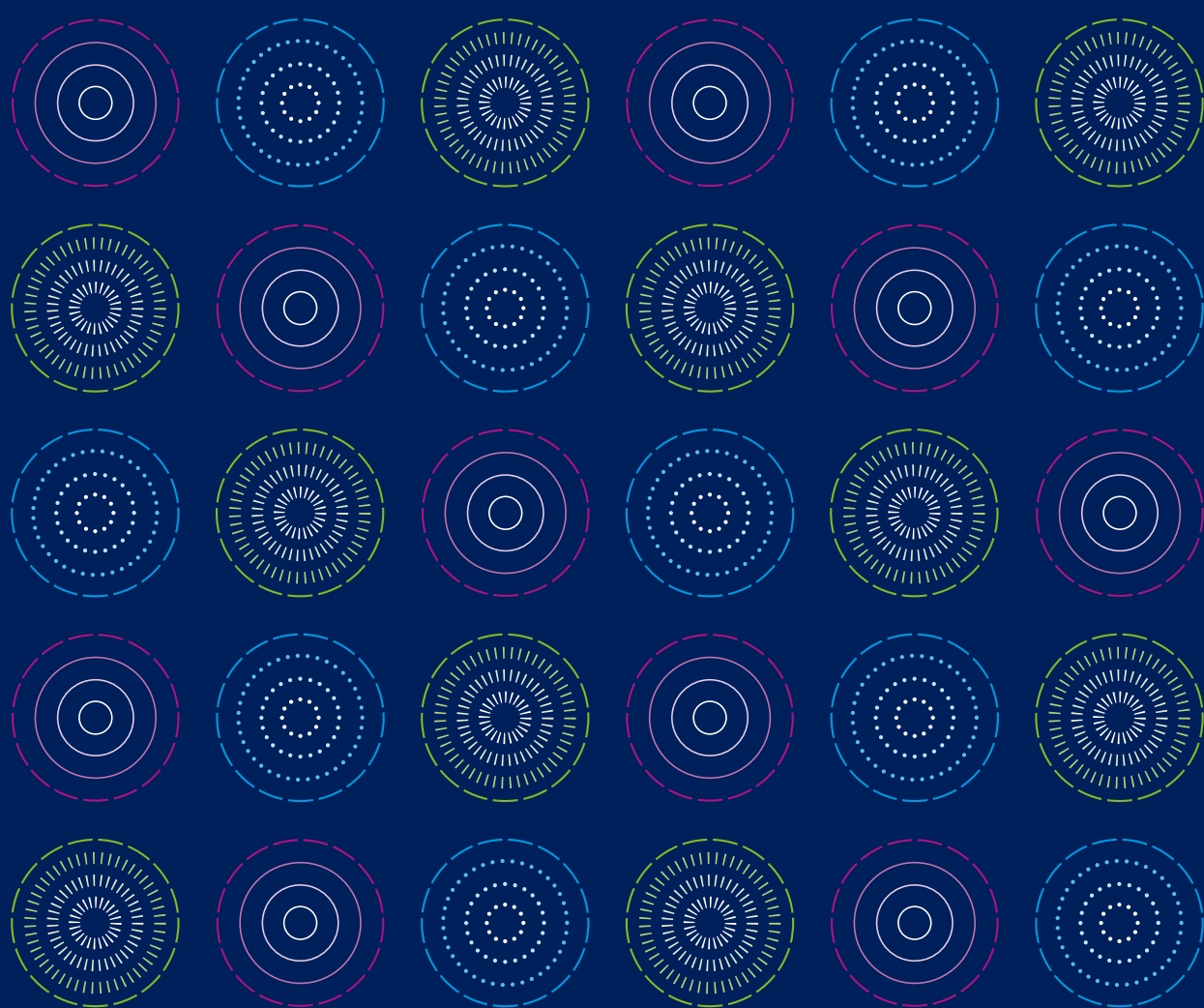


Medicines for HIV, viral hepatitis and sexually transmitted infections in low- and middle-income countries: forecasts of global demand for 2022–2026



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ISBN 978-92-4-008019-5 (electronic version)

ISBN 978-92-4-008020-1 (print version)

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Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

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Design and layout by ACW, London

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Acknowledgements

WHO, UNAIDS and Avenir Health are grateful to the Clinton Health Access Initiative for the successful collaboration on this project and appreciate the effort of all interested experts to reach agreement to develop and produce one consolidated forecast merging Clinton Health Access Initiative forecasts and other projections developed by WHO, UNAIDS and Avenir Health. WHO, UNAIDS and Avenir Health extend their gratitude to the people who reviewed this report and to the comments of the diagnostic meeting participants during plenary discussions.

WHO thanks everyone who contributed to this product, especially Rachel Baggaley, Meg Doherty, Fumni Lesi, Daniel Low-Ber, Morkor Newman and Teodora Wi for their leadership and support and WHO staff members and partners who participated in the joint WHO/UNAIDS consultation with diagnostics companies.

WHO expresses its special thanks to John Stover (Avenir Health), Jessica Fox and Zack Panos (Clinton Health Access Initiative), Jaime Atienza, Mary Mahy and Deepak Mattur (UNAIDS), Robert Matiru (UNITAID) and Boniface Dongmo Nguimfack (WHO).

A special thank you to Kelly Safreed Harmon (independent consultant), who put this report together.

Abbreviations

ART	Antiretroviral therapy
BPG	Benzathine penicillin G
CAB-LA	Long-acting injectable cabotegravir
CHAI	Clinton Health Access Initiative
DVR	Dapivirine vaginal ring
GHSS	Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030
MIU	Million international units
MPP	Medicines Patent Pool
NNRTI	Non-nucleoside reverse-transcriptase inhibitor
NRTI	Nucleoside reverse-transcriptase inhibitor
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
STIs	Sexually transmitted infections

Executive summary

For the global community to be able to achieve ambitious targets relating to the prevention and treatment of HIV, viral hepatitis and sexually transmitted infections (STIs), multiple types of medicines must be widely accessible to all affected populations in all countries.

The purpose of this report is to provide forecasts of future demand for medicines used in the fields of HIV, viral hepatitis and STIs. This report jointly presents medicines forecasts across three disease areas in recognition of the benefits of addressing HIV, viral hepatitis and STIs in a coordinated manner.

Regarding HIV medicines, this report presents findings about demand for antiretroviral therapy (ART) in low- and middle-income countries through 2025, as well as demand for oral pre-exposure prophylaxis (PrEP) globally through 2023. Key findings include the following:

- The number of people receiving ART in low- and middle-income countries increased from 23.6 million in 2019 to 26.6 million in 2021, and a further increase of 25% is expected to occur by 2025.
- Important changes in the antiretroviral drug market include the phasing out of stavudine-based antiretroviral regimens and the replacement of nevirapine and efavirenz with dolutegravir.
- The 880 000 children receiving ART in 2021 represents only about half of all children living with HIV. Reaching the UNAIDS target of 95% treatment coverage by 2025 would require the number of children receiving treatment to increase to 1.1 million.
- About 1.8 million people globally received PrEP at least once in 2021, representing an approximately five-fold increase from 2018.
- During 2018–2021, the WHO region with the greatest increase in PrEP use was the African Region.
- Projected growth in PrEP use may result in up to 5 million people using PrEP in 2023.

This report presents the following key findings about forecasted demand for viral hepatitis B and C medicines.

- The number of people receiving lifelong treatment for viral hepatitis B is projected to steadily increase to about 80 million in 2030.
- About 43 million people are projected to receive treatment for viral hepatitis C between 2021 and 2030.
- Costs for global viral hepatitis B and C elimination are expected to peak at about US\$ 7.4 billion in 2028, with viral hepatitis B accounting for about 80% of total expenditure.
- The WHO regions accounting for the largest share of forecasted costs are the African Region and the South-East Asia Region.

Regarding STIs, this report forecasts demand for benzathine penicillin G (BPG) and describes published findings on using BPG for treating pregnant women with syphilis. The following observations are made.

- Annual global BPG procurement is estimated to range between 74 million and 100 million doses of 1.2 million international units.
- BPG demand for treating pregnant women with syphilis is estimated to represent less than 5% of global BPG demand.
- Wide-scale adoption of the rapid dual HIV/syphilis test is expected to result in a substantial increase in demand for BPG in pregnant women, but such an increase would have a very small impact on overall global demand for BPG.

HIV, viral hepatitis B and C and STIs share modes of transmission, and some of the same key interventions can be used to address multiple disease areas. Further, people affected by these diseases face similar barriers to accessing prevention, screening and treatment commodities. Aligned and integrated responses to HIV, viral hepatitis B and C and STIs may present opportunities for shared treatment platforms to meet service delivery needs more efficiently and effectively.

Introduction

For the global community to be able to achieve ambitious targets relating to the prevention and treatment of HIV, viral hepatitis and sexually transmitted infections (STIs), multiple types of medicines must be widely accessible to all affected populations in all countries.

The purpose of this report is to provide forecasts of future demand for medicines used in the fields of HIV, viral hepatitis and STIs. These forecasts have multiple potential uses. First, they may inform advocacy efforts to increase access to medicines. Second, they may guide health systems and procurement organizations in planning how to obtain adequate supplies of medicines to fulfil service delivery needs. Third, they may aid manufacturers in identifying opportunities to contribute to meeting anticipated market demand.

This report jointly presents medicines forecasts across three disease areas in recognition of the benefits of addressing HIV, viral hepatitis B and C and STIs in a coordinated manner. These diseases share modes of transmission, and some of the same key interventions can be used to address multiple disease areas. Further, epidemics of these diseases are shaped in similar ways by social and structural determinants of health, and the people affected by these diseases face similar barriers to accessing prevention, screening and treatment commodities. Aligned and integrated responses to HIV, viral hepatitis B and C and STIs may present opportunities for shared treatment platforms to meet service delivery needs more efficiently and effectively.

1.1 The global burden of HIV, viral hepatitis B and C and STIs

An estimated 38.4 million people were living with HIV at the end of 2021, two thirds of whom (25.6 million) are in the WHO African Region (1). In 2021, 1.5 million people acquired HIV and 650 000 people died from HIV-related causes. Since 2016, WHO has recommended that all people living with HIV be provided with lifelong antiretroviral therapy (ART), regardless of their clinical status or CD4 cell count. Globally, 28.7 million people living with HIV were receiving ART in 2021, representing an ART coverage level of 75%.

