Market and technology landscape

HIV rapid diagnostic tests for self-testing

4th edition

July 2018

https://unitaid.org/assets/HIVST-landscape-report.pdf

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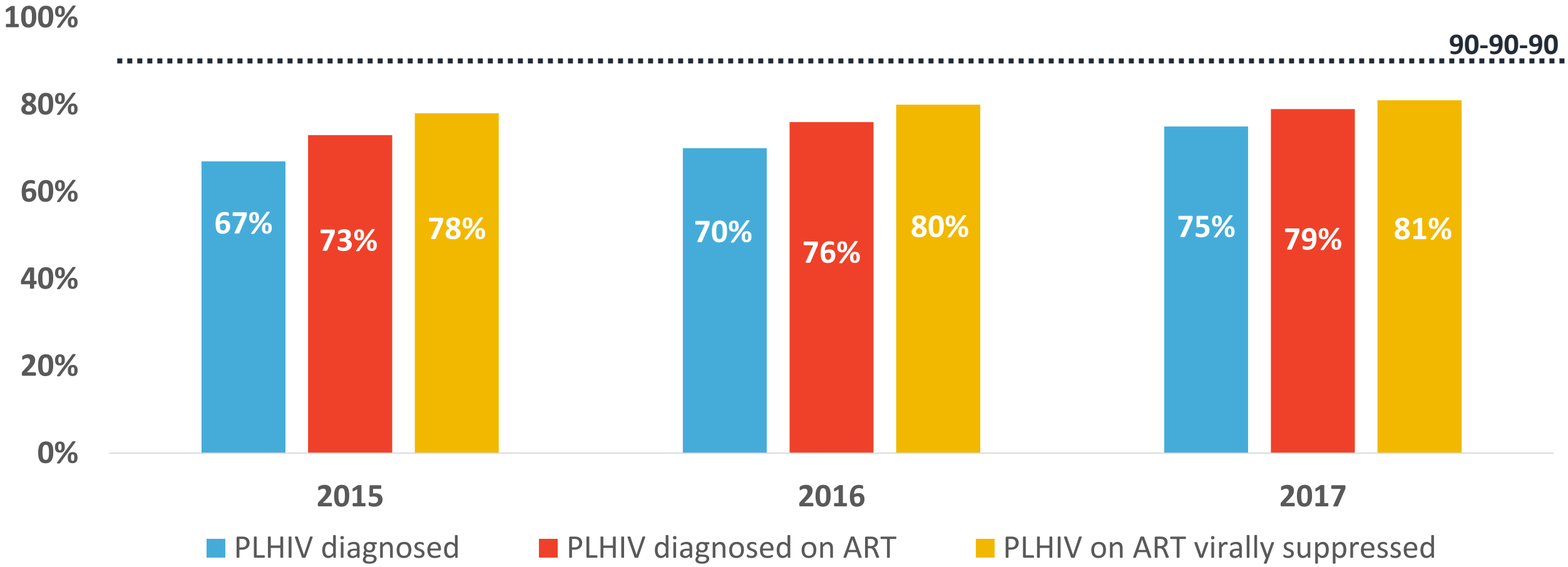
Progress toward the 90-90-90, 2015-2017

Substantial progress but the biggest gap continues to be the first 90

9.4 million people living with HIV (PLHIV) remain undiagnosed



Source: UNAIDS 2018

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What is HIV self-testing (HIVST)?

When a person collects his or her own specimen, performs a rapid HIV test and interprets their result

All reactive self-tests need further testing

Source: WHO 2016

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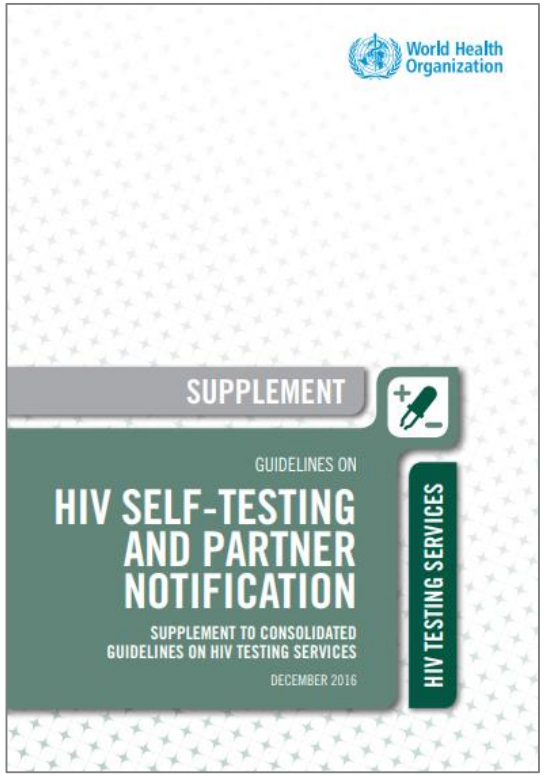
HIV self-testing: an important innovation



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 note test otherwise

WHO recommendation:

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

(strong recommendation, moderate quality evidence)

Source: WHO 2016

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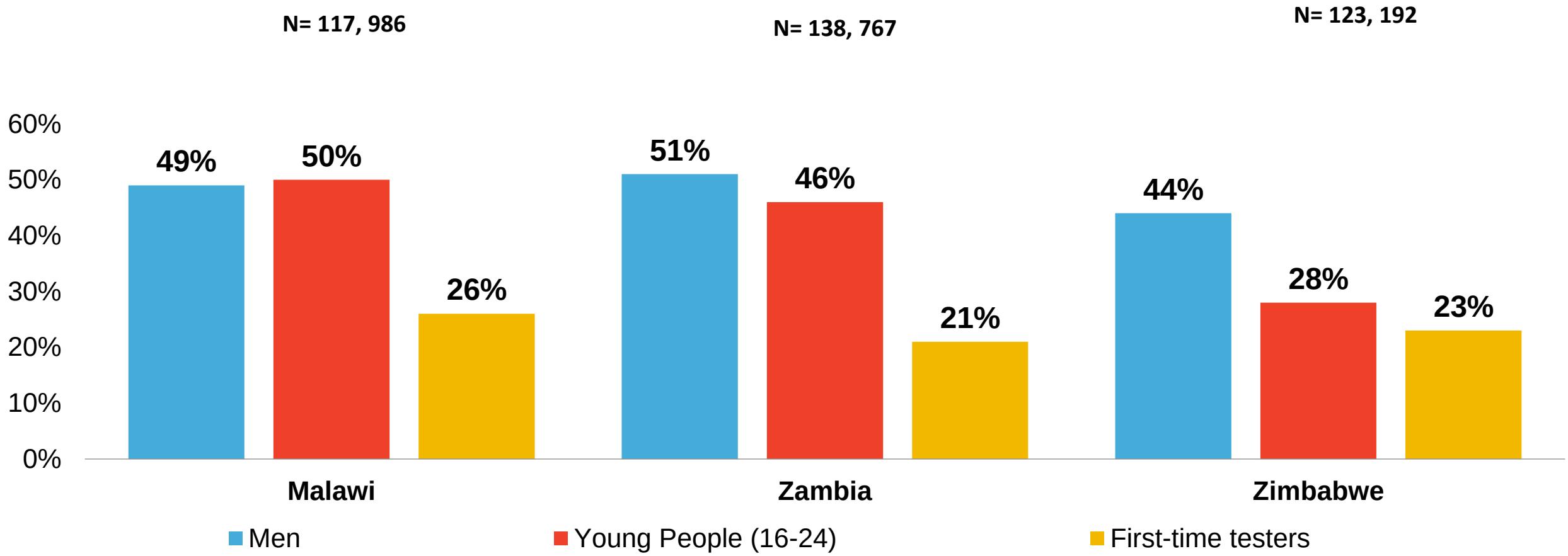
HIV self-testing can reach untested populations

Proportion of men, young people and first-time testers self-testing for HIV, STAR Initiative 2017



