Evaluation of Unitaid's COVID-19 Investments

Final Report

Unitaid

12 June 2024

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ACRONYMS

Acronym	Full description
ACT-A	Access to COVID-19 Tools Accelerator
AFROX	African Oxygen Ltd.
Ag-RDT	Antigen rapid diagnostic test
AIRE	Améliorer l'Identification des Détresses Respiratoires chez l'Enfant
ALIMA	The Alliance for International Medical Action
BMGF	Bill and Melinda Gates Foundation
C19RM	The Global Fund COVID-19 Response Mechanism
CHAI	Clinton Health Access Initiative
CSO	Civil Society Organisation
C-TAP	WHO COVID-19 Technology Access Pool
DNDi	Drugs for Neglected Diseases Initiative
EOI	Expression of Interest
EGPAF	Elizabeth Glaser Paediatric Aids Foundation
FIND	Foundation for Innovative New Diagnostics
FIOTEC	Foundation for Scientific and Technological Development in Health
ISGlobal	Barcelona Institute for Global Health
KVP	Key and Vulnerable Populations
LMIC	Low and middle-income country
MoH	Ministry of Health
MNCH	Maternal, neonatal, child health
MPP	Medicines Patent Pool
MTE	Mid-term Evaluation
PIH	Partners in Health
PPPR	Pandemic Prevention, Preparedness and Response
PSI	Population Services International
RfP	Request for Proposal
RT-PCR	Reverse transcription polymerase chain reaction
TA	Technical Assistance
TIMCI	Tools for Integrated Management of Childhood Illness
ToC	Theory of Change
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
USAID	The United States Agency for International Development
WHE	WHO Health Emergency Programme
WHO	World Health Organization

EXECUTIVE SUMMARY

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct an end-term evaluation of Unitaid's COVID-19 investments which concluded by 31 December 2023. The evaluation builds on CEPA's mid-term evaluation (MTE) of Unitaid's COVID-19 investments, which covered Unitaid's response to COVID-19 from March 2020 to December 2021.[1]

Evaluation objectives, scope, and approach

The evaluation objectives were to:

- assess the contribution of Unitaid's investments to the COVID-19 response and the sustainability of the response beyond the emergency; and
- draw lessons learnt and recommendations for Unitaid to apply to its future pandemic prevention, preparedness, and response (PPPR) work and continuing diagnostics and medical oxygen work

This evaluation covered 22 investments across eleven grantee organisations, with at least US$67 million in investments in therapeutics and diagnostics and US$83 million in medical oxygen including:

- COVID-19 Test and Treat (seven investments) plus the joint FIND-Unitaid investment in advocacy grants.
- Medical oxygen in the context of COVID-19 (eleven investments across five grantees); and
- Select investments under the therapeutics (one investment, ANTICOV by DNDi) and diagnostics (two investments by FIND and CHAI[2]) portfolios.

A mid-term evaluation was conducted previously by CEPA (2021/22), however at that time, most of the investments made by Unitaid were in their infancy or had only been running for up to one year in a fast-changing and evolving pandemic context, where there was no available vaccine and only limited treatment. As such, the mid-term review was primarily focused on the relevance and coherence of the investments and the efficiency of the response.

The evaluation was theory-based (although the theory of change for the portfolios had key limitations to aid a well-rounded evaluation discussed in the full report). An evaluation framework based on OECD DAC evaluation criteria was constructed around four key pillars (1) effectiveness and impact; 2) sustainability; 3) coherence and efficiency; and 4) evaluation conclusions, lessons learned and recommendations), with evaluation questions to respond to the evaluation objectives and scope.

The evaluation was implemented through a mixed-methods approach, with a specific focus on gathering country-level insight. The methodology included a rapid review of Unitaid grant documentation and wider documents from Unitaid and key stakeholders, interviews at the global level with 58 stakeholders (mainly Unitaid staff and grantees), and eight country case studies through which 144 stakeholders were consulted including grantees, government stakeholders, CSOs, partners, and healthcare workers. Three case studies were conducted in person (Zimbabwe, Brazil, and Peru) and five were conducted remotely (Bolivia, Cameroon, Ethiopia, Malawi, and India).

The evaluation was limited by the number of 'external' global stakeholders that were included (by design), and some difficulties in reaching relevant stakeholders at the country level due to staff turnover.

[1] https://unitaid.org/assets/Unitaid-COVID-19-mid-term-Evaluation_CEPA-Final-Report.pdf

[2] CHAI's diagnostics investment noted here related to work on the introduction of antigen RDTs.

Key findings by portfolio/ investments

Key findings	Supporting evidence from countries	Robustness
Overall findings on the Test & Treat portfolio • **The Test and Treat investments made important contributions to furthering the demand and adoption of COVID-19 diagnostics by supporting decentralisation of testing at lower levels of health care and providing an evidence-base and support to update policies and guidelines. However, the timing of the investments has meant that they have not supported the acute phases of the pandemic and thereby have had a lower COVID-related impact.** • **Noting this, the key results of the Test & Treat investments should be considered in terms of the portfolio's impact on health systems and pandemic prevention, preparedness, and response (PPPR), which the investments pivoted towards supporting. However, this contribution is misaligned with Unitaid's role as a one-time catalytic funder.**		
Detailed findings on contribution/ results related to COVID-19 pandemic		
1. The Test and Treat portfolio successfully supported an increase in the demand and adoption of COVID-19 diagnostics, by decentralising testing at the primary health care level and supporting updates of policies and guidelines.	**Zimbabwe**: • Decentralisation of antigen testing a *'game-changing contribution'*, which expanded access to testing in 1,848 public health facilities in Zimbabwe and reduced pressures on the national reference lab • Integration of COVID-19 services (incl. within HIV/TB services, outpatient services, and SRH services) shown to be a beneficial and feasible model • Grantees supported adoption of AgRDT testing guidelines, including self-testing guidelines which were *'adopted by the MOHCC faster than anticipated'* due to evidence generated	**Strong**
2. There was some useful contribution to the development and introduction of AgRDT through market shaping approaches, but this was not the mainstay of the portfolio.	**Cameroon:** • CHAI provided significant technical information to the Ministry of Health regarding rapid diagnostic tests in the pipeline, socialising the Ministry on different options and ensuring that a diversity of suppliers was introduced to keep prices affordable • CHAI was able to ensure rapid validation of AgRDTs through catalytic procurement and training of trainers. With CHAI's support, the Ministry of Health in Cameroon approved rapid diagnostic tests and was amongst the earliest adopters globally.	**Strong**
3. Attempts to establish a continuum of care with treatment options was largely not achieved, mainly due to external factors beyond Unitaid and grantee control, that is the non-availability of therapeutics globally.	• The Test & Treat portfolio was unable to meet the objective of establishing a continuum linking testing to therapeutics as relevant products were not available globally due to a range of upstream challenges including historic underinvestment • Grants made good efforts to "set the stage" for the arrival of therapeutics , for example. working across countries like **Ethiopia** to establish regulatory pathways for drugs and update guidelines.	**Strong**

Key findings	Supporting evidence from countries	Robustness
	• Antivirals had limited impact even when made available in countries later in the pandemic, due to reduction in COVID-19 severe cases	
4. Community engagement was a critical gap in the global COVID-19 response. The Test & Treat portfolio had a positive impact on the management of COVID-19 cases in project sites and significantly enhanced community trust in the primary health care system. However, the short-term nature of these investments limited their long-lasting impact. *This is similar to Finding 11 below, which evaluates another set of investments made by Unitaid aimed at community engagement and advocacy.*	**Bolivia:** • ISGlobal played a critical role in engaging communities within the COVID-19 response in Bolivia, by having conducted an assessment to characterize local barriers to access, co-created community advocacy campaigns with patients, nurses & community representatives, and worked closely with neighborhood social committees to relay community concerns around management of COVID-19 in primary health clinics (PHCs) to healthcare workers. • Stakeholders reported a lasting impact on community confidence and trust in PHCs	**Strong**
5. The timing of the investments has meant that they did not support the acute phases of the pandemic, resulting in lower COVID-related impact. In addition, there was wide variation across and within grants in terms of their impact on COVID-19. Many projects had localised impact without broader effects on other areas or at the national level.	Multiple country stakeholders suggested that the bundle of interventions supported through Test & Treat were highly pertinent and provided extremely useful support but were too late to have an impact on COVID-19 morbidity and mortality. • According to a clinic coordinator interviewed in **Cameroon**, only eleven COVID-19 cases were identified at a Unitaid-supported facility over the course of the project, with none being severe cases • Likewise, a clinic coordinator in **Peru** said that the Test & Treat interventions were *"extremely strong and welcomed"* but *"too late in the evolution of the pandemic to save lives"* • In **Bolivia**, a community representative stated that support *"did not arrive in the moment that it was most needed, it arrived too late."* Additionally, while projects contributed positively to the COVID-19 response at specific project sites, the extent to which impact was translated to non-project sites or the national level varied substantially. For example, in **Brazil,** the impact of the project was mainly limited to the specific sites where grantees supported the expansion of AgRDTs. In Rio de Janeiro in particular, stakeholders highlighted that the localised and smaller-scale support provided by the project made it difficult to negotiate with government stakeholders to achieve municipal-level impact and structural changes, such as adoption of new data systems.	**Moderate**
6. There has been some useful impact of the projects in terms of facilitating the decongestion of health facilities and the delivery of other essential health services, which were constrained by the focus on COVID.	While the Test & Treat portfolio was largely implemented when caseloads were already decreasing, stakeholders suggested that the interventions helped decongest secondary and tertiary level hospitals by allowing less severe cases of COVID-19 to be treated at the primary care level. In **Peru,** district health authorities noted that a cross-comparison of health data in Lima showed lower morbidity and mortality in districts where community screening and	**Moderate/ Limited**

Key findings	Supporting evidence from countries	Robustness
	primary healthcare centres were supported by Partners in Health. Authorities suggested that the decongestion of hospitals was a contributing factor, though the extent of attribution is difficult to determine.	
Detailed findings with regards to adaptation, transition and sustainability of investments and contribution to PPPR		
7. The Test and Treat investments worked hard to adapt to the evolving nature of the pandemic, ensuring valuable use of their commodities and services.	The changing context in countries and evolution of the pandemic required that the Test & Treat projects be highly flexible and adaptable. For example, in **Malawi**, PSI shifted to use cases for testing which supported groups at high risk of acquiring infectious diseases such as sex workers and in **Zimbabwe** EGPAF shifted focus towards diagnosis and treatment of long COVID.	**Moderate**
8. The most significant shift made by grantees as the pandemic waned was to focus more on sustaining health system gains achieved through Test & Treat grants and contribute to PPPR in countries.	Across countries, grantees strengthened systems supporting the COVID-19 outbreak response, including laboratory systems, data, and surveillance. Certain approaches championed by Test & Treat grantees such as integration and self-testing, have been maintained and adapted in the response to other diseases. For example: • In **Cameroon**, grantees strengthened supply chain monitoring and surveillance systems. In addition, the integration model implemented by EGPAF showed good acceptability and is likely to be adopted for other diseases. According to a district medical officer interviewed, *"Even if EGPAF leaves, the investment has strengthened the system… the number of COVID-19 cases has decreased but there is still a system to test for COVID-19 at different points of entry. In other emergency situations, we are going to use it."* • In **India,** given changing government priorities regarding COVID-19 grantees shifted towards mainly supporting PPPR objectives. In Madhya Pradesh for example, CHAI worked on an HIS portal for infectious diseases, supported development of outbreak response guidelines, and provided TA to strengthen private sector data reporting, including facilitating access to a World Bank loan.	**Strong**
9. Multiple Test and Treat grantees highlighted difficulties in sustaining some of the Health Systems Strengthening (HSS) and PPPR related activities, systems and impacts supported by the investments. This raises concerns about the appropriateness of Unitaid as a one-time funder in an area that requires sustained long-term funding.	The lack of country PPPR strategies coupled with endemic issues such as frequent rotation of healthcare workers, underinvestment in primary healthcare systems and community health systems, and capacity gaps. will impact the sustainability of the gains achieved. While the pivoting and adaptations of the Test and Treat grants for HSS and PPPR issues are noteworthy, especially given that the grants were not initially scoped and designed with these issues in mind, there is a question as to the suitability of this one-time, time-limited funding for these objectives, which instead require longer term sustained funding. The funded activities can also be viewed as ad hoc in relation to the PPPR priorities for countries. For example, in **India,** one government stakeholder noted the valuable technical assistance provided by CHAI to support PPPR objectives but was concerned that it covered only a few districts and was not longer-term in nature. In **Peru,** stakeholders suggested that the end of the project was too	**Moderate**

Key findings	Supporting evidence from countries	Robustness
	abrupt and the timeline too short to achieve long-term HSS or PPPR objectives, particularly due to the high turnover rates of both government functionaries and healthcare workers.	
Detailed findings on coherence and efficiency of the investments		
10. The Test & Treat portfolio effectively leveraged Unitaid's existing grantee footprint, albeit with trade-offs by not focusing on countries with the highest COVID burden and employed efficient processes in in response to the pandemic. However, the issue of timing detracts from the impact and, therefore. the value for money of the portfolio.	Unitaid was able to enhance the efficiency of grants by leveraging the existing footprint of its grantees. For example, PSI's work on introducing HIV Self-Testing in LMICs paved the way for its work on COVID-19 self-tests under the Test & Treat investment. Most grantees also implemented the Test & Treat investment in countries where they had established partners. Stakeholders highlighted this as extremely useful, as it facilitated connections with the national government and supported buy-in. However, the trade-off was that Unitaid grantees were not necessarily working in the countries or regions with the highest COVID-19 related morbidity or mortality. Unitaid trialled an expedited grant development and approval process and enhanced flexibilities in management, which were well-received by grantees and adapted to the emergency context. However, there were a few challenges around internal coherence. Additionally, value for money was challenged by misalignment of the investments with the peaks of the pandemic and lack of available antiviral options.	**Strong**
Overall findings on the FIND/ Unitaid advocacy grants & select other therapeutics and diagnostics grants		
11. The FIND-Unitaid co-funded advocacy grants were an important tool for community engagement and linking global and local awareness and understanding on COVID-19. However, the grant impact on improving demand and adoption of test and treat strategies was limited due to the short time frame of the projects and the delayed start when COVID-19 was already on the decline. *Similar to finding 4 above*	• In **Uganda**, the Coalition for Health Promotion and Social Development made important contributions, including tailoring advocacy messaging to improve awareness of COVID-19 among communities, calling on the national government to review clinical guidelines and the essential medicines list, and advocating for better integration of testing and vaccination services, and eventually shifting towards a wider PPPR agenda. • However, they have not been able to demonstrate impact through these grants due to their short-term nature and delayed implementation	**Moderate/ Limited**
12. ANTICOV had limited direct impact on the COVID-19 pandemic but leaves behind a legacy by highlighting the need for a LMIC-based clinical trial network to support future pandemics.	• ANTICOV had limited direct impact on COVID-19 and was principally unable to deliver as a platform for clinical trials in Africa. • However, it leaves behind a legacy by highlighting the importance of creating a multi-country, multi-site clinical trial structure based in LMICs to support future pandemics and epidemics	**Moderate**
13. The joint investment between Unitaid and FIND to develop regional manufacturing capacity for AgRDTs has had limited direct impact on COVID-19 but has	• The investment directly improved affordability of RDTs. This is due to the PMC AgRDT being committed for US$2.5 under the access terms with FIND/ Unitaid, and existing suppliers Abbott and BioSensor dropping their prices from US$5 to US$3 with the pre-	**Moderate/ Limited**

Key findings	Supporting evidence from countries	Robustness
contributed to the regional manufacturing priority deemed critical under the PPPR agenda	qualification of the PMC product (although some argue that the pricing changes are unrelated) • More importantly, the investment made a considerable inroad into the highly important regional manufacturing agenda, which is central to the PPPR focus today.	
Overall findings on the medical oxygen portfolio • **Unitaid's medical oxygen portfolio has been catalytic in terms of moving quickly during the pandemic and aiding the unlocking of other global-level funding, but it has still been too late, for the most part, to have a material COVID-related impact.** • **The portfolio adapted well to the changing demands of the pandemic and worked closely with governments to align systems and support PPPR. However concerns remain over the sustainability of the equipment and the availability of skilled personnel to maintain the oxygen investments established.**		
Detailed findings on contribution/ results of investments related to COVID-19 pandemic		
14. Unitaid's medical oxygen portfolio made an important contribution to the COVID-19 response through its ability to move fast and increase access to oxygen supplies in LMICs as well as being catalytic in unlocking global financing for medical oxygen.	**Cameroon**: CHAI was critical to the development of the National Oxygen Strategy, supported a funding request application to secure financing from the Global Fund, and supported the decentralization of oxygen access to harder-to-reach regions. A government stakeholder in the oxygen taskforce stated- *"CHAI went above and beyond what was expected while supporting the development of the National Plan, even pulling all-nighters with us"].*	**Strong**
15. The overall impact of the medical oxygen investments in the COVID-19 response has been limited by implementation delays, uncertainties about the sustainability of the investments and the extent to which global agreements and price reductions have translated into tangible benefits at the country-level.	**Ethiopia:** CHAI helped expedite procurement ahead of government processes, but experienced challenges in obtaining equipment due to shortage of supplies and complex custom clearance procedures. These delays resulted in increased oxygen supply after the second, most deadly, wave of COVID-19. However, the impact of creating new oxygen plants in three diverse districts was still found to be of significant value to the health systems. Across countries, the medium to long term impact of Unitaid's investments is challenged by the ability to keep newly developed and repaired oxygen systems operational and are transitioned to government-led services, as well as the extent that the impact of global resolutions and market-shaping agreements is translated to country level.	**Moderate**
16. Addressing community needs in the medical oxygen portfolio was not central to the plans and did not happen early enough.	**Malawi:** Notably, as noted by a consultee in Malawi, community engagement is an important component for medical oxygen: firstly, it helps dispel misinformation or misunderstanding that oxygen is a "treatment of last resort". Secondly, it raises awareness of the importance and availability of oxygen in health facilities. This focus on public awareness and demand generation was supported by grantees to some extent. For example, PIH reported that in Malawi the installation of a PSA plant at a local hospital, combined with community engagement, led to increased demand and uptake for oxygen. However, overall, across the portfolio, community outreach and engagement could have been better established.	**Moderate**
Detailed findings with regards to adaptation, transition and sustainability of investments and contribution to PPPR		

Key findings	Supporting evidence from countries	Robustness
17. The medical oxygen portfolio adapted well to the changing demands of the pandemic and worked closely with governments to align systems and support PPPR. However, concerns remain over the sustainability of the equipment and availability of skilled personnel to maintain the oxygen investments established.	**Peru:** To ensure sustainability of oxygen investments, PIH transitioned trainings to national government and School of Public Health with USAID funding and negotiated service level agreements (SLAs) for the preventive maintenance of oxygen plants. Several PSA plants supported by PIH are still producing oxygen, although not all are reporting. However, threats to the sustainability of the oxygen system include information and data gaps, a lack of bioengineers and personnel, low demand for oxygen post-pandemic, and mixed implementation of regionally managed maintenance plans.	Moderate
Detailed findings on coherence and efficiency of the investments		
18. Unitaid developed the medical oxygen portfolio with pre-existing implementing partners who had strong expertise in respiratory care systems, emergency response and country presence, facilitating a fast response. However, the strategic focus was limited by a lack of country data and costed oxygen plans regarding the country context and appropriate mix of oxygen services.	Grantee selection for the medical oxygen portfolio was based on pre-existing implementing partners of Unitaid that had experience or expertise in emergency response (ALIMA and WHO-WHE) respiratory infectious diseases and care systems (e.g., PATH and PIH) or strong country presence (e.g. CHAI). Notably, this approach allowed Unitaid to move ahead at speed and address critical gaps with their COVID-19 investment. • However, this approach diminished the organisation's capacity to operate responsively and strategically in response to countries where the oxygen crisis was most severe. • Another important hindrance to the design and implementation of the oxygen grants for Unitaid, was the absence of, or underdeveloped, costed national oxygen system plans to support identification of critical gaps and priorities as well as quantified need. • Another challenge relates to the selection of oxygen systems such as PSA-plants versus Liquid Oxygen (LOX)). Unitaid's investment predominantly supported oxygen concentrators, PSA plants, and cylinders within the medical oxygen portfolio. This decision was justified by the speed and immediate needs of the response. However, it raises the questions about whether it was the best or most appropriate solution, especially in the absence of available nation-wide oxygen plans.	Moderate

Portfolio-level findings, lessons learnt and recommendations

The COVID-19 virus has been "one step ahead" of any institution's response to the pandemic. The successive waves of the pandemic, varying in severity, combined with the geo-political complexities, has made every international organisation's response extremely challenging. Amid this, Unitaid has demonstrated innovation and agility by rapidly developing and adapting an extensive portfolio of investments in therapeutics, diagnostics, and oxygen. This capability was also captured in the mid-term evaluation of Unitaid's COVID-19 portfolio, stated that: "*There is clear value for organisations like Unitaid that "break the mould" and reinvent themselves to respond to unprecedented circumstances. Unitaid has clearly demonstrated the value in being a fast, agile mover, adapting to the needs of the hour*".

The main conclusions and lessons learnt from the end-term evaluation, with the Test & Treat portfolio as well as oxygen investments fully implemented, are as follows:

Unitaid has been strategic, an early thinker, and innovative as well as a risk-taker, and has lived up to its "pathfinder" role by initiating the Test & Treat portfolio that recognised the need to support the test and treat continuum and improve the country level demand for testing in LMICs. As well, supporting equitable access to oxygen by sequentially investing in emergency procurements, technical assistance (TA) and market-shaping investments have enhanced long-term sustainability.

Both portfolios have delivered significant outcomes in relation to the COVID-19 response, as described above in the detailed findings table. In particular, the Test & Treat portfolio decentralised testing and supporting the updates of national policies and guidelines of countries. The medical oxygen portfolio unlocked nearly 150,000Nm3 volumes of oxygen per day through investment in liquid oxygen tanks, pressure swing adsorption (PSA) plants, concentrators, and cylinders – sufficient to treat approximately 4,000 patients per day. Unitaid's catalytic funding in the medical oxygen space has demonstrated a proof of concept on increasing oxygen supplies, contributing to unlocking global financing of other larger funders for scale-up of efforts.

However, for the most part, these investments were implemented after the peak of the pandemic had subsided, resulting in lower-than-expected contribution to saving lives affected by COVID-19. . Despite this timing, their implementation made sense due to their "insurance value" during highly uncertain times. It is also recognised that the oxygen investments will continue to save lives affected by numerous other diseases beyond COVID-19.

The implication of the delayed timing was that several the Test & Treat investments became localised, project-focused lacking wider impact. From a value for money (VfM) perspective, it could be argued that certain investments did not deliver the expected value considering Unitaid's role in the global aid architecture. This outcome was influenced by the evolving nature of the pandemic.

For the oxygen investments, there is a significant concern regarding their sustainability. There is need for further work to build upon initial progress made in achieving global market agreements and international resolutions.

However, a positive, potentially unintended outcome of the implementation of these investments by the grantees and Unitaid was their astute adaptation throughout the process. This adaptation enabled them to meaningfully respond to the evolving dynamics of the pandemic and expand their scope to support PPPR.

In general, this evaluation concludes that the series of Unitaid investments initiated from around the third quarter of 2021, while originally aimed at addressing the impact of COVID-19, will leave a significant legacy by laying a foundation for PPPR efforts. This role and impact on PPPR are extremely valuable, given the importance of supporting PPPR today. The importance of demonstrating, and to a degree "entrenching" the importance of decentralisation of test and treat, integration of testing, and oxygen systems capacity and readiness cannot be overemphasised. Moreover, the legacy of ANTICOV, in highlighting the critical need for a clinical trial platform in LMICs to prepare for the next pandemic, along with insights gained from the joint FIND-Unitaid investments in LMIC manufacturing represent significant contributions to advancing PPPR objectives.

However there remains a question about the role and added value of Unitaid's for PPPR in the manner that unfolded through the two portfolios of Test & Treat and medical oxygen. The approach was perceived as somewhat ad hoc and unsustainable within the framework of the COVID-19 response portfolio.

Recommendations

1 Unitaid's role in the next pandemic/ emergency

Unitaid has demonstrated its ability to respond to a global health emergency, apriority affirmed in its Strategy 2023-27 as one of its programmatic priorities. Key recommendations stemming from this evaluation include:

(i) Align with Unitaid's comparative advantage as a Pathfinder (offering thought leadership and evidence), Influencer (facilitating co-ordination, alignment, and market-shaping) and Investor (investments and partnerships). Avoid roles that fall outside its comparative advantage, such as funding localised emergency support, or project-based initiatives lacking wider scale-up or catalytic impact or health systems investments that require long term, continuous funding).

(ii) Enhance outcome monitoring to ensure impact through strategic and continuous monitoring of results and associated risks a, and adopting a stage-gate approach where appropriate,

2 Unitaid's role for wider PPPR related work

Similar to the previous recommendation, it is important to ensure Unitaid aligns its role with its comparative advantage such as innovations, market shaping, private-sector engagement and regional manufacturing, rather than country-specific PPPR related activities, as was the case in the adapted Test and Treat investments and procurement of oxygen systems.

In addition, Unitaid has demonstrated t its unique position in the global health architecture, alongside its technical and operational capacities, which ensures that the organisation is well positioned to lead efforts, coordinate, and build coalitions, mobilise resources, identify innovative solutions and address critical gaps.

3 Unitaid's model and approach to grant-making

There are two aspects here:

- **Model and approach during business-as-usual times:** Unitaid should critically review the range of adaptations and flexibilities introduced in its grant development and management processes during COVID-19 and seek to incorporate the most relevant approaches in its standard operating model. This includes aspects such as: i) developing partnerships and joint financing initiatives with relevant partners, moving beyond the traditional donor-grantee relationship, ii) introducing closed-door RFPs where there are efficiencies in doing so such as where specific partner skills are well recognised and unique), iii) implementing lighter touch grant packages potentially building on years of experience with established grantees such as CHAI, PATH and PSI,
- **Model and approach during a pandemic: The most effective elements** of the Unitaid model during COVID-19 should be taken forward into future pandemics with consideration to address key gap areas such as i) increasing relationships with core emergency organisations, ii) developing partnerships across the globe and beyond the SSA focus, and iii) improving internal organisation by centralising management of the emergency response portfolios, with oversight from a dedicated senior focal point or team across all relevant investments, and iv) surge capacity to strengthen staffing as needed,.

4 Unitaid's future investments

- **Guidance for future Unitaid investments in diagnostics:** Unitaid should incorporate the global and country level learning and practices brought from the COVID-19 diagnostics portfolio within Unitaid's wider diagnostics work as a whole. This includes decentralisation of testing, integration of testing, and self-testing.
- **Guidance for Unitaid's future investments in medical oxygen:** Unitaid in collaboration with GO_2AL and its partners, should focus on addressing the critical challenges for medical oxygen in LMICs as outlined in the new GO_2AL strategy. These challenges include access (demand and supply), optimal infrastructure mix and pricing, planning and data, capacitated work force and longer-term sustainability of oxygen systems. These efforts should build on improving partner coordination, resource mobilisation, communication, and synergies. Unitaid should leverage its areas of comparative advantage such as market-shaping, innovation and supporting an enabling environment).

5 Community and civil society engagement

- **Community and civil society engagement:** Unitaid needs to develop a strategic, deliberate, and integrated approach to supporting CCSE in a pandemic and PPPR context, that also adequately considers the long-term nature of impacts from this support.

6 Other

- Noting the challenges faced by the evaluation in compiling information on research studies, Unitaid should make a greater effort to track studies conducted under its investments, including key results of studies that can have an impact on other areas of work.
- Build a constructive dialogue and engagement with WHO-ERC to jointly design expedited review processes, and address barriers and enablers to more efficient research protocol reviews.

1. INTRODUCTION

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct an end-term evaluation of Unitaid's COVID-19 investments which concluded by 31 December 2023. The evaluation builds on CEPA's mid-term evaluation (MTE) of Unitaid's COVID-19 investments, which covered Unitaid's response to COVID-19 from March 2020 to December 2021.[3]

This introduction section provides a background to the evaluation and the evaluation objectives (Section 1.1), key points of context to position the evaluation and its findings (Section 1.2), and the structure of the rest of the report (Section 1.3).

