Unitaid
SAVE LIVES FASTER

Unitaid Executive Board Meeting
44th Session
18-19 June 2024
Geneva, Switzerland

Agenda item 9

Area for Intervention:

Improving people-centered care through integrated diagnostic tools and delivery approaches

Programmatic Priorities: *Accelerate access to integrated diagnostics and self-testing/self-care (HIV and co-infections; TB; Malaria; responding to global health emergencies; women and children's health)*

Strategic Objectives: *Accelerate adoption of key health products (Create systemic conditions for sustainable, equitable access; Foster inclusive and demand-driven partnerships for innovation)*

For Information ☐ **For Review and Advice** ☐ **For Decision** ☒

Contents

1. Purpose and context of this document

This Area for Intervention (AfI), submitted for Executive Board endorsement, outlines a priority investment opportunity focusing on improving people-centered care by advancing demonstrated approaches to integration of diagnostic tools and delivery for high priority areas such as HIV, TB and cervical cancer. This is also in consideration of expanding access and use of self-testing and self-care tools and approaches. The purpose of this document is to provide a clearer strategic positioning of integration of diagnostics and delivery in Unitaid's strategy, outlining high potential opportunities for Unitaid's investments considering developments in the product landscape and the stakeholder ecosystem.

2. Introduction

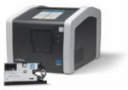
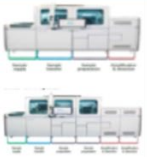
In response to Unitaid's Programmatic Priority to accelerate access to integrated diagnostics and self-testing/self-care, as well as a recent surge in momentum behind a number of key global health issues, such as cervical cancer elimination, ending TB, pandemic preparedness and elimination of vertical (mother-to-child) transmission (EMCT) of HIV and other infections, there are compelling opportunities to increase access to testing and improve people-centered care.

Integration can refer to a health product that addresses more than one disease or condition (e.g., multi-disease or multi-analyte diagnostic platforms), addressing the needs of people affected by more than one disease (e.g., treatment of co-infections), or reaching people for one health issue through a different programme or clinical interaction (e.g., leveraging child health programmes to diagnose malaria in children).

Put more simply, **sharing devices and/or sharing services across programmes** for people affected by one or more illness or condition has been observed to **improve access to and uptake of testing services**, as well as to gain cost and programme efficiencies in effective diagnostic delivery. From an equity perspective, increasing the availability and adoption of diagnostics can help ensure that vulnerable and underserved populations can access affordable, quality diagnostic tests.

Access to diagnostics and testing tools and services is critical to ensure health outcomes across many diseases. **Screening, early detection, and diagnosis** can help people link to prevention and treatment services. Considerable investments over the last two decades by Unitaid and partners working to advance HIV and TB response through introduction of technologies and building of programmes has led to significant infrastructure available across countries. Furthermore, an expanded availability and pipeline of multi-disease diagnostics, including investments made by Unitaid and other partners during the COVID-19 pandemic, provide an opportunity to leverage existing diagnostic infrastructure and achieve integration across diseases and programmes, with a significant benefit at various levels of care – patient, facility, laboratory, health system and globally. Some of these technologies are being designed for use at centralized laboratories, while others may be positioned for use at or near the point of care, or even in community or home-based settings. See Figures 1 and 2 for illustrative examples of diagnostics with multiplex/multi-disease capabilities (please note, these are illustrative, not exhaustive, and not indicative of product scope for future investment).

Figure 1: Pipeline of molecular assays with multiplex/integration capability

		Abbott m2000sp	Abbott m-PIMA	Cepheid GeneXpert GX-4, 16, 48, 80	Hologic Panther	Roche CAP/CTM 96	Roche 4800/ 6800/8800
							
Max daily throughput (incl. controls)		96 (8hrs) 288 (24hrs)	8 (8 hrs)	GX4: 16 (8hrs) GX16: 64 (8hrs)	320 (8hrs) 1,220 (24hrs)	168 (8hrs) 312 (24hrs)	384/960 (8hrs) 1,344/3,072 (24hrs)
Test menu	HCV VL	✔[a]	✘	✔[a]	✔	✔	✔[c]
	HBV VL	✔	✘	✔	✔	✔	✔
	HIV EID	✔[a]	✔[a]	✔[a]	✔	✔[a]	✔[c]
	HIV VL	✔[a]	✔[a]	✔[a]	✔[a]	✔[a]	✔[c]
	MTB	✔	✘	✔[b]	✘	✔	✔
	HPV	✔[a]	✘	✔[a]	✔	✔[c]	✔[c]

[a] Technologies with WHO prequalification listing
[b] Technologies endorsed by WHO (Global Tuberculosis Program)
[c] Technologies currently undergoing WHO prequalification review
Information included as of December 20, 2019. Pictures are not to comparable scale.

