Meeting Report
Roundtable on Access to Multi-disease Molecular Diagnostics
June 2, 2022

Meeting objectives

Multi-disease molecular diagnostics are capable of rapidly and accurately testing for multiple diseases including COVID-19, HIV, TB, HBV, HCV, HPV, and STIs at or near the point of care. Yet, access to these tests by low- and middle-income countries has been limited since their introduction over a decade ago due to factors including high prices of tests and instruments, inadequate service and maintenance, and insufficient scale-up by country programs. These access barriers have been structurally maintained by an unhealthy market with insufficient competition. Limited access to molecular diagnostics at or near the point of care has resulted in missed opportunities to close diagnostic gaps, which have been further exacerbated by COVID-19.

On June 2, 2022, Treatment Action Group (TAG) and Médecins Sans Frontières (MSF) hosted a Roundtable on Access to Multi-disease Molecular Diagnostics. The Roundtable brought together country program representatives, donors, members of civil society, and other global health actors to:

1. Identify ways to leverage the availability of new multi-disease molecular diagnostic platforms to create a more competitive market for COVID-19, HIV, TB, HBV, HCV, HPV, and STI testing;
2. Identify points of consensus on evidence-based pricing and innovative models for procurement, service, and maintenance; and
3. Develop a shared set of access principles that can be applied across actors and diseases in future negotiations with diagnostics suppliers.

The Access Principles, meeting agenda, and list of participants are included as annexes. Presentations can be downloaded as PDFs from: https://www.treatmentactiongroup.org/webinar/roundtable-on-access-to-multi-disease-molecular-diagnostics.

Background and introduction

David Branigan, TB Project Officer at TAG, and Stijn Deborggraeve, Diagnostics Advisor for Infectious Diseases at MSF Access Campaign, opened the meeting by highlighting that despite the value of molecular diagnostic tests to aid in correct diagnosis, the systems are often underused and negotiations with suppliers are fragmented by disease programs and actors, creating economic and operational inefficiencies within and across countries. Using the GeneXpert system from Cepheid as an example and citing data from an independent cost of goods sold (COGS)

analysis, they illustrated how production volumes drive the prices of diagnostic tests and how pooling volumes across diseases can strengthen price negotiations with suppliers. The opening remarks framed the meeting and its objectives with a compelling case for a more coordinated approach to negotiations with suppliers and for pooling test volumes across diseases. David and Stijn then summarized the main meeting objective: to identify and determine how shared principles can be operationalized to improve coordination, leverage, and access to testing across diseases. Finally, they shared the intention that outcomes of the Roundtable, including any necessary technical follow up discussions, be taken forward by existing structures and mechanisms for coordinating diagnostics integration and procurement, such as the Integrated Diagnostics Consortium (IDC).

The meeting Co-Chairs, Dr. Lucica Ditiu, Executive Director of the Stop TB Partnership (STBP), and Dr. George Alemnji, Senior Technical Advisor for Laboratory Services at the U.S. Office of the Global AIDS Coordinator (SGAC), endorsed the meeting objectives as an important step toward a more coordinated approach to negotiations, procurement, and implementation, and welcomed the 100+ people in attendance.

Session 1: Promoting competition

The first session was moderated by Heather Alexander, Chief, International Laboratory Branch, Division of HIV and TB at the U.S. Centers for Disease Control and Prevention (CDC). The presentations and facilitated discussion focused on promoting competition, a known key factor for driving down prices and improving services. Kavi Ramjeet, Head of Business Intelligence at FIND, opened the session by presenting the *Landscape and pipeline for multi-disease molecular diagnostic platforms*. Kavi provided an overview of molecular platforms and tests with multi-disease testing capabilities already on the market and in development. He flagged the importance of market shaping activities, especially to accelerate the development and support the introduction of new technologies appropriate for use at different levels of the health system.

Dr. Sandhya Kabra, Head of the India National Hepatitis Program, India Ministry of Health & Family Welfare, responded by sharing India's experience introducing multiple testing platforms and collaborating across disease programs and ministries to optimize the use of existing molecular testing infrastructure. Dr. Kabra highlighted how the use of both the GeneXpert and Truenat molecular testing platforms in India, along with a more integrated approach to testing across disease programs, has resulted in cost savings and other efficiencies and has benefited patients.

