World Health Organization

TECHNICAL REPORT

AIDS MEDICINES AND DIAGNOSTICS SERVICE

HIV DIAGNOSTIC TESTS IN LOW- AND MIDDLE-INCOME COUNTRIES: FORECASTS OF GLOBAL DEMAND FOR 2014–2018

JULY 2015

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ABBREVIATIONS AND ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
CHAI	Clinton Health Access Initiative
EID	early infant diagnosis
GARPR	Global AIDS Response Progress Reporting system
GPRM	Global Price Reporting Mechanism
HIV	human immunodeficiency virus
PEPFAR	United States President's Emergency Plan for AIDS Relief
PFSCM	Partnership for Supply Chain Management
PMTCT	prevention of mother-to-child transmission of HIV
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

EXECUTIVE SUMMARY

This report provides projections of the future demand for human immunodeficiency virus (HIV) diagnostic tests. These projections are intended to inform advocacy for the scale up of access to diagnostics, so that the UNAIDS 90-90-90 targets for HIV treatment access can be met. They will likely also be useful for producers, enabling them to plan for adequate supply and to procurement organizations in planning future funding and long-term purchase plans.

The projections rely on data from a number of different sources including an annual country survey conducted by the World Health Organization (WHO), purchases reported to the Global Price Reporting Mechanism, data on past use provided by the Clinton Health Access Initiative (CHAI) for 21 high-burden countries, and purchase data from United States President's Emergency Plan for AIDS Relief (PEPFAR) programmes supported by the Partnership for Supply Chain Management (PFSCM).

The projections consider a number of possible future paths. Four global projections were prepared for this report:

- Linear extrapolation of past trends in the use and/or procurement of diagnostics.
- Achievement of the 90-90-90 treatment targets proposed by UNAIDS.
- Linear extrapolation of national targets submitted by country programmes in response to the WHO survey.
- Expected demand if all countries followed the current WHO guidelines for HIV testing and monitoring of antiretroviral therapy (ART).

Also included are projections prepared by CHAI for 21 high-burden countries adjusted to represent global demand and projections of future purchases for PEPFAR by PFSCM.

The main results are as follows:

- **CD4 tests**: Total demand for CD4 tests is expected to grow from about 17 million in 2013 to 23–37 million by 2018. The highest estimate of future demand is from the extrapolation of country targets. Average annual increases in demand up to 2018 are expected to be between 10 and 17%. Future demand may be towards the lower end of the range (23–27 million) as programmes move from CD4 tests to viral load tests as the primary means of monitoring ART patients. The global demand for CD4 tests is expected to grow only by about 25% compared to a 2014 baseline.
- **Viral load tests**: Total demand for viral load tests is expected to grow from 7 million in 2013 to 15–30 million by 2018. Again the highest projection is based on the linear extrapolation of the country targets. The average annual increase in demand up to 2018 is expected to be 11–34%. The major factor affecting future demand is the rate at which national programmes adopt viral load as the primary tool for monitoring ART patients in their effort to achieve the 90-90-90 targets. If programmes transition as expected, the demand is likely to be higher than the linear extrapolation and closer to the guidelines scenario (23 million by 2018).
- **Early infant diagnosis (EID)**: Demand for EID is expected to rise from about 950,000 in 2013 to 0.9–3.0 million by 2018. The linear extrapolation of the country targets provides the highest estimate. While the coverage of EID has been expanding rapidly the number of HIV-infected pregnant women may be declining as a result of progress in reducing new infections among reproductive age women. This decline suggests that demand for EID may be relatively constant over the next several years at about 1 million tests.
- **HIV rapid diagnostic tests**: Limited data are available on the demand for HIV rapid diagnostic tests. Based on trends from the Global AIDS Response Progress Reporting system reports total demand for rapid diagnostic tests may rise to 160 million by 2018.

1. INTRODUCTION

The objective of this report is to provide projections of future demand for human immunodeficiency virus (HIV) diagnostics. These forecasts are intended to inform advocacy for the scale up of access to diagnostics, so that the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets for HIV treatment access can be met. They will likely 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 are:

- The annual World Health Organization (WHO) survey of low- and middle-income countries on HIV treatment and diagnostic tests. The number of countries reporting ranged from 52 in 2011 to 76 in 2013;
- The WHO's Global Price Reporting Mechanism (GPRM);
- Data on past use and projected testing volumes developed by the Clinton Health Access Initiative (CHAI) for 21 countries;
- Purchases and forecasts for a small number of countries supported by the Partnership for Supply Chain Management (PFSCM) funded by the United States President's Emergency Plan for AIDS Relief (PEPFAR); and
- The Global AIDS Response Progress Reporting (GARPR) for HIV testing.

To inform these projections we also used forecasts of the number of people receiving antiretroviral therapy (ART) through 2018 (the average projection agreed by all partners in the working group as the reference forecast) prepared by WHO, UNAIDS and Avenir Health (1), projections of the future need for the prevention of mother-to-child transmission of HIV (PMTCT) compiled by UNAIDS and global goals for ART under the 90-90-90 Initiative (2).

