HIV DIAGNOSTIC TESTS IN LOW- AND MIDDLE-INCOME COUNTRIES: FORECASTS OF GLOBAL DEMAND FOR 2015–2020

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AVENIR HEALTH, CHAI, CDC, GLOBAL FUND, PEPFAR/SCMS, UNAIDS, UNICEF, UNITAID, USAID AND WHO

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Global Forecasts of Diagnostic Demand for 2015-2020
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Purpose

• Project future demand for HIV diagnostic tests.

• These projections are intended to:
  • Support advocacy for countries and partners to scale-up access to HIV-related diagnostics;
  • Inform diagnostic manufacturers so that they can plan for adequate supply and make appropriate strategic investment decisions;
  • Encourage manufacturers and stakeholders to share data to improve projections; and,
  • Catalyze global health community to support countries in their effort to move towards 90/90/90 as illustrated in their ambitious country targets.
Technical Working Group

- CDC
- WHO
- Avenir Health
- Clinton Health Access Initiative (CHAI)
- Partnership for Supply Chain Management
- Global Fund to Fight AIDS, TB and Malaria
- UNAIDS
- UNICEF
- UNITAID
- USAID
Data Sources

• **WHO Survey**: Data about actual test utilization, provided by countries in response to an annual survey conducted by WHO.

• **CHAI Diagnostics Forecasts**: Reported consumption data and information on scale-up progress collected annually from Ministries of Health in 21 high-ART patient burden countries. Historical procurement data from global partners considered in CD4 forecast. EID forecast includes historical data from 2007 on from multiple global partners.

• **Projected ART and PMTCT patients**: Projections to 2020 of the number of ART and PMTCT patients by country prepared by *Avenir Health* based on UNAIDS estimates.
Consolidated Projections

• For 21-26 high burden countries: CHAI in-depth analysis and projections
  • For CD4 and VL (21 countries): Botswana, Brazil, Cameroon, China, Cote d'Ivoire, Ethiopia, India, Kenya, Lesotho, Malawi, Mozambique, Myanmar, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Vietnam, Zambia, Zimbabwe
  • For EID (26 countries): Angola, Botswana, Brazil, Burundi, Cameroon, Chad, China, Cote d'Ivoire, DRC, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Vietnam, Zambia, Zimbabwe
  • These countries represent most of current demand: 87% for CD4 tests, 77% for viral load and 96% for EID

• For the other 107 low- and middle-income countries: diagnostic use survey with extrapolation of past trends (2011-2014)
Extrapolation of past trends, based on WHO Survey

- For countries reporting data for 2, 3 or 4 years, use linear extrapolation.
- For countries with data for one year, apply the ratio of tests to ART patients in that year. For EID apply the ratio to HIV+ women receiving PMTCT.
- For countries with no data, apply the average ratio of tests to ART or PMTCT patients from countries with data.
- Constrain the EID forecast by the total need for PMTCT (95% of HIV-infected pregnant women) in each country, plus 10% to account for re-tests.
Estimated and Reported Tests, 2011-2014

CD4 Tests

Viral Load Tests

Reported  Estimated

Reported  Estimated
Overview of CHAI Forecast Methodology

CHAI leverages data regarding current testing volumes and future scale-up plans to build its forecasts for HIV diagnostics testing in the public sector.

Key Inputs
- Total disease burden
- Patient data (Pre-ART, ART, peds)
- Historical test volumes (service statistics), disaggregated by test and sample type
- Historical procurement volumes

Calculation of Testing Need
- Patient numbers
- Burden of disease
- Existing national guidelines for testing
- Global targets

Demand Modeling
CD4 and EID: Linear extrapolation of past demand model of future scale-up influenced by:
- Current system capacity
- Introduction of new technology
- Funding
- Anticipated guidelines changes
VL: Use of historical growth analogues and scoring index to estimate predicted coverage

Key Outputs
- Forecast outputs by sample type (POC vs. conventional), country, and test type
- Ex-works prices for POC and conventional reagents or test cartridges to demonstrate market value
CHAI CD4 Forecast Overview

- Forecast projects the total demand for CD4 tests in public sector within low and middle-income countries (LMICs) from 2015-2020

- Projected demand is modeled by applying a linear growth rate to 2014 reported testing volumes. The growth rate combines the expected CAGR for available country targets for 2015-2015 against observed historical growth from 2012-2014.