An estimated 296 million people were living with chronic hepatitis B infection in 2019, with 1.5 million new infections occurring each year. Hepatitis B resulted in an estimated 820 000 deaths in 2019. The burden of hepatitis B infection is highest in the WHO Western Pacific Region (1), with 116 million people chronically infected, and African Region (1), with 81 million people chronically infected. As of 2019, only 10% of all people estimated to be living with hepatitis B were aware that they were infected, and 6.6 million (22%) of the people diagnosed were receiving treatment. An estimated 12–25% of people with chronic hepatitis B infection will require treatment, depending on the setting and eligibility criteria. Most people who start hepatitis B treatment must continue it for life.

An estimated 58 million people were living with chronic hepatitis C infection in 2019, with 1.5 million new infections occurring each year. Hepatitis C resulted in an estimated 290 000 deaths in 2019. Direct-acting antiviral medicines can cure more than 95% of the people with hepatitis C infection, but access to diagnosis and treatment is low. In 2019, an estimated 21% of people living with viral hepatitis C (15.2 million) knew their status, and of those diagnosed with chronic hepatitis C infection, about 62% (9.4 million) people had been treated with direct-acting antiviral medicines by the end of 2019.

There are an estimated 374 million new infections annually with one of four curable STIs: chlamydia, gonorrhoea, syphilis and trichomoniasis. One of these, syphilis, is targeted in the WHO initiative for the

triple elimination of mother-to-child HIV, syphilis and hepatitis B (2). WHO estimates that 930 000 pregnant women annually have probable active syphilis (transmissible during pregnancy). This is thought to result in about 350 000 adverse birth outcomes, with neonatal death and stillbirth accounting for more than half of these outcomes. Other adverse outcomes include prematurity, low birthweight and organ deformity. Benzathine penicillin G (BPG) is the only recommended treatment to prevent the mother-to-child transmission of syphilis. Two BPG products have been prequalified by WHO for treatment of maternal syphilis and prevention of congenital syphilis: RH103, benzathine benzylpenicillin + water for injection (powder and solvent for suspension for injection 1 200 000 IU + 4 mL) (3) and RH104, benzathine benzylpenicillin + water for injection (powder and solvent for suspension for injection 2 400 000 IU + 6 mL) (4). BPG is underutilized in antenatal care in many countries, in part because of low levels of screening for maternal syphilis. Since 2019, WHO has recommended that antenatal care services use the rapid dual HIV/syphilis test to screen pregnant women for both diseases simultaneously, and efforts are underway to scale up this intervention worldwide.

1.2 The global health sector strategies for HIV, viral hepatitis and sexually transmitted infections

In 2022, the Seventy-Fifth World Health Assembly approved the implementation of WHO's global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022–2030 (GHSS) (5). These strategies propose a common vision to end epidemics and advance universal health coverage, primary health care and health security in a world in which everyone has access to high-quality, evidence-informed and people-centred health services.

The GHSS promote the disease-specific goals of ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections by 2030, with cross-cutting and disease-specific targets and milestones defined to drive progress toward these goals. Future demand for medicines for HIV, viral hepatitis B and C and STIs will be influenced in part by the efforts of national health systems and other stakeholders to achieve the following GHSS targets.

- **HIV.** The GHSS adopt the 95–95–95 targets set forth in the UNAIDS Global AIDS Strategy 2021–2026: End Inequalities, End AIDS (6). These targets call for the following to be achieved by 2025: 95% of the people living with HIV know their HIV status, 95% of the people who know their HIV-positive status are accessing treatment and 95% of the people receiving treatment have suppressed viral loads. The GHSS call for the 95–95–95 targets to be achieved in both 2025 and 2030.
- **Viral hepatitis B and C.** The GHSS call for 60% of people living with viral hepatitis B and C to be diagnosed by 2025 and for 90% of this population to be diagnosed by 2030. The GHSS call for 50% of people living with viral hepatitis B and C to be treated by 2025 and for 80% of this population to be treated by 2030.
- **STIs.** The GHSS call for the number of congenital syphilis cases per 100 000 live births per year to be reduced from an estimated baseline of 425 in 2020 to less than 50 in 2030. The GHSS also call for the percentage of pregnant women screened for syphilis in antenatal care to increase to at least 95% by 2030 and for the percentage of those who are treated following a syphilis diagnosis to increase to at least 95% by 2030.

1.3 How this report is organized

The remainder of this report presents forecasting information for medicines in three chapters.

- **Chapter 2: medicines for HIV.** This chapter forecasts demand for antiretroviral medicines in low- and middle-income countries through 2025. It also forecasts demand for oral pre-exposure prophylaxis (PrEP) globally through 2023. It shares information about market demand for three other types of medicines used in HIV interventions: dapivirine vaginal ring (DVR), long-acting injectable cabotegravir (CAB-LA), and post-exposure prophylaxis (PEP).
- **Chapter 3: medicines for viral hepatitis B and C.** This chapter forecasts demand for viral hepatitis B and C medicines.
- **Chapter 4: medicines for STIs.** This chapter forecasts demand for benzathine penicillin G for treating pregnant women with syphilis.

Medicines for HIV

This chapter reports on two forecasting exercises. One forecasting exercise was conducted to project demand for ART for HIV clinical management through 2025. The other was conducted to project demand for PrEP with oral tenofovir-based medication regimens to prevent HIV infection.

Key insights

- The number of people receiving ART in low- and middle-income countries increased from 23.6 million in 2019 to 26.6 million in 2021, and a further increase of 25% is expected to occur by 2025.
- Important changes in the antiretroviral drug market include the phasing out of stavudine-based antiretroviral regimens and the replacement of nevirapine and efavirenz with dolutegravir.
- The number of children living with HIV in low- and middle-income countries is projected to continue to decline from 1.7 million in 2021 to 1.3 million in 2025. However, the 880 000 children receiving ART in 2021 represent only about half of all children living with HIV. Reaching the UNAIDS target of 95% treatment coverage by 2025 would require the number of children receiving treatment to increase to 1.1 million. Since diagnosing children is difficult, especially older children, the number of children receiving ART has not increased in recent years and even decreased in 2020 and 2021.
- About 1.8 million people globally received PrEP at least once in 2021, representing an approximately five-fold increase from 2018.
- During 2018–2021, the WHO region with the greatest increase in PrEP use was the African Region.
- Projected growth in PrEP use may result in up to 5 million people using PrEP in 2023.

2.1 ART for HIV clinical management

2.1.1 Methods

The forecasting exercise that focused on ART for HIV clinical management utilized multiple methods to produce five sets of findings, which are reported respectively in the next five sections of this report. The method for each set of findings is described below.

Projected total number of people receiving ART.

The total number of people receiving ART in low- and middle-income countries was projected in three ways.

- a) A “linear projection” was developed based on country reporting to Global AIDS Monitoring. Actual data were available through 31 December 2021. A linear projection of the 2019–2021 trend was extended to 2025.
- b) A “country forecast projection” was developed using forecasts countries are asked to prepare alongside their annual HIV estimates. Some countries may draw forecasting data from sources such as past trends and operational plans. Others may develop their forecasts based on assumptions about global HIV targets being achieved. Thus, the projections are not developed by using a consistent method across all countries. The current report draws on forecasts from 134 low- and middle-income countries.
- c) A “95–95–95 projection” was developed to reflect the number of people who will be receiving ART by 2025 if the UNAIDS 95–95–95 targets are met. The 95–95–95 targets may represent the upper limit of what can be expected in regard to how many people will be receiving ART by 2025. Achieving the UNAIDS HIV prevention target would bring about a sharp reduction in the number of people acquiring HIV by 2025, meaning that fewer people would need to initiate ART.

Projected numbers of people receiving first-line and second-line ART. The numbers of people receiving first-line and second-line ART regimens in low- and middle-income countries were projected in two ways.

- a) The proportion of people receiving second-line ART as reported to Global AIDS Monitoring was projected by linear extrapolation to 2025. This proportion was applied to the total number of people receiving ART to estimate the number of people receiving first- and second-line ART.
- b) Country forecasts were used, with country data obtained as described in the preceding section. The total number of children receiving second-line ART could not be estimated because of a lack of available data. A forecast for children was developed by applying the percentage of adults receiving second-line ART to the total number of children receiving ART.

Historical and forecasted demand for individual antiretroviral drugs, adult first-line treatment population. Historical estimates of the proportions of individual antiretroviral drugs used by adults receiving first-line ART are based on data from WHO surveys (2011–2018) and Global AIDS Monitoring data (2019–2021). Projections (2022–2025) are based on the global antiretroviral forecast prepared by the Clinton Health Access Initiative (CHAI) (7). This forecast draws on data from CHAI country teams and published information on patient regimens, national guidelines, attrition rates, failure rates, toxicity rates, future antiretroviral drug trends and other key factors in 20 countries with high levels of ART use. The CHAI forecasting model uses these data to project antiretroviral drug demand by drug and by regimen in each of these countries over the next five years. CHAI then aggregates estimates across the countries and extrapolates these results to all remaining low- and middle-income countries. For tenofovir alafenamide, efavirenz, nevirapine and dolutegravir, the Medicines Patent Pool (MPP) also provided projections based on its perceptions of market growth potential.

Historical demand for individual antiretroviral drugs, adult second-line treatment population.

Historical data on the use of antiretroviral drugs for adult second-line ART came initially from country responses to an annual survey sent by WHO to each country. Since 2020, countries have been reporting this information directly to the Global AIDS Monitoring system.