2. METHODS

Several alternative projections of the future demand for HIV-related diagnostics have been prepared. Each method is described below.

2.1 Current demand

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

1. If data were reported for 2011 and 2012, we estimated demand in 2013 as a linear extrapolation to 2013.
2. If data were reported for either 2011 or 2012 but not both, we estimated demand in 2013 by multiplying need in 2013 by the ratio of demand in 2011 or 2013 to an estimate of need in that year. Need for CD4 tests and viral load tests were based on the number of people on ART. The need for early infant diagnosis (EID) was based on the number of HIV+ pregnant women.
3. If no data were reported for 2011, 2012 or 2013, we estimated demand in 2013 by multiplying need in 2013 by the average ratio of demand to need for all reporting countries in 2013. Need was defined as described in item 2 above. The ratios were 1.42 CD4 tests per person receiving ART, 0.71 viral load tests per person receiving ART and 0.80 EID tests per HIV+ woman receiving PMTCT.

2.2 Linear extrapolation of past trends

The WHO ARV survey provided data on the number of CD4, viral load and EID tests conducted in 2011, 2012 and 2013. Not all countries provided data for all three years.

- For those countries providing data for two or three years, the projection is a linear extrapolation of the past trend.
- For countries providing data for only a single year, the projection applies a ratio of tests to patients. For CD4 and viral load tests we calculated the ratio of the number of tests reported to the number of ART patients in the same year and applied that ratio to the estimated future number of ART patients. For EID tests we calculated the ratio of EID tests to the number of HIV+ women receiving PMTCT services and applied that ratio to estimated future numbers of women receiving PMTCT services.
- For countries with no data, we estimated future demand by multiplying the estimated number of ART patients for CD4 and viral load tests or PMTCT patients for EID tests by ratios of tests per patient. The ratios were calculated as the sum of all tests reported each year by reporting countries divided by the number of ART patients or PMTCT patients in the same countries in that year. Those ratios were:
  - CD4 tests: The ratio of 1.42 tests year per ART patient in 2013 was calculated as the sum of all tests reported each year by reporting countries divided by the number of ART patients. This is the ratio of the number of CD4 tests reported by reporting countries in the survey (10.9 million in 2013) divided by the reported number of people on ART in those same countries (7.5 million in 2013).
  - Viral load tests: Since the use of viral load tests has expanded the ratio varies by year and is the sum of the projected number of tests in a year for countries who reported at least two years of historic data divided by the sum of projected ART patients in that year for those countries. The resulting ratios are:
    - 2014: 0.71
    - 2015: 0.75
    - 2016: 0.78
    - 2017: 0.80
    - 2018: 0.82
  - EID tests: since the use of EID tests is expanding rapidly we calculated the ratio of EID tests to women receiving PMTCT for countries reporting data for 2013 through 2018. The reporting countries reported 781,000 tests in 2013. Based on estimates of the need for PMTCT in reporting and non-reporting countries we adjusted this figure upward by 22% to estimate total demand in 2013 which made 950,000 EID tests. The ratios are:
    - 2013: 0.80
    - 2014: 1.00
    - 2015: 1.06
    - 2016: 1.17
    - 2017: 1.29
    - 2018: 1.43

For EID tests we constrained the linear projection to be less than or equal to the estimated number of HIV+ women giving birth each year.

No country data were available for rapid diagnostic tests. We prepared two forecasts by extrapolating data on (1) the number of tests purchased from the GPRM and (2) country reports of the number of tests conducted annually from GARPR.

2.3 90-90-90 targets

In 2014 UNAIDS proposed a new set of global targets for scaling up treatment known as the 90-90-90 targets (2). They envision that by 2020:

- 90% of all people living with HIV will know their status,
- 90% of all people diagnosed with HIV will receive sustained ART, and
- 90% of all people receiving ART will have durable viral suppression.

If all low- and middle-income countries were on track to reach these targets there would be just over 23 million people on ART by 2018. This is 14% higher than a simple linear extrapolation of past trends. Therefore, we have projected the need for CD4 tests as 14% higher than the linear extrapolation scenario by 2018. The number of viral load tests is currently less than that recommended by the WHO ARV guidelines (two viral load tests in the first year of ART and then one annually in subsequent years). We have assumed that these guidelines would be achieved by 2018 and interpolated between 2013 and 2018 for the intervening years.

The global targets call for 95% coverage of PMTCT services. We have projected the demand for EID under this scenario to be 95% of all HIV+ pregnant women (as estimated by UNAIDS) plus 10% to allow for re-testing.

2.4 Country targets

In the 2014 WHO ARV survey 20 countries provided their targets for the number of CD4 tests up to 2017 as was indicated in the WHO HIV diagnostic survey. The weighted average of those targets for 2017 is 29% higher than the reported number of tests in 2013. We scaled this up to all countries for 2017 by applying a 29% increase to the estimated total number of CD4 tests in 2013 and extrapolated the linear growth rate to 2018.

Fourteen countries provided information on the number of viral load tests conducted in 2013 and their target for 2017. The average for all reporting countries is a 99% increase from 2013 to 2017. This increase was applied to the global total in 2013 to estimate the global country target for 2017.