Dr. Raiva Simbi, Deputy Director at the Zimbabwe Ministry of Health and Child Care, responded by explaining the challenges posed by vertical funding structures, including those imposed on country programs by donors. Dr. Simbi highlighted the importance of overcoming program and funding silos to start a dialogue about optimizing the use of existing machines and infrastructure and introducing new technologies to facilitate competition and multiplex testing. Dr. Simbi raised the need for countries to work across disease programs and funding proposals in order to establish a comprehensive strategy for integrated molecular testing and procurement.

Professor Wendy Stevens, Head of the National Health Laboratory Service (NHLS) of South Africa, pointed out that before COVID-19, South Africa had a variety of molecular platforms in place and

was able to effectively leverage competition and volumes in negotiations with diagnostics companies. However, during the COVID-19 pandemic, the shortage of tests shifted the power balance in favor the diagnostics companies, limiting the government's ability to negotiate. As a result of this experience, the South African government has started to look at local options, including open platforms that, while more difficult to implement at decentralized health care levels, leave the country less reliant on importation from diagnostic companies that often prioritize higher income country markets.

During the presentations and facilitated discussion, the following key points of consensus emerged:

- It is important to promote competition, including through market shaping interventions that break monopolies by supporting new companies and technologies to enter existing markets.
- Investments by public and philanthropic funders in support of the development and introduction of new technologies should include conditions to promote equitable access and market shaping activities to promote competition. Market shaping efforts should aspire to more than getting diagnostics companies to compete on the price of platforms and tests; it's also about getting them to compete on the provision of service and maintenance, training, and other peripheral support.
- Governments and donors should facilitate the integration of current vertical programs and the pooling of test volumes across diseases to increase leverage in negotiations with suppliers for better prices and terms of service and maintenance.
- Governments, donors, and global health actors should promote an enabling environment (including through harmonizing regulatory process and, where possible, technology transfer) for local manufacturers in low- and middle-income countries to reduce dependence on the importation of diagnostics from established large suppliers that often prioritize high-income markets over low- and middle-income markets, and to create a sustainable supply of diagnostics that meet local public health needs.

Session 2: Innovative models for procurement, service, and maintenance

The second session was moderated by Dr. Stijn Deborggraeve, Diagnostics Advisor for Infectious Diseases at MSF Access Campaign. The presentations and facilitated discussion were focused on examining different models of procurement and provision of service and maintenance. The models discussed included: (1) service level agreements[1] monitored according to key performance indicators (KPIs) with the costs of service and maintenance added as a surcharge to test prices across a volume commitment of tests (e.g., AccessCare); (2) reagent rental agreements[2] that incorporate the cost/placement of instruments in addition to service and maintenance costs added as a surcharge to test prices across a volume-commitment of tests; and (3) models through which programs pay per actionable result (not including failed/invalid results).

[1] Service level agreements do not cover instrument placement (i.e., reagent rental).

[2] Reagent rental agreements that include the cost of service and maintenance may also be referred to as all-inclusive pricing agreements.

Wayne van Gemert, Diagnostics Technical Officer at the Stop TB Partnership (STBP), presented on *Experience with service and maintenance of TB molecular diagnostics*. Wayne shared STBP's experience supporting countries to move away from purchasing extended warranties from Cepheid (priced at US$2,898 per year for 4-module instruments), which still leave programs responsible for sorting out in-country service. Using a test surcharge model, Cepheid's AccessCare covers both warranties and in-country service visits. Wayne discussed some of the limitations of AccessCare, including the lack of costing transparency, the absence of accountability mechanisms for holding the supplier accountable when they fail to meet KPIs, and feasibility issues in countries where the service provider has limited capacity or is unwilling to offer this pricing model. Wayne also discussed the warranty model offered by Molbio (priced at US$1,120 per year regardless of instrument model) with terms of services similar to AccessCare.

