Preliminary results

Assessment of diagnostic access and pricing in the Sub-Saharan Africa, Asia-Pacific and Latin American regions

May 2024

Supported by FIND and the other Asia-Pacific Dx Consortium partners

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Resolution WHA 76.5 - Strengthening diagnostics capacity: Access to affordable essential diagnostics is key to global health goals

Noting the emphasis of the Access to COVID-19 Tools Accelerator[1] (ACT-A) "to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines";

Noting the learnings derived from the Access to COVID-19 Tools Accelerator[8] (ACT-A), including its diagnostics pillar, regarding the strengths and weaknesses of ACT-A;

Noting that during the COVID-19 pandemic response, despite the sharing of the genome sequence of the novel coronavirus that paved the way for the rapid development of diagnostic tests, the lack of access for developing countries in particular to diagnostic tests created inequities in the public health response;

Noting that the benefit of diagnostics can be maximized by a suitable health system (including laboratories), which enables the selection/regulation and use of them in a proper way, with a skilled and licensed workforce operating in safe and operational facilities with the appropriate infrastructure and adequate financing;

Recalling resolution WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which underscores that timely, fair and equitable access to health products is a global priority and that the availability, accessibility, acceptability and affordability of health products are fundamental to tackling global public health emergencies;[2]

Recognizing the increasing burden of noncommunicable diseases[3] and the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2030,[4] which includes addressing the lack of diagnostics for noncommunicable diseases through multistakeholder collaborations to develop new technologies that are affordable, safe, effective and quality controlled, and improving laboratory and diagnostic capacity and human resources;[5]

Recognizing the need to ensure the integrated and coordinated provision of high-quality, affordable, accessible, age and gender sensitive and evidence-based diagnostic interventions, for all individuals without discrimination, with a view to achieving universal health coverage;

Noting the importance of point-of-care tests at the primary health care level as well a community level, including self-testing, to increase access to and the affordability and diagnostics;

Noting the opportunities for improved diagnostics including, but not limited to, the resea development of simple, affordable tests for diseases currently lacking good quality tests, digital

Noting resolution WHA72.8 (2019) on improving the transparency of markets for medicines, vaccines and other health products;[2]

Noting the challenges associated with the cost of diagnostic tests in developing countries that affect access;

Recalling resolution WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, which recalls "resolution WHA61.21 (2008), decision WHA71(9) (2018) and document A71/12 (2018), insofar as they address the role of technology transfer and local production of medicines and other health technologies in improving access";[3]

2. REQUESTS the Director-General:

(1) to collect data on affordability, availability and access to essential diagnostics;

(2) to support Member States, upon their request and as appropriate, with technical advice for procurement that will enable access to good quality, affordable diagnostics for all Member States;[2]

Background & key objectives

BACKGROUND

Pricing for in vitro diagnostics has been an area of concern, given the **impact of pricing on the ability of low-and-middle-income countries (LMICs) to access essential tests**. Evidence have emerged over the past few years that buyers:

- Do not always access global access prices (GAPs) published by manufacturers for LMICs, and
- Pay excessive prices for essential diagnostics, particularly where access prices are not available

With support from Unitaid, CHAI conducted a market assessment across a number of countries in Sub-Saharan Africa (SSA), Asia-Pacific (APAC) and Latin America (LATAM) regions, analyzing barriers to access to affordable pricing for diagnostics with and without global access prices. Phase 1 of the assessment (SSA) was completed in 2022[1] and Phase 2 (APAC and LATAM) was completed in 2024 with support from APAC Diagnostics Consortium Partners.[2]

OBJECTIVES

A. **Evaluate level of access to GAPs**

B. **Evaluate total landing costs for diagnostics**, including those that do not have access pricing agreements

C. **Identify main cost drivers and possible interventions** to ensure more affordable/fair pricing for a wide set of tests and geographies

[1] *See Unitaid: Distributor market assessment report, Q3 2022* [2] *See Unitaid: Diagnostic Pricing in APAC and LATAM report, Q2 2024*

Approach

Phase I

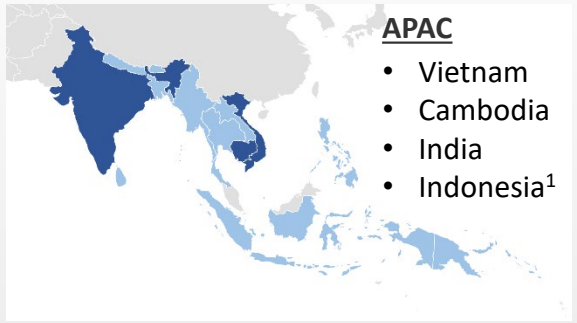
Phase II

FOCAL COUNTRIES:

SSA
- Eswatini
- Kenya
- Lesotho
- Nigeria
- Rwanda
- South Africa
- Uganda

APAC
- Cambodia
- Indonesia

Country selection aimed to enable generalizable results for LMICs in the regions but there are limitations (e.g. lack of small island states.)



APAC
- Vietnam
- Cambodia
- India
- Indonesia[1]

LATAM
- Guatemala
- Ecuador

Where available, data from additional LMICs (in light blue) were included to supplement focal country data.

Bangladesh, Bhutan, Mongolia, Myanmar, Nepal, Oceania, PNG, Philippines, Sri Lanka, Thailand, Laos, Solomon Islands, Timor-Leste

Cuba, Haiti, Nicaragua, Bolivia, Guyana, Venezuela, Caribbean, Dominican Republica, Paraguay, Peru, El Salvador, Honduras

ASSAYS IN SCOPE:

Assays with GAPs were selected.

PCR	• Covid-19 • HIV • HPV • TB • HCV
RDTs	• Covid-19 • HIV

APAC Consortium selected assays so that findings could be generalized across IVDs.

PCR	• TB • HPV
RDTs	• HBsAg • Dengue (NS1, IGG/IGM) • Malaria (multiple) • SARS-CoV-2 Ag
Other	• Blood glucose test strips

<u>Selection criteria</u>: See details in annex
- *At least 1 outbreak prone disease assay included*
- *At least 1 NCD assay included*
- *Majority high burden diseases*
- *Minimum of 2 assays selected have GAPs*
- *Balance of donor/domestic/both funding*
- *Balance of high/medium/low volume*
- *Balance of assay types (eg RDT, Molecular)*

[1] *CHAI was not supported to collect raw data from invoices in Indonesia but leveraged the online public procurement website, LKPP, to understand available public sector pricing. Unlike the other countries in light blue, it can be considered a full dataset representative of prices available to public sector buyers which is why it is listed here.*

Approach

QUALITATIVE DATA

Interviews were conducted with a wide range of stakeholders:

Suppliers & Distributors
- Abbott
- Roche
- Cepheid
- SD Biosensor
- CTK Biotech
- Thermo Fisher Scientific
- Premier Medical Corporation
- Ilex
- E-Medica
- V&H Surgical

Procurers
- MOHs
- National Reference Labs
- Sub-national governments/health departments
- Public hospitals
- MSF
- CDC
- FIND

Procurement Service Agents
- PFSCM
- UNDP
- UNICEF
- GHSC-PSM

Donors
- Global Fund
- USAID
- Unitaid

& other experts….