Source: Mutesta IAS 2017

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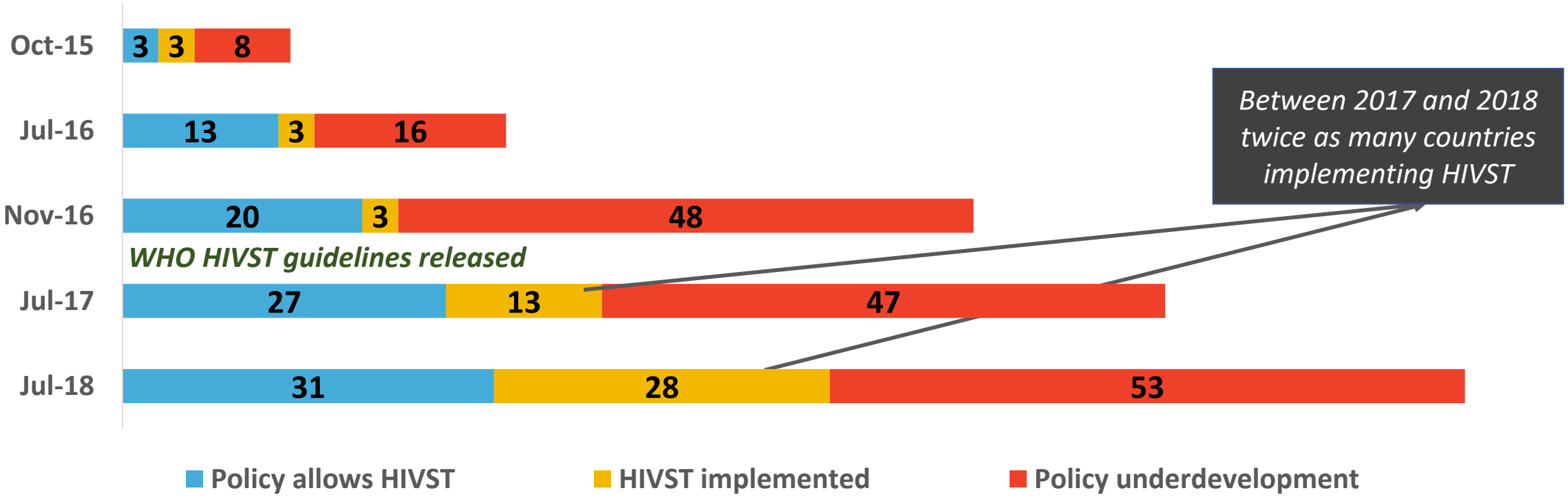
Total number of countries implementing and developing HIVST policies, 2015-2018

Rapid HIVST policy uptake and implementation continues



Source: WHO, UNICEF, UNAIDS GAM 2018, 18 July 2018

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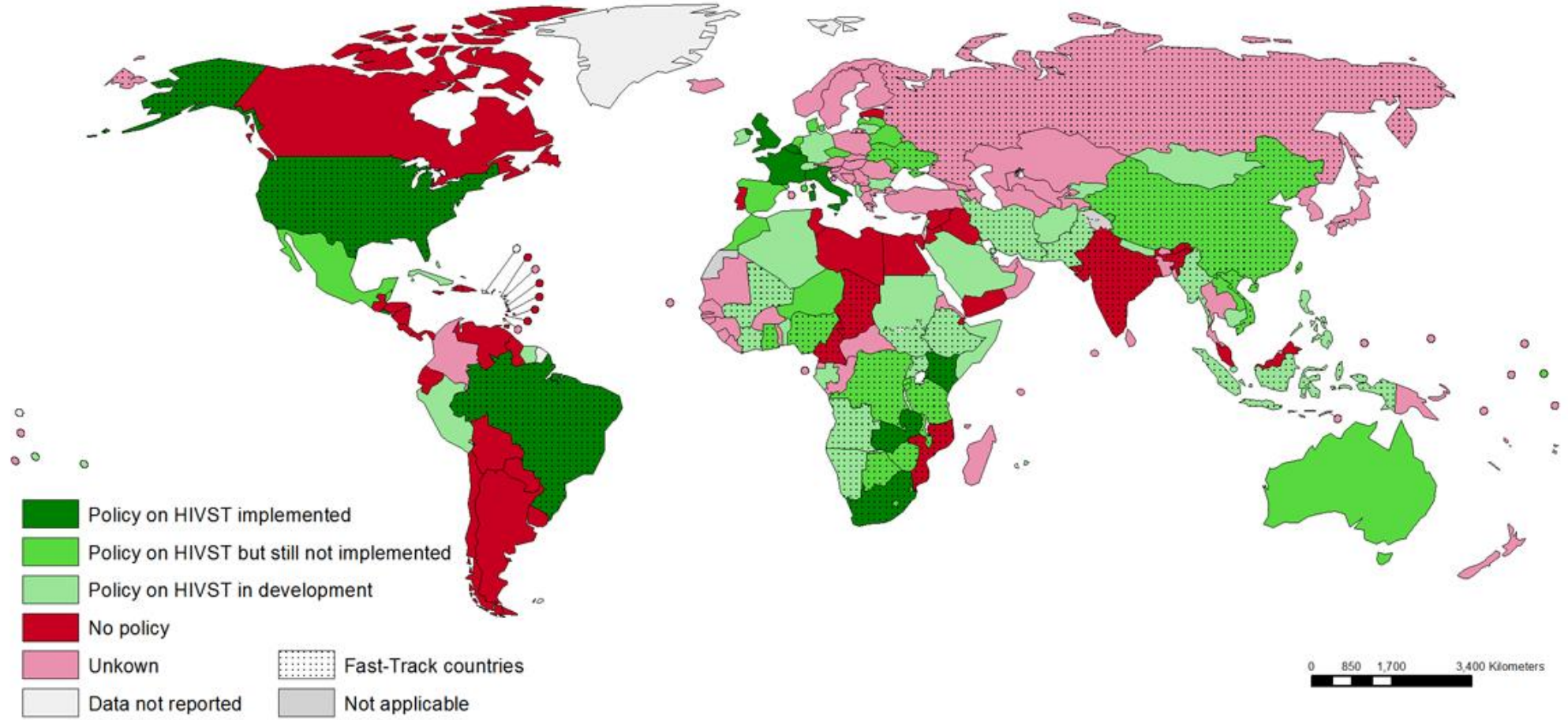
2017 HIVST policy and implementation map



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.

Data Source: World Health Organization
Map Production: Information Evidence and Research (IER)
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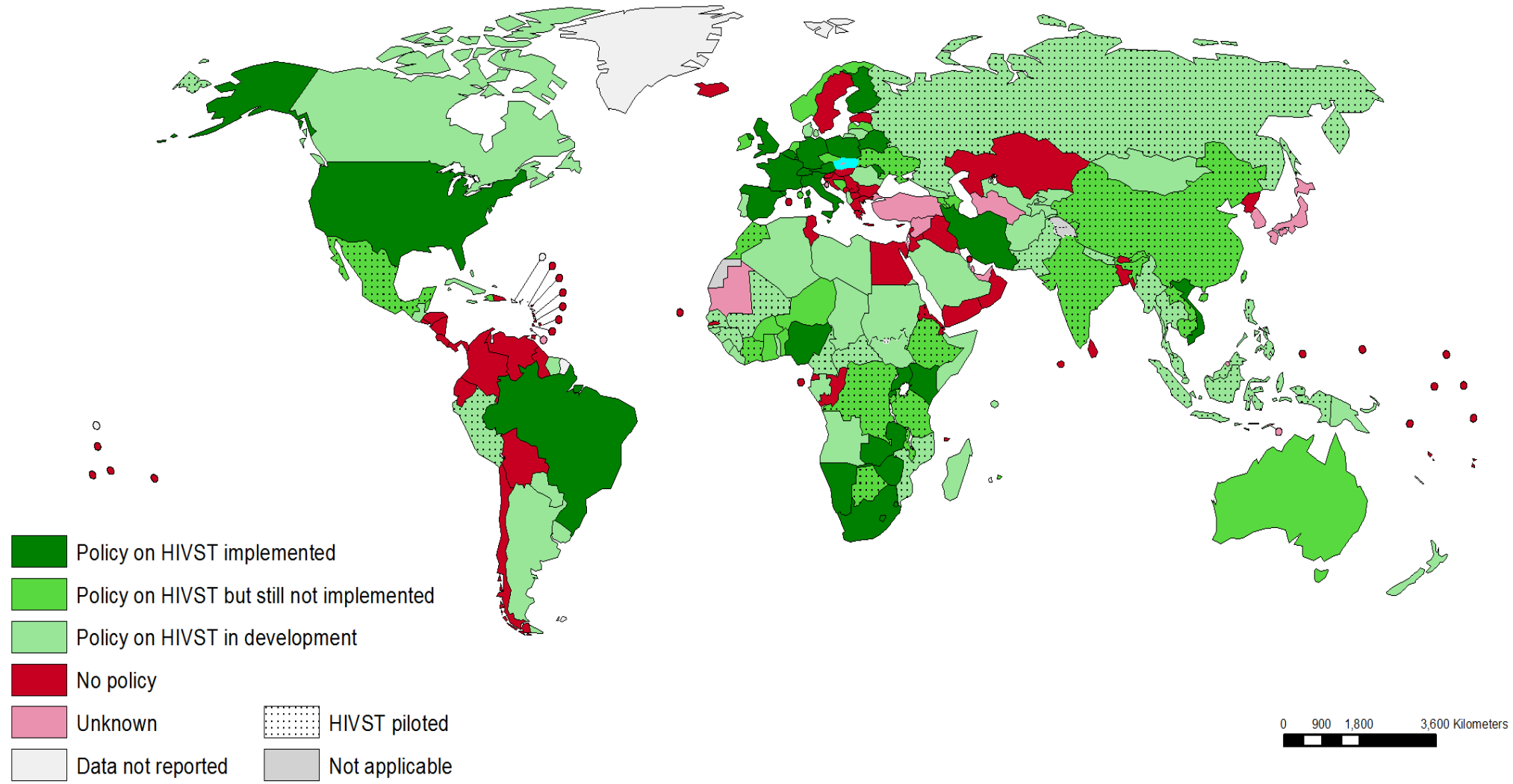
2018 HIVST policy and implementation map