- Projected demand is constrained by the total testing need, which accounts for shift to test and treat and scale-up of viral load

*Note: Dashed black lines on future testing targets graph indicate forecasted number of CD4 tests. Where targets are unavailable for countries, the expected need is used instead.*
- Forecast projects the total demand for viral load tests in public sector within low and middle-income countries (LMICs) from 2015-2020
- Projected demand for viral load tests is calculated based on the predicted viral load coverage for a country in a given year multiplied by the expected need
- The predicted coverage rate is derived based on the combined score of a set of index factors, including policy, procurement and funding, program age, and historical coverage
- These scores, dictating low, medium, high, or mature growth rates, are mapped to four historical growth analogues
- The analogues define approximate ratios of the number of viral load tests conducted annually compared to the number of patients on ART observed during the scale-up of viral load testing in South Africa, Kenya, and Rwanda
- 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
• The EID global forecast model projects the anticipated demand for Early Infant Diagnosis (EID) HIV testing as well as the unmet need from 2015 to 2020 across 26 high-burden countries, including all countries in the Global Plan, and estimates of testing in other low and middle-income countries.

• To forecast demand, historical EID test numbers, segmented by test type, are grown linearly using historical CAGRs.

• 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 4-6 week DNA-PCR test.

• For testing at birth, coverage in Year One (2016/2017) is assumed to mimic overall EID coverage in 2009 and is further decreased based on facility delivery rates.

Sources: CHAI annual lab data requests; government reports; UNAIDS data; Global Plan; CHAI-UNICEF Pediatric Project Grant Reports
Comparison Scenario: 90-90-90 Treatment Targets

By 2020:

- **90%** of all HIV+ people know their status
- **90%** of those diagnosed are sustained on antiretroviral therapy
- **90%** on treatment with durable viral suppression.
- This results in 26 million on treatment in 2020
- Estimates of demand for diagnostics to achieve 90-90-90 assume one CD4 test at initiation and one at 6 months plus tests for 10% of continuing patients to account for patients failing therapy and monitoring of those with risk for OIs; one VL test at treatment initiation and one annually while on ART; and average of 2.1 tests per exposed infant including tests at birth, at 6 weeks, confirmatory tests and tests at 9 months in some countries.
Demand for CD4 Tests: all LMIC

Data

Projection

Consolidated Forecast

90-90-90

Data

Millions

Top 10 Countries by Number of CD4 Tests in 2014

- South Africa
- India
- Uganda
- Brazil
- Tanzania
- Mozambique
- Ethiopia
- Kenya
- Thailand
- Zimbabwe
- Rest of World
Demand for Viral Load Tests

Data

Projection

Millions


Consolidated Forecast

90-90-90

Data
Viral Load Tests: Top 10 Countries in 2014

- South Africa
- Brazil
- Tanzania
- Zambia
- Thailand
- Botswana
- China
- Namibia
- Kenya
- Mexico
- Rest of World
Demand for EID Tests: all LMIC

- Trend has been flat the last three years at about 51% of need.
EID Coverage in 10 Countries with Most Tests

Number of Tests and Need for PMTCT

Number of EID Tests  Need for PMTCT

South Africa  Nigeria  Uganda  Mozambique  Tanzania  Zimbabwe  Kenya  Zambia  Malawi  Cameroon

0 50 000 100 000 150 000 200 000 250 000 300 000
Top 10 Countries for EID in 2014

- South Africa
- Uganda
- Zimbabwe
- Mozambique
- Kenya
- Zambia
- Tanzania
- Malawi
- Cote d'Ivoire
- Nigeria

Rest of World
Data from WHO survey only available for 2014 -2012 and 2013 are from GARPR
Top 10 Countries: Rapid HIV Test Kits in 2014

- China
- India
- Brazil
- Uganda
- Ethiopia
- Kenya
- Turkey
- Nigeria
- Mozambique
- South Africa
- Rest of World
Summary

• Gradual improvement in reporting: the proportion of estimated tests and reported tests has decreased since the first WHO diagnostic survey.
• Demand for **CD4 tests** is expected to continue to increase to 22-23 million in the near future and then plateau at that level for the near-term.
• Demand for **viral load tests** will likely reach 25 million by 2020.
• Demand for **EID tests** will likely grow driven by changes in the testing guidelines to include testing at birth, the introduction of POC EID testing, and additional partner funding.
• The demand for **RDTs** is projected to increase by 1/3 reaching over 400 million tests by 2020.
• 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.