Jason Williams, Technical Branch Chief, Senior Laboratory Advisor, Health Science Specialist at USAID, presented on *Transforming efficiency and access for viral load testing through strategic procurement*. Jason talked about how the introduction of a new competitor (Hologic) to the HIV viral load testing space changed the dynamic with existing suppliers (Abbott and Roche), enabling a shift from a reagent and instrument procurement approach to an all-inclusive pricing and services approach (through which instruments are leased and placed, service performance is measured regularly, and contracts are renegotiated annually). The ultimate result was reduced spending and increased services and accountability. Jason flagged, however, that ability to leverage volumes was key and that comparable success has yet to be achieved with Cepheid, for which PEPFAR has relatively smaller volumes. Under the all-inclusive pricing agreement negotiated for 16-module GeneXpert instruments and viral tests (covering instrument placement and service and maintenance), the price per viral load test has stayed at US$14.96.

Alan Staple, Vice President and Head of the Global Markets Team at Clinton Health Access Initiative (CHAI), presented on *Future considerations for negotiating all-inclusive pricing agreements with suppliers*. Alan emphasized the role of all-inclusive supply agreements to address operational issues and to provide a better position from which to negotiate with suppliers, shifting the focus from commodities needed to deliver results to the entire package of commodities and services required to deliver results. Alan suggested future actions be taken to expand coverage of molecular instruments, incorporate additional assays (HPV, COVID-19), and shift contract management and monitoring of KPIs from central procurement teams to country-based lab systems managers (in a way that preserves the ability of centralized procurement teams to leverage high volumes financed by a single entity).

Abdunoor Nyombi, Medical Laboratory Scientist at the National TB Reference Laboratory of Uganda, responded by sharing Uganda's experience with AccessCare. At annual volumes of 800,000 tests, including TB, HIV, and HPV, Uganda pays a US$0.92 service charge per test and monitors KPIs via monthly meetings. Though accountability from the service provider has improved under AccessCare, the service provider in Uganda still faces issues with maintaining stocks of supplies (i.e., tests and modules) in-country, which affects the service provider's response time. A participant from another country program suggested requiring at least a three-month supply be held by suppliers in-country (as is the case in South Africa).

Dr. Kim Patrick Tejano, Chief of Finance, Supply Chain and Logistics Monitoring at the Philippines Department of Health, responded by describing the variable and inflated costs of GeneXpert tests for different diseases in the Philippines resulting from dependency on a single local distributor. Dr. Tejano shared the Department of Health's solution, which was to centralize negotiations and develop a price cap.

Professor Wendy Stevens, Head of the National Health Laboratory Service of South Africa, shared that South Africa negotiated an agreement with Cepheid to only pay per result – failures and invalid test results are offset by the supplier, noting that this approach requires very close monitoring and holding suppliers responsible if KPIs are not being met. With three to five-year tenders, suppliers can get complacent. Another meeting participant suggested that adopting models where instruments are leased can make it easier to switch suppliers, which helps promote supplier competition and innovation.

During the presentations and facilitated discussion, the following key points of consensus emerged:

- There is no one-size-fits-all model, but we need to move beyond the individual procurement of commodities (tests and instruments) toward a more cost-efficient model. Service level agreements (as demonstrated by STBP's analysis of AccessCare), reagent rental agreements (as demonstrated by USAID and CHAI), and a pay-per-result approach (as demonstrated by South Africa NHLS), all offer potential solutions.
- In any model: service and maintenance terms should be guaranteed by the supplier; KPIs should be harmonized across end users and countries; accountability mechanisms should be in place to hold suppliers accountable if KPIs are not met; volumes should be pooled across diseases for both centralized and decentralized instruments; service and maintenance pricing should be transparent; and countries should be able to choose the service and maintenance and pricing model that is most appropriate for meeting country needs and preferences.
- Contract management and monitoring of KPIs should shift from central procurement teams to country-based lab systems managers (in a way that preserves the ability of centralized procurement teams to leverage high volumes financed by a single entity)
- Quality of service is as important as affordable pricing. Given the significant investment needed to install instruments and the direct impact on delivering health care when instruments are broken and repair services are inadequate, services should be guaranteed for both centralized and decentralized instruments.

