

Joint End-of-Grant Evaluations - Point-of-Care Molecular Diagnostics for HIV

Unitaid

21st July 2021

Final Report

Important notice

CEPA disclaimer

This report was prepared by CEPA for the exclusive use of the recipient(s) named herein.

The information contained in this document has been compiled by CEPA and may include material from other sources, which is believed to be reliable but has not been verified or audited. Public information, industry and statistical data are from sources we deem to be reliable; however, no reliance may be placed for any purposes whatsoever on the contents of this document or on its completeness. No representation or warranty, express or implied, is given and no responsibility or liability is or will be accepted by or on behalf of CEPA or by any of its directors, members, employees, agents or any other person as to the accuracy, completeness or correctness of the information contained in this document and any such liability is expressly disclaimed.

The findings enclosed in this report may contain predictions based on current data and historical trends. Any such predictions are subject to inherent risks and uncertainties.

The opinions expressed in this document are valid only for the purpose stated herein and as of the date stated. No obligation is assumed to revise this report to reflect changes, events or conditions, which occur subsequent to the date hereof.

CEPA does not accept or assume any responsibility in respect of the document to any readers of it (third parties), other than the recipient(s) named therein. To the fullest extent permitted by law, CEPA will accept no liability in respect of the report to any third parties. Should any third parties choose to rely on the report, then they do so at their own risk.

Unitaid disclaimer

This publication was prepared independently, by the authors identified on the cover page, at Unitaid's request. The authors' views expressed in this publication do not necessarily reflect the views of Unitaid. Unitaid expressly disclaims all liability or responsibility to any person in respect of use of the publication or reliance on the content of the publication.

Contents

ACRONYMS	IV
REPORT STRUCTURE	V
EXECUTIVE SUMMARY	VI
PART A: INTRODUCTION AND PORTFOLIO LEVEL FINDINGS	1
1. INTRODUCTION	1
1.1. Evaluation scope and objectives	1
1.2. Grant background and theory of change	1
1.3. Evaluation framework and methodology	5
2. GRANT DESIGN AND IMPLEMENTATION	8
2.1. Relevance.....	8
2.2. Coherence	10
2.3. Efficiency	12
3. ACCESS BARRIERS	12
3.1. Innovation and availability.....	15
3.2. Affordability	18
3.3. Demand and adoption	25
3.4. Supply and delivery	35
4. SUSTAINABILITY AND SCALABILITY	40
4.1. Sustainability/ transition	40
4.2. Global conditions for scale up.....	41
4.3. Country conditions for scale up.....	45
5. IMPACT ASSESSMENT	51
5.1. Findings from the impact modelling.....	52
5.2. Findings from the consultations and document review.....	56
6. CONCLUSIONS AND RECOMMENDATIONS	60
PART B: GRANT LEVEL FINDINGS AND COUNTRY CASE STUDIES	65
7. FINDINGS – GRANT LEVEL ASSESSMENT	65
7.1. EGPAF grant.....	65
7.2. UCPOC grant.....	72
8. COUNTRY CASE STUDIES	80
8.1. Cameroon (both grants).....	80

8.2.	Kenya (both grants)	82
8.3.	Lesotho (EGPAF grant only).....	84
8.4.	Mozambique (both grants)	87
8.5.	Uganda (UCPOC grant only, EID only).....	89
8.6.	Zimbabwe (both grants).....	92

ACRONYMS

Acronym	Full description
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral Treatment
ASLM	African Society of Laboratory Medicine
CEPA	Cambridge Economic Policy Associates
CEPAC	Cost Effectiveness of Preventing AIDS Complications (CEPAC)—Pediatric model
COP	Country Operational Plan (PEPFAR)
CHAI	Clinton Health Access Initiative
CSO	Civil society organisations
DBS	Dried Blood Spot
DNO	Diagnostics network optimisation
DRW	Diagnostics of the Real World
EGPAF	Elizabeth Glaser Paediatric AIDS Foundation
EID	Early Infant Diagnosis
HCWs	Health-care workers
HIV	Human Immunodeficiency Virus
IDC	Integrated Diagnostics Consortium
KPI	Key Performance Indicator
MoH	Ministry of Health
MTCT/ PMTCT	Mother-to-child transmission/ Prevention of Mother-to-child transmission
PBFW	Pregnant and breast feeding women
PEPFAR	United States President's Emergency Plan For AIDS Relief
PLHIV	People living with HIV
POC	Point of Care
TAT	Turn around time
TB	Tuberculosis
ToC	Theory of Change
ToR	Terms of Reference
TWG	Technical working group
VL	Viral load
UNICEF	United Nations International Children's Emergency Fund
UCPOC	UNICEF-CHAI Point of Care
WHO	World Health Organization
WHO PQ	WHO pre-qualification

