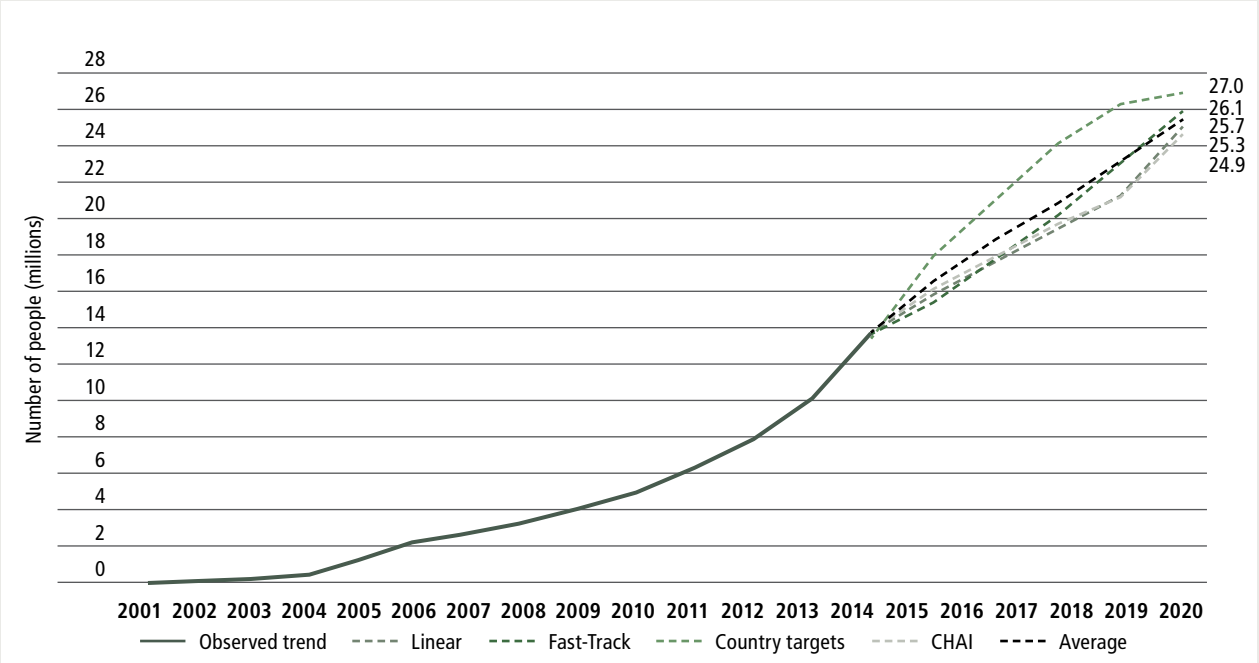
This forecast estimates the annual increase in the number of people living with HIV receiving treatment based on responses from the 146 countries mentioned in section 2.1, representing about 99% of the number of people receiving treatment in all 154 low- and middle-income countries. The survey data are then used to plot a linear regression line fitted to the number of adults and children receiving ART over the past three years (2012, 2013 and 2014), as reported in the reports on universal access to HIV prevention, treatment, care and support by WHO, UNAIDS and UNICEF *(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 total need for ART estimated by UNAIDS (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 cell count threshold for initiating treatment and the scale-up of treatment for prevention and option B+ for preventing mother-to-child transmission, the total number of people who need treatment is estimated to be 24.2 million by 2020. The linear approach is constrained by the estimated number of people who need ART projected for 2020 based on the 2013 WHO treatment recommendations.

Table 2. Number of adults and children living with HIV receiving treatment by scenario and average, 2015–2020

Forecasting method	Age group	2015	2016	2017	2018	2019	2020
Linear projection	Adults	14 770 000	16 630 000	18 490 000	20 350 000	22 210 000	24 050 000
	Children	890 000	980 000	1 070 000	1 160 000	1 250 000	1 300 000
	Total	15 660 000	17 610 000	19 560 000	21 510 000	23 460 000	25 350 000
Country target projection	Adults	15 590 000	17 910 000	20 110 000	22 230 000	23 890 000	25 400 000
	Children	1 120 000	1 280 000	1 370 000	1 480 000	1 530 000	1 580 000
	Total	16 710 000	19 190 000	21 480 000	23 710 000	25 420 000	26 980 000
CHAI projection	Adults	14 600 000	16 400 000	18 300 000	20 100 000	21 800 000	23 600 000
	Children	840 000	930 000	1 020 000	1 110 000	1 210 000	1 300 000
	Total	15 440 000	17 330 000	19 320 000	21 210 000	23 010 000	24 900 000
Fast-Track	Adults	14 570 000	16 730 000	18 850 000	20 900 000	22 880 000	24 680 000
	Children	840 000	930 000	1 040 000	1 160 000	1 290 000	1 440 000
	Total	15 410 000	17 660 000	19 890 000	22 060 000	24 170 000	26 120 000
Average (linear, country target and CHAI)	Adults	14 990 000	16 980 000	18 970 000	20 890 000	22 630 000	24 350 000
	Children	950 000	1 100 000	1 200 000	1 250 000	1 330 000	1 390 000
	Total	15 940 000	18 080 000	20 170 000	22 140 000	23 960 000	25 740 000

Fig. 2. Comparison of projections of the number of people receiving ART, 2001–2020



Since option B+ for preventing mother-to-child transmission[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. Table 6 in section 2.4 shows the number and proportion of pregnant women receiving various options for preventing mother-to-child transmission, including lifelong ART (option B+). This may overestimate the number of people receiving ART if some women receiving 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 2015–2020 country target projections, 35 country projections in successive global WHO ARV drug use surveys were used, accounting for about 32% of 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 35 countries. This equates to an average annual growth of nearly 700 000 people per year. We assume that the number of people receiving ART and the country target projections also account for the pregnant women who initiate lifelong ART through option B+.

2.1.3 CHAI projections

Each year, CHAI derives a five-year forecast of global demand for ARV drugs in low- and middle-income countries. The forecast is broken down into demand by regimen, country, first-line versus second-line, adults versus children and generic-accessible versus generic-inaccessible countries. The data input uses the total numbers in the progress reports published by WHO, UNAIDS and UNICEF as the baseline. The forecast assumes that the number of people receiving ART will increase at the same rate as the linear trend observed over the previous three years but plateauing as countries approach universal coverage of people living with HIV under the 2013 WHO guidelines. The ratio of people by regimen is evaluated based on data collected from CHAI country teams, national guidelines and historical uptake rates.

To arrive at a global forecast, CHAI applies this method 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, Myanmar, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

[1] Option B+ for preventing mother-to-child transmission means that pregnant women living with HIV initiate ART regardless of CD4 count.

2.1.4 Fast-Track projection

For comparison purposes, Table 1 and Fig. 2 also show the Fast-Track projection from UNAIDS *(7,8)*. This projection assumes that, by 2020, 90% of all people living with HIV know their HIV status, 90% of the people who know their HIV-positive status are accessing treatment and 90% of the people receiving treatment have suppressed viral loads. These projections and targets build on the 2015 WHO eligibility recommendations for ART. The Fast-Track projections were made using the Spectrum/Goals model applied to 28 high-burden countries, which account for over 85% of all people acquiring HIV infection, and the results are scaled up to represent all low- and middle-income countries. The model tracks the number of people newly infected over time by CD4 cell count, age and sex. It estimates the survival among people receiving ART as a function of CD4 cell 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 2012, 2013, 2014 and 2015 WHO surveys;
- linear regression of the proportion of the number of people receiving PIs based on the quantity of PIs reported by the Global Price Reporting Mechanism for 2012, 2013 and 2014 *(9)* and extrapolated using linear regression for 2020; and
- CHAI collecting data on the numbers of people receiving second-line treatment in 21 countries with high ART use from country teams and published literature. CHAI then estimates the future numbers of people receiving second-line treatment in each country by considering such factors as treatment failure rates and attrition rates. CHAI then aggregates the second-line estimates across the 21 countries and extrapolates these results to the people 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 people receiving treatment.

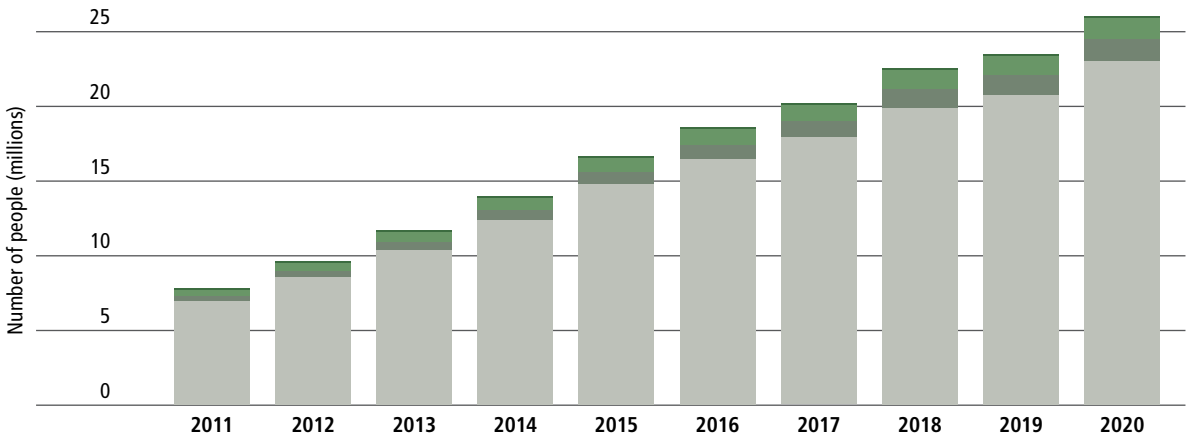
Table 3 shows the projected proportion of people receiving second-line therapy for each of the three data sources, which are within 1.5 percentage points of each other, as well as the average, which was used in estimating the demand for active pharmaceutical ingredients.

Table 3. Proportion of people receiving second-line ART

	Proportion of people receiving second-line ART (%)					
Data source	2013	2014	2015	2016	2017	2018
WHO AIDS Medicines and Diagnostics Service survey	5.9	6.0	6.1	6.3	6.4	6.6
Global Price Reporting Mechanism	5.8	5.9	6.5	7.1	7.8	8.4
CHAI	4.9	5.1	5.2	5.3	5.4	5.5
Average	5.5	5.7	5.9	6.2	6.5	6.8

The average proportions of people living with HIV receiving second-line therapy are then applied to the average number of adults and children receiving treatment as forecast for 2015–2020 (Table 2). Fig. 3 shows the number of adults and children receiving first- and second-line therapy. Fig. A1–A3 (Annex 1) show the number of adults and children receiving first- and second-line therapy for the linear, CHAI and country target scenarios.

Fig. 3. Number of adults and children living with HIV receiving first- and second-line ART, 2011–2020, based on the average of three projections



	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Children, second line	24 000	27 000	30 000	46 000	57 000	65 000	73 000	83 000	91 000	99 000
Children, first line	540 000	600 000	700 000	730 000	890 000	997 000	1 080 000	1 170 000	1 240 000	1 290 000
Adults, second line	340 000	440 000	600 000	690 000	820 000	950 000	1 080 000	1 220 000	1 350 000	1 480 000
Adults, first line	7 140 000	8 710 000	10 390 000	12 170 000	14 170 000	16 050 000	17 880 000	19 680 000	21 300 000	22 880 000

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 2016; Global Price Reporting Mechanism transaction data; Supply Chain Management System 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 adults and for children.

For adults, 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); and
- PIs: primarily ritonavir-boosted lopinavir (LPV/r) and ritonavir-boosted atazanavir (ATV/r).

For children, individual drugs were categorized by the following market categories:

- primary NRTIs and NtRTIs: d4T, AZT, TDF and ABC;
- secondary NRTIs: ddI and 3TC; and
- 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 2011 to 2014. 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 2015 to 2020 by country, a linear regression line was fitted to the reported ARV drug distribution from 2011 to 2014 projected to 2020 but constrained to be between 0% and 100%.

This method was applied to all PIs except indinavir, saquinavir and nelfinavir. It was assumed that, since these three ARV drugs will no longer be marketed, a negligible proportion of people receiving treatment will receive these by the end of 2016 and that the majority of people currently using these three drugs will be transitioned to LPV/r and ATV/r in a ratio of 9:1, based on current Global Price Reporting Mechanism data (that is, 90% are transitioned to LPV/r and 10% to ATV/r).

2.3.2 Observed procurement trends from the Global Price Reporting Mechanism database

Global procurement data reported in the Global Price Reporting Mechanism database were available for 2010, 2011, 2012, 2013, 2014 and 2015. 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.

2.3.3 Regimen distribution forecast by the Supply Chain Management System

The Supply Chain Management System supports or collaborates with PEPFAR, country health ministries 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 people 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[2] 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 drug 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 drug trends and other key factors in 21 countries with high ART use. 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 the people in the remaining low- and middle-income countries.

2.3.5 Regimen distribution forecast by the Global Fund

The Global Fund regimen distribution data were based on a procurement forecast based on procurement plans for approved grants in 54 countries (2014 projection)[3] and 24 countries (2015 and 2016 projection).[4]

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.

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

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

[4] Armenia, Burundi, Cabo 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, Timor-Leste, Uganda, United Republic of Tanzania and Viet Nam.

Fig. 4. Projected market share (%) of d4T for adults as a proportion of the volume of primary NRTIs for adults, 2011–2020

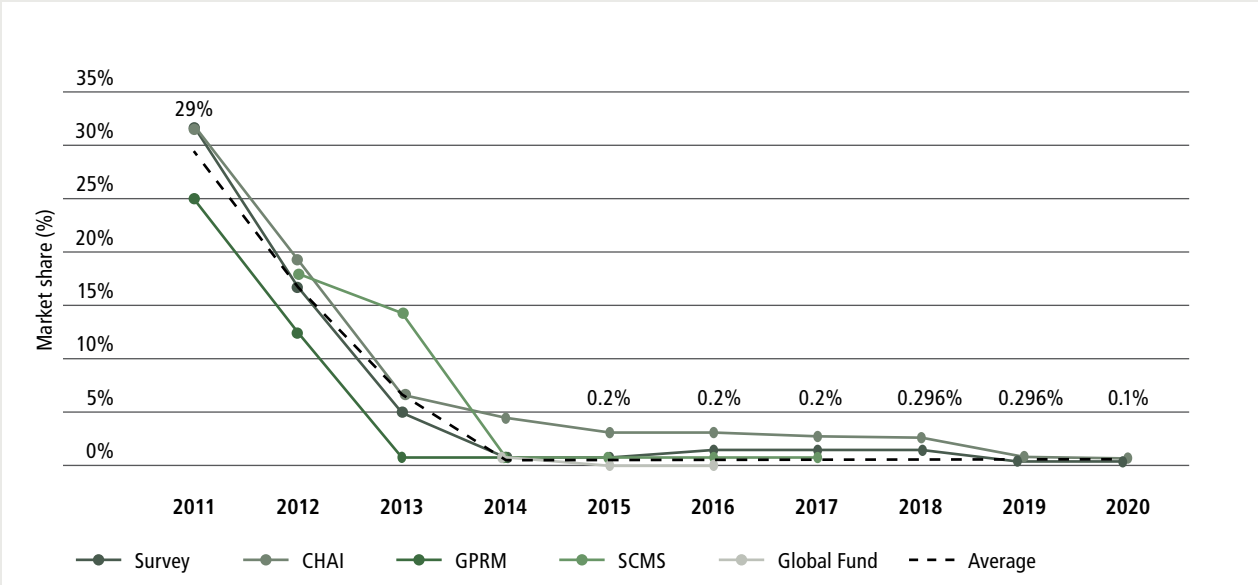


Fig. 5. Projected market share (%) of d4T for children as a proportion of the volume of primary NRTIs for children, 2011–2020