1.1. EVALUATION BACKGROUND AND OBJECTIVES

1.1.1. Evaluation background

In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic.[4] This announcement was followed by several waves of the pandemic across the globe, leading to increased mortality and morbidity rates, hampered economies, and restricted international trade and movement of people. Further, inequitable access to essential and novel health technologies in COVID-19 interventions (e.g. diagnostics, vaccines, oxygen and therapeutics) in low- and middle- income countries (LMICs) limited their impact on mortality. Globally, the pandemic started to wane from April 2022. By May 2023, after seven million COVID-19 linked deaths, the WHO officially declared the COVID-19 pandemic no longer a public health emergency of international concern.

Given its mandate to find innovative solutions to public health problems affecting LMICs, Unitaid responded to the public health crisis, with two initial waves of investments designed to enhance access to COVID-19 diagnostics, therapeutics and supporting tools, including oxygen. These two waves provided up to US$ 65 million of Unitaid's core funds, including: (i) Wave 1 of US$ 30 million in March 2020;[5] and (ii) Wave 2 of US$ 35 million in bridge funding in June 2020.[6] These funds were provided through expanding and reprogramming current investments and/ or funding new investments to address some of the immediate challenges in countries for detecting and treating COVID-19. At the same time, Unitaid, along with other global development agencies, heads of state, private sector partners and other stakeholders formed a global alliance named the Access to COVID-Tools Accelerator (ACT-A), which was unequivocally committed to a "global and time-limited collaboration to accelerate the development, production and equitable global access to new COVID-19 essential health technologies." Through ACT-A, a further US$192 million was mobilised for Unitaid COVID-19 investments.

The ACT-A organized the COVID-19 response into four pillars – Diagnostics, Therapeutics, Vaccines, and a crosscutting Health Systems Connector. Unitaid and Wellcome Trust co-convened the Therapeutics pillar. In the diagnostics pillar, Unitaid was co-leading the workstream on Market Readiness as well as supporting the work on supply and country preparedness. Under ACT-A, the Oxygen Emergency Taskforce was launched in February 2021 (co-led by Unitaid and Wellcome), which transitioned into the Global Oxygen Alliance (GO_2AL) in May 2023.

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[3] https://unitaid.org/assets/Unitaid-COVID-19-mid-term-Evaluation_CEPA-Final-Report.pdf

[4] www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020

[5] Unitaid (2020) Executive Board Meeting 34th Special Session. Resolution No.5-2020-e, UNITAID/2020/R5-e: Support for measures for the global response to COVID-19, 25 March 2020.

[6] Unitaid (2020) Executive Board Meeting 35th Session. Resolution No.4: Mandate and Process for Unitaid's involvement in the Access to COVID Technologies Accelerator, 17-18 June 2020.

1.1.2. Unitaid COVID-19 portfolio and investments in scope

Unitaid's work on the diagnostics and therapeutics pillars focused on three main areas to address critical gaps along the value access chain. This included both upstream research and downstream access to diagnostics and treatments in LMICs as they became available. The areas of work included:

- **Supporting R&D and product development:** generating rigorous evidence on safe and effective treatments for COVID-19 and evidence on feasibility and product performance required to optimize COVID-19 testing options for various use cases.
- **Country preparedness:** supporting procurement and deployment of therapeutic and diagnostic products in priority countries. This included assessing marketability, generating operational evidence on optimal approaches to integrate diagnostics and treatments within national programmes and routine health services, helping to create a policy framework and design service delivery programs that link testing with access to therapeutics, including through engagement with communities for demand creation.
- **Market readiness:** early engagement with manufacturers to ensure production at scale (through licensing, technology transfer, and data sharing) and commercialization, price negotiations and regulatory support to ensure equitable and rapid access to quality products.

Figure 1.1 maps out the full Unitaid COVID-19 portfolio of investments by these areas of work (including two critical non-investment specific initiatives– the work of the Medicines Patent Pool (MPP) on licenses and sub-licenses and the work on agreements with liquid oxygen manufacturers. The investments in scope for this review are highlighted with a red box – and reflect investments that were not significantly advanced at the time of the MTE as well as new investments since the MTE. They cover Unitaid investments in the following portfolios:

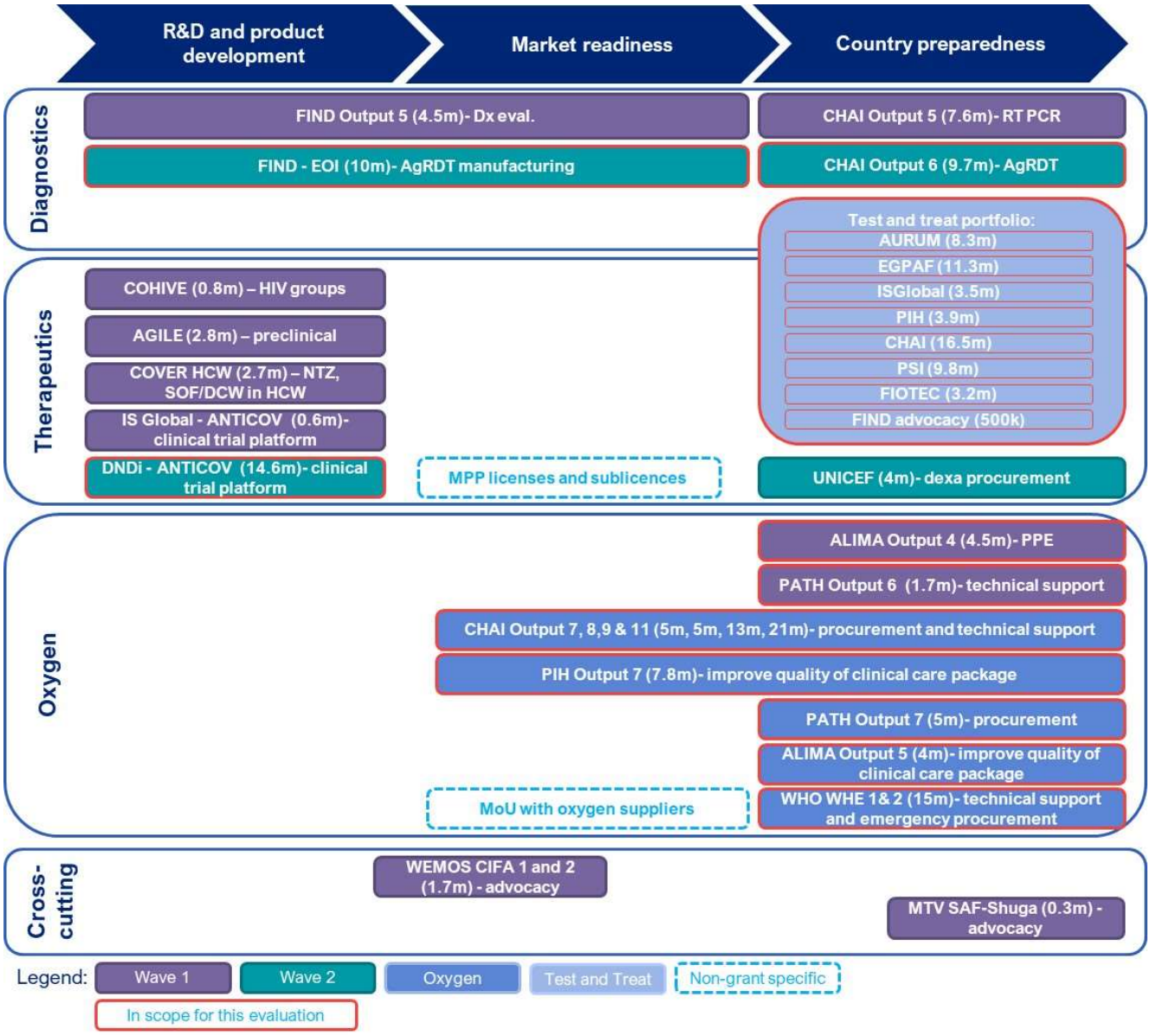
- COVID-19 Test and Treat (seven investments: AURUM, EGPAF, ISGlobal, PIH, CHAI, PSI, Fiotec) plus the joint FIND-Unitaid investments in advocacy grants.
- Medical oxygen in the context of COVID-19 (eleven investments across five grantees: CHAI, ALIMA, PIH, PATH, WHO WHE); and
- Select investments under the Therapeutics (1 investment, ANTICOV by DNDi) and Diagnostics (two investments by FIND and CHAI[7]) portfolios.

This covers 22 investments (across 11 grantee organisations), with at least US$67 million in investments in therapeutics and diagnostics and US$83 million in medical oxygen.

Appendix A provided a list of investments in scope for this evaluation.

[7] CHAI's diagnostics investment noted here related to work on the introduction of antigen RDTs. Given linkages with the work conducted by CHAI under its Test and Treat investment, and CHAI's seamless working between the two investments, it has not always been possible to separate out an assessment of the two investments.

Figure 1.1: Mapping of Unitaid COVID-19 portfolio of investments[8]



1.1.3. Objectives for the end-term evaluation

As noted, in May 2023, the WHO officially declared the pandemic over, and by December 2023 nearly all the Unitaid COVID-19 investments were closed. This end-term evaluation builds on the findings and recommendations of the mid-term review, with a focus on the outcomes and impacts achieved through the investments.[9] It is also forward-

[8] The UNICEF dexa procurement investment was for US$4m, but later recovered from UNICEF and hence no Unitaid funds were expended on this in the end.

[9] Most of the investments made by Unitaid were in their infancy or had only been running for up to one year when the mid-term review was conducted (at which point there was no available vaccine and only limited treatment options. As such, the mid-term review conducted by CEPA was primarily focused on the relevance and coherence of the investments supported by Unitaid within the global response and alongside other partners, and the efficiency of the response with limited assessment on outputs, outcomes and impacts. The full report is available here: https://unitaid.org/assets/Unitaid-COVID-19-mid-term-Evaluation_CEPA-Final-Report.pdf

looking and assesses how Unitaid has strengthened health systems and contributed to global and national capabilities in pandemic prevention, preparedness, and response (PPPR). In particular, the end-term evaluation objectives are to:

- assess the contribution of Unitaid's investments to the COVID-19 response and the sustainability of the response beyond the emergency; and
- draw lessons learnt and recommendations for Unitaid to apply to its future PPPR work and continuing diagnostics and medical oxygen work

Priorities for this evaluation highlighted during the inception phase have included the following:

- Focus on gathering country-level insight given need for more information on the country level in addition to grantee reporting and considerable information on the global level insights from other sources (e.g. evaluations of ACT-A, reviews by Unitaid).
- Lessons learnt covers an assessment of whether Unitaid reacted optimally to the COVID-19 pandemic and how and what it should do differently in the face of another health emergency. Lessons also cover whether Unitaid can adopt any of the features of its model under COVID-19 within its core portfolio approach. The learnings from the review are expected to inform how Unitaid should position its future diagnostics and oxygen work.
- While the focus is on results (including sustainability) as well as the forward-looking context for PPPR, the review is comprehensive and cover all aspects of the OECD DAC evaluation criteria for the portfolio. The Unitaid process aspects were largely covered in the mid-term evaluation.
- The analysis is at the portfolio and Unitaid level and has not entailed a deep dive into each investment. Select country case studies have however entailed a deeper review of the investments in the country.

1.2. KEY POINTS OF CONTEXT

It is important to highlight upfront the following contextual issues that present key "facts" related to the evolution of the pandemic and the Unitaid COVID-19 portfolio that have guided our analysis and assessments.

- First, as has become evident through multiple evaluations and reviews of global health/ donor organisations' funding for COVID-19, no organisation has been "ready in time" [10], with an assessment of "relative" agility being more instrumental. The mid-term evaluation noted that *"Unitaid acted very quickly after the start of the pandemic, before most other international organisations developed their response, and before ACT-A was set up"*. It has also been recognised that supporting the pandemic during the pandemic is already too late – and systems and capabilities needed to have been supported in advance of the start of a pandemic for an effective and impactful response. That said, it is also recognised that Unitaid's response to COVID-19 built on its years of experience in different aspects such as product licensing and decentralised testing,
- Second, this evaluation seeks to assess the extent of adaptability of the Unitaid COVID-19 investments to the pandemic, and especially towards PPPR when the pandemic severity began to wane. However, as none of the investments were designed with this objective and hence have had varying degrees of success in terms of being able to effectively pivot or adapt for impact. It is noted however that the thinking behind some of the later oxygen investments was more long term in nature, i.e., beyond an immediate response to the COVID-19 pandemic.
- Third, as highlighted in consultations with the Unitaid Secretariat, investment related decisions had to be made quickly and in a context of uncertainty. It was necessary therefore, for Unitaid to take certain risks recognising potential benefits of "no-regret decisions" and implement investments with limited information and in dynamic

[10] For example, see Open Consultants, 2022, External Evaluation of the Access to COVID-19 Tools Accelerator (ACT-A)

circumstances. The oxygen investments were particularly key in this regard, as Unitaid took a calculated risk acknowledging that oxygen would serve as a life-saving commodity even beyond the COVID-19 pandemic.

- Fourth, Unitaid's response to COVID-19 is broader than its portfolio of COVID-19 specific investments and includes its work through ACT-A as well as other wider work such as on intellectual property by the Medicines Patent Pool (MPP) and engagement with oxygen manufacturers as part of its market shaping efforts. This role and wider engagements have impacted the results from the specific investments, which is important to acknowledge and account for.
- Fifth, sustainability in the context of the investments made by Unitaid under its COVID-19 response has a very different connotation from its standard investments in HIV, TB and malaria (HTM). Unlike HTM investments, sustaining COVID-19 response investments at pandemic level is unnecessary, and the drivers for sustainability differ. For example, sustainability of these investments is linked with health systems strengthening and greater attention on funding through governments for PPPR. This distinction is particularly evident in the Medical Oxygen portfolio, which requires careful consideration regarding scale-up for PPPR and other medical oxygen uses, compared to the Test & Treat portfolio.

1.3. STRUCTURE OF THE REPORT

Following this introduction section, the rest of the report is organised as follows: Section 2 presents the evaluation approach and methodology; Section 3 presents the evaluation of the Test and Treat portfolio and select investments on therapeutics and diagnostics; Section 4 presents the evaluation of the medical oxygen portfolio; and Section 5 collates a cross-portfolio summary of findings and conclusions, lessons learnt and recommendations.

The main report is supported by the following appendices: Appendix A lists the investments in scope; Appendix B provides the Theory of Change; Appendix C contains the bibliography; Appendix D lists the interviewees consulted; Appendix E includes the interview guides; Appendix F presents Unitaid progress against mid-term review recommendations; Appendix G offers supporting information for Section 3 (Test & Treat Evaluation), and Appendix H provides supporting information for Section 4 (Medical Oxygen Evaluation). In addition, a separate Annex contains country case study reports for Brazil, Peru and Zimbabwe (Appendices I-K).

2. EVALUATION APPROACH AND METHODOLOGY

This section presents the evaluation approach comprising the evaluation framework and questions as well as a description of the theory-based approach employed for this evaluation and the supporting Theory of Change (Section 2.1); evaluation methods and limitations (Section 2.2) and framework for assessment of robustness of findings (Section 2.3).

2.1. EVALUATION FRAMEWORK AND THEORY-BASED APPROACH

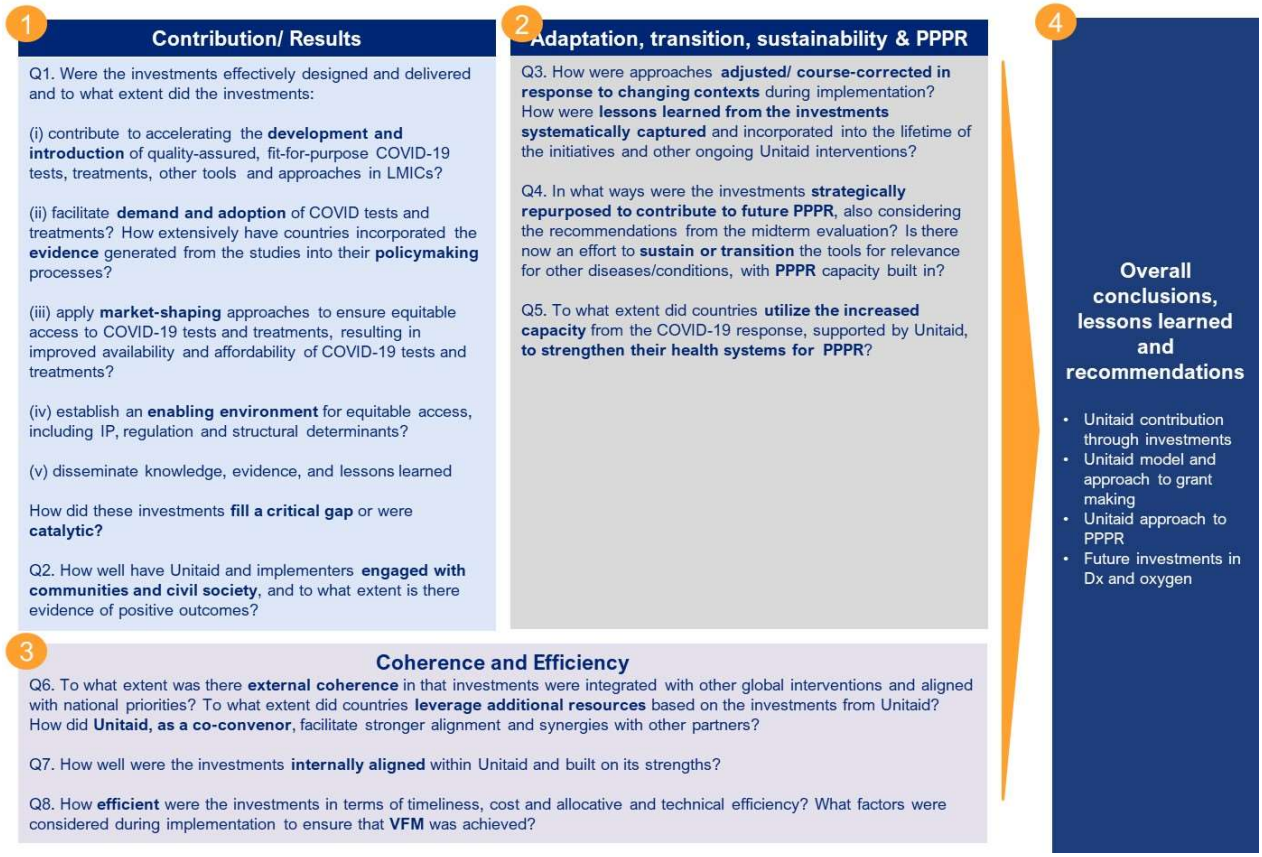
2.1.1. Evaluation framework and questions

The evaluation framework, comprising four key pillars, with key evaluation questions is set out in Figure 2.1 over page. As the figure demonstrates:

- Pillar 1 assesses the contribution of Unitaid's COVID-19 investments ("Contribution/ Results"), and primarily covers the OECD DAC evaluation criteria of effectiveness and impact. The focus is on assessing the longer-term/ next level of results i.e., outcome and impacts, as feasible based on the investment scope and available data.
- Pillar 2 assesses the sustainability of the investments and their effective transition to PPPR ("Adaptation, transition, sustainability and PPPR"). It covers the OECD DAC criteria of sustainability.
- In addition to the two core pillars of our evaluation framework, there is a third "cross-cutting" pillar on "Coherence and Efficiency" that covers a range of questions relevant to these two OECD DAC evaluation criteria. As noted previously, most of the evaluation questions included in this pillar build on the assessments conducted under the MTE but have been updated for additional information and findings.

Findings across the evaluation questions contribute to the development of evaluation conclusions, lessons learned and recommendations (pillar 4).

Figure 2.1: Evaluation framework and questions



2.1.2. Theory of Change and theory-based approach

In line with good evaluation practice, we have employed a theory-based approach to this evaluation. This is based on the Theory of Change (TOC) of the Unitaid COVID-19 portfolio, developed by Unitaid (reproduced in Appendix B).

In the application of this TOC for this evaluation, we have noted the following:

- Outputs and outcomes have not been sufficiently differentiated (e.g., evidence availability is mentioned under both outputs and outcomes). For the purposes of this evaluation, we have considered outputs to be the immediate effect of the investment work (e.g., generation of evidence, supply of Dx and Tx, etc.). Given the objectives of the evaluation to focus on outcomes and impacts, we have not focused on output measurement in detail. Further, under outcomes we have also considered aspects that are noted as impacts (specifically, PPPR- related contributions, efficient responses through integration of services). Our measurement of impacts is closer to aspects identified in the draft TOC for PPPR developed by the Unitaid Secretariat (e.g., improved public health impact in LMICs during and between pandemics (reduced mortality and severe disease, reduced disease transmission), minimized LMIC economic and social impact of pandemics and accelerated recovery, improved equitable access to health tools for LMICs for non-pandemic diseases).

- In addition, important "impact pathways" have not been adequately reflected in the Unitaid COVID-19 response TOC. For example, in terms of outcomes, we have considered what is the result of a "failed" investment (which can be expected given Unitaid's risk-taking role as an innovator, pathfinder, etc.). This means, if an investment has not met its intended objectives (for any number of reasons including reduced relevance with the evolution of the pandemic), what can be understood to be the results of that investment (e.g., could be still important to support wider evidence generation and capacity building from a PPPR perspective). Other extensions of the impact pathway have been with regards to contributions to health systems strengthening (HSS) and PPPR, as

well as ultimately public health and economic impacts beyond COVID-19 related health issues (where the investments have facilitated a re-focusing on routine services for other diseases by taking up some of the burden, and as the technologies and tools have been employed for other disease areas).

- The evaluation has highlighted additional risks and assumptions than noted in the TOC. The current TOC notes risks and assumptions that were important at the time of the peak of the pandemic. However, in the current context, other risks and assumptions assume more importance. Key amongst these is the prioritisation of COVID-19 following the waning of the pandemic. Also, an important assumption is that the grantees' work is relevant for other disease and health areas and can be translated across and sustained. Another risk is with regards to the evolution of the global political economy in terms of effectively managing inequitable access for LMICs.

2.2. EVALUATION METHODS AND LIMITATIONS

2.2.1. Description of evaluation methods

The table below (Table 2.1) details the key methods applied for the evaluation.

Table 2.1: Evaluation methods

Method	Detail
Document review	Rapid review of Unitaid grant documentation (project plans and amendments where relevant, with a focus on the latest available progress reports); wider Unitaid documentation such as the Strategy 2023-27, PPPR related documents, etc.; and documents from other key stakeholders including ACT- A, Global Fund, UNICEF, WHO, amongst others. The bibliography is provided in Appendix C.
Quantitative data analysis	Review of grant data (including results data, programmatic data, budget). *As Unitaid is aware of this data we have not conducted an in-depth analysis of grant data.*
Global level interviews	Semi-structured key informant interviews (KIIs) and focused group discussions (FGDs) have been conducted with: (i) 29 Unitaid staff involved in the COVID-19 portfolio; (ii) 27 individuals representing grantees for different investments; and (iii) 2 partners/ external stakeholders, given the focus of this evaluation on country level insights. The list of global level interviews is provided in Appendix D along with relevant interview guides in Appendix E.
Country case studies	Given the priority accorded in this evaluation to country feedback and assessing the contribution of the Unitaid COVID-19 investments at the country level, country case studies are a key method for this evaluation. A total of 8 country case studies have been conducted. Three country case studies have been carried out in person by a mix of CEPA team members (Peru and Zimbabwe) and associates (Brazil). A further five country case studies have been carried out desk-based with online/telephone interviews (Bolivia, Cameroon, Ethiopia, Malawi, and India). For each country we have consulted with in-country teams of the grantees, government representatives, civil society representatives, partners, and health facility staff and workers. The number of interviews for the in-person country case studies has been more extensive than the desk-based case studies. In total, 144 stakeholders were included in consultations across the eight case studies. The selection of countries was based on where multiple and diverse investments have been implemented and was ultimately guided by Unitaid. Country case study reports for Peru, Zimbabwe and Brazil are included in a separate annex (Appendix H-J), alongside report-specific bibliographies and interview lists. Interview lists for the remaining countries are included in Appendix D alongside interview guides in Appendix E.

2.2.2. Limitations

Key limitations are as follows:

- The evaluation focuses on country-level input on investment results and does not benefit from global stakeholders' perspectives on the relevance and positioning of these investments in the wider funding landscape (particularly important for assessment of evaluation questions on relevance and coherence. For example). As such, the evaluation of the results of the investments is very much from the country perspective only, and largely limited to

key stakeholders familiar with the Unitaid investment. Further, global level interviews have largely been with the Unitaid Secretariat and grantees, so there could be an element of bias in the assessment of results given potential conflict of interest from these "internal" stakeholders.

- Country selection for case studies was determined by Unitaid based on a mix of regions, countries that received multiple investments and countries which were of specific interest to Unitaid. Because an independent selection panel was not used, it cannot be assumed that the findings are representative of all countries or represent a balance between good and poor performing country investments, which would be the approach followed with an independent selection approach
- Given closure of projects and staff turnover, it has sometimes been difficult to engage with most relevant stakeholders, including project staff and government counterparts, given the Additionally, the gap between the end of the emergency phase of the pandemic and this final evaluation may have led to recall bias, with some details of the investments being forgotten and waning interest among stakeholders.
- Non-grantee and non-Unitaid stakeholders make up a very small proportion of consultees at the global level, so there could be an element of bias in the assessment of results given potential conflict of interest from these "internal" stakeholders. However, the focus of this evaluation was on country feedback and assessment of portfolio results at the country level, and the proportion of non-grantee/non-Unitaid stakeholders at the country level was much higher, approximately 60%.
- Document and data review has been light touch with a focus on the latest progress reports, to ensure completion in the compressed timelines and available budget for this evaluation.

2.3. Robustness assessment

We have critically analysed and triangulated the evidence gathered through these methods to draw evidence-based and robust conclusions for the evaluation. A specific robustness assessment framework has been employed that considers both the quality (i.e., source of evidence and its validity) and quantity (i.e. triangulation) of evidence and assesses robustness across a four point scale (see Table 2.2 below). All robustness rankings are *relative* robustness rankings, based on careful consideration and are ultimately based on the judgement of the evaluators.

Table 2.2: Robustness rating for emerging themes/main findings

Rating	Assessment of the findings by strength of evidence
Strong (1)	The finding is supported by data and/or documentation which is categorised as being of good quality by the evaluators; **and** the finding is supported by majority of consultations, with relevant consultee base for specific issues at hand
Moderate (2)	The finding is supported by majority of the data and /or documentation with a mix of good and poor quality; **and/or** the finding is supported by majority of the consultation responses
Limited (3)	The finding is supported by some data and/or documentation which is categorised as being of poor quality; **or** the finding is supported by some consultations as well as a few sources being used for comparison (i.e., documentation)
Poor (4)	The finding is supported by various data and/or documents of poor quality; **or** the finding is supported only by a few consultations or contradictory consultations

3. EVALUATION OF THE TEST AND TREAT PORTFOLIO AND SELECT DIAGNOSTICS AND THERAPEUTICS INVESTMENTS

This section provides an evaluation of the Test and Treat portfolio of seven investments (Section 3.1), the FIND-Unitaid joint investment in advocacy grants (Section 3.2), the ANTICOV investment (Section 3.3), and the joint FIND-Unitaid investment in RDT manufacturing (Section 3.4). Each section provides a full evaluation of the portfolio/ investment covering all evaluation questions included in the evaluation framework described in Section 2.1.

3.1. TEST & TREAT PORTFOLIO

3.1.1. Portfolio context and description

Following an initial set of investments by Unitaid in diagnostics and therapeutics for COVID-19, the evolution of the pandemic around mid-2021 highlighted the need to support a continuum of testing and treatment. This approach aimed to address declining testing rates, gaps in community-based diagnostics and self-testing, and to support the rollout of anticipated new antivirals through updates to guidelines and regulations. Despite diagnostics and therapeutics being at different stages of development and typically considered separate markets with independent stakeholders, it was globally recognised that integrating test-and-treat strategies would be a fundamental component of the COVID-19 response.[11]

The Test and Treat portfolio was conceived based on this context. CEPA's mid-term evaluation indicated that Unitaid was a frontrunner in responding to these challenges, a finding also confirmed through discussions with the Unitaid Secretariat for this end-term evaluation. In collaboration with FIND, Unitaid issued a request for proposals (RFP) for test and treat investments in various countries and awarded seven investments in September/ October 2021. These investments, detailed in Table 3.2, totalled US$47 million and aimed to support the early adoption of comprehensive packages of care across 22 countries in Africa, Latin America, Southeast Asia, and the Western Pacific. In particular:[12]

- For diagnostics, the focus was on addressing access and implementation barriers for Ag-RDTs and self-tests, integrating these products within existing laboratory and testing networks and decentralising access. Additional objectives included increasing awareness and demand for COVID-19 testing tools, shortening diagnosis time, and supporting national policies to identify and validate priority use cases for different diagnostic tests.
- For therapeutics, the objective was to support governments in preparing for the introduction of WHO-recommended therapeutics, including the enabling environment for product rollout. Other priorities included support for treatment literacy and demand creation, as part of a COVID-19 care package. The grants were positioned to rapidly accelerate adoption and scale-up once products came to market and ensuring linkages between testing and treatment services were strong.

