

Market and Technology Landscape 2020

HIV rapid diagnostic tests for self-testing



MARKET AND TECHNOLOGY LANDSCAPE
**HIV RAPID DIAGNOSTIC TESTS
FOR SELF-TESTING**

December 2020

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Executive summary

- Total HIVST need for LMICs is estimated to be **177m** HIV self-tests in 2020, growing to **192m** HIV self-tests by 2025
- Total LMIC HIVST Demand is projected to reach **29 million** tests by 2025
- Private sector volumes in HICs and UMICs are estimated to be **3.2m** HIV self-tests in 2020, growing to **4.8m** HIV self-tests by 2025
- HIVST has been highlighted globally and by WHO as an important approach to maintain and scale-up future testing in the context of COVID-19 disruptions

WHO recommendations on HIV self-testing



Key evidence showed HIVST is:

- Safe and accurate
- Highly acceptable
- Increased access
- Increased uptake and frequency of HIV testing among those at high risk and who may not test otherwise
- Comparable linkage and HIV+
- Empowering
- Can be affordable and cost-effective when focused

WHO recommendation:

HIV self-testing should be offered as an approach to HIV testing services

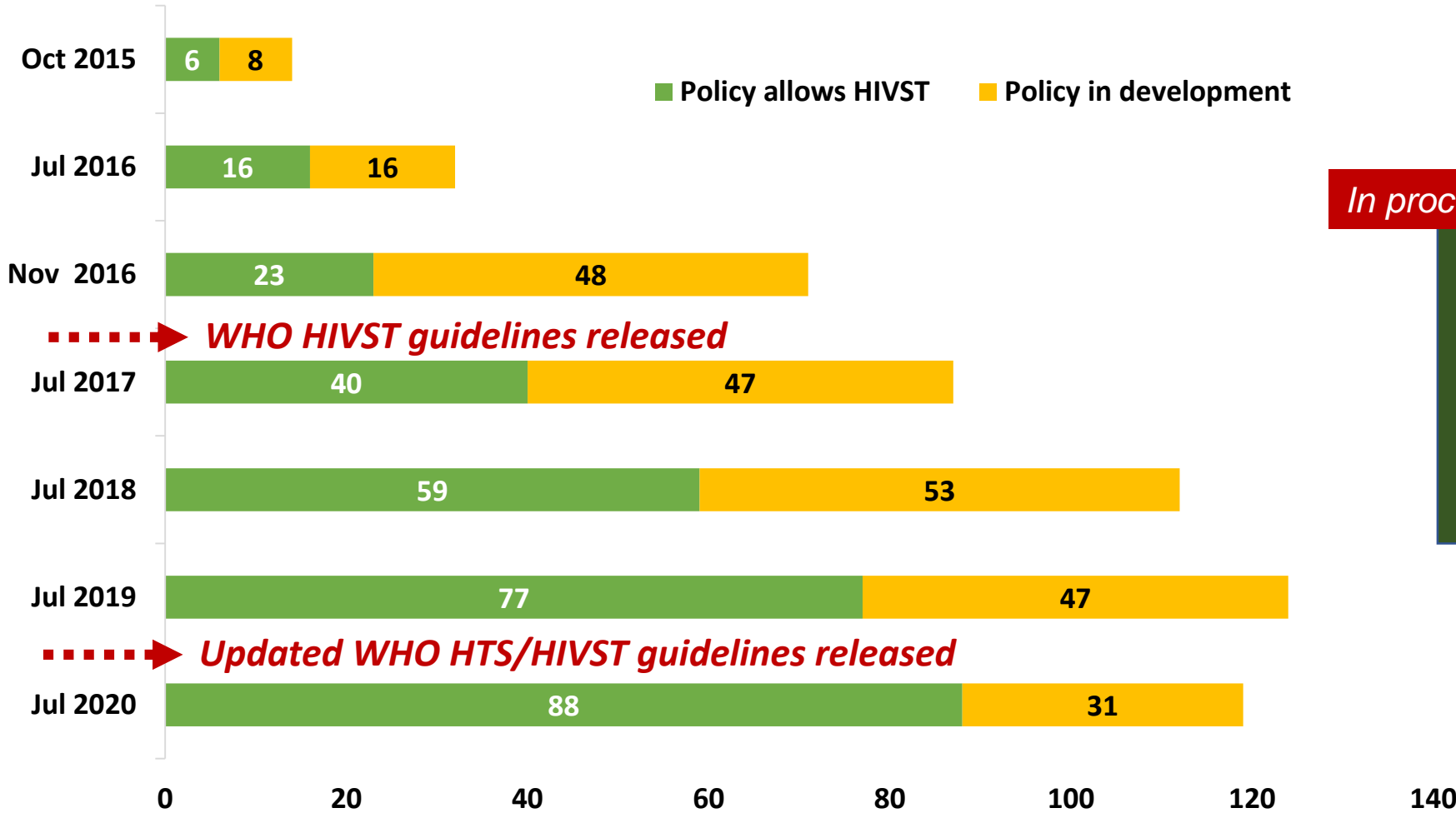
(strong recommendation, moderate quality evidence)

NEW remarks

- Providing HIVST service delivery and support options is desirable.
- Communities need to be engaged in developing and adapting HIVST models.
- HIVST does not provide a definitive HIV-positive diagnosis. Individuals with a reactive test result must receive further testing from a trained tester using the national testing algorithm.