Session 3: Evidence-based pricing

The third session was moderated by Kaiser Shen, Senior TB Diagnostic Technical Advisor at USAID. The presentations and facilitated discussion focused on how to define and establish evidence-based pricing as a new norm for diagnostics. Dr. Stijn Deborggraeve, Diagnostics Advisor for Infectious Diseases at Médecins Sans Frontières (MSF) Access Campaign, presented on *Fair and equitable pricing based on cost-of-goods-sold (COGS) and volumes*. Stijn emphasized the importance of transparency and a standardized methodology for calculating COGS. He flagged the need to define the structure of what constitutes a fair price, including defining a "reasonable" profit markup that considers public investments, and maturity/market share of companies. He

made the case that by pooling volumes across diseases, countries can share in the benefits of the manufacturing efficiencies that companies currently enjoy exclusively. He suggested that low volume countries might be supported to achieve comparable benefits through regional pooling efforts. Finally, Stijn emphasized that a fair price has to be inclusive of service and maintenance, and that beyond what is offered by the manufacturer, distributor markups need to be better controlled.

Dr. Bill Rodriguez, Chief Executive Officer of FIND, responded by sharing how FIND has built transparency and access conditions into the terms of its funding agreements with diagnostics companies, including transparency of COGS and pricing structures, and noted the importance of negotiating the final purchase price (including freight, etc.) and not just the ex-works price. He also highlighted a new requirement for FIND-supported companies to match prices of comparable products entering the market and to meet demand in all low- and middle-income countries preferentially, which is a necessary safeguard following companies prioritizing supply to high-income countries over low- and middle-income countries during the early stages of the COVID-19 pandemic, even after receiving significant public funding. He also flagged that it can be challenging to advance discussions regarding these requirements with newer companies that do not yet have experience with global distribution.

Professor Wendy Stevens, Head of the National Health Laboratory Service of South Africa, responded by emphasizing the value of data for informing a multidisciplinary and bottom-up approach to costing that considers both pre- and post-analytical activities (e.g., sample collection and transport, results delivery, quality control, biosafety costs, etc.). She suggested that countries consider this approach to evaluate the overall cost per result and establish systems to support such costing monitoring, and that the overall cost per result should factor into negotiations with suppliers.

During the presentations and facilitated discussion, the following key points of consensus emerged:

- Investments by public and philanthropic funders in support of the development and introduction of new technologies should include conditions that promote equitable access, such as transparency of COGS and pricing structures, commitment to price matching, and commitment to meet demand in low- and middle-income countries.
- Global health actors should develop a standardized methodology for determining COGS and a fair pricing structure (including any necessary mark ups) and establish a framework for using this information in pricing negotiations with suppliers.
- To move beyond the focus on just the test prices, country governments and global health actors should support country programs to collect data on the full cost of molecular diagnostic testing, including pre- and post-analytical costs, and should consider using this comprehensive costing data in negotiations with suppliers.
- Lower-volume countries should benefit from the same pricing and high-quality service and maintenance as higher-volume countries at comparable costs relative to volumes; regional pooled procurement may help to facilitate this, but countries should not be restricted to go through pooled procurement mechanisms to receive adequate and equitably priced service and maintenance.

- Local distributor mark-ups can be a significant contributor to excessive pricing; countries and global health actors should explore opportunities to coordinate and develop shared approaches for the regulation of local distributor mark-ups

Summary and next steps

Improving access to multi-disease molecular diagnostics will require the combined efforts of all stakeholders, including country governments, donors, global health actors, diagnostics developers and manufacturers, and members of communities and civil society. To support these combined efforts, a set of *Principles for Access to Multi-disease Molecular Diagnostics* has been developed (see Annex 1) based on areas of consensus that emerged during the Roundtable discussions on promoting competition; innovative models for procurement, service, and maintenance; and evidence-based pricing.

To support the application and operationalization of these principles in future funding agreements, tenders, and other negotiations, participants raised the need for a series of technical follow-on discussions, including to: (1) develop a standardized methodology for determining COGS; (2) generate alignment on a fair pricing structure and reasonable profit markup; (3) determine how to control and regulate local distributor markups; (4) develop guidance for countries on selecting the optimal service and procurement model, including the collection of relevant costing data; (5) harmonize KPIs across countries and build consequences into agreements when suppliers do not meet the KPIs; (6) determine how an enabling environment can be created to support competition and promote local manufacturing specifically; (7) develop a shared approach to ensure that adequate service and maintenance can be guaranteed for all centralized and decentralized instruments across disease programs; (8) identify the most appropriate venue for high level negotiations with suppliers and an appropriate structure for contract management and monitoring for centrally negotiated agreements with suppliers.