REPORT STRUCTURE

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a portfolio-level evaluation of its investments in Point of Care (POC) molecular diagnostics for HIV alongside end-of-grant evaluations of the two grants within this portfolio implemented by the Clinton Health Access Initiative (CHAI) and United Nations International Children's Emergency Fund (UNICEF) (the UCPOC grant) and the Elizabeth Glaser Paediatric AIDS Foundation (the EGPAF grant).

Part A of the report starts with an introduction and evaluation framework and methodology (Section 1) and then presents the portfolio-level evaluation in terms of findings on grant design and implementation (Section 2), progress against access barriers (Section 3), assessment of sustainability and scalability (Section 4), impact assessment (Section 5), and finally, conclusions and key recommendations (Section 6). Given the nature of the Unitaid HIV molecular diagnostics portfolio, wherein both the UCPOC and EGPAF grants have similar objectives and activities, the portfolio-level review is more detailed and considers the wider context and implications of the achievements.

Part B of the report presents the end-of-grant evaluations for the two individual grants, where the aim has been not to be duplicative of the portfolio level assessment where feasible (Section 7). In addition, summary findings from the country case studies supporting the review are included here (Section 8).

The main report is supported by the following appendices: Appendix A presents the bibliography; Appendix B includes a list of consultations; Appendix C depicts the scalability assessments for the EGPAF and UCPOC grants; Appendix D presents the stakeholder interview guides; Appendix E and F include achievements against the UCPOC and EGPAF logframes respectively; Appendix G gives an overview of Unitaid's past and current molecular diagnostics grants; Appendix H maps grant activities to the Theory of Change (ToC) outputs; Appendix I includes the Terms of Reference (ToR) for this review; Appendix J gives an overview of the impact modelling approach; and Appendix K presents our impact assessments at the grant level for the EGPAF and UCPOC grants.

EXECUTIVE SUMMARY

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a portfolio-level joint end-of-grant evaluation of its investments in Point of Care (POC) molecular diagnostics for HIV implemented by the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) and CHAI-UNICEF (UCPOC) as per the following summary:

- The **EGPAF** grant (US\$ 62.1 million, 2015-2019) had the goal to introduce new-to-market, innovative POC early infant diagnosis (EID) technologies into the laboratory network systems of nine sub-Saharan African countries in order to increase the number of infants and caregivers receiving HIV test results in a timely manner and ultimately increase the number of children on life-saving treatment.
- The **UCPOC** grant (US\$ 74 million, 2016-2021) had the goal to utilise the availability of long-awaited POC EID/ viral load (VL) technologies to speed-up clinical decision-making (especially by reducing test turnaround time (TAT)), improve patient outcomes and improve programme efficiency. The aims of this grant were to be achieved through accelerating market entry and uptake of POC EID/VL products and strengthening centralised laboratory systems to optimise the national EID and VL networks.

The **main evaluation** objective was to consider at a portfolio level, the extent to which Unitaid's HIV POC molecular diagnostics investments have contributed to increased access to innovative HIV diagnostics in resource-limited settings. The evaluation also encompassed an assessment of the impact of these investments and specific grant-level evaluations of each of the two individual grants. The **evaluation framework** was structured along four pillars reflective of the scope: (i) grant design and implementation; (ii) access barriers; (iii) sustainability and scalability; and (iv) impact assessment. The **methodology** employed was a Theory of Change (ToC) based approach with mixed methods comprising document review, stakeholder interviews, country case studies (Cameroon, Lesotho, Kenya, Uganda, Zimbabwe and Mozambique), impact modelling, and data and quantitative analysis.