Countries implementing and developing HIVST policies, 2015-2020

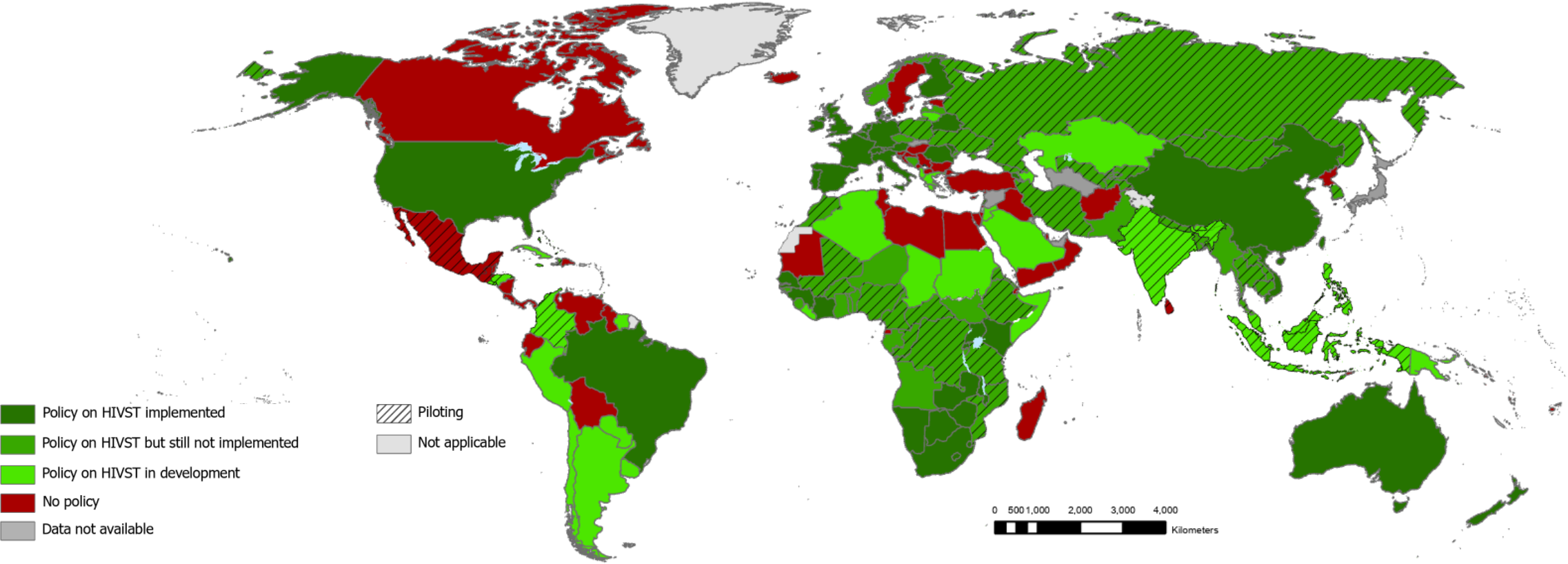


In process of updating for July 2021

*Between 2017 and 2020
three times as many
countries implemented
HIVST*

Source: GAM WHO, UNAIDS, UNICEF July 2020. For details of specific countries please refer to the UNAIDS Laws and Policies site (<https://lawsandpolicies.unaids.org/>)

Status of HIV self-testing (HIVST) in national policies (situation as of June 2020)



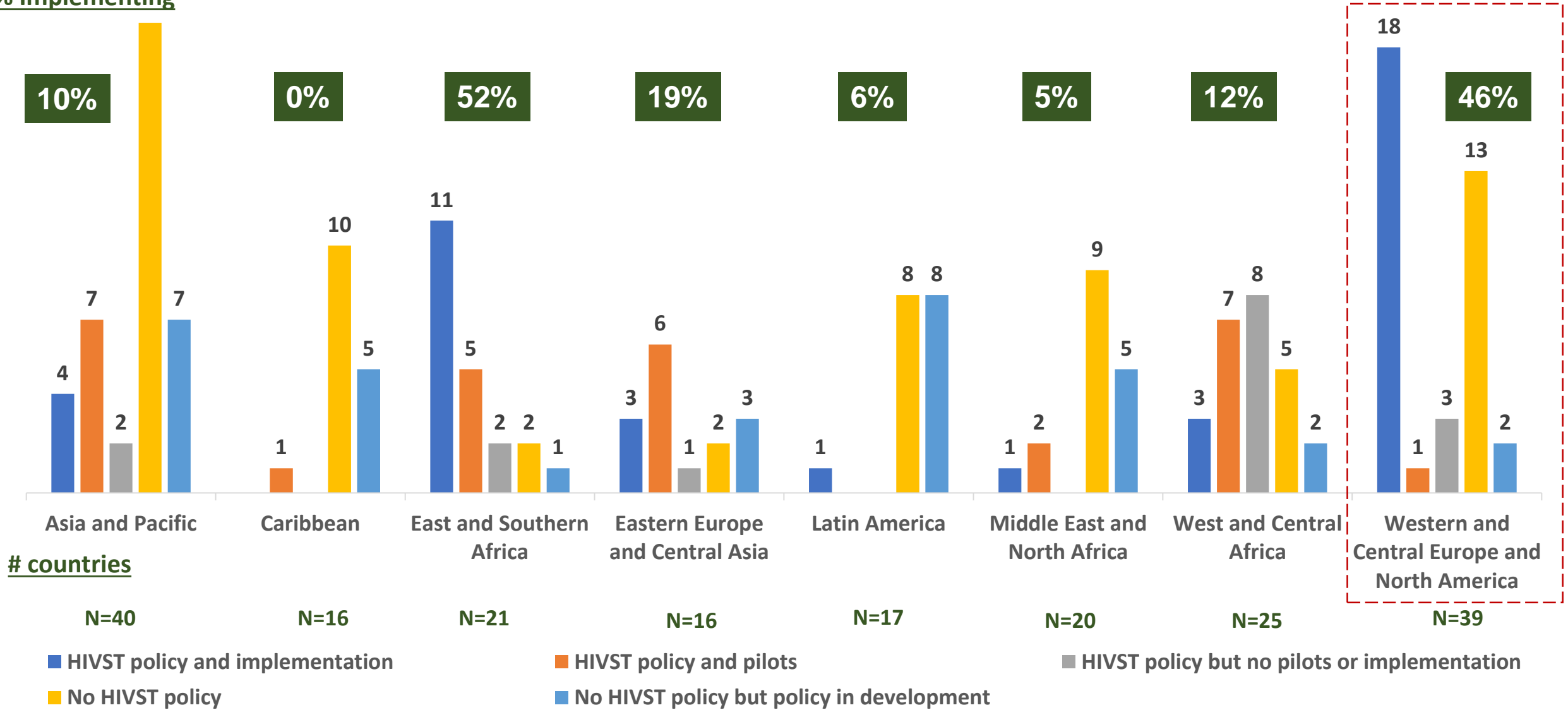
Source: Global AIDS Monitoring (UNAIDS/WHO/UNICEF) and Global HIV, Hepatitis and STIs Programmes (HSS), WHO, 2020

Disclaimer: The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

National HIVST policy and implementation 2020, by region

44% (86/194) reporting countries have HIVST policies, of these only 48% (41) are implementing

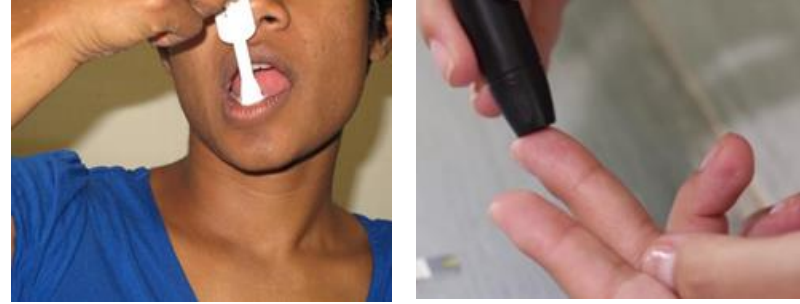
% Implementing



Realizing the role of HIVST in COVID-19 Context

Considerations for HIVST

- HIVST may be acceptable alternative to maintain services while adhering to physical distancing guidance.
- Important to strategically implement HIVST **prioritizing areas & populations** with greatest needs and gaps in testing coverage.
- **HIVST approaches include:**
 - distribution for personal use and/or sexual and/or drug injecting partners of PLHIV and social contacts of key populations
 - in high HIV burden settings, pregnant women may also provide HIVST kits to their male partners.
- **Priority settings to consider**
 - pick up at facilities or community sites
 - online platforms (e.g. websites, social media, digital platforms) and distribution through mail
 - pharmacies, retail vendors, vending machines



Countries with HIVST programmes

Expand and adapt HIVST

- replace facility with HIVST (to decongest health facilities)
- use HIVST for partner and social network testing

Countries yet to use HIVST

- Lobby for rapid HIVST approval



CONSIDERATIONS FOR HIV SELF-TESTING
IN THE CONTEXT OF THE COVID-19
PANDEMIC AND ITS RESPONSE:
AN OPERATIONAL UPDATE



COVID-19 HTS & ART Initiation Adaptation strategy (1 of 2)