Ten countries (nine small countries and one large country, Kenya) provided information on the number of EID tests conducted in 2013 and their target for 2017. The weighted average is a 184% increase from 2013 to 2017. Since Kenya was the only large country to provide an EID target this increase is essentially based on Kenya's target. This increase was applied to the global total in 2013 to estimate the global country target for 2017. Targets for 2018 were estimated by extrapolation using the same rate of increase.

2.5 CHAI projections

CHAI has forecast the future demand for HIV diagnostics, including EID, CD4 and viral load testing, based on a detailed analysis of 21 high-burden countries[1] and made assumptions regarding additional testing volumes in other low- and middle-income countries. CHAI collects data annually regarding service delivery and scale up plans for HIV diagnostics from its country teams. The forecast is prepared by considering historic demand, modified by assumptions about country scale up plans, anticipated policy changes, funding, and current laboratory infrastructure capacity. Results are scaled up from the 21 high-burden countries to all low- and middle-income countries on the basis of the number of ART patients.

2.6 PFSCM projections

The PFSCM project supports the procurement and distribution of HIV diagnostic tests in a number of PEPFAR countries. They provided data on actual and planned procurements for the countries in which they work. There has been no attempt to scale up these figures to global totals. Rather they are intended to show trends in key countries with significant PEPFAR programmes. The PFSCM figures include historic data for all countries where PFSCM works and linear extrapolations to 2018 of the 2011–2013 trends.

2.7 Procurement data

For some tests procurement data are available through the GPRM. These data are a major source of information on rapid diagnostic test kits but are incomplete for CD4 and viral load tests.

2.8 PFSCM projections

For CD4, viral load and EID tests, we have included a guideline projection which shows the number of tests that would be required if all countries followed guidelines recommended by WHO (3). We have applied them to the projected number of people receiving ART, from the 'average scenario' developed for scaled up ART in 2015 (1) as follows:

- CD4 tests: two CD4 tests at initiation of ART and one test annually while on ART.
- Viral load tests: two tests in the first year of ART then one test annually while on ART.
- EID tests: one test for infants born to HIV+ mothers and a confirmatory test for those found to be HIV+.

1. Twenty-one high-burden countries selected by CHAI: Botswana, Brazil, Cameroon, China, Côte d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Thailand, Uganda, Zambia and Zimbabwe. For EID, this list of countries has been expanded to include all countries in the *Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive*, including Angola, Burundi, Chad, the Democratic Republic of the Congo and Ghana.

3. RESULTS

3.1 CD4 tests

Estimates of historic use and forecast demand for CD4 tests are shown in Table 1 and Fig. 1. The linear extrapolation, the 90-90-90 targets, country targets and CHAI scenarios all show significant growth in CD4 tests from 15–19 million in 2013 to 25–33 million by 2018. These trends are well above the guidelines scenario which assumes two tests per new ART patient and one test per year for continuing patients. Even though the guidelines call for viral load tests to replace CD4 tests for monitoring ART patients, country programmes still expect demand for CD4 tests to increase. If programmes do switch from relying primarily on CD4 tests to viral load tests for monitoring patients, then we would expect the forecasts based on linear extrapolation of past trend to overestimate future demand.

Table 1. Trends in demand for CD4 tests, 2011–2018 (millions)

	2011	2012	2013	2014	2015	2016	2017	2018
Linear extrapolation	13.9	9.2	16.5	18.9	21.0	23.0	25.0	27.0
90-90-90 targets	13.9	9.2	16.5	18.9	21.7	22.8	26.9	30.8
Country targets	13.9	9.2	16.5	18.9	23.3	27.7	32.1	36.5
CHAI (high)			19.0	22.0	23.0	26.0	28.0	30.0
CHAI (low)			19.0	22.0	23.0	25.0	26.0	27.0
PFSCM (in eight countries[2])	4.5	5.3	6.8	7.9	9.1	10.2	11.4	12.6
Guidelines		11.4	13.4	15.3	17.2	19.1	21.0	22.9

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

Table 2. Indexes of demand for CD4 tests (2013 = 1.0)