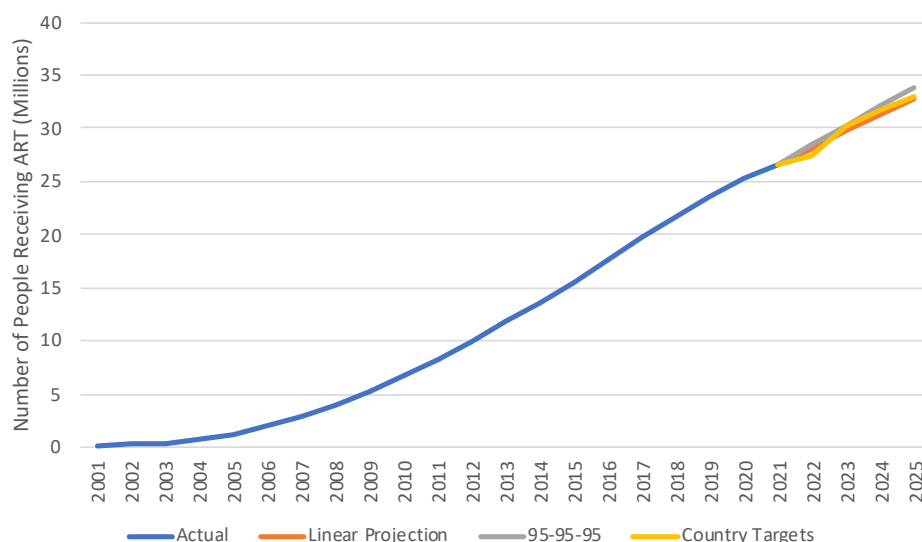
Historical demand for individual antiretroviral drugs, children. Historical data on the use of antiretroviral drugs for children came initially from country responses to an annual survey sent by WHO to each country. Since 2020, countries have been reporting this information directly to the Global AIDS Monitoring system.

This method for forecasting demand has multiple limitations. Although 75% of all adults receiving ART in low- and middle-income countries reside in the 20 countries from which the CHAI data were obtained, these countries may not be representative of other countries not included in the data set. In country reporting, the classification of children can differ depending on whether they are taking adult or paediatric formulations. As such, some children may be classified as adults. Projections prepared for countries not covered by CHAI assume linear increases from past trends. Actual trends may deviate from a linear trend because of several factors, including saturation, price changes and the availability of new drugs. Linear extrapolation may work well for short-term projections but should be used with caution for longer-term projections.

2.1.2 Projected total number of people receiving ART

As shown in Fig. 2.1, the total number of people projected to be receiving ART by 2025 in low- and middle-income countries ranges from 32.8 million in the linear projection to 33.8 million in the 95–95–95 projection. The total in the country forecast projection, 33.1 million, is only slightly higher than the total in the linear projection. The percentage increase in the total number of people receiving ART from 2021 to 2025 ranges from 23% in the linear projection to 27% in the 95–95–95 projection.

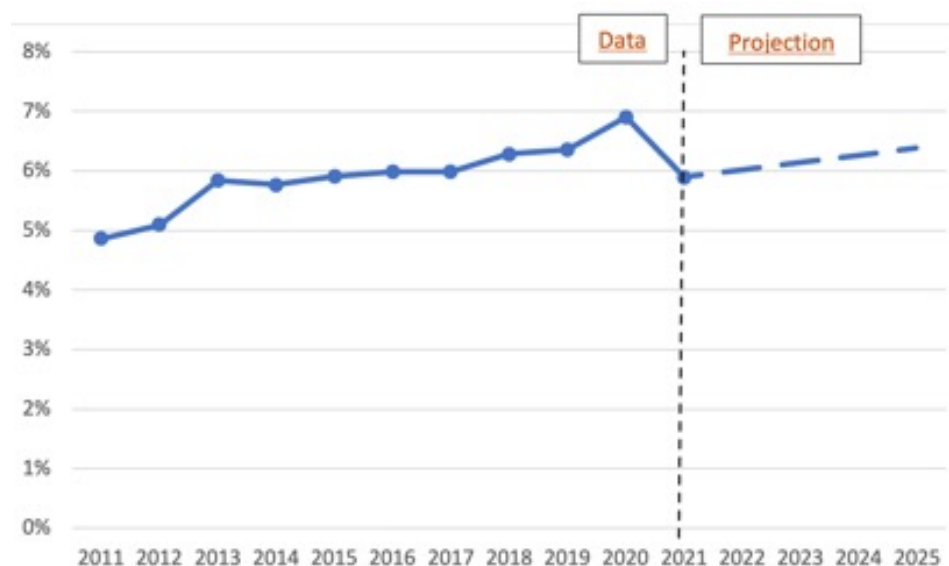
Fig. 2.1. Projected number of adults and children in low- and middle-income countries receiving ART by 2025



2.1.3 Projected numbers of people receiving first-line and second-line ART

About 94% of adults in low- and middle-income countries were receiving first-line ART regimens in 2021. The proportion of adults receiving second-line ART regimens increased slightly overall from 2011 to 2021, and this trend is projected to continue (Fig. 2.2).

Fig. 2.2. Historical and forecasted proportion of adults in low- and middle-income countries receiving second-line ART, 2011–2025



For children, 86 countries reported data on children receiving second-line ART regimens. Reporting countries accounted for 75% of all children receiving ART in low- and middle-income countries. These countries reported that 8.3% of children receiving ART were receiving second-line regimens in 2021.

Table 2.1 shows the number of adults and children projected to be receiving first- and second-line ART according to the “country forecast projection”. Because of a lack of available data on children receiving second-line ART, the adult second-line percentage has been applied to children as well.

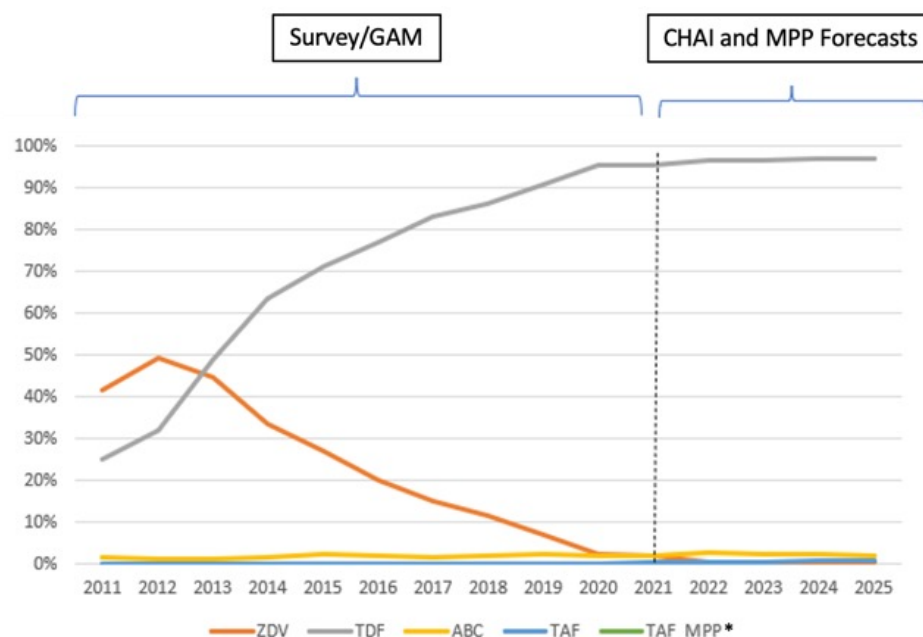
Table 2.1. Projected numbers of adults and children receiving first-line and second-line ART, low- and middle-income countries, 2020–2025

Population	Reported		Projected			
	2020	2021	2022	2023	2024	2025
Adults, first-line ART	22 630 000	24 200 000	24 900 000	27 400 000	28 700 000	30 000 000
Adults, second-line ART	1 680 000	1 520 000	1 590 000	1 790 000	1 920 000	2 050 000
Children, first-line ART	829 000	800 000	877 000	890 000	898 000	922 000
Children, second-line ART	75 300	72 700	79 600	80 900	81 500	83 700
Total	25 200 000	26 600 000	27 400 000	30 200 000	31 600 000	33 100 000

2.1.4 Forecasted demand for individual antiretroviral drugs, adult first-line treatment population

Fig. 2.3 shows the historical trends and projections for primary nucleoside reverse-transcriptase inhibitors (NRTIs) for adults. Tenofovir alafenamide has clearly come to dominate this market. However, there continues to be some demand for other drugs in this category, as detailed in Table 2.2. Ensuring a consistent supply of zidovudine and abacavir for people who cannot tolerate tenofovir will remain important.

Fig. 2.3. Historical and forecasted demand for primary NRTIs in adult first-line ART, 2011–2025



Survey = WHO survey, GAM = Global AIDS Monitoring, CHAI = Clinton Health Access Initiative, MPP = Medicines Patent Pool, ZDV = zidovudine, TDF = tenofovir disoproxil fumarate, ABC = abacavir, TAF = tenofovir alafenamide, TAF-MPP = tenofovir alafenamide projected by MPP.

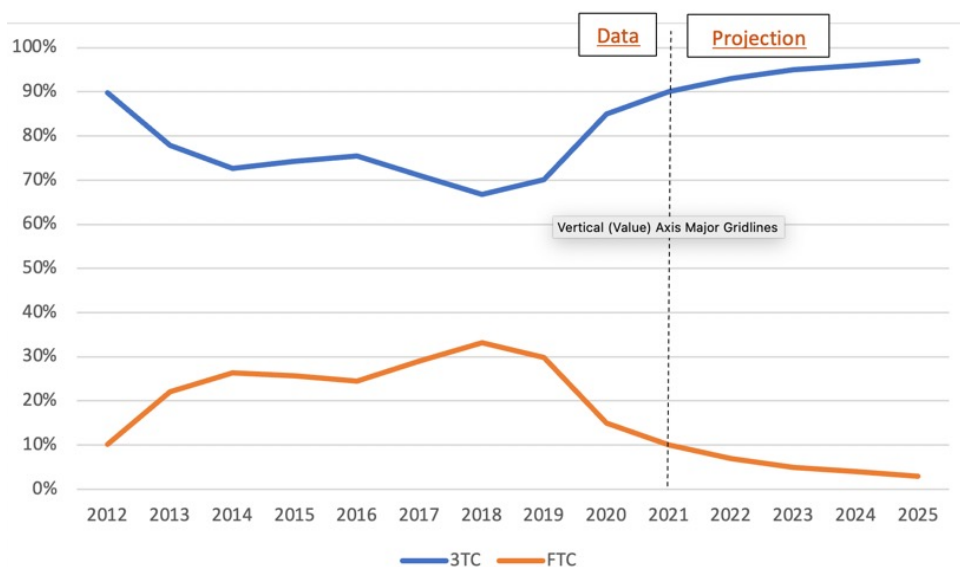
*TAF-MPP is not visible in the figure because reported demand was close to zero.