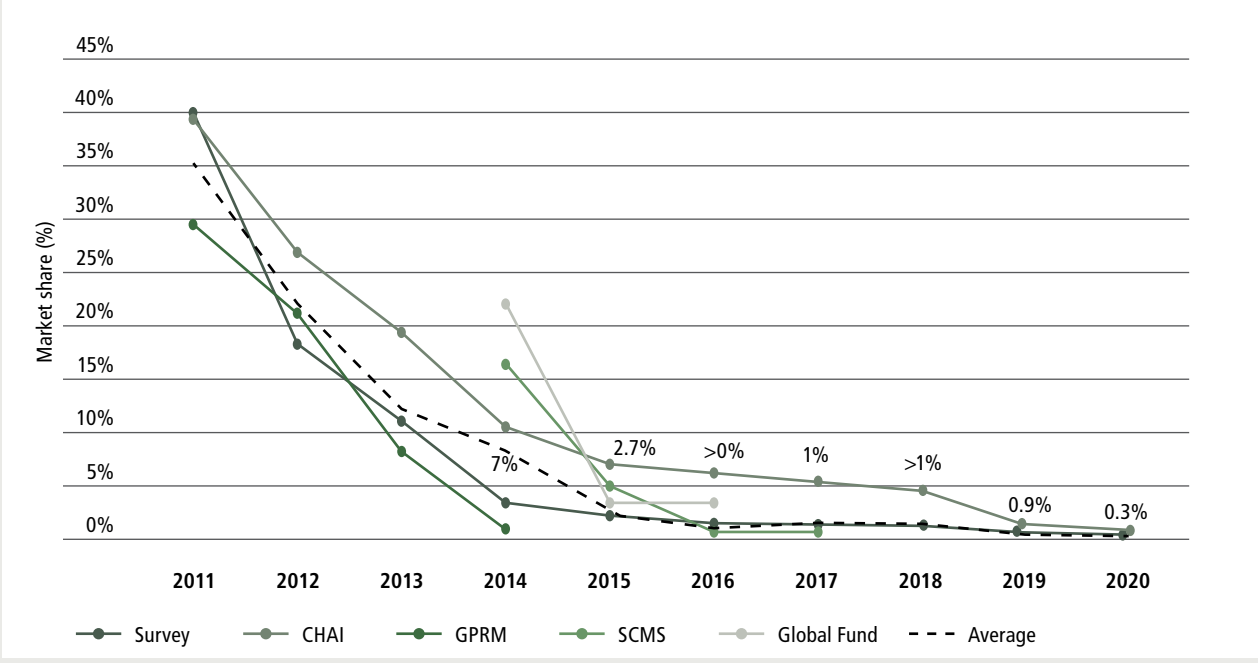


Fig. 6. Projected market share (%) of TDF for adults as a proportion of the volume of primary NRTIs for adults, 2011–2020

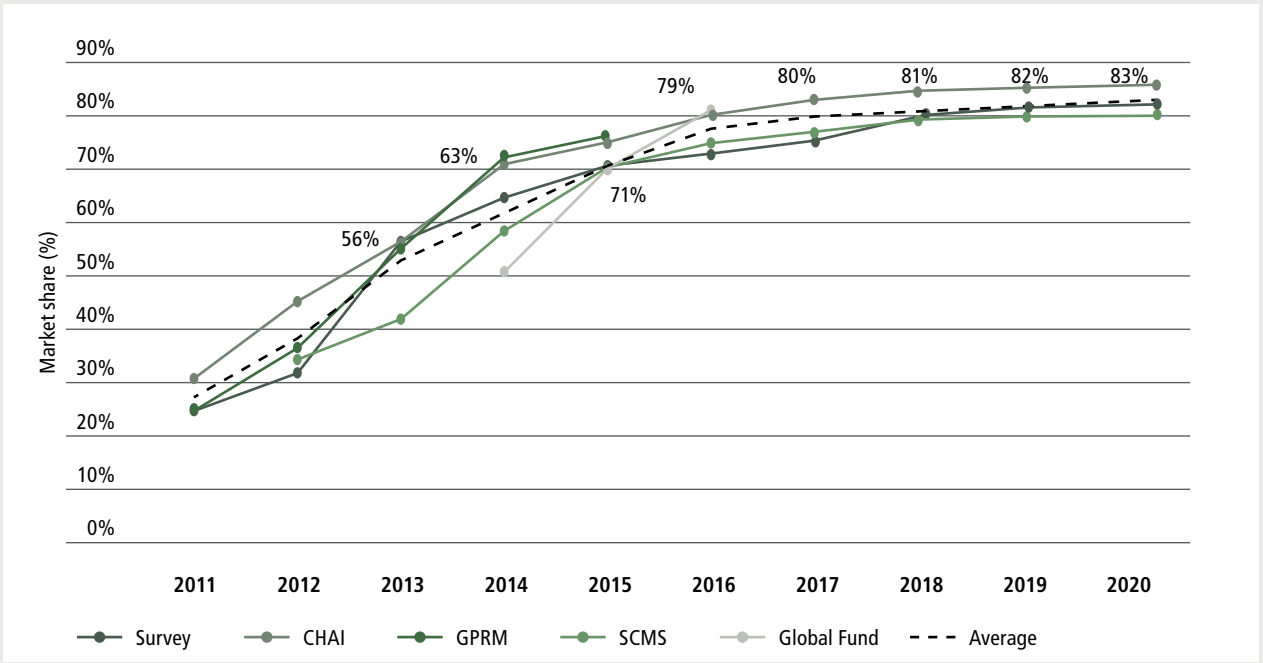


Fig. 7. Projected market share (%) of TDF for children as a proportion of the volume of primary NRTIs for children, 2011–2020

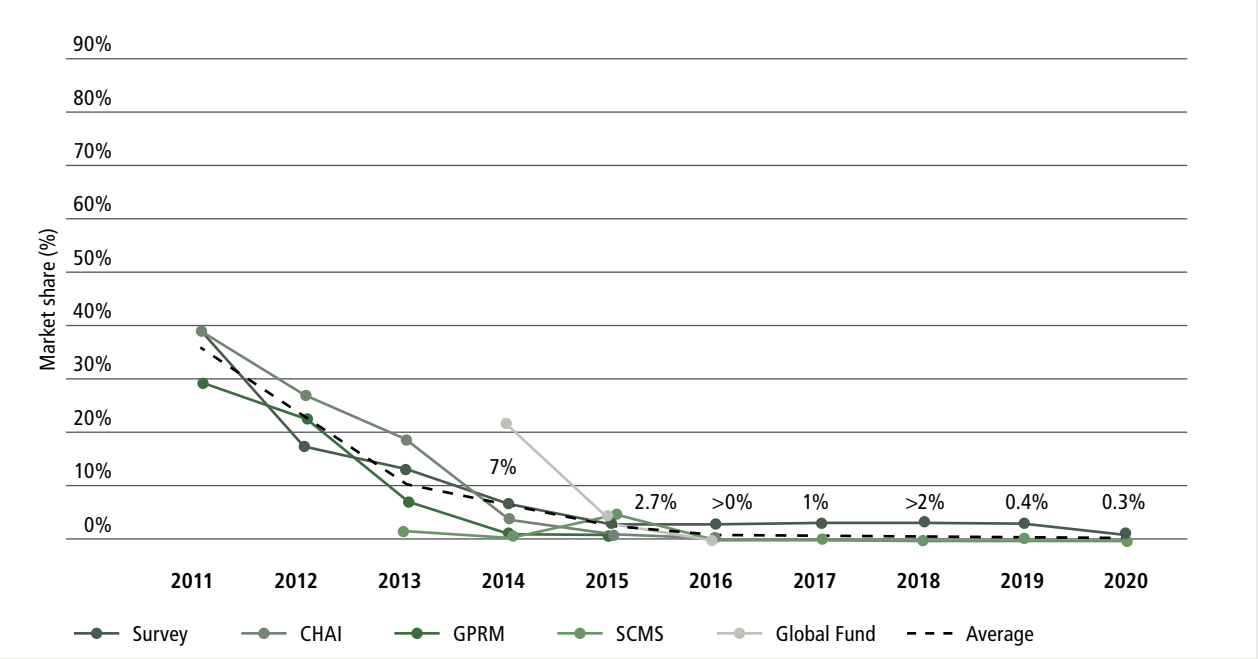


Fig. 8. Projected market share (%) of AZT for adults as a proportion of the volume of primary NRTIs for adults, 2011–2020

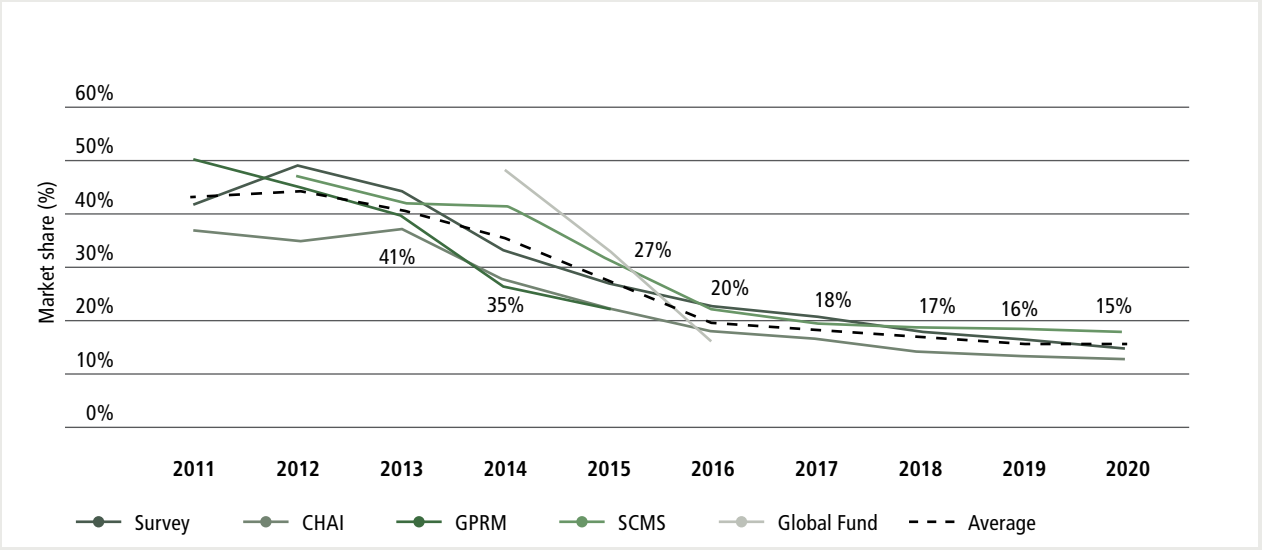


Fig. 9. Projected market share (%) of AZT for children as a proportion of the volume of primary NRTIs for children, 2011–2020

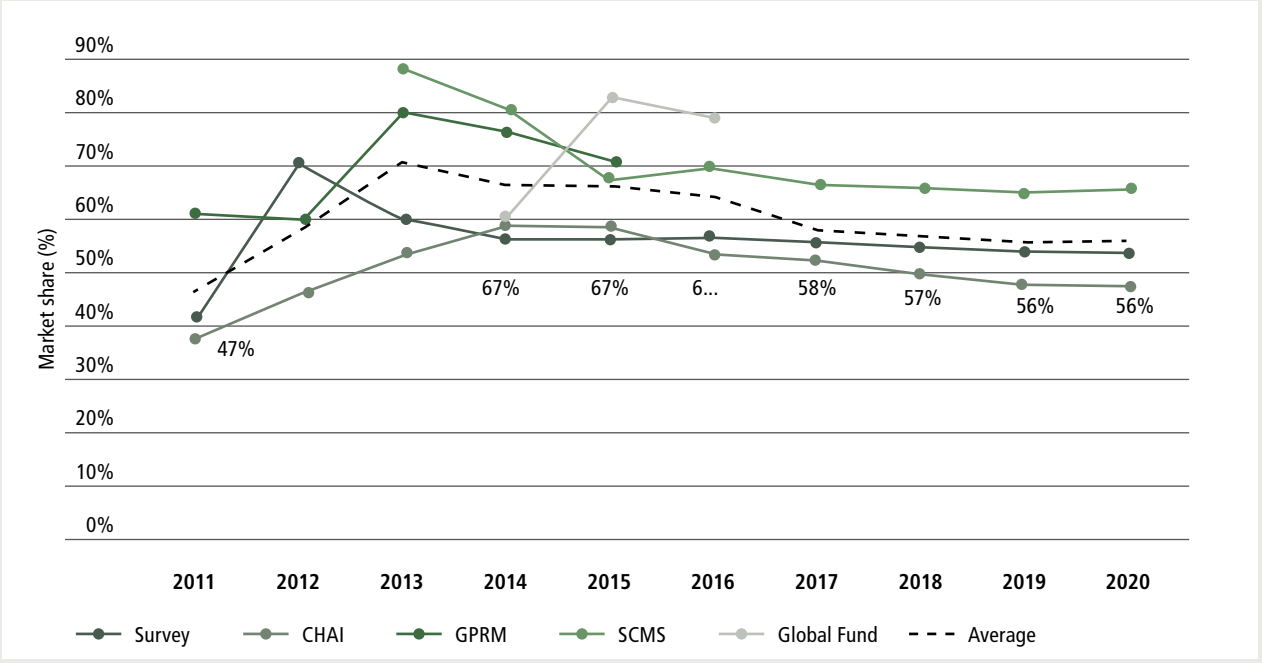


Fig. 10. Projected market share (%) of ABC for adults as a proportion of the volume of primary NRTIs for adults, 2011–2020

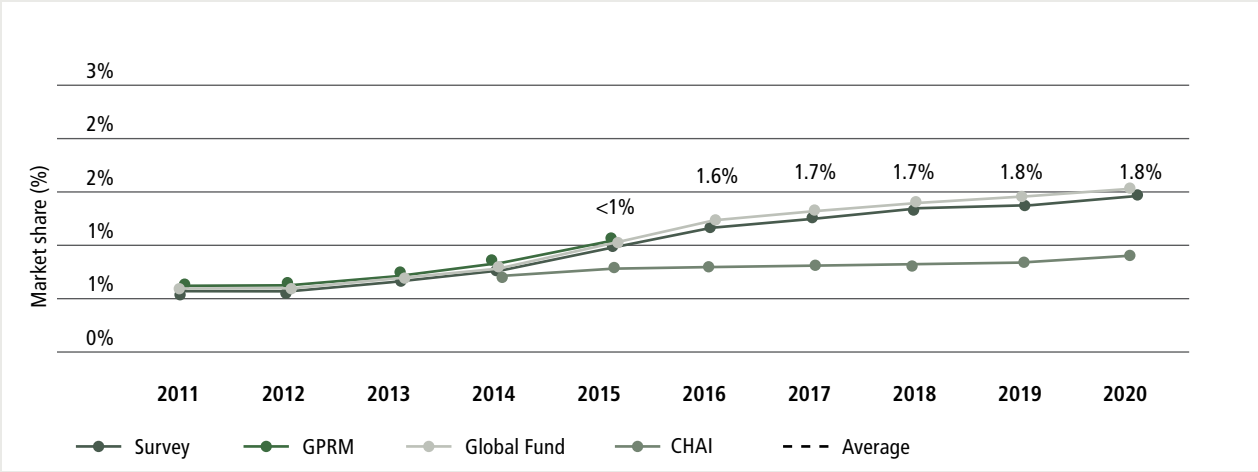


Fig. 11. Projected market share (%) of ABC for children as a proportion of the volume of primary NRTIs for children, 2011–2020