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Lessons Learned

1. Important disruptions in 2020 in HTS and ART initiations. HTS still impacted in most countries by end 2020 (UNAIDS).
2. Differences **between** countries due partly to different COVID-19 pandemic dynamics, service suspension and social measures
3. Differences **within** countries: some services, population (especially non-ANC) or regions could have been more impacted.
4. Decrease on **offer** side: Reallocation of staff, sick leaves, closure/suspension of services
5. Decrease on **demand** side : underutilization of services due to fear, limitation of movements
6. Disruption of ART initiation among **advanced HIV**. Potentially a mix of explanations: overall decrease in HIV testing, decrease in TB diagnostic services, underutilization of OPD and emergency services
7. **Positive experiences to build on:** HIV services at ANC, Scale-up of ST, Index testing, Virtualization of services

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In Depth Analysis

1. Epidemiological: To quantify disruptions and identify groups, regions or services most affected; Take in account pandemic dynamics and disruptions in other services; To be repeated regularly
2. Supply and Stock Analysis: Existing stock of HIV Tests and ST; Supply chain analysis
3. HR & Finance

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Guiding Principles for HTS COVID-19 Adaptation

1. Uncertainty about the future dynamics of COVID-19 and availability and roll-out of vaccines or treatments: simultaneous HTS catch-up and adaptation
2. Maintain HTS while protecting health workers and patients and preventing the spread of COVID-19
3. HIV testing remains the entry door to care and treatment and essential testing services should remain operational even in case of severe disruptions.
4. HTS strategies and planning must be reviewed according to the local and national COVID-19 policies

COVID-19 HTS & ART Initiation Adaptation strategy (2 of 2)

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HTS Adaptation: 10 Key Advices

1. To prepare a strategy for HTS adaptation gradual and proportional COVID-19 community circulation and Health system disruptions
2. Protecting and supporting frontline HIV care providers: IPC training, availability of PPE, access to COVID-19 care and vaccine
3. Prioritization of HTS:
 - Individuals suspected of Advanced HIV
 - Individuals suspected or diagnosed with TB, STI, malnutrition
 - ANC, including retesting as well as EID
4. ART Services: ART initiation should be offered on the same day as HIV testing to people who are ready to start
5. Explore potential Synergy between COVID-19 & HTS: simultaneous testing, HIV Testing during vaccination, mask distribution
6. Scale-up HIV Self-testing especially outside of facilities
7. Maintain services for Key population using virtual interventions (risk assessment before testing appointment; information on COVID-19; tracing; virtual medical consultation)
8. HTS with higher yields like index testing prioritized
9. Mitigate impact of COVID-19 on demand side factors: Promote use of services; protect patients; ensure access to essential services
10. Data monitoring and Operational Research: report & scale-up initiatives

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Development a HTS Catch-Up strategy

1. **When?** As immediate and mid-term future remains uncertain, catch-up strategies should take in account risks of further disruption
2. **Who?** Define intervention targets and who will be conducted the interventions
3. **What Strategy:** introduce or scale-up activities with higher yields like HIVST or Index testing / Synergy COVID-19 and HIV response
4. **Where?** Region most affected by disruptions

HIVST products available or under development

HIVST products with WHO PQ, ERPD or approval from founding IMDRF* member countries (1 of 2)

Test (manufacturer)	Specimen	Approval	Markets	Price per test (US\$)
Mylan/Viatris HIV Self Test (Atomo, Australia)	Blood	CE mark, WHO PQ, TGA	Kenya, South Africa, various LMICs, Taiwan, Australia	Public sector: \$ 1.99 for 135 countries
autotest VIH® (AAZ Labs, France)	Blood	CE mark, WHO PQ, FDA	15 European countries	HIC retail: \$ 20–28 Distributors/NGOs: \$ 8–15
BioSURE HIV Self Test (BioSURE , United Kingdom Ltd)	Blood	CE mark, ERPD-3 ANVISA (Brazil) KMLTTB & PPB (Kenya) GFDA (Ghana) SAHPRA (South Africa)	South Africa, Brazil, Kenya, Ghana, United Kingdom	HIC retail: \$ 25–40 HIC public sector: \$ 6–10 LMIC public sector: \$3.80-6 LMIC retail: \$ 10-18
Exacto® Test HIV (Biosynex, France)	Blood	CE mark, ERPD-3	Europe	Dependent on volume
INSTI® HIV Self Test (bioLytical Lab., Canada)	Blood	WHO PQ CE mark	All European countries accepting CE mark, Nigeria, Kenya,	HIC retail: \$ 25–40 HIC public sector: \$ 7–22 LMIC public sector: \$3 - 6 LMIC retail: \$ 6 - 14

Note: Product details based on most recent information provided by manufacturers, which in some cases has not been updated since 2019

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaid/Global Fund Expert Review Panel

HIC, high-income countries; **FDA**, Food and Drug Administration; **ERPD**, Expert Review Panel for Diagnostics; **Gen**, test generation; **LMIC**, low- and middle-income countries, **MRSP**: maximum suggested retail price; **PPB**, Pharmacy and Poisons Board; **SAHPRA**, South African Health Products Regulatory Authority, **KMLTTB**, Kenya Medical Laboratory Technicians & Technologists Board; **GFDA**: Ghana Food and Drug Authority; **ANVISA**, Brazilian Health Surveillance Agency

., **WHO PQ**, World Health Organisation Prequalification; **IMDRF**, International Medical Device Regulators Forum , **CE**: Conformité Européenne

HIVST products with WHO PQ, ERPD or approval from founding members of IMDRF* (2 of 2)

Test (manufacturer)	Specimen	Approval	Markets	Price per test (US\$)
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark	USA	HIC retail: \$ 40 Public sector prices vary.
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ Nat. Reg. Authorities in several countries	Several LMIC countries ⁱ	LMIC ex-works: \$2 for 50 countries ^j
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	WHO, PQ, ERPD-3		Based on annual volume and if LTAs apply LMIC Public: \$2.99 ex-works
CheckNOW (Abbott Laboratories, USA)	Blood	ERPD Plan to apply for WHO PQ, CE		LMIC Public: \$1.50

Note: Product details based on most recent information provided by manufacturers, which in some cases has not been updated since 2019

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ⁱ: Afghanistan, Brazil, Chad, Congo, Gambia, Kenya, Mali, Mozambique, South Africa, Uganda, Zambia, Zimbabwe, Nigeria, Eswatini, Lesotho, Malawi, Tanzania, Ethiopia, Rwanda, Cote d'Ivoire, Burundi, Senegal, Cameroon, Ghana, Namibia, Botswana, Sierra Leone, Liberia, Somalia, Benin, Togo, Burkina Faso, Guinea Bissau, Morocco, Lebanon, Somalia, Nepal, Mongolia, Laos, Indonesia, Armenia, Kazakhstan, Ukraine, Georgia, Haiti, Russia, India

^j: Countries covered in the Bill and Melinda Gates Foundation (BMGF) buy-down

HIVST products with national-level approval

Test (manufacturer)	Specimen	Approval status	Availability	Pricing (US\$)
Alerta (Wama Diagnóstica, Brazil)	Blood	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	No information
Amethyst HIV 1&2 Test Kit (Bedford Biotech Nigeria Ltd., Nigeria)	Oral fluid	NAFDAC, Nigeria (National Agency for Food and Drug Administration and Control)	Nigeria	\$ 14 recommended market price. Prices for public sector and NGOs may vary.
HIV Detect (Eco diagnóstica, Brazil)	Oral fluid	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	No information
Saliteste (Ebram Produtos Laboratoriais, Brazil)	Oral fluid	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	No information
Unnamed test (Belarus)	Not available	Manufactured and approved in Belarus	Belarus	No information

Note: Product details based on most recent information provided by manufacturers, which in some cases has not been updated since 2019

* Includes products prequalified by WHO, approved by a regulatory authority in one of founding-member countries of the International Medical Device Regulators Forum or eligible for procurement on recommendation of Unitaïd/Global Fund Expert Review Panel.