Source: 2022, CHAI

Figure 2: Pipeline of point-of-care (POC) assays with multiplex/integration capability

Source: 2022, FIND

Unitaid is well placed to make a difference in this area, drawing on longstanding expertise in accelerating access to diagnostics, as well as a rich portfolio of grants that include HIV early infant diagnosis, HIV viral load, screening for HIV prevention, and HIV self-testing; TB screening, detection and resistance testing tools; hepatitis C testing; hypoxia detection using pulse oximetry; HPV screening and diagnosis for cervical cancer; and other strategic initiatives, such as responding to COVID-19 and global health emergencies. Further, in 2018 Unitaid developed a *Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB*

and other Coinfections.[1] During the COVID-19 pandemic, Unitaid was able to build on these investments and leverage the availability of molecular technologies in countries to support national COVID-19 clinical and surveillance needs, while also continuing to deliver the HIV or TB services on these same platforms. Pilot programmes demonstrated stronger outcomes when integrating COVID screening with HIV, TB and MNCH platforms[2]. This level of integration, starting at health facilities where a patient seeks care, but facilitated by the diagnostic platforms, presents opportunities to pursue more integrated and sustainable approaches that could have a transformative public health impact. Further, these opportunities could reduce the burden to health workers and patients that are often experienced through vertical programme delivery. Under COVID-19 investments, Unitaid and partners have made contributions to advancing the pipeline of new technologies that can be further decentralized near the point of care, many of which have promising assay menus that could facilitate broader integration of testing and care for priority diseases. Through 2023 investments in multiplex diagnostics, supported by specified funds, preliminary work is underway to accelerate market preparation for this promising class of technologies – informing which and how multiplexing solutions in the pipeline could support integrated service delivery models. This first phase of work, currently underway, aims to better understand which diagnostic solutions countries need and demand, to characterize use cases, suitability and cost-effectiveness of these tools at different levels of care, the role of these tools across public health programmes and surveillance, and the accessible market. Considering the cross-cutting nature of this programmatic priority, **there is an opportunity to catalyze expansion of more efficient and integrated testing models that will support national disease programmes, in the immediate term for priority diseases in Unitaid's portfolio**, and for other areas over time.

Following an analysis of possible interventions, their potential impact and fit for Unitaid (using the prioritization framework), the Secretariat proposes to position this opportunity for 2025 funding in the Investment Plan, with potential further interventions in subsequent years depending on pipeline advances. In addition, Unitaid has included efforts to provide catalytic product development support to advance key diagnostic priorities in the 2025 upside, a strong additional investment prospect for Unitaid should further funding become available. This responds to stated priorities of government and other country stakeholders to reduce vertical programming, with global alliances for long-term scale and sustainability. This therefore addresses Unitaid's strategic objectives on partnerships (SO3), alongside compelling work on access to key products (SO1) and systems conducive to their use (SO2).

3. Public health challenge and key access issues

Overall, efforts are off track to achieve national, regional, and global disease targets across a number of key conditions, including HIV, malaria, TB, cervical cancer, hepatitis, and syphilis. This is largely due to limited access to testing and diagnostics. Diagnostics are critical to identifying those who need care/treatment services, as well as to curb disease transmission. Nearly half (47%) of the global population has little to no access to diagnostics.[3] In fact, modelling has shown that 1.1 million premature deaths in low-income and middle-income countries could be avoided annually by reducing this diagnostic gap for six priority conditions: diabetes, hypertension, HIV, and tuberculosis in the overall population, and hepatitis B virus infection and syphilis for pregnant women. Further challenges in access are compounded by an often vertical and siloed approach to delivering diagnostics, which limits the technological and programmatic potential of technologies to specific disease programmes. Reducing the diagnostic gap is estimated to result in averting 38.5 million disability-adjusted life-years (DALY) annually. Fortunately, five out of the six priority conditions, as well as many others, can be screened on existing integrated platforms. Many others are soon to come to market.