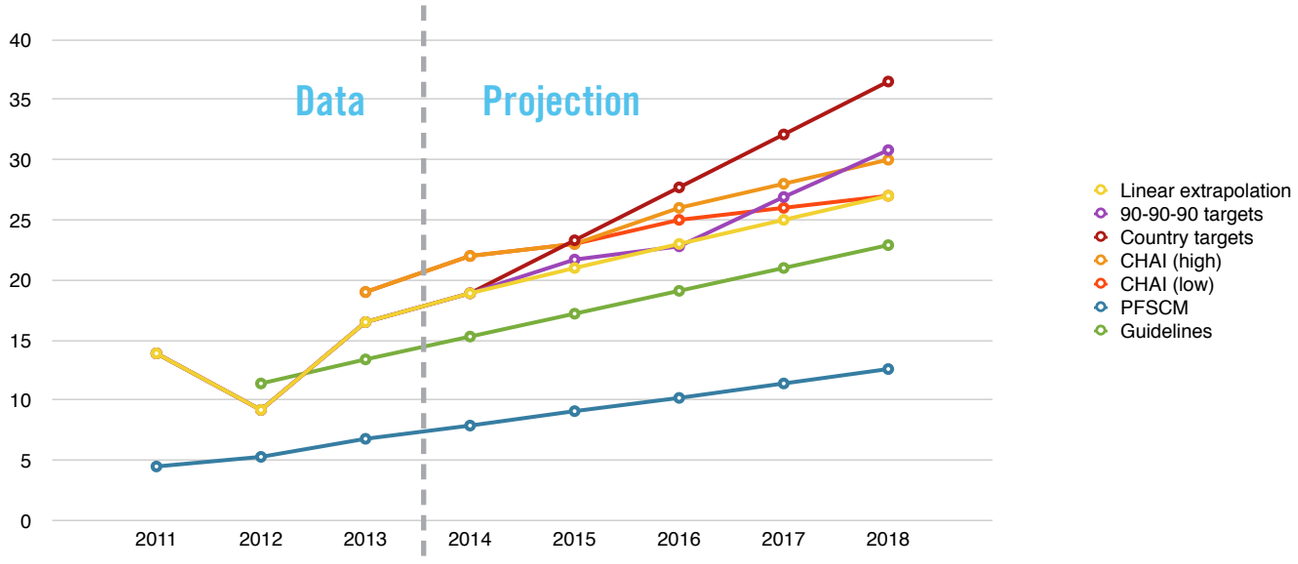
	2013	2014	2015	2016	2017	2018	2013–2018*
Linear extrapolation	1.0	1.1	1.3	1.4	1.5	1.6	10%
90-90-90 targets	1.0	1.1	1.3	1.4	1.6	1.9	13%
Country targets	1.0	1.1	1.4	1.7	1.9	2.2	17%
CHAI (high)	1.0	1.2	1.2	1.4	1.5	1.6	10%
CHAI (low)	1.0	1.2	1.2	1.3	1.4	1.4	7%
PFSCM	1.0	1.2	1.3	1.5	1.7		
Guidelines	1.0	1.1	1.3	1.4	1.6	1.7	11%

** Average annual increase.*

Table 2 and Fig. 2 present indexes of demand relative to 2013 in order to show the relative increase over time. Note that the figures from PFSCM represent only a subset of countries (those supported by PEPFAR through PFSCM; see footnote to Table 1) so their figures will always be lower than other methods. Their figures are included in order to show the trend. Table 3 shows the trends in demand for CD4 tests by region for the linear extrapolation scenario.

2. Countries supported by PFSCM are Botswana, Burundi, Côte d'Ivoire, Haiti, Mozambique, Nigeria, Rwanda and Zimbabwe.

Figure 1. Trends in demand for CD4 tests, 2011–2018 (millions)



Note: PFSCM forecast is for a limited number of countries.

Figure 2. Indexes of demand for CD4 tests (2013 = 1.0)

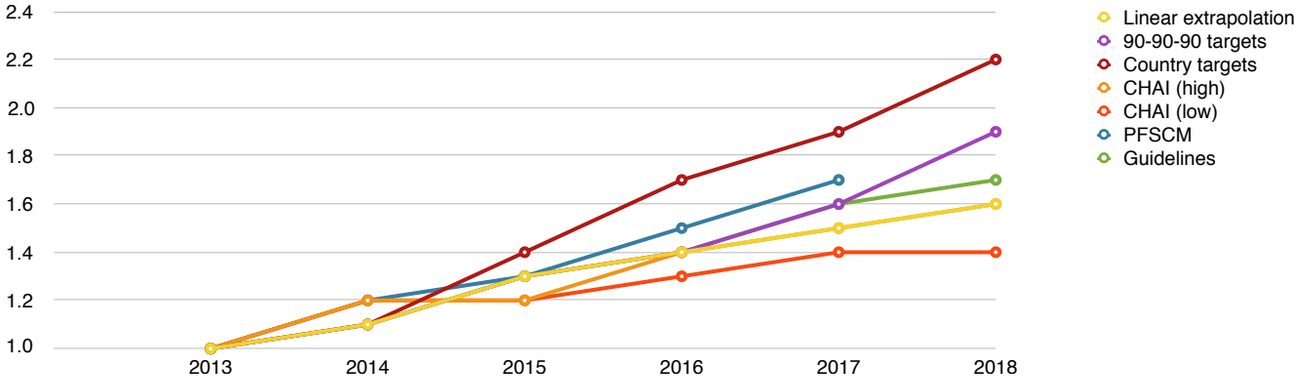


Table 3. Trend in demand for CD4 tests by region (millions)

	2011	2012	2013	2014	2015	2016	2017	2018
Africa	11.6	7.4	10.0	11.2	12.5	13.8	15.1	16.4
Asia & Eastern Europe	2.3	2.6	3.4	4.0	4.5	5.1	5.6	6.2
Latin America	1.6	1.1	1.4	1.4	1.6	1.7	1.9	2.0
Total	15.5	11.1	14.8	16.6	18.6	20.6	22.6	24.6

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

3.2 Viral load tests

Table 4 and Fig. 3 show the projected trends in demand for viral load tests. The linear extrapolation and CHAI projections show similar trends with demand reaching 15–16 million by 2018. If all countries followed the guidelines the trend would be somewhat higher, reaching almost 23 million tests by 2018. The country targets and the 90-90-90 projections show much more rapid growth reaching double the level of the other projections by 2018.