Most projects received No-Cost Extensions and were closed between August and December 2023.

Table 3.2: Test and Treat portfolio – details on the seven investments

Grantee	Grant title	Budget	Geography (CCS in bold font)
CHAI	Enhancing access to COVID-19 test, isolate, care, and treat interventions within healthcare systems in LMICs	US$11.8m	Cambodia, **Cameroon**, DRC, **Ethiopia**, Kenya, Ghana, **India**, Laos, LATAM, Lesotho, **Malawi**, Nigeria, Papua New Guinea, Vietnam, **Zimbabwe**

[11] ACT-A, Report of ACT-A Council Working Group on Diagnostics and Therapeutics, 2022

[12] Unitaid, Test & Treat and Oxygen Extension Package: Executive Board Report, 2022

Grantee	Grant title	Budget	Geography (CCS in bold font)
Population Services International (PSI)	STAR, Africa, Asia, Americas COVID-19 Preparedness (3ACP)	US$8.8m	**Brazil, India, Malawi,** Nigeria, South Africa, Uganda, **Zimbabwe**
Aurum	Improving public health outcomes through enhancing accelerated access to care and treatment innovation for COVID-19	US$8.4m	**Ethiopia**, Philippines (KNCV), Ghana, Mozambique, South Africa
EGPAF	Catalytic COVID-19 Action Project (CCA)	US$7.3m	Kenya, **Cameroon, Zimbabwe**
Partners in Health (PIH)	Enhancing access to COVID-19 test, isolate, care, and treat interventions	US$3.9m	**Peru**
IS Global	Enhanced and equitable coverage of COVID-19 testing and treatment in Bolivia and Paraguay	US$3.5m	**Bolivia,** Paraguay
Fiotech	Implementation and effectiveness analysis of testing, quarantine, e-health and tele monitoring (TQT) Program at Primary Health Care to decrease acute respiratory syndrome attributed to infection by the SARS-COV-2 virus in Northeast Brazil.	US$3.3m	**Brazil**

3.1.2. Summary of mid-term evaluation findings

Test & Treat investments had just begun implementation when CEPA conducted the mid-term evaluation of the Unitaid COVID-19 portfolio between late 2021 and early 2022. Key findings through the mid-term review were as follows:

- The Test & Treat investments were viewed as **highly relevant** as they frame the COVID-19 response from a holistic perspective– taking into account the full continuum of care and focusing on piloting various models (e.g., integration with HIV, TB and MNCH services; introduction of self-testing). The investments are supporting country-level demand creation and adoption, as well as evidence generation about various test and treat models, thereby **addressing a much-needed gap** to encourage the scale-up of existing diagnostics and the introductions of treatments which are beginning to come through the pipeline.
- The investments were **sensibly set up as a package** and **implemented in a wide range of geographies**.
- The portfolio was **in line with Unitaid's comparative advantage** in terms of piloting/testing models of care and generating evidence, whilst also introducing innovative solutions.
- Although it is widely acknowledged that there was an absence of proven therapeutics which could be linked to diagnostics, some global stakeholders noted that the Test & Treat RfP, launched by Unitaid one year after the other therapeutic grants – came **"late in the game"**. This issue has also been identified in the ACT-A Strategic Review in relation to the global approach to COVID-19.
- Unitaid adopted a **novel and proactive approach** to the Test & Treat investments, by issuing an RfP to preselected grantees and requiring a **lighter-touch proposal package**. This enabled investments to be approved much faster than standard Unitaid timelines for Grant Agreement Development processes.
- The initial **one-year timeline** for the Test & Treat investment was viewed as tight and unrealistic in relation to the investment objectives. However, it was also recognised that the intention of the short timelines has been driven by the emergency needs of the pandemic.

3.1.3. Evaluation pillar 1: Contribution/ Results

This section sets out the achievements of the Unitaid Test & Treat investments and the impact in countries.

Overall finding: The Test and Treat investments made important contributions to increasing the demand and adoption of COVID-19 diagnostics by decentralising testing to lower levels of health care and providing evidence and support for updating policies and guidelines. However, because these investments were made later. They did not support the acute phases of the pandemic, resulting in a lower impact specifically related to COVID..

The key results of the Test & Treat investments should be considered in terms of the portfolio's impact on health systems and PPPR, which the investments pivoted towards supporting. However, this contribution is misaligned with Unitaid's role as a one-time catalytic funder.

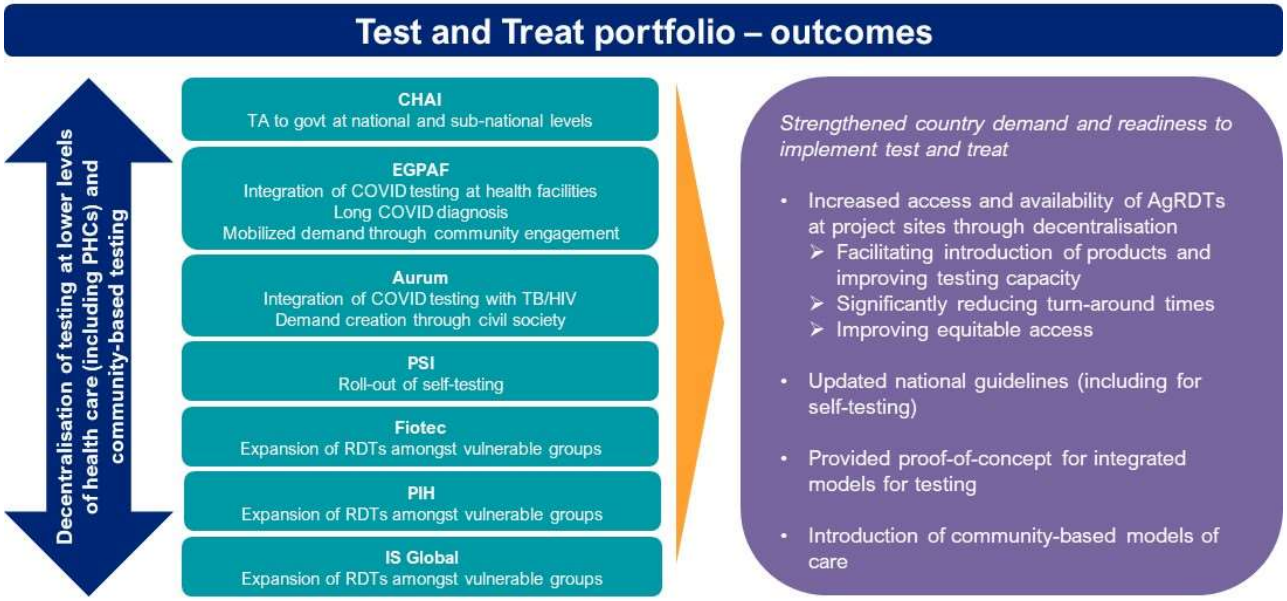
Detailed findings	Robustness
1. The Test and Treat portfolio successfully supported an increase in the demand and adoption of COVID-19 diagnostics, by decentralising testing at the primary healthcare level and supporting policy and guidelines updates.	**Strong**
2. There was some useful contribution to the development and introduction of AgRDT through market shaping approaches, but this was not the mainstay of the portfolio.	**Strong**
3. Attempts to establish a continuum of care with treatment options was largely not achieved, mainly due to external factors beyond Unitaid and grantee control such as the non-availability of therapeutics.	**Strong**
4. Community engagement was one of the critical gaps in the global COVID-19 response. Across the Test & Treat portfolio investments in community engagement had a positive impact on the management of COVID-19 cases in project sites and importantly helped enhance community trust in the primary health care system. However, the short-term nature of the investments limited their long-lasting impact.	**Strong**
5. The timing of the investments has meant that they have not supported the acute phases of the pandemic and thereby have had a lower COVID-related impact. In addition, there has been wide variation across and within grants in terms of their impact on COVID, with many examples of localised project-based impact without a wider impact on other areas or at the national level.	**Moderate**
6. There has been some useful impact of the projects in terms of facilitating decongesting of health facilities and delivery of other essential health services which were constrained due to the focus on COVID.	**Moderate/ Low**

Finding 1: The Test and Treat portfolio successfully supported an increase in the demand and adoption of COVID-19 diagnostics, by decentralising testing at the primary healthcare level and supporting policy and guidelines updates.

Robustness: Strong, well supported in the document review and consultations at the country level as well as with Unitaid and the grantees.

Based on the outcomes that Unitaid seeks to affect, the Test and Treat portfolio has mainly contributed to facilitating the demand and adoption of COVID tests. Figure 3.1 outlines the different ways in which each of the seven grants impacted demand and adoption for COVID-19 testing in their focus countries.

Figure 3.1: Contribution of the Test and Treat portfolio to demand and adoption in countries



As shown in the right-hand side box of Figure 3.1, the Test and Treat portfolio has primarily supported an increase in demand and adoption of COVID-19 tests mainly RDTs and self-tests, through:

- increasing availability and access to testing, including for vulnerable groups through decentralisation.
- developing and updating policies and guidelines through evidence dissemination and technical assistance.
- strengthening the delivery of testing through integration of services.

In addition to the contributions above, projects also supported community engagement and demand generation for COVID-19 tests and tools, discussed further under finding 4. Each of these aspects with country-specific examples is described in turn below.

Decentralisation of COVID-19 testing and increased availability of AgRDTs at project sites

As per the Unitaid COVID-19 progress report, through the Test & Treat portfolio, Unitaid grantees supported **9,954 health facilities in 22 countries** to decentralise and integrate COVID-19 testing within existing services. Over **352,000 COVID-19 tests were administered** at research and implementation sites, with 6% positivity and 90% of positive people linked to care. **92,500 self-tests** were also conducted.[13] Grantees also supported the roll-out of community-based testing strategies. Country specific examples of this decentralisation, its importance and impact are as follows:

- **First time introductions:** In Malawi, PSI supported the first in-country training to use and deliver professional AgRDTs outside of laboratory services and made testing available within outpatient clinics. Through Unitaid's support, PSI was able to train clinicians and nurses on testing and introduce testing into sites which were most readily accessible to communities. In Zimbabwe, stakeholders reported that decentralisation of antigen testing, was a "game-changing" contribution. This was most significant for the provider-administered Ag-RDT which came at a crucial time, and later for self-testing. Approximately 6,000 healthcare workers were trained by grantees to

[13] Unitaid (2023), Annual COVID-19 Results Report

deliver COVID-19 services across all countries in the Test & Treat portfolio, although this is likely an underestimate as not all grantees reported the exact number of health workers trained.[14]

- **Significant reductions in test result turnaround times:** Prior to the work by ISGlobal, the municipal government of Cochabamba in Bolivia had to send PCR tests to the United States with a turnaround time of approximately five days for results. Through the Unitaid investment, ISGlobal not only expanded access to AgRDTs, but also strengthened the molecular laboratory in the region. This significantly improved turnaround times, and the capacity of the region to diagnose COVID-19 and intervene within a clinically relevant period. ISGlobal found through baseline and endline assessment that the time from onset of symptoms to diagnosis decreased from 4.1 days in September 2021, to 2.3 days in July 2023[15], a finding which was corroborated by government stakeholders. Another example is in the Northeast of India, where PSI/ PATH helped fund a genetic sequencing machine which contributed to the testing capability in the region. Previously tests had to be sent to other states of India with long turnaround times. The equipment support was timely and allowed for the highest detection of cases amongst the northeastern states which, according to stakeholder interviews, also contributed to lower case fatality rates.

- **Improvements in equitable access:** The decentralisation of testing services not only increased the volume of people tested, but also contributed to improving equitable access to COVID-19 tools and services at project sites, with several grantees specifically targeted more vulnerable populations. For example, Fiotec actively expanded testing infrastructure at health facilities serving socioeconomically vulnerable populations in Salvador and Rio de Janeiro. In these areas, 63% of individuals tested through health units supported by Fiotec reported never having been tested before. Similarly, in Bolivia, ISGlobal strengthened health facilities in the South of Cochabamba to provide COVID-19 testing services, focusing on populations that are socioeconomically deprived with limited access to health services. Additional examples of grantees expanding testing access to vulnerable groups are discussed under Finding 4 on community engagement.

Evidence dissemination and policy and guideline updates

Several grantees under the Test & Treat portfolio conducted operational research and provided technical assistance which led to updates in national diagnostic policies and guidelines. Across country case studies and excluding operational research conducted by CHAI, grantees conducted at least 31 operational research studies.[16] Although an exact number of studies supported by CHAI across all countries is difficult to ascertain with the available information, across all Test & Treat countries, CHAI conducted research on ten use cases for AgRDTs. Grantees also made significant efforts to disseminate the results from projects and research studies including through international and national conferences, published manuscripts, online forums, and meetings with key stakeholders including policy and decision makers. A list of studies conducted per country case study is presented in Table G.2 and a summary of all operational research and studies conducted by grantee is presented in Table G.3 of Annex G.

As reported in Unitaid's COVID-19 summary progress report, 12 countries updated their COVID-19 diagnostic norms including four countries, Cameroon, Ethiopia, Malawi and Zimbabwe, which included self-testing. Stakeholders credited grantees as having accelerated the development of guidelines, with one stakeholder in Zimbabwe remarking that *"self-testing guidelines were adopted by the MoHCC faster than anticipated"* due to support from PSI.

[14] Grantee annual reporting

[15] ISGlobal (2023), Informe Final de Evaluación

[16] This is based on a review of the grantee reports and where it was possible to clearly decipher number of studies conducted. This wasn't possible to glean from the CHAI reports, so has been excluded from this total.

Table 3.3 focuses on key areas of progress on case study countries[17], in terms of diagnostic policy changes. Some of the policy changes highlighted also relate to integration of services.

Table 3.3: Diagnostic policy changes in case study countries[18]

Country	Policy changes enabled (diagnostics)
Cameroon	• CHAI supported updates made to National Guidelines on COVID-19 RDT testing in pharmacies (public and private) • CHAI supported updates made to National Guidelines on COVID-19 testing • Evidence generated by EGPAF demonstrating that integration was a feasible and beneficial approach eventually contributed to a Ministry of Health memo. However, as will be explained in this section on the country example, the implementation status of the memo remains unclear.
Ethiopia	• CHAI and Aurum supported revision of COVID-19 AgRDT strategy • CHAI and Aurum prepared new national guidelines on COVID-19 AgRDT self-testing • CHAI provided support in developing minimum standards for an integrated sample transport and result delivery system, and assessment of alternative transport options
India	• CHAI supported development of a governance framework for COVID-19 surveillance
Malawi	• CHAI and PSI provided guidance on a national COVID-19 testing policy which included self-testing
Zimbabwe	• CHAI and EGPAF supported Zimbabwe to adopt WHO guidelines on Ag-RDT testing and developed job aids and training tools for cascading Ag-RDT training nationally • Evidence on self-testing established by PSI and CHAI is credited with having accelerated the acceptance of self-testing guidelines

Integration of services

The Aurum Institute and EGPAF supported and provided proof-of-concept that integrating COVID-19 within other essential services offered at healthcare facilities was beneficial and feasible. In Ethiopia and other countries, Aurum promoted bidirectional screening for patients presenting with TB or COVID-19 symptoms. In Cameroon and Zimbabwe, EGPAF supported the integration of COVID-19 testing within points of entry such as HIV and SRH services, TB services, maternal and child health, urgent care services and outpatient services (see Box 3.1).

Box 3.1: Zimbabwe: Decentralisation and Integration for stronger test & treat service delivery

A key value-add of Unitaid investments was the integration of COVID-19 testing with essential services and with HIV and SRH services for vulnerable and key populations. EGPAF's leadership in integrating COVID-19 testing in Harare facilities, the epicentre of the COVID-19 pandemic in 2021-2022 in terms of volume and treatment of severe cases, was praised by government as enabling essential health services such as tuberculosis, HIV, maternity, and outpatient to continue. EGPAF's support initially focused on the three high-volume public hospitals in Harare where severe cases were being referred. In total, EGPAF trained 100 staff in integrated COVID-19 services into the MNCH, TB, and HIV clinics at the seven supported sites, providing a single-entry point for client services. This integrated model was intended to be scaled but became less relevant as the pandemic waned.[19] EGPAF has since established a long COVID clinic within Parirenyatwa Hospital and Wilkins Infectious Disease Hospital. While stakeholders considered this has come late and only in Harare, it has integrated NCD and long COVID services.

[17] In addition to changes made to policies in case study countries, the following Test & Treat portfolio countries also made policy changes related to diagnosis and integration enabled by grantees (and in particular, CHAI): Democratic Republic of Congo, Ghana, Kenya, Guyana, Lesotho, Nigeria, Papua New Guinea, Laos.

[18] Sources for information include final progress reports from grantees, and country case study consultations.

[19] This is primarily because EGPAF support was limited to a small number of hospitals and this is through the public sector. Additional funding would be required to scale up the integrated services.

PSI introduced COVID-19 testing in New Start Centres, and in outreach services, through community health workers (CHW) and peer mentors for key and vulnerable populations (KVPs), in formal and informal workplaces, and sex worker clinics alongside the Centre for Sexual Health and HIV/AIDS Research (CeSHHAR). Clinically, the availability of COVID-19 testing was highly relevant for HIV and TB-infected patients, given their immunocompromised status. Further, the availability of COVID-19 testing was considered by clinic stakeholders to have attracted new clients to New Start Centres, serving as an entry point for HIV and SRH services and for mental health services for which demand increased during the pandemic.

Clinic staff confirmed that integration has had lasting impact with ongoing efforts to screen for NCDs amongst HIV and TB patients and integrate screening for cholera in HIV and SRHR given the recent outbreak. This is discussed further in Box 3.8 on the sustainability of test & treat interventions.

Integration of COVID-19 testing was shown to be a highly successful model, which increased the number of people tested and standardised the approach to COVID-19 testing at the primary health care level including for asymptomatic cases. The approach was clinically relevant for HIV- and TB- patients, given their immunocompromised status and because TB patients and COVID-19 patients may present with similar symptoms. The model also provided continued monitoring of COVID-19 rates within high-risk and vulnerable groups even as the number of COVID-19 cases waned. For example, in Ghana, Aurum found that tri-directional testing initiatives for TB, HIV and COVID-19 among high-risk mining communities was able to uncover critical health data and forge a path for more inclusive and high-quality healthcare in remote communities. The National Tuberculosis Plan is expecting to leverage insights from the project and replicate similar models in underserved regions.[20] Furthermore in Malawi, integration of routine COVID-19 testing in outpatient clinics by PSI helped demonstrate that the pandemic followed a seasonal pattern of approximately six months. This allowed hospitals to predict when the next wave of COVID-19 might occur. This proof of concept showed that integrated and routine testing, including at lower levels of the health system could strengthen disease surveillance efforts.

There were instances where integration models, despite initial success in project sites, did not see widespread adoption. For example, in Cameroon, government stakeholders noted that facilities supported by EGPAF under the integration model provided stronger COVID-19 test and treat services. The Ministry of Health issued a memo encouraging other facilities to adopt this strategy. However, it was unclear to what extent other facilities in Cameroon implemented the model. Consultees reported limited evidence suggesting that adoption in other facilities was hindered by resource constraints and insufficient supervision from the Ministry of Health or other partners. Therefore, the impact of the memo remains uncertain.

Finding 2: There was some useful contribution to the development and introduction of AgRDT through market shaping approaches; however, this was not the mainstay of portfolio.

Robustness: Strong, well supported in the document review and consultations at the country level as well as with Unitaid and the grantees.

Although not the mainstay of the Test and Treat portfolio, certain investments contributed to the development and introduction of affordable rapid antigen tests (professional and self-tests), including through market-shaping approaches. Some of these aspects are also covered in the demand and adoption related achievements described above, due to overlap in workstreams and achievements.

Facilitating the introduction of rapid antigen tests in countries was quite challenging. For countries to efficiently transition from PCR testing to antigen testing for COVID-19, a paradigm shift was needed to increase the acceptability of antigen testing. This shift required major policy changes and adjustments to logistics of diagnostic systems. However, the switch from PCR testing to rapid antigen tests is crucial for ensuring the decentralisation of testing. Within the Test & Treat portfolio, CHAI and PSI made the most significant contributions to the development and

[20] Aurum Institute (2023), Country Impact Story: Ghana

introduction of AgRDTs in countries, as also discussed in the mid-term evaluation report.[21] Both CHAI and PSI specifically facilitated the introduction of a mix of Ag RDTs to ensure supplier diversity, avoid the risk of creating a monopoly and keep prices low. In particular:

- According to grantee consultations, **CHAI** supported procurement of AgRDTs and engaged closely with governments to establish systems and policies quickly, allowing LMICs to receive, deploy and use tests. CHAI also assessed diagnostic capabilities in country and leveraged existing mechanisms using a diagnostic network optimisation approach. Through catalytic procurement and parallel technical assistance, CHAI was able to familiarise governments with testing products early in order to expedite registration. Up until March 2021 alone, CHAI had already contributed to the procurement of more than 14 million AgRDTs across its fourteen supported countries in Sub-Saharan Africa.[22] Box 3.2 provides a specific example of CHAI's work in this regard in Cameroon.

Box 3.2: Cameroon: CHAI's support for introduction of AgRDTs in Cameroon

In 2022 CHAI assessed Cameroon's existing capacity to deliver and analyse COVID-19 tests and implemented a diagnostic network optimisation approach.[23] They provided significant technical information to the Ministry of Health regarding rapid diagnostic tests in the pipeline, socialising the Ministry on different options and ensuring that a diversity of suppliers was introduced to keep prices affordable. CHAI was able to ensure rapid validation of AgRDTs through catalytic procurement and training of trainers. With CHAI's support, the Ministry of Health in Cameroon approved rapid diagnostic tests and was amongst the earliest adopters globally.[24]

PSI also supported the development and introduction of AgRDTs, focusing more on self-tests and building on its previous work. With Unitaid support, PSI collaborated with manufacturers in China and India to provide evidence on market volumes and bring six self-testing products to the LMIC market. During this period, PSI engaged with manufacturers PMC, ACON, Osang and SD BIO for COVID-19 self-tests and Abbott, SD Bio, and PMC for professional use AgRDTs. Each of the products had FDA approval, were high quality and met WHO requirements for diagnostic performance on both specificity and sensitivity, yet cost no more than US$1 to allow for sales in pharmacies and through out-of-pocket payments. In 2022, a total of 123,000 professional antigen tests and 46,000 self-tests were procured across the seven PSI- supported countries, facilitated by PSI's support in introduction and market-shaping.[25]

Overall, market-shaping work by CHAI and PSI was viewed as positive by consultees and successfully facilitated the rapid national registration and introduction of AgRDTs. Contributions by PSI to the introduction of self-testing did not align with peaks in the pandemic (see Finding 5) and therefore had a reduced impact, but consultees suggested that the work done had the potential to open the door to more efficient and effective use of self-testing in future outbreaks.

Beyond the work of CHAI and PSI, other grantees in the Test & Treat portfolio also conducted limited activities to support the introduction of AgRDTs in LMICs. All grantees procured tests, ensuring they were available for free. In several countries, including Bolivia and Cameroon, stakeholders identified cost as significant barrier to access. In

[21] This evaluation has not been able to distinguish between the CHAI investment on RDTs and the separate investment on Test and Treat as CHAI worked seamlessly in countries across these two Unitaid investments. It is likely that some of the achievements being discussed here fell into the CHAI RDT investment and not Test and Treat.

[22] Unitaid (2021), One-Pager

[23] CHAI (2022), Annual Report

[24] Esso et al, 2021, Cameroon's bold response to the COVID-19 Pandemic during the first and second waves (Comment), The Lancet

[25] PSI (2023), Annual Report

some instances, grantees supported catalytic procurement as a stop-gap measure before commodities became more widely available, facilitating the establishment of procurement and distribution systems for rapid uptake. For example:

- Aurum supported demand quantification and procured 100,000 tests at the start of the pandemic in order to serve as a stop-gap before commodities became more widely available in Ethiopia, where no RDTs were previously available in the country.
- ISGlobal took a similar course of action, procuring 20,000 rapid tests to serve as a stop-gap measure for the municipality of Cochabamba in Bolivia due to an extremely limited supply. This was done before any tests arrived from the national government. They also supported the district in developing testing protocols. Once protocols were established, ISGlobal procured an additional 77,000 RDTs for use across the district, prioritising but not limiting distribution to facilities directly supported by ISGlobal

Finding 3: Attempts to establish a continuum of care with treatment options were largely unsuccessful, mainly due to external factors beyond the control of Unitaid and its grantees such as non-availability of therapeutics.

Robustness: Strong, well supported in the document review and consultations at the country level as well as with Unitaid and the grantees.

The Test & Treat portfolio was unable to meet the objective of establishing a continuum linking testing to therapeutics, largely because of factors outside of the control of Unitaid and grantees, as the relevant products were not made available globally. However, grants made good efforts to "set the stage" for the arrival of therapeutics, working across countries, for example on establishing the regulatory pathways for these drugs and updating case management guidelines. Overall, twenty project countries updated COVID-19 case management guidelines to include novel antivirals.[26,27] In addition, all grantees in the Test & Treat portfolio except for Fiotec and PSI supported procurement of antivirals. Some key examples of the work and results across grants is as follows:

- A CHAI agreement with generic manufacturers in 2022 ensured the generic production of nirmatrelvir/ritonavir, made available to LMICs at US$25 per treatment course. CHAI's COVID treatment access team then developed several tools to support the planning and implementation of LMIC therapeutic programmes including an antiviral treatment algorithm, patient register, trainings, and country readiness assessment tool. CHAI also specifically supported the approval of guideline changes to include generic nirmatrelvir/ritonavir as a recommended treatment in Laos, Cameroon, and Ethiopia.
- EGPAF worked very closely with the National Scientific Committee in Cameroon to expedite approval of tocilizumab and its inclusion in national treatment guidelines for COVID-19. EGPAF also supported the endorsement of tocilizumab in Kenya.
- ISGlobal also undertook a market analysis and forecasting in Bolivia and Paraguay to examine the regulatory status, pricing details, terms of use, expected availability, reimbursement policies, and market shares for tocilizumab, molnupiravir, and nirmatrelvir/ ritonavir, and supported registration of generic nirmatrelvir/ritonavir in country. Additionally, ISGlobal trained health workers on the use of novel antivirals to facilitate their expedited update upon their arrival in country.

[26] Unitaid (2023), COVID-19 Annual Report

[27] Countries include Cambodia, Cameroon, Ghana, India, Kenya, Guyana, Malawi, South Africa, Mozambique, Ethiopia, Philippines, Uganda, Lesotho, Zimbabwe, Laos, Papua New Guinea, Panama [based on available documentation including annual grantee reporting, but may not represent a complete list of all countries].

- Aurum was able to ensure registration of at least one oral antiviral in all five supported countries, and update in case management guidelines in four of five supported countries.[28]

As has been set out within Unitaid's document 'Access is not an Afterthought'[29], there were multiple upstream challenges that delayed availability of therapeutics globally including historic underinvestment in therapeutics resulting in a slow R&D pipeline, and unnecessarily long negotiations with manufacturers. Even once antivirals were globally available, country adoption was delayed due to complex landscapes and guidance, despite Unitaid-supported efforts highlighted above. This meant that in some cases therapeutics never arrived in country. In other cases, by the time that therapeutics were introduced by projects, positivity rates and severity of the disease had decreased to the point where there were very few cases that would require treatment with antivirals. For example, the EGPAF team estimated that 85% of tocilizumab vials delivered to Cameroon would expire by July 2024 without being used to treat COVID-19. In Bolivia, of the four therapeutic options explored by ISGlobal only tocilizumab arrived in country, too late to be used for COVID-19 treatment. The drug was reallocated to treat rheumatic arthritis).

Another factor that further delayed projects was the lack of guidance from WHO on therapeutics and test & treat approach. Grantees indicated that without strong WHO guidance, countries were initially hesitant to commit to a treatment course and update guidelines expecting a stronger treatment option to emerge and due to conflicting evidence on effectiveness. Despite Unitaid agreeing to countries moving forward with treatment before WHO guidance being published. Some countries developed conflicting guidelines on the various treatments, making operationalization extremely challenging.