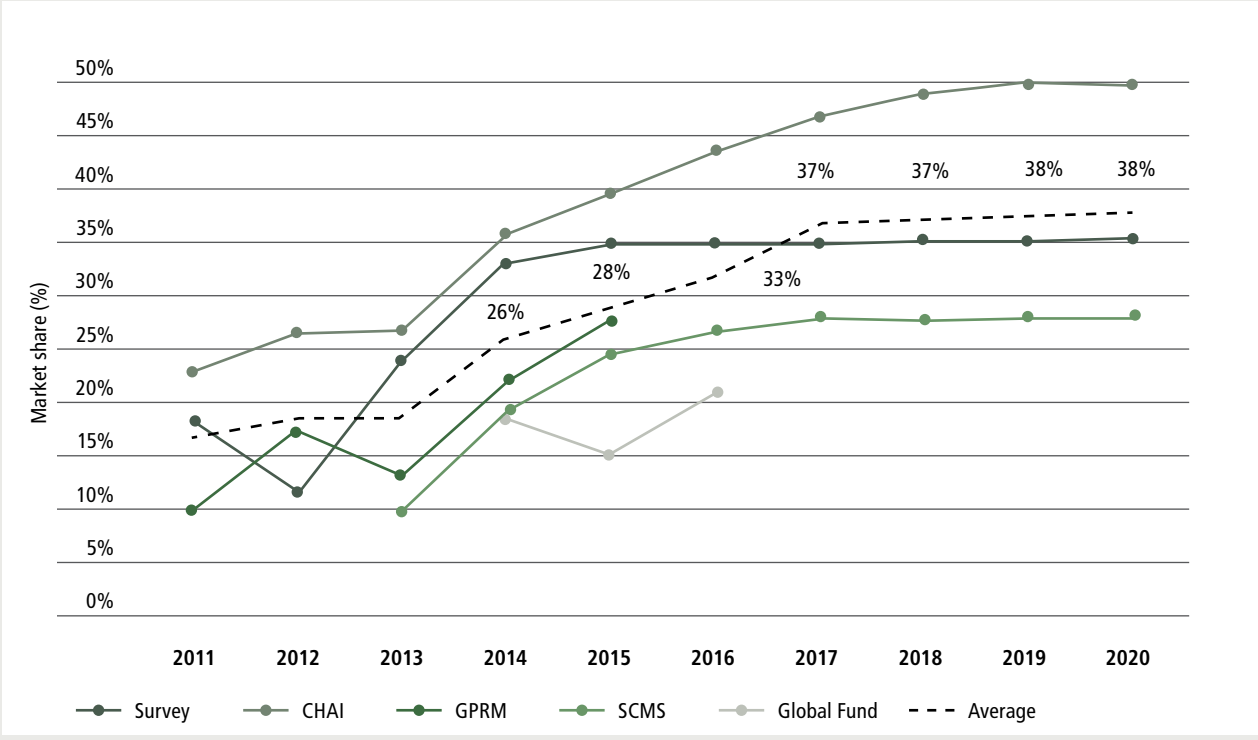


Fig. 12. Projected market share (%) of 3TC and FTC for adults as a proportion of the volume of secondary NRTIs for adults, 2011–2020

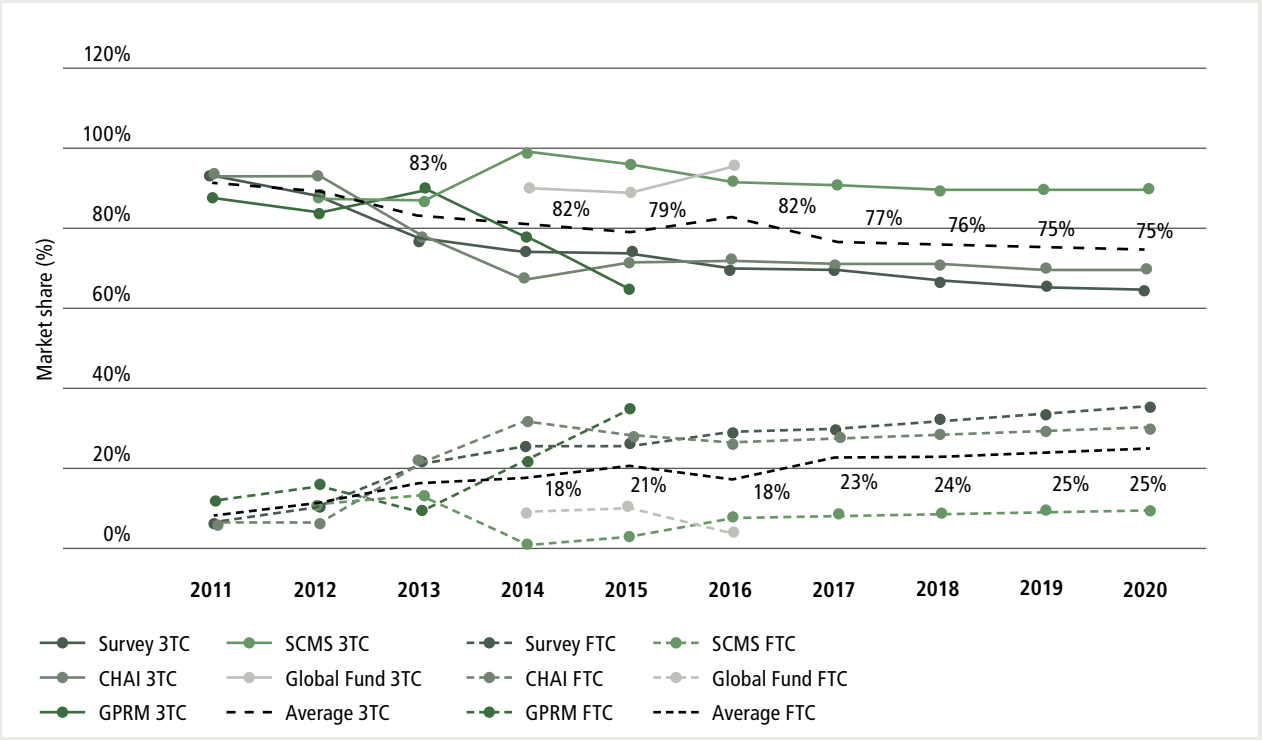


Fig. 13. Projected market share (%) of 3TC for children as a proportion of the volume of secondary NRTIs for children, 2011–2020

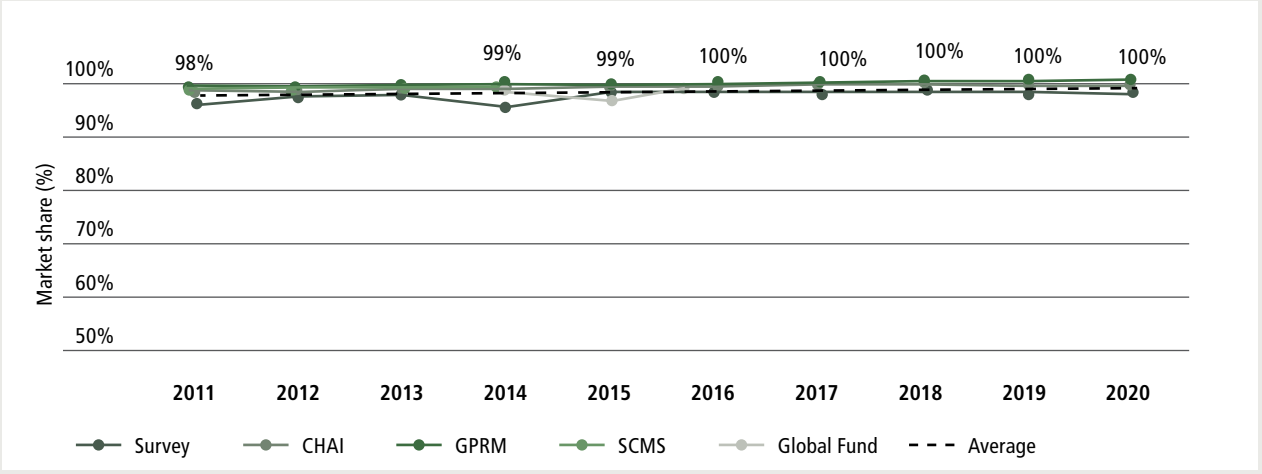


Fig. 14. Projected market share (%) of NVP and EFV for adults as proportions of the volume of NNRTIs for adults, 2011–2020

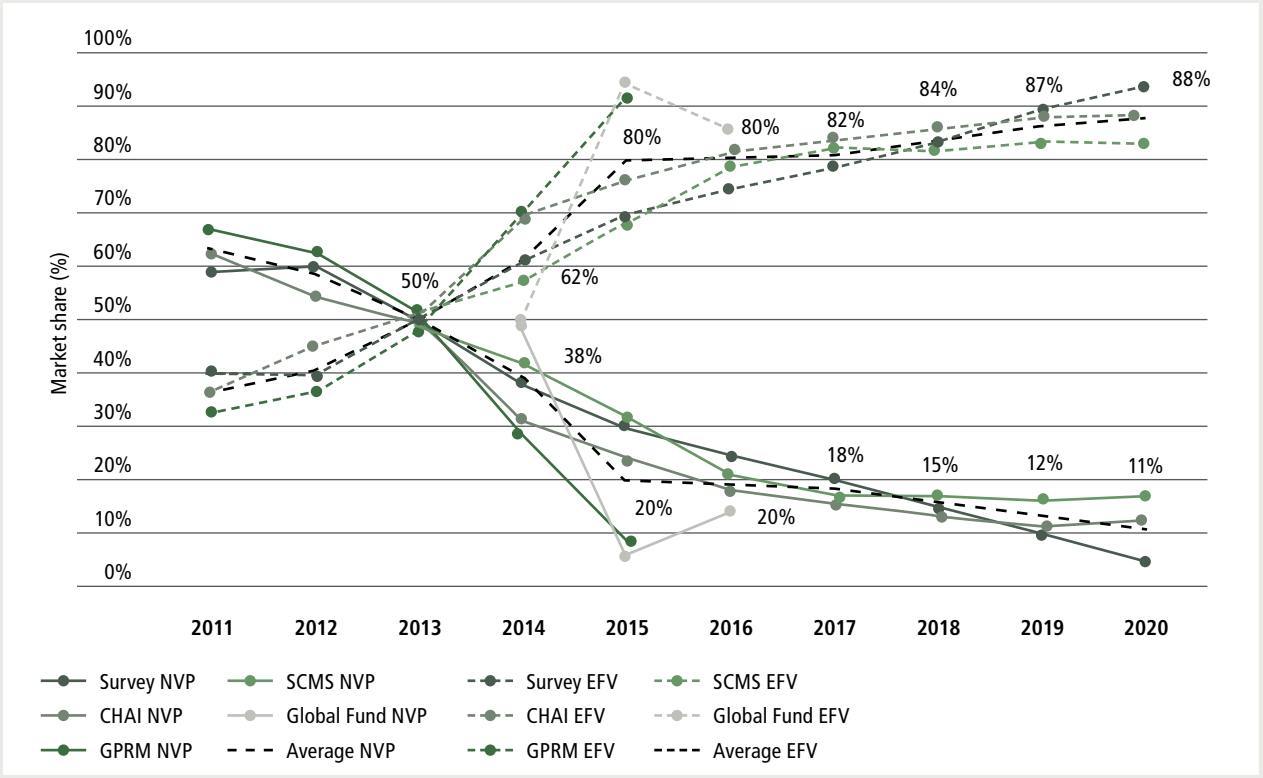


Fig. 15. Projected market share (%) of NVP and EFV for children as proportions of the volume of NNRTIs for children, 2011–2020

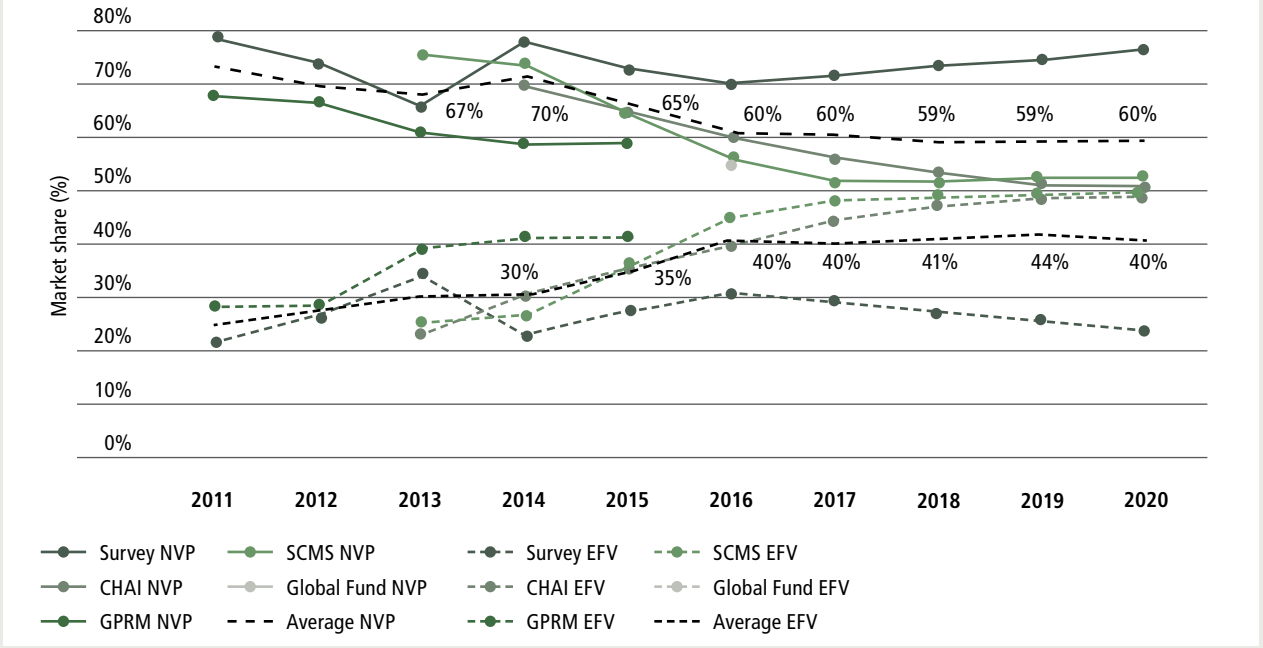


Fig. 16. Projected market share (%) of LPV and ATV for adults as proportions of the PI volume for adults, 2011–2020