Table 2.2. Historical and forecasted demand for atazanavir, abacavir and tenofovir alafenamide in adult first-line ART, 2020–2025

Drug	2020	2021	2022	2023	2024	2025
Zidovudine	2.2%	2.0%	0.3%	0.3%	0.3%	0.2%
Abacavir	2.0%	1.9%	2.5%	2.4%	2.2%	2.0%
Tenofovir alafenamide	0.2%	0.6%	0.5%	0.6%	0.7%	0.8%

In the market for secondary NRTIs for adult first-line treatment, demand for lamivudine increased to about 97% in 2021 and is expected to remain high (Fig. 2.4).

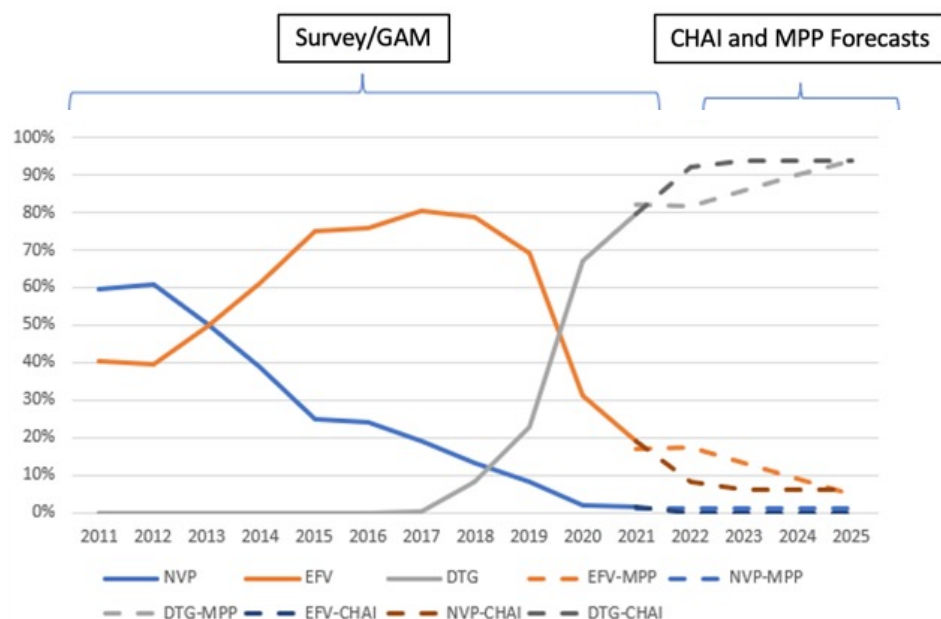
Fig. 2.4. Historical and forecasted demand for secondary NRTIs in adult first-line ART, 2012–2025



3TC = lamivudine, FTC = emtricitabine

Fig. 2.5 shows the historical trends and projections for non-nucleoside reverse-transcriptase inhibitors (NNRTIs) and dolutegravir for adults. Demand for dolutegravir has increased and is expected to continue increasing until it accounts for about 95% of the market by 2025. Demand for efavirenz is expected to drop to about 6% during this time. Use of nevirapine is expected to be phased out in the near future.

Fig. 2.5. Historical and forecasted demand for NNRTIs and dolutegravir in adult first-line ART, 2011–2025

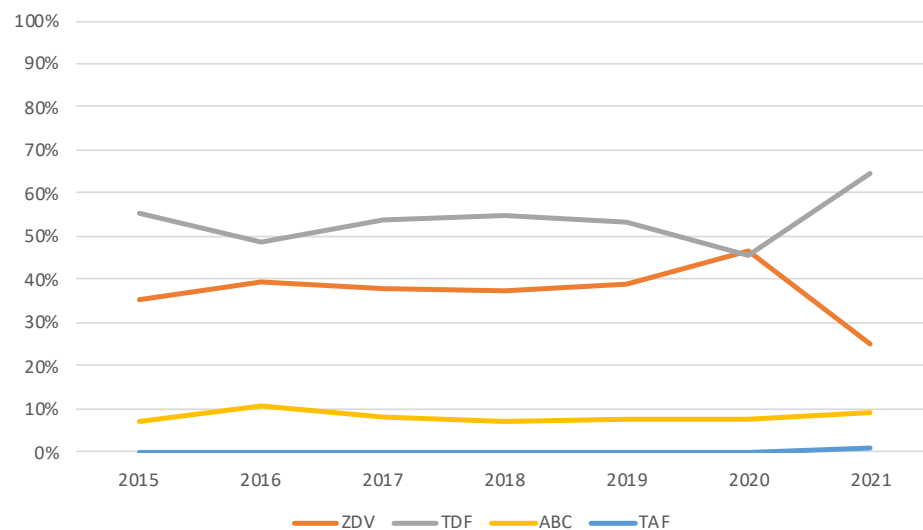


Survey = WHO survey, GAM = Global AIDS Monitoring, CHAI = Clinton Health Access Initiative, MPP = Medicines Patent Pool, NVP = nevirapine, EFV = efavirenz, DTG = dolutegravir, EFV-MPP = efavirenz projected by MPP, NVP-MPP = nevirapine projected by MPP, DTG-MPP = dolutegravir projected by MPP, EFV-CHAI = efavirenz projected by CHAI, NVP-CHAI = nevirapine projected by CHAI, DTG-CHAI = dolutegravir projected by CHAI.

2.1.5 Historical demand for individual antiretroviral drugs, adult second-line treatment population

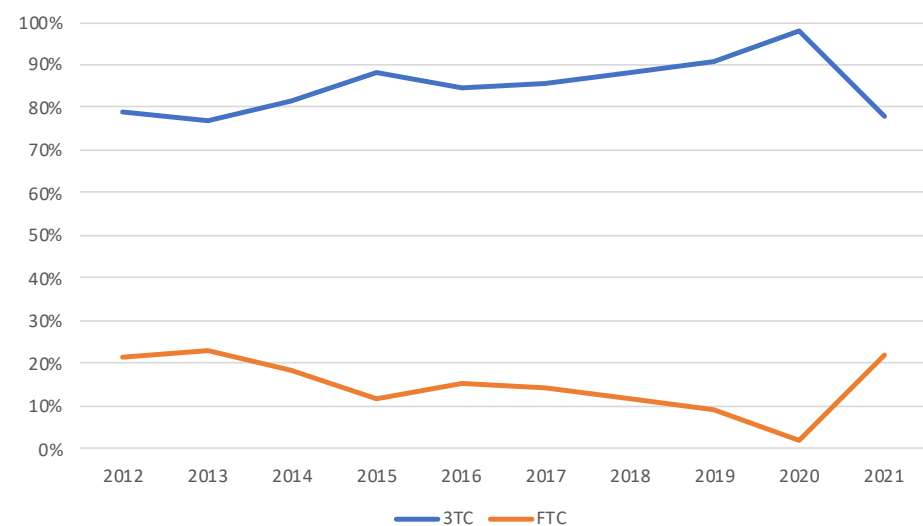
Fig. 2.6, Fig. 2.7 and Fig. 2.8 show historical trends for adult second-line primary NRTIs, adult second-line secondary NRTIs and other second-line drugs, respectively.

Fig. 2.6. Historical demand for primary NRTIs in adult second-line ART, 2015–2021



ZDV = zidovudine, TDF = tenofovir disoproxil fumarate, ABC = abacavir, TAF = tenofovir alafenamide.

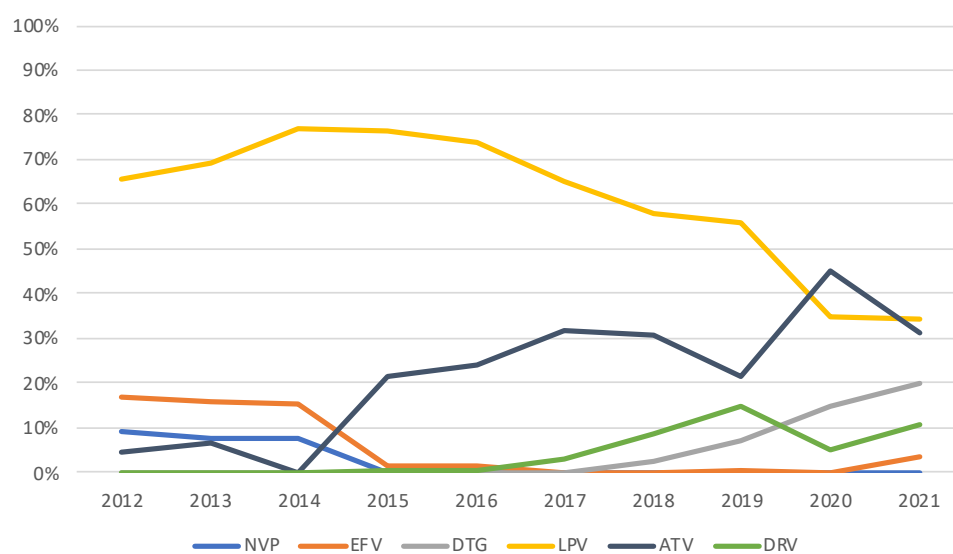
Fig. 2.7. Historical demand for secondary NRTIs in adult second-line ART, 2015–2021



3TC = lamivudine, FTC = emtricitabine.

Note: The abrupt change in 2021 resulted from more countries reporting in 2021. For countries that reported in both 2020 and 2021, the shares are nearly identical in both years.

Fig. 2.8. Historical demand for NNRTIs, protease inhibitors and dolutegravir in adult second-line ART, 2012–2021

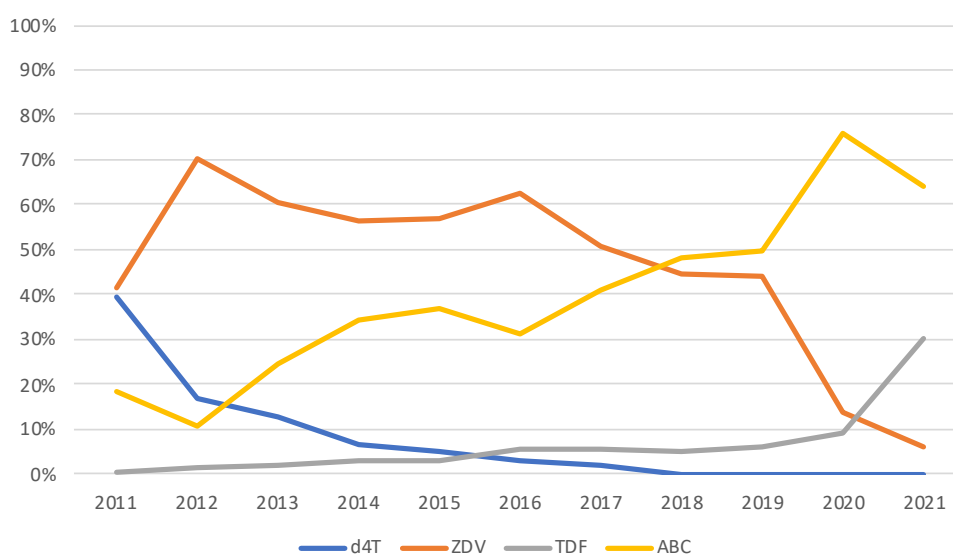


NVP = nevirapine, EFV = efavirenz, DTG = dolutegravir, LPV = lopinavir, ATV = atazanavir, DRV = darunavir.