For example, in Peru, there was a lack of consensus among the scientific community regarding the effectiveness and side effects of using tocilizumab. Consequently, tocilizumab was not included in the latest iteration of COVID-19 clinical management guidelines. These conflicting guidelines made it difficult for Peruvian healthcare workers to use therapeutics effectively. Additionally, the emergence of new virus variants necessitated genotyping before treatment, as certain antivirals could only target specific variants. As cases declined in some countries, interest in updating guidelines waned.

Grantees also highlighted a gap in pricing transparency and key information, such as the shelf life of commodities, which complicated projects navigation. Some grantees suggested Unitaid could have done more to expedite approval processes for therapeutics, including development of a body of work ensuring that countries have emergency protocols in place to expedite approval of medicines. Regulatory hurdles led to significant delays- as Aurum noted in their final report '*the slow pace of drug registration and the dependency on delayed WHO guidelines became significant roadblocks, hindering the quick adoption of lifesaving tools.'* Grantees noted that countries would benefit from streamlined regulatory process, with a potential support from Unitaid and other partners. Furthermore, some stakeholders suggested that perhaps countries should not have been pushed so strongly to register and approve antivirals at a late stage in the pandemic when the use was limited. However, they noted that given uncertainties related to the future trajectory of the pandemic, it was a risk worth taking.

Table 3.4 summarises grantee activities supporting increased accessibility of therapeutics in case study countries, and their subsequent use.

[28] Supported countries included South Africa, Ghana, Mozambique, Ethiopia, and Philippines. South Africa did not update treatment guidelines.

[29] Unitaid (2023), Access is not an afterthought: learnings and opportunities for equitable access to lifesaving therapeutics in future pandemics

Table 3.4: Grantee support for antiviral introduction and uptake and subsequent status of therapeutics[30]

Country	Grantee support for antiviral introduction and uptake	Status of therapeutics
Bolivia	• IS Global supported registration of generic nirmatrelvir/ritonavir • Supported delivery of tocilizumab, molnupiravir, and nirmatrelvir/ritonavir in Cochabamba municipality • Trained health workers to expedite their eventual use. • Procured 210 vials of tocilizumab.	Investment had limited impact as due to external factors, molnupiravir and nirmatrelvir/ritonavir never arrived in country, and tocilizumab arrived in October 2022 (10 months after request). By then, there were very few severe cases, and the drug was reallocated to a rheumatology hospital for the treatment of arthritis.
Cameroon	• CHAI supported the Public Health Emergency Centre to revise treatment guidelines and include nirmatrelvir/ritonavir • EGPAF engaged with the National Government Scientific Committee to expedite registration of tocilizumab • EGPAF procured 1,050 vials of tocilizumab and 598 doses of generic nirmatrelvir/ ritonavir • CHAI and EGPAF strengthened supply chain monitoring to facilitate uptake of therapeutics (see Box 3.7)	Investment had limited impact. By the time generic nirmatrelvir/ritonavir and tocilizumab were available for use in country, there were very few severe COVID-19 cases. EGPAF estimated that 85% of the 1,050 vials of tocilizumab would expire before use and received permission to distribute vials for use for arthritis. Some stakeholders suggested that perhaps there was too much of a push to register antivirals without a strong understanding of price and sustainability following the end of the project.
Ethiopia	• CHAI and Aurum supported approval of nirmatrelvir/ritonavir (including generic), molnupiravir, and tocilizumab • Aurum supported procurement of 4,271 treatment courses of generic nirmatrelvir/ ritonavir	Investment had limited impact as demand for procured nirmatrelvir/ritonavir was low
Peru	• PIH procured tocilizumab for delivery at three hospitals in northern Trujillo	Investment had limited impact as by the time that tocilizumab was procured the number of severe cases was very low. In addition, there was a lack of consensus among the scientific community on the effectiveness and side effects of tocilizumab. Guidelines related to tocilizumab were therefore conflicting and difficult to operationalise, and tocilizumab was not included in the latest iteration of clinical management guidelines.
Zimbabwe	• Case management guidelines were delayed, and CHAI supported approval of tocilizumab for research purposes	Investments had limited impact as case management guidelines were delayed and have yet to be signed off by the Ministry at the time of this report

Given the lack of available therapeutics however, grantees adapted to a test & care paradigm and followed national treatment protocols. Grantees pivoted from preparing for the arrival of oral antivirals, to providing other care options

[30] Source for the second column of Table 3.4 on grantee support for antiviral introduction and uptake is annual reporting from grantees. Source for the third column of Table 3.4 on status of therapeutics is consultations from country case studies.

which was done effectively in some cases. The approach taken by PIH is a good example - as they were the only grantee to link investments in testing to oxygen as a treatment option. Details are presented in Box 3.3.

Box 3.3: Peru: Adaptation to a test & care paradigm

PIH referred people who tested positive for COVID-19 to Centros de Oxigenación Temporal (COTs) which they supported in Lima Norte and Trujillo. At these primary health care centres, patients received oxygen therapy delivered through cylinders and concentrators. Healthcare workers and community health volunteers then provided follow-up care through telephone calls, home visits, and the distribution of pulse oximeters for at-home monitoring of oxygen levels. A ChatBOT was introduced which was a digital application for symptom reporting, including monitoring patients in need of mental health support. According to beneficiaries, this follow-up care was conducted in an ethical and efficient way and ensured that patients at greatest risk of developing severe symptoms were prioritised and referred to higher levels of care. The interventions also freed up beds at higher levels of the healthcare system, as hospitals transferred patients with lower oxygen needs to the COTs. PIH also supported development of a policy validating the use of COTs to manage COVID-19 cases. It is important to note however, that timing limited the impact of this strategy – discussed in depth under Finding 5.

Finding 4: Community engagement was a critical gap in the global COVID-19 response. Within the Test & Treat portfolio, it had a positive impact on the management of COVID-19 cases in project sites and helped enhance community trust in the primary health care system. However, the short-term nature of the investments limited their long-lasting impact.

Robustness: Strong, well supported by consultations at the country level.

An important contribution of the Test & Treat portfolio was demand creation at the community level. Community engagement had been identified as a key gap within the COVID-19 response globally, and within national responses. Evaluations of ACT-A, for example, found insufficient inclusion and meaningful engagement with CSOs and community representatives when it was launched.[31] Country stakeholders also emphasised that misinformation and stigma were key barriers to early testing amongst communities. Through the Test & Treat portfolio however, Unitaid was one of the first organisations to engage with civil society organisations and communities. Stakeholders were clear that this engagement was an important contributor to increased demand for COVID-19 testing and services at project sites. Across all countries in the Test & Treat portfolio, at least 700 communities were reached with demand creation initiatives. Strategies employed by the seven Test & Treat grantees include:

- *Aurum, EGPAF, and ISGlobal conducted qualitative assessments to understand local barriers to access.* These assessments improved the tailoring of demand generation interventions and community sensitisation materials to respond to community-specific challenges. This approach resulted in a positive impact on the management of COVID-19 cases discussed further below.

- *Co-creation of informational materials and interventions to improve community knowledge around COVID-19 and awareness of testing and treatment options.* In Bolivia for example, ISGlobal collaborated with community representatives to co-create informational materials including songs, radio shows, and social media content in both Quechua and Spanish, which were scaled up to cover all of Cochabamba. In Zimbabwe and Cameroon, EGPAF implemented advocacy and demand creation interventions such as songs and school quizzes with school-age children, and engagement with media outlets to educate them on COVID-19 prevention and risks. These demand-generation interventions aimed not only to increase demand for COVID-19 services, but also to build trust in PHC facilities in communities where this was a barrier to early diagnosis such as in in Bolivia, Peru and Cameroon.

[31] Open Consultants (2022), External Evaluation of the Access to COVID-19 Tools Accelerator (ACT-A)

- *Training of community health volunteers and health care providers in risk communication.* Multiple grantees including CHAI, EGPAF, and ISGlobal provided training to over 6,000 health workers to improve their communication around COVID-19 prevention, risks, and treatment.

- *Communication and collaboration with community representatives to increase buy-in for interventions.* Fiotec and PSI in Brazil led meetings and roundtable discussions with community representatives, and worked closely with civil society organisations, social groups, and religious organisations to ensure engagement and feedback on project implementation and results. Similarly in Bolivia, ISGlobal worked closely with neighbourhood committees to spread information on COVID-19. ISGlobal relied on community representatives from neighbourhood committees to sensitise the population in Cochabamba to the need for early testing and dispel any myths or misconceptions. They also communicated any concerns raised by community representatives with healthcare workers, which helped ensure that PHC facilities were responsive to community needs.

In addition to the demand generation and community engagement activities outlined above, as described in detail under Finding 1, grantees also expanded testing strategies at the community level and targeted populations viewed as vulnerable in the context of COVID-19.

In some countries where community engagement was a strong focus of the project, grantees demonstrated a positive impact on managingCOVID-19 cases at project implementation sites. For example, IS Global's project in Cochabamba, Bolivia, emphasized community engagement and demand generation of. Through a baseline and endline assessment, ISGlobal was able to demonstrate an increase in early presentation of community members to clinics with COVID-19 symptoms. ISGlobal found that six months of community outreach and campaigning contributed to an increase in the percentage of patients who presented to clinics in the first five days of experiencing symptoms from 71.8% in September 2021, to 88.9% in July 2023. This was a significant achievement, as prior to the start of the project, trust in the primary healthcare system among the community in Cochabamba was extremely low according to community, health worker, and government representatives. the ISGlobal project was credited with strengthening ties between healthcare workers and community representatives, leading to an **overall improvement in levels of trust in the lower levels of healthcare system amongst the community.** Although no baseline assessment was conducted, ISGlobal found that at the end of the project 46.7% of community members surveyed felt confident in their health centres. Stakeholders also suggested that there were long-lasting improvements made to the public awareness of disease prevention and treatment. At the end of the project 78% of people surveyed were aware of the importance of early diagnosis.

However, stakeholders across countries also emphasised that community perspectives on COVID-19 were difficult to shift through relatively short-term projects. Stakeholders suggested that despite an increase in community engagement initiatives, community perception of COVID-19 including misinformation and stigma continued to be a barrier to projects due to testing hesitancy. In Cameroon and Peru for example, stakeholders suggested that even as the project was being implemented some people did not report symptoms because of concerns that they would be separated and isolated from their families and would experience income loss. While community engagement efforts were developed to address these fears, clinicians, government officials and project implementers confirmed that this remained a challenge.

Box 3.4 provides details on community engagement within the Test & Treat portfolio, across country case studies.

Box 3.4: Community engagement across country case studies

- **Bolivia:** ISGlobal conducted an assessment to characterise barriers to access in Bolivia, and adapted interventions to barriers identified. IS Global's project was also highly community-owned, and interventions and community advocacy campaigns were co-created with patients, nurses, and community representatives. Campaign materials were scaled up to the regional level and adopted by the municipal government of Cochabamba. ISGlobal worked closely with neighbourhood social committees to relay community concerns around the management of COVID-19 in the primary healthcare system to healthcare workers. The project was reported to have a lasting impact on community confidence in healthcare clinics.

- **Brazil:** Both PSI and Fiotec collaborated with civil society organisations, community-based organisations, religious groups, and education institutions to increase outreach in the communities. They led community meetings and roundtables to allow for feedback from the community and developed informational materials. Active community outreach and feedback processes allowed for greater understanding of the most acceptable use cases for self-tests, and their optimal utilisation.
- **Cameroon:** EGPAF conducted an assessment to characterise barriers to access locally and adapt demand creation activities. By decentralising care and treatment to the primary healthcare level, the EGPAF project ensured that potentially vulnerable people like pregnant women or people with HIV/ TB were being appropriately screened for COVID. Additionally, stakeholders confirmed that EGPAF's community sensitisation activities helped increase trust in the primary healthcare system, mitigating the decrease in the number of people coming to health facilities due to fears around COVID. However, high levels of testing hesitancy within communities and stigma were cited by clinic coordinators as having contributed to low screening numbers at certain sites.
- **India:** One of the project sites was in Chhattisgarh where they worked with an NGO that particularly focuses on tribal populations in rural areas, which helped expand access to vulnerable population groups.
- **Ethiopia:** Aurum conducted an assessment to characterise barriers to access locally and adapt demand creation activities. In collaboration with eighty-five different CSOs, Aurum actively supported health promotion initiatives. CSOs also conducted training to build the capacity and mobilise community health workers to deliver COVID-19 information on vaccination, testing and treatment. This resulted in significant shifts in knowledge and awareness of COVID-19, and increased uptake of interventions.
- **Malawi:** PSI identified that the biggest problem with community acceptance was individual hesitation to engage with the health system, largely due to misinformation that the health system was killing people, rather than the disease itself. PSI worked closely with the community structures, particularly key community leaders, to provide accurate information on the disease, changes in outpatient services and the importance of testing. This approach helped to build confidence in the health system. As a results, less than 10% rejected the self-testing tool.[32]
- **Peru:** PIH was one of the few organisations focused on community engagement and mass testing. They developed community-based testing strategies to target high risk groups, including the elderly, individuals with comorbidities, and those returning to economic activities. The project also trained young people to serve as community health volunteers, given high levels of youth unemployment and lower levels of mortality. PIH was viewed as well-suited to deliver this project, given their extensive community presence.
- **Zimbabwe:** PSI and the CeSSHAR's support for key and vulnerable populations has the potential to strengthen the evidence base on tailored solutions for these groups during health emergencies. CeSSHAR, for example, conducted research on the impact of providing food baskets to sex workers who tested positive for COVID-19. They found that these food baskets helped support self-isolation in line with government guidelines. PSI has since disseminated these findings. EGPAF contributed to improving risk communication and dispelling misinformation through training community health workers and healthcare providers, as well as conducting sensitisation activities with media firms. Additionally, the FIND subgrant to PATAM, focused on mobilising civil society to advocate for access and financing for diagnostics. However, evidence was lacking to assess PATAM's impact to awareness among decision-makers or financing.

Finding 5: The timing of the investments resulted in them not being aligned with the acute phases of the pandemic, and thus limiting their COVID-related impact. In addition, there has been significant variation across and within grants in their impact on COVID-19. While some projects had localised impact, they often did not extend to broader areas or achieve national-level impact.

Robustness: Moderate, with many examples communicated through consultations at the country level.

The impact of the Test & Treat portfolio was limited by timing of the interventions and the natural evolution of the pandemic. Unitaid and the grantees moved very quickly to develop and implement activities and ensure supply of AgRDTs in country to facilitate decentralisation at the primary care and community level. However, by the time

[32] In 2022, there were 12 health facilities integrating COVID-19 services and 3 additional access points for COVID-19 testing- with 25,500 professional use tests conducted and 12,500 self-tests (meeting 100% of intended targets). 113 positive cases were identified, and all were linked to care according to PSI reporting.

projects were implemented in 2022 for most of the Test & Treat grants, the deadliest waves of the pandemic in April-June 2021), had already passed, and cases were waning due to natural immunity as well as vaccination efforts.

Timelines for the Test & Treat portfolio was also delayed by challenges related to the global supply chain. Grantees pointed out that it is important to consider results of the investments against a context of global challenges in supply and logistics. Shortages and stockouts of therapeutics, diagnostics, and PPE, as well as limited mobility caused delays in the grantee's ability to procure necessary equipment in a timely manner.

Another important factor that further delayed activities within the Test & Treat portfolio was the need to receive WHO ERC approval for research. Multiple grantees stated that despite attempts to establish an expedited process for COVID-19 related protocols, obtaining WHO ERC approval was highly inefficient and involved extensive back and forth about study protocols. By the time study protocols were approved, they often required updating due to changes in country contexts. This was a key reason for the No-Cost Extensions granted to Test & Treat projects. For example, grantees such as Fiotec and PSI did not receive ERC approval until late 2022. In addition, delays in obtaining local IRB approval contributed to the setbacks. For example, ISGlobal received IRB approval for the self-testing component of their work in Bolivia too late for timely implementation.

In some countries, multiple stakeholders suggested that the bundle of interventions supported through Test & Treat were highly pertinent and provided extremely useful support but were too late to have an impact on COVID-19 morbidity and mortality. As already discussed under Finding 3, oral antivirals, if available at all, did not arrive in most countries until the end of 2022 for reasons largely outside of the control of Unitaid or grantees, at a point where there were very few cases severe enough to require treatment. Other work done under the Test & Treat portfolio such as establishing a test & care continuum, decentralising access to AgRDTs, and strengthening community engagement and community demand generation activities, were welcomed. However, these were also too late to align with peaks in the pandemic in most cases. Proof-of-concept around self-testing in most LMICs for example, came too late to support roll-out during the acute phases of the pandemic. According to a clinic coordinator interviewed in Cameroon, only eleven COVID-19 cases were identified at a Unitaid-supported facility over the course of the project, and none were severe. Likewise, a clinic coordinator in Peru said that the Test & Treat interventions were *"extremely strong and welcomed"* but *"too late in the evolution of the pandemic to save lives"* and in Bolivia, a community representative stated that IS Global's support *"did not arrive in the moment that it was most needed, it arrived too late."* Across multiple country case studies, stakeholders indicated that had the interventions been implemented earlier, the projects under the Test & Treat portfolio would have been of much greater value-add to the national COVID-19 response.

However, some stakeholders presented a minority viewpoint suggesting that the interventions were well-timed. They argued that the projects came at a point when the national responses were slowing down, funding from other partners was waning[33], and health worker motivation was declining. The Test & Treat projects were therefore able to sustain the COVID-19 response and support the transition to routine service delivery (see Section on Sustainability below).

Additionally, it is important to emphasise decisions regarding the Test & Treat portfolio were made in a context of uncertainty. If the pandemic had remained active for a longer period and, therapeutics had been secured through the projects, the implementation of test & treat strategies would have been more impactful. Therefore, the investments carried an important "insurance value" by preparing for potential scenarios where these strategies could have played a critical role.

Examples from country case studies on the impact of timing challenges are included in Box 3.5.

Box 3.5: Timing and impact on COVID-19 morbidity and mortality

[33] Note that this comment from country case studies refers to funding supporting national COVID-19 responses as a whole rather than test & treat or community engagement specifically, which in some settings was not supported by other funders.

- **Bolivia:** Stakeholders noted that timing of the project was a challenge, as it was implemented after the peak of the pandemic had already passed. One community representative stated that although the knowledge and equipment provided by the project would help the community prepare for future public health threats, it did not save lives. The coordinator for the clinical network of Cochabamba also noted that by the time RDTs arrived supported through ISGlobal, tests had arrived through the Ministry of Health resulting in an oversupply of tests, which were redistributed to the North of Cochabamba. Tocilizumab also arrived too late to be useful for the treatment of severe COVID and was redirected to the rheumatology service. Additionally, the self-testing component of the project could not be implemented in Bolivia because of delays in approving the study protocol.
- **Brazil:** The unpredictable nature of the pandemic made planning more challenging as the situation was changing rapidly, requiring adjustments prior and during project implementation. For example, initially a much higher volume of diagnostic tests was planned for delivery in Salvador, however demand reduced substantially as cases dropped. Additionally, the WHO ERC approval process was delayed which impeded timely commencement of project activities.
- **Cameroon:** CHAI's efforts to change testing and clinical management guidelines and validate AgRDTs allowed for rapid decentralisation of AgRDTs and molecular tests. However, by the time Project CCA was implemented in Cameroon to support wider delivery of COVID-19 diagnostics and test & treat strategies, some facilities were presenting with very few cases. One clinic coordinator said that over the course of EGPAF's CCA project, eleven COVID-19 cases were identified, and none were severe. Tocilizumab and nirmatrelvir/ ritonavir also arrived in country too late to be used for COVID-19. Given the late implementation of the project, some stakeholders suggested that it would have been reasonable if a greater focus was placed on facing other epidemics such as cholera, particularly in trainings. A few felt that the project lost relevance, although it did reinforce the need for testing for surveillance. Alternatively, some people felt that that the project came at the right time because it was the moment in which the response and support from other partners was dropping.
- **India:** Overall, the impact of the investments on the COVID-19 response in India has varied significantly, largely due to the timing of the grants relative to the most critical wave of the pandemic (the Delta variant peak from April to July 2021). Most of the grants commenced after the peak of the Delta wave, resulting in lower than anticipated impact on COVID-19. For example, t**he** PSI/PATH projects a**i**med to generate evidence on use case scenarios for AgRDT testing and self-tests, develop a mobile application for reporting COVID-19 results, and support bidirectional screening for COVID-19 and tuberculosis. However, by the time the funds were disbursed, government interest had **shifted**. As a results, these projects sustained the COVID-19 response at s**pecific** project sites where government e**ngagement** was w**aning** and supported PPPR, potentially paving the way for future use of self-tests for other diseases. Likewise, the CHAI grant mainly focused on PPPR as government priorities around COVID changed**.**
- **Malawi:** In Malawi, PSI moved ahead with professional RDTs as this was already approved at the country level, however there were delays in self-test as there were no national guidelines or protocols on their use. Policies were under review, and PSI could not move ahead without a policy framework in place, which delayed self-testing study. By the time the study on self-testing was launched, the COVID-19 case load had dropped thereby limiting impact. However, there was still enough evidence generated to share with policymakers, resulting in an update of guidelines.
- **Peru:** The most significant challenge affecting impact of the PIH project was timing. The project was implemented following waves one and two of COVID-19 in Peru, which were by far the deadliest. Clinical staff who worked with PIH suggested that while Test & Treat interventions were very strong and highly welcomed, the delayed timing heavily limited the number of lives saved. The health centre supported in Los Olivos was only operational for a few months, at a point in the pandemic when less patients needed oxygen therapy. Additionally, by the time that tocilizumab was made available, the number of severe cases had drastically decreased. PIH jointly with the Peruvian government requested an extension to continue to support the national response during a third wave of the pandemic. However, the extension was not granted**,** and stakeholders felt that the end of the project was too abrupt.
- **Zimbabwe:** While t**he** overall portfolio is viewed as highly significant and impactful, t**he** activities in 2023, as the pandemic waned after **the** 4th wave, – represent less value for money due to delayed timelines for implementation. The rollout of self-testing through the public health system, **in particular faced challenges**. As t**he** virulence and transmission o**f COVID-19** declined from 2022 to 2023, COVID-19, the **disease became less of a public health priority and a community concern**. **Consequently, some activities implemented during this period were likely less impactful than initially planned.**:
  - i) The roll-out of self-testing, which began i**n** 2023, s**tarted** with national training, which **was** cascaded to provincial level. However, it has reportedly not been further cascaded to districts due to a perceived decline

in relevance. A significant delay in WHO ethical approval for the self-testing study conducted by the Centre for Sexual Health and HIV/AIDS Research contributed to this delayed roll-out.

- ii) EGPAF's integrated testing model was generally a success, although some hospital departments implemented testing too late to achieve maximum impact. For example, the outpatient department, which began testing patients in April 2023, reported the highest COVID-19 positivity rate.
- iii) The EGPAF TREAT study on therapeutics faced limitations due to an insufficient number of severe cases, resulting in a small sample size.

While projects contributed positively to the COVID-19 response at specific project sites, their impact varied significantly when it came to broader regional or national levels. Some investments had a transformative effect locally but were less effective in influencing other regions or achieving national-level impact. Box 3.6 provides examples of these localised impacts and their limitations.

One reasons for this localised impact was a misalignment between research and service delivery objectives during the pandemic. Some stakeholders believed that evidence generation to support the national adoption and scale-up of tools, which aligns with Unitaid's traditional role, should have been a larger focus of Test & Treat projects. However, others argued that during an emergency, service delivery is crucial, and that the objectives of operational research may not always match this need. At times, it was not clear whether projects within the Test & Treat portfolio were focused on research or service delivery, reflecting some misalignment between Unitaid, grantees, and country stakeholders.

Box 3.6: Examples of localised impact of Test & Treat portfolio

- **Bolivia:** The project delivered by ISGlobal in Bolivia was highly localised, with the expansion of COVID-19 testing and treatment services mainly supported in the South of Cochabamba. Some stakeholders suggested this was a weak point of the project, as facilities in the North also struggled to respond to the pandemic due to a lack of resources and equipment. That said, there were a few activities adopted by the municipal government and delivered to the entire district such as demand creation campaigns. Additionally, ISGlobal had a component on data strengthening which was relevant at the national level, which was supporting national adoption of data visualisation tools and transition to DHIS2. However ultimately the tools were not adopted or sustained past the end of the project limiting impact. Overall, the project was viewed as transformative at the project sites only with no spill-over effects to other municipalities or national-level impacts.
- **Brazil:** Although PSI and Fiotec did intensively disseminate evidence regarding the acceptability of mass testing strategies and self-testing through community meetings and roundtables, formal meetings with health authorities, scientific publications, and a national workshop organised by PSI, strategies for the acquisition and distribution of rapid tests at the national level are still under development and have not yet been implemented. Additionally, support to strengthen COVID-19 data collection and surveillance was at the municipal level only in Salvador, and at supported facilities in Rio de Janeiro. The project was therefore mainly limited to the specific study sites where Fiotec and PSI supported expansion of AgRDTs both professional and self-tests, without wider or national level catalytic impact as of date. In Rio de Janeiro in particular, stakeholders highlighted that the localised and smaller-scale support provided by the project made it difficult to negotiate with government stakeholders to achieve municipal-level impact and structural changes. PSI's work in Brazil may potentially lead to more national-level outcomes if the Brazilian Ministry of Health moves forward with plans to support self-testing distribution for specific risk groups, informed by PSI evidence alongside a national consulting committee.
- **India:** In India, part of the PSI/ PATH Test & Treat investment was allocated to Alert India who worked in specific districts in the state of Maharashtra. The impact of their project was limited to the project sites. They conducted activities such as generating evidence on the use case scenarios for Ag-RDTs, which according to consultees reduced the burden on RT-PCR testing. They also examined use case scenarios for self-testing in Mumbai. In addition, Alert India conducted bi-directional screening for COVID and TB. This work led to the publication of several reports available on the PATH website but have not been actively disseminated within the state or country and have had no impact beyond the project sites. In addition, a mobile application for reporting C19 results was developed but was discontinued after the project ended.
- **Peru:** PIH supported community-based testing and the delivery of test & treat strategies through two Centros de Oxigenación Temporal (COTs, discussed in Box 3.3 above) in Lima Norte and Trujillo. Although the intervention package was viewed favourably and produced positive results, there was no significant impact of the Test & Treat interventions beyond the project sites. Certain initiatives supported by PIH, such as the COTs

and self-testing, including a catalytic procurement of 2,000 tests for a pilot in South Lima, are being incorporated into COVID-19 response guidelines. However, government stakeholders indicated that these guideline changes were not directly influenced by evidence generated by PIH. Additionally, although the Test & Treat project provided evidence on the benefits of strengthening community-based screening, surveillance, and the primary health care system through regional workshops, high turn-over among government officials and health workers poses a risk to achieving a lasting catalytic impact (see Finding 9 on sustainability).

Finding 6: The projects have had a positive impact by helping to decongest health facilities and facilitate the delivery of other essential health services that were constrained due to the focus on COVID-19.

Robustness: Moderate/ limited, with some examples communicated through consultations at the country level.

Strengthening test & treat approaches at the primary care level strengthened the diagnosis, triage and care given to patients at specific sites. While the Test & Treat portfolio was largely implemented when caseloads were on the decline (see Finding 5), stakeholders suggested that the interventions influenced decongesting secondary and tertiary level hospitals. This was because less severe cases of COVID-19 could be treated at the primary care level even though they would potentially have been greater impact had the interventions been implemented earlier. Within facilities, the presence of project staff enabled healthcare workers to maintain delivery of other essential healthcare services more effectively. There are some examples of impact on improving COVID-19 related morbidity and mortality. For example, in Peru, district health authorities noted that a cross-comparison of health data in Lima showed lower morbidity and mortality rates in districts where community screening and a primary healthcare centre was supported by PIH. They suggested that the decongestion of hospitals contributed to this outcome, though the extent of this attribution is difficult to determine due to concurrent interventions implemented by district health authorities. Additionally, Aurum's implementation of bidirectional and tridirectional testing for TB and COVID-19 helped maintain essential TB services, despite challenges posed by the pandemic that threatened progress in TB control.

Lessons learnt from evaluation findings on the contribution/ results of the Test and Treat portfolio

Test & Treat Portfolio Contribution/ Results: Lessons Learned

- Starting pandemic response work during a pandemic is already too late. The core work on pandemic preparedness needs to be developed well in advance to be effective during a pandemic.
- There is strong merit in emphasising the continuum of test and treat in pandemic response, as it supports a people-centred approach. This holds true even when relevant therapeutics are not developed in time, as seen during COVID-19.
- Decentralised and primary health care services are at the cornerstone of an effective pandemic response.
- Engaging with community and civil society is crucial for a successful pandemic response. This engagement should be thoughtful and deliberate, taking into account the specific needs of different communities and the appropriate timing for interventions to be impactful. Unitaid needs to carefully define its role in future pandemics to ensure its catalytic role is maximised. While small-scale projects at the country level can provide benefits, they may not always offer the best value for money for Unitaid, especially when focused on localized emergency response. Achieving specific outcomes does not guarantee broader impacts, particularly in uncertain and complex situations like a pandemic.