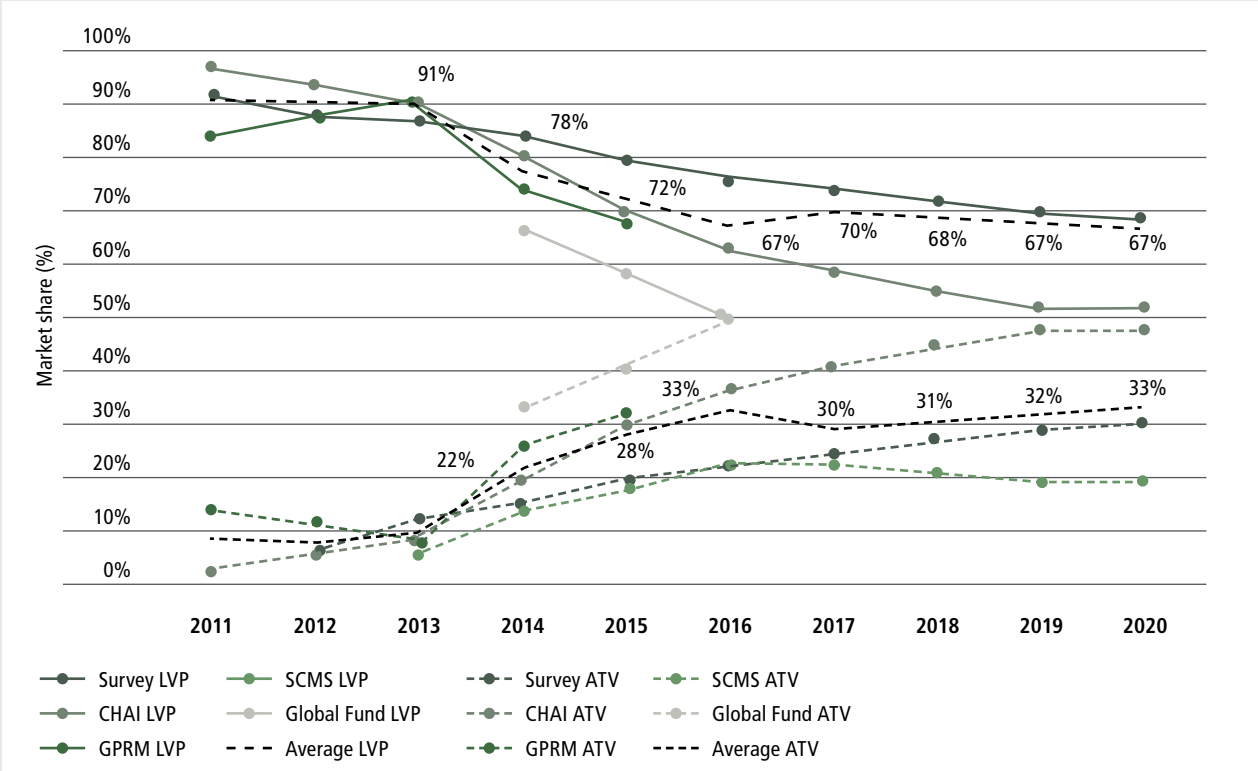
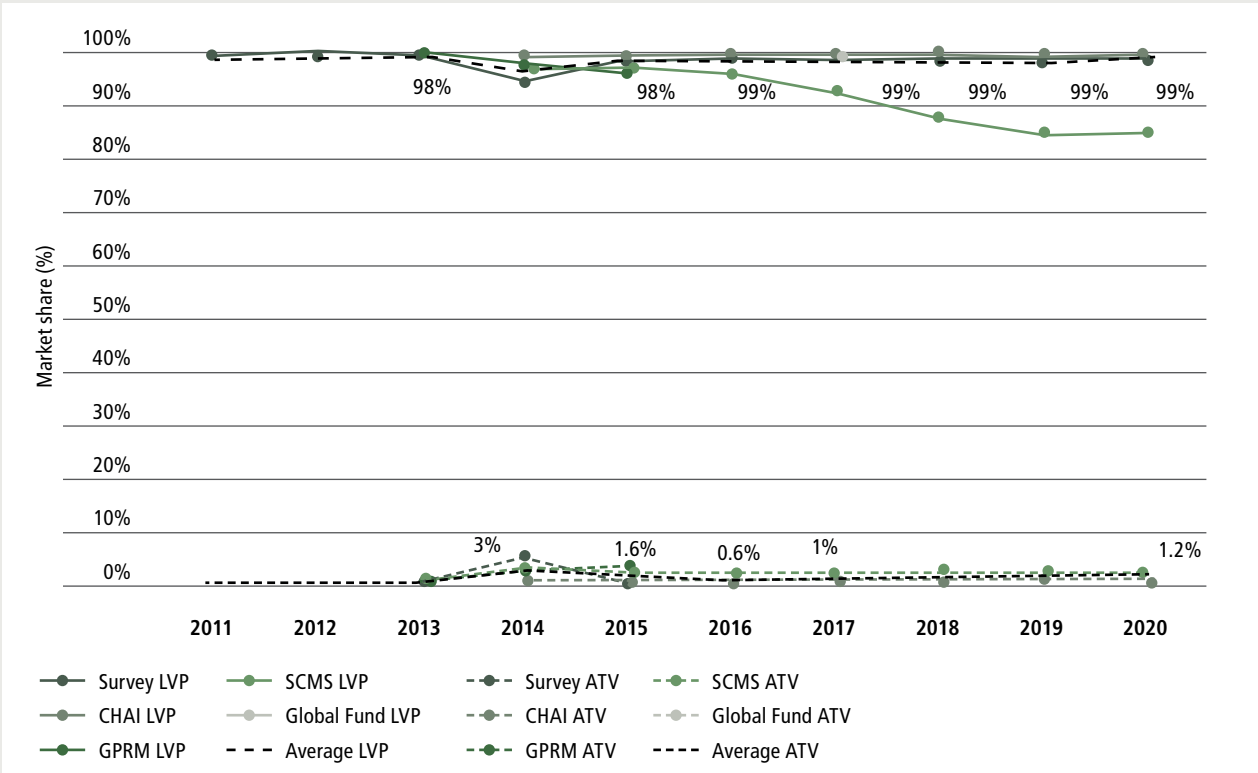


Fig. 17. Projected market share (%) of LPV and ATV for children as proportions of the PI volume for children, 2011–2020



Tables 4 and 5 show the annual average market share of the projections for each ARV drug for adults and children separately.

Table 4. Average market share for ARV drugs for adults

ARV drug	Average market share (%)					
	2015	2016	2017	2018	2019	2020
d4T, TDF, AZT and ABC share of primary NRTIs						
d4T	0.3	0.2	0.2	0.2	0.2	0.1
TDF	71	79	80	81	82	83
AZT	27	20	19	17	16	15
ABC[a]	1.5	1.6	1.7	1.7	1.7	1.8
3TC and FTC share of secondary NRTIs						
3TC	85	82	77	76	75	75
FTC	15	18	23	24	25	25
NVP and EFV share of NNRTIs						
NVP	24	20	18	16	13	12
EFV	76	80	72	74	77	88
LPV/r and ATV/r share of PIs						
LPV	72	69	67	65	62	60
ATV	28	31	33	35	38	40

[a] Average market share based on WHO survey and Global Price Reporting Mechanism data.

Table 5. Average market share for ARV drugs for children

ARV drug	Average market share (%)					
	2015	2016	2017	2018	2019	2020
d4T, TDF, AZT and ABC share of primary NRTIs						
d4T	3	1	0.8	0	0	0
TDF	2.5	2.9	4.4	4.7	5.1	5.3
AZT	64	64	58	57	56	56
ABC[a]	30	31	36	37	38	38
3TC and FTC share of secondary NRTIs						
3TC	99.9	99.6	99.6	99.6	99.6	99.6
FTC	0.1	0.4	0.4	0.4	0.4	0.4
NVP and EFV share of NNRTIs						
NVP	65	60	60	60	59	59
EFV	35	40	40	40	41	41
LPV/r and ATV/r share of PIs						
LPV	99	99	99	99	99	99
ATV	1	1	1	1	1	1

[a] Average market share based on WHO survey and Global Price Reporting Mechanism data.

2.4 Calculating the number of women receiving ARV drugs for preventing mother-to-child transmission

The number of women receiving ARV drugs for preventing mother-to-child transmission was based on two projections – linear and country target. The linear projection is based on linear regression of data on preventing mother-to-child transmission from 2012 to 2020, whereas the country targets are based on the goals set by 35 countries. Table 6 shows the projected number of women receiving ARV drugs for preventing mother-to-child transmission for each projection as well as the average of the two projections. Table A2 (Annex 1) shows the estimated average number of women receiving ARV drugs for preventing mother-to-child transmission by region, based on linear and country target projections.

Table 6. Total and average number of women receiving ARV drugs for preventing mother-to-child transmission, 2015–2020

Forecasting method	Number of women receiving ARV drugs for preventing mother-to-child transmission					
	2015	2016	2017	2018	2019	2020
Linear projection	1 400 000	1 500 000	1 600 000	1 700 000	1 800 000	1 900 000
Country target projection	1 600 000	1 800 000	1 900 000	2 000 000	2 100 000	2 200 000
Average	1 500 000	1 650 000	1 750 000	1 850 000	1 950 000	2 050 000
Annual rate of increase (%)	–	10	6	6	3	3

As the average of the two projections shows, the number of women receiving ARV drugs for preventing mother-to-child transmission is expected to increase, mostly because of expanded coverage of services for preventing mother-to-child transmission.

To project the demand for ARV drugs for women receiving ARV drugs for preventing mother-to-child transmission, the total number of women currently receiving different options (Table 6) – WHO 2006 AZT, option A, option B and option B+ – was determined through the WHO ARV drug use survey and the Global AIDS Response Progress Reporting *(10)*. Most country programmes are rapidly scaling down option A and B, and several countries with a high burden of preventing mother-to-child transmission, 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 preventing mother-to-child transmission 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 7.

The number of women receiving each option for preventing mother-to-child transmission is determined by multiplying the number of women receiving services for preventing mother-to-child transmission 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 7. Projected regimen mix for women receiving ARV drugs for preventing mother-to-child transmission, 2014 and 2020

Regimen	Projected regimen mix for women receiving ARV drugs for preventing mother-to-child transmission	
	2014[a]	2020
Single-dose NVP (%)[b]	0	0
WHO 2006 AZT (other) (%)[c]	0	0
Option A (%)[d]	0	0
Option B (%)[e]	46	5
Triple ART (%)[f]	54	95

[a] Proportion of various preventing mother-to-child transmission options developed by WHO and UNAIDS and provided by the Strategic Information Planning Unit, Department of HIV, 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 six 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 active pharmaceutical ingredient 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 active pharmaceutical ingredient person-years

The number of person-years is estimated as the number of people living with HIV 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 8 shows the active pharmaceutical ingredient volume in person-years for each ARV drug based on the average of the three projections – linear, country target and CHAI.

Table 8. Demand volume for active pharmaceutical ingredients in person-years based on the average of three projections

Drug	Demand for active pharmaceutical ingredients (person-years) based on the average of linear, CHAI and country target projected number of people and market share for active pharmaceutical ingredients					
	2015	2016	2017	2018	2019	2020
d4T	103 000	15 000	16 000	7 000	5 000	0
AZT	3 700 000	3 700 000	3 700 000	3 800 000	4 000 000	3 900 000
TDF	9 600 000	12 200 000	14 300 000	16 500 000	18 500 000	20 500 000
ABC	433 000	510 000	641 000	744 000	840 000	974 000
ddI	12 000	12 000	12 000	11 000	10 000	200
3TC	10 600 000	12 600 000	13 500 000	14 900 000	16 100 000	17 300 000
FTC	3 000 000	3 000 000	4 000 000	4 500 000	5 000 000	6 500 000
NVP	3 550 000	3 460 000	3 400 000	3 200 000	3 100 000	2 900 000
EFV	9 600 000	11 400 000	13 100 000	14 800 000	16 500 000	18 100 000
LPV	648 000	760 000	859 000	960 000	1 059 000	1 161 000
ATV	180 000	250 000	320 000	410 000	500 000	590 000
RTV[a]	800 000	1 000 000	1 200 000	1 400 000	1 600 000	1 700 000

[a] The volume of demand is based on combined LPV and ATV demand.

3.2 Calculating the total volumes of active pharmaceutical ingredients 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 9 shows the recommended daily doses for adults and children.

Table 9. Daily doses for ARV drugs for adults and children based on WHO recommendations, 2015-2020

Drug	Daily dose for adults (mg/day)	Daily doses for children 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	6	8.5	15	20	20	60
AZT	600	120	170	200	300	300	600
TDF	300	6	6	6	6	6	200
3TC	300	60	80	105	150	225	300
FTC	200	–	–	–	–	–	–
ABC	600	80	150	205	300	450	600
NVP	400	120	165	200	300	400	400
EFV	600	–	–	200	200	200	200
LPV	800	80	140	160	180	240	800
ATV	300	–	–	–	–	–	–
RTV (with LPV/r)	200	–	–	–	–	–	–
RTV (with ATV/r)	100	–	–	–	–	–	–

3.3 Forecast demand for active pharmaceutical ingredients for 2015–2020

Table 10 shows the volume of active pharmaceutical ingredient in metric tonnes required for each ARV drug based on the average estimates of the numbers of people receiving treatment (Table 2), the proportion receiving first- and second-line therapy (Table 3) and the distribution of ARV drug regimens (Fig. 4–17). Tables A3–A5 (Annex 1) show the demand in detailed volumes for each of the three projections individually. Tables A6–A11 (Annex 1) show the volume of demand in metric tonnes based on the average of the linear and country target projections for each of the three projections individually.

The need for active pharmaceutical ingredients 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 drug 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 preventing mother-to-child transmission: 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 ARV drugs for preventing mother-to-child transmission (shown in Table 7).

Table 10. Volume of demand for active pharmaceutical ingredients in metric tonnes based on the average of linear, CHAI and country target projections, 2015–2020

Drug	Demand for active pharmaceutical ingredients (metric tonnes) based on the average of linear, CHAI[a] and country target projections					
	2015	2016	2017	2018	2019	2020
d4T	1	0	0	0	0	–
AZT	853	827	798	845	878	915
TDF	1039	1322	1546	1781	1995	2211
ABC	54	61	76	89	101	117
ddI[b]	2	2	2	2	1	0
3TC	1093	1298	1392	1534	1666	1792
FTC	218	221	290	326	364	469
NVP	418	435	436	424	411	386
EFV	2045	2419	2783	3158	3509	3865
LPV	148	171	193	215	237	258
ATV	19	27	35	44	54	63
RTV	51	60	69	78	87	96

[a] Based on demand for adults in metric tonnes.

[b] The volume of demand is based on the averages for the linear and country target projections.

Table 11. Volume of demand for active pharmaceutical ingredients in metric tonnes for women receiving ARV drugs for preventing mother-to-child transmission based on the average of linear and country target projections, 2015–2020

Drug	Demand for active pharmaceutical ingredients (metric tonnes) for women for preventing mother-to-child transmission based on the average of linear and country target projections[a]					
	2015	2016	2017	2018	2019	2020
NVP	5.4	4.8	4.0	3.1	2.1	0.9
AZT	213	196	168	134	95	51
3TC	107	98	84	67	48	26
LPV	284	261	224	179	127	69
RTV	95	89	77	62	45	26

[a] The forecast volume demand for preventing mother-to-child transmission does not include women receiving triple ART for their health or option B+. This has been included in ARV drugs for adult HIV treatment.

3.4. ARV drug formulations

In this year's report, projections of ARV drug formulation requirements were compiled from two major sources – the Supply Chain Management System and the Government of South Africa. Formulation requirement data from the Supply Chain Management System were projected for 2016, 2017, 2018 and 2019, and data from South Africa were projected for 2016 and 2017. The data from both sources were translated from quantities of each ARV drug formulation to person-years by multiplying the number of bottles or packages by the smallest units in each bottle or package and dividing the total quantity of the smallest units of each ARV drug formulation by the daily dose times the number of days in one year (365 days). Table 12 shows aggregated data on procurement of ARV drug formulations by the Supply Chain Management System and Government of South Africa. Tables A15 and A16 (Annex 1) show ARV drug formulation data from each of the two sources.

Table 12. ARV drug formulation forecast aggregation of the Supply Chain Management System and South Africa procurement data in person-years, 2016–2019

Product	2016	2017	2018	2019
3TC, 10 mg/ml	3 283	3 394	3 439	3 484
3TC, 150 mg	189 546	205 579	89 067	94 149
ABC, 20 mg/ml	2 723	2 759	2 794	2 830
ABC, 300 mg	79 028	80 033	64 142	68 516
ABC, 300 mg; 3TC, 150 mg; AZT, 300 mg	568	676	841	841
ABC, 60 mg	13 528	14 014	14 486	14 521
ABC, 60 mg; 3TC, 30 mg	44 504	54 392	54 638	56 773
ABC, 600 mg; 3TC, 300 mg	144 178	167 886	69 023	72 711
ATV, 150 mg	271	271	271	271
ATV, 200 mg	440	554	605	605
ATV/r, 300 mg/100 mg	67 645	81 763	89 492	92 262
AZT, 10 mg/100 ml	162	139	139	139
AZT, 10 mg/240 ml	699	1 113	1 523	1 934
AZT, 100 mg	150	161	158	156
AZT, 300 mg	19 779	24 958	17 534	18 940
AZT, 300 mg; 3TC, 150 mg (Combivir®)	400 078	421 789	334 049	342 589

Table 12. (continued)

Product	2016	2017	2018	2019
AZT, 300 mg; 3TC, 150 mg; NVP, 200 mg	760 742	730 979	729 261	735 049
AZT, 60 mg; 3TC, 30 mg	31 898	36 458	37 470	39 585
AZT, 60 mg; 3TC, 30 mg; NVP, 50 mg	99 564	104 930	105 153	105 197
d4T, 30 mg; 3TC, 150 mg; 60 tablets	83	–	–	–
ddI, 250 mg	408	389	389	389
ddI, 400 mg	176	172	172	172
ddI, 25 mg	170	144	144	144
DRV, 150 mg	240	653	1 241	1 926
DRV, 300 mg	130	173	182	191
DRV, 600 mg	466	655	877	1 086
EFV, 200 mg; tablets, capsules	87 126	102 727	105 897	105 654
EFV, 50 mg	388	388	388	388
EFV, 600 mg	436 195	430 254	224 413	226 186
ETV, 100 mg	328	597	965	1 354
IDV, 400 mg	5	–	–	–
LPV/r, 80/20 mg/ml	25 047	22 796	22 906	22 885
LPV/r, 100 mg/25 mg	2 724	3 522	3 659	3 786
LPV/r, 100 mg/25 mg (Aluvia®)	15 572	17 348	14 718	21 545
LPV/r, 200 mg/50 mg	376 853	433 553	294 879	343 018
LPV/r, 200 mg/50 mg (Aluvia®)	28 930	33 107	35 376	35 376
LPV/r, 40 mg/10 mg	1 814	3 359	3 293	3 235
NVP, 10 mg/ml, 100 ml	3 989	1 756	1 874	1 895
NVP, 10 mg/ml, 240 ml	2 090	2 148	2 223	2 229

Table 12. (continued)

Product	2016	2017	2018	2019
NVP, 10 mg/ml, suspension	371	437	437	437
NVP, 200 mg	241 905	217 176	215 499	217 218
NVP, 50 mg	1 805	2 505	2 453	2 422
RAL, 200 mg	160	435	828	1 284
RAL, 400 mg	500	628	727	775
RAL, 400 mg (Isentress®)	385	554	732	939
RTV, 100 mg, 30 tablets	280	342	370	370
RTV, 100 mg, 60 tablets	3 060	3 169	3 178	3 190
RTV, 100 mg, capsules	580	726	900	1 094
SQV, 200 mg	24	31	38	46
SQV, 500 mg	231	202	202	202
TDF, 150 mg	4 851	6 149	6 537	6 936
TDF, 200 mg	3 382	5 295	5 933	6 515
TDF, 250 mg	447	828	828	828
TDF, 300 mg	16 250	18 163	20 050	20 909
TDF, 300 mg; 3TC, 300 mg; EFV, 600 mg	3 118 657	3 622 650	3 855 408	3 977 714
TDF, 300 mg; FTC, 200 mg	611 056	632 739	415 483	455 808
TDF, 300 mg; FTC, 200 mg; EFV, 600 mg	2 745 935	3 217 872	467 687	485 396

4. DISCUSSION

The approach outlined in this report builds on previous annual forecasts by providing an average of projections, market share for active pharmaceutical ingredients and formulations from multiple sources, as explained in this report. This process builds on and improves on the separate methods to estimate the number of adults and children receiving treatment, the proportion of people receiving first- and second-line therapies and the distribution of adults and children on the use of different ARV medicines as well as on projected demand for formulations for adults and children. Importantly, the target of 15 million people receiving treatment globally by 2015 has been surpassed in 2015, since 17 million people are reported to be receiving ART at the end of 2015. It is encouraging to note that the trend in the number of people receiving treatment continues to grow annually despite flat-lined or reduced international funding. Nevertheless, the annual growth rate for children receiving treatment continues to lag behind that of adults. Since new initiatives, such as WHO's 2016 consolidated treatment guidelines *(11)* and PEPFAR's Accelerating Children's HIV/AIDS Treatment are being adopted or scaled up, the growth rate of the number of children receiving ART is expected to increase *(12)*.