Multi-disease diagnostics are increasingly capable of rapidly and accurately testing for multiple diseases including HIV, TB, HPV, HBV, HCV, COVID, and sexually transmitted infections (STIs) at or near the point of care. Several of these products are now being offered in rapid test format, either as combined assays or bundled packages of rapid diagnostic tests (RDTs), including those with capability of use with self-collection or self-testing approaches. Also in the pipeline are diagnostic tools with digital capacity, such as portable ultrasounds and x-ray devices with cross-disease utility. However, access to these tests in LMICs remains

[1] Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and other Coinfections, Unitaid, January 2018.
[2] Mid-term evaluation of Unitaid's COVID-19 portfolio of investments. CEPA. April 2022.
[3] The *Lancet* Commission on diagnostics: transforming access to diagnostics. Lancet 2021; 398:1997-2050.

limited due to various factors, including the high prices of tests and instrumentation, inadequate service/commercial support from manufacturers, and lack of adoption from country programmes. These barriers have been maintained to date by a small market dominated by very few players, and a donor landscape operating through largely vertical financing and approaches.

In summary, access barriers affecting integrated diagnostics include:

- **Innovation and availability:** Though a number of multiplex products capable of integration exist, capabilities remain limited. At present, only one rapid diagnostic test is available that tests beyond one assay (HIV/syphilis) and most molecular products are laboratory-based. LMICs lack access to additional multiplex rapid diagnostic tests, including those for self-testing and self-care as well as specific panels, such as those for fever or respiratory-related illnesses. Though a rich pipeline exists for point-of-care and near point-of-care molecular assays, spurred by innovations during the COVID-19 pandemic, very few have been able to enter or remain in the market. In addition, assay offerings could expand to meet recent target product profiles (TPPs)[4].
- **Affordability:** Normative guidelines recommend that programmes adopt higher performing tests for HPV or TB detection, but major barriers deter adoption and uptake. These include the high upfront cost of instrumentation or limited competition to bring down the cost of assays. Countries routinely rely on external donors – particularly the Global Fund and PEPFAR – to support testing and diagnostic programmes. Though both entities encourage diagnostic integration, vertical programming can deter effective implementation of this approach. At the same time, procurement and funding is linked to demonstration of feasibility and cost-effectiveness.
- **Quality:** At present, WHO prequalification has limited approval processes for single assay technologies; therefore, approval processes and country regulatory systems for multi-disease or multi-purpose tests may require additional engagement and capacity development for approaches that go beyond an assay-by-assay approach.
- **Demand and adoption:** Poor access to diagnostics persists in LMICs. Amongst those in need, there can be little to no awareness of critical testing and diagnostic services they require and deserve. For the most part, end-users and those receiving services in LMICs are accustomed to fragmented or siloed care and services, causing significant overburdening of strained healthcare systems and provision of suboptimal health services. Further, current diagnostic networks tend to be complex and duplicative due to funding and programmatic silos, with limited consideration of contextualized needs.

4. Potential of integrated tools and delivery approaches along with self-testing and care

In May 2023, the World Health Assembly adopted the resolution to ‘Strengthen Diagnostics Capacity’, which elevates the vital role of diagnostics in health programming, and points to key gaps that need to be overcome through coordinated action and response from global and national partners. While the recommendations from the resolution range widely, among them, **breaking down silos through more integrated approaches to screening and diagnosis** was a key recommendation for action. Another noted the importance of **decentralizing testing to the point-of-care, both in primary care settings, as well as at the community level**, which reinforces the opportunity to **increase availability and affordability of self-testing** and self-care approaches. With emerging tools, the goals of integration and decentralization are not mutually exclusive – but careful consideration is needed to inform optimal introduction of new tools: which products will address country needs and fit with national programmes, where, and how. Further, it will be important to assess which products could support integrated service delivery models, and which models are likely to achieve the greatest impact.

[4] https://www.who.int/news-room/articles-detail/public-consultation-for-the-target-product-profile-tb-diagnostic-tests-for-peripheral-settings; https://www.who.int/news-room/articles-detail/public-review-of-the-target-product-profiles-(tpp)-for-human-papillomavirus-(hpv)-screening-tests-to-detect-cervical-precancer-and-cancer

Unitaid's critical investments in diagnostics during the COVID-19 pandemic, as well as historical funding in molecular diagnostics and self-testing, have established Unitaid as a catalytic and critical partner in expanding access to diagnostics. Exploratory efforts, supported by specified funds, are underway to assess which multi-disease diagnostic solutions have the greatest potential and would serve national priorities, and which products could support integrated delivery models. The first phase of activities will answer questions about the total need and accessible market beyond TB and HIV, with opportunities to advance programmes or populations that remain underserved, like HPV testing for cervical cancer or TB detection in children. To unlock the potential of promising near and true point-of-care tests, further investment is needed for in-country introduction, operational research that will accelerate the demonstration of integration at the country level, as well as demand creation to support adoption and scale. **The transformative potential of the tools and integrated delivery strategies lies in their ability to leverage gains in HIV and TB to bring other health services to unreached populations**.