Global AIDS Monitoring (UNAIDS/WHO/UNICEF) and WHO HIV Country Intelligence Tool, 2018

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HIVST market procurement forecast 2017 – 2020

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Methods

- Built bottom-up forecast based on national policy and historical donor procurement data
- Data combined actual and planned procurement and sales data between 2017 and 2020 and spanned public and private sector
  - Key public sector data sources included: Unitaid, Global Fund, PEPFAR, CIFF, and MSF
- Informed and developed three levels within the forecast
  - Global (Public + Private Sector)
  - Public Sector (primarily low- and middle-income countries [LMICs])
  - Private Sector

Methods

Six scenarios combined to create total forecast

Public

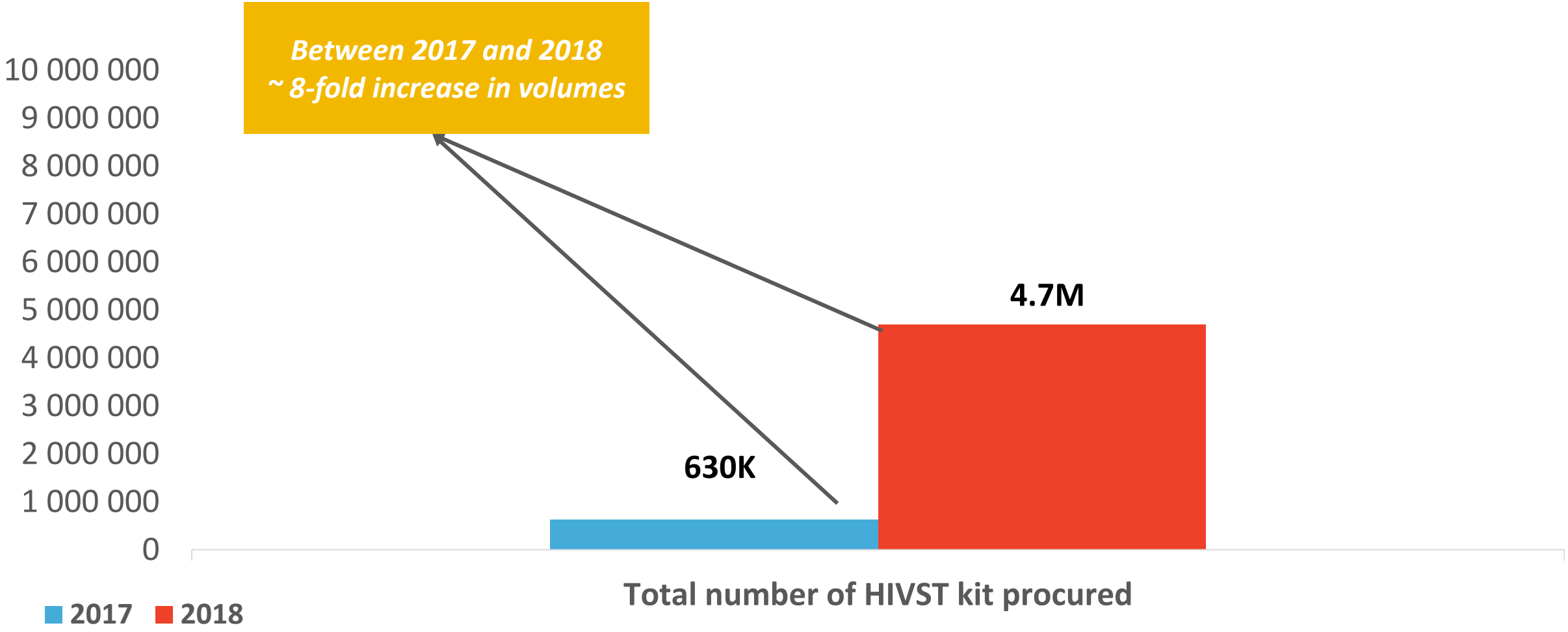
- **Conservative** – Estimated PEPFAR, Global Fund and residual volumes
- **Moderate** – Conservative + estimate of policy-signaled uptake and scale-up
- **Aggressive** – Moderate + estimate of uptake and scale-up without direct policy signal

Private

- **Moderate** – Private sector estimate based on combined manufacturers' forecasts
- **Conservative** – Moderate -10%
- **Aggressive** – Moderate +10%

HIVST actual and planned donor procurement, 2017-2018

for the public sector in low-and middle-income countries



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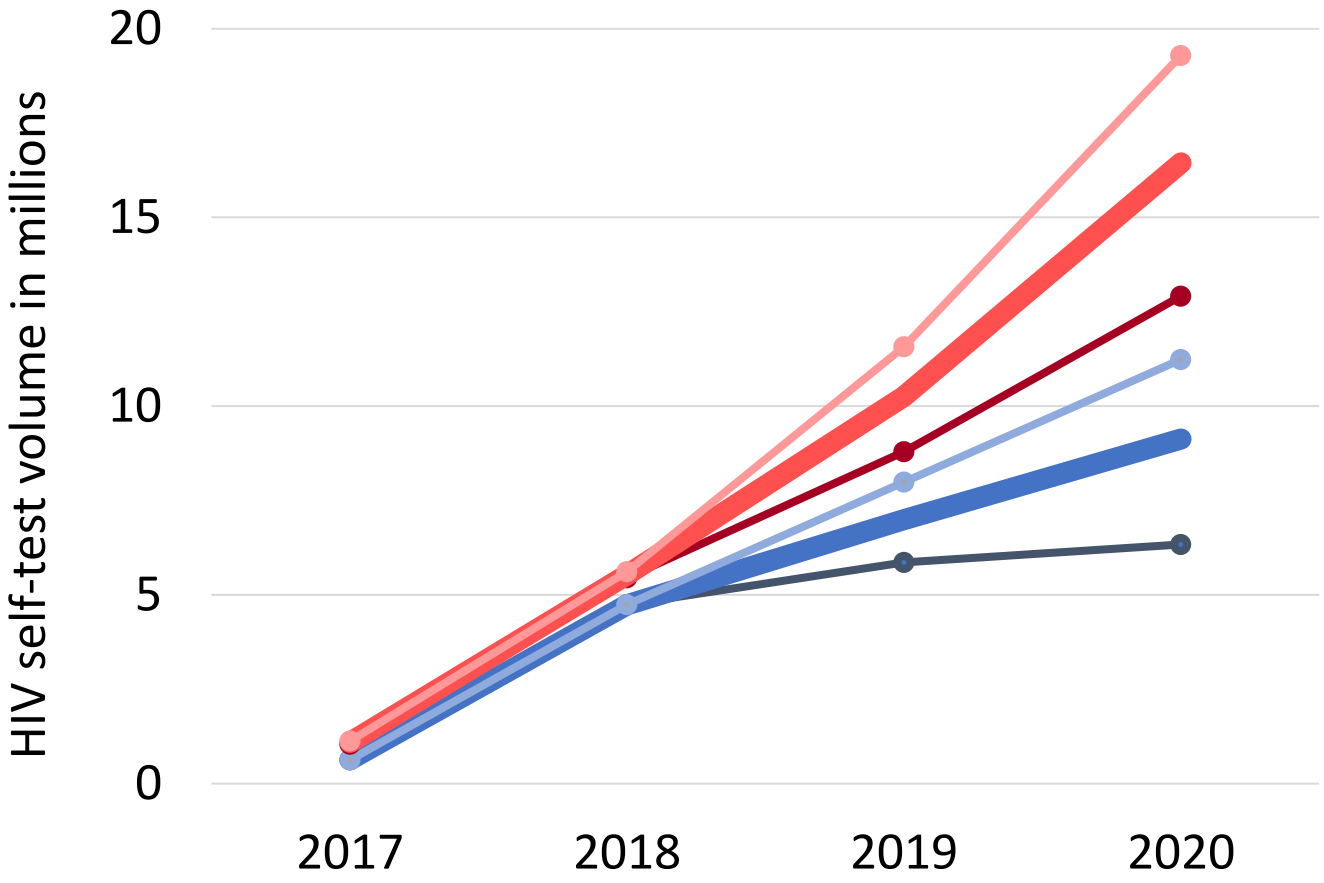
99 countries considered in the global forecast