To improve the utility of the ARV drug demand forecast, this year's report aggregates ARV drug formulation procurement projections from the Supply Chain Management System (2016–2019) and the Government of South Africa (2016 and 2017). These demand estimates assist suppliers, funding partners supporting national ART programmes as well as global and regional policy-makers with a range of the volume of active pharmaceutical ingredients and ARV drug formulations required to meet the needs of the new and continuing people receiving treatment.

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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, 2015–2020

Region	Age group	Projected number of people receiving ART by region based on the average of linear and country target projections					
		2015	2016	2017	2018	2019	2020
Sub-Saharan Africa	Adults	11 800 000	13 400 000	15 000 000	16 500 000	17 900 000	19 200 000
	Children	880 000	980 000	1 060 000	1 160 000	1 220 000	1 260 000
Latin America and the Caribbean	Adults	770 000	860 000	940 000	1 020 000	1 090 000	1 150 000
	Children	17 000	18 100	18 700	19 500	19 600	19 600
Eastern Mediterranean	Adults	45 000	52 000	58 000	64 000	70 000	75 000
	Children	2 400	2 700	2 900	3 200	3 300	3 500
Europe	Adults	370 000	420 000	470 000	520 000	570 000	620 000
	Children	9 300	10 000	11 000	12 000	12 000	12 000
South and South-East Asia	Adults	1 420 000	1 600 000	1 780 000	1 960 000	2 130 000	2 270 000
	Children	76 000	86 000	94 000	103 000	107 000	113 000
Western Pacific	Adults	569 000	654 000	737 000	822 000	898 000	963 000
	Children	16 000	17 000	18 000	19 000	20 000	20 000

Table A2. Number of women receiving ARV drugs for preventing mother-to-child transmission by region, based on the average of linear and country target projections, 2015–2020

Region	Projected number of women receiving drugs for preventing mother-to-child transmission based on the average of linear and country target projections					
	2015	2016	2017	2018	2019	2020
Sub-Saharan Africa	1 390 000	1 480 000	1 570 000	1 660 000	1 740 000	1 830 000
Latin America and the Caribbean	31 000	34 000	37 000	39 000	41 000	42 000
Eastern Mediterranean	7 500	8 700	9 900	11 200	12 500	13 900
Europe	22 000	25 000	27 000	28 000	30 000	32 000
South and South-East Asia	63 000	73 000	82 000	92 000	101 000	110 000
Western Pacific	12 000	14 000	15 000	16 000	17 000	19 000

Table A3. Volume of demand for active pharmaceutical ingredients in person-years: linear projection, 2015–2020

Drug	Demand for active pharmaceutical ingredients (person-years) based on linear projection					
	2015	2016	2017	2018	2019	2020
d4T	218 000	79 000	21 000	22 000	11 000	7 000
AZT	4 200 000	4 000 000	4 000 000	4 100 000	4 100 000	4 400 000
TDF	7 100 000	9 800 000	12 500 000	14 600 000	16 900 000	19 100 000
ABC	338 000	452 000	499 000	637 000	742 000	846 000
ddI	18 000	18 000	18 000	17 000	16 000	14 000
3TC	9 000 000	11 100 000	13 100 000	13 700 000	15 100 000	16 400 000
FTC	2 900 000	2 700 000	2 600 000	3 700 000	4 200 000	4 700 000
NVP	4 500 000	2 900 000	3 100 000	3 200 000	3 200 000	3 100 000
EFV	6 700 000	9 900 000	11 400 000	13 000 000	14 600 000	16 300 000
LPV	652 000	706 000	816 000	921 000	1 026 000	1 136 000
ATV	100 000	210 000	269 000	339 000	421 000	515 000
RTV	800 000	900 000	1 100 000	1 300 000	1 400 000	1 700 000

Table A4. Volume of demand for active pharmaceutical ingredients in person-years: country target projection, 2015–2020

Drug	Demand for active pharmaceutical ingredients (person-years) based on country target projection					
	2015	2016	2017	2018	2019	2020
d4T	218 000	84 000	24 000	25 000	12 000	7 000
AZT	4 200 000	4 200 000	4 300 000	4 500 000	4 700 000	5 000 000
TDF	7 100 000	10 100 000	13 400 000	15 800 000	18 400 000	20 700 000
ABC	338 000	496 000	597 000	774 000	902 000	1 017 000
ddI	18 000	18 000	19 000	19 000	18 000	15 000
3TC	9 000 000	11 600 000	14 100 000	15 000 000	16 600 000	18 000 000
FTC	2 900 000	2 800 000	2 700 000	4 000 000	4 500 000	5 100 000
NVP	4 500 000	4 300 000	4 100 000	3 900 000	3 700 000	3 500 000
EFV	6 700 000	10 300 000	12 200 000	14 000 000	15 900 000	17 600 000
LPV	652 000	748 000	917 000	1 050 000	1 184 000	1 311 000
ATV	100 000	218 000	291 000	374 000	470 000	576 000
RTV	800 000	1 000 000	1 200 000	1 400 000	1 700 000	1 900 000

Table A5. Volume of demand for active pharmaceutical ingredients in person-years: CHAI projection, 2015–2020

Drug	Demand for active pharmaceutical ingredients (person-years) based on CHAI projection					
	2015	2016	2017	2018	2019	2020
d4T	146 000	–	–	–	–	–
AZT	2 800 000	2 600 000	2 500 000	2 500 000	2 500 000	2 500 000
TDF	9 000 000	10 700 000	12 400 000	14 100 000	15 600 000	17 100 000
ABC	400 000	400 000	500 000	600 000	700 000	700 000
ddI	800	–	–	–	–	–
3TC	9 119 000	10 532 000	11 713 000	12 865 000	13 959 000	15 007 000
FTC	3 551 000	3 825 000	4 328 000	4 851 000	5 370 000	5 827 000
NVP	3 500 000	3 100 000	2 900 000	2 800 000	2 700 000	2 600 000
EFV	8 600 000	10 500 000	12 300 000	14 000 000	15 500 000	17 000 000
LPV	500 000	500 000	600 000	700 000	700 000	800 000
ATV	100 000	200 000	300 000	300 000	400 000	500 000

Table A6. Volume of demand for active pharmaceutical ingredients in metric tonnes: linear projection, 2015–2020

Drug	Demand for active pharmaceutical ingredients (metric tonnes) based on linear projection					
	2015	2016	2017	2018	2019	2020
d4T	1.4	0.3	0.4	0.2	0.1	–
AZT	964	921	864	926	967	1025
TDF	1052	1350	1573	1819	2053	2306
ABC	70	76	95	111	127	150
ddI	1.8	1.8	1.8	1.6	1.4	0.0
3TC	1161	1365	1432	1575	1717	1866
FTC	195	185	266	299	336	475
NVP	396	433	447	438	428	402
EFV	2115	2424	2756	3115	3471	3869
LPV	168	194	219	244	270	296
ATV	22	29	36	45	55	67
RTV	50	58	66	74	82	90

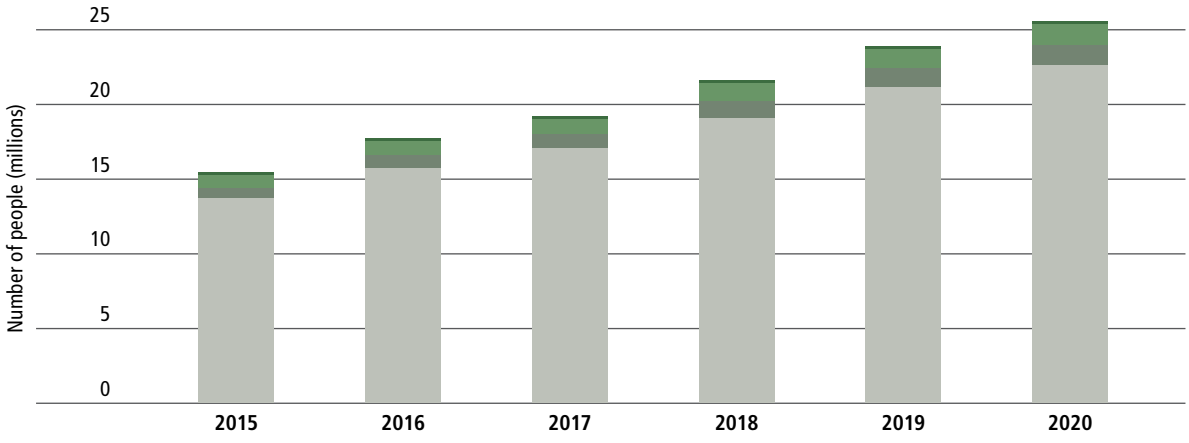
Table A7. Volume of demand for active pharmaceutical ingredients in metric tonnes: country target projection, 2015–2020

Drug	Demand for active pharmaceutical ingredients (metric tonnes) based on country target projection					
	2015	2016	2017	2018	2019	2020
d4T	1.4	0.4	0.4	0.2	0.2	–
AZT	972	981	971	1057	1112	1170
TDF	1085	1439	1702	1985	2229	2459
ABC	76	88	112	131	149	174
ddI	1.9	2.0	1.9	1.8	1.5	0.0
3TC	1201	1466	1560	1727	1870	1996
FTC	201	197	287	325	364	505
NVP	413	475	498	493	478	446
EFV	2177	2586	2970	3378	3737	4089
LPV	176	213	244	276	305	332
ATV	23	31	40	51	62	74
RTV	52	63	73	83	92	101

Table A8. Volume of demand for active pharmaceutical ingredients in metric tonnes based on CHAI projection, 2015–2020

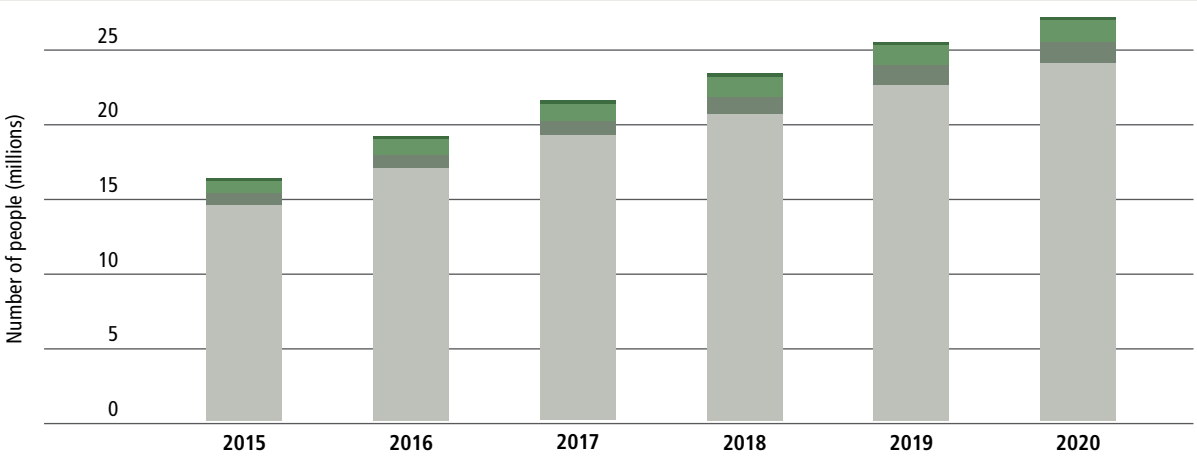
Drug	Volume of demand for active pharmaceutical ingredients (metric tonnes) based on CHAI					
	2015	2016	2017	2018	2019	2020
AZT	621	579	558	552	554	550
TDF	980	1176	1362	1539	1704	1870
ABC	15	18	21	24	26	28
3TC	917	1062	1182	1299	1409	1514
FTC	259	279	316	354	392	425
NVP	446	397	364	343	326	309
EFV	1844	2246	2623	2980	3318	3638
LPV	99	107	117	126	135	145
ATV	12	20	28	35	43	49
RTV	49	60	72	83	94	103

Fig. A1. Number of people receiving first- and second-line ART based on linear projection, 2015–2020



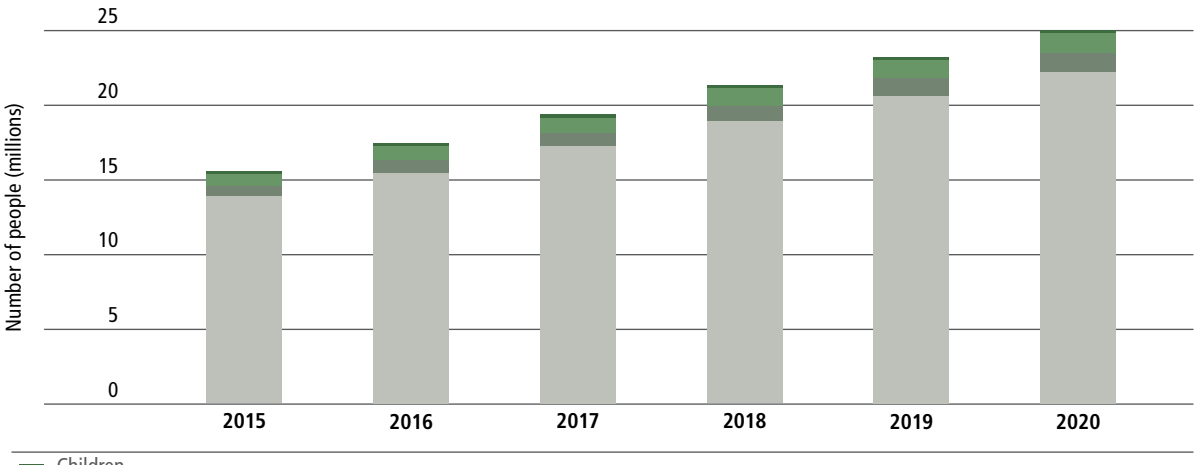
	2015	2016	2017	2018	2019	2020
Children, second line	50 000	60 000	70 000	80 000	90 000	100 000
Children, first line	830 000	920 000	1 000 000	1 080 000	1 160 000	1 200 000
Adult, second line	830 000	970 000	1 090 000	1 200 000	1 400 000	1 500 000
Adult, first line	13 900 000	15 700 000	17 400 000	19 100 000	20 800 000	22 600 000

Fig. A2. Number of people receiving first- and second-line ART based on country target projection, 2015–2020



	2015	2016	2017	2018	2019	2020
Children, second line	70 000	80 000	90 000	100 000	100 000	100 000
Children, first line	1 100 000	1 200 000	1 300 000	1 400 000	1 400 000	1 500 000
Adult, second line	910 000	1 100 000	1 200 000	1 400 000	1 500 000	1 600 000
Adult, first line	14 700 000	16 800 000	18 900 000	20 900 000	22 400 000	23 800 000

Fig. A3. Number of people receiving first- and second-line ART based on CHAI projection, 2015–2020



	2015	2016	2017	2018	2019	2020
Children, second line	50 000	54 000	59 000	65 000	70 000	76 000
Children, first line	790 000	880 000	960 000	1 050 000	1 140 000	1 220 000
Adult, second line	710 000	830 000	940 000	1 060 000	1 180 000	1 300 000
Adult, first line	13 900 000	15 600 000	17 400 000	19 100 000	20 700 000	22 300 000

PART II. GLOBAL DEMAND FORECASTS FOR HIV DIAGNOSTICS IN LOW- AND MIDDLE-INCOME COUNTRIES FROM 2015 TO 2020

LIST OF FIGURES

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EXECUTIVE SUMMARY

This report provides projections of the future demand for HIV diagnostics through 2020. In this report, "HIV diagnostic tests" refers to in vitro diagnostics for HIV screening, diagnosis and monitoring. These projections are intended to inform advocacy for the scaling up of access to diagnostics, so that the UNAIDS 90–90–90 target for HIV treatment access can be met. The projections will probably also be useful for producers, so that they can plan for adequate supply, and to procurement organizations in planning future funding and long-term purchase plans.