The Integrated Diagnostics Consortium (IDC), which meets quarterly, an upcoming World Health Organization (WHO) and African Society for Laboratory Medicine (ASLM) Global Diagnostics Synergy Meeting, which takes place annually, and the WHO Fair Pricing Forum, which meets every two years (next meeting in 2023), were raised as possible venues for advancing these discussions.

Annex 1: Access Principles

Principles for Access to Multi-disease Molecular Diagnostics

August 2022

Access to knowledge of one's health status and to quality diagnosis in accordance with World Health Organization (WHO) recommendations is a human right, and country governments are obligated under international human rights law[3,4] to realize this right. Country governments, global health actors, and diagnostics suppliers must work together to maximize access to multi-disease molecular diagnostics and address the current market failures of inadequate supply, insufficient competition, high pricing, and inadequate service and maintenance, as well as the sociotechnical[5] and other factors that affect access, to promote the realization of this right. By applying the following principles in funding decisions, policy making, and negotiations with diagnostics suppliers, country governments and global health actors can meet their obligations to improve access to multi-disease molecular diagnostics according to the standards set by the WHO. These principles were developed based on discussions held during the Roundtable on Access to Multi-disease Molecular Diagnostics, held on June 2, 2022.

Promoting competition

1. Competitive markets promote innovation, lower pricing, and improve the quality of service and maintenance of medical devices. Country governments and global health actors should stimulate competition by increasing investment in the development, uptake, and procurement of a diverse range of multi-disease molecular diagnostic technologies. Public and philanthropic investments in diagnostic development and introduction should include access conditions that drive equity, such as requiring transparency of cost-of-goods-sold (COGS) based on volumes sold, guaranteed fulfillment of orders from low- and middle-income countries, price matching of comparable products that enter the market, and, where possible, terms for licensing/technology transfer that promote equitable access.

2. Ensuring a diverse and reliable supply of multi-disease molecular diagnostics requires not only sufficient competition but prioritizing regional and local ownership[6] of the research, development, manufacturing, and supply of diagnostics in future investments, in accordance with countries' needs. Country governments and global health actors can

[3] Universal Declaration of Human Rights: Article 25 – Right to Health, Article 27 – Right to Science: https://www.un.org/en/about-us/universal-declaration-of-human-rights.
[4] International Convention on Social, Economic and Cultural Rights: Article 12 – Right to Health, Article 15 – Right to Science: https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights.
[5] Engel et al. Rapid molecular tests for tuberculosis and tuberculosis drug resistance: a qualitative evidence synthesis of recipient and provider views. Cochrane. April 2022. https://doi.org/10.1002/14651858.CD014877.pub2.
[6] USAID Administrator Samantha Power on a New Vision for Global Development: https://www.usaid.gov/news-information/speeches/nov-4-2021-administrator-samantha-power-new-vision-global-development

improve competition and supply chain security by prioritizing investments in regional and local innovation and manufacturing of multi-disease molecular diagnostics in low- and middle-income countries; ensuring these products meet international quality-assurance standards; and strengthening and harmonizing national, regional, and global regulatory processes.

Innovative models for procurement, service, and maintenance

3. Well-functioning and reliable diagnostic instruments are critical to minimizing disruptions at the earliest stages of the care cascade. Any supply agreement supported by public funds should include service and maintenance terms guaranteed by the supplier,[7] and supply agreements should include mechanisms to hold suppliers accountable to these terms. Suppliers should regularly report to and be evaluated by country programs according to a set of standardized key performance indicators (KPIs) (e.g., response time for: module replacement, component replacement, complete instrument replacement, temporary loan instrument, preventive maintenance, calibration, etc.), and mechanisms should be put in place with consequences to hold suppliers accountable when KPIs are not met.

4. When negotiating the pricing of service and maintenance, country governments and global health actors should consider the total number of centralized and decentralized instruments and test volumes pooled across diseases (and, in the case of global or regional pooled procurement, across countries) as well as individual country needs and preferences. In negotiations, suppliers should provide full transparency of the costs of service and maintenance. Country governments should be able to select how they prefer to pay for and structure service and maintenance, e.g., via service level agreements,[8] reagent rental agreements,[9] individual warranties, or pay-per-result models.