Representing more than 85% of the global HIV burden

Of these, 83 countries below had forecast volumes

Afghanistan	Botswana	China	Eswatini	India	Lebanon	Mozambique	Peru	Sudan	Zambia
Albania	Brazil	Colombia	Ethiopia	Indonesia	Lesotho	Myanmar	Philippines	Suriname	Zimbabwe
Algeria	Bulgaria	Congo, Dem. Rep.	Fiji	Iran (Islamic Republic of)	Libya	Namibia	Republic of Moldova	Tajikistan	
Angola	Burkina Faso	Cook Islands	Gabon	Jamaica	Malawi	Nepal	Rwanda	United Republic of Tanzania	
Armenia	Burundi	Côte d'Ivoire	Georgia	Kenya	Mali	Niger	Senegal	Uganda	
Azerbaijan	Cambodia	Cuba	Ghana	Kiribati	Mauritius	Nigeria	Sierra Leone	Ukraine	
Belarus	Cameroon	Dominica	Guatemala	Kosovo	Mexico	Niue	Somalia	Uzbekistan	
Benin	Central African Republic	El Salvador	Guinea	Kyrgyzstan	Mongolia	Pakistan	South Africa	Venezuela	
Bolivia (Plurinational State of)	Chad	Eritrea	Haiti	Lao People's Democratic Republic	Morocco	Paraguay	South Sudan	Vietnam	

Global HIVST forecast



- Public sector – conservative
- Public sector – moderate
- Public sector – aggressive
- Global – conservative
- Global – moderate
- Global – aggressive

	2017	2020
Global market	1 M	16M (13-9M)
Public sector	0.6 M	9M (6-11M)

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Methods - Public sector conservative forecast

- Minimum baseline of planned and funded procurement per country

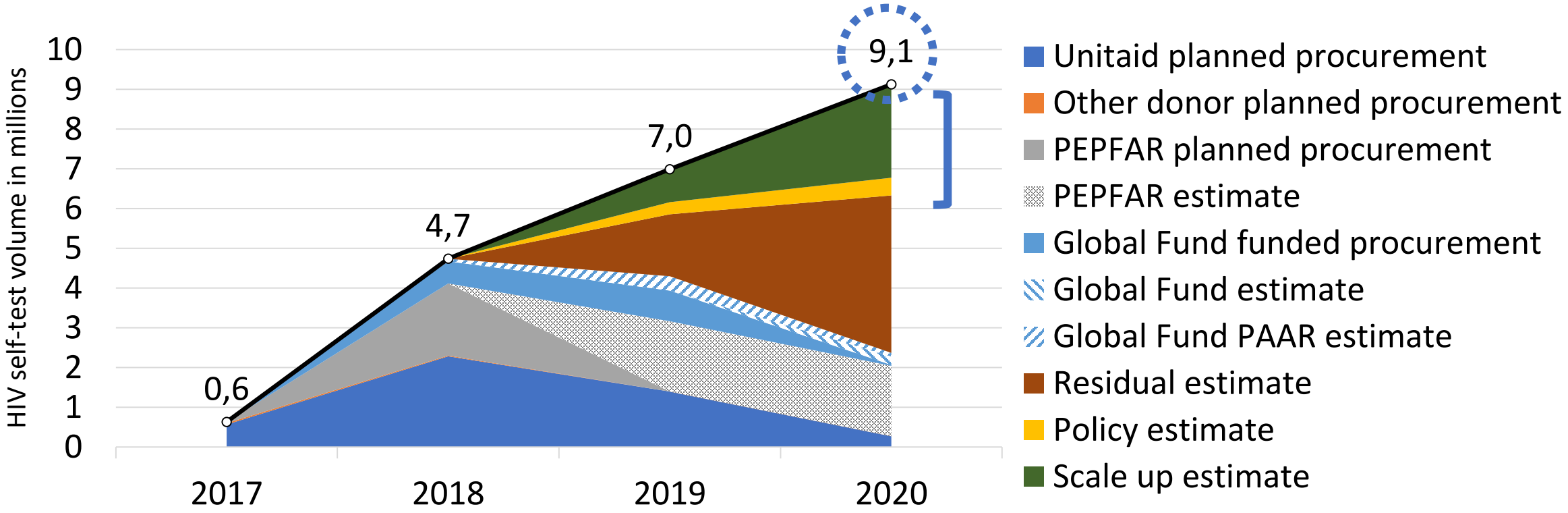
- Estimated PEPFAR, Global Fund and residual volumes
  - **PEPFAR**: projected 2019 and 2020 Volumes (Flat year-on-year, YOY)
  - **Global Fund**: planned procurement and Global Fund prioritized above allocation request (PAAR) estimates based on Global Fund provided data
  - **Residual estimates**: per country based on either
    - maintaining at minimum YOY volumes for countries with >1 year planned procurement, or
    - maintaining at least 2018 actual/planned volumes for countries with <1 year procurement.

Methods - Public sector moderate forecast

- Conservative scenario + estimated procurement for countries signaling policy uptake or active implementation
  - **Policy uptake estimate**: Countries reporting HIVST implementation to WHO without known volumes assumed to generate HIVST kit volumes of 5% of total HIV RDT volumes or minimum of 5,000 self-tests for piloting.
  - **Scale-up estimate**: Countries reporting HIVST implementation to WHO with known volumes assumed to generate HIVST volumes equal to or higher of: conservative forecast volumes; 2.5% of RDT volumes (2019) - 5% (2020) RDT volumes; or 5000 tests.

Public sector moderate forecast

- Policy estimate adds 750 000 tests by 2020 from 17 additional countries
- Scale-up estimate adds 3.2M tests by 2020 from 10 additional countries



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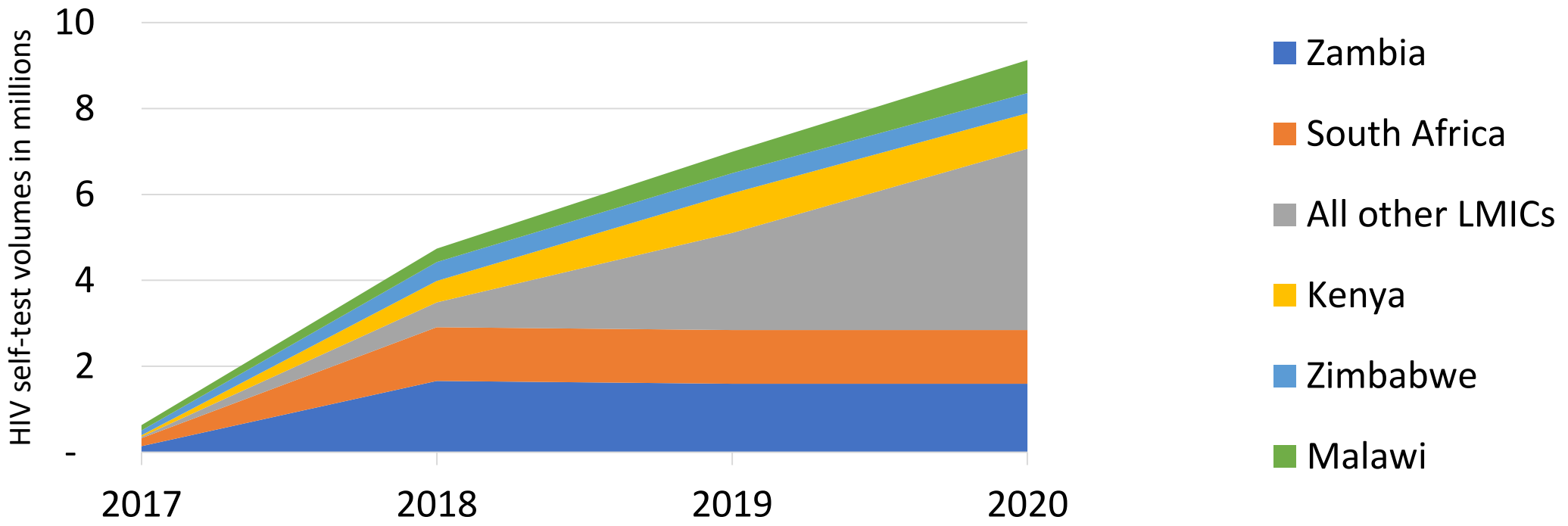
Public sector moderate forecast

- HIVST volumes from STAR countries and Kenya are critical to market foundation
- Future growth expected to originate mostly from all other LMICs, with 7.1M tests by 2020 (inclusive of 2018,2019,2020)