2.1.6 Historical demand for individual antiretroviral drugs, children

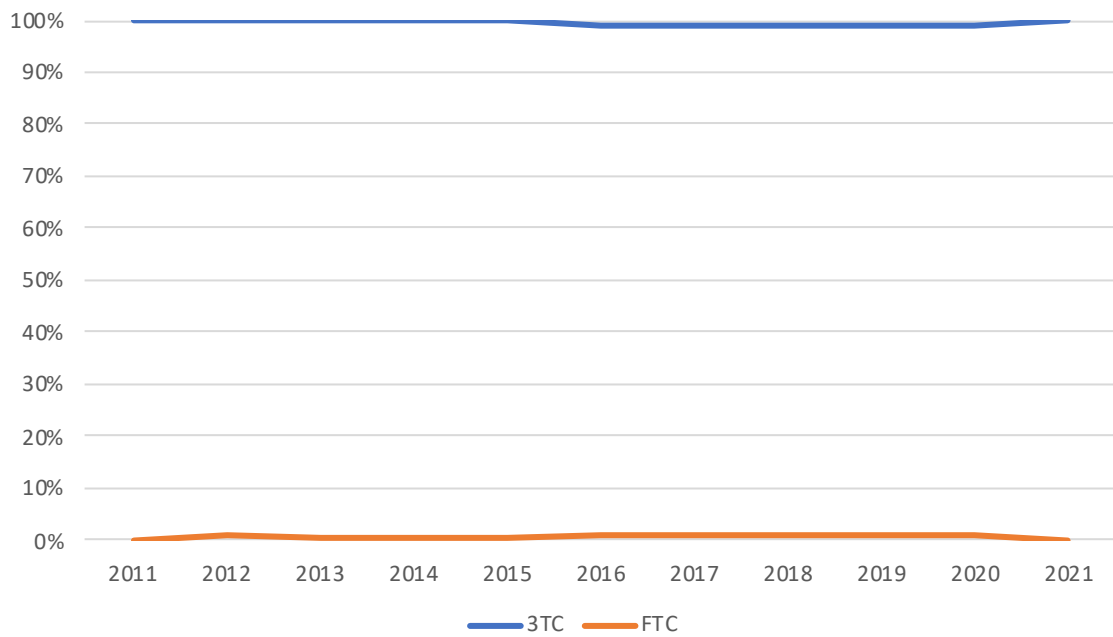
Fig. 2.9, Fig. 2.10 and Fig. 2.11 show historical trends for primary NRTIs for children, secondary NRTIs for children and other drugs for children, respectively. In 2020, the use of abacavir increased greatly in the primary NRTI market (Fig. 2.9). This was driven principally by large increases in Kenya, Nigeria, Uganda, Zambia and Zimbabwe. The preferred secondary NRTI historically has been lamivudine (Fig. 2.10). From 2019 to 2020, more than half of nevirapine use was replaced by dolutegravir use (Fig. 2.11).

Fig. 2.9. Historical demand for primary NRTIs in ART for children, 2011–2021



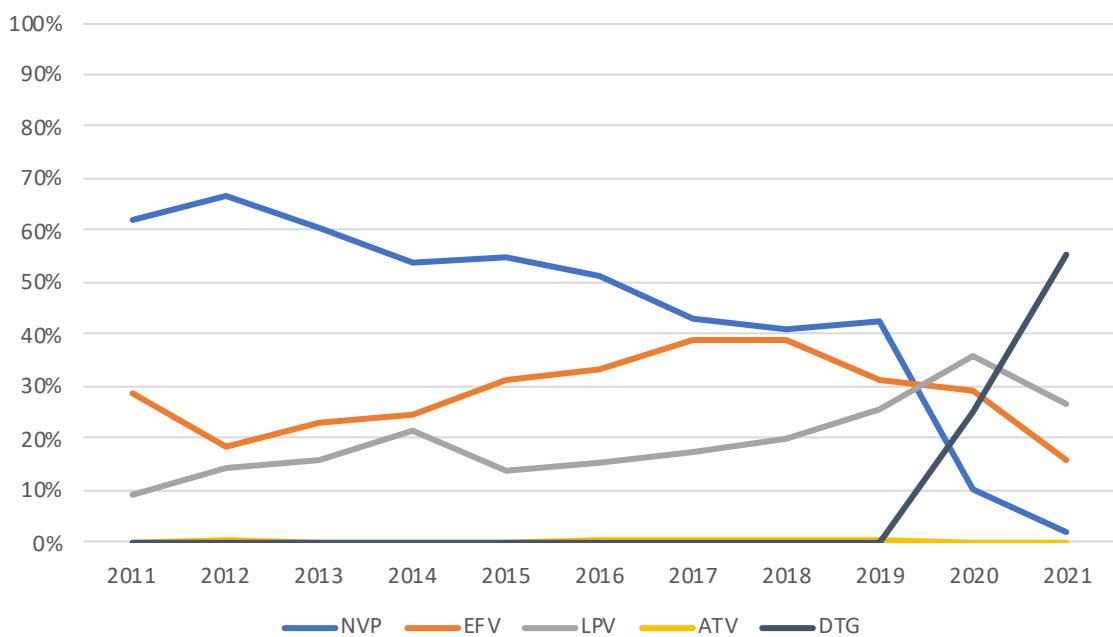
d4T = stavudine, ZDV = zidovudine, TDF = tenofovir disoproxil fumarate, ABC = abacavir.

Fig. 2.10. Historical demand for secondary NRTIs in ART for children, 2011–2021



3TC = lamivudine, FTC = emtricitabine

Fig. 2.11. Historical demand for NNRTIs, protease inhibitors and dolutegravir in ART for children, 2011–2021



NVP = nevirapine, EFV = efavirenz, LPV = lopinavir, ATV = atazanavir, DTG = dolutegravir.

2.2 Oral PrEP

2.2.1 Methods

Demand for oral tenofovir-based PrEP was forecasted using the following method, described in detail in a previous publication (8).

Historical numbers of PrEP users by country and WHO region for 2016–2021 were estimated using data from Global AIDS Monitoring and country-specific reporting to WHO. Historical numbers of PrEP users for 2012–2015 were drawn from a peer-reviewed study of PrEP use in the United States, which was one of the few countries with widespread PrEP use during that period (9).

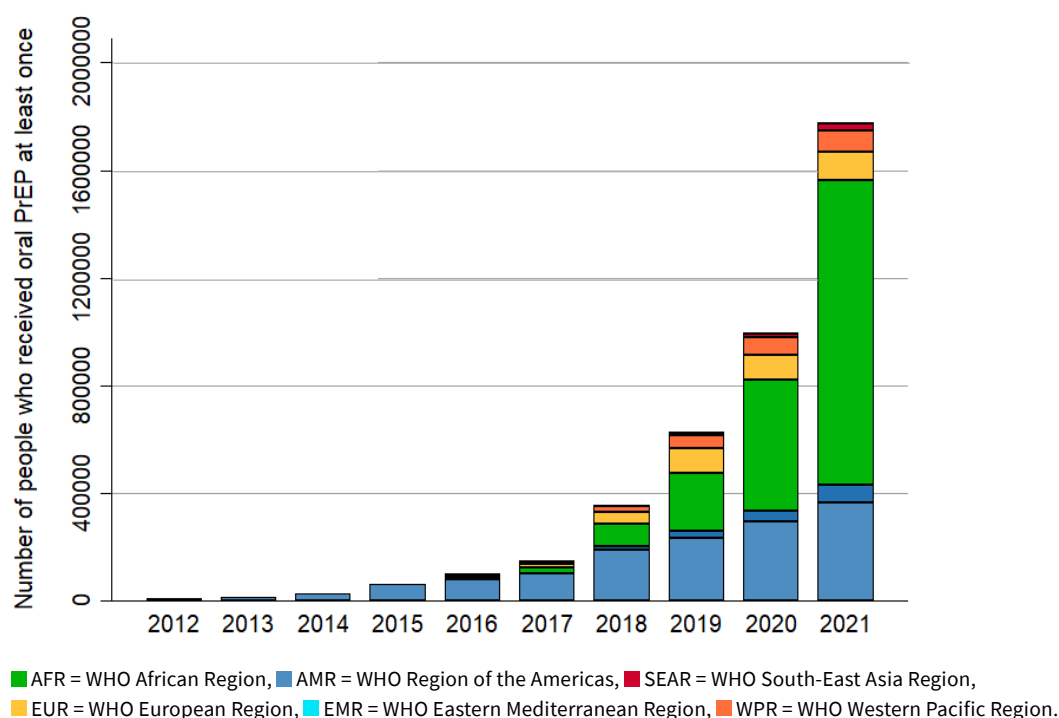
PrEP user numbers were forecasted for each year from 2020 to 2023, based on data through 2019. Forecasts were developed by selecting two to three “example” countries with at least three years of PrEP user data per WHO region and drawing on data from these countries to estimate future trajectories of PrEP use. The example countries were selected to represent different HIV epidemics and PrEP programme histories. For regions that lacked sufficient data for generating PrEP trajectories for three example countries, PrEP trajectories from example countries in other regions

were applied. These proxy example countries were chosen based on similarities in HIV epidemics and PrEP programme histories as well as geographical proximity to the region lacking sufficient data. In addition to the three observed PrEP trajectories for each region, three additional “low-growth” trajectories were estimated by reducing the anticipated increase in PrEP users by 25% for each respective trajectory. The resulting six example trajectories for each region were used to forecast PrEP use in all countries in that region, with trajectories applied in accordance with information about each respective country’s reported history of PrEP use or lack thereof as well as the country’s adoption or non-adoption of WHO PrEP recommendations.