Many government programmes have shown strong interest in moving towards integrated approaches to diagnostics, and recognize there could be economic benefits to doing so. When informed by relevant implementation data, **diagnostic integration has been shown to be cost-effective, and thus could allow for budgets to be maximized and funding provided in more neglected areas**. Current diagnostic solutions are offered in a siloed manner across diseases – resulting in duplicative supply chain systems, sample transport systems, human resources, and other related testing and diagnostic systems. This inefficiency has tremendous financial and public health costs – **implementation platforms/pilots could demonstrate how to streamline services and create more optimized, comprehensive testing and diagnostic systems as well as improve the range of services that can be offered to patients during a single clinic visit**. Further, integration of diagnostics provides an opportunity to develop a more flexible, agile health network that can adapt to meet the changing needs of a health system more efficiently than one without an integrated diagnostic network – for example, when a new product comes to market, or in the context of the health pandemic. Finally, diagnostic integration allows countries to maximize their standard funding portfolios from key disease-specific donors to provide initial and greater access to testing of other critical diseases, many often being co-morbidities of the disease-specific programmes (e.g., HPV testing for women living with HIV). This aligns with scale-up opportunities presented by donors such as the Global Fund – which, anticipating requests from countries to introduce products, has developed a requirement for countries to consider integration in their procurement requests.[5] Additional work from Unitaid could inform optimal deployment, accelerate the timeline to adoption, and de-risk the pathway to scale. This work could also help develop a case for countries on packages of care that might benefit most from diagnostic integration. **Creating more comprehensive, efficient, cost-saving, and inclusive diagnostic programmes will respond more efficiently to new and a broader range of health threats.**

Efforts to increase and decentralize access to testing and care services will directly benefit high-risk, marginalized populations, reaching more people whose health needs are currently unmet. Patients with comorbidities can be more effectively identified and receive more comprehensive care, while integrated diagnostics could also provide a wider range of screening tests at a single visit, making the most of touch points with the health system, such as antenatal care. Further, increased access to self-testing and self-care, including self-collection and self-swabbing tools, empowers greater patient-centered management and ensures that diagnostic information – and, ultimately, lifesaving health tools for treatment and prevention – can reach more people. Communities, NGOs, civil society and other stakeholders must be central in leading the adoption, education, and demand for integrated tests and services.

Modelling work has shown the economic benefit of integrated testing approaches[6] – whether at the country level in reducing burden on healthcare workers and patients as described above, or through coordinated supply approaches, such as pooling procurement across diseases or across regions. Unitaid has played a leadership role in identifying innovative models for procurement, service, and pricing – as well as applying a set of access principles that have been used successfully in negotiations with diagnostic suppliers. To date, many supplier engagements and approaches in diagnostics remain focused on leveraging volumes from single diseases. Partners are increasingly thinking differently and more often about disease integration, but

[5] https://www.theglobalfund.org/media/3230/lfa_laboratoryservicessupplychain_review_en.docx
[6] Economic benefits of integrated molecular testing, evidence-based pricing, across diseases. Treatment Action Group. 2022

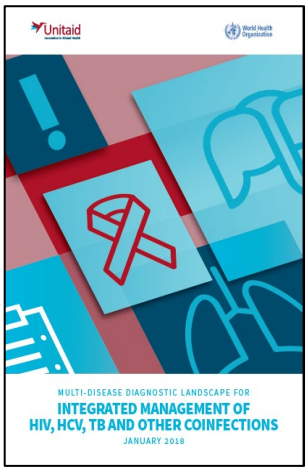
further efforts are needed that require strategic partnering and coordination and the global, regional and national levels to apply terms and engage in negotiations in a manner that will realize benefits across multiple diseases.