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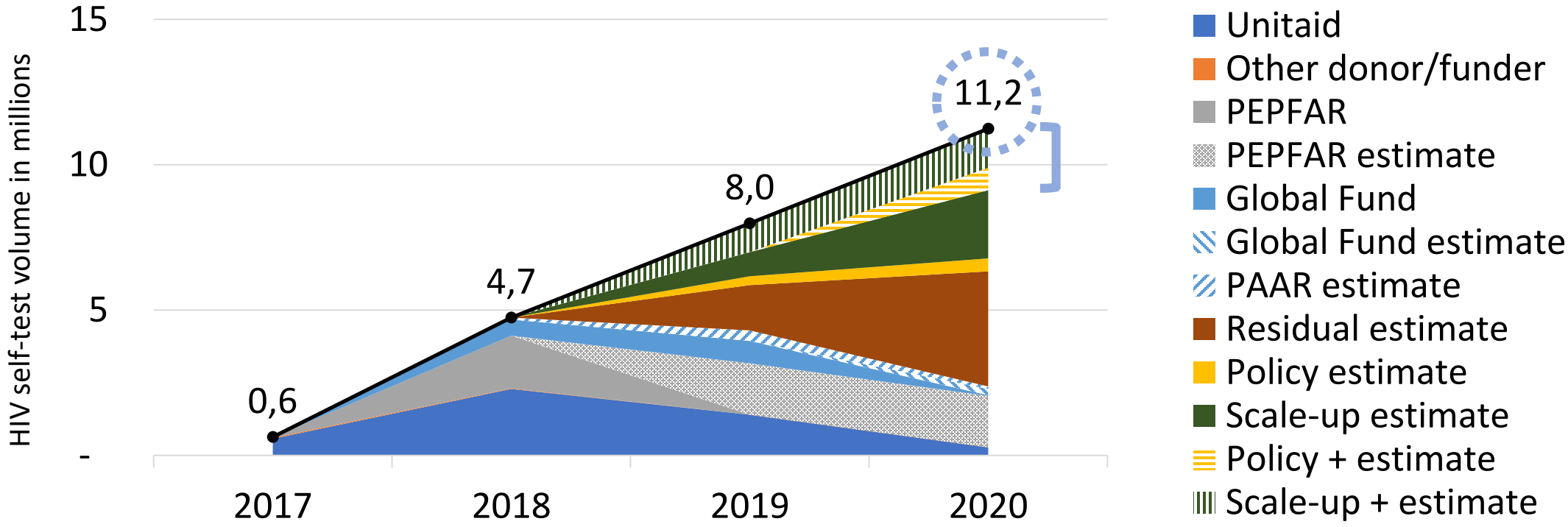
Methods - Public sector aggressive forecast

- Moderate scenario + estimated procurement for countries with no known policy signal and an additional amount of scale-up volumes.
  - **Policy uptake estimate**: Countries with an HIVST plan, but neither an implementation date reported to WHO nor any known volumes are assumed to generate HIVST kit volumes ≥ 5% RDT volumes or 5000 tests for pilot.
  - **Scale-up estimate**: Countries with an HIVST implementation date reported to WHO with known volumes are assumed to generate HIVST kit volumes equal to the greater of conservative forecast volumes; 5% (2019) of RDT volumes - 7.5% (2020) of RDT volumes; or 5000 tests.

Public sector aggressive forecast

- Policy estimate adds 770 000 tests by 2020 from 44 additional countries
- Scale-up estimate adds 2.3M tests by 2020 from same 10 countries as before
- HIVST volumes in key 5 countries still conservatively flat



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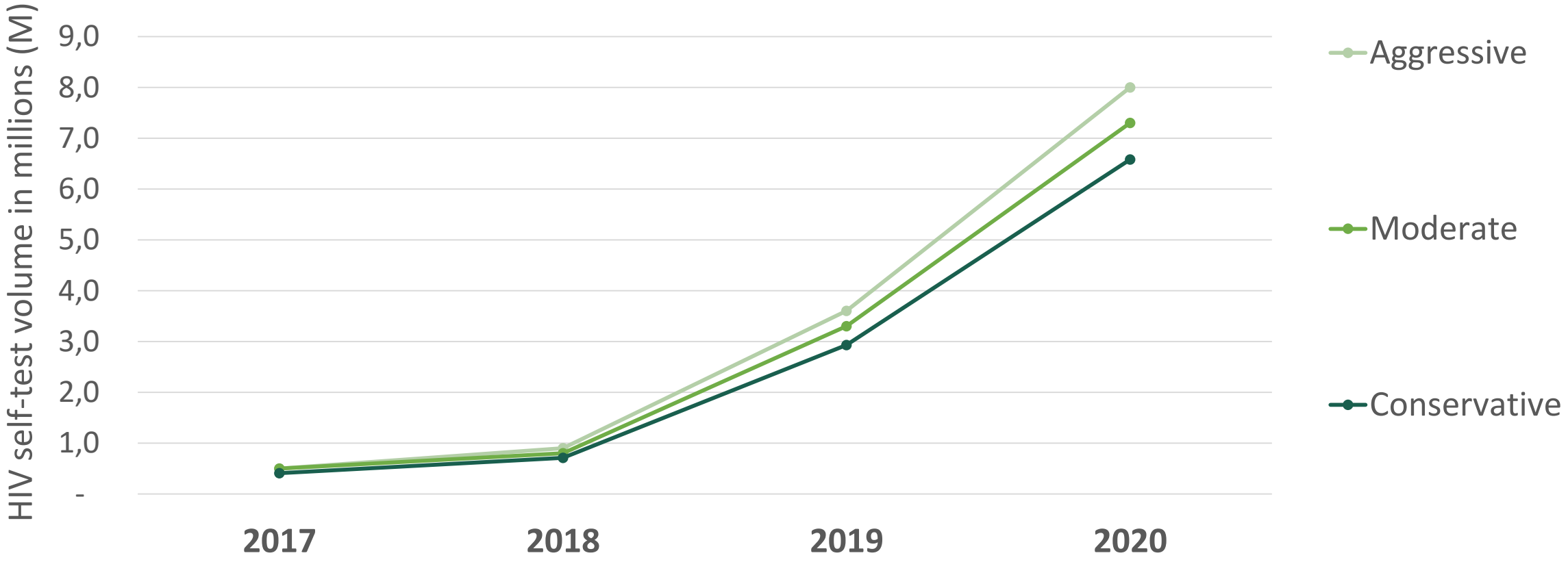
Methods – Private Sector

- Manufacturers' private sector sales and volume forecasts were reviewed and adjusted by WHO based on market entry progress, country regulation and policy environment.
- Manufacturer forecasts were standardized across geographic and time periods. These adjustments resulted in the amalgamated forecasts being reduced by a little more than 2 million tests.
- These forecasts should be considered with caution due to some subjective elements and faster moving nature of the private sector market.

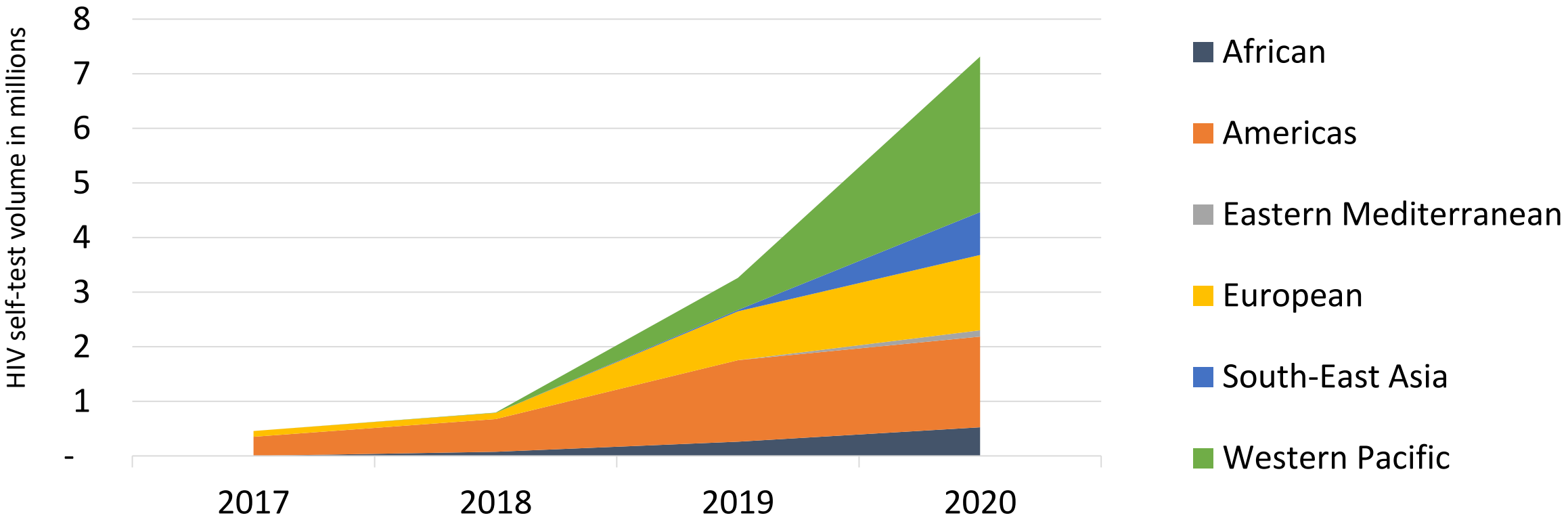
Private sector forecast

- Growth in private sector predominantly reflects new countries implementing HIVST.
- Growth predominantly originates from upper middle income countries



Private sector forecast, by WHO region

- Americas is expected to provide a strong foundation for private sector volumes.
- Eastern European and Western Pacific markets are expected to present significant growth.