Table 5 and Fig. 4 present indexes of demand relative to 2013 in order to show the relative increase over time.

Regional trends are shown in Table 6 for the linear extrapolation scenario.

Table 4. Trends in demand for viral load tests, 2011–2018 (millions)

	2011	2012	2013	2014	2015	2016	2017	2018
Linear extrapolation	3.8	5.1	6.8	9.2	11.0	12.7	14.5	16.2
90-90-90 targets				9.0	11.8	15.6	20.6	27.2
Country targets				11.4	16.0	20.6	25.2	29.9
CHAI			3.4	4.0	5.2	7.8	11.6	14.8
PFSCM		0.1	0.2	0.3	0.8	0.8	0.9	
Guidelines				15.3	17.2	19.1	21.0	22.9

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

Figure 3. Trends in demand for viral load tests, 2011–2018 (millions)

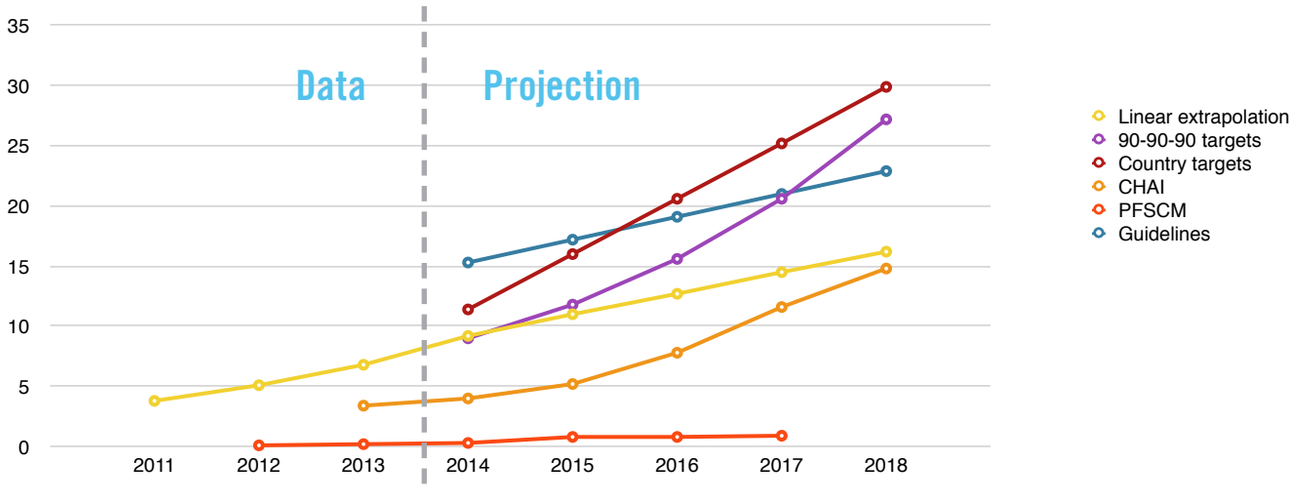


Table 5. Indexes of demand for viral load tests (2013 = 1.0)

	2013	2014	2015	2016	2017	2018	2013–2018*
Linear extrapolation	1.00	1.24	1.47	1.71	1.94	2.18	17%
90-90-90 targets	1.00	1.30	1.68	2.17	2.81	3.62	30%
Country targets	1.00	1.68	2.36	3.04	3.72	4.40	34%
CHAI	1.00	1.18	1.53	2.29	3.41	4.35	34%
PFSCM	1.00	1.51	1.91	2.31	2.72		
Guidelines	1.00	1.14	1.28	1.43	1.57	1.71	11%

** Average annual increase.*

Figure 4. Indexes of demand for viral load tests (2013 = 1.0)