2.2.2 Historical and forecasted users of oral PrEP

About 1.8 million people globally received PrEP at least once in 2021, representing an approximately five-fold increase from 2018 (Fig. 2.12). During 2018–2021, the WHO region with the greatest increase in PrEP use was the African Region.

Fig. 2.12. Numbers of people who received oral PrEP at least once per year by WHO region, 2012–2021



The countries with the largest numbers of PrEP users in 2021 were Kenya, Nigeria, South Africa, Uganda, the United States of America and Zambia (Fig. 2.13).

Fig. 2.13. Global distribution of users of oral PrEP, 2021

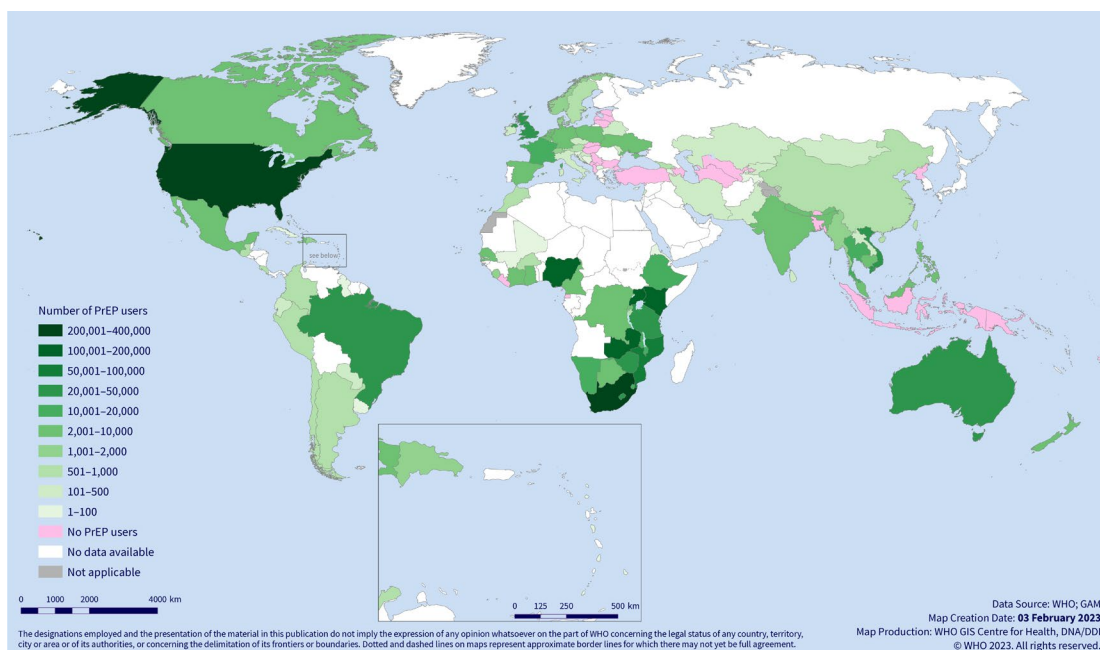
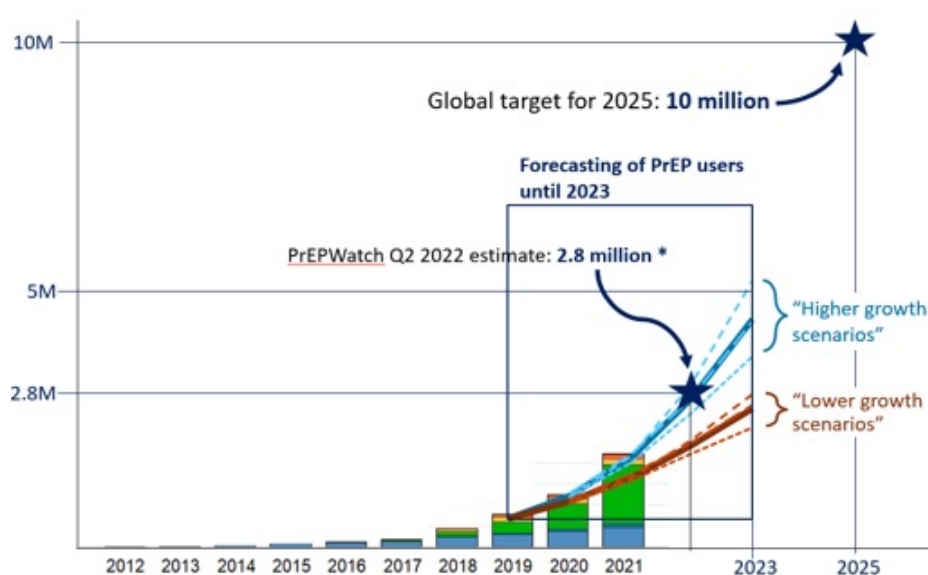


Fig. 2.14 shows observed PrEP user numbers from 2012 to 2021 together with projected PrEP user numbers for 2020 to 2023. Observed growth in 2020 and 2021 as well as preliminary information for 2022 suggest that PrEP user number growth is in accordance with “higher growth” forecast scenarios. Following these trends, there may be up to 5 million people using PrEP by 2023. However, significant growth will be needed to reach the global target of 10 million PrEP users by 2025.

Fig. 2.14. Forecasted global numbers of oral PrEP users per year until 2023



*Estimates by PrEPWatch are for cumulative PrEP initiations, not current users, and tend to be higher than WHO estimates.

2.3 DVR, CAB-LA and PEP

Although demand for the DVR, CAB-LA and PEP were not forecast, the dynamic nature of the markets for these products should be noted.

In 2021, WHO recommended that the DVR may be offered as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches. The DVR is a female-initiated option to reduce the risk of HIV infection. Properly using the product, which is a ring made of silicone, requires wearing it inside the vagina for a period of 28 days, after which it should be replaced. The ring works by releasing the antiretroviral drug dapivirine into the vagina slowly over 28 days. Several African countries have authorized the use of the DVR, and regulatory approval in other African countries is pending. Acceptability and feasibility studies are currently underway in countries in Africa and Asia and the Pacific.

In 2022, WHO recommended CAB-LA as a safe and highly effective prevention option for people

at substantial risk of HIV infection. CAB-LA is an intramuscular injectable, long-acting form of PrEP, with the first two injections administered four weeks apart, followed thereafter by an injection every eight weeks. Regulatory approval is currently pending in 11 countries.

According to WHO recommendations, PEP should be offered and initiated as early as possible for all individuals with exposure that have the potential for HIV transmission, preferably within 72 hours. Tenofovir in combination with lamivudine or emtricitabine is recommended as the preferred backbone regimen, and dolutegravir is recommended as the preferred third drug. Although the effectiveness of PEP in preventing the acquisition of HIV has been recognized since the mid-1990s, this intervention is not widely available or accessible in many countries. WHO is currently exploring strategies for expanding community-based access to PEP.

Treatment for viral hepatitis B and C

This chapter reports on a forecasting exercise that projects demand for viral hepatitis B and C treatment.

Key insights

- The number of people receiving lifelong treatment for viral hepatitis B is projected to steadily increase to about 80 million in 2030.
- About 43 million people are projected to receive treatment for viral hepatitis C between 2021 and 2030.
- Costs for global viral hepatitis B and C elimination are expected to peak at about US\$ 7.4 billion in 2028, with viral hepatitis B accounting for about 80% of total expenditure.
- The WHO regions accounting for the largest share of forecasted costs are the African Region and the South-East Asia Region.

3.1 Method

The following method was used to forecast demand for viral hepatitis B and C treatment.

A model was created to project the annual numbers of people treated for viral hepatitis B and C from 2021 to 2030. The same model was also used to project the annual numbers of screening and laboratory tests performed for people with both diseases, as reported in a separate publication (10), and to project total programme costs for viral hepatitis B and C elimination.

The model drew on a target-setting exercise that was developed to chart the anticipated course of progress toward 2030 viral hepatitis B and C impact and coverage targets. The findings from this exercise, presented in Table 3.1, reflect current guidelines and prices as well as the anticipated effects of diffusion trends and innovations from 2025 onward. WHO's 2019 viral hepatitis B and C data were used as target-setting inputs. The method for obtaining the 2019 data is described in the Global report on HIV, viral hepatitis and sexually transmitted infections, 2021 (11).

Table 3.1. Viral hepatitis B and C target-setting exercise based on 2019 data and 2030 targets

Product adoption curves	Indicator	Baseline – 2020	Targets – 2025	Targets – 2030
Impact	Hepatitis B incidence	–10%	–45%	–90%
	Hepatitis C incidence	–14%	–43%	–90%
	Hepatitis B mortality	–7%	–32%	–65%
	Hepatitis C mortality	–33%	–45%	–65%
Coverage	Hepatitis B cascade (testing/eligible/treatment)	5%/30%/40%	42%/43%/57%	90%/60%/80%
	Hepatitis C cascade (testing/treatment)	18%/12%	46%/38%	90%/80%

A modelling scenario was then developed to forecast demand for viral hepatitis commodities and associated costs in the adult population (Table 3.2), with the impact and coverage assumptions in the scenario guided by findings from the target-setting exercise.

The modelling scenario was used to forecast the following annual outcomes for 2021–2030 for viral hepatitis B and viral hepatitis C: (1) the number of screening tests performed, assuming that one person has one test per year; (2) the number of laboratory tests required for treatment initiation and treatment monitoring; (3) the number of people receiving treatment; and (4) the total programme costs, assuming that 2030 targets are achieved. The outcomes were stratified by WHO region (African Region, Region of the Americas, South-East Asia Region, European Region, Eastern Mediterranean Region and Western Pacific Region). The treatment findings are reported below, and the diagnostic findings are reported in a separate publication (10).

This method has multiple limitations. Countries may encounter barriers to obtaining the price reductions specified in the model, with the consequence that achieving specified targets would be more costly. Reductions in viral hepatitis B and C incidence and mortality were modelled using diffusion curves rather than being directly associated with changes in prevalence or treatment. This may underestimate costs if more interventions are needed to achieve the targets.