QUANTITATIVE DATA

Public procurement price data from the previous 2 years[1] was collected from:

- Sample of invoices from focal country buyers
- Indonesia E-katalog
- USAID GHSC-PSM database
- Global Fund Price and Quality Reporting (PQR) database[2]

GAP and reference price data was collected from:

- Global Fund
- UNICEF
- PAHO Strategic Fund
- African Society for Laboratory Medicine Molecular Pricing Database[3]

Note: Invoice data were only collected from focal countries (see prev. slide). For all other countries, data are only availab le from GF PQR and GHSC-PSM databases.

[1] *The study in Africa was conducted in 2022 and therefore included data from 2020-2022 whereas the study in LATAM and APAC included data from 2021-2023.*
[2] *This publicly available database is where Global Fund Principal recipients (PRs) are supposed to report products and the prices at which they procure.*
[3] *Supported by CHAI and Unitaid.*

Explanation of “landed price” for the purpose of this analysis

There are many components that need to be accounted for to obtain a full picture of a price per test (see list below). For the purposes of this analysis the **“landed price” is used to enable like-with-like comparison of prices**. We define landed price to include the cost of getting proprietary reagents to the test site (excluding price components in light grey.) As opposed to the price per test, the landed cost excludes the cost of device services and any non-proprietary consumables.

Less inclusive pricing

Test supplies

- Proprietary reagents & consumables (EXW)
- Non-proprietary reagents and consumables[3]

Supply Chain Services[1]

- Loading from warehouse, pre-carriage, export clearing (FCA)
- Handling at departure, transportation (CPT)
- Insurance (CIP)
- Handling at arrival, post-carriage (DAP)
- Duties and import taxes (DDP)
- Import customs clearance
- Local storage and transportation

Device Services[2]

- Service & maintenance
- Device installation & placement

Other Components

- Other taxes
- Distributor fee

More inclusive pricing

[1] *The three-letter incoterms in brackets next to some of these items are a standardized way of denoting specific logistics services and more precise information on each can be found online.* [2] *Relevant for device-based tests only, not rapid tests*

Distributor fees

The “distributor fee”, which is included in some GAPs but excluded in most, accounts for the **multitude of services required to distribute and enable testing offered by local distributors**.[1] When not paid by suppliers it is paid by buyers.

Pre-Sale Activities	After-Sale Activities	Ongoing Customer Service
• Local registration of agency • Product & service taxes • Import permit application • Relationship management with regulatory authority • Clinical validation studies • Product registration • Advocacy for product inclusion in national procurement list and program algorithm • Facilitate meetings for MOH & manufacturer • Relationship management with stakeholders • Product awareness, market generation and intelligence • Alerts to manufacturers for tenders • Financing	• Customs clearance • Distribution of products • Warehouse storage • Delivery to last mile • Logistical support • Device placement • Training • Supply chain QA • Invoice settlement as needed	• Ongoing training • Customer service • Troubleshooting and managing issues • Vendor managed inventory • Service & Maintenance (S&M)

Note: A number of distributor services are subject to high business and financial risk (i.e. delayed payments), which is factored into higher mark-ups.

[1] *The services distributors offer for specific products/suppliers depends on a number of different factors, including type of product, country serviced, price incoterm, procurement mechanism etc. This is in indicative list.*

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There is a significant variability in price paid for the same assay across all regions, ranging between 1.4X and 90X, and price points for the same assay are typically higher in LATAM

	SSA PRICES			APAC PRICES			LATAM PRICES		
Assay	Min. landed price	Max. landed price	Price discrepancy (max. price/min. price)	Min. landed price	Max. landed price	Price discrepancy (max. price/min. price)	Min. landed price	Max. landed price	Price discrepancy (max. price/min. price)
HIV Ab	$ 0.98	$ 4.35	~4X	$ 1.74	$ 5.15	~3X			
HIV PCR	$ 8.44	$ 39.08	~5X	$ 10.10	$ 68.99	~7X			
HCV	$ 10.68	$ 35.08	~3X	$ 10.10	$ 35.30	~3X			
Covid PCR	$ 7.76	$ 68.74	~9X	$ 19.36	$ 38.99	~2X			
Covid Ag	$ 2.50	$ 11.09	~4X	$ 1.82	$ 5.88	~3X	$ 2.09	$ 7.42	~4X
TB PCR	$ 9.52	$ 13.31	~1.4X	$ 5.78	$ 27.11	~5X	$ 9.83	$ 72.26	~7X
HPV PCR	$ 6.53	$ 21.33	~3X	$ 3.35	$ 39.90	~12X	$ 22.85	$ 56.65	~2X
Dengue RDT				$ 0.47	$ 6.50	~14X	$ 1.20	$ 5.40	~4X
Glucose test strip				$ 0.01	$ 0.36	~36X	$ 0.12	$ 0.80	~7X
HBsAg				$ 0.06	$ 2.50	~90X	$ 0.44	$ 5.40	~12X
Malaria RDT				$ 0.12	$ 2.11	~18X	$ 0.37	$ 3.42	~9X

- **Prices in APAC tend to be more variable than in LATAM and SSA;** on average, the price discrepancy (max. price/min. price) for the same assay is 25X in APAC, 6.5X in LATAM, and 4.2X in SSA.
- **Prices in LATAM tend to be even higher than in APAC and SSA;** the max. price for the same assay in LATAM is higher by >50% for 4 of the 7 tests assessed in APAC and for 2 of 3 tests in SSA

TB PCR tests: Prices paid are significantly higher (up to >2X in APAC and >5.9X in LATAM) than estimated landed price based on GAPs[1]

Key: Products with GAPs Products without GAPs

HIGHLIGHTS

- **Procurement mechanism:** GAPs are accessed in all purchases through centralized donor mechanisms; outside of these mechanisms, 83% of purchases of products with GAPs are at a price greater than the associated est. landed price.
- **Pricing level:**
  - No GAPs- 42% of purchases are at a price greater than the highest est. landed price based on GAPs.
- **Transparency**: In data reported by Ministries of Health/TB programs, it is not always clear whether GAPs are accessed; landed prices are within reasonable range but transparency is lacking.