The projections based on data from a number of different sources including an annual country survey conducted by WHO, purchases reported to the Global Price Reporting Mechanism, forecasts and historical testing volumes provided by the Clinton Health Access Initiative (CHAI) for countries with a high burden of antiretroviral therapy and purchase data from programmes of the United States President's Emergency Plan for AIDS Relief (PEPFAR) supported by the Partnership for Supply Chain Management.

This report presents consolidated estimates. They rely on detailed county-specific analysis conducted by CHAI for 21–26 countries with a high burden of antiretroviral therapy and linear extrapolations of past trends for the other countries based on annual surveys of test utilization conducted by WHO.

The main results are as follows.

- **CD4 tests**. Total demand for CD4 tests is expected to grow from just under 15 million in 2014 to 22–23 million by 2017 and then to stabilize at that level. Further increases in demand for CD4 will be constrained as most countries move to viral load testing for routine monitoring, but demand is expected to drop only slowly from the peak, since CD4 testing will continue to be used at baseline and for treatment failure. Moreover, many programmes may be slow to fully switch to viral load monitoring.
- **Viral load tests**. Total demand for viral load tests is expected to more than triple from nearly 7 million in 2014 to almost 25 million by 2020. The full need for viral load tests would be even higher, at about 30 million in 2020, if all countries adopted the WHO guidelines and reach the 90–90–90 target.
- **Early infant diagnosis**. Demand for early infant diagnosis tests is expected to rise from about 800 000 in 2014 to 1.8 million by 2020. The growth in demand will be driven by changes in the testing guidelines to include testing at birth, the introduction of point-of-care early infant diagnosis testing and additional partner funding. The full need under 90–90–90 would be even larger: about 2.8 million tests in 2020.
- **Rapid diagnostic tests**. Demand for rapid diagnostic tests is projected to increase by about one third, exceeding 400 million tests per year in 2020.

1. INTRODUCTION

The objective of this report is to project future demand for HIV diagnostics through 2020. In this report, "HIV diagnostic tests" refers to in vitro diagnostics for HIV screening, diagnosis and monitoring. These forecasts are intended to inform advocacy for the scaling up of access to diagnostics, so that the UNAIDS 90–90–90 target for HIV treatment access can be met. The forecasts will probably also be useful for producers, so that they can plan for adequate supply, and to procurement organizations in planning future funding and long-term purchase plans.

The key sources of data on diagnostics for this report include:

- an annual WHO survey of low- and middle-income countries on HIV treatment and diagnostic tests, with 63 countries reporting in 2012, 62 in 2013, 76 in 2014 and 67 in 2015 and the data from these surveys referring to the previous 12-month period;
- the Global Price Reporting Mechanism of WHO;
- data on past use and forecasted testing volumes developed by the Clinton Health Access Initiative (CHAI) for countries with a high burden of antiretroviral therapy;
- purchases and forecasts for a small number of countries supported by the Partnership for Supply Chain Management Project funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR); and
- Global AIDS Response Progress Reporting for HIV testing.

To inform these projections, data were also used on the number of people receiving antiretroviral therapy by country annually through 2014 from UNAIDS global reports and projections for use of antiretroviral therapy through 2020 based on the UNAIDS Fast-Track targets, which include the 90–90–90 target.

2. METHODS

The consolidated forecast combines information on past and current demand from the WHO antiretroviral medicine survey, detailed forecasts for countries with a high burden of antiretroviral therapy prepared by CHAI and linear extrapolations of past demand for countries not covered by CHAI. Each of these is explained below.

2.1 Current demand

The WHO antiretroviral medicine and diagnostic use survey received responses from 67 countries in 2015, 76 countries in 2014, 62 in 2013 and 63 in 2012. The estimates presented here for total demand in 2014 (from the 2015 survey) use the figures reported by these countries plus an estimate for the missing countries. Demand in the countries not reporting in 2014 was estimated according to the following rules.

1. If data were reported for 2011, 2012 and 2013 or for any two of these years, demand was estimated for 2014 as a linear extrapolation to 2014.
2. If data were reported for only one year, demand was estimated for 2014 by multiplying the need in 2014 by the ratio between demand in 2011, 2012 or 2013 and the estimated need in that year. The need for CD4 tests and viral load tests was based on the number of people receiving antiretroviral therapy. The need for early infant diagnosis was based on the number of pregnant women living with HIV.
3. If no data were reported for 2011, 2012 or 2013, demand was estimated for 2014 by multiplying the need in 2014 by the average ratio between demand and need for all reporting countries in 2014. Need was defined as described in point 2 above. The ratios were 1.26 CD4 tests per person receiving antiretroviral therapy, 0.55 viral load tests per person receiving antiretroviral therapy and 0.90 early infant diagnosis tests per woman living with HIV receiving antiretroviral medicine for preventing the mother-to-child transmission of HIV infection.

2.2 Projections by the Clinton Health Access Initiative[5]

CHAI's HIV diagnostics forecasts project the total need and anticipated demand (tests run) for CD4 count, early infant diagnosis and viral load from 2015 to 2020. The forecasts use a bottom-up approach to estimate the demand in countries with a high burden of antiretroviral therapy.[6] The data for these countries has been obtained from annual data requests to country teams as well as publicly available sources. The diagnostic forecasts are updated at least annually using new service delivery statistics and programme plans from CHAI country teams.

The methods for each of the market forecasts for CD4 count, early infant diagnosis and viral load vary based on the state of the market and the types of data available for analysis. For all forecasts, historical numbers of people receiving antiretroviral therapy have been obtained from the figures reported in the UNAIDS AIDSinfo database (http://aidsinfo.unaids.org) and CHAI country data requests. Annual growth in the numbers of people receiving antiretroviral therapy has been extrapolated based on linear growth trends. CHAI publishes these figures in aggregate annually in its antiretroviral medicine market report.[7] Where applicable, the numbers of people in pre-antiretroviral therapy care have been estimated using UNAIDS data on the total number of people living with HIV that are expected to know their status compared with the total number of people receiving antiretroviral therapy in each country. These figures have

[5] The CHAI projections are dated from December 2015 and do not incorporate the actual results for 2015. CHAI will update and release the forecasts for 2016–2020 in the coming months.

[6] For CD4 and viral load forecasts, the following 21 countries are considered to have a high burden of antiretroviral therapy: Botswana, Brazil, Cameroon, China, Côte d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe. For early infant diagnosis, the countries considered to have a high burden include all 21 priority countries in the Global Plan towards the elimination of new HIV infections among children and keeping their mothers alive and five other countries: Angola, Botswana, Brazil, Burundi, Cameroon, Chad, China, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe.

[7] ARV market report: the state of the antiretroviral drug market in low- and middle-income countries, 2014–2019. Issue 6, 2015. Boston: Clinton Health Access Initiative; 2015 (http://www.clintonhealthaccess.org/content/uploads/2015/11/CHAI-ARV-Market-Report-2015_FINAL.pdf, accessed 27 May 2016).

been further reduced using assumptions from literature about pre-antiretroviral therapy care retention and access to CD4 testing.[8]

CD4 testing forecast by CHAI

In generating this forecast, available procurement data from CHAI, UNICEF, WHO, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Partnership for Supply Chain Management for 2012–2014 were compared with country-reported procurement and service statistics to produce estimates of historical demand for the procurement of CD4 count tests. Projected demand was modelled by applying a linear growth rate to the testing volumes reported for 2014. The growth rate combines the expected compound annual growth rate for available country targets for 2015–2020 and the observed historical growth from 2012–2014. This analysis has been performed on a country-by-country basis. In the baseline scenario, the growth rate for historical testing volumes is weighted at 70% and the growth rate for country targets is weighted at 30%, given the varying methods with which targets were constructed.

At the country level, the projected demand is further constrained by the maximum number of tests required to deliver CD4 count testing to everyone living with HIV (the need).[9] The theoretical need reflects the scaling up of viral load testing as well as the gradual shift to a test-and-treat policy in countries as they reach antiretroviral therapy coverage rates exceeding 75% of all people living with HIV.

The forecast calls for about 20 million tests to be run in 2016 in low- and middle-income countries, maintaining relatively flat growth at a compound annual growth rate of 0.43% worldwide through 2020. The volumes are expected to peak in 2017 and then gradually begin to decline as countries begin to reach higher coverage rates of viral load and adopt a test-and-treat policy. In 2020, about 19 million tests will be performed across low- and middle-income countries based on CHAI forecasts.

Early infant diagnosis forecast by CHAI

The forecast for early infant diagnosis draws on several data points, including annual reported data from CHAI country teams, CHAI-UNITAID paediatric grant reports (2007–2011), UNAIDS data, the 2013 Global Plan, UNICEF children and AIDS stocktaking reports (2007–2013) and health ministry guidelines and programme reports. This forecast bases historical demand on the largest figure available from all sources, which results in some inconsistencies for countries for which multiple data points are unavailable.

To estimate future demand, historical test volumes, segmented by test type, have been increased linearly based on historical use of early infant diagnosis testing for 2009–2014. The model assumes that testing at birth will be introduced beginning in 2016 in South Africa and in 2017 in other countries, in addition to the 4- to 6-week DNA–polymerase chain reaction (PCR) test. For testing at birth, coverage in 2016 and 2017 is assumed to mimic overall early infant diagnosis coverage in 2007 and has been further modified based on facility delivery rates. Coverage of testing at birth has been increased based on the reported historical coverage rates for each country. The model also assumes that countries will begin deploying point-of-care early infant diagnosis in 2016. The model does not assume that the introduction of point-of-care early infant diagnosis will change overall growth trends, since no available data suggest the magnitude by which this might affect overall volumes.

The forecast calls for about 1.2 million early infant diagnosis tests to be run in 2016 in low- and middle-income countries, growing at a compound annual growth rate of 12% worldwide to about 1.8 million tests by 2020. The need will grow substantially in 2017 as a result of the presumed adoption of testing at birth in countries.

CHAI forecast for viral load testing

In contrast to the early infant diagnosis and CD4 forecast models, which are largely based on historical testing volumes, viral load testing is a new market for low- and middle-income countries. Hence, CHAI developed a forecast based on historical analogues. Demand has been calculated based on the predicted viral load coverage for a country in a given year multiplied by the expected need. The predicted coverage rate has been derived based on the combined score of a set of index factors, including:

- the status of funding and procurement

[8] Forty-four per cent of adults living with HIV are assumed to be monitored and staged using CD4 testing but not yet eligible for antiretroviral therapy, based on: Rosen S, Fox MP. Retention in HIV care between testing and treatment in sub-Saharan Africa: a systematic review. PLoS Med. 2011;8:e1001056.

[9] Need is defined as the total number of people expected to receive CD4 testing in a country multiplied by the number of CD4 tests per person per year recommended in the WHO guidelines. The 2016 WHO guidelines recommend CD4 testing for antiretroviral therapy monitoring where viral load monitoring is not yet available. As part of these guidelines, WHO recommends "treat all", which relieves the need for CD4 testing to stage people living with HIV but maintains its use for patient monitoring where viral load is not available, for testing at initiation and for evaluating risk for opportunistic infections in certain populations of people living with HIV. The model accounts for the gradual implementation of a treat-all approach beginning in 2016 in select countries that have made policy plans publicly available or that will have achieved at least 75% coverage of antiretroviral therapy for people living with HIV.

- the age of the routine monitoring programme
- status of guidelines and policy
- the historical ratio between the number of viral load tests and the total need.

In the scoring index, funding and procurement, the programme age and the historical testing volumes weigh most highly. The scores correspond to the predicted coverage categories, including high, medium, low and mature growth rates. The sources consulted to generate scores include country implementation plans, procurement and supplier sales records, country-reported volumes and global policy documents.

Country scores, dictating low, medium, high, or mature growth rates, have been mapped to four historical growth analogues. The four analogues define approximate ratios of the number of viral load tests conducted annually compared with the number of people receiving antiretroviral therapy observed during the scaling up of viral load testing in several countries in sub-Saharan Africa. Where country targets are more conservative than the predicted coverage estimates, the targets instead are used as the demand figures, under the assumption that these targets reflect unknown funding or systemic constraints to scale-up. In a growing market, these estimates may be conservative, and the figures will be adjusted as countries further denote their scale-up plans.

The forecast calls for about 8.9 million viral load tests to be run in 2016 in low- and middle-income countries, growing at a compound annual growth rate of 30% worldwide to about 22.6 million tests by 2020. The highest growth rates will occur in countries in sub-Saharan Africa outside South Africa as well as the rest of the world.

The forecasts for CD4 count and viral load testing include 21 countries: Botswana, Brazil, Cameroon, China, Côte d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe. For early infant diagnosis, 26 countries are included: Angola, Botswana, Brazil, Burundi, Cameroon, Chad, China, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Uganda, United Republic of Tanzania, Viet Nam, Zambia and Zimbabwe. Together these countries represent 87% of the demand for CD4 count tests, 77% of the demand for viral load tests and 96% of the demand for early infant diagnosis.

2.3 Consolidated forecast

The consolidated forecast combines the CHAI forecast for the countries included in the CHAI analysis with linear extrapolation for the remaining countries. For the countries not included in the CHAI forecast, past trends were extrapolated using data from the WHO survey of antiretroviral medicines. That survey provided data on the number of CD4 count, viral load and early infant diagnosis tests conducted in 2011, 2012, 2013 and 2014. Not all countries provided data for all four years.

- For the countries providing data for 2, 3 or 4 years, the projection is a linear extrapolation of the past trend.
- For countries providing data for only a single year, the projection applied a ratio of tests to the number of people living with HIV. For CD4 and viral load tests, the ratio between the number of tests reported and the number of people receiving antiretroviral therapy in the same year was calculated, and this ratio was applied to the estimated future number of people receiving antiretroviral therapy. For early infant diagnosis tests, the ratio between the number of early infant diagnosis tests and the number of women living with HIV receiving services for preventing the mother-to-child transmission of HIV was calculated, and this ratio was applied to the estimated future numbers of women receiving services for preventing the mother-to-child transmission of HIV.
- For countries with no data, the future demand was estimated by multiplying the estimated number of antiretroviral therapy for CD4 and viral load tests or the number of people receiving services for preventing the mother-to-child transmission of HIV for early infant diagnosis tests by ratios of tests per person. The ratios were calculated as the sum of all tests reported each year by reporting countries divided by the number of people receiving antiretroviral therapy or the number of people receiving services for preventing the mother-to-child transmission of HIV in the same countries in that year. These ratios were as follows:
    - **CD4 tests**. The ratio of 1.26 tests year per person receiving antiretroviral therapy in 2014 was calculated as the sum

of all tests reported each year by the reporting countries divided by the number of people receiving antiretroviral therapy. This is the ratio of the number of CD4 tests reported by reporting countries in the survey divided by the reported number of people receiving antiretroviral therapy in the same countries.