3.1.4. Evaluation pillar 2: Adaptation, transition, sustainability and PPPR

This section reviews the extent to which the Test and Treat investments were able to successfully adapt and transition over the course of the pandemic, and especially their contribution to PPPR.

Overall finding: The key results of the Test & Treat portfolio should be considered in terms of the portfolio's sustainable impact on health systems and PPPR, which grants pivoted towards supporting. However, the extent to which Unitaid can provide long term systems strengthening support given its one-time funding approach is a challenge.

Detailed findings	Robustness
7. The Test and Treat investments worked hard to adapt to the evolving nature of the pandemic, ensuring valuable use of their commodities and services.	Moderate
8. The most significant shift made by grantees as the pandemic waned, was to focus more on sustaining health system gains achieved through Test & Treat grants and contribute to PPPR in countries.	Strong
9. Multiple Test and Treat grantees reported challenges in sustaining some of the HSS/ PPPR related activities, systems and impact supported by the investments. This raises concerns about the suitability of Unitaid as a one-time funder area that requires sustained, long-term funding.	Moderate

Finding 7: The Test and Treat investments made significant efforts to adapt to the evolving nature of the pandemic, ensuring valuable use of their commodities and services.

Robustness: Moderate, with many examples communicated through consultations at the country level.

The changing context in countries and evolution of the pandemic required that the Test & Treat projects be highly flexible and adaptable. Significant changes had to be made by grantees to adapt to the decreasing COVID-19 case load. For example, grantees petitioned for the repurposing of drugs such as tocilizumab, which were not being used due to the limited number of severe COVID cases, to treat other diseases such as rheumatoid arthritis. Grantees also adapted the use of diagnostics to different scenarios. In Cameroon, due to reduced demand in healthcare facilities, grantees supported testing management during the African Cup of nations, a football competition, and for people returning from Hajj, an annual Islamic pilgrimage to Mecca. In Malawi as cross-border testing became less relevant, PSI shifted its focus to groups at high risk of infection such as sex workers, and patients with comorbidities, who needed referrals for treatments such as nirmatrelvir/ ritonavir and other antivirals. In Zimbabwe, EGPAF redirected efforts towards managing long COVID, establishing a dedicated clinic and focusing on the diagnosis and treatment of long COVID alongside NCDs. In India, due to limited government interest in COVID-19, CHAI shifted its focus to support PPPR objectives across several states. In some countries, the evolving epidemiological context resulted in adaptations in grant implementation. For example, in Malawi, an outbreak of cholera coincided with the COVDI-19 response efforts, affecting prioritisation and resource allocation. As the same personnel were involved in both responses, grantees adapted by including linked messaging addressing both cholera and COVID-19.

Finding 8: As the pandemic waned, the most significant shift made by grantees, was to focus on sustaining the health system gains achieved through Test & Treat grants and contribute to PPPR in countries.

Robustness: Strong, well supported in the document review and consultations at the country level as well as with Unitaid and the grantees.

Given limited direct impact on COVID-19 morbidity and mortality, this shift was critical to the maintenance of the relevance and value-add of the Test & Treat portfolio.

With regards to HSS, grantees strengthened systems supporting the COVID-19 outbreak response including coordination, laboratory systems, and data systems. All countries reviewed within this evaluation received support through Unitaid funding to strengthen COVID-19 surveillance particularly at the primary care level and community level. This support included development of digital tools for data collection and data visualisation dashboards, distribution of equipment such as tablets, and training of healthcare workers on data collection and reporting. In some countries such as Cameroon, stakeholders confirmed that the investments significant strengthened supply chain

monitoring systems. Instead of supporting project-based data systems, grantees ensured that data collection and analysis tools and approaches were integrated by national and regional governments. However, the results across countries were mixed (see Box 3.7 below).

Additionally, although not a core focus of the Test & Treat portfolio some grantees – notably CHAI – also worked to strengthen laboratory and outbreak coordination systems. In Zimbabwe for example, a stakeholder stated that *"Unitaid did a sterling job to reinforce the laboratory and the country."* With funding from Unitaid, CHAI served as administrator of the Laboratory Pillar of the national COVID-19 response, responsible for working closely with the National Microbiology Reference Laboratory (NMRL), WHO, and other stakeholders (including the private sector) to coordinate implementation, financial and TA for COVID-19 testing and avoid duplication of efforts. NMRL stakeholders regard this support as instrumental as the NMRL was "drowning" at the start of the pandemic. Coordination under the Laboratory Pillar was considered superior to joint partner responses in previous emergencies, and CHAI's coordination function also eased the pressure on the NMRL, enabling it to focus on the quantification, procurement, and supply management (PSM) of testing materials.

An important facilitator of success was when grantees leveraged pre-existing systems in countries to support the delivery of the COVID-19 response and sought integration with national systems and processes. For example, most grantees were able to incorporate data collection tools and visualisation dashboards within national data dashboards. Departing from this approach tended to threaten the sustainability and value-add of the contributions. In Cameroon and Bolivia, for instance, the national government was unable to adopt tools that were incompatible with or not integrated with national HIS. Additionally, in some cases when grantees hired staff to facilitate reporting due to human resources shortages, for example EGPAF in Zimbabwe and Cameroon, or PIH in Peru, core staff were not trained regarding COVID-19 data collection and reporting. This led to a reduction in the number of facilities reporting on COVID-19 cases after the projects ended.

Box 3.7 provides additional details on contributions of the Test & Treat portfolio to health systems strengthening.

Box 3.7: Country examples: Contributions of the investments towards health systems strengthening (HSS)

Cameroon:

- Stakeholders indicated that the investments in Cameroon led to a significant strengthening of supply chain monitoring systems. EGPAF supported the creation of a stock monitoring tool to track procurement, distribution, and inventory of RDTs and therapeutics at central warehouses and project sites. The tool was integrated in the Ministry of Health DHIS2 platform. CHAI supported use of an open LMIS software within the Emergence Operations Centre of the Ministry of Health to streamline processes for supply chain reporting from the regional level to the central level. CHAI also ensured that Ministry of Health technicians were trained on OpenLMIS.
- Regarding surveillance systems, EGPAF provided tablets at facilities to support digitisation of Electronic Health Records and incorporated COVID-19 data collection tools into the DHIS2, with a dashboard for monitoring COVID-19 cascade data. Towards the end of the Test & Treat grant, CHAI developed an initiative to integrate all COVID-19 related data tools into a single system that would be interoperable and serve as the middle layer of the national HIS. However, this effort was less successful as government stakeholders preferred to adopt something of their own design and for partners to use data systems already integrated within the national HIS.
- CHAI also contributed to a strengthening the laboratory systems by supporting the National Public Health Laboratory to decentralise analysis of molecular testing to all the regions and roll-out AgRDTs.

Zimbabwe:

- According to a stakeholder, *"Unitaid did a sterling job to reinforce the laboratory and the country."* With funding from Unitaid, CHAI served as administrator of the Laboratory Pillar of the national COVID-19 response, working closely with the National Microbiology Reference Laboratory (NMRL), WHO, and other stakeholders, (including the private sector to coordinate implementation, financial and TA for COVID-19 testing and avoid duplication of efforts. Coordination under the Laboratory Pillar was considered superior to other joint partner responses in previous emergencies, which eased the pressure on the NMRL, enabling it to focus on the quantification, procurement, and supply management of testing materials.
- Regarding data systems, CHAI supported the expansion of digital systems for the reporting of national Ag RDT testing data, and the rollout of the WHO software Go Data to 1,433 sites, which was used for contact tracing. EGPAF also provided tablets at facilities to support digitisation of Electronic Health Records as well as an offline

application to address connectivity issues, and incorporated COVID-19 data collection tools in the DHIS2 with a dashboard for monitoring COVID-19 cascade data.

Bolivia:

- In Bolivia, facilities were provided tablets, and simple data collection and visualisation tools were established to report the number of diagnostic kits distributed, register positive cases, and facilitate follow-up at the community-level. Project indicators developed through Project ECO and visualisation dashboards were adopted as national tools, and ISGlobal worked closely with the Bolivian Ministry of Health to promote data exchange. The project made a critical contribution to stronger data-driven decision-making during the COVID-19 response.
- However, following the end of the project the data visualisation platform is no longer being used by the Bolivian government, because it is not an open-source tool or affordable. Similarly, while government stakeholders appreciated sensitisation conducted by ISGlobal to support a transition to DHIS2, progress on this has stalled as the Bolivian Ministry of Health found that for now DHIS2 does not fulfil all its data needs.

Ethiopia:

- Aurum's investments greatly strengthened Ethiopia's infectious disease surveillance system. The country now has early reporting systems established at all health facilities, including the primary healthcare level, which previously was limited to specialised tertiary hospitals and the national referral lab.

There were some significant impacts of the portfolio on PPPR. In particular:

- Certain approaches championed by the projects such as integration and strengthening of primary healthcare systems have also been maintained and adapted for other diseases such as dengue and cholera.
- High acceptability of COVID-19 self-testing approaches championed by PSI and Unitaid is likely to result in its use during future epidemics or pandemics in LMICs.

Grantees supported the elaboration of specific PPPR strategies in a few countries, for example in Ethiopia and India (state level). In addition, there are examples of grantees identifying transition funding for PPPR and HSS. CHAI and EGPAF supported development of the GC7 and C19RM funding requests to secure Global Fund funding in Zimbabwe (see Box 3.8). Likewise, quantification work done by Aurum in Ghana helped support an application for US$14M through the C19RM. Finally, grantees held several technical meetings and workshops with regional and national government stakeholders to discuss PPPR and relevant project findings. A particularly unique regional initiative funded through Unitaid, was a workshop organised by ISGlobal in Panama and attended by stakeholders from Peru, Bolivia, and Paraguay to regenerate recommendations for optimising the interpandemic period to strengthen PPPR. Specific recommendations included developing cross-border responses to outbreaks of COVID-19 but also diseases endemic to the region such as dengue. The workshop was viewed as highly transformative by those who attended, but the long-term impact on regional coordination is difficult to ascertain.

Box 3.8 highlights the impacts of the Test & Treat project on PPPR across the country case studies.

Box 3.8: Sustainability of Test & Treat Portfolio: PPPR

Bolivia:

- In Cochabamba, IS Global's work on strengthening the primary healthcare system is expected to have lasting effects according to stakeholders. Approaches such as working through neighbourhood associations, community sensitisation and outreach, and use of tablets to register data on outbreaks are still in place and have been applied in the response to dengue.

Cameroon:

- Based on evidence from both EGPAF and CHAI projects, the Ministry of Health will be developing an Institute of Public Health and strengthening national laboratories, with the objective of improving response to future epidemics.
- EGPAF's integration model is also likely to be adopted for other diseases as it has been widely accepted by national stakeholders. One district medical officer stated that "*even if EGPAF leaves, the investment has strengthened the system… the number of COVID-19 cases has decreased but there is still a detection system*

in the hospitals, and the system to test for COVID-19 at different points of entry is all operationalised. In other emergency situations, we are going to use it."

India: Given changing government priorities around COVID-19 as the pandemic waned, grantees mainly supported PPPR. For example, in Madhya Pradesh, CHAI:

- worked on developing a new portal for the infectious disease programmes including new dashboards for integration into the national level Integrated Health Information Portal.
- supported development of guidelines on outbreak response at the state level; and
- provided TA to strengthen private sector reporting of data (also facilitating access to a US$5M loan from the World Bank for PPPR). Stakeholders were very positive regarding this technical assistance.

In addition, although the work by PSI/ PATH on self-testing was too late to have an impact on COVID-19, stakeholders suggested that strong acceptance of COVID-19 self-testing during the pandemic may pave the way for the use of self-tests in the management of other outbreaks in the future.

Ethiopia:

- Following dissemination of lessons learned from the CHAI and Aurum projects, Ethiopia has developed a pandemic preparedness and response plan.

Peru:

- Approaches such as strengthened triage and mobile teams for community outreach have been used to respond to other epidemics, such as dengue (although not specifically based on evidence disseminated by PIH).
- There is also a plan still under development to potentially adapt the Centros de Oxigenación Temporal for use in the care and treatment of tuberculosis patients. If this approach is adopted, it would be a major achievement of the investment for having helped demonstrate the feasibility of delivering oxygen at the primary healthcare level (one of the activities under Test & Treat investment).
- PIH also sought to ensure the sustainability of interventions by organising eight workshops to discuss and share lessons learned with various stakeholders.

Zimbabwe:

- PPPR components reported to have been strengthened include i) Infection Prevention and Control (IPC); and ii) diagnostic systems and approaches.
- There is some agreement that Zimbabwe's ongoing cholera outbreak response has benefitted from the experience of COVID-19. In particular, the Incident Management System used during COVID-19 is being used in the cholera response. Point of Care testing, multiplex testing, and genomic sequencing are also considered to be a game-changing approaches that will be maintained in the approach to other diseases.
- Additionally, clinic staff have confirmed that that it is now common practice to screen for NCDs amongst HIV and TB patients following interventions targeting long COVID, and that they have also integrated cholera screening at HIV and SRHR services (a direct adaptation from the approach used to address COVID). However, sustainability and preparedness are undermined by the exodus of health providers from the public sector.
- CHAI and EGPAF have supported development of the GC7 and C19RM funding requests to secure Global Fund funding in Zimbabwe. This funding will support laboratory information management system strengthening and waste management, based on lessons learned from implementation of Test & Treat projects.

Finding 9: Multiple Test and Treat grantees highlighted difficulties in sustaining some of the HSS/ PPPR related activities, systems and impact supported by the investments. This brings to bear the appropriateness of Unitaid as a one-time funder in this area which requires sustained long-term funding.

Robustness: Moderate, with many examples communicated through consultations at the country level.

Not all the interventions introduced by the Test & Treat portfolio could be sustained at the same level in a cost-effective manner. Lack of country PPPR strategies as well as other endemic issues such as frequent rotation of healthcare workers, underinvestment in primary healthcare systems and community systems for health, and gaps in the capacity of the health workforce to respond to epidemics, will impact the sustainability of the gains achieved.

While the pivoting and adaptations of the Test and Treat grants to HSS and PPPR issues is noteworthy especially given the fact that the grants were not initially scoped and designed with these issues in mind, there is a question as

to the suitability of this one-time, time-limited funding for these objectives – which instead require longer terms sustained funding. The funded activities can also be viewed as ad hoc in relation to the PPPR priorities for countries (in that they built off the existing grant framework rather than were strategically designed based on country PPPR needs). In India, one of the government stakeholders we spoke to noted the valuable TA support provided by CHAI to support PPPR objectives but was concerned that it covered a few districts only and was not long-term enough to build capacity. Similarly in Peru, stakeholders suggested that the end of the project was too abrupt and the timeline too short to really achieve long-term HSS or PPPR objectives, particularly due to high turnover rates of both government functionaries and healthcare workers. In Cameroon, one district health officer interviewed suggested that EGPAF's project was *"not implemented with enough time for personnel to really have ownership over the project- it came too fast and left too fast."*

In addition, stakeholders noted that because grants were not initially designed to focus on PPPR, in some cases it was not possible to pivot projects away from emergency provision of services and timelines were too short to foster long-term sustainable impact. Others suggested that perhaps more could have been done to adapt the portfolio to a multi-disease perspective- for example, the trainings conducted with healthcare workers at later stages of the pandemic could have been less focused on COVID-19 and more on epidemic and pandemic surveillance and response more generally.

Lessons learnt from evaluation findings on the adaptation, transition and sustainability of the Test and Treat portfolio

Test & Treat Portfolio Sustainability and PPPR: Lessons Learned

- There is considerable merit in adapting to changing circumstances, and Unitaid's flexibility with grantees has helped ensure appropriate pivoting of COVID-19 investments to PPPR supporting objectives.
- The Test and Treat investments has helped build public confidence in PHCs, which serves as the cornerstone of a successful PPPR approach.
- Unitaid needs to carefully consider its role in PPPR, given Unitaid is not a long-term health systems funder.

3.1.5. Crosscutting pillar: Coherence and Efficiency

Finding 10: The Test & Treat portfolio well leveraged Unitaid's existing grantee footprint (albeit with trade-offs on not focusing on countries with highest COVID burden) and employed efficient processes in the face of the pandemic. However, the issue of their timing detracts from the impact and therefore value for money of the portfolio.

Robustness: Strong, well-recognised by Unitaid, grantees and country stakeholders.

Summary findings which link up with the assessments described previously as well as those noted in the MTE are as follows:

The timing of the Test & Treat portfolio and its misalignment with the peaks of the pandemic alongside the unavailability of expected antiviral options until late in the pandemic was challenging and affected value for money of the grants. See detailed discussion under Finding 5.

The Test & Treat portfolio however was largely coherent and efficient, by leveraging pre-existing capacities and networks of the grantees.

Unitaid was able to enhance the efficiency of grants by leveraging the existing footprint of its grantees. For example, PSI's work on introducing HIV Self-Testing in LMICs paved the way for its work on COVID-19 self-tests under the Test & Treat investment. Multiple stakeholders suggested self-testing policies were approved with PSI support faster than expected. Similarly, both EGPAF and AURUM had previously rolled-out integration models for the treatment of HIV and TB, and the same mechanisms were then adapted to COVID-19. This also meant that facility staff had experience

implementing an integrated testing system. Further, CHAI has significant experience providing TA to country governments to create enabling environments for product uptake and scale-up through guideline development. In some countries where multiple grantees were working together, Unitaid leveraged synergies between more 'upstream' partners and 'downstream' partners. For example, in Cameroon, CHAI worked to expedite approval and guidelines for nirmatrelvir/ritonavir and relied on EGPAF to deliver the therapeutic to patients.

Most grantees also implemented the Test & Treat investment in countries where they had established partners. This was highlighted by stakeholders as extremely useful, as it facilitated connections with the national government and supported buy-in. Certain implementers who were less established in countries that they were supporting, for example ISGlobal, had more difficulty in establishing a Memorandum of Understanding with national government although they worked effectively at the municipal level.

However, the trade-off was that Unitaid grantees were not necessarily working in the countries or regions with the highest COVID-19 related morbidity or mortality. Most of the Unitaid grantees are focused in Africa, however it was countries in Asia and Latin America who experienced the earliest and most severe waves of the pandemic and would have benefitted from wider spread access to rapid testing in particular.

Finally, through the Test & Treat portfolio, Unitaid trialled an expedited grant development and approval process and enhanced flexibility in management that was well-received by grantees and adapted to the emergency context. As discussed extensively in the MTE, Unitaid issued a closed RfP to trusted implementers, and allowed partners to submit a light-touch proposal. This shortened the process for approving grants from six months to a matter of weeks. Additionally, Unitaid allowed increased budget flexibility whereby up to 25% of the budget within an expense group could be reallocated without the need for review and approval by portfolio and financial managers.

Some of these flexibilities will be carried forward in new iterations of Unitaid's Strategy and funding model (including the 25% budget flexibility which has been formalised in Unitaid financial guidelines and is applicable to all Unitaid funded projects, and the possibility for a light-touch proposal process for small and catalytic amounts of money).

Although Unitaid was generally viewed as having been nimble in adapting its funding model to the emergency context, there were a few challenges which impacted internal coherence. For example, the Test & Treat portfolio was dispersed among several different project managers and officers which did not facilitate engagement and cross-learning between the grantees. Additionally, Unitaid staff suggested there was a lack of a clarity around when it was appropriate to approve grant extensions which were needed several times throughout the course of the projects. Finally, there are certain processes and protocols that are useful when operating in emergency contexts which Unitaid has not implemented. This includes direct communication with emergency response units of supported countries, and engagement with coordination platforms for global partners in country which is particularly important in emergency situations. Due to these communication issues, some country level grantees/ sub-grantees indicated their country-specific issue (e.g., on specific strategy to employ, or change in circumstances) got "diluted" by the time it was discussed at the global level between the lead grantee and Unitaid.

3.2. COVID-19 Test & Treat advocacy programme

Finding 11: The FIND-Unitaid co-funded advocacy grants were an important tool for community engagement and linking global and local awareness and understanding on COVID-19. However, the grant impact on improving demand and adoption of test and treat has been limited due to the short time frame of the projects and delayed start when COVID-19 was on the decline

Robustness: Moderate/ Limited (Findings of the FIND-Unitaid Advocacy Grant is not a full evaluation of all 21-advocacy grantees. Our findings are based on a review of key documents along with a consultation with FIND, and a selection of the country project grantees (India – TB Alert and Pi-consulting, Zimbabwe-PATAM, and Uganda-HEPS).

3.2.1. Background

A major challenge to the COVID-19 response identified by Unitaid, FIND and ACT-A partners was the testing gap i.e. individuals and communities failing to test, because the diagnostics were not available, lack of understanding on how to access tests, or an unwillingness to do so due to misconceptions and misinformation. Importantly, at the start of pandemic, testing was the only tool that could support in breaking disease transmission and as such, testing was an essential tool in the COVID-19 response, where previously diagnostics had been undervalued or overlooked within emergency response. However, as vaccines were developed and rolled out, the demand for diagnostics dropped. And yet, before vaccines became available, the COVID-19 diagnostics were the main defense in the COVID-response. As the pandemic progressed, there was a decline in reported testing rates, with low-income countries testing at an average of 0.21 tests per day 1,000 population per week at the end of August 2022, while the recommended WHO surveillance test target remained at 1 test per 1,000 population per week – the minimum testing rate required for timely identification of new variants.[34] As such, it became a priority issue of ACT-A partners to generate demand for testing and ensure that affordable tests were accessible and linked to equitable access to COVID-19 treatment; endorsing the test and treat approach.

To address the challenges of testing and treatment, in mid-2021, the ACT-Accelerator Diagnostics Pillar's Country Support Working Group (CSWG) identified the need to engage directly with in-country stakeholders to drive demand generation for COVID-19 testing, which in January 2022 resulted in the launch of a request for proposals (RFP) on COVID-19 testing and treatment advocacy (launched globally in four languages – English, French, Spanish and Portuguese). The RFP was co-developed by FIND and Unitaid, with a total funding envelope of US$2.13m (US$1.5m from FIND (ACT-A Programme), US$500k from Unitaid and US$136k from United Nations Foundation (UNF). Following the RFP selection process, in June 2022, FIND and Unitaid, announced the selection of 21 advocacy partners across 19 countries in Africa, Asia and South America to raise awareness of COVID-19 testing and treatment among the public, key opinion leaders, and high-risk and vulnerable groups.[35] The average award disbursed to each partner ranged from US$50,000 – US$100,000 with an average project duration ranging from 6 to 18 months.[36]

3.2.2. Contribution and results

As noted in the Unitaid Annual Report 2023, across the 21-advocacy partners, there were varying levels of success in engaging with communities, such as religious groups, community leaders and civil society, which led to increased understanding and demand for COVID-19 diagnostics and treatments.[37] On the positive side, the grants were innovative in their approaches, and the Community of Practice (CoP) established to support learning across the grantees worked well. In particular:

- **The partner organisations identified new and innovative approaches to conduct advocacy campaigns and engage with communities within the context of lockdowns and restrictions on physical meetups.** This included engagements with religious groups, radio shows, door to door engagements, local IEC materials, such as posters and pamphlets in a diverse range of languages, street plays, and discussions with religious leaders, media-outlets, policymakers, members of parliament, different population, and patient groups.
- **Advocacy Community of Practice (CoP) collaborated and shared learnings, information, and the latest COVID-19 data regularly between partners**. The CoP was established as a network for the 21 grantees and an online meeting was held bi-monthly. This network became an important platform for sharing the latest COVID-19

[34] United Nations Foundation Donor Report (2023), COVID-19 Test and Treat Advocacy Programme

[35] FIND (2022), Publications and Statements, FIND and Unitaid invest US$2 million to support advocacy for COVID-19 test-and-treat approaches in low- and middle-income countries, https://www.finddx.org/publications-and-statements/press-release/find-and-unitaid-invest-us2-million-to-support-advocacy-for-covid-19-test-and-treat-approaches-in-low-and-middle-income-countries/

[36] United Nations Foundation Donor Report (2023), COVID-19 Test and Treat Advocacy Programme

[37] Unitaid (2023), Annual Report, COVID-19

messaging and ensured that all 21 grantees had up-to-date guidance on self-testing, diagnostics and therapeutics. To support the dissemination of new guidance and develop the knowledge and capacity of all partners, FIND regularly made and shared recorded webinars. As such, this network enabled smaller advocacy grantees the opportunity to be part of the global COVID-19 response efforts and was an important tool to combat misinformation and common misunderstandings. For example, in Uganda, the focus of the grant was unique as all other advocacy efforts were directed towards vaccine uptake, and there was limited awareness and communication provided on test and treat.

Box 3.9 presents a case study from Coalition for Health Promotion and Social Development (HEPS- Uganda).

Box 3.9: Uganda HEPS Case Study

At the time the grant started, Uganda had very limited COVID-19 testing available for the public. Priority testing was reserved for use at borders for those who were travelling and frontline health workers, but it was not available to the public. However, as the pandemic progressed, it became evident that testing was a critical component to managing the spread of disease, particularly in the absence of treatment and when vaccination rates were low with only 18% coverage in the country. As such the timing of the project worked well, as it raised awareness and generated demand for testing, even before the testing platforms were fully established.

Notably, on treatments, at the time the project started, Uganda had just experienced the deadliest second wave of COVID-19, and as such, communities were eager to engage on the importance of therapeutics. Subsequently the global landscape changed with the introduction of vaccines and a fall in the COVID-19 case load and virulence. In the end, therapeutics were not introduced within the project lifetime – however this trajectory was not known at the time the project started, and so the emphasis on supporting treatment was well received.

As the advocacy campaign started, the RDT-test kits and diagnostic scale up services evolved away from priority populations to becoming accessible to the general population. However, although there was a national shift in strategy, individuals and communities were not aware of the testing services or where they could access tests, and as a result uptake of testing was limited. As a starting point, the HEPS-Uganda team collected data on what services were available and conducted a survey on community awareness. The team worked closely with PIH, and the national community empowerment department to conduct this baseline study. Through this work, HEPS tailored their messaging to address issues identified in the survey, such as common misunderstandings and misconceptions on COVID-19, testing and treatment. The HEPS team also supported the national government on a review of clinical guidelines and the national essential medicine guidelines and called for the inclusion of testing alongside vaccines as well as better integration between testing and vaccination services. Although the project ended before the introduction of treatments into Uganda, the messaging helped build awareness to prepare for the introduction of treatments, as well as focusing on reducing the misuse of antibiotics and managing symptoms.

Overtime, the project adapted, and the advocacy shifted from COVID-19 specific messaging to a broader focus on global health security and PPPR, in line with shifting national priorities. There were other health emergencies emerging, such as Ebola and cholera, and overall demand for COVID-services fell. However, as a result of HEPS COVID-19 work in Uganda, civil society organisations have been invited to join the national PPPR technical working group advising on the WHO pandemic accord negotiations and supporting the negotiations with World Trade Organization, around the use of TRIPS waivers.

HEPS-Uganda have monitored developments on these global policy processes and engaged national representatives to call for an enabling environment that is favourable to equitable access for essential medicines within Uganda and LMICs in general. In addition, HEPS-Uganda has developed an advocacy guide for CSOs to facilitate engagement of other civil society partners on accountability, domestic resource use and financial transparency within the PPPR agenda, as well as building the foundations for stronger health systems and inclusive access to services. In connection to the wider PPPR-agenda, HEPS is also engaged in advocacy related to intellectual property rights and access to essential medicines and have started to assess the current use of flexibilities and the opportunity for local manufacturing.

Notwithstanding the positive examples in Uganda, there have been several challenges with demonstrating impact through these grants – due to their short-term nature and delayed implementation. In particular:

- **Community engagement was increased by the advocacy grants, although the short-term nature of the grants resulted in limited measurable impact.** This was an important advocacy project to broaden community

engagement and raise awareness on COVID-19, with an estimated 2,300 communities reached.[38] It was also regarded as an important mechanism to link global and local action in response to the pandemic, including sharing up-to-date knowledge and guidance as well as combatting misinformation or common misconceptions around the disease, testing and treatment. A good example of progress is presented in Box 3.9 above which describes the experience of Coalition for Health Promotion and Social Development (HEPS- Uganda) Uganda.