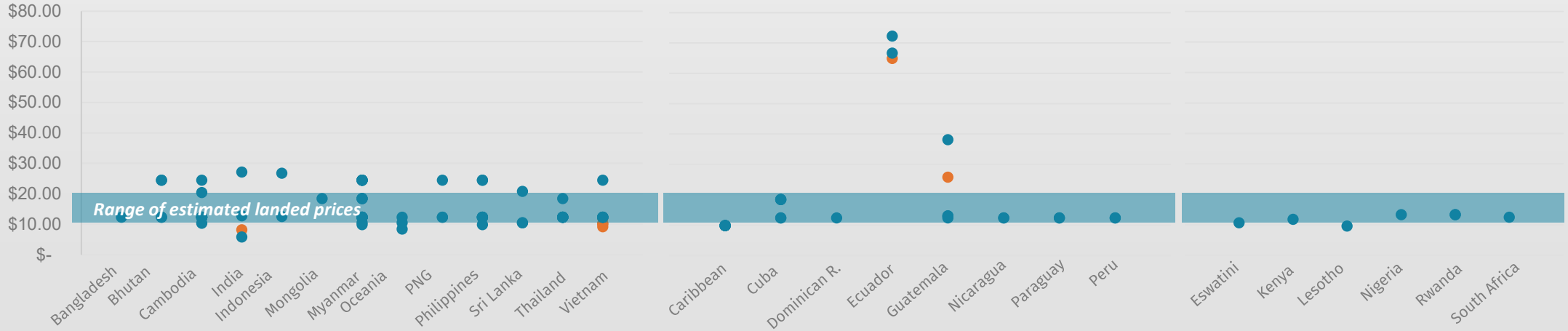
TB PCR PRICES

Product	GAP[1]	Est. landed price[2]	Highest price paid
Cepheid Xpert MTB/XDR	$14.90 EXW	$19.88	APAC: $27.11 LATAM: $72.79
Cepheid Xpert MTB/RIF Ultra	$7.97 EXW	$10.63	
MolBio TrueNat MTB/RIF, MTB/MTBPLUS	$7.90 EXW	$10.54	
Roche Cobas MTB/RIF INH	$7.90 CPT or DAP	$9.09	
Products without GAPs	-	-	APAC: $12.01 LATAM: $25.80

APAC PRICES

LATAM PRICES

SSA PRICES



[1] *Some GAPs were adjusted during the analysis period. For simplicity, the chart and graphs show current GAPs. Some data points just above the est. landed price range may represent purchases at the historical GAP. The historical GAPs were considered in the highlights.*
[2] *Based on GAP and reasonable PSM costs for the relevant product; see the assumptions used to calculate in the annex.*

HIV PCR example: HIV PCR shows there can be variation in pricing based on volumes and price inclusivity, but the biggest markups are driven by purchases from distributors

HIGHLIGHTS

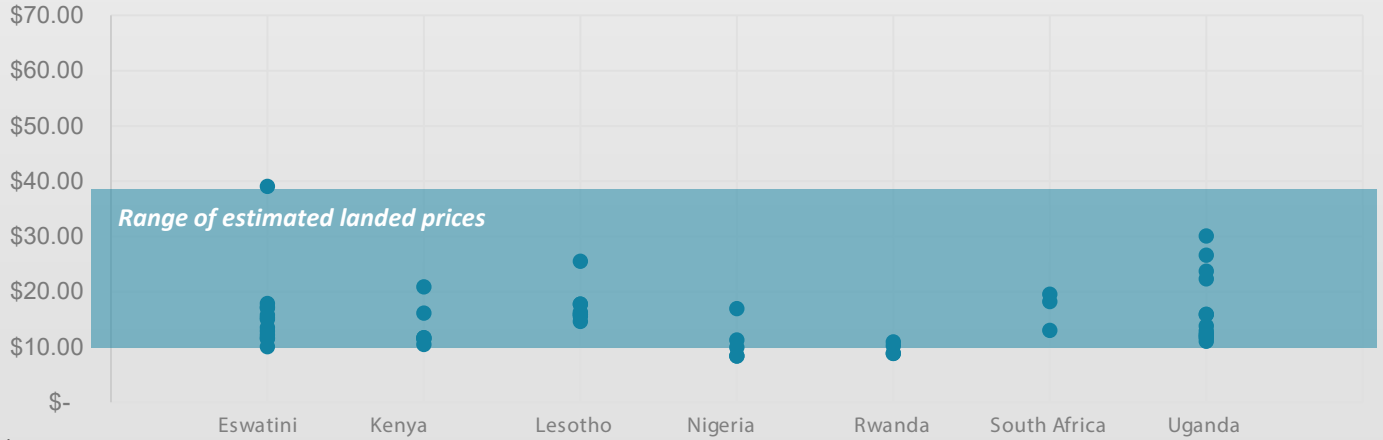
- **Pricing level:**
  - 48% of purchases are at a price greater than the associated est. landed price
  - There are a handful of instances where buyers access below the GAP and/or est. landed price
- **Variability**: There can be some variation in the price accessed by different buyers (e.g. MOH, GF, and PEPFAR procurement agents) but the variation tends to be marginal unless procurement is from a distributor
- **Transparency:** It is possible to confirm GAPs are accessed in only 25% of invoices; the other 75% are inclusive of more than the GAP and not broken down, so like-with-like comparison isn't feasible

HIV PCR PRICES

Product	GAP[1]	Est. landed price[2]	Highest price paid
Abbott mPima HIV	$19.40-$30.00 FCA (placed) $25.00 FCA (purchased)	$24.38-$38.52 $33.35	APAC: $68.99 SSA: $39.08
Abbott Alinity m & m2000 HIV	$9.60-$15.50 FCA (plasma) $11.10-$17.0 FCA (DBS)	$12.81-$20.68 $14.71-$22.74	
Cepheid Xpert HIV	$14.90 EXW, CIP, or CPT	$19.88	
Hologic Aptima HIV	$6.90 FCA	$9.20	
Roche cobas HIV	~$7.90 CPT or DPT	$9.09	
MolBio HIV	$12 (HIV 1) EXW $16 (HIV1/2) EXW	$16.01 $21.34	

APAC PRICES

SSA PRICES



Key: Products with GAPs Products without GAPs

[1] *Some GAPs were adjusted during the analysis period. The chart and graphs show current GAPs. Some data points may represent purchases at the historical GAP, but we do not have data on the timing of purchases nor time periods of GAP offers to confirm.*
[2] *Based on GAP and reasonable PSM costs for the relevant product; see the assumptions used to calculate in the annex.*

HPV PCR example: For HPV tests with GAPs, the average price accessed is ~2.4X more than the estimated landed price[1] based on the relevant GAP

Key: Products with GAPs Products without GAPs

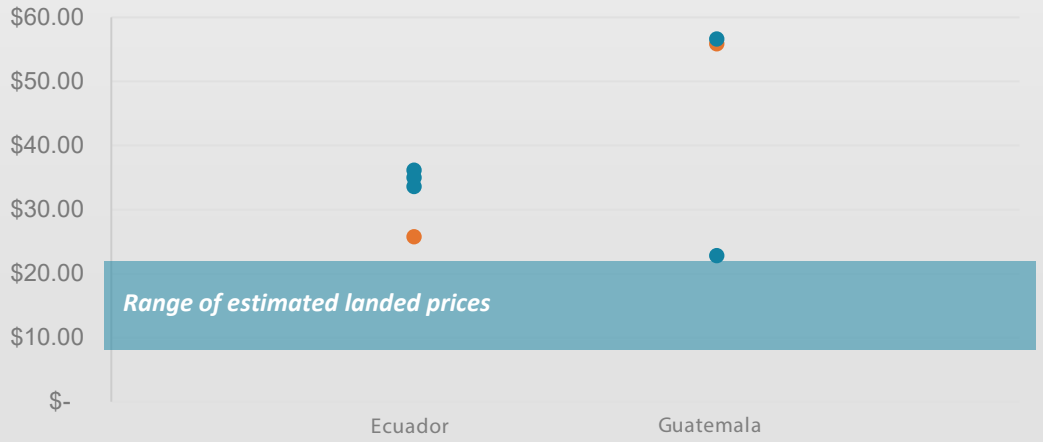
HIGHLIGHTS

- **Pricing level:**
  - GAPs- 89% of purchases are at a price greater than the associated est. landed price.
  - No GAPs- 38% of purchases are at a price greater than the highest est. landed price based on GAPs.
  - Prices below GAP prices are for open PCR systems.
- **Variability**: For HPV PCR products with GAPs, some buyers access prices approximately equal to the estimated landed price while others pay up to 3.9X the estimated landed price**.**
- **Transparency:** In almost all instances it is unclear from available invoices whether the GAP was accessed.