- **Viral load tests**. The ratio of 0.55 tests year per person receiving antiretroviral therapy in 2014 was calculated as the sum of all tests reported each year by reporting countries divided by the number of people receiving antiretroviral therapy. This is the ratio of the number of viral load tests reported by reporting countries in the survey divided by the reported number of people receiving antiretroviral therapy in the same countries.
- **Early infant diagnosis tests**. Since the use of early infant diagnosis tests is expanding rapidly, we calculated the ratio of early infant diagnosis tests to women receiving services for preventing the mother-to-child transmission of HIV for countries reporting data for 2013 through 2014. The reporting countries reported 781 000 performing early infant diagnosis tests in 2013. Based on estimates of the need for services for preventing the mother-to-child transmission of HIV in reporting and non-reporting countries, this figure was adjusted upward by 22% to estimate total demand in 2013, which made 950 000 early infant diagnosis tests. The ratios are:
  - 2013: 0.80
  - 2014: 0.90
  - 2015: 1.06
  - 2016: 1.14
  - 2017: 1.23
  - 2018: 1.32
  - 2019: 1.32
  - 2020: 1.32

  For early infant diagnosis tests, the linear projection was constrained to be less than or equal to the estimated number of women living with HIV giving birth each year.

- Rapid diagnostic tests. Data on the use of rapid diagnostic tests are available by country for one year only: 2014. Global estimates were available for 2012 and 2013 from (1) the number of tests purchased from the Global Price Reporting Mechanism and (2) country reports of the number of tests conducted annually from Global AIDS Response Progress Reporting from 2012 to 2014. Since not all countries reported, the demand for kits from countries not reporting was estimated by comparing the number of people receiving antiretroviral therapy in these countries to the number in reporting countries.

The consolidated forecast combines the CHAI forecast and the linear extrapolation. For CD4 tests, the CHAI forecast accounts for about 80% of the total, and the rest is based on linear extrapolation. The CHAI forecast accounts for about 85% of the total for viral load tests and 97% for early infant diagnosis.

2.4 The 90–90–90 treatment target

In 2014, UNAIDS proposed a new target for scaling up treatment: the 90–90–90 treatment target. The targets envision that, by 2020:

- 90% of the people living with HIV know their HIV status;
- 90% of the people who know their HIV-positive status are accessing treatment; and
- 90% of the people receiving treatment have suppressed viral loads

The number of people receiving antiretroviral therapy under the 90–90–90 target was estimated for all low- and middle-income countries based on the UNAIDS Fast-Track scenario. To do this, the Goals model was applied to 45 countries with a high burden of antiretroviral therapy using the Fast-Track coverage targets for all interventions, including biomedical prevention, behavioural prevention and treatment. The results were expanded to all countries based on their contribution to the epidemic in the UNAIDS global estimates and projections.[10] It is assumed that countries will scale up linearly from their current coverage to reach the 90–90–90 target by 2020. If all low- and middle-income countries end up on track to reach these targets, about 26 million people would receive antiretroviral therapy by 2020.

The testing demand was estimated by applying WHO guidelines to these numbers. For CD4 tests, this includes one test at when treatment starts, a second test after six months to establish viral suppression and annual tests for 10% of the people for monitoring treatment failure. For viral load tests, this includes one test six months after treatment starts, one at 12 months and one viral load test per year thereafter. For early infant diagnosis, we assume an average of 2.12 tests per infant born to a mother living with HIV to account for tests at birth, six weeks and/or nine months.

[10] Stover J, Bollinger L, Izazola JA, Loures L, De Lay P, Ghys PD, Fast-Track modeling working group. What is required to end the AIDS epidemic as a public health threat by 2030? The cost and impact of the Fast-Track approach. PLOS One. 2016;11:e015489.

3. RESULTS

3.1. CD4 tests

Fig. 1 shows estimates of historical use and forecast demand for CD4 tests. The blue line represents the consolidated forecast, the best estimate of future demand. The orange line represents the need under the 90–90–90 scenario as described above. The forecast indicates continued growth in demand as programmes continue to scale up the number of people receiving antiretroviral therapy. This growth is expected to level off as the increase in number of new people receiving antiretroviral therapy is offset by the transition from CD4 count to viral load tests for most patient monitoring. Fig. 1 shows a slight increase from 2018 to 2019 because of an increase in the number of people receiving treatment, which is not outweighed by growing viral load coverage, but the volumes do not surpass the 2017 level. These projections are updated every year and will be monitored as more information is received from countries.

The 90–90–90 line illustrates what the demand for CD4 tests would be if all countries transitioned immediately to viral load testing in accordance with the WHO guidelines. The actual transition is likely to be slow in some countries. As a result, the market is expected to continue to grow to 22 million to 23 million tests before beginning to decline after 2019.

Fig. 1. Demand for CD4 count tests, 2011–2020

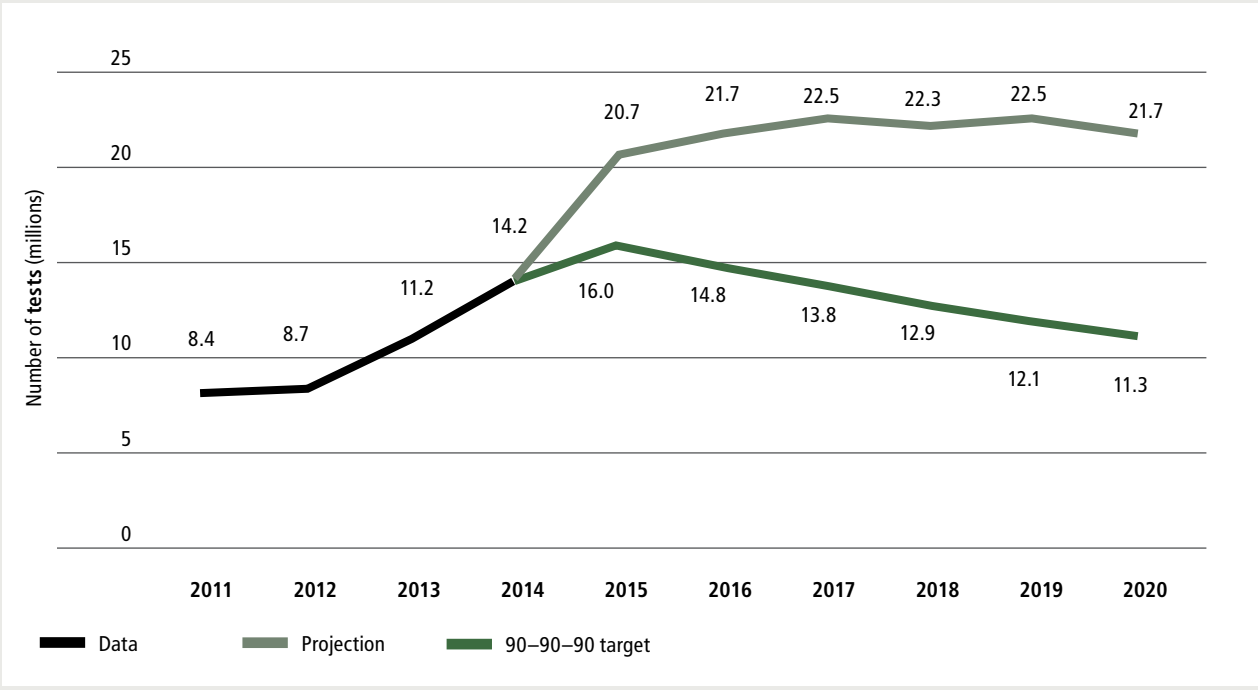
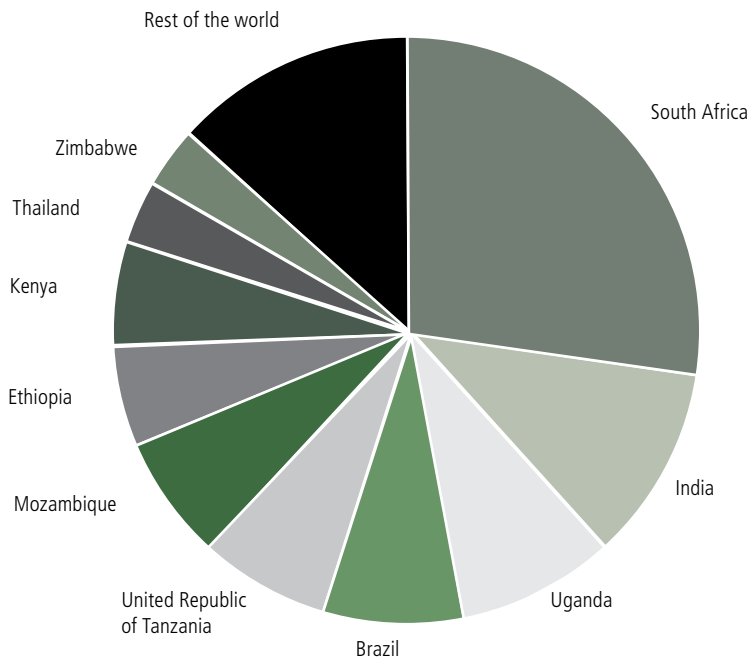


Fig. 2 shows the distribution of reported consumption by country in 2014. South Africa is the largest market, followed by India, Uganda, Brazil and the United Republic of Tanzania.

Fig. 2. Distribution of reported consumption for CD4 tests in 2014 by country



3.2. Viral load tests

Fig. 3 shows the historical trends and projected demand for viral load tests. Demand is expected to increase rapidly to reach 23 million viral load tests in 2020 as the number of people receiving antiretroviral therapy increases and as more countries adopt viral load testing for patient monitoring. The consolidated forecast takes into account CHAI's assessment of national guidelines and plans.

The 90–90–90 projection for 2020 assumes two viral load tests in the first year of treatment and one annually thereafter. For the intervening years, the 90–90–90 projection is a linear projection from 2014 to 2020 to account for the gradual phasing in of 90–90–90. The 90–90–90 viral load estimate for 2020 is based on 26 million people receiving antiretroviral therapy. This works out as 4.4 million people newly receiving treatment and 21.7 million continuing to receive treatment. Two viral load tests for people newly receiving treatment is 8.8 million tests plus one test for the people continuing to receive treatment (21.7 million tests) equals 30.5 million tests for 2020.

Fig. 3. Demand for viral load tests, 2011–2020

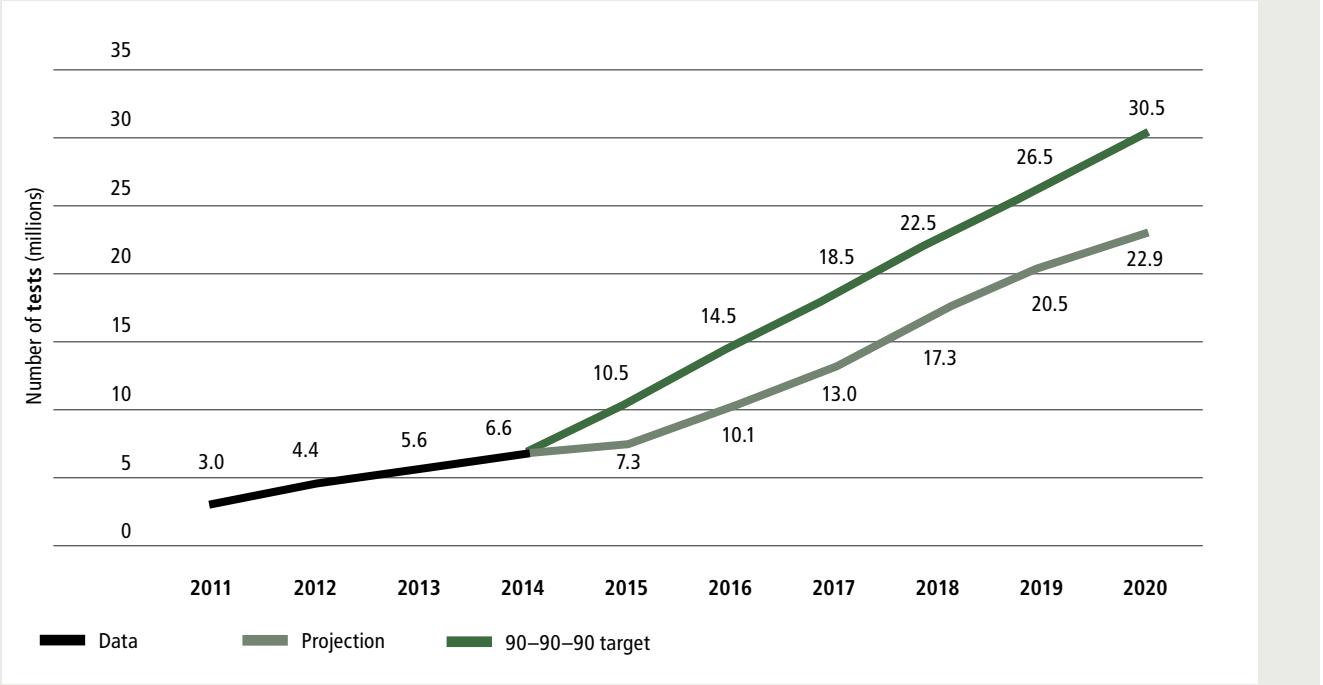
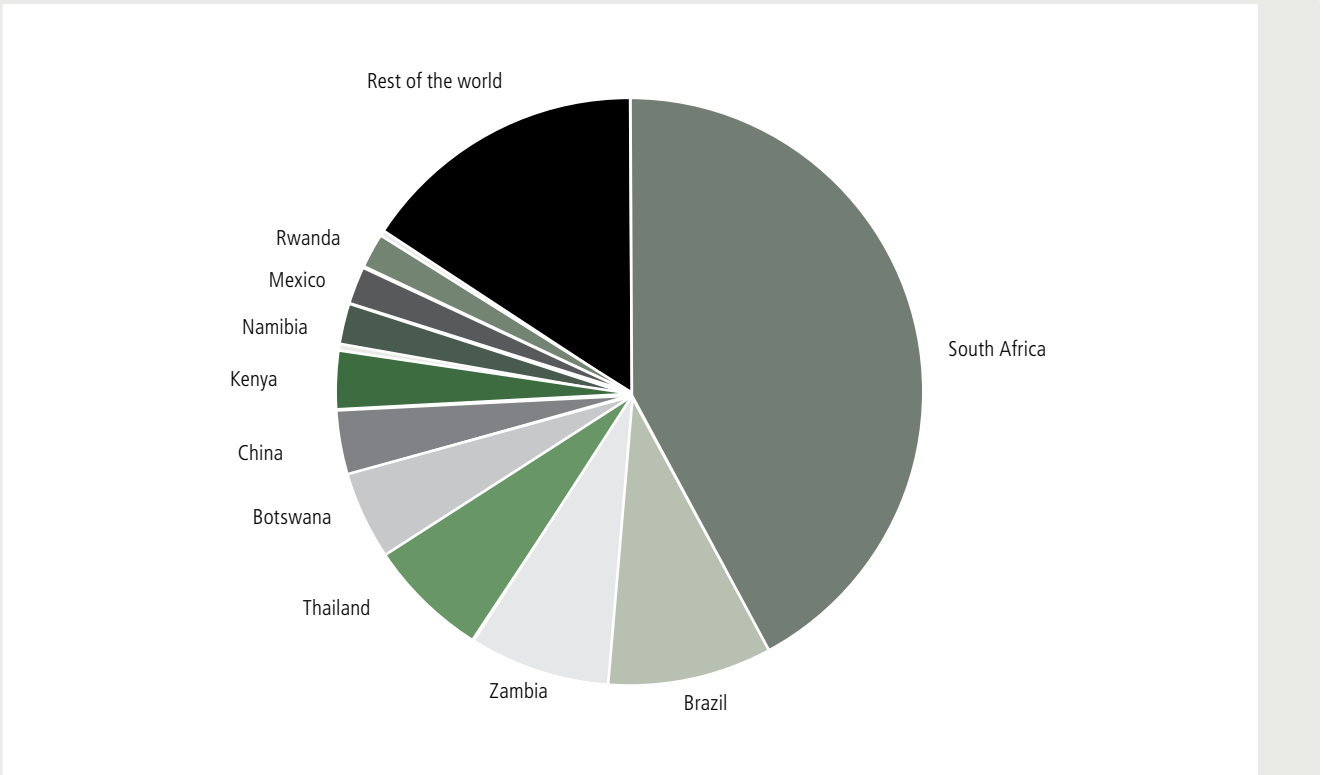


Fig. 4 shows the distribution of viral load tests performed in 2014 by country. Again, the largest market is South Africa, followed by Brazil, Zambia, Thailand and Botswana.

