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[1,2] 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[3] 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[4] of the research, development, manufacturing, and supply of diagnostics in future investments, in accordance with countries' needs. Country governments and global health actors can

[1] 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.
[2] 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.
[3] 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.
[4] 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,[5] 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,[6] reagent rental agreements,[7] 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.

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

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 (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[8] to achieve the lowest sustainable pricing.[9] 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.

[8] 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.

[9] 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.

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 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[10,11] 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.

[10] 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.)

[11] 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