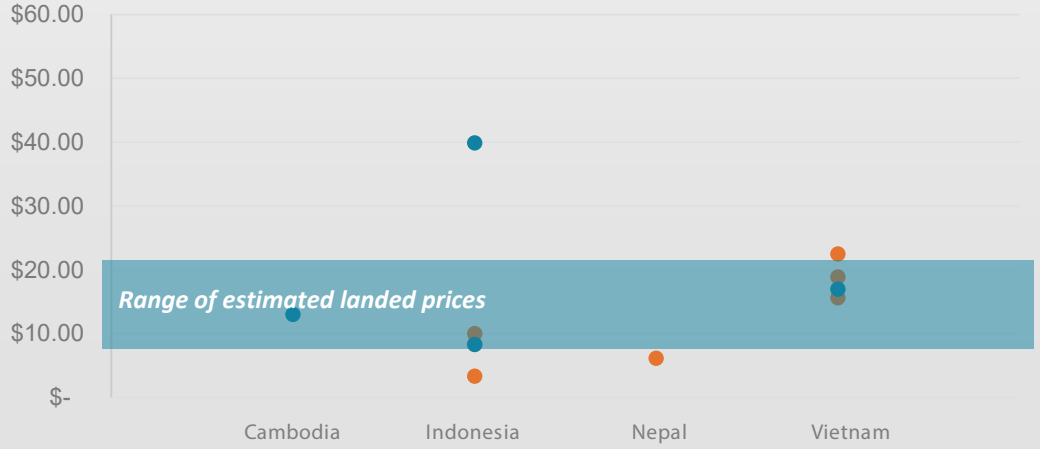
HPV PCR PRICES

Product	GAP[1]	Est. landed price[2]	Highest price paid
Abbott Alinity m & RealTime High-Risk HPV[2]	$6.24 FCA (existing footprint) $6.99 FCA (purchased) $8.49 FCA (placed)	$8.32 $9.32 $9.83	
Cepheid Xpert HPV	$14.90 EXW, CIP, or CPT	$19.88	APAC: $39.90 LATAM: $56.65
Hologic Aptima HPV	$9.00 DAP	$9.34	
MolBio HPV-HR	$16.00 EXW	$21.34	
Roche Cobas HPV	$7.90 CPT or DAP	$9.09	
Products without GAPs	-	-	APAC: $22.52 LATAM: $55.91

LATAM PRICES



APAC PRICES



[1] *Some GAPs were adjusted during the analysis period. For simplicity, the chart and graphs show current GAPs. Some data points just above the est. landed price range may represent purchases at the historical GAP. The historical GAPs were considered in the highlights.*
[2] *Based on GAP and reasonable PSM costs for the relevant product; see the assumptions used to calculate in the annex.*

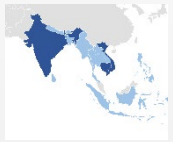
Key findings: There are 5 key factors that influence pricing of diagnostics

The **landed cost per test for the same/similar products can vary significantly within and across countries**. The key factors that determine/influence access to predictable and affordable pricing are as follows:

GAP Eligibility and Access	**While GAP agreements help to control pricing** they are only available for a subset of diagnostic products and even where they exist, there can be contractual or policy **barriers to accessing them and challenges in executing them** (>20% of purchases for products with GAPs were at a price greater than the estimated landed price based on the relevant GAP).
Price Inclusivity & Transparency	For ~30% of purchases of products with GAPs it is not possible to confirm whether GAPs are offered/accessed due to **lack of transparency in invoicing practices.** Furthermore, unless they are all-inclusive, GAPs and reference prices state a reasonable cost for **only a portion of all cost components**. Where there are no GAPs, costs can fluctuate and there is no reference for what is reasonable. This challenge is compounded by the fact that cost components are rarely delineated in adequate detail for buyers, so it impossible for buyers to evaluate cost individual drivers and determine what is reasonable.
Procurement & Supply Chain	**Nearly 100% of purchases funded by PEPFAR and GF are within the range of expected pricing while 60% of decentralized purchases were higher than expected.** This speaks to the fact that procurement mechanisms and distribution processes adopted by buyers can impact the prices accessed; **decentralized purchases increase price**.
Market Competitiveness	Situations of **monopolies or duopolies by suppliers and/or distributors** for certain market segments or countries contribute to less affordable and consistent prices.
Pricing Awareness	**Buyers are often not aware of GAPs or other references prices and lack a toolkit of best practices** to access more affordable and predictable diagnostic prices.

GAP eligibility & access : The affordability and predictability of prices with GAPs is better on average than products without GAPs across APAC and LATAM

In the assessment dataset, prices were more affordable and predictable in product categories with GAPs (Covid Ag RDT, TB PCR, HPV PCR, blood glucose) compared to those without (Malaria RDT, HBsAg RDT, Dengue RDT) in both LATAM and APAC:

	Products with GAPs	Products without GAPs
APAC 	On average, the max. price paid **was** **14 X** the minimum price paid for the same product.	On average, the max. price paid **was** **40 X** the minimum price paid for the same product.
LATAM 	On average, the max. price paid **was** **5 X** the minimum price paid for the same product.	On average, the max. price paid **was** **8 X** the minimum price paid for the same product.

When they are available, GAPs support the affordability and predictability of diagnostic pricing.