NAFDAC, National Agency Food and Drug Administration and Control , ANVISA, Brazilian Health Surveillance Agency

HIVST products under development or in pipeline (1 of 2)

Test (manufacturer)	Specimen	Plan for regulatory approval
Asanté™ HIV Self Test (Sedia Biosciences Corporation, USA)	Oral fluid (also, a version is under development that can test either an oral fluid or whole blood specimen in a single device)	No information
Aware™ HIV-1/2 OMT Oral HIV Self Test (Calypte Biomedical, USA)	Oral fluid	Plan to apply for WHO PQ, CE, USFDA, ERPD
First Response HIV 1-2.0 Card Test (Self Test) (Premier Medical Corporation, India)	Blood	Plan to apply WHO PQ, CE, ERPD, CDSCO Nat. Reg. Authority
To be named (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China)	Urine	National regulatory approval in China (CFDA) pending

Note: Product details based on most recent information provided by manufacturers, which in some cases has not been updated since 2019

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HIVST products under development or in pipeline (2 of 2)

Test (manufacturer)	Specimen	Plan for regulatory approval
Morcheck (Morsef Lifesciences, LLP)	Blood	No information
STANDARD™ Q HIV Self-Test (not final) SD Biosensor	Blood	No information
To be named (InTec Products Inc.)	Blood	Plan to apply for WHO PQ, CE, ERPD, TGA and other Regulatory Authorities
To be named (Invex Health Private Ltd, India)	No information	No information
To be named (Trinity Biotech, Ireland)	Blood	No information

CE: Conformité Européenne; PQ: prequalification; WHO: World Health Organization.

Note: Product details based on information provided by the manufacturers at the time of report preparation.

HIVST Need Estimate for LMIC

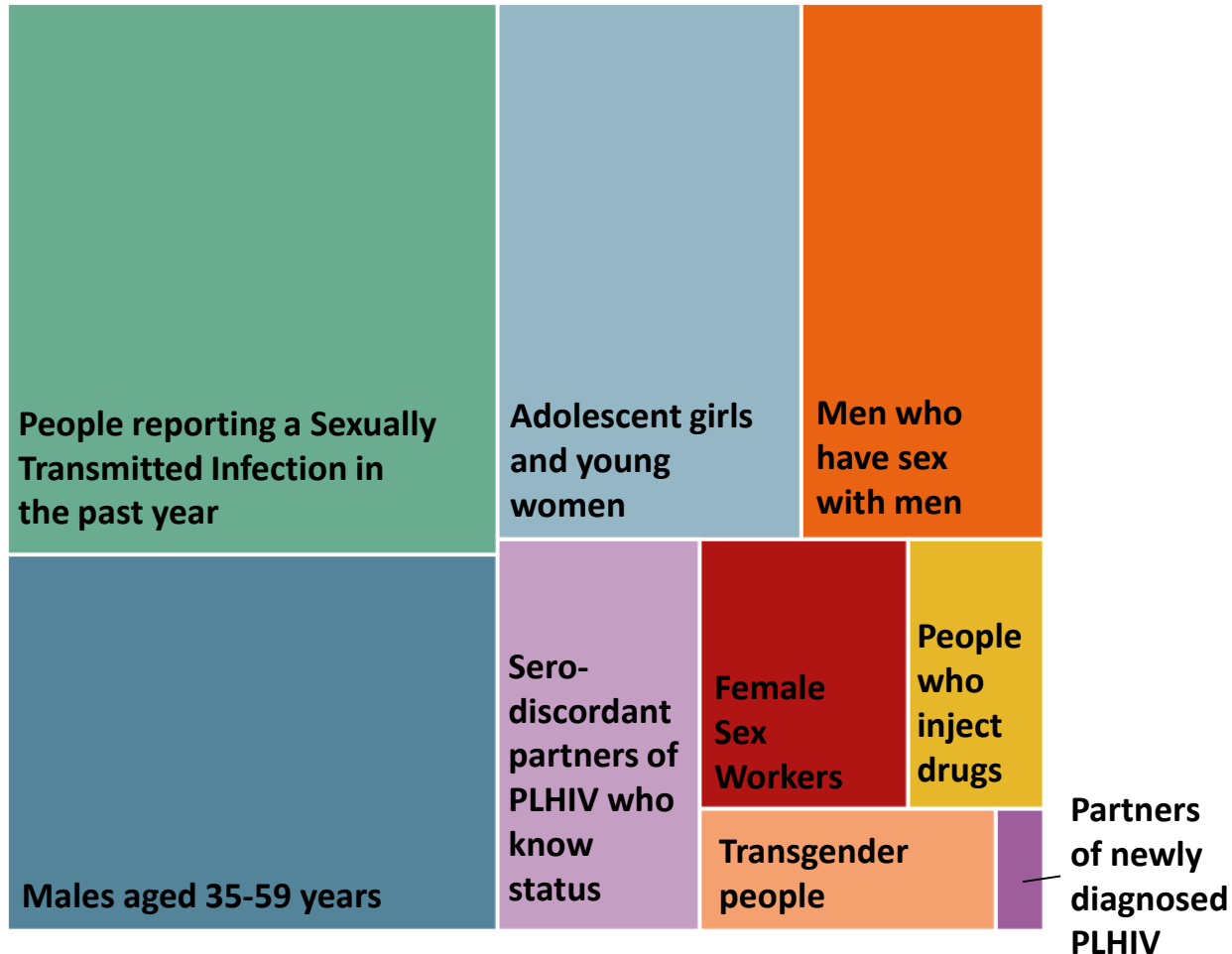
An epidemiological based, deterministic estimate of HIV testing need amongst populations recommended for HIV self-testing to achieve the 2030 global target of 95% of PLHIV knowing their status.