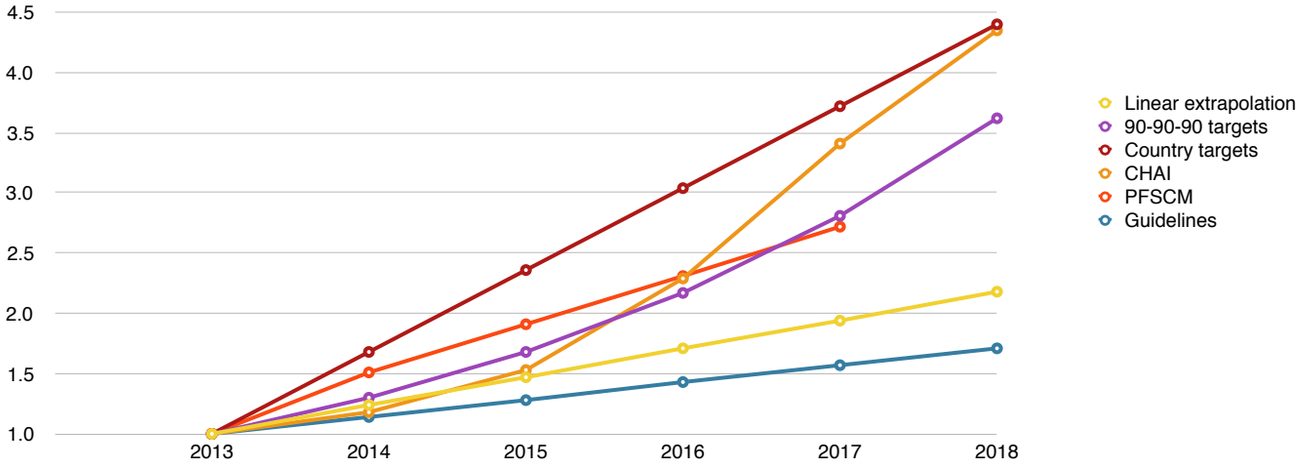


Table 6. Trends in demand for viral load tests by region (millions)

	2011	2012	2013	2014	2015	2016	2017	2018
Africa	2.3	3.8	4.3	5.5	6.5	7.5	8.5	9.5
Asia & Eastern Europe	0.5	0.5	1.0	1.3	1.5	1.8	2.0	2.3
Latin America	1.0	0.9	1.3	1.4	1.5	1.7	1.9	2.1
Total	3.8	5.3	6.7	8.2	9.6	11.0	12.4	13.8

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

3.3 EID tests

Trends in demand for EID tests are shown in Table 7 and Fig. 5. In this case the various scenarios diverge significantly from each other. The linear extrapolation scenario shows no growth because it is constrained by the total need for PMTCT in each country which is expected to decline by 12% from 2013 to 2018 as a result of declining HIV prevalence among women of reproductive age in many countries in sub-Saharan Africa. The 90-90-90 scenario is somewhat higher because it assumes that all countries reach 95% of need, whereas in the linear extrapolation scenario some countries reach 100% of need but the trend in others is for lower coverage. The CHAI and the country targets scenarios project a doubling (CHAI) or tripling (country targets) of demand by 2018, well above the guidelines trend.

Table 8 and Fig. 6 present indexes of demand relative to 2013 in order to show the relative increase over time.

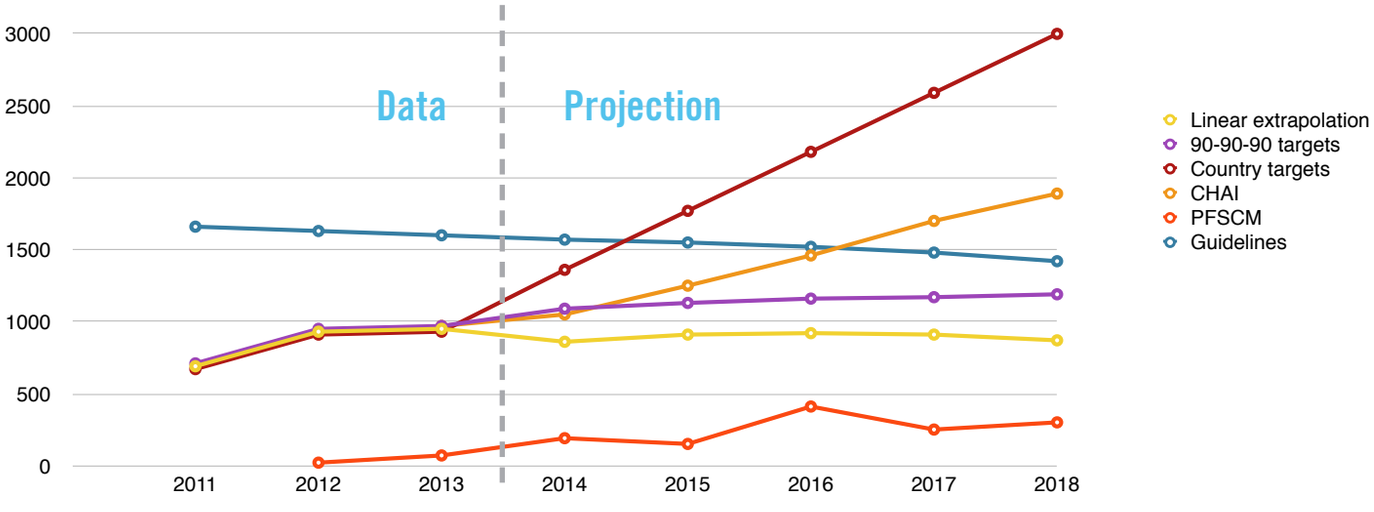
Table 9 shows trends in demand for EID by region for the linear extrapolation scenario.