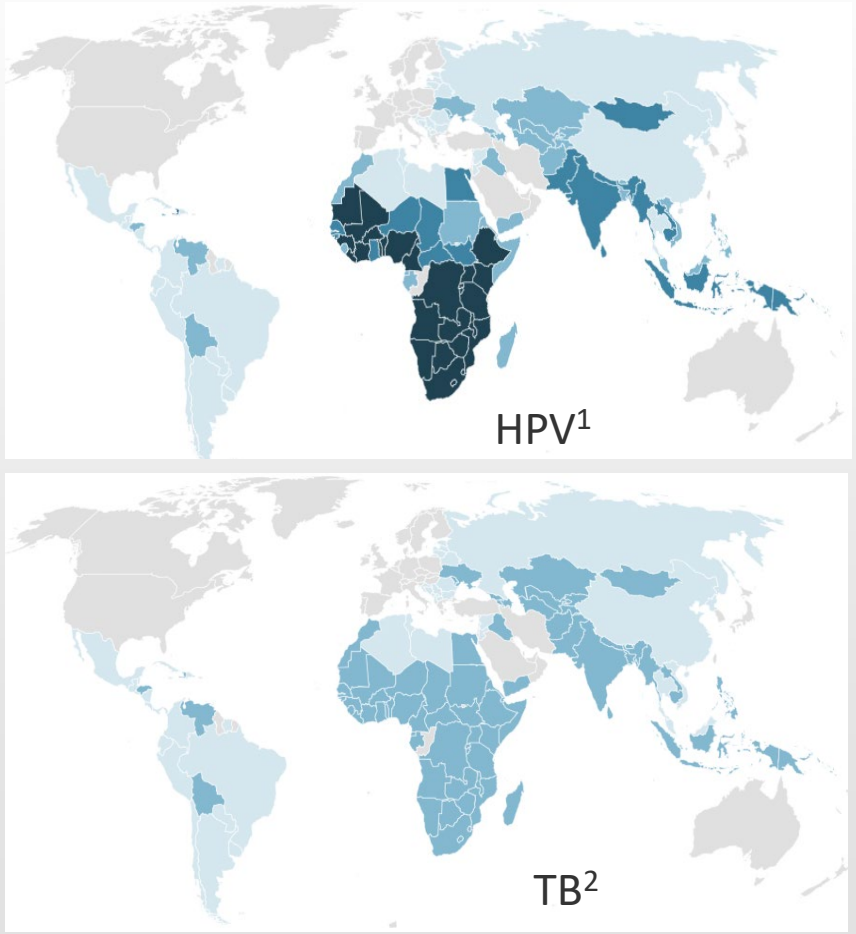
1. Provide a **mechanism to hold suppliers accountable** for price of products under GAPs, and
2. Provide **publicly available price information** for all buyers of similar products to reference to inform their purchase

GAP eligibility & access : GAPs helped reduce price variability across countries and buyers; however, **access to GAP agreements is limited**

Assays	• GAPs apply to a **limited number of assays**, reflecting priorities and resources allocated by global agencies (HIV, TB, malaria, Covid-19, and to some degree HPV and hepatitis) while GAPs do not exist for other essential diagnostics.
Country eligibility	• **Country eligibility** in GAP agreements is typically based on income status, disease burden, expected market, and the company's ability to operate in the geography; APAC and LATAM have access to fewer GAPs than Sub-Saharan Africa.
Procurement eligibility	• **Procurement eligibility** is typically limited to the public sector while the private sector is excluded, even though the private sector plays a significant role in serving low-income populations in some countries in the APAC and LATAM regions. Furthermore, decentralized public buyers (e.g. public hospitals or sub-national governments) are often considered not eligible.
Volume thresholds	• **GAP volume thresholds** have to be met for the GAP contract to be applicable, and often higher volumes are associated with more affordable, more inclusive prices. This means that newer programs and smaller/lower-burden countries may have difficult time accessing GAP agreements.
Payment terms	• **Payment terms** are often restrictive, requiring payments in USD or full upfront payment amount at the time of purchase. Some countries find these requirements difficult or impossible to meet, especially if local procurement laws require otherwise.
Direct procurement	• **Direct procurement** from the originating supplier rather than a distributor is a requirement for some GAPs. Buyers that are unable to procure from originating suppliers due to policies requiring local procurement, difficulty getting suppliers to tender, or other reasons, may not access GAPs.

GAP eligibility & access: Country eligibility for GAPs is more limited in APAC and LATAM

Eligibility criteria can include country lists among other things; while sub-Saharan Africa has the greatest eligibility coverage across molecular test assays, **LATAM, the Caribbean, and APAC have more limited coverage of GAP contracts**.



The majority of **countries in SSA have access to 4 HPV GAPs** and the majority of **countries in LATAM have access to no HPV GAPs**.

% of region accessing GAPs for each test type

	TB			HPV		
	LATAM	**APAC**	**SSA**	**LATAM**	**APAC**	**SSA**
None	13%	13%	13%	13%	13%	13%
One	75%	23%	2%	71%	16%	0%
Two	13%	65%	85%	13%	39%	17%
Three	N/A	N/A	N/A	4%	32%	17%
Four	N/A	N/A	N/A	0%	0%	53%
Average # GAPs	***1.01***	***1.53***	***1.72***	***1.09***	***1.90***	***2.97***

Note: for blood glucose test strips there are no geographic eligibility criteria. Geographic exclusions for Covid RDTs could not be confirmed.

[1] ***HPV***: *Abbott m2000 RealTime, Cepheid Xpert, Hologic Aptima, Roche cobas 4800, 6800, 8800.* [2] ***TB***: *Cepheid Xpert HPV, Roche cobas HPV 4800, 6800, 8800.*

Price inclusivity & transparency : Where quoted prices do not represent landed prices, it is difficult for buyers to understand and control the remaining costs

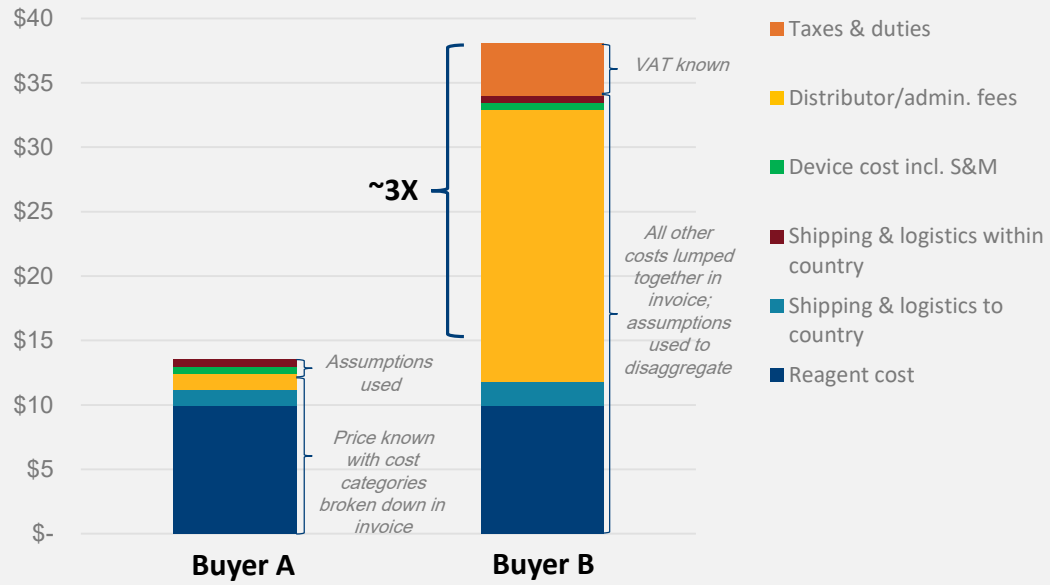
- There is a wide **range in the market in terms of how inclusive and transparent quoted prices are.**
- **Buyers lack visibility** into how prices are broken down, especially in cases of decentralized procurement where buyers see only one consolidated price; hence it is not possible to determine whether GAP prices are accessed (if applicable) or whether individual service charges are reasonable.