5. Countries with smaller volumes of instruments and tests should be offered the same high-quality service and maintenance as countries with moderate to high volumes, with comparable pricing relative to volumes. Global or regional pooled procurement may help facilitate the negotiation of better supply agreements for service and maintenance particularly for small volume countries, but countries should not be restricted to go through pooled procurement mechanisms in order to receive adequate and equitably priced service and maintenance.

6. Countries should have the option to procure new centralized and decentralized multi-disease molecular diagnostic instruments using a reagent rental model, which distributes the cost of instrument placement and service and maintenance over a volume commitment of tests. The volume commitment of tests should be pooled across diseases

[7] If suppliers use local agents for service and maintenance, the local agents must be adequately trained and supported by the supplier.
[8] Service level agreements do not cover instrument placement (i.e., reagent rental).
[9] Reagent rental agreements that include the cost of service and maintenance may also be referred to as all-inclusive pricing agreements.

(and, in the case of global or regional pooled procurement, across countries) and include tests expected to be run on previously purchased "legacy" instruments. The price per test should be fully transparent and evidence-based and should be reduced after a volume sufficient to cover the cost of instrument placement is reached. Reagent rental agreements may also be negotiated to require regular instrument upgrades to the newest models or may be structured according to a pay-per-result model. Additionally, countries should be offered the option to directly purchase instruments according to individual country needs and preferences.

Evidence-based pricing

7. Pricing for multi-disease molecular diagnostic instruments and tests should be based on full transparency and verifiable evidence of the cost of manufacturing (which decreases as volumes increase), with volumes of tests pooled across diseases and countries, plus a minimal profit mark-up[10] to achieve the lowest sustainable pricing.[11] The amount of profit mark-up should be evidence-based with full transparency of the costs of research and development and consider whether public entities or public funding supported the development and introduction of the diagnostic platforms and tests. Costs of service and maintenance as well as costs of reagent rental should also be fully transparent and evidence-based. Depending on the preferred procurement model and approach to service and maintenance, the cost of service and maintenance may be added as a surcharge to the baseline evidence-based price, and the cost of instrument placement may also be amortized and added as a surcharge on a specific volume of tests.

8. Country governments and global health actors should provide funding and technical support to country programs to engage in the collection of data on the full cost of molecular diagnostic testing, including pre- and post-analytical costs, and should consider using the total cost per result in negotiations with suppliers, across diseases. Suppliers should be responsible for collecting and transparently reporting data to country programs related to instrument fleet management and the provision of service and maintenance.

9. In addition to evidence-based pricing by suppliers, the pricing mark-up allowed for local distributors of diagnostics to public and private buyers should be regulated and limited to ensure lowest sustainable pricing. Countries and global health actors should develop

[10] The percent of profit mark-up should take into account research and development and regulatory costs borne by the supplier, start-up costs if applicable, re-investment plans to scale-up manufacturing, and overall volumes across which these costs will be distributed. For example, the percent of profit FIND negotiated with Cepheid in 2006 for Xpert MTB/RIF cartridges, before volumes significantly increased, was 20%: https://www.tbonline.info/media/uploads/documents/cepheid_xpert_mtb-rif_communication_september_2011.pdf. For established suppliers with higher volumes, this percent should be lower. For start-up companies with low volumes, this percent may be higher. If public or philanthropic funding de-risked research and development, regulatory approval, and/or manufacturing scale-up, the mark-up should be lower.

[11] FIND is in the process of developing a standardized methodology for determining COGS for sequencing technologies, which may be adapted and applied to determine COGS of molecular diagnostic tests and instruments. The WHO Fair Pricing Forum, taking place in 2023, is a key opportunity to develop normative guidance on fair and equitable pricing of diagnostics, to support alignment across actors.

shared norms and expectations in regard to regulation of local distributor mark-ups, which should allow for a minimal and fair profit mark-up that is transparent and evidence-based[12,13] for commodities necessary to ensure the health of the public, such as diagnostic tests for infectious diseases. Where possible, countries should consider lowering or eliminating tariffs and sales or value-added taxes and wherever possible waiving national requirements for public procurement via local distributors.