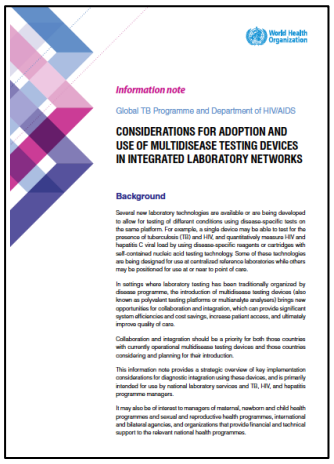
Investment is also needed to accelerate the assay menu expansion of some platforms to drive multi-disease testing, along with accompanying go-to-market support. Investments have been made to date on TB and COVID-19, but resources are needed to ensure adequate engagement for commercialization strategies – such as ensuring the right product features, commercial support and supplier capabilities for product validation, regulation and registration. Similar opportunities exist for self-collection or self-testing approaches, in particular for technical assessment and evaluation of these tools, and support for regulatory approval to facilitate introduction.

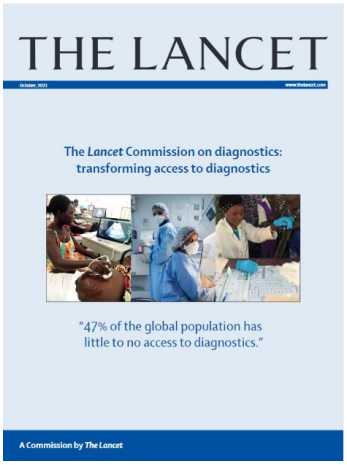
5. Partner engagement

In 2017, WHO published *Considerations for adoption and use of multidisease testing services in integrated laboratory networks*[7], a joint publication between the Global HIV, Hepatitis, and STI Programme and the Global TB Programme. Following this, in 2018, Unitaid published a *Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and other Coinfections*.[8] Subsequently, with Unitaid funding, WHO hosted the first global meeting focused on *Molecular diagnostics integration* in 2019 that brought together over 15 countries and all key global stakeholders.[9]

Based on this, and work linked to Unitaid's investments in point of care HIV diagnostics showing early experiences and impact of diagnostic platform sharing between HIV and TB, WHO convened a Guideline Development Group to issue a good practice statement regarding integrated diagnostics within the *Updated recommendations on service delivery for the treatment and care of people living with HIV*, published in 2021.[10] Subsequently in 2023, the *Lancet Commission on Diagnostics* highlighted the vast remaining gaps in testing and diagnostic access in LMICs[11],







With the release of these key documents and emergence of the COVID-19 pandemic highlighting the need for integration, a number of countries began to consider and implement integrated diagnostics, though primarily through existing instruments in country. Initial exercises of diagnostic network optimization, oftentimes conducted with technical and/or financial support from ASLM, US-CDC, CHAI, FIND, Global Fund and USAID, highlighted the national political will, as well as the link to broader health objectives, such as the aim to reach universal health coverage which requires a fundamental shift to ensure services are integrated and focused on the needs of people and communities. However, many of these activities remain limited and

[7] Considerations for adoption and use of multidisease testing devices in integrated laboratory networks, WHO, 2017.
[8] Multi-disease Diagnostic Landscape for Integrated Management of HIV, HCV, TB and other Coinfections, Unitaid, January 2018.
[9] Molecular Diagnostics Integration Global Meeting Report, WHO, July 2019.
[10] Updated recommendations on service delivery for the treatment and care of people living with HIV, WHO, 2021.
[11] The *Lancet* Commission on diagnostics: transforming access to diagnostics. Lancet 2021; 398:1997-2050.

focused on individual diseases. To ensure broader reach and impact, it was imperative to expand and maintain this critical intervention across different diseases.

In August 2022, Unitaid, with WHO and ASLM, hosted a *Global Diagnostic Synergy* consultation which was held in person and virtually, and brought together over 150 participants from around the world to discuss challenges and opportunities in integrating diagnostics, which could inform normative efforts to support public health policy change, and accelerate uptake in countries. The consultation included diagnostic programme experts across several diseases, funders, regulators, normative representatives from WHO and regional bodies, as well as community and civil society representatives. Community and civil society organizations expressed strong support of diagnostic integration, acknowledging its potential to bring more comprehensive care to patients, oftentimes bringing testing closer to the patient (with multiplex/panel RDTs and point-of-care molecular technologies). The strong participation and engagement from countries and civil society partners in particular has continued to inform Unitaid's approach to this AfI.