Specific projects were effective at implementing activities and adapting to needs, however the short-term nature of the grants has limited impact. The projects on average were supported for one year. This timeframe of one year has been found by the grantees to be very limited in scope, especially for an advocacy grant where more time is required to shape and influence public opinion, political support, and health-seeking behaviors. Furthermore, a number of the CSOs engaged through the project, either as grantees or sub-grantees, would be interested in continuing related health advocacy work for COVID-19 and PPPR more generally but there is no funding available. For example, in India, where PI-consulting focused on policy makers and opinion leaders and TB Alert developed COVID ambassadors within HIV and TB key population groups, their activities progressed well but the short-term nature of the grant was not appropriate for advocacy, which relies on longer term relationship building and trusted community engagement. Both organisations have had to rely on their own limited resources to support the continuation of work which has evolved into advocacy campaigns focused on disease integration and community testing for TB and high-risk COVID patient groups. Across the interviews with advocacy partners, a common concern was the need for continued funding to sustain the networks and communications channels established through the grant. Many partners reported that, in several cases, the closure of the grant resulted in a complete halt of activities, preventing any further progress.

Delayed project selection and introduction undermined the impact of the advocacy campaigns in most countries. The need for greater in-country engagement and advocacy to support test and treat services was recognized in mid-2021, but it took about eight months to shape the partnership between FIND and Unitaid, select and announce the advocacy grantees. As a result, the advocacy projects were starting in country towards the latter half of 2022, after the global COVID 19-rates had already started to fall, and overall provisions and uptake in COVID-19 tests and treatments had declined. In addition, several countries had already shifted services and priorities to other health emergencies, including for example, the cholera outbreak in Zimbabwe. The delay in the grant's inception was primarily due to Unitaid's funding mechanism, which required disbursing funds through an existing FIND grant. This process took time as it involved forming the partnership and agreeing on reporting structures, especially since FIND had initiated the proposal. Additionally, FIND's contracting procedures were overly burdensome, affecting both the independent experts on the selection panel and the selected advocacy grantees. FIND contracting processes are set up for conducting clinical trials and not emergency response or advocacy grants, as such this required internal capacity building and the development of new approaches, both of which cost time.

- **Misalignment between advocacy and COVID-19 services.** The advocacy focused on tests and treatments, but often the campaign messages did not correspond with the actual services available in a particular region or for a particular community, which undermined public confidence and overall uptake. For several the countries where the advocacy grants operated, there was no available treatment, and services were limited or deprioritised beyond Q2 of 2022. The guidance and messaging provided during the CoP meetings, and used in campaigns, did not always therefore align with country context. For example, guidance on isolation was initially limited, but it quickly became the priority action for individuals who tested positive or exhibited symptoms (even without testing). This misalignment was further highlighted by the fact that the advocacy grants operated independently from the test-and-treat portfolio, despite being designed in coordination. As a result, the advocacy grants experienced varying degrees of success in integrating with national COVID-19 response platforms.

[38] United Nations Foundation Donor Report (2023), COVID-19 Test and Treat Advocacy Programme

- **The grants' catalytic effect in terms of securing additional funding so far has been limited, but there are a few examples of progress.** The Advocacy CoP concluded at the end of the project funding. However, FIND has continued to support grantees in exploring new funding opportunities, and many grantees have expressed interest in continuing their work in health advocacy. To date, HEPS-Uganda have been further supported by the Hilton Foundation with funding for community delivery for supporting Test and Treat services and addressing community hesitancy. PATAM in Zimbabwe have gone on to successfully set up the Diagnostic Equity Consortium - a partnership between PATAM and the Georgetown Law's O'Neil Institute, Center for Global Health Policy & Politics.[39] In addition, in Burkina Faso the grantee received a conditional offer from the national government, committing to provide 10% of the required funding, contingent upon securing additional support from another partner. To date this has not been confirmed but demonstrates the interest and confidence of grantees in seeking new opportunities for funding. One advocacy partner noted *"The advocacy strategy we developed with the support of the grant has helped many partners, attracted, and picked interest in working together. We also have also drawn attraction from other funders and been able to join many government technical working groups… so it was catalytic and opened doors."* In addition, the first application round for World Bank Pandemic Fund did not support any advocacy programs, however it is understood that the second round of applications will open soon with new opportunities for grantees and will be mandatory to include community and civil society partners. To date however, follow-on funding has proven a challenge for the advocacy grantees as the projects have ended.

- **More generally, the grants had a limited M&E framework, making it difficult to assess overall results.** The reporting and M&E framework focused on the outputs rather than outcomes and impact, such as the number of meetings held, social media engagement, and the dissemination of IEC materials. As such there is little detailed feedback on the extent to which the advocacy projects achieved their objective of increasing demand and adoption of test and treat services. At the start of the project, FIND had had a test tracker which showed the rate of testing per country on specific timelines, with the intention that this would align with and demonstrate the advocacy impact of the grants. However, the project grants were working at the district level, and sub-regions, and the tracking data only looked at national numbers, so it was hard to draw any relationships between the data and activities of the grantees. In addition, the advocacy grants had different timelines, geographies, country COVID-contexts and different community sizes, so it was hard to also draw direct comparisons between projects.

3.3. CLINICAL TRIAL PLATFORM FOR THERAPEUTICS: ANTICOV

Finding 12: ANTICOV had limited direct impact on the COVID-19 pandemic but has left behind a legacy by highlighting the importance of establishing a clinical trial network based in LMICs to support responses to future pandemics.

Robustness: Moderate *(Findings are well-known and published by Unitaid, but this evaluation has not conducted a detailed review and consultations with partners on this investment)*

ANTICOV was one of the early investments made by Unitaid under its COVID-19 portfolio and aimed to generate evidence on the safety and efficacy of repurposed medicines for COVID-19 in 13 African countries. The investment extended over the period September 2020 to October 2022 for a total of US$14.6m with approximately equal co-funding from the Germany government. According to Unitaid's annual reports, the trial faced several challenges, including delays with import permits for investigational medicines a well as low recruitment in study sites. At least two countries were unable to recruit patients, Brazil was added to the trial in June 2022 to boost recruitment, but ultimately this initiative failed as Brazil was also unable to recruit the necessary number of patients. The trial was placed on hold in November 2022 due to the lack of funds and shifting priorities.[40]

[39] https://oneill.law.georgetown.edu/projects/diagnostics-equity-consortium/

[40] Unitaid, 2023, COVID-19 Annual Report

CEPA's mid-term evaluation recognised the strategic relevance of ANTICOV but noted challenges in the design of the platform. The evaluation noted that the large consortium and complex decision-making processes hindered agility, making it slow to respond to emerging drug evidence. This resulted in significant delays in trial operationalization within countries and in evidence generation, further compounded by difficulties in securing country regulatory approvals. At the time of the mid-term evaluation, the conclusion regarding ANTICOV's effectiveness was low. No promising repurposed therapeutics had emerged from the research and patient recruitment was low.

This end-term evaluation has similar conclusions given the state of therapeutics for COVID-19. However, while ANTICOV had limited direct impact on COVID-19, and principally it was unable to deliver as a platform for clinical trials in Africa which could also be leveraged in the future, it leaves behind a legacy in terms of highlighting the importance of creating a multi-country/ multi-site clinical trial structure based in LMICs to support future pandemics and epidemics.

The ANTICOV experience offers several valuable lessons, including challenges in recruitment processes, issues with regulatory approvals, and the potential benefits of collaborating with regional regulatory bodies. It underscores the need to balance engagement between Western/developed countries and low- and middle-income countries (LMICs), as well as the importance of rapid response during emergencies through mechanisms like master protocols and harmonized ethical reviews. Additionally, it highlights the need for a well-designed yet agile governance structure, a lesson derived from the difficulties encountered with ANTICOV's governance. Although ANTICOV did not provide the ideal model for future mechanisms, it has illuminated key issues and lessons that will guide the development of more effective mechanisms in the future.

"No results" from a clinical trial platform, such as ANTICOV, where no therapeutics were identified, is still valuable as it reveals what aspects are not functioning effectively. ANTICOV's experience underscores the notion that initiating a response during a pandemic is often too late. In response to these insights, several initiatives have evolved, including PANTHER[41], originally hosted by DNDi hosted but now an independent initiative needing further buy-in from LMIC governments, and the Oxford University clinical trial network ISARIC.[42] These initiatives aim to build on the lessons learned from ANTICOV and address the gaps identified.

3.4. REGIONAL DX MANUFACTURING STRENGTHENING: FIND-UNITAID JOINT INVESTMENT

Finding 13: The joint investment between Unitaid and FIND to develop regional manufacturing capacity for AgRDTs has had limited direct impact on COVID-19 but has contributed to the regional manufacturing priority deemed critical under the PPPR agenda.

Robustness: Moderate/ Limited (Findings are well-known and published by Unitaid, but this evaluation has not conducted a detailed review and consultations with partners on this investment)

Unitaid and FIND jointly issued an expression of interest (EOI) aimed at driving equitable access to fit-for-purpose AgRDTs for COVID-19. This was a unique partnership when launched, with a shift from the donor-grantee relationship that Unitaid and FIND had to date to a partnership-based relationship. FIND provided US$40m of funds while Unitaid co-funded with US$10m.

CEPA's mid-term evaluation applauded the strategic relevance of this work and its direct fit with Unitaid's comparative advantages, and also highlighted the value of the partnership-based approach. Progress at that time indicated an increase in manufacturing capacity and technology transfers, albeit with delays in bringing new products to the market. This end-term evaluation notes the following areas of results:

[41] DNDi, Pandemic preparedness platform for Health and Emerging infectious Response, https://pantherhealth.org/

[42] Oxford University, the International Severe Acute Respiratory and Emerging Infection Consortium, https://isaric.tghn.org/

- First, directly for COVID in terms of improving affordability of RDTs. This is on account of the PMC AgRDT being committed for US$2.5 under the access terms with FIND/ Unitaid, and existing suppliers Abbott and BioSensor dropping their prices from US$5 to US$3 with the pre-qualification of the PMC product. Although it is argued by some that the pricing changes are unrelated, others strongly attribute the price decline to the availability of the PMC product. The decline in price has also contributed to estimated savings of US$32.6m by the Global Fund.

- Second, and more significantly, the investment has made considerable progress in the crucial regional manufacturing agenda, which is central to the PPPR focus today. The experience gained from this investment has generated substantial learning about local manufacturing, which has been shared and sensitised amongst various stakeholders.[43,44] It has also paved the way for further work in the area such as the new joint RFP between Unitaid and FIND focused on HIV tests produced by regional manufacturers.[45]

According to Unitaid's 2023 annual COVID-19 report, the investments established three regional manufacturing sites for COVID-19 rapid diagnostic tests in Brazil (Wama), India (PMC) and Senegal (Diatropix). The report highlights that the investments contributed to additional supply of 50 million tests per year for WAMA and 120 million per year for PMC. Supported tests received WHO PQ and were listed on WAMBO, the Global Fund procurement catalogue.[46] However despite these results, the manufacturers have not been able to sell their product due to the delays and the additional manufacturing line has created additional costs. In particular:

- Due to the price decline described above and being the third market entrant (as well as an export ban in India), PMC was not able to make a market entry and there were no sales of its product. As such the investment in PMC did not yield direct benefits for PMC.

- WAMA faced delays and several challenges such as issues with raw materials. By the time its test was ready, the demand had declined due to the waning of the COVID-19 pandemic. Consequently, the company now faces increased maintenance costs due to the additional line of COVID tests, which has significant financial implications for the company. That said, there was important impact in terms of increasing capacity and knowledge of the manufacturer and the first in Brazil doing end to end manufacturing.

- Diatropix in Senegal also experienced considerable delays and the manufacturing is being built as of now. That said, there could be impact in the future for other diseases in Africa, with this capacity being built in the company. As the Unitaid report notes: Diatropix in Senegal, is the first platform manufacturing RDTs on the African continent which targets several diseases, starting with COVID. [47]

- Wondfo also faced challenges and was rejected by WHO prequalification initially, although did eventually receive WHO PQ with support from FIND/Unitaid in June 2022. There has been limited impact from this investment although it is hoped some impact transfers with regards to its engagement in Africa more generally.

These experiences have provided important lessons on developing a viable and sustainable business model for regional manufacturers addressing pandemic and epidemic diseases, where demand can fluctuate. Key takeaways include the importance of managing risks through end-to-end production and ensuring that manufacturers have access to tiered markets to mitigate the impact of demand variability.

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[43] FIND (2023), Building for Sustainability: Accelerating Regional Manufacturing for Diagnostics, a FIND & Unitaid Consultation with Diagnostics Manufacturers

[44] FIND (2023), Meeting Report: Strengthening cooperation to enable sustainable development and manufacturing of effective, quality, and affordable diagnostic countermeasures

[45] FIND, Enabling regional supply of diagnostic tests in LMICs Request for Proposals 1: RDTs made in Africa, for Africa, https://www.finddx.org/wp-content/uploads/2023/10/20231020_rfp_african_made_rdt_FV_EN.pdf

[46] Unitaid, 2023, Annual COVID-19 Report

[47] Unitaid, 2023, Annual COVID-19 Report

4. EVALUATION OF THE MEDICAL OXYGEN PORTFOLIO

This section provides a review of the Unitaid oxygen portfolio for COVID-19. It starts with a background/ context section summarising the rationale for Unitaid's investments in oxygen, a description of the portfolio and key findings from CEPA's mid-term evaluation (Section 4.1), and then provides an evaluation across the evaluation pillars and questions (Sections 4.2-4.4).

4.1. PORTFOLIO CONTEXT AND DESCRIPTION

The COVID-19 pandemic caused widespread oxygen shortages in LMICs. As co-lead of the ACT-A Therapeutic Pillar, Unitaid together with the Global Fund and Wellcome Trust launched the Oxygen Emergency Taskforce in February 2021 to coordinate and advocate for increased access to oxygen supplies. The Taskforce made significant progress in securing oxygen access for LMICs, including raising over US$ 1 billion to support procurement and delivery of oxygen systems, market shaping to improve oxygen affordability and supplies, and TA on the development, financing, and implementation of national oxygen response plans.

Unitaid's medical oxygen portfolio between 2020-23 comprised 11 projects (five grantees, with additional outputs related to medical oxygen added to their existing grants from Unitaid) across 51 countries for a total investment of US$ 83m. Table 4.1 presents the medical oxygen portfolio with details on each investment. The early investments were mainly focused on emergency response and PSA plant repair, while later investments focused on technical assistance, market shaping and sustainability. In addition, Unitaid supported market-shaping interventions at the global level to reduce prices and improve supply to promote sustainable and equitable oxygen access.

Table 4.1: Summary information on Unitaid's medical oxygen portfolio for COVID-19

Grantee	Grant reference	Duration	US $	Summary description	Countries
ALIMA	Output 4	Apr 20 – Mar 22	4.5m	To reinforce and improve access to oxygen in six ALIMA supported hospitals	Mali, Niger, Cameroon, CAR, and Nigeria
ALIMA	Output 5	Dec 21 – Apr 23	4.5m	To install PSA plants and related piping systems, assess facilities and make repairs, install solar power, procure all materials (including mobile filling stations) and implement biomedical and clinical training on ETAT and oxygen therapy	Sudan, Burkina Faso, Mali and Guinea
CHAI	Output 7	Apr 21 – Sep 22	5m	To support procurement of respiratory care medical devices and commodities	Ethiopia, Liberia, Nigeria, Rwanda and Uganda
CHAI	Output 8	Jun 21 – Sep 22	5m	To provide technical support to countries to facilitate strong respiratory care planning and implementation as part of the COVID-19 emergency response	Cameroon, Ghana, Mozambique, Zimbabwe, Ecuador, Guatemala, Tanzania, and Lesotho supported by CHAI, CHAI sub-contracted PATH to work to support Tanzania and Burkina Faso, and PIH was sub-contracted in Lesotho and Peru.
CHAI	Output 9	Aug 21 – Jul 23	13m	To accelerate access to medical oxygen through market and demand-side interventions as well as technical support	Cambodia, Cameroon, DRC, India, Kenya, Laos, Lesotho, Malawi, Nigeria, and Vietnam
CHAI	Output 11	Dec 21 – Dec 23	20.7m	To increase sustainable access to medical oxygen with a focus on local and global-level market interventions	Cameroon, Ecuador, Eswatini, Ghana, Guatemala, Indonesia, Lesotho, Mozambique, South Africa, Zambia and Zimbabwe
PIH-BRING O2	Output 7	Dec 21 – Dec 23	7.8m	To conduct PSA assessments and facilitate the purchase of respiratory care equipment, service level agreements and training of healthcare workers	Malawi, Rwanda, Peru, Lesotho, and Madagascar.
PATH	Output 6	Apr 20 – Mar 22	1.7m	To provide emergency response – donate pulse oximeters and repair oxygen equipment (PSA-plants and concentrators) To provide technical support to Ministries of Health to unlock relief funding and increase access to respiratory support systems	Tanzania, Senegal, Kenya, Myanmar, and India
PATH	Output 7	Mar 21 – Nov 22	5m	To assess national oxygen provision, facilitate the purchase of respiratory care equipment and procured services	Malawi, Zambia, DRC, and Senegal
WHO-WHE	WHO-WHE 1	Jan 21 – Dec 22	5m	To provide oxygen TA and acute biomedical needs procurement	Chad, Djibouti, DRC, Somalia, Syria, and Yemen
WHO-WHE	WHO-WHE 2	Jan 22 – Dec 23	10m	To expand WHO's WHE oxygen procurement capabilities	Bhutan, Chad, DRC, Guinea- Bissau, Lao PDR, Liberia South Sudan, and Tunisia

The medical oxygen investments had begun implementation when CEPA conducted the mid-term evaluation of the Unitaid COVID portfolio (2021/22), albeit the grants were at different stages of implementation.[48] The initial assessment through the midterm review made the following findings:

- **For the oxygen portfolio, the range of Unitaid funded support has been critical and much needed for project countries.**
- **Unitaid investments have supported the procurement of emergency respiratory care equipment as well as longer term infrastructure improvements**, contributing to an improvement in the availability of respiratory care equipment in countries. However, delays in procurement and delivery of equipment, as well as lack of metrics with regards to use and deployment make it challenging to assess improvements in access in these countries.
- The range of **trainings/ TA work across investments** have supported strategic planning and capacity building for oxygen.
- Unitaid has supported the **market shaping agenda for oxygen** by engaging with manufacturers of industrial oxygen to pave the way for increased access to medical oxygen in LMICs, although unlocking the potential of these agreements has been slow with some initial achievements at the end of 2021.

Based on the findings, the mid-term review had recommended Unitaid closely consider its role in oxygen systems as it relates to **health systems strengthening**, work with global partners to develop **relevant metrics and KPIs** to measure the results of oxygen investments and consider the **sustainability of investments**.

4.2. Evaluation pillar 1: Contribution/ Results

This section reviews the achievements of the Unitaid medical oxygen investments and the impact of these initiatives in countries.

Overall finding: Unitaid's medical oxygen portfolio has been catalytic in terms of moving fast under the pandemic and aiding the unlocking of other global level funding, but it has still been too late, for the most part, for material COVID-19 related impact.	
Detailed findings	**Robustness**
14. Unitaid's medical oxygen portfolio made an important contribution to the COVID-19 response through its ability to move fast and increase access to oxygen supplies in LMICs as well as being catalytic in unlocking global financing for medical oxygen.	**Strong**
15. The overall impact of the medical oxygen investments in the COVID-19 response has been limited by implementation delays, uncertainty as to the sustainability of the investments and the extent to which global agreements and price reductions have translated to the country-level.	**Moderate**
16. Addressing community needs in the medical oxygen portfolio was not central to the plans and did not happen early enough.	**Moderate**

Finding 14: Unitaid's medical oxygen portfolio made an important contribution to the COVID-19 response through its ability to move fast and increase access to oxygen supplies in LMICs as well as being catalytic in unlocking global financing for medical oxygen.

Robustness: Strong, well supported in the documents review and consultations at the country and global levels as well as with Unitaid and the grantees.

Unitaid has been recognised, by global actors and grantees as well as in country-level consultations, for acting fast to move into the medical oxygen space and showing flexibility to procure and repair oxygen generation equipment to increase supplies within LMICs and mobilise national governments and other larger funders through catalytic

[48] Unitaid (April 2022), mid-term review, Evaluation of Unitaid's COVID-19 portfolio of investments (conducted by CEPA)

procurement. This support has significantly helped in the COVID-19 response to cover the urgent oxygen needs of countries and contributed to addressing the high demand placed on health systems during the pandemic. Notably the success of the medical oxygen portfolio has been achieved through:

Unitaid's unique understanding of the medical oxygen space, from earlier investments in childhood fever management (i.e., pneumonia), malaria and TB.

At the start of the pandemic, Unitaid was one of the global health partners with the most advanced understanding of the access barriers and possible solutions to affordable, safe and high-quality medical oxygen. No other donors fit easily into the space with the necessary breadth of understanding of the technical and operational side, as well as familiarity with private sector engagement to navigate the highly fragmented medical oxygen system market.

Unitaid was one of the first global health partners to invest in the access to medical oxygen space and unlock broader global financing.

Prior to the COVID-19 outbreak, support to countries to address gaps in their medical oxygen systems was limited (predominantly cylinders and concentrators supported by WHO Foundation and UNICEF Procurement), and with respect to global multilaterals it was deemed an "empty space" into which Unitaid first invested. As such Unitaid has played a pioneering role in their leadership to address the gaps and barriers facing countries in accessing medical oxygen. This timing element, and the fact that Unitaid was one of the first global health partners to invest in the space, is very important, as some of its investments were not very different in type and much smaller from the Global Fund, for example, procurement, but worthy of note as Unitaid forged a path. The procurement grants overall were small in the context of the global or even country-level responses, although they did make significant impact at the specific facilities and catchment areas where equipment and training was delivered. However, it is also recognised that Unitaid is not set up as a procurement and service delivery agency and as such it made most sense for the organisation to focus in on its strengths, including catalytic funding, market shaping and TA (country preparedness). The catalytic procurement approach taken by Unitaid demonstrated a proof of concept on how best to support countries increase oxygen supplies and helped unlock global financing allowing other larger funders to build off and also move into the medical oxygen space, for example, GF-C19RM, World Bank, USAID, and Jhpiego discussed further under Finding 17. As such, even though the value of Unitaid investments does not compare with larger procurement mechanisms such as Global Fund and WHO, Unitaid has played a recognisable role as a "pathfinder", also with respect to the oxygen system market and engaging with suppliers, that was able to mobilise at speed ahead of other larger entities and worked closely with partners to share learnings around the complexity of the respiratory care system and best practices to address barriers.

Unitaid's agility to move fast and address the medical oxygen crisis with established implementing partners.

Unitaid demonstrated agility to provide catalytic funding to increase supplies of medical oxygen early in the pandemic, with investments as part of an emergency response set-up as early as April 2020. According to Unitaid's Annual COVID-19 Reports, through Unitaid support, grantees were able to provide emergency oxygen supplies including more than 26,000 cylinders, 52,000 concentrators and 14,000 pulse oximeters. Grantees also installed, procured, or repaired 53 PSA plants. Unitaid was uniquely positioned to respond fast through engaging with pre-existing implementing partners who already had familiarity with national and sub-national medical oxygen systems, predominantly through earlier work on pulse oximeters in a selection of LMICs, as well as strong government relations and technical expertise. For example:

- ALIMA was set up as an emergency humanitarian oxygen provider and was able to respond rapidly to the outbreak of COVID-19. ALIMA supported hospitals at the start to protect healthcare workers through the provision of protective equipment, and then expanded to support facilities to rehabilitate and repair electrical networks and installation of new power sources. ALIMA also supported facilities to procure key equipment for oxygen therapy, pulse oximeters, consumables, and medicines.

- PATH, having worked on an earlier pulse oximeter innovation study, was well placed to respond initially through the donation of pulse oximeters. Additionally, on recognising the delays in procurement and limited availability in global supply lines for medical oxygen equipment, PATH opted to repair (rather than procure new) equipment - concentrator and PSA-plants - to increase the availability of medical oxygen at speed.

- Prior to Unitaid's COVID investments, CHAI had already started to support countries develop costed plans on oxygen access to provide a basis for greater awareness of the critical gaps and build support for investments from national governments and global partners. As such, CHAI was able to respond quickly and support on the procurement of respiratory care medical devices, as well provide TA and lead on addressing market and demand-side interventions.

- PIH, also had some experience with oxygen systems planning and introduction resulting from earlier work supported by USAID. In addition, the organisation has strong country presence, government relations and technical expertise, including novel approaches for innovative partnership with the private sector, for example, leadership on service level agreements. By building on these strengths, PIH also ensured that when they started in 2021, they were also able to move ahead quickly.

- WHO-WHE, with the support of Unitaid, were able to assist over thirty countries[49] in the implementation of between 1-3 facility-based oxygen systems, with a specific commitment to countries where there was limited, or no other, partner support, such as Chad, Djibouti, DRC, Somalia, Syria, and Yemen. Unitaid's close relationship with WHO and joint involvement on the Oxygen Taskforce at that time, facilitated this fast response with WHO-WHE and enabled them to provide significant support towards country-level TA, as well as procurement and implementation of large-scale oxygen production plants in predominantly fragile and conflict-affected setting.

Unitaid's investments in catalytic procurement and technical assistance, along with market shaping (discussed in the next point below) have contributed to improving access to medical oxygen in project countries, contributing to the COVID-19 response.

The catalytic procurement and TA support (combined with market shaping discussed below) led by the grantees under the medical oxygen portfolio has, as stated by the Unitaid COVID annual reports 2022 and 2023 unlocked nearly 150,000Nm3 volumes of oxygen per day through investment in liquid oxygen tanks, pressure swing adsorption (PSA) plants, concentrators, and cylinders - treating an estimated 4,000 patients. Grantees also provided technical support and strengthened local capacity to provide oxygen therapy by supporting health facilities' infrastructure in 54 facilities across ten countries.[50] To this extent, at the sub-national level, where grantees operated, and oxygen supplies increased, it is reasonable to conclude that these activities contributed to the COVID-19 response and the overall public health impact of saving lives (no estimates provided). Box 4.1 presents country case study findings on grants impact on medical oxygen access. In addition, grantees supported the strengthening of national guideline environments which is expected to contribute more broadly to greater quality and more sustainable supply of oxygen, but this is not accounted for in current impact estimates. Lastly, although outside the scope of this evaluation, we note Unitaid's contributions to an enabling environment at the global level, including: i) Unitaid's contributions to the development of global tools such as the WHO Resolution on Increasing Access to Medical Oxygen, WHO key performance indicators, and the O2COV2 study on oxygen requirements and approaches to respiratory support among COVID-19 patients in LMICs; as well as ii) Unitaid's leadership role in the Oxygen Emergency Taskforce (now Global Oxygen Alliance) which contributed to unlocking over US$ 1 billion for medical oxygen and aims to mobilise partners around a further call for at least US$ 4 billion over the next 7-year period, which together with their direct investments will have a significant multiplying effect on Unitaid's impact within access to medical oxygen.

Box 4.1: Country examples: Impact on medical oxygen access

- **Cameroon:** CHAI had a transformative impact on oxygen access in Cameroon. Stakeholders commented that the TA provided by CHAI was critical to the development of the National Oxygen Strategy at an expedited pace during the pandemic. One stakeholder on the National Oxygen Taskforce stated that "*CHAI went above and beyond what was expected while supporting the development of the National Plan, even pulling all-nighters with*

[49] Support was provided to WHO Regional offices as well as specific member states including Chad, DRC, Guinea Bissau, South Sudan, Liberia, Ghana, Malawi, Nigeria, South Africa, North Macedonia, Montenegro, Armenia, Kazakhstan, Azerbaijan, Ukraine, Bhutan, Nepal, Afghanistan, Djibouti, Iraq, Libya, Pakistan, Somalia, Republic of Sudan, Syria, Yemen, Lao PDR, Cambodia, Cook Islands, PNG, Solomon Islands, and Vanuatu.

[50] Unitaid COVID-19 Annual Report (2023)

us [oxygen taskforce]. If CHAI had not pushed the Ministry of Health, the National Oxygen Strategy would not have been developed in such a timely way." CHAI also supported the Ministry of Health to quantify oxygen need in the country and current capacity to produce oxygen, helped define a set of indicators for integration in the DHIS2 related to medical oxygen, and informed norms and standards governing the utilisation, monitoring and maintenance of medical oxygen plants. CHAI trained health personnel and engineers. Finally, CHAI procured medical oxygen equipment including cylinders (the latter often functioned as an emergency stop-gap for facilities during the pandemic). CHAI worked on securing supply of both gaseous and liquid oxygen- sensitising government stakeholders to the benefits of liquid oxygen and facilitating its inclusion in the National Strategy as well as procuring cryogenic tanks to allow for the storage of liquid oxygen. CHAI's work not only increased the oxygen supply in Cameroon, but it also decentralised access. Stakeholders in the Western Region of Cameroon stated that support from CHAI helped facilities meet demand even in the most remote districts. Likewise, installation of a cryogenic tank at the Regional Hospital of Limbe ensured the autonomy of the facility but also supported provision of oxygen to neighbouring facilities in the Southwest district. Additionally, ALIMA very early in the pandemic was able to mobilise PPE and concentrators to provide emergency support to a facility in Cameroon. While the intention was not to support long-term impact with this project, it provided needed and stop-gap emergency assistance.