Click these links for additional information or see the index for a full list of additional resources

- [HIVST Need Estimate Methodology](#)
- [2020 Global LMIC HIVST Need Estimate Forecast Model](#)

Need Estimate is the sum of 25 country and target population specific estimates extrapolated to rest of LMIC

Target Populations



Focus countries

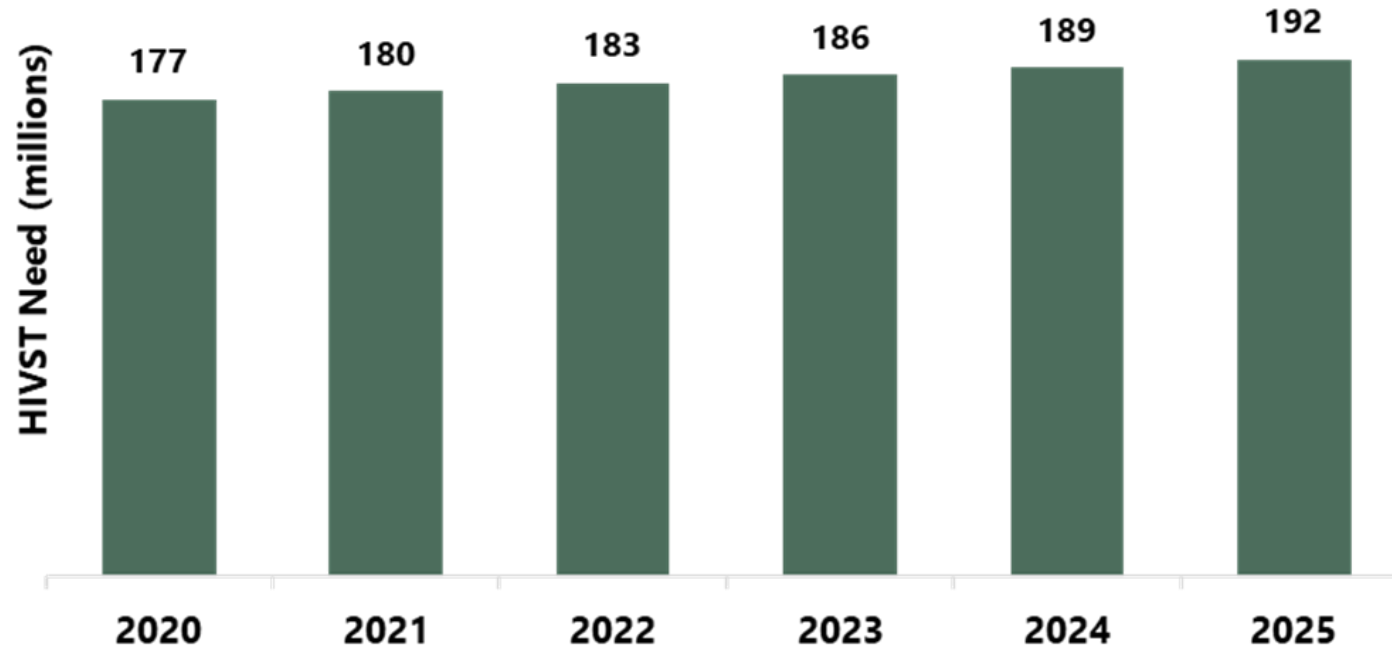
- | | |
|---------------|--------------|
| Angola | Brazil |
| Côte d'Ivoire | Mexico |
| Congo, DR | Myanmar |
| Ethiopia | Peru |
| Nigeria | Thailand |
| Indonesia | Tanzania |
| India | Uganda |
| Kenya | Ukraine |
| Mozambique | Vietnam |
| Malawi | South Africa |
| Pakistan | Zambia |
| Eswatini | |

25 focus countries have been selected to ensure:

- (1) a representative sample of all LMICs for the purpose of extrapolation
- (2) Inclusion of countries with the highest HIVST need & demand

Total HIVST need for LMICs is estimated to be 177m HIV self-tests in 2020, growing to 192m HIV self-tests by 2025

LMICs: Total Estimated HIV Self-Testing Need
2020 (millions)



Total number of LMICs included in the forecast = 108

HIVST Demand in LMIC

A forecast of future HIVST procurement based on historical and current procurement and funding data

Click these links for additional information or see the index for a full list of additional resources

- [HIVST Demand Forecast methodology](#)
- [2020 Global LMIC HIVST Demand Forecast Model](#)

The demand forecast is based on confirmed procurement and funding volumes (confirmed volumes) from major donors and implementers

Data represented on following slides represents an analysis of the funding, procurement and distribution data obtained from global donors, funders, procurers, implementers and some national government representatives. This data should not be considered a report of 'official' HIVST volumes from these organizations.

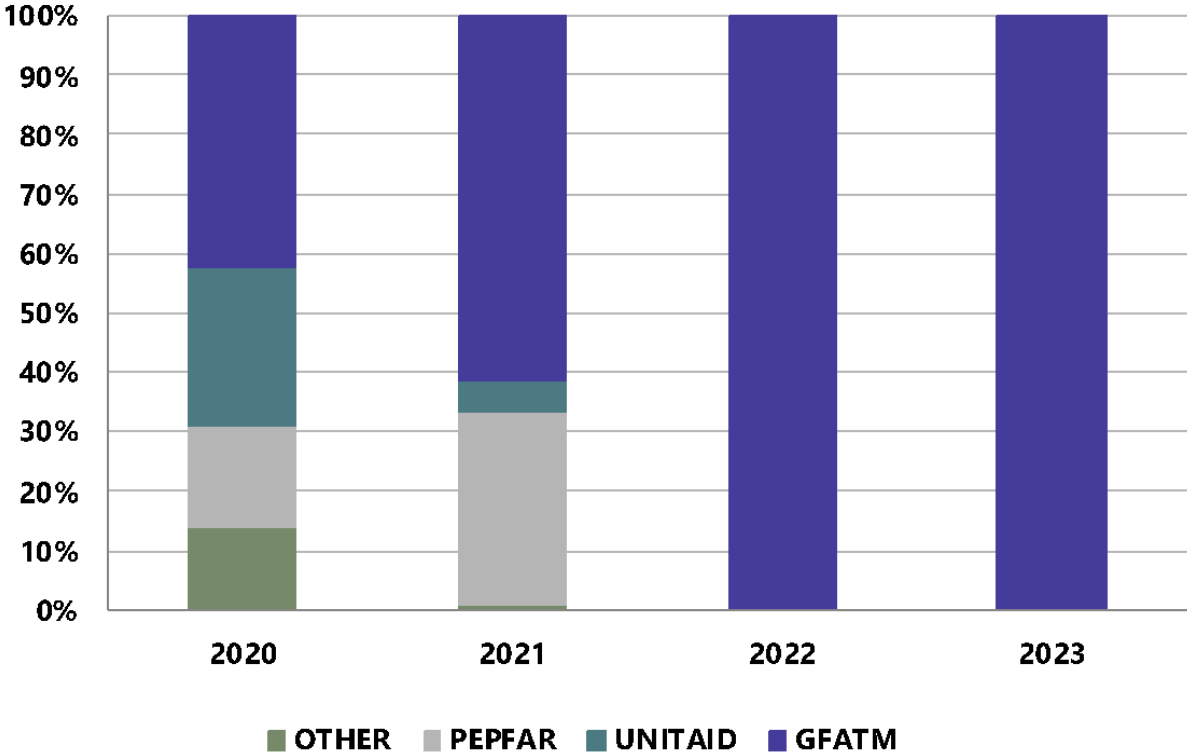
EIC and the WHO cross-reference the data provided and compare to expectations and other data sources to remove duplications (especially within the procurement and distribution data). We apply some assumptions and calculations to the funding data based on the qualitative knowledge available to convert it into Confirmed HIVST volumes.

Big thank you to all those who have provided data, especially The Global Fund, PEPFAR, GHSC-RTK, Unitaid, UNAIDS, CIFF and the WHO.