Additional engagements have continued to take place through 2023 to validate opportunities for integration, and to ensure complementarity of initiatives. These include engagement and coordination with those involved in developing the pipeline for multi-disease and point-of care products, such as BMFG, FIND, The Right Foundation, The Indian Health Fund, PATH. Other donors/funders have also been engaged, notably USAID, PEPFAR, and Global Fund. This has relevance, in particular in the context of Global Fund's next-generation market shaping efforts, given unique opportunities to leverage the revolving fund and support transition and scale, for which multiplex diagnostics has been identified as a product with high potential. Finally, input from infectious disease experts has been sought through opportunities at the Union Lung Conference, the African Society for Laboratory Medicine Conference, and the Conference on Retroviruses and Opportunistic Infections. Most recently in 2024, Unitaid hosted a meeting on TB DX Demonstration Platforms to discuss needs and opportunities for the new class of TB diagnostics and collection methods. Most recently, Unitaid engaged strongly on the agenda to eliminate cervical cancer at a convening in Cartagena, committed to accelerating screening and diagnosis of HPV through integrated and people-centered approaches. Both TB and cervical cancer are conducive to self-sampling techniques, which Unitaid is beginning to validate through current work.

Throughout the initial work within integrated diagnostics and self-testing, Unitaid has been at the forefront, supporting integration efforts and creating demonstration platforms to showcase the benefits, convening and coordinating across partners, and leading the Integrated Diagnostics Consortium, which Unitaid co-chairs. Unitaid continues to engage across a number of infectious diseases (HIV, TB, HPV, Hepatitis, STIs, emerging pathogens, etc.) through core investments, which will be instrumental for this intervention and ensure strong alignment with recent global initiatives. Unitaid remains well positioned to continue leadership and coordination at this level, and to continue to enable strong partnerships along the value chain to inform and support rapid product introduction, adoption, and scale.

6. Potential opportunities for Unitaid investment

A number of integrated diagnostics technologies already exist – for example, HIV/syphilis dual RDTs and laboratory-based molecular technologies. Fortunately, a strong pipeline of products also exists from efforts during the COVID-19 pandemic and Unitaid's involvement in the upstream pipeline work of the ACT-Accelerator. Support is needed to identify the highest value, most appropriate technologies, and bring these products responsibility to market – to register products, introduce them within national disease programmes, and generate evidence on delivery models across the most viable use-cases across surveillance and clinical management of disease. Unitaid's unique mandate and positioning can be a catalyst to accelerating the progress for more effective and comprehensive diagnostic integration and expanded access to testing and diagnostics beyond high priority diseases, such as HIV, cervical cancer and TB. In turn, this will also not only leverage past Unitaid investments but also propel current investments forward, including those in HIV, cervical cancer, RMNCH, TB, STIs and triple elimination.

As described above, Unitaid is currently supporting exploratory work on multiplex diagnostics with specified funding. The following questions have been considered and will be assessed as part of this work, which will further inform and focus opportunities under this AfI:

- What diagnostic solutions do countries need and demand to better serve national priorities?
- Which multiplex solutions have greatest potential to make a transformative public health impact?
- Which and how multiplex and self-care products in the pipeline could support integrated service delivery models to serve patients in a cost effective way?
- What is the optimal commercialization plan for the most promising solutions?
- What is the accessible market for the most promising products, in particular beyond HIV?
- What approaches can be taken to lower the cost of these products across the span of development through procurement and adoption, and which supply mechanisms can play a role?
- What use cases apply to these solutions in the pipeline, and which health programmes can be served by the same technologies?
- What are the main barriers to entry and adoption of these technologies?
- What types of demand generation and adoption activities will be required to catalyse uptake?

Proposed interventions in the short and medium term will proactively address challenges affecting access to diagnostics through increased availability and access to multi-disease diagnostic technologies and through implementation pilots demonstrating optimized delivery of integrated approaches.

In the short term, Unitaid is well positioned to support opportunities for catalytic introduction and adoption of multi-disease technologies with three areas of focus, as follows (**see also 6.1-6.3** for further detail):

1) Technical and programmatic support that will improve testing and patient needs at various levels of care. Unitaid can establish demonstration platforms to optimize introduction of new technologies, in the context of existing infrastructure and other tools to improve case detection and screening approaches.
2) Overcoming supply constraints and regulatory barriers through coordinated efforts on access and procurement.
3) Driving uptake and demand through regional approaches to coordination, and community- and civil society-led demand-generation efforts.

In the medium term, Unitaid could support late-stage development of priority products with multi-disease capability, and to facilitate validation and approval of new approaches to people-centered care (**see also 6.4** for further detail). Unitaid will continue to monitor the pipeline to support targeted investments, including market shaping interventions informed by implementation and technology readiness, that are aligned with this AfI and provide opportunities to advance LMIC disease priorities.