Coordinated approach to procurement

10. Major procurers of multi-disease molecular diagnostics, including countries and global health actors, should apply these principles in negotiations with diagnostics suppliers and coordinate to pool volumes across diseases and across countries (when not to the detriment of individual disease programs or countries) to increase leverage in negotiations, reduce prices, and secure improved instrument delivery models and terms of service and maintenance.

[12] In addition to the ex-works price, the base cost may also include "pass through" costs (e.g., freight/insurance to get the product to the country, customs duties charged, VAT/GST charged, in-country distribution and freight charges, etc.)

[13] The Initiative for Promoting Affordable and Quality TB Tests (IPAQT) in India, a successful example of how distributor profit mark-up may be regulated, was able to reduce distributor margins for Xpert MTB/RIF tests to 8%: https://healthmarketinnovations.org/sites/default/files/Initiative%20for%20promoting%20Affordable%20and%20Quality%20TB%20Tests%20%28IPAQT%29%20Supporting%20Document.pdf

Annex 2: Meeting Agenda

Roundtable on Access to Multi-disease Molecular Diagnostics
June 2nd, 2022, 14:00–16:40 CEST

Chairs: Lucica Ditiu (STBP), George Alemnji (PEPFAR)

14:00– 14:10 CET	**Opening and background – 10 min**	David Branigan (TAG) Stijn Deborggraeve (MSF)
14:10– 14:15 CET	**Meeting objectives – 5 min** 1. Identify concrete ways to leverage the availability of new multi-disease molecular diagnostic platforms to create a more competitive market for COVID-19, HIV, TB, HBV, HCV, HPV, and STI testing 2. Identify specific points of consensus and red lines on evidence-based pricing and innovative models for procurement, service, and maintenance 3. Develop a set of shared principles that can be applied across actors and diseases in future negotiations with diagnostics suppliers	Lucica Ditiu (STBP) George Alemnji (PEPFAR)
14:15- 14:45 CET	**Promoting competition – 30 min** Presentation: *Landscape and pipeline for multi-disease molecular diagnostic platforms* – 8 min - **Respondent 1: Dr. Sandhya Kabra**, Head of India National Hepatitis Program, India Ministry of Health & Family Welfare – 3-4 min - **Respondent 2: Dr. Raiva Simbi**, Deputy Director at the Zimbabwe Ministry of Health and Child Care – 3-4 min - Facilitated discussion – 15 min ***Expected outcome:*** *increased buyer awareness of new multi-disease molecular diagnostic platforms and consensus regarding actions necessary to create a more competitive market, including through local innovation and manufacturing.*	**Presenter:** Kavi Ramjeet (FIND) **Moderator:** Heather Alexander (CDC)
14:45- 15:45 CET	**Innovative models for procurement, service, and maintenance – 60 min** Presentation: *Service and maintenance* – 8 min Presentation: *Reagent rental agreements* – 13 min - **Respondent 1: Abdunoor Nyombi**, Uganda National TB Reference Laboratory – 3-4 min - **Respondent 2: Dr. Kim Patrick Tejano**, Philippines Department of Health – 3-4 min - Facilitated discussion – 30 min ***Expected outcome:*** *specific points of consensus and red lines regarding innovative models for procurement, service, and maintenance.*	**Presenters:** Wayne van Gemert (STBP) Jason Williams (USAID) & Alan Staple (CHAI) **Moderator:** Stijn Deborggraeve (MSF)

15:45- 16:15 CET	**Evidence-based pricing – 30 min** Presentation: *Fair and equitable pricing based on cost-of-goods-sold (COGS) and volumes* – 8 min - **Respondent 1: Wendy Stevens**, Head of the National Priority Program, South Africa National Health Laboratory Service – 3-4 min - **Respondent 2: Bill Rodriguez**, FIND – 3-4 min Facilitated discussion – 15 min ***Expected outcome:*** *specific points of consensus and red lines regarding evidence-based pricing.*	**Presenter:** Stijn Deborggraeve (MSF) **Moderator:** Kaiser Shen (USAID)
16:15– 16:35 CET	**Summary of discussions and proposed shared principles – 20 min** - Present summary of areas of consensus and red lines, and propose a set of shared principles that can be applied in future negotiations with diagnostics suppliers - Request any objections or nuances to be considered for finalizing the shared principles ***Expected outcome:*** *specific points of consensus and red lines inform shared principles buyers agree to adopt for future negotiations with diagnostics suppliers.*	David Branigan (TAG) Stijn Deborggraeve (MSF)
16:35- 16:40 CET	**Closing and next steps – 5 min** - Closing remarks and next steps	David Branigan (TAG) Stijn Deborggraeve (MSF)