Table 3.2. Modelling scenario for forecasting demand for viral hepatitis B and C commodities and associated costs

Viral hepatitis B	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Target diagnosed proportion	5%	10%	15%	21%	30%	42%	56%	69%	79%	86%	90%
Target treatment-eligible proportion	30%	32%	33%	35%	39%	43%	48%	53%	56%	59%	60%
Target treatment proportion	40%	42%	44%	47%	52%	57%	64%	70%	75%	78%	80%
Mortality change	93%	90%	87%	83%	76%	68%	59%	49%	42%	38%	35%
Mortality rate (all cause)	0.86%	0.84%	0.86%	0.88%	0.91%	0.94%	0.91%	0.94%	0.96%	0.99%	1.03%
Incidence change	90%	86%	81%	75%	67%	55%	42%	30%	20%	14%	10%
Screening cost (US\$)	3.00	3.00	1.99	0.87	0.86	0.79	0.78	0.75	0.73	0.69	0.65
Laboratory costs – treatment eligible (US\$)	21.5	21.5	18.5	15.2	15.1	14.9	14.9	14.8	14.7	14.6	14.5
Laboratory costs – treatment ineligible (US\$)	21.5	21.5	18.5	15.2	15.1	14.9	14.9	14.8	14.7	14.6	14.5
Treatment cost (annual) (US\$)	600	600	356	86.6	83.6	68.2	64.0	58.7	52.1	43.8	33.6
Viral hepatitis C	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Target diagnosed proportion	18%	22%	27%	33%	39%	46%	55%	64%	74%	83%	90%
Target treated proportion	12%	16%	21%	26%	31%	38%	46%	56%	65%	73%	80%
Average sustained virological response	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%	95%
Mortality change	67%	65%	63%	61%	58%	55%	51%	46%	42%	38%	35%
Mortality rate (all cause)	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%	1.5%
Incidence change	86%	82%	77%	71%	65%	57%	48%	37%	27%	17%	10%
Screening cost (US\$)	2.00	2.00	1.07	0.77	0.77	0.73	0.72	0.71	0.69	0.67	0.65
Laboratory costs (US\$)	28	28	18.3	15.2	15.2	14.9	14.8	14.6	14.5	14.3	14
Treatment cost ^a – access countries ^b (US\$)	150	150	95	77	77	75	74	74	73	71	70
Treatment cost ^a – non-access countries ^b	3,000	3,000	1,273	721	721	653	634	611	582	545	500

.....
a Treatment cost reflects full three-month course of therapy.

“Access countries” are countries that have been granted access to generic pricing for medications; “non-access countries” are countries that cannot obtain generic pricing.

3.2 Forecasted demand for viral hepatitis B and C treatment

Fig. 3.1 and Fig. 3.2 show the forecasted global and regional demand for viral hepatitis B and C treatment, respectively. Almost 90 million people are projected to be receiving treatment in 2030, with lifelong treatment for viral hepatitis B accounting for more than 90% of this market. About 43 million people are projected to receive treatment for viral hepatitis C between 2021 and 2030.

Fig. 3.1. Projected annual number of people treated for viral hepatitis B and C globally, 2021–2030

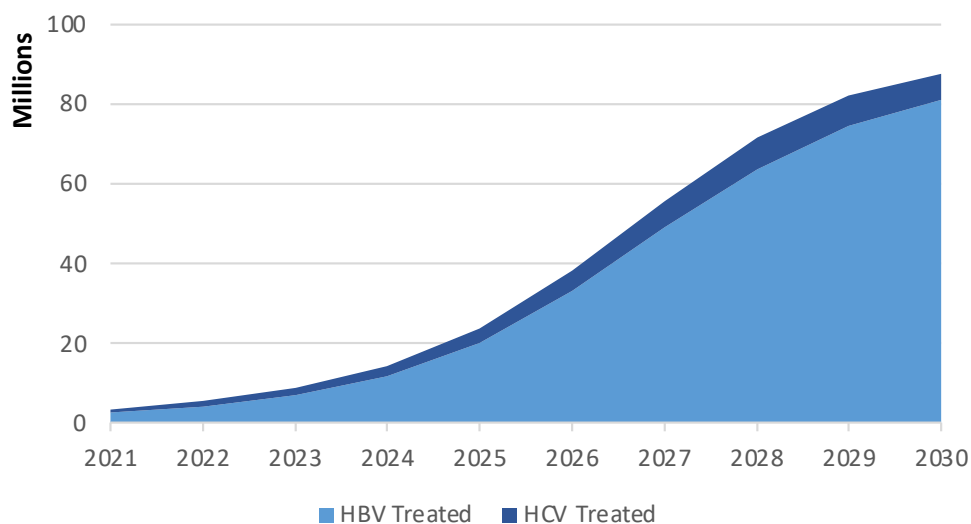
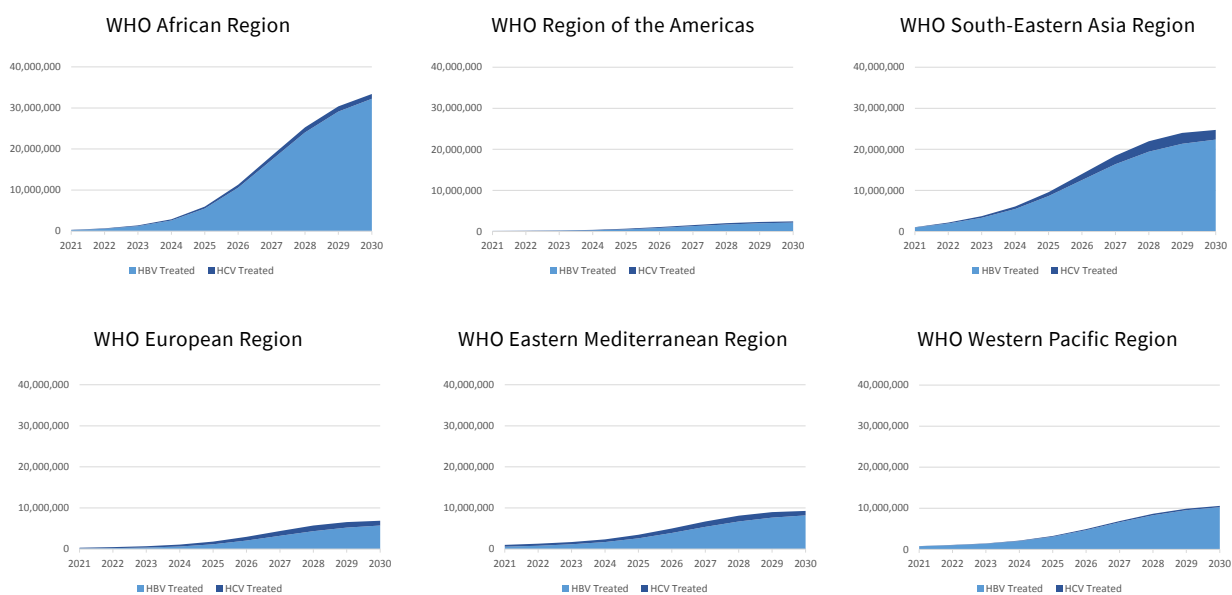


Fig. 3.2. Projected annual number of people treated for viral hepatitis B and C, by WHO region, 2021–2030



3.3 Forecasted total costs for eliminating viral hepatitis B and C

Fig. 3.3 presents the forecasted total costs for viral hepatitis B and C elimination globally. The costs are expected to peak at about US\$ 7.4 billion in 2028, with viral hepatitis B accounting for about 80% of total expenditure. The WHO regions accounting for the largest share of the forecasted costs are the African Region and the South-East Asia Region (Fig. 3.4)

Fig. 3.3. Projected programme costs for eliminating viral hepatitis B and C globally, 2021–2030

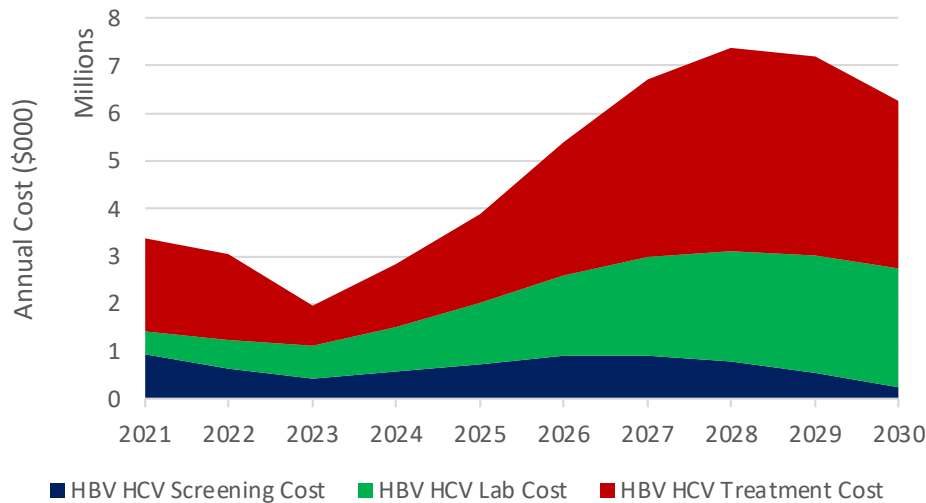
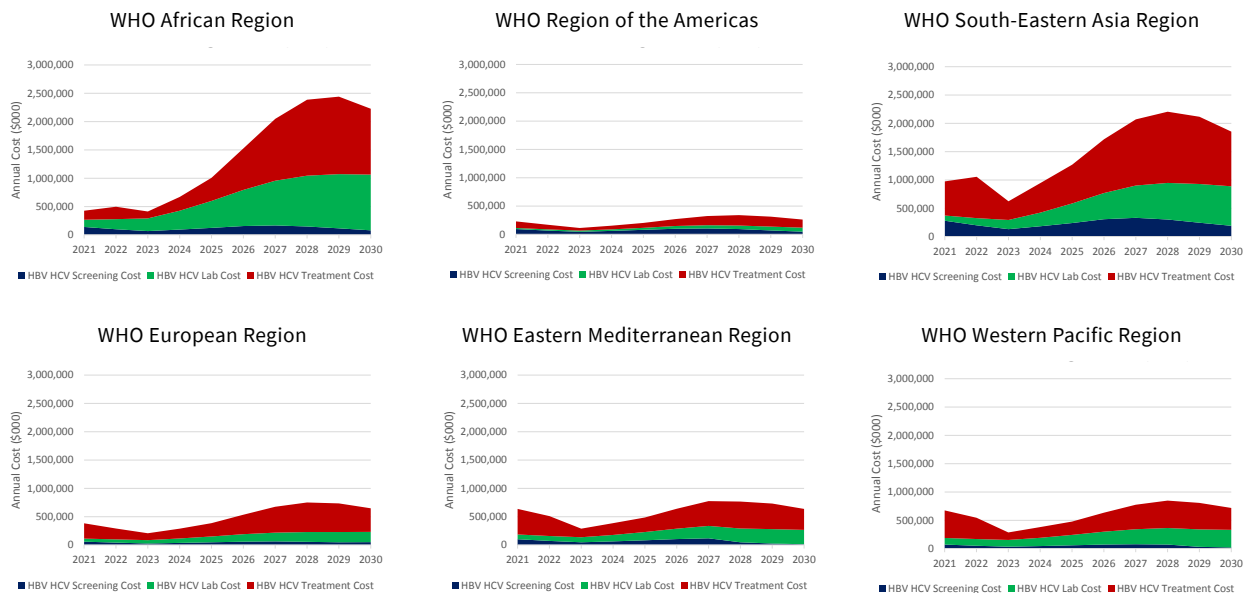