6.1 Catalytic introduction and adoption

Adoption and implementation of integrated diagnostics is possible now with existing technologies, as well as new technologies that are soon to come to market. Political, programmatic, and technical support for introduction, adoption, and widespread implementation will be necessary. As products of high potential come to market, catalytic procurement to support introduction could be considered alongside implementation pilots to help countries gain experience with the solutions, and to integrate them with health programmes. Understanding optimal service delivery models, acceptability, and feasibility could validate approaches to use multiplex diagnostics as part of integrated service delivery. Considerable efforts within this opportunity would be made to ensure that integrated testing and diagnostics facilitate broader disease integration to create more efficient, comprehensive, and optimized networks for a range of diseases and conditions and streamline care and services for the patient. In addition to HIV, there are particularly strong opportunities to build on existing Unitaid investments in accelerating access to diagnostics for TB and cervical cancer. For both, investments in integration of diagnostics could facilitate more holistic packages of care.

6.2 Market-shaping and access

Significant gaps remain in addressing market barriers for diagnostics, which include pricing and quality, as well as broader supply security, particularly for countries with low volumes. A competitive market promotes better pricing and improves both services and supply chains for diagnostics. Where appropriate, and aligned with other stakeholders, Unitaid's work can leverage the availability of new multi-disease diagnostics to build consensus on pricing and innovative models for sustainable procurement, service and maintenance. Unitaid's leadership can be applied across actors and diseases in ongoing access negotiations with diagnostic companies.

6.3 Demand generation and regional coordination

To further catalyze integrated diagnostics in the pipeline, in particular leveraging HIV, TB and cervical cancer work, it is critical to recognize the need to introduce these diagnostic tools as part of a quality package of services that link to treatment and care. These packages of care, which could build on (and reinforce) normative guidance, as well as experiences from implementation pilots, could be complemented by country and regional efforts. Through engagement with partners, such as the African Society of Laboratory Medicine, the Asia-Pacific Diagnostic Consortium, as well as national and sub-national partners, such as PAHO, Unitaid recognizes the need to coordinate and leverage activities to complement and strengthen introduction and adoption.

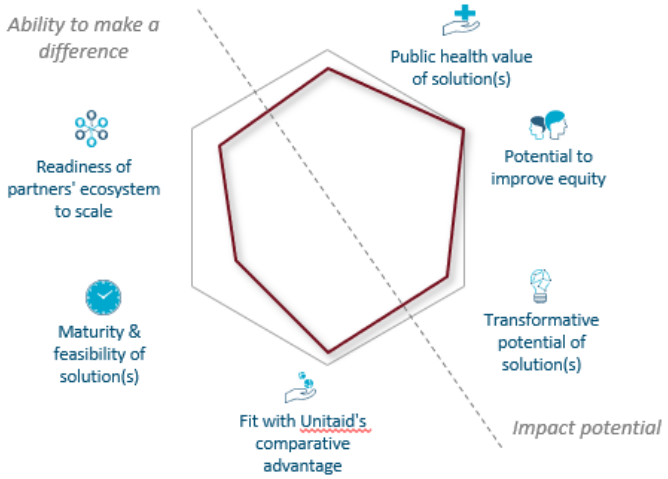
6.4 Targeted product development

Though technologies already exist, these have been relatively limited. The only multiplex RDT being implemented in LMICs (and with related WHO recommendations and/or prequalification) is the HIV/syphilis dual assay. Targeted product development of new suppliers and assays would support more favourable country selection choices and negotiating leverage. Additionally, significant gaps remain in product development and validation of self-collection or self-testing products that could decentralize screening and/or facilitate community-based approaches. In the event of future (respiratory) pandemics like COVID-19, respiratory panels could be instrumental in supporting better patient care and reducing epidemiological spread. MNCH panels that support testing and identification of critical diseases and conditions outside of HIV and syphilis for both maternal and neonatal health are in development, but have not seen the necessary financial or technical support. Finally, self-testing panels for STIs remain an elusive yet essential consideration.

7. Assessment of the opportunity

7.1 Impact potential, including the public health value of the solution, the potential to improve equity and the transformative potential of the solution

Unitaid interventions in integrated diagnostics have the potential to reduce life years lost and improve access to diagnostics, particularly in LMICs and those receiving care at the primary health care level. Given the scope of near-term opportunities, and the benefit of proposed interventions, the impact would be most significant in areas that build off existing investments – in particular for cervical cancer and TB, as well as strengthening the investments made during COVID-19 in pandemic prevention, preparedness and response.