Drivers of cost variation include taxes, transportation costs, and other cost components that vary by country, but **one of the key drivers appears to be distributor margins**; this is evidenced by the fact that different distributors in the same country charge vastly different prices for the same product.

Example

- *Buyer B was charged an all-inclusive price that is ~3X higher than what Buyer A paid for the same test and services (used assumptions to normalize prices)*
- *This analysis suggests that a **high distributor margin is the main driver of the cost difference**.*
- *However, in the absence of easy-to-access reference prices, Buyer B had limited capacity to negotiate fairer prices.*

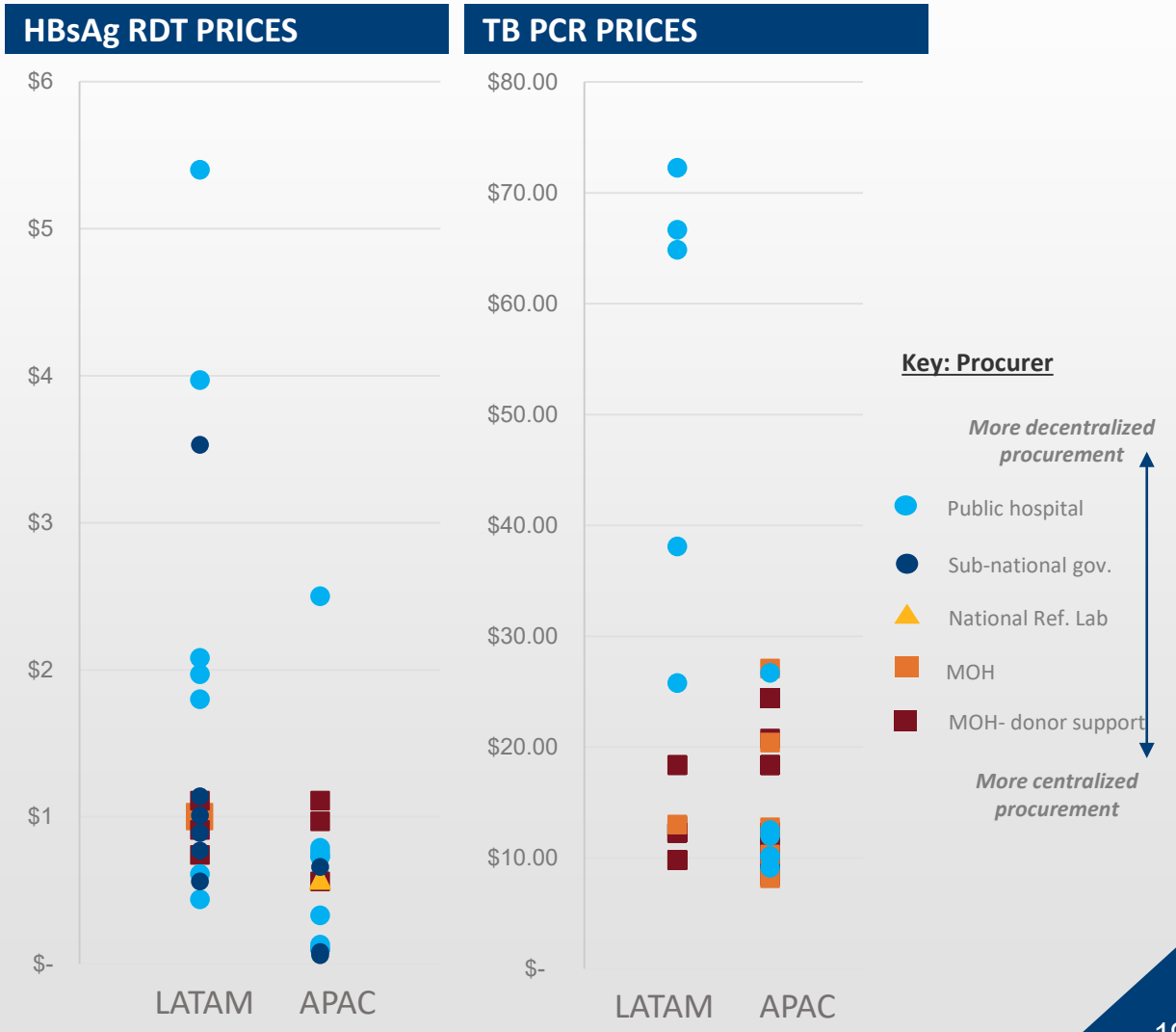
Breakdown of the price accessed for the same product by two buyers



Procurement & supply chain : Centralized buyers typically access more affordable and predictable prices while decentralized purchases are more unpredictable

Prices can vary significantly based on the procurer and procurement channel used *(see graph of HBsAg and TB PCR prices as examples of price paid by type of procurer)*

- **Centralized procurement, whether donor or domestically funded, tends to deliver relatively low, predictable prices (esp. through donor-supported mechanisms, PAHO Strategic Fund PPM, and central MOH tenders)**
  - *For HBsAg, The max price paid by donor-funded purchases was $1.11; all purchases made higher than that cost were from decentralized procurers e.g. public hospitals or sub-national governments*
- While some decentralized procurers access lower-priced assays, there is **significant variation in pricing (esp. public hospitals and sub-national governments)**
  - *For HBsAg, the range in prices paid by buyers that procure outside of centralized mechanisms is $0.06-$5.40*



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To address these barriers, suppliers and procurement/ price negotiating partners need to continue improving the GAP regime and commercial offering

Assays	• Negotiate **GAPs for a wider set of assays,** guided by data and especially when offered by the same supplier
Geography	• Negotiate **GAPs to apply to a broader range of geographies,** especially to LATAM and APAC
Eligibility	• **Suppliers to work with distributors** to ensure GAPs are available through indirect procurement (e.g. develop a system to confirm the **eligibility of all public sector buyers** even when volumes are not consolidated) • Negotiate GAPs and delivery models, with terms modified as appropriate, for **the private sector**
Volume thresholds	• **Negotiate prices based on global or regional, multi-disease volumes** rather than by country • Use **tiered pricing thresholds**, ideally starting with a minimum tier accessible to all countries
Payment terms	• Negotiate pricing terms **aligned with countries' procurement policies and capabilities** (e.g. avoiding advanced payments)
Define roles & process	• **Define roles, responsibilities, and processes** for buyers, distributors and suppliers when it comes to ensuring eligible buyers access GAPs (especially for instances of decentralized procurement) • **Define an accountability process** to mediate instances where potentially eligible buyers may not access GAPs
Adapt operations	• **Adapt business operations** to accommodate making GAPs available to more eligible buyers, including through decentralized channels (e.g. monitoring/limiting distributor markups)
All-inclusive pricing	• GAPs and other **procurement agreements should be (re)negotiated to include as many cost components as possible, especially distributor margins,** especially critical for device-based tests
Transparent invoicing	• Sellers should provide **transparency about the cost breakdown** of goods and services purchased