With confirmed volumes as at Oct 2020 of 21 million HIVST kits in 2020 – 2023, the procurement and funding pipeline is stronger than last year

	2020	2021	2022	2023
GFATM	2,744,150	4,599,615	4,456,735	2,891,987
PEPFAR	1,120,000	2,415,000	-	-
UNITAID	1,634,520	403,780	-	-
OTHER	900,571	64,305	10,260	-
TOTAL	6,474,241	7,482,700	4,466,995	2,891,987

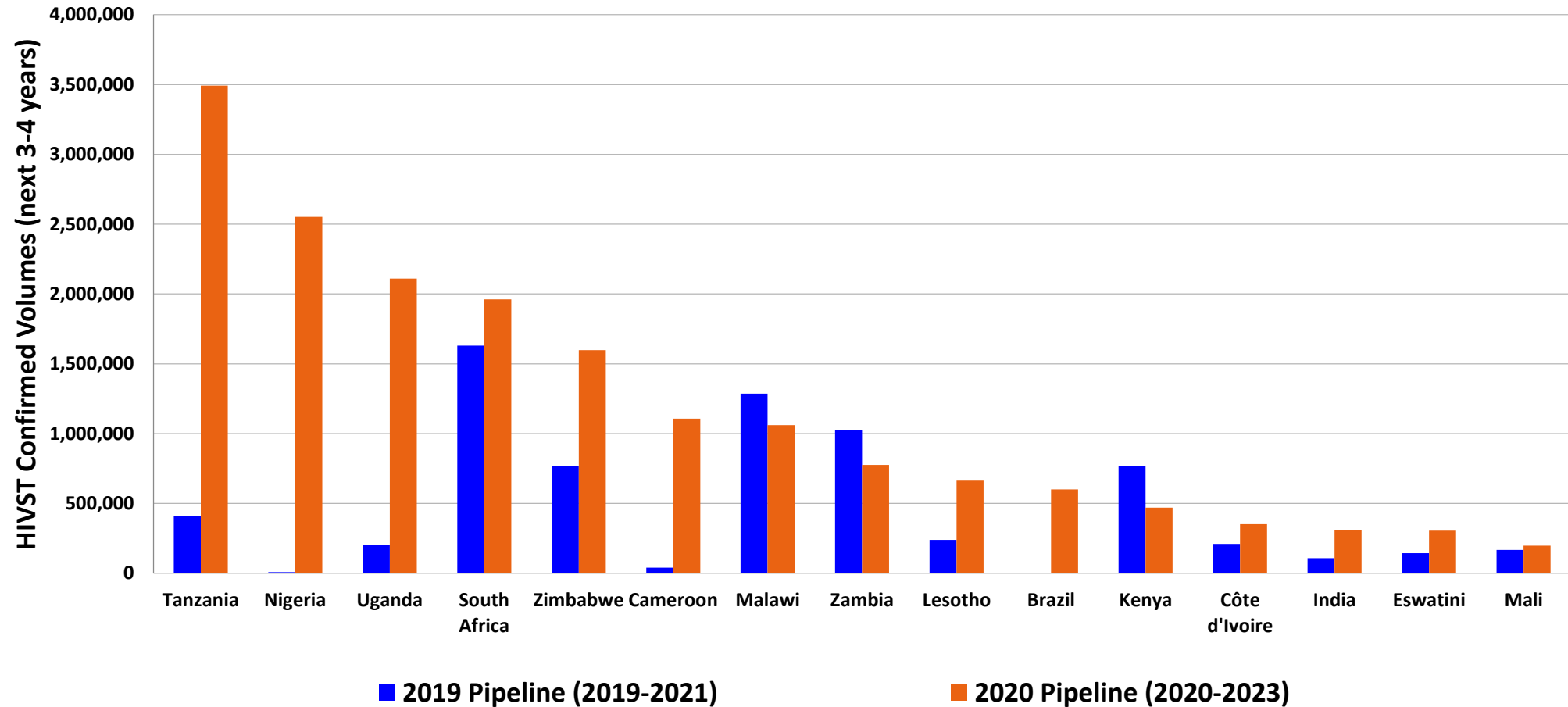
Confirmed HIVST volumes per donor 2020 - 2023



*Volumes are EIC analysis and not official figures and include estimates

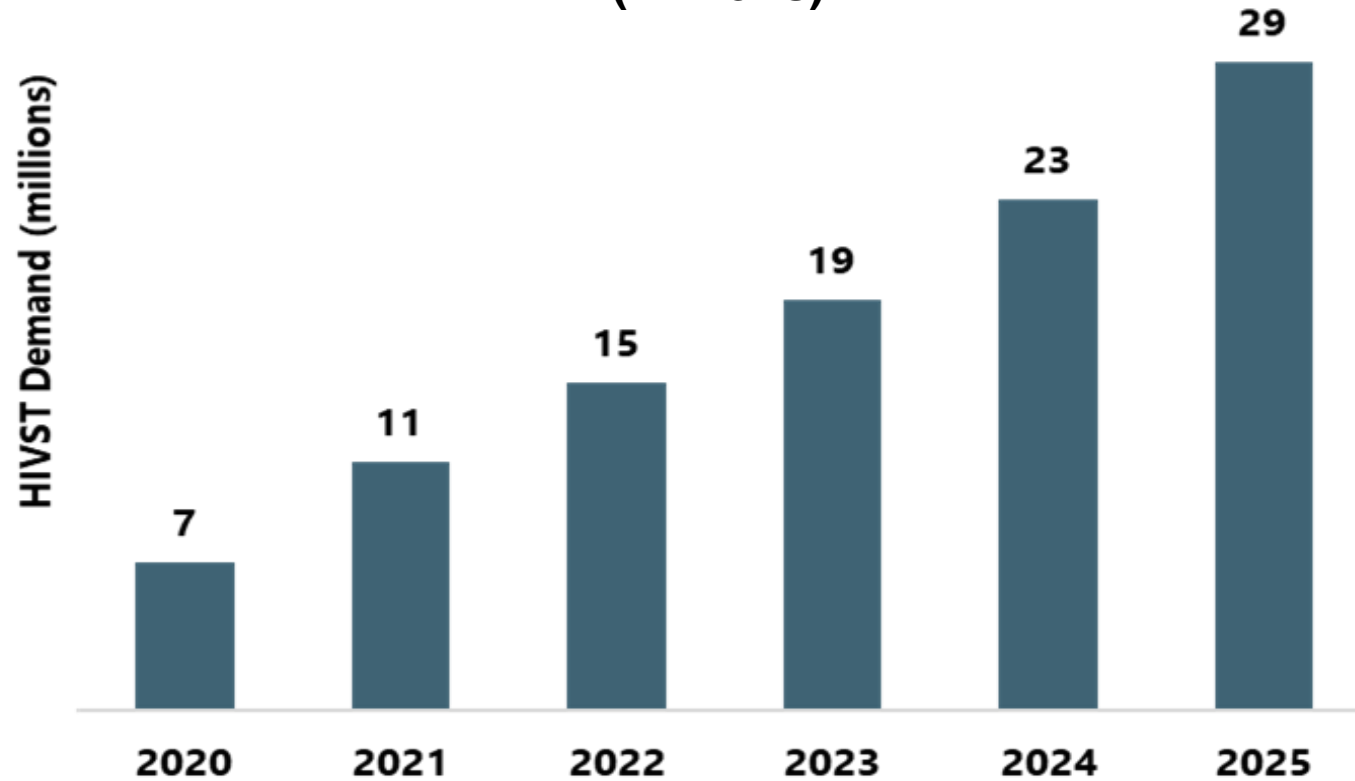
Due to the nature of the PEPFAR and Unitaid funding cycles confirmed volumes for 2022 and 2023 were not yet available for these organizations as at October 2020.