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HIVST forecast summary

- Global HIVST market is estimated to grow to 16.4 million (12.9 – 19.3 million) tests by 2020
  - Public sector: 9.1 (6.3 – 11.2) million
  - Private sector: 7.3 (6.6 – 8.0) million
- Public sector volumes are currently concentrated in 5 key countries including 4 STAR countries.
- By 2020 other LMICs are expected to procure 46% of HIVST kits in public sector.
- The funding gap in 2020 is estimated to be US$ 13.5 – $ 23.5 million. The forecast does not yet consider domestic funding sources and data on funding cycles for 2020 are not yet available.
- In the private sector, beyond 2019 upper middle-income countries are expected to drive growth.

HIVST products available or under development

HIVST products approvals, developments and pipeline

July 2018

- 8 HIVST kits with WHO PQ, ERPD-3 or approval from regulatory authority in a founding member of IMDRF
  - 5 HIVST kits available for procurement through donor funding in LMICs
    - *1 HIVST kit WHO prequalified; 4 for operational research (ERPD-3)*
- Locally manufactured self-tests with national-level approvals have emerged in some countries (6 self-tests identified)
- At least 6 other HIVST products are under development or in pipeline

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

Test (manufacturer)	Specimen	Approval	Markets	Price per test (US$)
atomo HIV Self Test (Atomo Diagnostics, Australia)	Blood	CE mark ERPD-3	Kenya, South Africa	Public sector: $ 3
autotest VIH® ** (AAZ Labs, France)	Blood	CE mark	15 European countries[d]	HIC retail: $ 20–28 Distributors/NGOs: $ 8–15
BioSURE HIV Self Test ** (BioSURE , United Kingdom Ltd)	Blood	CE mark ERPD-3)[b,e]	South Africa, United Kingdom	HIC retail: $ 42–48 HIC public sector: $ 7.5–15 LMIC retail: $ 11.75
Exacto® Test HIV (Biosynex, France)	Blood	CE mark	Europe[d]	Not available
INSTI® HIV Self Test ** (bioLytical Lab., Canada)	Blood	CE mark ERPD-3[b,c]	Several countries in Europe[d], Nigieria	Price: $ 3–12 MSRP: $ 7–36
OraQuick® In-Home HIV Test (OraSure Technologies, USA)	Oral fluid	FDA, CE Mark	USA, Not yet marketed in Europe	HIC retail: $ 40 Public sector prices vary.
OraQuick® HIV Self Test (OraSure Technologies, USA)	Oral fluid	WHO PQ[h]	Burundi, Kenya, South Africa, Uganda, Zambia, Zimbabwe	LMIC ex-works[i]: $ 2 for 50 countries[j]
SURE CHECK® HIV Self Test (Chembio Diagnostic Systems Inc., USA)	Blood	ERPD-3[b]	NA	NA

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; **NA**, not available.
* 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 for Diagnostics. ** These products sold in more than one packaging format.
Note: Product details based on information provided by the manufacturers at the time of report preparation.

HIVST products with national-level approval, select countries

Test (manufacturer)	Specimen	Approval status	Availability	Pricing (US$)
Action! (Orangelife Comércio e Indústria LTDA, Brazil)	Blood	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Free-on-board*: $ 9.80
Alerta (Wama Diagnóstica, Brazil)	Blood	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Not available
Amethyst HIV 1&2 Test Kit (Bedford Biotech Nigeria Ltd., Nigeria)	Oral fluid	Approved in Nigeria	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	Not available
Saliteste (Ebram Produtos Laboratoriais, Brazil)	Oral fluid	ANVISA, Brazil (National Health Surveillance Agency)	Brazil	Not available
Unnamed test (Belarus)	Not available	Manufactured and approved in Belarus	Belarus	Not available

NGO: Nongovernmental organization
Note: Product details based on information provided by the manufacturers at the time of report preparation.
* Free on board: This includes ex-works price plus freight cost to distributors.

HIVST products under development or in pipeline

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)	Not available
AwareTM HIV-1/2 OMT Oral HIV Self Test (Calypte Biomedical, USA)	Oral fluid	Plan to apply for WHO PQ and CE mark
First Response HIV 1-2.0 Card Test (Self Test) (Premier Medical Corporation, India)	Blood	Plan to apply for WHO PQ
To be named (Abbott Laboratories, USA)	Blood	Not available
To be named (Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., China)	Urine	National regulatory approval in China pending
To be named (Trinity Biotech, Ireland)	Blood	Not available

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.

Key HIVST market growth opportunities

- HIVST market forecast projects steady growth through 2020, and likely to go beyond.
- Large market growth opportunities in high burden countries yet to widely implement HIVST.
- Additional growth opportunities expected through new distribution channels, such as workplace programmes and medical insurance schemes.
- Expansion of self-test/self-sampling market and technologies beyond HIV emerging – increasing total market potential and size.

Key HIVST market barriers

- Limited consumer choices, market competition and supply security. Donor-funded public sector in LMICs is dominated by a single product.
- Lengthy and uncertain national registration and regulatory processes for in-vitro devices.
  - Key barrier to product importation for several countries is HIVST policies and registration is missing in country of product origin or assembly
- Knowledge and awareness of HIVST remains low in many settings.
- Cost and investment case concerns from national programme perspective remain

Overall landscape summary

- HIVST policy and implementation continues to expand rapidly
- HIVST global market is forecast to grow over 16 million tests by 2020
- Growth is expected in both public and private sector markets and anticipated to continue beyond 2020
- Several HIVST products now available, and the pipeline of products continues to grow
- WHO prequalification of additional products is needed to support the expected market growth
- Clarity in HIVST regulatory processes and development of national investment cases is needed to support wide-scale implementation of HIVST

Key recommendations

1. WHO prequalification of additional HIVST products to diversify and increase number of HIVST products available for procurement, supported by streamlined national regulatory, registration and product selection processes;
2. adapt and develop national-level investment cases to demonstrate public health benefit, inform strategic HIVST implementation and support scale-up;
3. implement and harmonise strategies to support and achieve sustainable market and enhance affordability (for individual users, governments, donors) ;
4. increase awareness and demand for HIVST through health promotion and implementation of innovative service delivery models across public and private sectors;
5. establish and leverage strategic partnerships between manufacturers and local distributors to reduce manufacturers' risk and to facilitate entry into new and emerging markets; and
6. continue product optimization and innovation, alongside efforts to expand the use and adaptation of HIVST products for other relevant disease areas to establish broader self-testing market.

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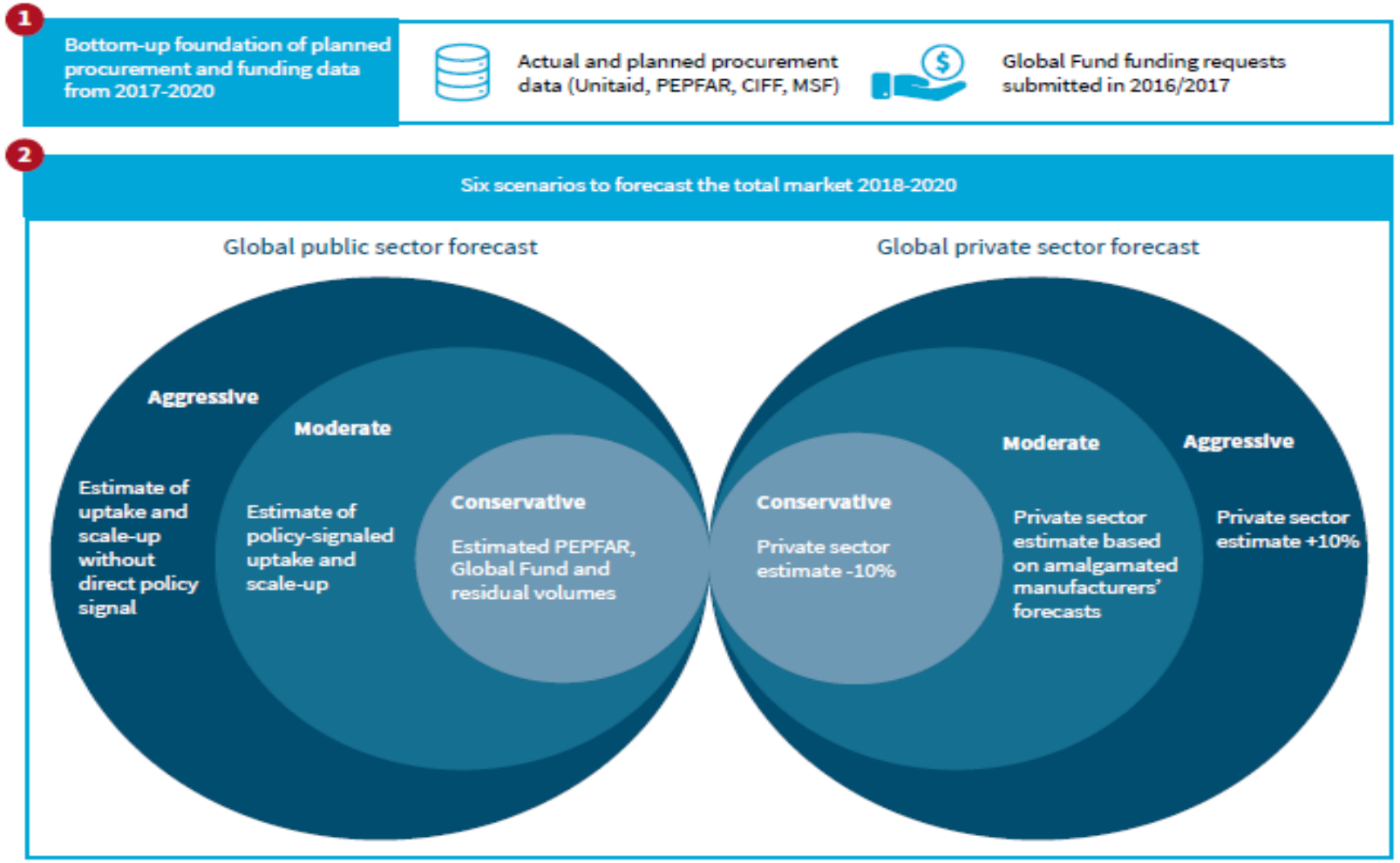
Appendix