Key findings

The HIV POC molecular diagnostics landscape is complex and dynamic, with a challenging supply situation where there are limited number of suppliers offering different types of products (i.e. “differentiated products”) and there is a need for careful consideration of POC use within the wider diagnostics system in terms of fit with laboratory based centralised testing, leveraging of multiplexing capacity and overall optimisation of device use and placement. In addition, the stakeholder arena has proven to be complex particularly in terms of coordination with the strategic priorities of PEPFAR and the Global Fund. Notwithstanding this challenging context, the Unitaid HIV POC molecular diagnostics portfolio has served an important need to increase testing coverage and patient access to testing, and thereby potentially covering the remaining gaps in the 90/95 targets as well as improving patient outcomes. In this context, the two grants have been very relevant investments by Unitaid.

The grants have made important contributions in establishing and furthering global awareness and guidance for POC EID and VL including key contributions to WHO and funder guidelines, initiating and encouraging country demand and adoption of POC testing supporting improved service delivery, negotiating improved pricing agreements, and normalising/ mainstreaming diagnostics integration and network optimisation including through the Integrated Diagnostic Consortium (IDC) coordinated by Unitaid. However, key challenges remain in terms of access, where there continues to be a largely monopolistic and asymmetric market for POC technologies with products that have relatively higher pricing, and where donor support for scale up is tenuous, or moderate at best, particularly so for POC VL. Whilst the grants have aided progress with regards to diagnostic network optimisation and integration (with the benefits accruing for COVID-19), more progress is needed in this regard.

In general, the fundamental value-add of the portfolio has been the shift they have brought about from a situation where countries did not have experience with POC testing (including knowledge regarding the benefits of POC testing and the best means to introduce these technologies optimally) to one where countries have adopted POC EID and VL in their national policies, guidelines and service delivery models. In addition, global-level discussions have evolved from one where there were differing views on the role of POC within the diagnostic landscape to one where donors and partners are considering and supporting their use.

Detailed findings by pillar and overall conclusions and recommendations are presented below.

Pillar 1: Grant design and implementation¹

The Unitaid HIV molecular diagnostics portfolio has been extremely relevant given the important public health need that it serves. However its initial design heralded POC in its own regard, although rightfully evolved to a more holistic approach and consideration of integration and optimisation priorities over time. The public health case for POC diagnostics for EID and VL monitoring is strong given the need for further emphasis on improving the coverage and quality of testing (e.g. timeliness, linkage to faster clinical action). The challenge with the Unitaid portfolio however was with the initial approach which set up to champion POC technologies on their own merit, without adequate consideration of the network and environment within which they are to be placed and the need to optimise the use of platforms to obtain the best value for money. However, over time this approach evolved to be better reflective of the diagnostics system and stakeholder arena, and several reprogrammings and course-corrections of both grants have sought to better incorporate these aspects.

A key learning for Unitaid has been the need for upfront assessment and engagement on product positioning with the range of relevant global and country level stakeholders. Limited dialogue and engagement with other stakeholders supporting diagnostics in the initial grant design and implementation period, especially donors, created a disconnect between the catalytic objectives of this portfolio and what has been feasible in terms of scale up and

¹ A high-level review of this pillar was conducted, focusing on specific questions on relevance, coherence, coordination and efficiency.

transitioning. One of the key lessons learnt from this portfolio has been the need for a clearer mapping and dialogue on product positioning with the range of relevant stakeholders right from the very start of Unitaid grants.

It is unclear if the portfolio represented the right approach from a market shaping perspective, given the ongoing challenging supply situation. With the benefit of hindsight, there is a question as to whether the substantial monies invested through the grants on procuring diagnostic equipment represented the right market shaping approach, given the expected pipeline of products did not materialise, and the market remains concentrated and “asymmetric” – in that: (i) technologies are not similar with a mix of near and true POC platforms so products cannot be directly compared (i.e. differentiated products); and (ii) products are at different level playing fields, also due to their history and donor support e.g. GeneXpert has a longer history with its tuberculosis (TB) footprint and pricing impacted by the original buy-down supported by Unitaid, the Gates Foundation and others. While the two grants were set up as demonstration projects to support the development of global normative guidelines as well as country introduction, these objectives were premised on a pipeline of technologies coming to market which did not materialise. Some consultees at Unitaid have commented on whether more “direct” supplier focused engagements would have yielded better results and represented greater value for money, while others have commented that such approaches can be market distorting and create precedence for other suppliers/ markets. While it is challenging to predict what approach might have yielded desired results, the experience of this portfolio suggests the need for Unitaid to continually review the appropriateness of their investment approaches in relation to desired end goals.