Table 7. Trends in demand for EID, 2011–2018 (thousands)

	2011	2012	2013	2014	2015	2016	2017	2018
Linear extrapolation	690	930	950	860	910	920	910	870
90-90-90 targets	690	930	950	1090	1130	1160	1170	1190
Country targets	690	930	950	1360	1770	2180	2590	3000
CHAI			970	1050	1250	1460	1700	1890
PFSCM		20	70	190	150	410	250	300
Guidelines	1660	1630	1600	1570	1550	1520	1480	1420

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

Figure 5. Trends in demand for EID tests, 2011–2018 (millions)



Note: PFSCM forecast is for a limited number of countries.

Table 8. Indexes of demand for EID tests (2013 = 1.0)

	2013	2014	2015	2016	2017	2018	2013–2018*
Linear extrapolation	1.00	0.94	0.99	1.00	0.99	0.95	-1%
90-90-90 targets	1.00	1.15	1.19	1.22	1.23	1.25	5%
Country targets	1.00	1.45	1.91	2.36	2.81	3.26	27%
CHAI	1.00	1.08	1.29	1.51	1.75	1.95	14%
PFSCM	1.00	1.57	2.14	2.71	3.43	4.00	32%
Guidelines	1.00	0.98	0.97	0.95	0.93	0.89	-2%

** Average annual increase.*

Figure 6. Indexes of demand for EID tests (2013 = 1.0)

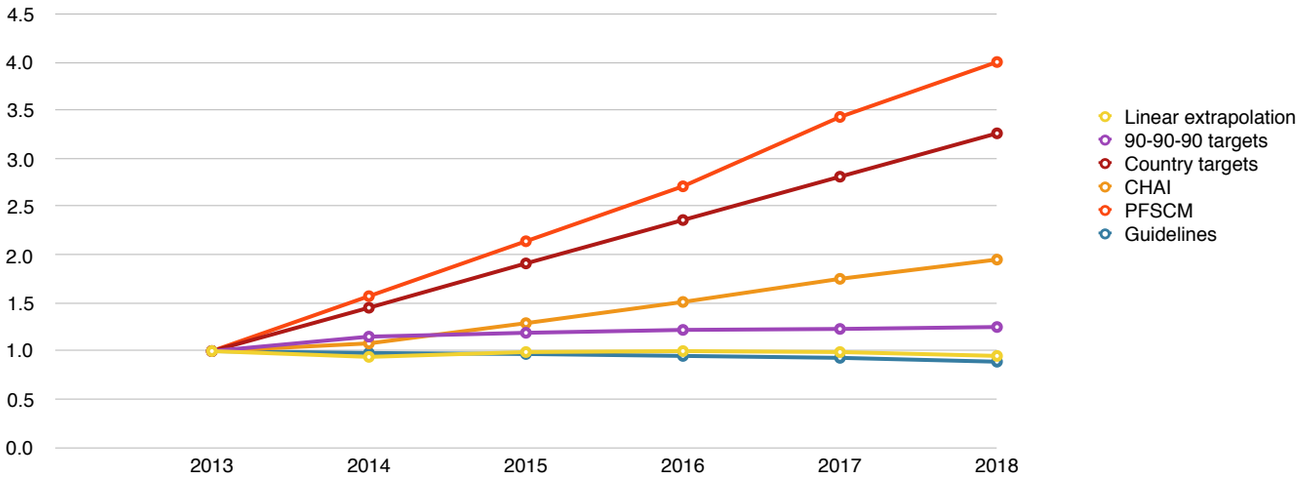


Table 9. Trends in demand for EID by region (thousands)

	2011	2012	2013	2014	2015	2016	2017	2018
Africa	623	849	879	804	851	867	859	823
Asia & Eastern Europe	49	56	48	39	38	37	35	33
Latin America	20	29	27	20	20	19	17	16
Total	693	934	954	864	909	923	912	872

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

3.4 HIV testing

Table 10 and Fig. 7 show the trends in the uptake of HIV testing (from GARPR) and the procurement of rapid diagnostic (HIV serology) tests (RDTs) from GPRM and their linear extrapolation. The 90-90-90 scenario for HIV testing is still being developed by UNAIDS as UNAIDS is estimating the total number of tests required to achieve the first 90 under different testing strategies.