As recognized during COVID, equitable access to diagnostics is critical, and integrated testing and diagnostics can address challenges in access through offering more comprehensive screening and testing services at the point-of-care, including and especially for those with co-morbidities. Integrating diagnostics has been shown to result in greater access and reach of diagnostics within a health system network – thereby reaching more people whose health needs

are currently unmet, or providing a wider range of screening tests at a single visit for patients thereby reducing the duplicative health system touch points. Further, with the introduction of single or multi-disease self-testing, RDTs, and point-of-care tools, this decentralization would bring testing closer to the patient and foster more of a person-centered testing and diagnostic approach.

Current diagnostic solutions are offered in a siloed manner across diseases – resulting in duplicative supply chain systems, sample transport systems, human resources, and other related testing and diagnostic systems. This inefficiency has tremendous financial and public health costs – integration provides an opportunity to streamline services and create more optimized, comprehensive testing and diagnostic systems as well as improve the range of services that can be offered to patients during a single clinic visit. Integration of diagnostics provides an opportunity to develop a more flexible/agile health network that can adapt to meet the changing needs of a health system more efficiently than one without an integrated diagnostic network - for example, when a new product comes to market, or in the context of the health pandemic. Further, diagnostic integration allows countries to maximize their standard funding portfolios from key disease-specific donors to provide initial and greater access to testing of other critical diseases, many often being co-morbidities of the disease-specific programmes (ie. HPV testing of women living with HIV).

Integrated diagnostics has significant opportunities for impact at both the patient level (the management of the disease) and at the health system level (cost sharing between programmes, optimized and more efficient systems, and greater access to non-high priority testing, etc.).

7.2 Ability to make a difference, including fit Unitaid's comparative advantage, maturity and feasibility of the solution and readiness of partner ecosystem

Efforts in multiplex diagnostics build on Unitaid's historical work and investments across a number of areas, including investments in HIV paediatrics and point-of-care diagnostics, cervical cancer grants advancing screening of HPV, TB case-detection grants that support molecular and next-generation sequencing technologies with multi-disease functionality, and current work on multiplex diagnostics. Strong synergies are also linked to future work exploring AMR, STIs, women and children's health, PPPR, as well as to climate and health. Diagnostic integration would fit a number of Unitaid's key goals and comparative advantage: an opportunity to be catalytic in a space that already includes products and political will, but requires a critical push/catalytic effort to achieve impact, and would maximize and support expansion of previous and current Unitaid investments, such as POC HIV, TB, HPV, etc. Further, with Unitaid's mandate and portfolio, funding could be complementary to GF/PEPFAR and support the latest pipeline of innovations and to play a key role to move forward diagnostic integration.

Work on integrating diagnostics has already kicked off during existing Unitaid investments in HIV, TB and in multiplex diagnostics, and the forthcoming work on 3E will explore multiplex RDTs - **this intervention, therefore, is immediately operational and will build on many previous investments and focus activities**. Further, several products are commercially available that can be available across various levels of the health system now, with strong backing from partners (WHO, USAID, BMGF, Right Foundation, etc). Initial pilots of HIV and TB integration, as well as experiences during COVID-19 where laboratories integrated testing immediately in order to be able to establish testing systems quickly, have proven successful. As with any diagnostics, however, an evolving understanding of the business and use-cases for product in development will still be needed.

7.3 Risk

The opportunity under this Area for Intervention boasts a robust pipeline of products, an ecosystem of country and programme readiness, and a high potential for impact. Overall the opportunity is well aligned with the global health landscape and with Unitaid's specific experience and leadership in global health. Despite the complexity of working across multiple diseases or conditions, **strategic risks** are low to medium given the high public health value of the opportunity, the prioritization of this area amongst global and national partners, and its strong fit with Unitaid's comparative advantage and historical portfolio of investments. There are potential **implementation risks** related to delays in technology commercialization timelines, regulatory pathways, the complexity of integrated interventions, as well as buy-in across vertical disease programme stakeholders. The early phase of activities funded under COVID-19 for market preparation will help to de-risk and define pathways for responsible introduction. **Scalability risks** remain dependent upon the coordination

of technical and financial support, though the outlook is positive from initial consultations and interest from partners including the Global Fund. Nevertheless, additional partner and donor technical and financial support can remain disease-focused and siloed, even if there is widespread overall support for diagnostic integration and available funding.