Fig. 3.4. Projected programme costs for eliminating viral hepatitis B and C, by WHO region, 2021–2030



Treatment for STIs

This chapter reports on anticipated demand for BPG for treating pregnant women with syphilis. WHO has prequalified two BPG products for maternal syphilis and prevention of congenital syphilis: RH103, benzathine benzylpenicillin + water for injection (powder and solvent for suspension for injection 1 200 000 IU + 4 mL) (3) and RH104, benzathine benzylpenicillin + water for injection (powder and solvent for suspension for injection 2 400 000 IU + 6 mL) (4).

Key insights

- Annual global BPG procurement is estimated to range between 74 million and 100 million doses of 1.2 million international units.
- BPG demand for treating pregnant women with syphilis is estimated to represent less than 5% of global BPG demand.
- Widescale adoption of the rapid dual HIV/syphilis test is expected to result in a substantial increase in demand for BPG for pregnant women, but such an increase would have a very small impact on overall global demand for BPG.

4.1 Method

A modelling exercise was performed in 2020 to assess global and regional demand for BPG using data from 20 countries representing about one third of the global population. Public-sector procurement data for 2013–2016 were collected from 15 countries with high prevalence of conditions that are treated with BPG: Brazil, Cambodia, Cameroon, Eswatini, Ethiopia, Indonesia, Kenya, Liberia, Malawi, Mozambique, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe. Market estimates were obtained from five additional countries: Australia, Canada, India, New Zealand and the United States of America. Additional public-sector and private-sector market data were obtained from import and export databases in India, export databases in China and BPG suppliers, including final dose formulators and manufacturers of the active pharmaceutical ingredient. Global estimates were extrapolated from this information.

The findings were triangulated with findings from two additional data sources. First, sales data for about 20 countries were obtained from leading global suppliers. Sales data from a three-year period, 2018–2020, were averaged for each country. Second, CHAI obtained up-to-date public sector data samples for five countries and analysed these data to determine procurement trends from 2016 to 2020.

The dosage of BPG was standardized to 1.2 million international units for reporting purposes.

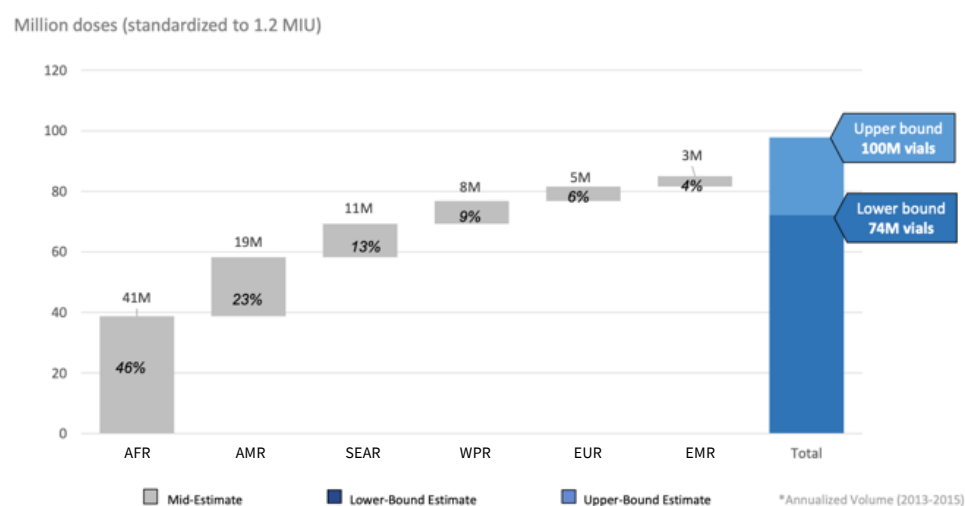
This method has multiple limitations. The 20 countries that served as data sources for modelling may not be representative of other countries, and unmet demand for BPG because of shortages or lack of access is not reflected in the modelling inputs. In addition, only limited procurement data are available for the private sector, which may underestimate demand. Finally, the use of 2013–2016 data as the basis for modelling and data from before 2021 for triangulation may yield findings that do not reflect more recent changes in BPG demand.

4.2 Modelling findings

Annual global BPG procurement based on 2013–2016 inputs was estimated to range between 74 million and 100 million doses of 1.2 million international units (Fig. 4.1). The small sample of sales data from 2016–

2020 indicated that this estimate may be too high. CHAI data suggested that levels of BPG procurement were relatively stable in five sample countries from 2016 to 2020.

Fig. 4.1. Estimated annual global and regional demand for BPG



MIU = million international units, AFR = WHO African Region, AMR = WHO Region of the Americas, SEAR = WHO South-East Asia Region, EUR = WHO European Region, EMR = WHO Eastern Mediterranean Region, WPR = WHO Western Pacific Region.

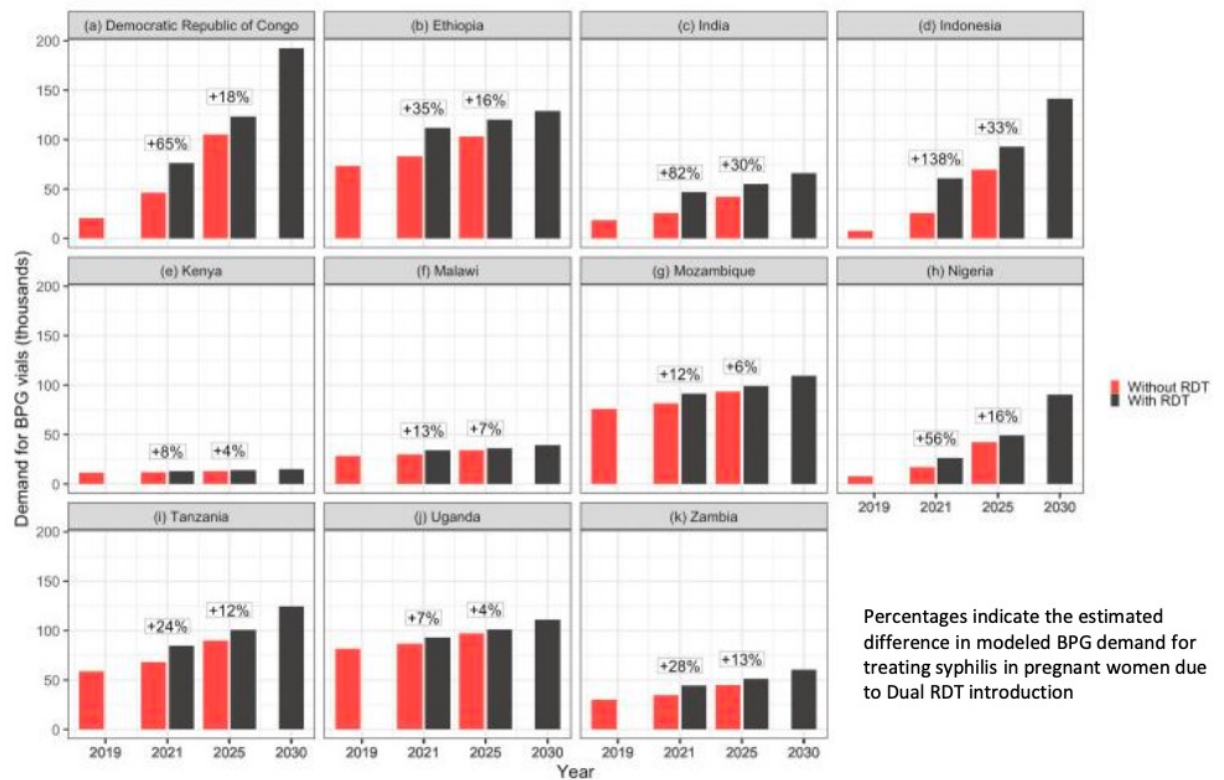
4.3 Dual HIV/syphilis testing in antenatal care: anticipated impact on BPG demand

Based on data from the global burden of maternal and congenital syphilis and associated adverse birth outcomes, BPG demand for treatment of syphilis in pregnant women is estimated to be approximately two million doses of 2.4 million international units annually. This represents less than 5% of global BPG demand.

In a 2021 article, Shah et al. (11) estimated the impact of increased use of rapid dual HIV/syphilis tests on BPG demand among pregnant women in 11 countries: Democratic Republic of the Congo, Ethiopia, India, Indonesia, Kenya, Malawi, Mozambique, Nigeria, Uganda, United Republic of Tanzania and Zambia.

These countries accounted for 38% of all births with congenital syphilis in 2016. The study projected that replacing HIV-only testing with rapid dual HIV/syphilis testing in antenatal care would cause demand for BPG (2.4 million international units) for treating pregnant women with syphilis to increase from 0.4 million doses in 2019 to 0.7 million doses in 2021. It also projected that if the screening and treatment of pregnant women for syphilis are scaled up to achieve the global targets of 95% coverage of both interventions by 2030, total demand for BPG for treating pregnant women with syphilis would increase to 1.1 million doses (2.4 million international units) by 2030 (Fig. 4.2).

Fig. 4.2. Projected future BPG demand for the treatment of syphilis in pregnant women in 11 countries



Source: Shah et al. (12).

Although the study thus anticipates that achieving the 95% targets would result in a 160% increase in demand for BPG to treat pregnant women with syphilis, such an increase would have a very small impact on overall global demand for BPG.

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