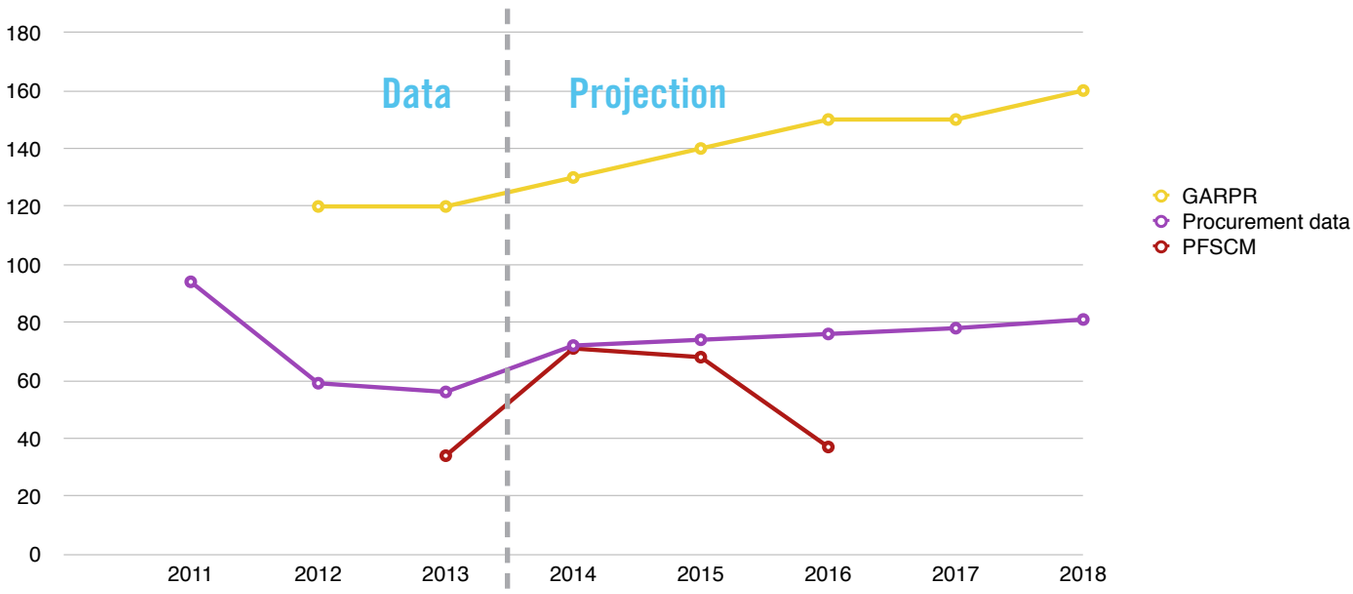
Table 11 and Fig. 8 display indexes of demand relative to 2013 in order to compare the trends in the two sources. While divergent in absolute number of tests done, they are consistent in their trend analysis: both show slowly increasing demand for HIV testing.

Table 10. Trends in demand for HIV rapid diagnostic tests, 2011–2018 (millions)

	2011	2012	2013	2014	2015	2016	2017	2018
GARPR		120	120	130	140	150	150	160
Procurement data	94	59	56	72	74	76	78	81
PFSCM			34	71	68	37		

Note: 2011–2013 are estimates based on data; 2014–2018 are projections.

Figure 7. Trends in demand for HIV rapid diagnostic tests, 2011–2018 (millions)



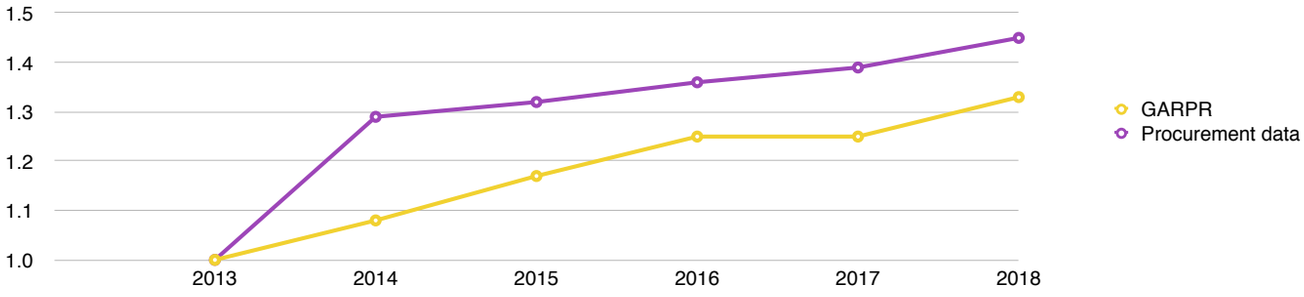
Note: PFSCM forecast is for a limited number of countries.

Table 11. Indexes of demand for HIV rapid diagnostic tests (2013 = 1.0)

	2013	2014	2015	2016	2017	2018	2013–2018*
GARPR	1.00	1.08	1.17	1.25	1.25	1.33	6%
Procurement data	1.00	1.29	1.32	1.36	1.39	1.45	8%

** Average annual increase.*

Figure 8. Indexes of demand for HIV rapid diagnostic tests (2013 = 1.0)



SUMMARY

- The different projections show that the demand for **CD4 tests** is expected to continue to increase substantially, reaching 23–37 million by 2018.
- Demand for **viral load tests** will likely reach between 15 and 30 million by 2018 as the different projections show.
- Demand for **EID tests** will likely grow. But, decreasing HIV prevalence among pregnant women will gradually reduce the demand for EID tests after 2018.
- The demand for **RDTs** is projected to increase from 120 million to 160 million RDTs between 2013 and 2018, which represents a slow growth with an average increase of 6-8% annually from 2013 to 2018. There were no projections calculated to estimate the number of HIV tests required to diagnose HIV infections under the fast track scenario known as the 90-90-90 scenario.
- All the scenarios, except the country target scenario, are below the 90-90-90 scenario by end of 2018 for CD4 and VL tests. This is due to under-reporting leading to low baseline data that are expected to improve in future forecasts.
- In view of resource constraints, **advocacy for the uptake of HIV testing and viral load testing** will be critical to reach the 90-90-90 target.

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