Global organizations can support greater information sharing about diagnostic pricing, innovation, and further research into the topic

Information sharing

- **GAPs should be publicized and socialized** widely
- Where GAPs are not available, other forms of **reference pricing**, although not contractually enforceable, **should be made publicly available and socialized widely among buyers**
- To support this, buyers with data on pricing should share openly and suppliers should not require, and buyers should **not agree to secrecy clauses around pricing**
- Where price information is made available by supplier or buyers it is critical to ensure it is **broken down into cost components** to enable meaningful interpretation
- Price information should be accompanied by **best-practices on procurement** to promote access to said prices

Innovation

- To facilitate transparency and implementation of other reforms, **all partners should leverage data, technology and innovation** to address challenges identified in the supply chain (e.g. e-procurement systems, Klear procurement and financing solution for distributors, online marketplaces, etc.)
- Partners should support **pilots of innovative approaches** in countries

Research

- Further investigation would help to guide interventions, including by prioritizing geographies and product areas; in particular, greater **research on health financing and procurement channels used** is needed.
- Partners should study whether **regional/local manufacturing** initiatives deliver more affordable pricing, under what conditions, and why

In parallel, country level action, with support from partners including WHO, can be taken to increase access to GAPs and improve affordability

Program improvement	• **Scale-up testing programs and conduct diagnostic network optimization** to optimize volumes across integrated diagnostic networks, meet volume thresholds, improve price negotiation leverage • Develop clear, **funded testing plans and forecast** and monitor demand
Procurement reform	• **Provide diagnostic procurement standards** especially where procurement is more decentralized and/or decision-makers may lack diagnostic expertise, coupled with **capacity building** • Introduce reforms to achieve **national pooled procurement**, while maintaining local autonomy in deciding and executing orders (e.g. framework agreements or prime vendor agreements), especially in countries/product areas that rely on decentralized procurement • Promote wider **adoption of procurement platforms** that enable pooling/placing orders directly to suppliers and consider furthering regional pooled procurement solutions • **Consider national policies promoting fair pricing** (e.g. caps on distributor markups, as recommended by the WHO for pharmaceuticals) or reference pricing practices
Enabling environment	• **Reform procurement policies** including payment terms, tax liability, local registration requirements, etc. if relevant • **Provide clear regulatory standards, procurement preferences, and importation requirements and consistently enforce** such standards to help supply-side actors plan and reduce risks and costs passed to consumers • **Buyers should demand transparency about cost breakdowns**, including codifying this in tender laws
National supply-side intervention	• Conduct **supply-chain optimization** exercises, including **engaging with distributors** in each country context to develop an understanding of market dynamics and take targeted steps to reduce pricing barriers • Distributors can also be engaged by suppliers and countries on local **price commitments** • **Monitor for disproportionate market power** concentrated in a small number of suppliers and take targeted steps to reduce the impact on pricing (e.g. introduce competitors, engage in tender re-negotiation, etc.)

Looking forward

This assessment shows that **affordable and equitable access to diagnostics is far from the reality in LMICs.** While many donor-funded and other centrally procured purchases have benefited from efforts to improve affordability and predictability (e.g. GAPs, pooled procurement) there are still significant barriers, **especially for country-level buyers**.

To address these challenges, WHO should consider:

1. **Ensuring WHO procurement follows best-practices (e.g. transparent, inclusive)** and continues to promote evolution of the ecosystem toward more improved procurement and price negotiation practices.

2. **Building in-country procurement capacity to inform and empower a diverse set of buyers,** including: sharing best practices and lessons from partner-supported procurement and encouraging use of platforms such as PAHO Strategic Fund PPM, providing tendering templates to be used as a reference, sharing simple and practical guidelines to negotiate prices and assess quotes, conducting workshops around procurement of diagnostics or management of all-inclusive SLAs, disseminating GAPs and other reference prices.

3. **Collecting data and supporting further assessments** to quantify and characterize what is procured through decentralized mechanisms and likely impacted by avoidable markups, identify especially problematic products/countries, and contribute to the evidence-base of best practices.

4. **Coordinating stakeholders** to leverage experience and ensure shared progress.

Furthermore, the execution of GAPs needs to be improved to ensure all eligible buyers, especially decentralized buyers, can access them

Because of the barriers to GAP access, some eligible buyers end up in the category of "commercial transactions". In the future, greater attention needs to be paid to the **execution of GAP agreements** to ensure all eligible buyers can access GAPs. For example, when publishing GAPs it is important to:

Define roles

Define roles, responsibilities, and processes for buyers, distributors and suppliers when it comes to ensuring eligible buyers access GAPs (especially for instances of decentralized procurement).

- One model to consider is asking Ministries of Health provide a list of all entities providing services with little-to-no profit on behalf of the public sector; these buyers should be ensured the GAP.

Define process

Define an accountability process to mediate any instances where buyers who believe they are eligible can have their case reviewed and the GAP made available if eligibility criteria are met.

- One model to consider is hiring a third-party entity for oversight.

Adapt business operations

Business operations may need to be adapted to accommodate making GAPs available to more eligible buyers, including through decentralized procurement channels.

- For example, where suppliers charge distributors a differential price according to whether the final sale is GAP or commercial price, there will need to be improved coordination to ensure the distributor is not charged more than the GAP by the supplier and is therefore unable to provide the product at the GAP price to the eligible buyer

Improving price inclusivity & transparency may help ensure that landed prices are reasonable by providing clarity and accountability on landed prices

All-inclusive pricing

- Tenders, service level agreements, GAPs and other **procurement agreements should be (re)negotiated to include as many cost components as possible, especially distributor margins.** This is especially critical for device-based tests.
- **Where establishing fully inclusive prices is not immediately feasible, suppliers can commit to publishing estimated landed costs for different geographies with a breakdown of cost components on a regular basis.** This approach has been adopted by some suppliers and can build buyer understanding of cost breakdowns and drivers of those costs, including fluctuation over time, and increase predictability of landed costs thus fortifying buyer negotiation power.

Transparent invoicing

- **Buyers should demand, and sellers should provide, transparency about the breakdown in cost of goods and services purchased:**
  - In cases where procurement is done through tenders, tender rules should enforce this requirement
  - Global health partners that host platforms (e.g. online marketplaces or donor-supported procurement platforms) that provide price transparency should make the platforms more widely available and work to increase awareness among all buyers

Supplier influence

- Until there are solutions to empower buyers to monitor distributor markups, **suppliers should start/continue monitoring what their distributors charge and exert influence as they are able** to minimize excessive charges.