Annex 3: List of participants

1	Abdunoor Nyombi	Biotechnologist, National TB Reference Laboratory, Uganda
2	Alexander Lim	Department of Health, Philippines
3	Abdallah Makhlof	Chief, Health Technology Centre, UNICEF
4	Ademola Osigbesan	Technical Manager, Strategic Sourcing and Supply, Unitaid
5	Ajay Rangaraj	Technical Officer, WHO Global HIV, Hepatitis and STIs Programmes
6	Alan Staple	Head of Global Markets and Vice President, Clinton Health Access Initiative (CHAI)
7	Allan Fabella	National TB Program, Philippines
8	Alexandre Costa	Diagnostics Advisor, UNICEF
9	Alexandra Bertholet	Deputy Director, Market Innovations, FIND
10	Amy Piatek	Senior Tuberculosis Technical Advisor, USAID
11	Andrew Auld	Medical Epidemiologist and Senior Disease Advisor, The Global Fund to Fight AIDS, Tuberculosis and Malaria
12	Anisa Ghadrshenas	Technical Officer, Strategy Team, Unitaid
13	Annabel Baddeley	Technical Officer, WHO Global TB Programme
14	Anne Moller	Project Manager, Global COVID-19 Response, Partners In Health
15	Annette Gaudino	U.S. and Global Health Policy Co-Director, Treatment Action Group
16	Arika Garg	Senior Manager, Diagnostics, Clinton Health Access Initiative (CHAI)
17	Aziz Jafarov	Manager of Global Sourcing Health Technologies, The Global Fund to Fight AIDS, Tuberculosis and Malaria
18	Bill Rodriguez	Chief Executive Officer, FIND
19	Blessi Kumar	Chief Executive Officer, Global Coalition of TB Advocates (GCTA)
20	Brenda Waning	Chief, Global Drug Facility, Stop TB Partnership
21	Brian Kaiser	Technical Officer, Global Drug Facility, Stop TB Partnership
22	Brown Chiwandira	ART Programme Officer, Department of HIV & AIDS, Ministry of Health, Malawi
23	Candice Sehoma	Advocacy Advisor, Médecins Sans Frontières (MSF) Access Campaign
24	Catia Bila	Ministry of Health, Mozambique
25	Catherine M Lee Ramos	Health Technology Assessment, Department of Health, Philippines
26	Charles Sandy	National TB Programme Manager, National TB Program, Zimbabwe
27	Chase Perfect	Project Manager, International Relations and Human Rights Unit, Advocacy Department, Coalition PLUS
28	Chris Connolly	Associate Director, Global Diagnostics, Clinton Health Access Initiative (CHAI)
29	Chris Obermeyer	Advisor, HIV Prevention Product Introduction, The Global Fund to Fight AIDS, Tuberculosis and Malaria
30	David Branigan	TB Project Officer, Treatment Action Group
31	David Kamkwamba	Executive Director, Network of Journalists Living with HIV and AIDS (JLWHA), Malawi

32	David Ruiz Villafranca	Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
33	Donald D. Tobaiwa	Director, Jointed Hands Welfare Organisation, Zimbabwe
34	Edna Tembo	Executive Director, Coalition of Women Living with HIV and AIDS (COWLHA), Malawi
35	Edward Low	Director, MTAAG+, Malaysia
36	Elom Emeka	Community Health Worker, Tulsi Chanrai Foundation, Nigeria
37	Emi Okamoto	Associate Director, HIV/Hepatitis Diagnostics, Clinton Health Access Initiative (CHAI)
38	Ezio Távora dos Santos Filho	Coordinator, REDE-TB, Brazil
39	Fatim Jallow	Senior Medical Laboratory Specialist, The Global Fund to Fight AIDS, Tuberculosis and Malaria
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