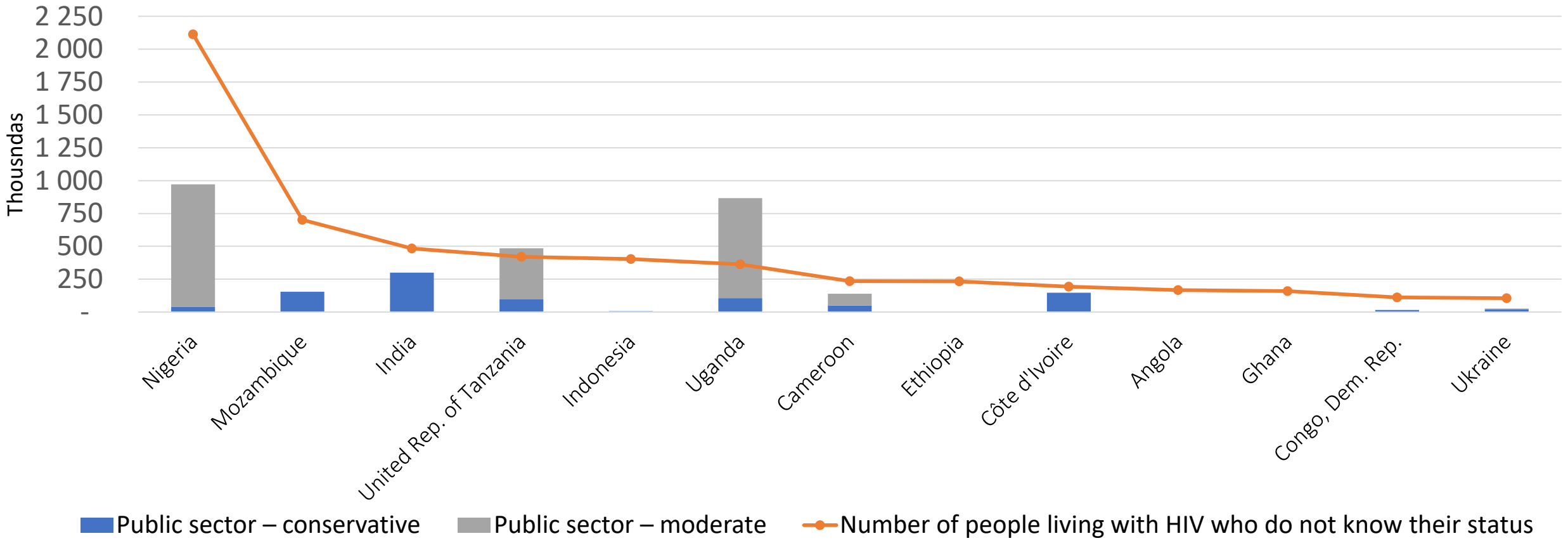
Forecast methodology



CIFF: Children's Investment Fund Foundation; **MSF:** Médecins Sans Frontières; **PEPFAR:** President's Emergency Plan for AIDS Relief; **Global Fund:** Global Fund to Fight AIDS, Tuberculosis and Malaria.

Market growth expected beyond 2020 as initial implementation/policy scales up to meet need

Opportunities exist in at least these 13 countries to significantly scale up HIVST to push the public sector market past 10M tests.



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Total HIVST market forecast 2018-2020

WHO HIVST Global Forecast Range Data Table	2018	2019	2020
Public Sector - Conservative	4,700,000	5,900,000	6,300,000
Private Sector - Conservative (-10%)	700,000	2,900,000	6,600,000
TotaL Market - Conservative	5,500,000	8,800,000	12,900,000
Public Sector - Moderate	4,700,000	7,000,000	9,100,000
Private Sector - Moderate	800,000	3,300,000	7,300,000
Total Market - Moderate	5,500,000	10,300,000	16,400,000
Public Sector - Aggressive	4,700,000	8,000,000	11,200,000
Private Sector - Aggressive (+10%)	900,000	3,600,000	8,000,000
Total Market - Aggressive	5,600,000	11,600,000	19,300,000

* Rounded to nearest 100,000 tests. Totals summed before rounding which may result in totals not summing correctly after rounding.

Key Points

- The Global market is expected to grow rapidly from 1.1M tests in 2017 to 16.4M (12.9M – 19.3M) in 2020
- Public sector provides solid foundation for market with 9.1M (6.3M – 11.2M) tests expected by 2020

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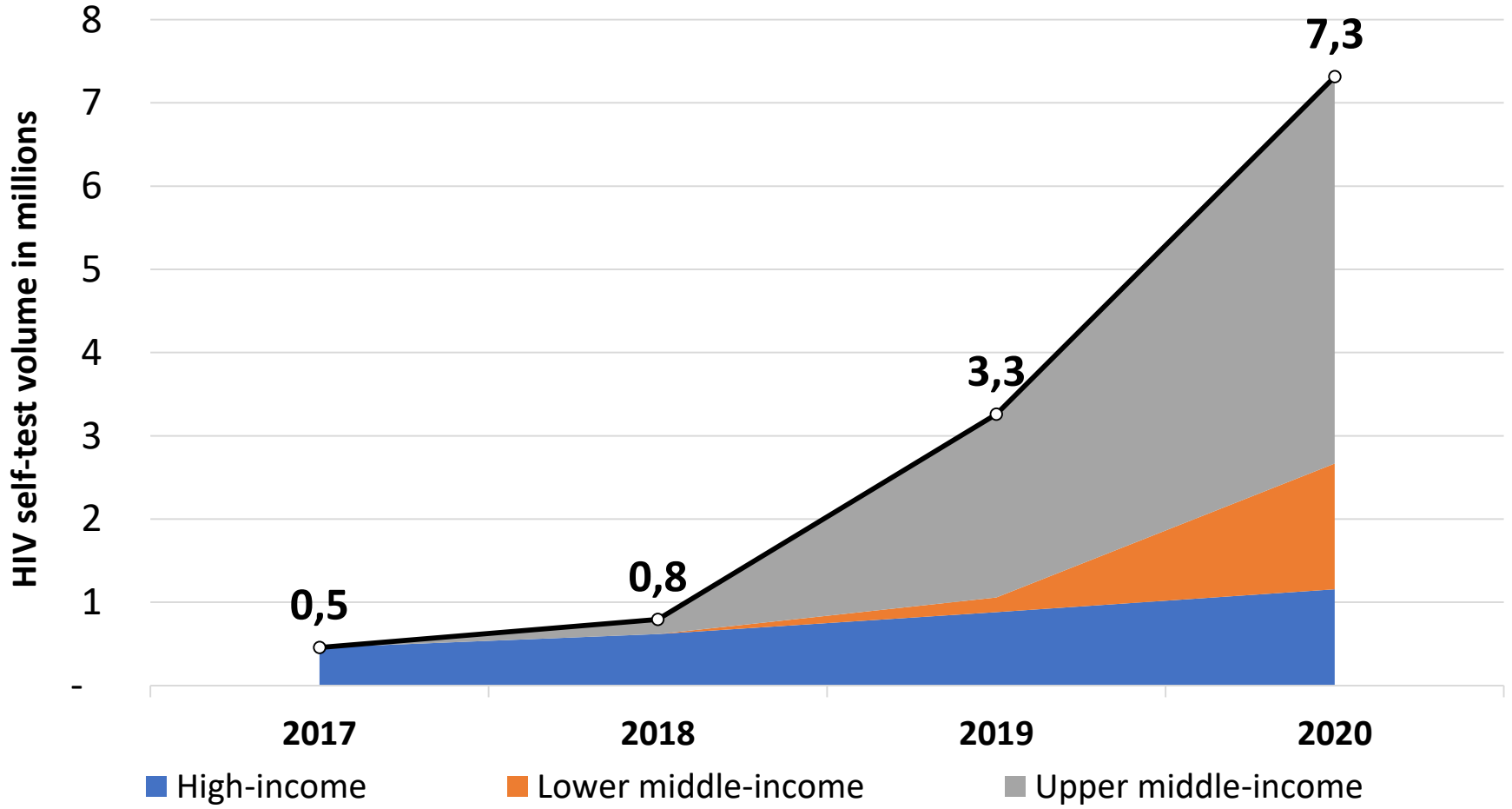
Private sector moderate forecast by country income classification



Key Points

- Majority (64%) of Private Sector volumes in 2020 are in upper middle-income countries, having increased sharply from 2018.
- Majority of growth is driven by new country market entries.