Fig. 4. Distribution of viral load tests performed in 2014 by country



3.3 Early infant diagnosis tests

Fig. 5 shows the trends in the early infant diagnosis tests performed (2011–2014) and forecast demand for early infant diagnosis tests. The trend has been flat for the last three years at about 50% of the need. The projection assumes that programmes will expand their use of early infant diagnosis in accordance with WHO guidelines. Some countries are already adopting testing at birth as well as later tests for the same infants. The demand is expected to more than double to 1.8 million tests by 2020. The number of tests would be even higher if all countries achieved the 90–90–90 treatment target. The 90–90–90 estimate for 2020 assumes 95% coverage of exposed infants and 2.12 tests per exposed infant. This is to allow for one early infant diagnosis test at six weeks, a test at birth in some countries and a later test at 9–12 months in some countries. The number of exposed infants is based on UNAIDS estimates and drops slightly from 1.45 million in 2015 to 1.38 million in 2020. The intervening years in the 90–90–90 scenario assume linear scale-up from 2014 to 2020.

Fig. 5. Demand for early infant diagnosis tests, 2011–2020

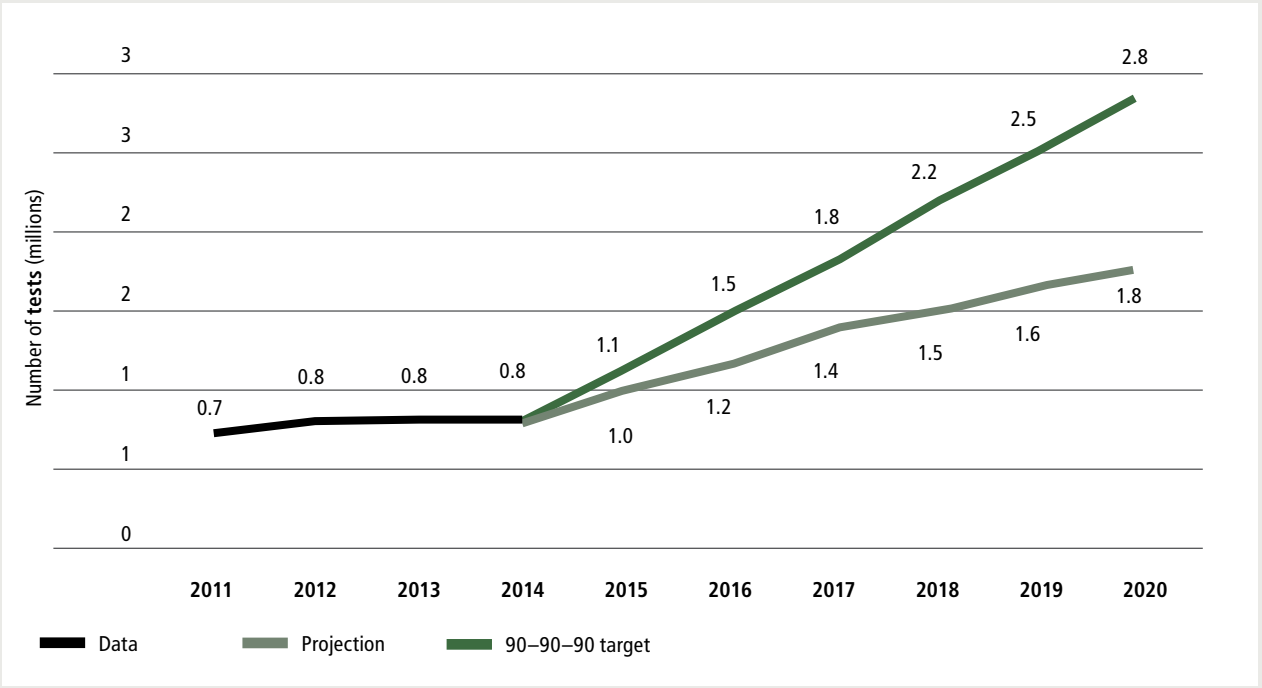
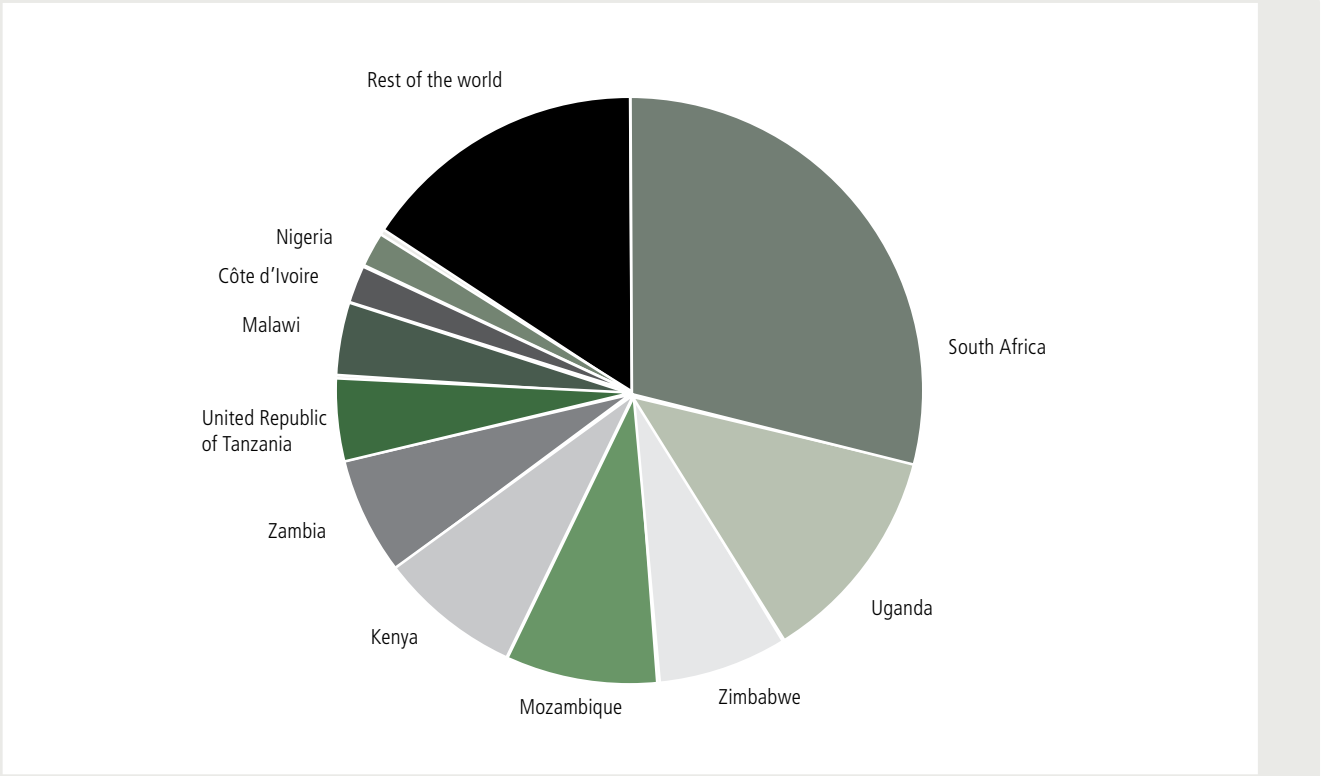


Fig. 6 shows the distribution of the reported early infant diagnosis tests performed by country in 2014 according to the WHO survey. The largest market is in South Africa, followed by Uganda, Zimbabwe, Mozambique and Kenya.

Fig. 6. Distribution of early infant diagnosis tests performed in 2014 by country



3.4 HIV testing

Fig. 7 shows the trends in the uptake for rapid diagnostic tests. The data on the use of rapid diagnostic tests were collected globally from Global AIDS Response Progress Reporting for 2012–2014 and from country-specific reports from the 2015 WHO survey. The linear projection is not particularly reliable since there are only three data points from two sources. A better estimate is expected next year when a second data point from the WHO survey is available.

The 90–90–90 projection uses the following assumptions. In generalized epidemics and hyperepidemics, the percentage of the adult population testing annually increases to 35% by 2020 and then declines after 2020 once most people living with HIV are identified. In countries with heterogeneous epidemics, the coverage target applies only to the geographical areas with the highest prevalence, encompassing two thirds of the people living with HIV. This applies to Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Djibouti, Ethiopia, Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Liberia, Madagascar, Mali, Mauritania, Mauritius, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Somalia, South Sudan, Togo, Uganda and United Republic of Tanzania. In concentrated epidemics, by 2020, there is annual testing for all sex workers, men who have sex with men, people who inject drugs, transgender people and prisoners and 35% annual testing for people with multiple partners and people with TB infection.

Fig. 7. Demand for rapid diagnostic test kits, 2012–2020

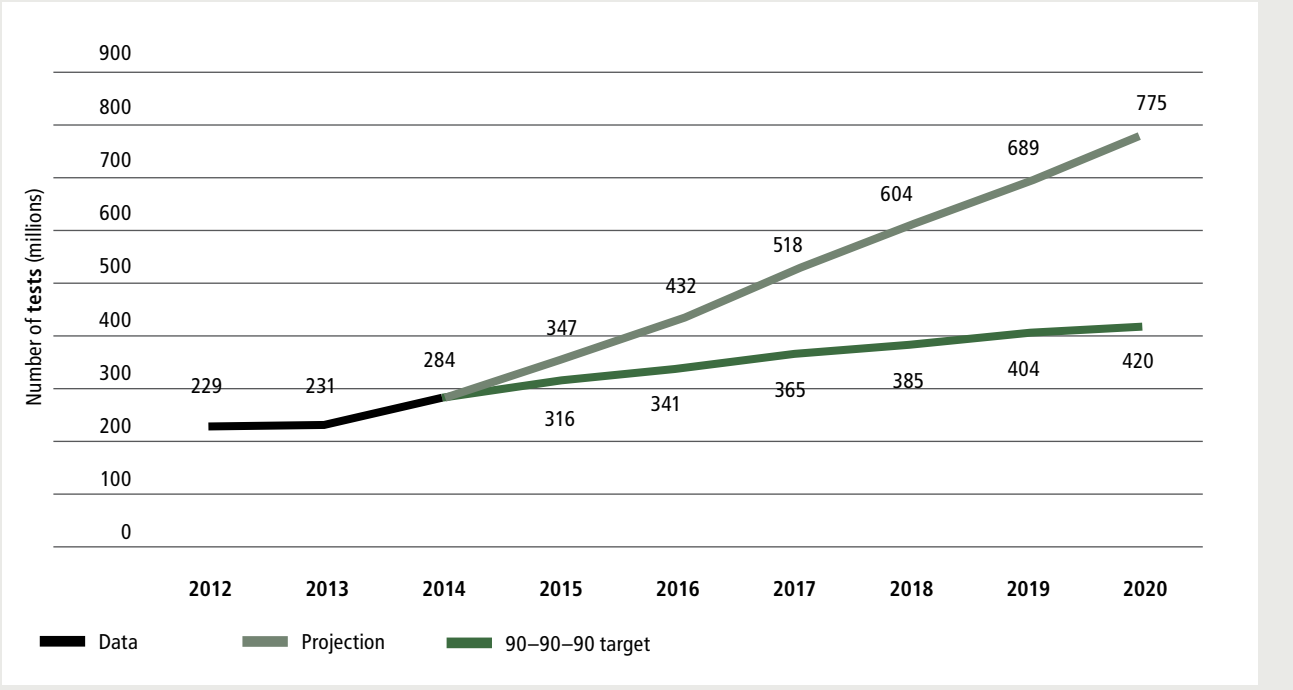
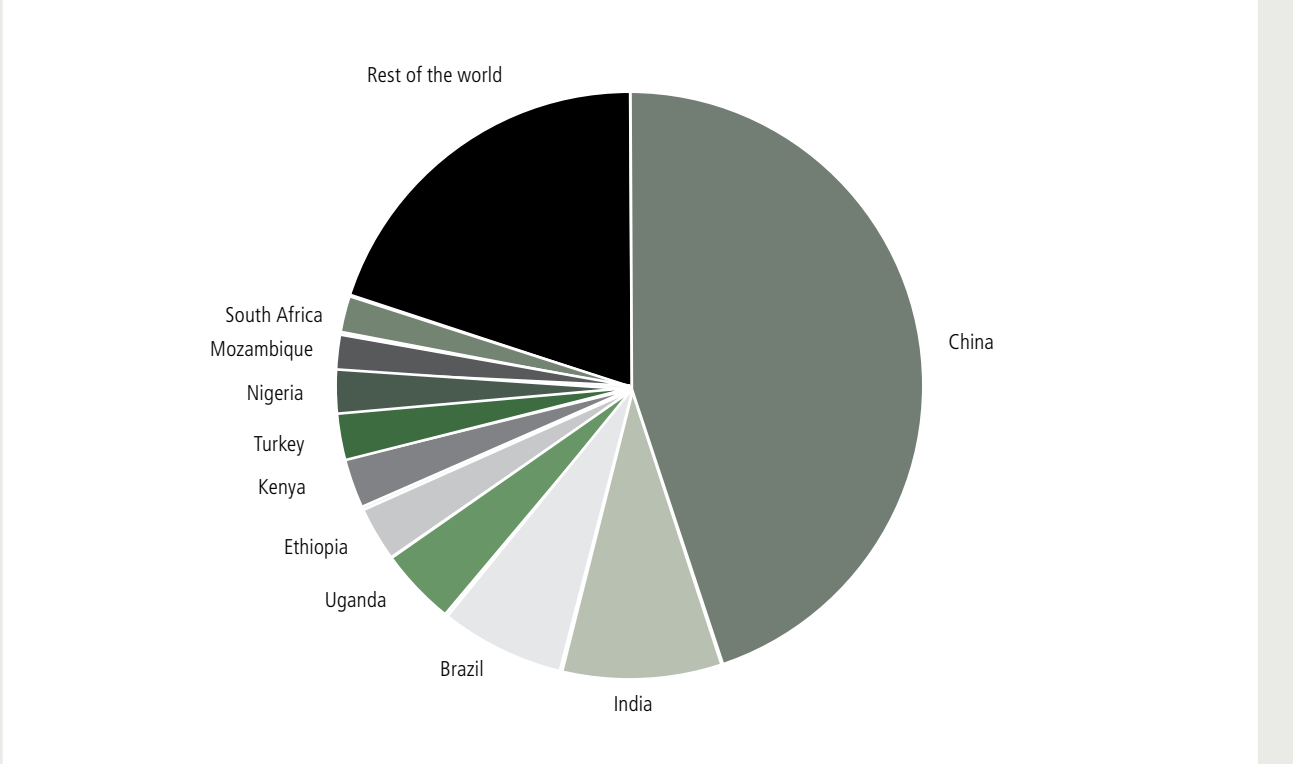


Fig. 8 shows the distribution of the demand for rapid test kits according to the 2014 WHO survey. The largest market is in China, followed by India, Brazil, Uganda and Ethiopia.

Fig. 8. Distribution of rapid test kits used in 2014



4. CONCLUSION

- The demand for CD4 tests is expected to continue to increase and reach >22 million CD4 tests per year in the near future and then plateau at that level for the near term before it starts decreasing.
- The demand for viral load tests will likely reach 23 million per year by 2020.
- The demand for early infant diagnosis tests will probably grow, driven by changes in the testing guidelines to include testing at birth, the introduction of point-of-care early infant diagnosis testing and additional partner funding.
- The demand for rapid diagnostic tests is projected to increase by one third, reaching more than 400 million tests per year by 2020 based on the 90–90–90 projections.
- The future trends in demand will be influenced by efforts to reduce visit and testing frequency, shift monitoring from CD4 to viral load and make testing more efficient.

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