- **Ethiopia:** At the start of the pandemic, Ethiopia's oxygen capacity was quite limited. There were two medical oxygen plants, which were unable to match the demand for oxygen during the pandemic and access was highly centralised in Addis, while wider regions were underserved. Although Ethiopia had previously developed an oxygen ecosystem roadmap, it had not been prioritised or implemented. CHAI was the first partner to specifically support the strengthening of medical oxygen systems through establishment of three PSA-plants situated in regions which were purposely at a distance from capital, for example, up to 700km from Addis Ababa. A key value-add was the speed at which CHAI was able to procure necessary equipment and increase access to oxygen. According to stakeholders due to complex regulations and processes, government procurement would have taken approximately two years longer. CHAI also maintained responsibility for service contracts with suppliers and maintenance for two years to ensure continued repairs, and trained personnel and biomedical engineers at the Ministry of Health and PSA plants on the operation and maintenance of plants.
- **India:** CHAI's support to oxygen system strengthening in India focused on technical assistance, as the government of India already had considerable funding to support procurement of oxygen infrastructure. However, the Ministry of Health and Family Welfare (MoHFW) required TA to coordinate the installation of 4,100 PSA plants across the country. CHAI therefore embedded staff in the programme management unit (PMU) in the MoHFW and across several states in India, to support optimisation of the facility mix, planning for ancillary equipment, asset maintenance, demand quantification (and the design of related analytical tools), and the design of 'mock drills' to ensure functioning of oxygen plants. CHAI also supported training in line with government ambitions to have one person per district trained in oxygen use. Consultations with government officials confirmed that the TA provided by CHAI was critical, as no oxygen strategy existed to guide planning.
- **Malawi:** PIH in Malawi supported an increase in the supply of oxygen for seven districts (Neno, Chikwawa, Nsanje, Balaka, Nkhatabay, Mwanza, Ntcheu) through the set-up of two new PSA-plants, PSA plant repairs, and oxygen piping installed at 6 facilities, alongside delivery of concentrators and cylinders – unlocking 1,633 m3/day of oxygen per day with the potential to treat almost 15,000 patients annually. The new PSA-plants were established on a hub and spoke operational model which was able to serve the health facilities within six districts. This also demonstrated to the Ministry of Health how oxygen can be provided to lower levels of healthcare facilities such as primary healthcare with a more effective and cost-efficient model rather than relying on monthly subscriptions with private-sector suppliers. In addition, PATH supported last mile distribution with a focus on concentrators and cylinders reaching nearly all regions to improve equitable access to oxygen supply.
- **Peru:** Through the assessment and repair of over 20 prioritised PSA plants, PIH unlocked 9,551 m3/day of oxygen per day with the potential to treat 86,504 patients annually. PIH contribution was seen as particularly helpful in settings where private sector providers were unlikely to intervene, such as hard-to-reach and remote areas and demonstrated the benefits of autonomous production of oxygen in these regions (including cost-related benefits). PIH also maintained responsibility for service contracts and developed maintenance plans for the plants, trained the health workforce and engineers on the use and maintenance of medical oxygen, helped somewhat disrupt market monopolies by sourcing procurement alternatives, and provided technical input during meetings with government stakeholders relevant to the costing and maintenance of PSA plants. Following support from PIH in combination with the efforts from other partners and the national government, the Ministry of Health confirmed that all regions in Peru can produce more oxygen than they consume.
- **Zimbabwe:** CHAI's key contribution to the oxygen system in Zimbabwe focused on TA and helping to provide clarity on Zimbabwe's oxygen needs, as increasing the supply of oxygen was funded by other partners. At the start of the pandemic, CHAI conducted a needs assessment of Zimbabwe's oxygen supply and equipment. CHAI's attempts to develop a national oxygen strategy based on the assessment stalled during the pandemic,

however CHAI did support three rural provinces to develop micro-strategies. A Technology Policy Guidance for the Ministry of Health on the procurement, maintenance, and disposal of oxygen equipment is under review. Additionally, although efforts to improve medical oxygen affordability have been met with resistance, CHAI recently helped broker a volume guarantee and reduce the unit cost of filled cylinders for 25 mission hospitals in Zimbabwe. The agreement lowers the price from US$5.25/ kg to US$3/kg (this will eventually increase to US$3.44). The agreement is promising but has not yet been implemented.

Unitaid's market shaping investment in PSA-plants and liquid oxygen has made important progress in securing increased oxygen production capacity, reducing prices, and securing better and sustainable agreements with suppliers and service providers.

Unitaid, through its investments with implementing partners, has successfully negotiated with suppliers to secure short-term supply of liquid oxygen at more affordable prices, more competitive long-term global level agreements with bulk liquid oxygen suppliers, and negotiated service level agreements (SLA) for both liquid and PSA-plants. This includes Unitaid's- BRING O2 project: PIH working closely with suppliers to establish SLAs for new and repaired plants, with over 40 agreements with a mix of different context relevant business models being developed.[51] For example, where PIH operated in Peru, there were only a small number of vendors that could provide maintenance to plant manufacturers due to exclusivity agreements for the provision of maintenance/ spare parts. Some vendors use this as an opportunity to impose beyond fair market pricing. In response, PIH developed specifications and standards for alternative source of equipment and parts, and by doing so exerted pressure on these vendors to reduce prices. PIH also ensured that SLAs included system strengthening terms such as a requirement of training to be provided for biomedical staff at public sector facilities. In addition, further market shaping activities have been achieved through CHAI Output 11, who committed US$ 5m for an innovative funding approach to facilitate procurement and market-shaping activities, namely, "Collateral Funds". This approach has allowed governments and ministries of health to move quickly, which has been critical in the context of an emergency response and given the heightened demand on global markets for medical oxygen system supplies. This funding modality has been used for catalytic procurement of liquid oxygen across nine countries (Eswatini, Ghana, Indonesia, Kenya, Laos, Lesotho, Malawi, Mozambique, Zambia) and reduced procurement lead times to secure vacuum insulated evaporator (VIE) tanks by at least 8 months, even within the context of COVID-19 case surges.[52] In addition, although outside of this portfolio evaluation, further market shaping activities have also been led by Unitaid in partnership with CHAI. Worthy of note are two global level agreements with the world's largest medical oxygen suppliers (Air Liquide and Linde) announced in June 2021, leading to price reductions of 22% for liquid oxygen and 43% for cylinders and cylinder filling as a basis for long-term affordable supply. This is seen as a significant development and marks the first time that a global health partnership has signed agreements with medical oxygen suppliers as an approach to expand affordable oxygen access at the country level. However, to what extent these agreements translate to price reductions at the country-level or are available to other funders needs to be evaluated over time, given the complex and fragmented nature of the oxygen supply market (see next finding below).

Finding 15: The overall impact of the medical oxygen investments in the COVID-19 response has been limited by implementation delays, uncertainty as to the sustainability of the investments and the extent to which global agreements and price reductions have translated to the country-level.

Robustness: Moderate, with many examples communicated through consultations at the country level (delays and sustainability) and documentation reporting on translation of price reductions to country-levels (limited examples provided without wider analysis).

A key component of the Unitaid investments in supporting medical oxygen access was through procurement, and their achievements came down to whether equipment was coming into countries, operational and providing increased access to oxygen therapy to COVID-19 patients when it was needed. The additional impact is an assessment as to

[51] PIH (2023), Case Study, PSA Plant Service Level Agreements

[52] Unitaid (2023), Annual Report, COVID-19

the sustainability of the investments both in terms of affordability and availability beyond COVID-19 and the lifespan of the Unitaid grants. This is particularly important in the context of medical oxygen which has a broad health system application, for example, maternal and neonatal health, surgery and other respiratory diseases beyond COVID-19. On this assessment our findings conclude:

Despite Unitaid's quick action as described above, most projects were implemented and completed in countries after the acute phase of the pandemic and thereby had lower than expected impact. Further, although oxygen supply and access had already made progress by early 2022 (at the time of the mid-term review) challenges faced in procurement delays, due to extended lead time for items procured globally and availability of technical personnel led to delays, and all projects were extended into 2023.

As mentioned by several stakeholders at both the global and national level "if you are building your oxygen systems at the time of a pandemic, you are already too late." Notably, although implementation had started, the Unitaid oxygen portfolio in the main was not able to respond in time to provide support to countries during the critical window of Q4 2021 and Q1/Q2 2022, when countries were most affected by the delta variant wave, which was particularly acute in India, Ethiopia, Peru, and Brazil. Further, procurement of oxygen system equipment, piping, spares, and accessories, as with all medical devices, were affected by the challenges of the global procurement markets, which experienced high demand, nationalistic purchasing as well as disrupted supply chains, making it extremely challenging to ensure the efficient and cost-effective procurement and delivery of oxygen equipment in countries. All the grantees experienced these delays which predominantly stemmed from interrupted timelines for the manufacturing and shipment of parts for oxygen systems. Box 4.2 presents the country case study findings related to delay and logistical challenges faced by implementing partners. Additional factors also contributed to the delays for example, ALIMA reported that the lack of trained biomedical engineers and high turnover of staff at clinical sites limited the functionality of the oxygen systems. CHAI also reported on several political and public health challenges such as conflict in northern Ethiopia, socio-political unrest in Cameroon.

As a result of the delays experienced by all the grantees, a no cost extension was awarded, extending the awards to between June and December 2023. Although we recognise that this context of disrupted supply lines was a challenging environment for all seeking to procure oxygen system parts, we cannot ignore that it was a major factor that undermined the overall impact of the portfolio. See Box 4.2 below detailing the impact of the delays from the country case studies.

Box 4.2: Delay and logistical challenges affecting impact of the oxygen work

Cameroon

- Logistical issues related to the manufacturing and delivery of equipment were particularly challenging given the tight timelines. The project needed to ensure that hospitals were equipped to receive infrastructure, e.g. transportation and access to electricity.

Ethiopia

- CHAI helped expediate procurement ahead of government processes, but it still experienced challenges in obtaining equipment due to shortage of supplies and complex custom clearance processes. A particular challenge was having all the components for the PSA-plant together in location at the same time, along with pipes and electric generators, as they were all imported from external sources. The delays resulted in oxygen supply increasing after the second (most deadly) wave of COVID-19, but the impact of creating new oxygen plants for three diverse districts was still found to be important and of significant value to the health systems in those local hospitals and catchment area facilities.

India

- The project was initiated after the Delta wave, which was the critical peak in the pandemic, limiting impact on COVID-19. However, stakeholders highlighted that TA provided by CHAI was critical including to longer-term oxygen planning. The scale of the support was also quite limited due to budget, as TA was focused on only a few districts whereas the government sought state-wide support.

Malawi

- BRINGO2 introduction of new PSA-plants in Malawi was delayed by challenges in sourcing and importing the needed materials across all six districts. Oxygen piping needed to be sourced from France and this impacted on the overall timelines and oxygen delivery. In addition, without a pre-existing team of biomedical engineers, it

was difficult to secure skilled labour during the pandemic and this became a particular challenge as the overall project timelines were so tight, resulting in a high turnover of staff. However, the most significant delays impacted construction of new PSA plants in four out of six districts, and supply problems were mitigated through the transportation of oxygen from districts with functional plants to those where construction was still underway. The PATH oxygen project focused on concentrators and cylinders which were important for last mile distribution, but met challenges due to disrupted electricity provisions, lack of training on use of the equipment and challenges in obtaining sufficient accessories, such as oxygen cylinder regulators where some facilities only received one regulator for multiple cylinders.

Peru

- COVO2 and BRINGO2 were implemented following the first two waves of the pandemic in Peru, and the projects were further delayed due to global supply chain disruptions which made it challenging to ensure the efficient and cost-effective procurement and delivery of oxygen equipment. However, the life-saving potential of oxygen beyond COVID-19 was highlighted by stakeholders as a key value-add, mitigating challenges related to timing. The scale of the support given was limited by resource constraints to seven regions, although the plants selected for assessment and repair were priorities according to the Ministry of Health. Stakeholders highlighted that the long-term operationality of plants (past the expiration of SLAs, as well as plants not supported directly by PIH) and the sustainability of the oxygen system was at risk however due to a weak market, high oxygen prices, limited technical personnel, and organisation of the medical oxygen system (discussed further below).

Zimbabwe

- Zimbabwe's COVID-19 response and medical oxygen work has been affected by bureaucratic delays and political challenges with consequences on overall support for the national response. For example, in 2022, CHAI drafted priorities for funding assistance to support Zimbabwe's national response, but only 10% of the total budget needed (US$86k) was signed off by the government, impacting the scale of support provided by CHAI.

The medium to longer term impact of Unitaid's investments is challenged by the extent to which the newly developed and repaired oxygen systems can remain operational and sustained within health systems, including the feasibility of transitioning large amounts of oxygen equipment and maintenance to government led services.

During the COVID-19 response, Unitaid support delivered a significant amount of emergency oxygen supplies discussed under Finding 14. However, the sustainability of oxygen equipment – including spare parts, accessories, piping, energy sources and backup systems - is a major challenge to the overall functionality and supply of oxygen provided by this equipment. A concern raised by grantees and country stakeholders was the limited funding for oversight and post-installation assessments of equipment, which heightened the risk that equipment may not be functioning within two years. This point on maintenance and repair is discussed within finding 17 (transition and sustainability) and expands on the steps taken by grantees to mitigate against this risk, for example, close collaboration with national health services and context appropriate service level agreements.

All the equipment within medical oxygen delivery system is highly specialised, and as noted in the 2023 Unitaid COVID report, for a functional oxygen system in country, significant technical expertise is required to install, operate, maintain, and repair. At present however, this expertise is either limited in LMICs and/or affected by high-turnover rates of staff, limiting the capacity of biomedical engineering staff in the public sector and local providers in the private sector. During the COVID-19 response, Unitaid made significant efforts in capacity building and training of staff, including improving human resource capacity with an additional 17,500 clinical and biomedical staff trained on medical oxygen, particularly through the CHAI, PIH, PATH and WHO grants. However, long-term capacity building and health system strengthening programmes are not within Unitaid's core competency and mandate as a catalytic funder, and future work of this nature is reliant on other funders moving into this space to provide this support. At present, we understand that all the grant countries are supported by Global Fund C19RM until the end of 2025, but beyond this, it is unclear to what extent transition plans will be able to sustain the new provision of equipment, maintenance, and technical personnel. Additionally, it was noted by stakeholders in Cameroon for example that funding under C19RM in support of oxygen systems was purely in support of infrastructure and equipment development and did not cover 'softer' components such as training or TA to plan financing and maintenance. We also note that as a component of the CHAI grant, the team have worked closely with 19-project countries to identify additional domestic, bilateral, multilateral, and donor funding for oxygen systems including LOX amounting to approximately $593m. WHO also worked with countries to develop comprehensive overview of medical oxygen ecosystems in countries to support policy makers

and health facility administrators plan oxygen scale up projects. However, the maintenance of medical oxygen systems remains a major challenge to cost-effective and sustainable oxygen delivery models, and further consideration needs to be given to integrating oxygen-related expenses within facility budgets including spare parts, consumables, maintenance/repair, energy costs, transport, and distribution. The experience of transition planning and the ability to sustain these systems has varied across countries, and Box 4.3 presents these different findings.

The impact of the wider market shaping and strategy-level work on oxygen supported by Unitaid is yet to be realized at country level.

Global level agreements between Unitaid/ CHAI and Air Liquid and Linde have already supported in country-level procurement negotiations to some extent, for example in Zambia, AFROX industrial cylinder filling station was converted into a medical cylinder filling station. Lesotho bulk liquid oxygen price was negotiated from US$ 1.08 / kg to US$ 0.84 / kg), Kenya in procurement of bulk tanks and in Laos supply agreements with liquid oxygen refill suppliers.[53] The LOX global agreement aimed to bridge the gap between global-level negotiations and the needs and actions of national actors by ensuring grantee-led procurement was conducted in conjunction with local stakeholders, so all parties were brought in on the access and affordability discussions. However, to what extent these agreements translate to sustainable and affordable prices at country-level for national governments and donors more broadly needs to be evaluated over time, given the complex and fragmented nature of the oxygen supply market. In the consultations, CHAI noted that the global level agreement is only one piece of the puzzle and other factors determine the price of medical oxygen in country such as subsidiary companies and distribution handlers.

In support of country preparedness, at the global level the WHO-WHE alongside WHO Department for Medicines and Health Products and Member States – led by Uganda and supported by Australia, Bangladesh, Central African Republic, European Union and its 27 Member States, Kenya and Turkey - championed the adoption of an Oxygen Resolution at the WHO World Health Assembly 2023[54]. This resolution aims to enhance visibility for medical oxygen and address global needs by mandating countries to implement a 20-point preparedness plan. This plan includes developing national medical oxygen strategies, including oxygen and related devices in essential medicine lists, assessing access gaps, and increasing public awareness. While the resolution's full impact on national health policies and infrastructure is still unfolding, it represents a significant advancement and provides a strong policy foundation for Unitaid and GO2AL to support countries in aligning with these commitments.

Finding 16: Addressing community needs in the medical oxygen portfolio was not central to the plans and did not happen early enough.

Robustness: Moderate, supported by documentation and Unitaid consultations as well as the country level

The concept of community engagement and demand generation came later in the development of the medical oxygen portfolio. The discussions that were raised on community within Unitaid and amongst grantees remained high level and technical, mostly focusing on “who are the CSOs and community groups in relation to oxygen.” The challenge of identifying the appropriate communities arises as individuals tend to only receive oxygen therapy in acute health situations, rather than as response to a long-term chronic illness such as HIV or Hepatitis C. On the other hand, it can be seen that all patient groups should have an interest in oxygen, as well as healthy individuals who may be suddenly in need of oxygen, for example, respiratory infection, childbirth, surgery or road traffic accidents. Notably, as mentioned by a consultee in Malawi, community engagement is an important component for medical oxygen: firstly, to expel misinformation or misunderstanding that oxygen is a “treatment of last resort” which you receive only as palliative care before dying, and secondly to raise awareness of the importance and availability of oxygen in health facilities. This focus on public awareness and demand generation was supported by grantees to some extent, for example PIH reported that in Malawi the installation of a PSA-Plant at a local hospital in conjunction with community engagement led to increased demand and uptake for oxygen. CHAI also worked closely with Ministries of Health to form national coordination platforms in most focal countries, which included several civil society and community

[53] Unitaid (2023), Annual Report, COVID-19

[54] WHO (2023), WHO Resolution, Seventy-Sixth World Health Assembly, WHA76.3, Agenda item 13.1, Increasing Access to Medical Oxygen

focused groups. These platforms were also a forum for sharing lessons learned, including between countries. However overall, across the portfolio, community outreach and engagement could have been better established, and more central within Unitaid's COVID response. Notably, from the inception of GO2AL, considerable effort has been made to engage CSOs and patient groups, and these community representatives are active and vocal in the development of the Alliance plans. GO2AL has also engaged with Unitaid's network for advocacy champions to build further support.

Lessons learnt from evaluation findings on the contribution/ results of the medical oxygen portfolio

Oxygen Portfolio Results and Contribution: Lessons Learned

There are two similar lessons to that under the Test and treat portfolio, namely:

- Starting work on pandemic response during a pandemic is already too late. The core work on pandemic preparedness needs to be built up well in advance to then bear fruit during a pandemic.
- Achievement of outcomes does not ensure achievement of impacts, especially during uncertain and complex times such as during a pandemic.

Other lessons include:

- There has been significant merit in Unitaid's first-mover and swift action for the COVID-19 response, catalysing other donors and unlocking additional funding for the pandemic.
- Unitaid's early work in the oxygen space, as well as its core competencies in market shaping, catalytic procurement, and TA (for country preparedness), put Unitaid in a strong position to be an early mover in trying to address inequitable access to oxygen during the pandemic.
- There is a need for further attention on the sustainability of oxygen investments by Unitaid and other partners.
- Community engagement and demand generation have been an afterthought in the development of medical oxygen systems in LMICs, and more thought needs to be given to ensuring comprehensive demand side activities to target access barriers.

4.3. Evaluation pillar 2: Adaptation, Transition, Sustainability and PPPR

Oxygen Portfolio Pillar 2 Finding: Adaptation, Transition, Sustainability and PPPR	
Detailed findings	**Robustness**
17. The medical oxygen portfolio adapted well to the changing demands of the pandemic and worked closely with governments to align systems and support PPPR, but concerns remain over the sustainability of the equipment and skilled personnel to maintain the oxygen investments established.	Moderate

Finding 17: The medical oxygen portfolio adapted well to the changing demands of the pandemic and worked closely with governments to align systems and support PPPR, but concerns remain over the sustainability of the equipment and skilled personnel to maintain the oxygen investments established

Robustness: Moderate, with many examples communicated through consultations at the country level.

A key achievement of the portfolio was the ability to adapt the grants over time, with the changing context of the pandemic. At the beginning of the pandemic, the focus of oxygen grants was catalytic procurement to address the immediate needs of countries and was intended to fill a critical gap ahead of national governments and larger partners providing more substantial long-term support. As such, Unitaid moved ahead earlier than other global health partners to assess the needs and gaps of oxygen systems more widely including oxygen generation, distribution, storage, and delivery along with human resources within LMICs. As the context of the pandemic progressed the

different grant interventions were adapted to the shifting COVID-19 environment and evolved to focus more on sustainable oxygen access. In particular, the focus was on integration into primary health care and system preparedness to ensure adequate oxygen for potential new waves of COVID-19 as well as establishing infrastructure to better support medium- and long-term health system planning. This progression can be seen across the changing focus of the grants:

- In the first year ALIMA and WHO-WHE were important implementing partners as they had strong expertise in operating in emergency and fragile contexts. They focused on the procurement of emergency oxygen equipment, for example, concentrators and cylinders along with some training of technical staff and medical staff on the use of the equipment. Equally, given the urgency of the situation, PATH also adapted and provide pulse oximeters as donations. Alongside this, through early grants PATH and CHAI were already starting to provide technical support to MoH and contribute to country preparedness and national oxygen plans in an emergency context, including mapping where oxygen was needed and how best to procure and distribute.
- In the second year, PATH and CHAI shifted to strongly focus on procurement and system repairs to ensure systems were operational and could rapidly increase oxygen supplies in facilities and surrounding catchment areas.
- In the third year, as the context of the pandemic started to wane in April 2022 with falling COVID caseloads, the medical oxygen grants adapted further to provide for longer term system planning and development of sustainable access to medical oxygen and ensuring health systems are better prepared for future emergencies. CHAI pivoted towards more long-term sustainability through its market shaping work focusing more on liquid oxygen, moving away from an emergency response focus on concentrators and PSA-plants. Through this work CHAI also expanded its stakeholder reach and engaged with manufacturers and suppliers on expanding oxygen system capacity and on the other hand with local authorities to build demand, creating a more conducive O2 market in countries with greater competition, lower prices, and increased efficiency.
- In addition, independent of Unitaid but made possible by the earlier Unitaid investments, PATH and PIH also shifted efforts to focus on LOX plants and support governments on longer term oxygen system planning and finance.

The portfolio successfully shifted from procurement of emergency oxygen to adapting investments with more sustainable and long-term focus. This was recognised as one of the strongest achievements of medical oxygen investments and provides a clear example of where Unitaid has been willing to expand its adaptability.

Transition and sustainability efforts have been accommodated into the later oxygen investments with a view to longer term system planning, however maintaining skilled personnel and procuring adequate spare parts remains a challenge (also noted as a barrier to impact under Finding 15). As the COVID-19 pandemic progressed, so did the nature of the investments, and as such it is reasonable to review these grants differently on the consideration of transition and sustainability. The earliest oxygen investments with ALIMA, CHAI and PATH were constructed with the aim to deliver an emergency response and as such limited consideration on transition/ sustainability planning had been built into the design of these grants. As the pandemic evolved however and the oxygen investments adapted to longer-term system building approaches then efforts for transition and ensuring sustainability became a central component of success, particularly in the later grants with PIH, PATH and CHAI. See Box 4.3 on the considerations of sustainability as reported within the country case studies. The grantees have supported investment sustainability through:

- **The implementing partners have supported in the development of national oxygen road maps, system assessments (including the identification of gaps and demands) and support for national health policy and development to ensure careful integration of equipment and capacity building within existing health system platforms.** Grantees have worked with MoH and sub-national health authorities to develop a supportive enabling environment to ensure investments are aligned with an overall national strategy and the country needs and priorities. Importantly in this regard CHAI provided TA to MoH and supported countries on costed oxygen system planning including in India, for example. Equally PATH led on demand and quantification assessments to guide national policy and programme development in Malawi, Myanmar, Tanzania, Senegal and Kenya.

- **Availability and affordability of spare parts.** Procurement of equipment, including oxygen system spare parts and accessories has been greatly supported by the grantees. It was noted by country level consultees that the support of organisations such as CHAI, PIH and PATH has not only been important in respect of funding but it also expediated processes and access to necessary equipment. As noted in the context of Ethiopia, the government procurement processes would have taken 2-years longer due to complex regulations, international bidding processes and wider currency constraints. However, as these projects came to an end, a major concern that has been raised is limited capacity to procure spare parts and accessories to maintain the functionality of these systems, which in many settings where Unitaid has invested (excluding India) require importation of system parts from outside of the country and are reliant on global markets.

- **Training and capacity building has been a key component of the Unitaid oxygen investments**, with a focus on local teams in public and private sector to ensure that the capacity built is retained within countries. This has been further supported by "training of trainer" programmes which aim to expand and decentralize expertise on oxygen system maintenance and delivery beyond specialist or centralized hospital. For example, in Peru, PIH was able to integrate their oxygen training into the National School of Public Health and used funding from USAID to scale up the training and expand the reach of the programme. However, it remains that at the country level the number of skilled personnel to maintain and operate oxygen systems is still below capacity, and in particular countries reported on the lack of skills within the public sector. This was highlighted as a challenge in Malawi, where stakeholders suggested that it was *"hard to find skilled labour to fill positions"* and that *"there was a need for more specialised training as training so far was not sufficient."* For example, hospitals with PSA-plants often lack personnel who can conduct system checks and troubleshoot basic issues, which risks leaving equipment and systems out of service. The projects have in the main focused on biomedical engineers, which is appropriate for the maintenance of oxygen systems, however given that PSA-Plants and LOX-systems are production plants up to the point of delivery, it should also be possible to expand this pool of skilled labour to also include mechanical-, production-, process- and chemical engineers.

- **Design of sustainable operational models for oxygen systems, particularly PSA-plants have been an important component to ensure the up-keep and affordability of systems within the public health services and reduces the reliance on private sector suppliers.** For example, in Malawi, PIH set-up a PSA-plant in a hub and spoke model, and CHAI took a similar approach in Ethiopia. The approach of this model is designed to first enhance healthcare outcomes by expanding oxygen accessibility from a main hospital with PSA Plant (hub) to catchment area secondary and primary healthcare facilities (spokes). In addition, this approach ensures the financial sustainability for the continued operation and maintenance of the PSA plants. Ensuring the appropriate business and service model supports the established infrastructure has been an important aspect of sustainability and transitioning ownership to national health systems. Where services have been required from the private sector, PIH and CHAI have also aimed to set up favourable service level agreements that are affordable for governments, and have broader capacity building terms, for example, "a clause on private sector engineers required to conduct training with the public sector engineers." An approach the WHO is now considering taking up to include in their oxygen system guidelines.