Confirmed country specific volumes have mostly increased



Total LMIC HIVST Demand is projected to reach 29 million tests by 2025

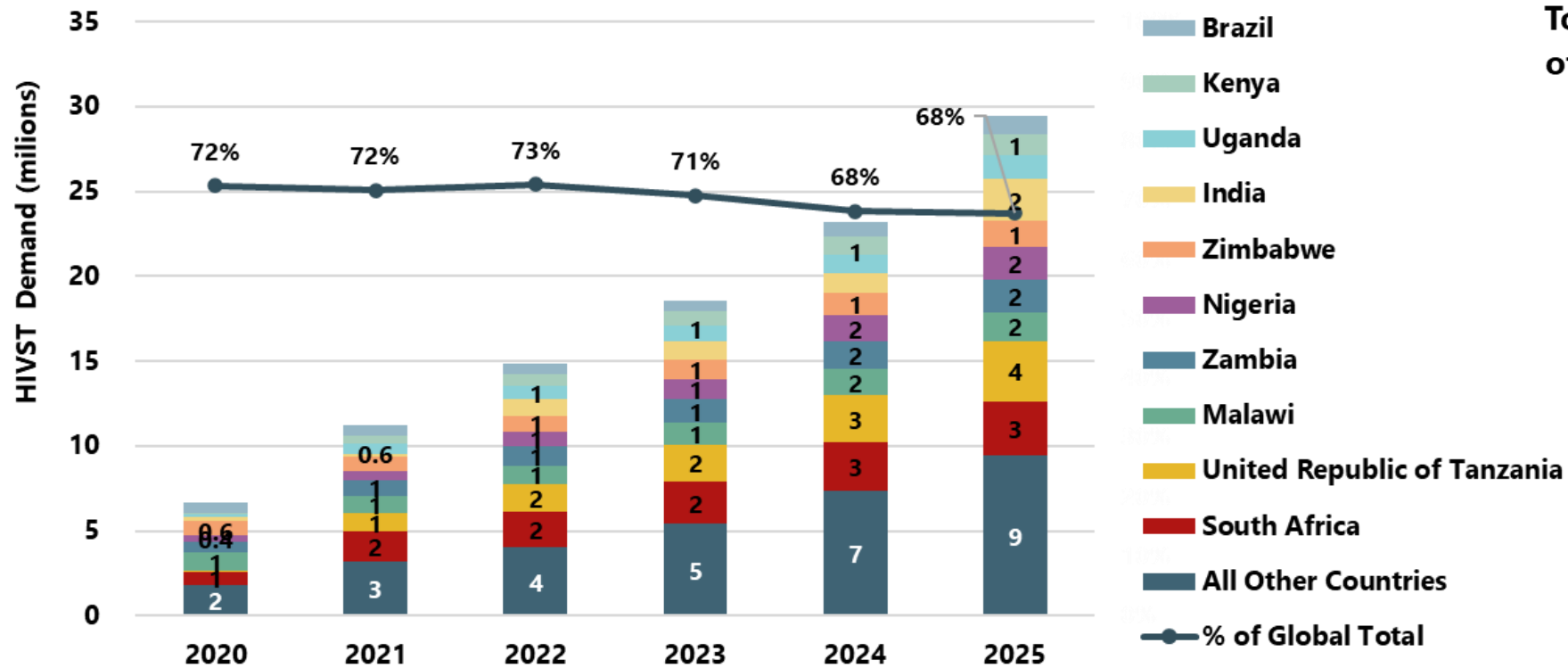
Projected volume of HIV self-test demand in LMIC (millions)



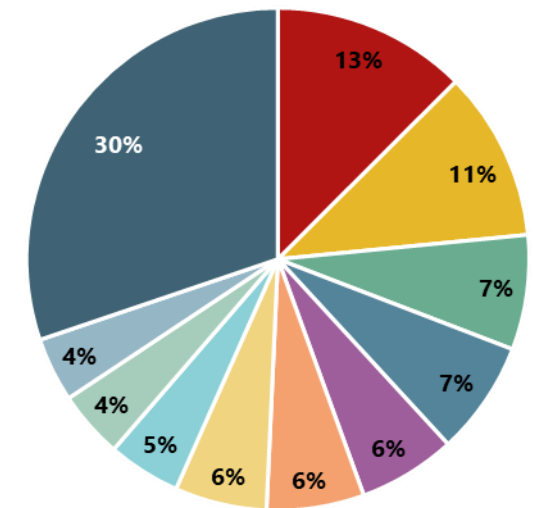
**Projected volumes in this chart reflect the total projection for 108 countries*

Top 10 countries by total volumes account for approximately 70% of expected volumes over the forecast period: 2020-2025

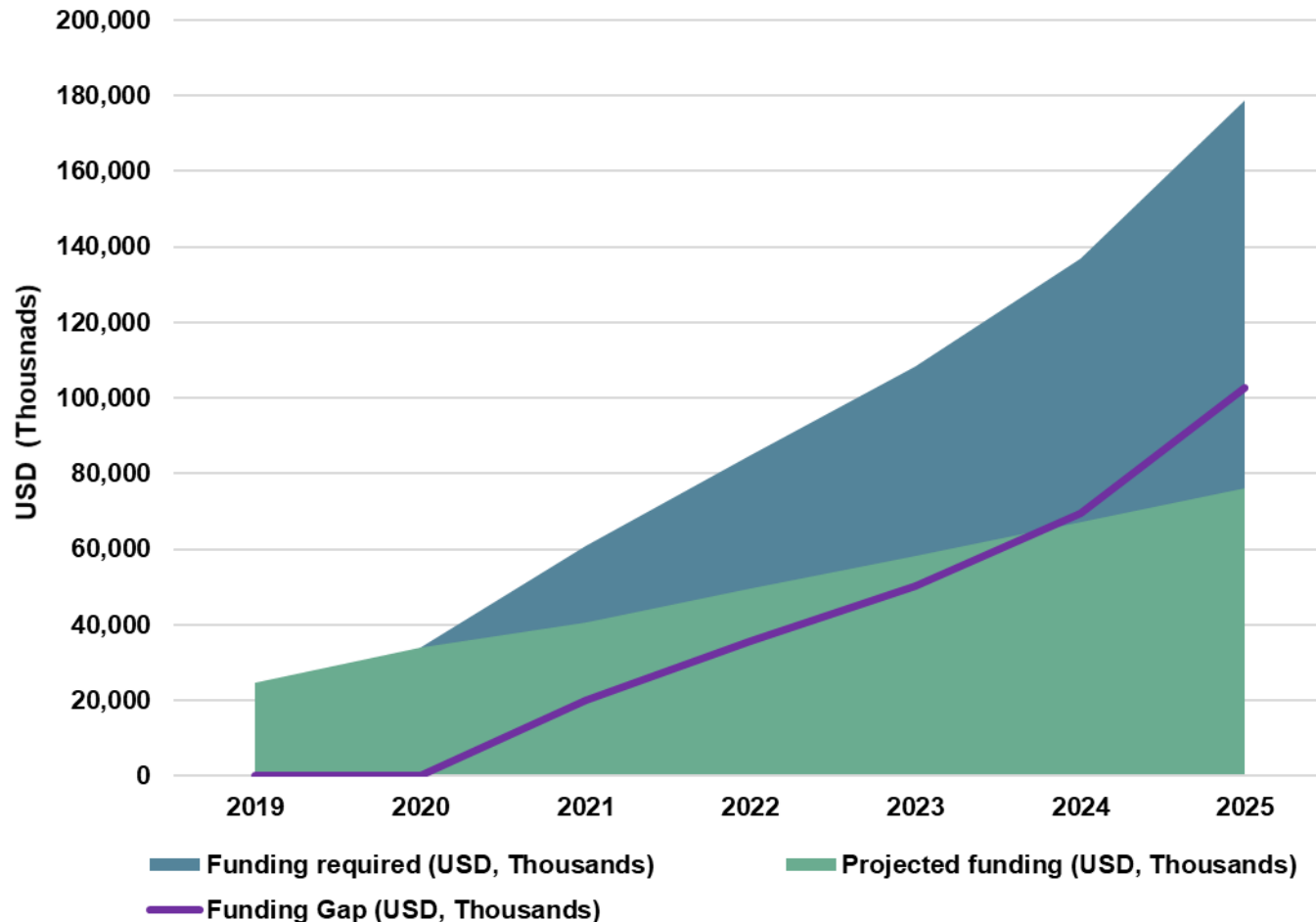
Top 10 Drivers of Total LMIC Demand Projection (millions)