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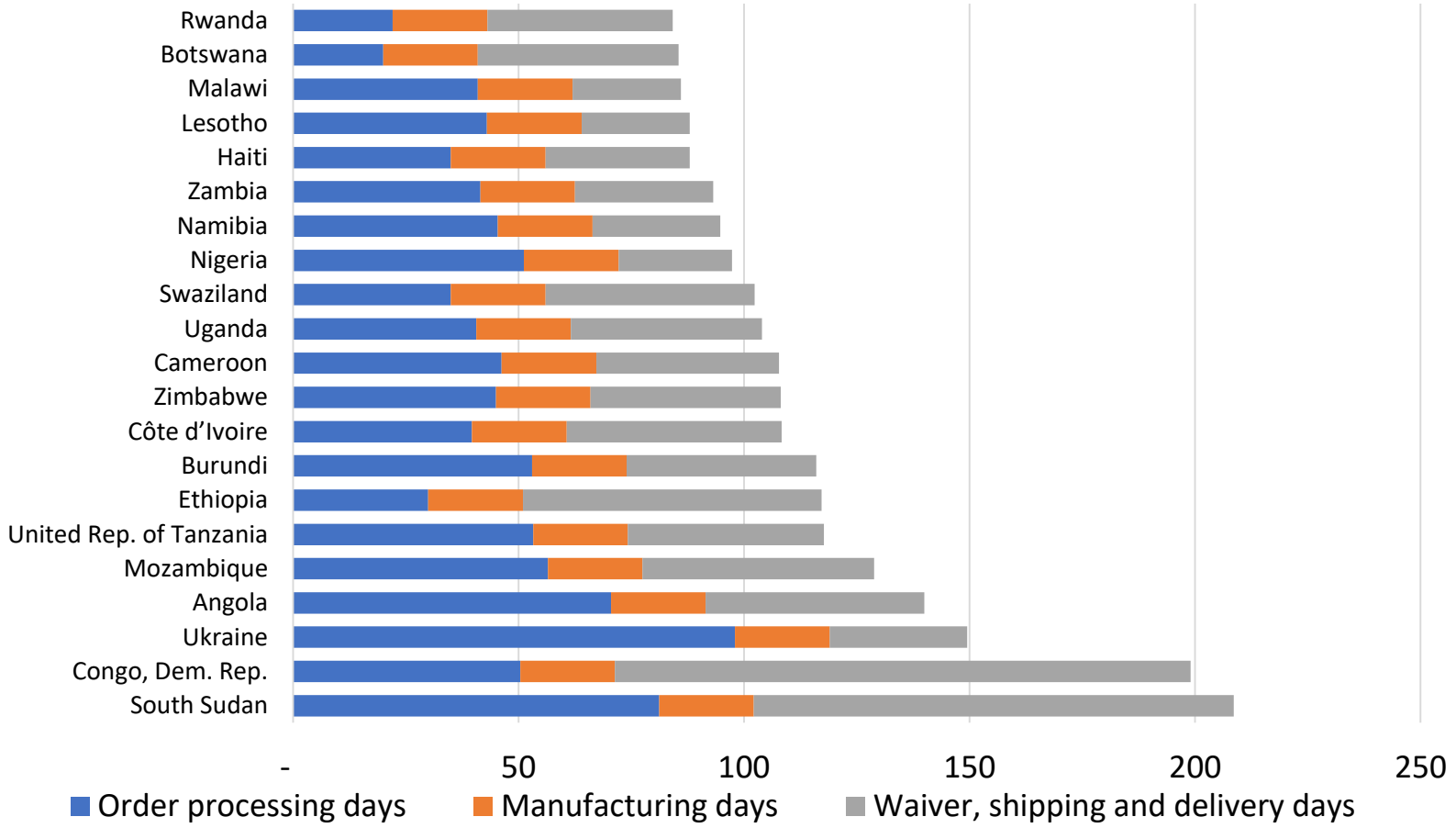
Global Fund - funding timelines

- Global Fund financing is an important element in the process of sustainably transitioning financing for HIVST
- The process of financing HIVST will vary considerably from country to country and may take more than 2 years to complete

Country	TRP Date	GAC meeting date	Board approval date	Quarter year estimate for procurement	Procurement Agent
Country 1	May-17	Oct-17	Dec-17	2018 Q2	Local
Country 2	May-17	Oct-17	Dec-17	2018 Q3	International
Country 3	May-17	Oct-17	Dec-17	2018 Q4	Local
Country 4	May-17	Nov-17	Dec-17	2019 Q1	Global Fund Pooled Procurement Mechanism (PPM)

This table represents actual elapsed timelines relating to HIVST line items in GF and GF PAAR database. The timelines presented excludes the time required to prepare the proposal. Expected procurement dates are estimated by GFATM based on discussion with GFATM country team, managers and health commodity specialists. The elapsed time between Board Approval and Quarter year estimate for procurement is dependent on different factors, many of which are not under GFATM control. The procurement agent utilized is expected to influence the elapsed time to procurement.

GHSC-RTK sales order processing and delivery days, 2017-2018



Key Points

- The process of procuring RDTs takes about 120 days on average from date of price request to delivery.
- This process does not necessarily take into account time required to forecast and quantify the volume of RDTs needed.

This chart represents the elapsed number of days on average per country that it takes for GHSC-RTK to process quote requests from countries into confirmed sales orders and delivered units.

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Funding situation by country

- Table presents the proportion of known and unknown volumes provided by each major donor under the public sector conservative scenario for 2017 - 2020.
- Many countries (14/33) with funding are supported by only one donor.
- The leading 5 countries (Kenya, South Africa, Zimbabwe, Zambia and Malawi) have mostly secured diversified funding although Zimbabwe and South Africa are still reliant on Unitaid funding.
- More than 70% of the public sector conservative scenario volumes from 2017-2020 are funded.

	Funded				Unfunded
Countries	Other donors (CIFF, MSF)	Global Fund (including PAAR)	PEPFAR	Unitaid	Residual estimate
Angola	0.00%	100.00%	0.00%	0.00%	0.00%
Botswana	0.00%	0.00%	100.00%	0.00%	0.00%
Burundi	0.00%	0.00%	100.00%	0.00%	0.00%
Cameroon	0.00%	0.00%	100.00%	0.00%	0.00%
Côte d'Ivoire	0.00%	0.00%	24.37%	75.63%	0.00%
Congo, Dem. Rep.	25.81%	0.00%	37.63%	0.00%	36.56%
Eritrea	0.00%	100.00%	0.00%	0.00%	0.00%
Eswatini	0.00%	2.29%	81.17%	16.54%	0.00%
Ghana	0.00%	100.00%	0.00%	0.00%	0.00%
Guinea	33.33%	0.00%	0.00%	0.00%	66.67%
India	0.00%	26.47%	0.00%	0.00%	73.53%
Indonesia	0.00%	100.00%	0.00%	0.00%	0.00%
Kenya	1.53%	26.05%	50.52%	0.00%	21.89%
Lesotho	0.00%	0.00%	0.00%	91.36%	8.64%
Malawi	0.00%	13.73%	21.02%	28.07%	37.18%
Mali	0.00%	0.00%	0.00%	100.00%	0.00%
Mauritius	0.00%	100.00%	0.00%	0.00%	0.00%
Morocco	0.00%	88.89%	0.00%	0.00%	11.11%
Mozambique	0.00%	90.94%	9.06%	0.00%	0.00%
Namibia	0.00%	0.00%	100.00%	0.00%	0.00%
Nepal	0.00%	62.75%	0.00%	0.00%	37.25%
Nigeria	0.00%	32.34%	39.27%	0.00%	28.38%
Pakistan	0.00%	100.00%	0.00%	0.00%	0.00%
Rwanda	0.00%	0.00%	100.00%	0.00%	0.00%
Senegal	0.00%	0.00%	4.65%	95.35%	0.00%
South Africa	0.15%	0.00%	0.08%	55.96%	43.82%
South Sudan	0.00%	100.00%	0.00%	0.00%	0.00%
United Rep. of Tanzania	0.00%	20.69%	79.31%	0.00%	0.00%
Uganda	0.00%	0.00%	100.00%	0.00%	0.00%
Ukraine	0.00%	25.76%	22.73%	0.00%	51.52%
Viet nam	0.00%	66.67%	0.00%	0.00%	33.33%
Zambia	0.00%	14.00%	32.20%	11.76%	42.04%
Zimbabwe	0.00%	3.23%	49.34%	37.71%	9.73%
Total	0.30%	11.86%	30.65%	25.74%	31.44%

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