There is room to improve pricing by making current procurement & supply chain practices more efficient, especially in cases where procurement is decentralized

Principles for procurement efficiency[1] should be embraced in all procurement by countries and those who procure on their behalf:

Pool procurement	• Develop clear, **funded testing plans and forecast** and monitor demand • Consider **regional pooled procurement** solutions • Introduce reforms that aim to achieve **national pooled procurement**, while maintaining local autonomy in deciding and executing orders, especially in countries/product areas that rely on decentralized procurement
Competitive bidding	• Develop **national sourcing and procurement strategies and guidelines** to standardize and rationalize procurement practices • **Tendering** and negotiation processes should consider incentivising more competitive bidding and provision of more comprehensive and transparent breakdowns of pricing • **Diagnostic procurement standards** should be provided, especially where procurement is more decentralized and/or decision-makers may lack diagnostic expertise, and should be coupled with capacity building • Establish **accountability and transparency mechanisms** to promote competition, trust, fair outcomes
Tax reductions	• In line with WHO recommendations for pharmaceuticals, countries should **consider exempting all essential diagnostics from taxation** while working to ensure that the cost savings translates into improved access for end users[2]
Supply chain optimization	• Conduct **supply chain mapping and optimization** to find and exploit efficiencies

[1] *Rao, Raja, Peter Mellon, David Sarley. 2006. Procurement Strategies for Health Commodities: An Examination of Options and Mechanisms within the Commodity Security Context. Arlington, Va.: DELIVER, for the U.S. Agency for International Development.*
[2] *WHO guideline on country pharmaceutical pricing policies, second edition. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO.*

Ensuring markets are competitive between suppliers and distributors across geographies can support greater access to affordable pricing

Policies and interventions directed at improving supply-side market dynamics are needed and may include:

Suppliers

- Countries should **monitor for disproportionate market power** concentrated in a small number of suppliers and take targeted steps to reduce the impact on pricing (e.g. introduce competitor products, seek partner support, engage in tender re-negotiation, etc.)

Distributors

- Countries and partner organizations should **engage with distributors** in each country context to develop an understanding of market dynamics and take targeted steps to reduce pricing barriers.
- Distributors can also be engaged by suppliers and countries on **price commitments**.
- **Suppliers should work to influence the distributor market** for their products to promote competitiveness and efficiency (e.g. monitor invoices from distributors, provide pricing guidance)

Supportive environment

- **Governments should communicate clear regulatory standards, procurement preferences, and importation requirements and consistently enforce** such standards to help supply-side actors plan and reduce risks and costs that may be passed to consumers.
- **National policies promoting fair pricing** (e.g. caps on distributor markups, as recommended by the WHO for pharmaceuticals) can support more affordable, predictable pricing.

Lyudmila Nepomnyashchiy and Prashant Yadav. 2022. "Decentralized Purchasing of Essential Medicines and Its Impact on Availability, Prices, and Quality: A Review of Current Evidence." CGD Working Paper 605. Washington, DC: Center for Global Development. https://www.cgdev.org/publication/ decentralized-purchasing-essential-medicines-and-its-impact-availability-prices-and

Greater information sharing about diagnostic pricing, including improved awareness of available GAPs, is needed alongside dissemination of best-practices to access affordable pricing

Pricing Information sharing

- **GAPs should be publicized and socialized** widely by suppliers and global health partners
- Where GAPs are not available, other forms of **reference pricing**, although not contractually enforceable, are useful to inform buyers and **should be made publicly available and socialized widely among buyers**; this means buyers with more data on pricing should openly share as much as possible
- Countries should consider **instituting internal and/or external reference pricing as part of procurement regulations**; reference pricing is recommended by the WHO for pharmaceuticals under certain conditions and used by countries like Ecuador for diagnostics with some success
- Where price information is made available by supplier or buyers it is critical to ensure it is broken down and includes relevant detail to meaningfully interpret it, given the complexity of diagnostic pricing
- Suppliers should not require, and buyers should **not agree to secrecy clauses around pricing**

To facilitate the above, all partners should leverage data, technology and innovation to address challenges identified in the supply chain:

- Countries should be supported to develop e-procurement systems which enable sub-national procurers to access centrally negotiated and approved pricing and provides a source of information for buyers (as in Indonesia)
- All partners should consider using digital tools to monitor and inform procurements, ensure supply chain transparency, and create better awareness among buyers

Assumptions

Assumptions for calculating landed price (without device costs) to ensure like-with-like comparisons

Logistics	Adjustment
If EXW or FCA assume 15% for shipping to country, 3% for distributor margin, 4% for insurance based on GF published references	18.4%
If landed in country assume 5% for shipping and warehousing in country based on countries with available data	5%
If GF or USG, tax exempt, otherwise 10% tax	10%
Device costs	
If device inclusivity unknown, assume not included for sake of conservativeness. Where it was included it was removed using the following assumptions:	
BGM cost (avg. $30/2000 tests)	$ 0.02
PCR device cost - assume 80% utilization (calculated for previous CHAI assessments)	
Cepheid	$ 0.53
Roche	$ 1.00
Abbott	$ 1.50
Other	$ 1.01

Methodology

The analysis investigated **accessibility to global access prices for diagnostics where global pricing agreements are in place** and assessed **price affordability and variability for diagnostics that are not part of global access pricing agreements**.

ASSAYS WITH GLOBAL ACCESS PRICES (GAPs):

- For products with GAPs, the analysis **compared prices paid to the relevant GAPs**
- For products without GAPs the **highest GAP in the assay category** was used as a reference price

ASSAYS WITHOUT GAPS:

- Used the highest available **reference price[3] from Global Fund, UNICEF and/or PAHO Strategic Fund** to assess markups paid for all products in the assay category

LIMITATIONS:

- **Assumptions to enable like-with-like comparisons:** Every effort was made to collect "landed prices"[2], but these values were often not available. To estimate a landed cost and enable like-with-like comparison, assumptions were made based on available data on breakdown of prices for the goods and services involved, including donor-published prices and raw data collected (see Annex for detail). Where applicable, prices without the cost of devices were used and are shown as such in this report.
- **Non-representative sample**: Data collection was done purposively and for a limited sample size, so the data are illustrative but not representative of the whole market. The intent was to obtain prices from buyers that represent the range of the market (e.g. larger or smaller volumes, more or less distance to port, higher or lower capacity) so as to get a "snapshot" of what pricing can look like.
- **Do not account for diagnostic quality when comparing prices:** This analysis did not compare performance or quality standards when comparing pricing but rather assumes that the relevant donor and/or local quality standards are upheld and sufficient. This is highly reasonable assumption for donor-funded products but may be less likely for other purchases, depending on the country.

[1] Molecular test GAPs and detailed information can be found in the ASLM pricing database. Blood glucose test strip GAP information can be found on the FIND website.
[2] For the purposes of this report, landed prices are the price paid for all the inputs required in running a test to arrive at the site where the testing occurs. Landed prices include the price of reagents, consumables, and all procurement and logistics, but not HR costs, electricity, or other costs to running the test. Where applicable, device price and S&M are also not included. See slide 9 for more details.
[3] Reference pricing is just a publicly cited price at which some buyer is buying; it is not applicable to other buyers, as GAPs are, but does provide some context about the price accessed typically by large, high-capacity donor agencies often with pooled volumes. Given this, reference prices can be thought of as a a "fair" price to aim for.
[4] Additional notes on data analysis- Data used were from 2022 onwards. Where data seemed likely to be erroneous, they were excluded from analysis. Where there were gaps in the data, country personnel were leveraged to develop the best possible assumptions.