Total Projected Demand 2020-2025 of 10 Drivers as % of LMIC Demand

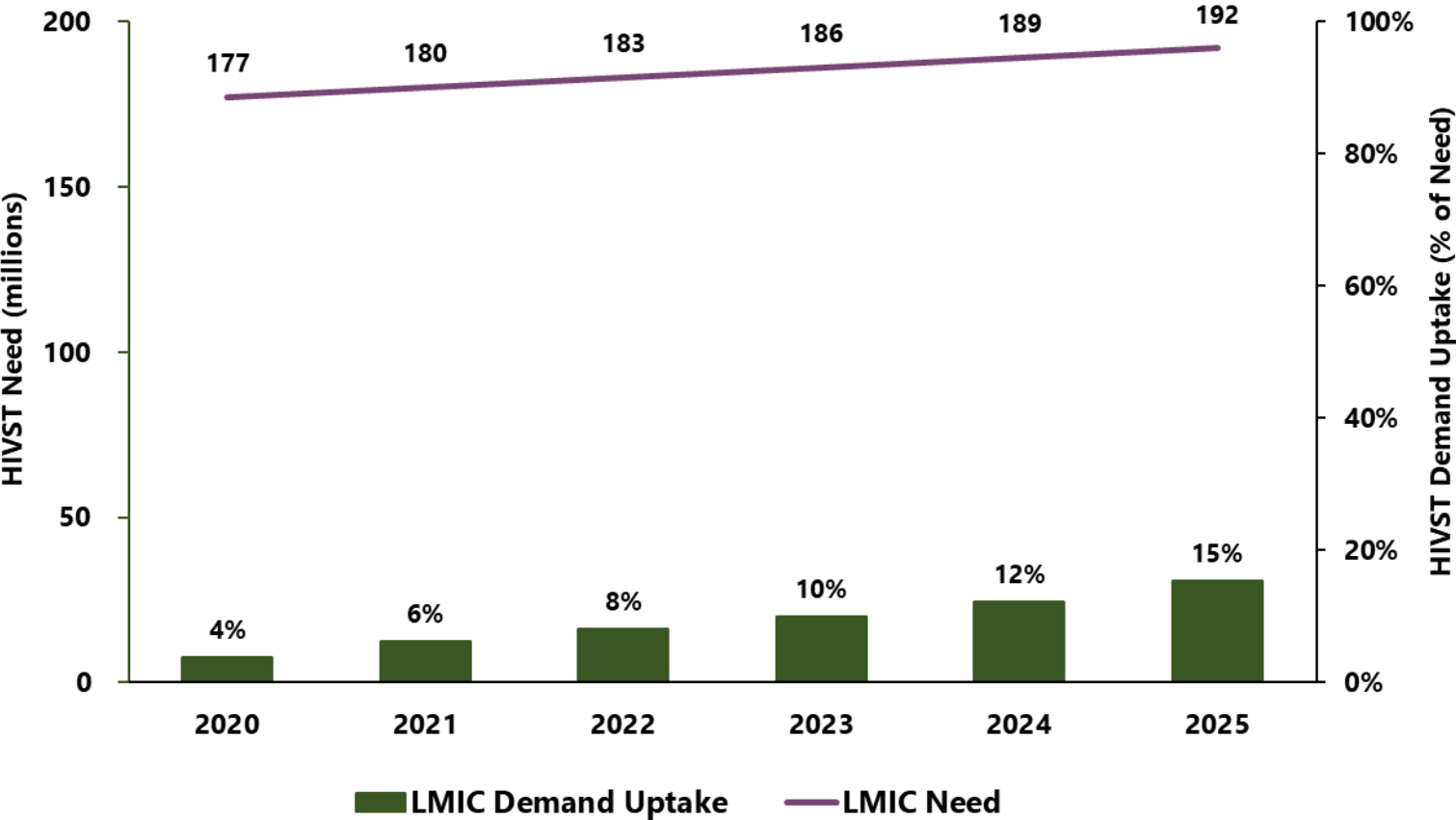


Funding allocated to HIVST implementation has increased rapidly but expected future demand will require continued growth to address funding gap of \$104 million in 2025



- Forecasted demand of 29 million HIVST in 2025 will require estimated funding of USD \$180 million to implement assuming an average cost to implement of \$5.46 per test remains constant.
- Funding trend indicates potential funding gap of \$104 million by 2025 based on linear projection of confirmed volumes converted to funding value at country specific estimated cost per test
- See Annex for assumed cost per test per country based on HIVST implementation status.

Low but increasing LMIC Demand volumes as a percentage of need is anticipated, reaching 15% of need by 2025



HIVST Market Landscape 2020: A summary

- HIVST policy adoption and implementation continues to grow, with three times as many countries implementing HIVST in 2020 as compared to 2017.
- The confirmed volumes look very strong with 21 Million HIVST in the pipeline between 2020 and 2023 and slightly more confirmed volumes for 2020 than previously forecasted.
- Total LMIC HIVST Demand is projected to reach 29 million tests by 2025, which is very similar to what was projected in the 2019 forecast.
- Nearly 90% of the estimated LMIC demand will come from the 25 Focus Countries. 10 of these (9 in Africa) account for about 70% of the total LMIC demand.
- The demand forecast has an implicit funding gap that increases from \$40 Million in 2022 to \$104 Million in 2025. This funding gap is inclusive of estimated implementation costs as well as commodity costs.
- Total LMIC Demand is anticipated to reach 15% of the need for HIV testing among populations recommended for HIVST by 2025.

HIVST volumes have grown significantly from 1 million tests in 2017 to nearly 10 million in 2020.

Continued additional growth and diversification is needed to optimize the mix of HIV testing services and reach the goal of 95% of PLHIV knowing their status by 2030.

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- Richard Thayer (Halteres Associates).
- Kim Marsh, Jo Dy, and Victoria Bendaud (UNAIDS)
- John Stover (Avenir Health)

Contact

For more information on HIV testing services

WHO HIV Testing
Services Dashboard

WHO HIV Testing
Services Info App

Questions?

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