Unitaid's investments for improving access to medical oxygen has been recognized as important, both for the immediate emergency COVID-19 response, but also in respect of pandemic prevention, preparedness, and response. The COVID-19 pandemic exposed the importance of having reliable access to a sustainable and affordable supply of medical oxygen in all countries, and in LMICs, where other specialized treatments may not exist or be readily available. In addition, the likelihood of a future pandemic being an airborne disease is high, given the speed of spread and complex nature of containing such an outbreak. The Unitaid investments supported PPPR in the following ways:

- **The grantees worked with countries to have a diverse and appropriate mix of oxygen supply and technical support to ensure flexibility and resilience within the systems.** The grantees approached this in a range of different ways to provide countries with need and gap assessments of their oxygen systems, such as sub-regional reviews (led by WHO-WHE), PSA equipment assessments (PIH), facility gap assessments (PATH) and costed oxygen plans (CHAI). All of these approaches have supported countries to have great visibility as to the reach and functionality of national oxygen equipment and system delivery. In addition, the procurement focus of the

investments supported in ensuring that oxygen equipment was available in countries and has been a critical contribution to setting up oxygen delivery systems, both through direct investments and because of unlocking financial support from national governments and other funders. Notably, the main emergency response for oxygen supply supported by Unitaid was PSA-plants and cylinders, easy to deliver but hard to maintain during the onset of COVID-19. However, in the long-term a more sustainable and far-reaching, high-volume oxygen delivery system is best advanced with liquid oxygen plants, specialized infrastructure but requires no electricity and less maintenance requirements. Although considerations for liquid O2, predominantly through CHAI output 11, started in the pandemic this infrastructure has come later with other funders and a new Unitaid grant that will start in summer 2024 with CHAI. This shift to support for liquid oxygen and having a diverse and appropriate mix of oxygen generation and delivery in country is likely to best support PPPR-capacity as well as wider health system strengthening requirements. In addition, the investments supported the recruitment and training of technical personnel, both biomedical engineers and clinicians to maintain and deliver high quality and safe oxygen. All personnel were recruited from within countries and included both public and private sector professionals to build and retain capacity within local systems, which is an important factor for PPPR. A number of country consultations continued however to report on the shortages and high turnover of skilled personnel, as well as being reliant on imports for spare parts, as challenges to maintaining an uninterrupted supply of oxygen in country as such questioning whether the balance of investments between equipment and HR adequately supported system sustainability and preparedness.

- **Addressing maintenance and ensuring surge capacity**. A challenge to all countries and oxygen systems remains around the maintenance of the systems in intra-pandemic periods and ensuring sufficient surge capacity when required in the context of a health emergency. Efforts have been made to ensure long-term sustainability by Unitaid and its implementing partners through working closely with ministries of health and country stakeholders at national and sub-national levels to ensure long-term agreements are in place for monitoring, repair, and routine maintenance. These agreements and regular service checks are intended to ensure the supply of oxygen in countries is readily available when needed. However global partners and country -level consultations raised concerns as to the extent to which post-installation checks and maintenance are being conducted and how much of the equipment installed during the pandemic is still operational now and will be in the future. This concern was further articulated, given the current shortage there is for biomedical engineers in LMICs with the adequate skills and training to maintain the systems that have been installed.

- **Partner coordination to build coalitions and engage the private sector in increasing access to medical oxygen**. Unitaid demonstrated that it is well positioned in terms of networking with global partners but also country partners, implementing partners, and private sector engagement to be able to lead on the coordination for increased oxygen access, as demonstrated through their role in the Oxygen taskforce and GO2AL. This work has proven an important contribution to pandemic response both in terms of shaping partnerships and addressing the needs of LMICs in respect of respiratory care systems. Equally at the country-level Unitaid supported oxygen system assessments to better advocate for and align resources between global finance, national governments, and the requirements of health systems.

Box 4.3: Medical oxygen: sustainability and long-term impact

- **Cameroon:** Key components of CHAI's work developing medical oxygen systems in Cameroon will have a long-lasting and sustainable impact: including installation of cryogenic tanks (which have a lifetime of ten to fifteen years), trainings on PSA maintenance, integration of indicators monitoring oxygen production and consumption into DHIS2, and development of policies and guidelines including the National Oxygen Strategy. CHAI also ensured that service agreements with manufacturers included maintenance for two years and the training of institutional staff to promote skills transfer. Finally, CHAI played an instrumental role in preparing a funding request which secured US$25M from the Global Fund for the installation of oxygen infrastructure.
- However, stakeholders suggested that while significant progress was made during the project, progress against the National Plan has since stalled due to a lack of funding and motivation. This includes the need to scale up training (the scale of trainings delivered through the project was relatively limited), strengthen data-driven decision-making, strengthen the procurement and supply chain for oxygen, scale-up of liquid oxygen infrastructure, and financing. Global Fund funding will only support equipment and infrastructure, and stakeholders felt that the country still lacked the supporting capacity to manage the system which was a major

risk to long-term impact. Additionally, one stakeholder raised concerns that facilities previously supported by CHAI are now struggling to meet demand because of the high costs of oxygen.

- **Ethiopia:** CHAI has worked closely with the government to develop an oxygen sustainability manual. The aim is that hospitals who produce oxygen will sell any surplus to other facilities, which will finance the maintenance, repair, and eventual replacement of the plant. However, despite a suitable financing mechanism in place the three PSA-plants dispersed across different locations often have overlapping needs for support, and this can be a challenge due to limited skilled personnel able to address issues in a timely manner.
- **India:** The primary focus of CHAI's work in India was to provide TA to guide planning of the oxygen system including data collection and analysis to optimise installation of PSA plants. Stakeholders confirmed that tools that were developed to strengthen oxygen management were used in the third wave of COVID.
- **Malawi: PIH** have worked in Malawi for over 17-years, so they understood the importance of setting up service level agreements for equipment and working closely with the Ministry of Health to be able to transition equipment and the operational costs. In addition, the government in Malawi have now established an oxygen access roadmap identifying the gaps, and other partners are also supporting on these efforts, including FIH-360 piloting liquid oxygen and BIH working on service level agreements and longer-term system planning. However, it was raised in the country-level consultations that sustainability is a concern as often in the longer-term this equipment degrades due to high upkeep cost and challenges in procuring spare parts. PATH reported that the national tracking of equipment, for example, concentrator and cylinder location and post-installation reviews were limited, and this lack of national coordination posed a challenge to sustainability.
- **Peru:** PIH integrated several activities within oxygen grants that were aimed at increasing the sustainability of investments in the oxygen system. For example, PIH ensured that trainings on oxygen use and maintenance were transitioned to the national government and National School of Public Health, and through USAID funding reached national coverage. In addition, they negotiated service level agreements for the preventive maintenance of oxygen plants which were transitioned to the government with provisions related to capacity-strengthening and training of institutional staff. Several of the plants supported by PIH are still producing oxygen. However, many are not reporting to the national database and PIH did not have the scope or resources to continue to conduct follow-up assessments. Through the work of PIH and others, Peru has developed its oxygen ecosystem in a way that facilitates continued use of medical oxygen for other disease.

  However, stakeholders highlighted multiple threats to the sustainability of oxygen systems, suggesting that the supply of medical oxygen in Peru increased dramatically but without a strengthening in the government's capacity to manage and organise it. For example, there are information gaps about oxygen consumption and demand, the optimal configuration of oxygen infrastructure, and the extent to which newly installed plants remain functional. A lack of bioengineers and low demand for oxygen post-pandemic also threatens the sustainability of interventions. Additionally, although a budget for the maintenance of plants is technically managed by regional governments, implementation is mixed. There is a need to strengthen government ownership and planning of the oxygen system, to avoid the risk of degradation over time.
- **Zimbabwe:** Although the needs assessment of Zimbabwe's oxygen supply and equipment did not lead to the development of a national oxygen strategy, it provided the evidence base to inform the Global Fund C19RM funding request resulting in US$11M for Oxygen Systems Strengthening. Additionally, CHAI has developed several guidance documents at the provincial and national level to support government in the procurement, maintenance, and disposal of equipment. More recent work to broker a volume guarantee will also have a long-term impact on the affordability of oxygen in Zimbabwe.

Lessons learnt from evaluation findings on the adaptation, transition, and sustainability of the medical oxygen portfolio

Oxygen Portfolio Sustainability and PPPR: Lessons Learned

- Despite progress made in establishing functional oxygen systems in LMICs during the pandemic, certain limitations related to human resources, capacity and continued market monopolies are likely to threaten the ability of countries to maintain oxygen systems during intra-pandemic periods and ensure sufficient surge capacity when required in an emergency.
- Unitaid has an important role to play at the global level, having demonstrated that it is well positioned in terms of networking with global partners but also country partners, implementing partners, and private sector partners to be able to lead on the coordination for increased oxygen access through GO2AL

- Unitaid needs to carefully consider how it can affect PPPR for countries, recognising it is not a scale up and long-term funder.

4.4. Crosscutting pillar: Coherence and Efficiency

Finding 18: Unitaid developed the medical oxygen portfolio with pre-existing implementing partners who had strong expertise in respiratory care systems, emergency response and country presence facilitating a fast response, however the strategic focus was limited by a lack of country data and costed oxygen plans regarding the country context and appropriate mix of oxygen services.

Robustness: Moderate, with examples communicated through consultations with Unitaid and at the country level.

The coherence and efficiency of the medical oxygen portfolio is assessed from the perspective of whether the investments contributed and addressed the critical gaps in the pandemic response for LMICs, and whether the investments have been structured in a manner that is timely and impactful. The consultations identified three key issues in this regard:

- **Grantee selection for the medical oxygen portfolio** was based on pre-existing implementing partners of Unitaid that had experience or expertise in emergency response (ALIMA and WHO-WHE) respiratory infectious diseases and care systems, for example, PATH and PIH or strong country presence, for example, CHAI. Notably, this approach allowed Unitaid to move ahead at speed and address critical gaps with their COVID-19 investments, which was commendable, and the first grants started as early as April 2020. Given that Unitaid had not previously been set up as an emergency response organisation this approach facilitated a path forward which expediated Unitaid's overall response. However, this approach diminished the organisation's capacity to operate responsively and strategically in response to countries where the oxygen crisis was most severe and remain reactive to the demands of the COVID-19 pandemic. Geographically, most of the medical oxygen portfolio funding, especially with the first wave of grants, went to partners with country presence in Africa when initially the high mortality rates and excessive demand for oxygen supplies rose first in LAC, then Asia, particularly India and Bangladesh had major oxygen supply shortages in 2020/21) and the peaks later followed in Africa. Additionally, in Q3/Q4 2020 some of the highest death rates started within Eastern Europe and the Middle East, but the Unitaid response did not respond to these priorities and had no strategy to do so. On the other hand, it is recognised that at the start of the pandemic it was not know which countries would be most affected by the pandemic and given the Unitaid grantees work in predominantly weak healthcare settings, it could be argued that there was a strategic relevance in ensuring these countries had sufficient investment to protect their health systems and respond.
- **An important hinderance to the design and implementation of the oxygen grants for Unitaid, and all funders, was the absence of, or underdeveloped, costed national plans** to increase access to quality assured, affordable medical oxygen systems and support identification of critical gaps and priorities. A further challenge comes from estimating national oxygen needs, including a lack of consensus on the methodology, and has delayed the development of national oxygen strategies in several countries. As a result, this has also led to disruptions in several activities to ensure integration with national policy and prevent duplication. Notably, in the COVID-19 response Unitaid required that all grantees start with national or sub-national assessment of needs and functionality of equipment in country, however this delayed implementation of increasing oxygen supplies and has made it difficult to track to what extent Unitaid has addressed priorities and contributed to the oxygen demands in the country. As such published metrics have focused on the equipment and training provided, as well as the volume increase of oxygen, but it is not possible to calculate if this is sufficient to meet demand or define the size of the gap that remains. An important contribution that has come out of the WHO-WHE grant and in support of medical oxygen scale-up is the development of Key Performance Indicators to measure and track global oxygen delivery as a response to the amount being invested in medical oxygen and respiratory therapy. This was raised in the portfolio mid-term review of the investments and is an important development that indicates a shift in how countries and funders are required to consider and address challenges in relation to medical oxygen; GOAL-partners will work with countries to implement these KPIs and support in how best to develop

adequate M&E systems around oxygen services as a component of system planning, policy development and resource mobilisation.

- **Appropriate selection of oxygen systems such as PSA-plants vs LOX.** Unitaid's investment predominantly supported oxygen concentrators, PSA-plants, and cylinders within the medical oxygen portfolio. Although the CHAI grant (output 11) supported plans for liquid oxygen delivery in some settings, it was not set-up as the main means of oxygen provision in response to the pandemic. This decision has been justified given the speed and needs of the response but raises the questions as to whether it was the best or most appropriate solution, especially given lack of available nation-wide oxygen plans. The selected oxygen system for a country will be dependent on the unique country context and in general require a mix of diverse oxygen sources from cylinders, concentrators, PSA-plants, and liquid oxygen plants. This raises two concerns, 1) were the systems set up in country responsive to the unique needs of the country and 2) will the PSA-systems be sustained if a country is now moving over to liquid oxygen plants. In addition, the shift in focus away from emergency response towards sustainable and affordable oxygen system planning prioritises liquid oxygen both with larger funders and in the GO2AL executive strategy, but it is unclear if this prioritisation of LOX will improve access and best deliver for LMIC-setting and underserved communities.

5. OVERALL PORTFOLIO-LEVEL FINDINGS, LESSONS LEARNT AND RECOMMENDATIONS

5.1. PORTFOLIO-LEVEL FINDINGS AND LESSONS LEARNT

The COVID-19 virus has been "one step ahead" of any institution's response to the pandemic. The successive waves of the pandemic and the changing nature of their severity on the one hand, and the geo-politics of the response on the other hand, has made the global response extremely challenging.

Amid this, Unitaid has exhibited innovation and agility by very quickly developing and adapting an extensive portfolio of investments on therapeutics, diagnostics, and oxygen. The early vision and swiftness of Unitaid is to be applauded, initiating investments before the global health community could organise itself through ACT-A, leveraging its solid footprint in countries through its HTM grantees, and simplifying and speeding up its investment application, approval, and monitoring processes. Indeed, this was also captured in the mid-term evaluation of Unitaid's COVID-19 portfolio which notes that "*Unitaid's COVID-19 investments have largely been strategically relevant and responsive to the priority needs of the pandemic in LMICs*" and "*Unitaid moved with speed and agility at the start of the pandemic to identify niches and gaps where it could meaningfully contribute to the global response*". One of the overall conclusions and lessons learnt from the mid-term evaluation was a powerful statement exemplifying Unitaid's successful response: "*There is clear value for organisations like Unitaid that "break the mould" and reinvent themselves to respond to unprecedented circumstances. Unitaid has clearly demonstrated the value in being a fast, agile mover, adapting to the needs of the hour*".

At the time of the mid-term evaluation, based on the progress made through the then portfolio of investments, the view was that good progress was being made across the portfolio, except for therapeutics, which has been a global challenge. The assessment was that Unitaid had made a solid contribution (with some gaps/ missed opportunities). With the end-term evaluation, with the Test & Treat portfolio as well as oxygen investments fully implemented, the assessment is as follows:

Unitaid has been strategic, an early thinker, and innovative as well as a risk-taker, and has lived up to its "pathfinder" role by initiating the Test & Treat portfolio that recognised the need to support the test and treat continuum and improve the country level demand for testing in LMICs. As well, supporting equitable access to oxygen by sequentially investing in emergency procurements, TA and market-shaping investments have enhanced long-term sustainability.

Both portfolios have delivered important outcomes in relation to the COVID-19 response:

- The **Test & Treat portfolio** made an important contribution to enhancing the demand for COVID-19 diagnostics, by decentralising testing and making tests available at lower levels of health care (PHCs) and supporting community-based testing. Innovative models of service integration have been pilot tested and adopted across countries. There have been updates to national policies and guidelines for several countries. The investments also supported an improvement in equitable access to AgRDTs in countries by targeting harder to reach and vulnerable populations. Results in terms of supporting demand for therapeutics have been limited given the global lack of development and availability of appropriate therapeutics and the evolution of the nature of the pandemic, but the investments have supported product registrations and updates to case management guidelines in select countries.

- The **medical oxygen portfolio** unlocked nearly 150,000Nm3 volumes of oxygen per day through investment in liquid oxygen tanks, pressure swing adsorption (PSA) plants, concentrators, and cylinders – sufficient to treat approximately 4,000 patients per day. The TA work of the grantees in-country has also supported the updating of oxygen supplies at health facilities, decentralising and improving oxygen access at primary health care facilities, training of relevant manpower as well as contributing to national guidelines and other practical reference tools. Unitaid's catalytic funding in the medical oxygen space has demonstrated a proof of concept on increasing oxygen supplies, contributing to unlocking global financing of other larger funders for scale-up of efforts, such as GF-C19RM, World Bank, USAID, Jhpiego. Beyond its direct investments, the role of Unitaid in the ACT-A Oxygen

Emergency Taskforce (now GO_2AL) has supported unlocking over US$ 1 billion for improving access to medical oxygen alongside negotiating agreements with two major industrial liquid gas companies that has contributed to longer-term sustainability.

Table 5.1 maps contributions of the two portfolios against Unitaid's strategic objectives for 2023-27.

Table 5.1: Contributions of Test & Treat and medical oxygen portfolios against Unitaid's strategic objectives

Unitaid strategic objective	Contribution
Accelerate the introduction and adoption of key health products	• Decentralised testing and making tests available at lower levels of health care (PHCs) and supporting community-based testing • Supported rapid validation and registration of AgRDTs (professional and self-tests), and some therapeutics • Unlocked nearly 150,000Nm3 volumes of oxygen per day through investment in liquid oxygen tanks, pressure swing adsorption (PSA) plants, concentrators, and cylinders – sufficient to treat approximately 4,000 patients per day • Demonstrated a proof of concept on increasing oxygen supplies, contributing to unlocking global financing
Create systemic conditions for sustainable, equitable access	• Supported updates and development of national policies and guidelines for several countries in diagnostics, therapeutics including oxygen. • Innovative models of service integration have been pilot tested and adopted across countries • Targeted harder to reach and vulnerable populations, improving equitable access to AgRDTs • TA work of the grantees in-country has supported decentralisation and improvement of oxygen supplies access at primary health care facilities, training of relevant manpower
Foster inclusive and demand-driven partnerships for innovation	• The role of Unitaid in the ACT-A Oxygen Emergency Taskforce (now GO_2AL) has supported unlocking over US$ 1 billion for improving access to medical oxygen • Negotiated agreements with two major industrial liquid gas companies • Across the Test & Treat portfolio in particular, grantees employed creative strategies to engage with communities and generate demand for COVID-19 tools

However, for the most part, these investments came in after the peak of the pandemic had subsided, and therefore their contribution to ultimate impact in terms of saving lives affected by COVID-19 was lower than expected/ minimal. This does not take away from the agility of Unitaid, as it is understood that Unitaid acted as fast as it could (and faster than most other international organisations) given the rapid onset of the pandemic, the changing epidemiology and major disruption to global economies. Within the overall portfolio, there are also examples of the investments being timely and impactful. For example, in Zimbabwe, stakeholders described the decentralisation of antigen testing, as a "game-changing" contribution. Equally in respect of oxygen, in Ethiopia, with Unitaid support, CHAI **was** the first partner to support on procuring oxygen equipment, three new regional PSA-plants, selected at sites located at a distance from the capital (e.g., 700km, 500km and 350km away from Addis Ababa). In Uganda, an advocacy partner stated that the timing of the project worked well as it raised awareness and generated demand for testing, even before the testing platforms were fully established. **Equally, while the investments were delayed in relation to the peak of the pandemic, at the time they were initiated and being implemented they made sense by virtue of their "insurance value" during highly uncertain times.** It is also recognised that the oxygen investments will support saving of lives affected by numerous other diseases where oxygen can serve as a suitable therapy.

The implication of the delayed timing was that several the Test & Treat investments became localised, project-focused investments without a wider impact. This was our understanding from speaking with investment stakeholders across several countries including Bolivia, Peru, Brazil, and India. IS Global's work in Cochabamba Bolivia impacted the project sites at the municipal level and had very little national impact. Select activities under the PSI/ PATH investment in India supported increase in local testing and amongst vulnerable populations but with no lasting effect or wider effect outside the project sites. From a value for money (VfM) perspective, it could be argued

that these investments did not deliver the value expected from Unitaid's role in the global aid architecture, noting that this was a function of the progression of the pandemic.

For the oxygen investments as well, a larger issue looms regarding the sustainability of the investments and the need for further work to take forward some of the early progress made in the sector with regards to global market agreements and international resolutions. The sustainability of oxygen equipment, spare parts and accessories is a major challenge to the overall functionality and longer-term impact of these systems. Efforts have been made to ensure long-term sustainability by grantees working closely with ministries of health and country stakeholders at national and sub-national levels, as well as ensuring favourable service level agreements (albeit time-limited) for monitoring, repair, and routine maintenance. However global partners and country-level consultations raised concerns as to the extent to which post-installation checks and maintenance will continue and how much of the equipment installed during the pandemic is currently operational. For example, in Malawi, PATH reported that the national tracking of equipment such as concentrator and cylinder location and post-installation reviews were limited, and this lack of national coordination posed a challenge to system functionality and long-term sustainability. In Peru, the lack of bioengineers and low demand for oxygen post-pandemic also threatens the sustainability of interventions. Additionally in Peru, there is a need to strengthen government ownership and planning of the oxygen system, to avoid the risk of degradation over time, which is currently managed by regional governments with mixed outcomes. Further the global LOX agreements are yet to be translated into country level impact. Finally, the full potential of the WHO Oxygen Resolution and ability to drive change within national health and infrastructure policy, planning and finance is yet to be realized, but it marks an important step forward, and provides a strong policy basis for Unitaid and the work of GO2AL to support countries to move forward in line with the commitments under the resolution.

However, a positive, potentially unintended feature of the implementation of the investments by the grantees and Unitaid was their astute adaptation along the way, to meaningfully support what was feasible with the progression of the pandemic and broaden their scope to support PPPR. Several investments in the Test & Treat portfolio continued to provide COVID-19 services when governments were retracting on provision of these services and thereby served as an essential stop gap for COVID-19 support until the pandemic fully subsided. This also allowed public health services to return to supplying routine health care services to their populations, which was severely constrained during the COVID-19 pandemic. Many grantees also pivoted to providing support for PPPR by strengthening of laboratory and data systems for outbreak surveillance, data management and reporting. In Zimbabwe, which is currently facing a major Cholera outbreak, their response has already benefitted from some of the structures developed during COVID-19, for example, the Incident Management System and the Infection Prevention and Control (IPC) practices. CHAI and EGPAF in Cameroon supported capacity-strengthening at facilities and within the Ministry of Health on supply chain monitoring including the development of stock monitoring tools. In Ethiopia, grantees supported the development of a pandemic preparedness and response plan. In India as well, CHAI/ Clinton Foundation pivoted its work towards PPPR in the state of Madhya Pradesh by developing a new portal for the infectious disease programmes including new dashboards for integration into the national level Integrated Health Information Portal, supporting the development of guidelines on outbreak response at the state level, and providing TA to strengthen private sector reporting of data. In Latin America, IS Global brought together stakeholders from Peru, Bolivia, and Paraguay in a regional workshop to optimise the interpandemic period to strengthen PPPR. Unitaid medical oxygen grants have supported PPPR by ensuring there is an appropriate and diverse mix of oxygen supply in countries. Notably the grantees provided countries with need and gap assessments to have greater visibility on the reach and functionality of national oxygen equipment and system delivery. In addition, all training and recruitment of skilled personnel such as biomedical engineers focused on local workforces to retain capacity and build resilience into the oxygen systems.

In general, this evaluation finds that the series of Unitaid investments initiated from around the third quarter of 2021, while effectively designed for impact on COVID-19 at that time, will leave a greater legacy in terms of laying a foundation for PPPR work. This role and impact on PPPR can be considered as extremely valuable, given the importance of supporting PPPR today. The importance of demonstrating, and to a degree "entrenching" the importance of decentralisation of test and treat, integration of testing, and oxygen systems capacity and readiness cannot be overemphasised. Equally, the legacy of ANTICOV, in terms of highlighting the critical need for a clinical trial

platform in LMICs to prepare for the next pandemic, as is the experiences and learning from the joint FIND-Unitaid investments in LMIC manufacturing are important contributions to PPPR.

However, there is also the question on the role and value-add of Unitaid supporting PPPR in the manner that unfolded through the two portfolios of Test & Treat and medical oxygen – which was essentially ad hoc and unsustainable under the COVID-19 portfolio. For example, the TA activities conducted by CHAI in Madhya Pradesh/ India were focused on a few districts and the government indicated that there is a need to provide this TA support to the remaining districts of the state as well and for a longer term. Some of the initial oxygen investments and the reach of later investments as well was focused on emergency response without a longer-term strategic plan to build stronger and resilient systems to address future outbreaks and global health emergencies. Notably, as identified in a Unitaid Board Report, the shift to PPPR requires that organisations evolve from being firefighters to architects, meaning greater consideration needs to be given to the structures, systems and building blocks of PPPR, and Unitaid's value add within that space.[55]

5.2. RECOMMENDATIONS

The following recommendations are suggested based on the evaluation conclusions and learnings and build on progress we understand that Unitaid has made against recommendations from the mid-term evaluation (summarised in Appendix F). Recommendations are made in **six** key areas:

1. Unitaid's role in the next pandemic/ emergency:

Unitaid has demonstrated its ability to respond to a global health emergency and this is also recognized in its Strategy 2023-27 as one of its programmatic priorities. Key recommendations include:

(i) Deliver in line with Unitaid's comparative advantage as a Pathfinder (thought leadership and evidence), Influencer (co-ordination, alignment, and market-shaping) and Investor (investments and partnerships). Avoid roles which do not reflect its comparative advantage as was the case under certain investments under its COVID-19 portfolio, such as funding localised emergency support, or project-based work which does not have wider scale-up or catalytic impact or health systems investments that require longer term and continuous funding.

(ii) Enhance monitoring of outcomes for impact, for example, through strategic and continuous monitoring of results and risks alongside each other and adopting a stage-gate approach where appropriate.

2. Unitaid's role for wider PPPR related work:

Similar to the above recommendation, ensure Unitaid aligns its role with its comparative advantage (e.g., innovations, market shaping, private-sector engagement and regional manufacturing) rather than country-specific PPPR related activities as was the case through the adapted Test and Treat investments and procurement of oxygen systems.

In addition, Unitaid has demonstrated that its unique standing in the global health architecture, alongside its technical and operational capacities ensures that the organisation is well positioned to lead e.g., coordinate, and build coalitions, mobilise resources, identify innovative solutions and address critical gaps.

3. Unitaid's model and approach to grant-making:

There are two aspects here:

- **Model and approach during business-as-usual times:** Unitaid should critically review the range of adaptations and flexibilities introduced in the Unitaid grant development and management processes during COVID and seek to incorporate the most relevant approaches in its standard operating model. This includes aspects such as: developing partnerships/ joint financing initiatives with relevant partners, that is, moving beyond the traditional donor-grantee relationship, introducing closed-door RFPs where there are efficiencies in doing so, such as, where

[55] Unitaid (2022), Request for Investment Extension (Test and Treat; Medical Oxygen), Report for Executive Board Approval, Unitaid/EB/2022/TBC

specific partner skills are well recognised and unique, lighter touch grant packages, potentially also building on the years of experience with several grantees such as CHAI, PATH, and PSI.

- **Model and approach during a pandemic:** It is clear that the "best parts" of the Unitaid model during COVID-19 should be taken forward for another pandemic as well, but with further consideration of key gap areas such as: increasing relationships with core emergency organisations, developing partnerships across the globe and beyond the SSA focus, improved internal organisation such as centralised management of the emergency response portfolios with oversight from a dedicated senior focal point/ team across all relevant investments, as well as surge capacity to strengthen staffing as needed.

4. **Unitaid's future investments:**

- **Guidance for future Unitaid investments in diagnostics:** Consider the learning (global and country) and practices brought about through the COVID-19 diagnostics portfolio in terms of the importance of decentralisation of testing, integration of testing with other testing services, and self-testing, and seek to incorporate these aspects within Unitaid's wider diagnostics work as a whole.

- **Guidance for Unitaid's future investments in medical oxygen:** Unitaid in collaboration with GO_2AL and its constituent partners should focus on improving the critical challenges for oxygen in LMICs which are well-recognised in the new GO_2AL strategy including access (demand and supply), optimal infrastructure mix and pricing, planning and data, capacitated work force and longer-term sustainability. These efforts should build on improving partner coordination, resource mobilisation, communication, and synergies, with Unitaid leveraging its areas of comparative advantage such as market-shaping, innovation and supporting the enabling environment.

5. **Community and civil society engagement:** Unitaid needs to develop a strategic, deliberate, and integrated approach to supporting CCSE in a pandemic and PPPR context, that also adequately considers the long-term nature of impacts from this support.

6. **Other:**

- Noting the challenges faced by this evaluation in compiling information on research studies, Unitaid should make a greater effort to track studies conducted under its investments, including key results of studies that can have an impact on other areas of work.

- Build a constructive dialogue and engagement with WHO-ERC to jointly design expedited review processes, and address barriers and enablers to more efficient research protocol reviews.

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