The individual grant designs played to the strengths of each implementing organisation and were complementary but did not represent a coherent whole for internal and external stakeholders for a number of reasons. Coherence with other Unitaid molecular diagnostics grants (both for HIV and other diseases) and other funders has also been relatively weak. While both grants played to the strengths of each implementing organisation, together as a portfolio they represented quite different (albeit complementary) approaches, with EGPAF focusing on service delivery at lower health levels and UCPOC adopting a national-level systems approach with a focus on network optimisation. Our consultations indicated some external stakeholder confusion as to the overall objective of Unitaid in terms of the balance of support for POC and laboratory based, centralised testing, possibly also reflective of the evolution on this aspect in the grants. Further, it is noted that Unitaid has diagnostics grants across diseases (e.g., TB and Hepatitis C Virus (HCV)) using the same/ similar platforms with limited coordination and integration between the approaches and grantees. Some of our consultees also commented that the upstream work of Unitaid in terms of bringing suppliers/ products to market is not well coordinated with the research and development (R&D) work of the Gates Foundation and other R&D funders. While there are issues of confidentiality and it is noted that R&D investments are high risk-high failure in nature, it was noted that greater coherence was needed between the work of Unitaid and other partners in this regard.

Grant reprogrammings were largely appropriate in terms of content but inefficient in terms of process. The UCPOC grant underwent several reprogrammings and the EGPAF grant underwent one reprogramming and several budget realignments. These were on account of the evolving landscape and priorities such as changing WHO guidelines, delays in the product pipeline, and the evolution of a more holistic approach to POC and laboratory based, centralised testing. In general, the reprogrammings have been viewed as appropriate and responsive to the changing external environment and dynamic for POC diagnostic testing, however the changes also caused some confusion amongst country stakeholders as to the core objectives of the projects as well as challenges for manufacturers who were less incentivised to reduce prices with reduced procurement levels. Importantly however grantees in particular have highlighted that the reprogramming processes by Unitaid are arduous and time-consuming and would merit efforts at greater efficiency. They noted that in contrast to other donors, Unitaid’s processes are considered to be much more time consuming.

Pillar 2: Access barriers

The evaluation’s assessment of the progress made by the portfolio of grants against each of the defined Unitaid access barriers is presented below (with the following scale in use: fully achieved, largely achieved, moderately achieved, slightly achieved, not achieved (N/A). Different from the Unitaid Secretariat’s assessment of the access

barriers which considers the direct achievements of the specific activities funded under the two grants, this evaluation adopts a wider lens that considers the context and implications of the grant activities and overall progress made.

Innovation and availability² – slightly achieved

- **Market structure and supply base:** While innovation was not directly targeted by the portfolio, their work has had an indirect impact on the supply base for POC diagnostics for EID and VL by facilitating the availability of these products in countries (i.e. through a “market creation” role). Our assessment is that alongside other Unitaid grants on molecular diagnostics as well as wider issues and developments (such as the pipeline not materialising, small size of EID market), the supply side for POC diagnostics has become fairly asymmetrical, in that not only are the technologies fairly differentiated, with a mix of near and true POC platforms, there is also no level playing field for the different products (e.g. GeneXpert has a longer history with its TB footprint and pricing impacted by the buy-down supported by Unitaid and others). However, on a smaller scale, both grants, especially EGPAF, contributed to the development of product adaptations or implementation-related innovations through digital solutions. Also, the work of the grants through partnerships and on all-inclusive pricing have been useful market/supply shaping approaches and tools.
- **Availability:** The UCPOC and EGPAF grants have facilitated suppliers to make their product available in the market for POC EID and VL. This included both grants, and particularly the UCPOC grant, helped facilitate the availability of products in countries through supporting the registration of products and creating clearer and faster processes for product registration. By the end of the grants, all nine EGPAF countries had POC EID available, and out of the 11 UCPOC countries, 11 have POC EID available (overlap of four countries with EGPAF) and nine have POC VL testing available. With these achievements, the portfolio of grants has kick started/ initiated the POC EID and VL diagnostics market in countries.

Affordability – moderately achieved

- **Price reductions:** Some test price reductions were achieved, including through more inclusive pricing for m-PIMA and GeneXpert e.g. for GeneXpert, reduction from US\$17.95 to US\$14.90 all-inclusive, and a 33% decrease to US\$12.00 for the cartridge price alone, attributed to Unitaid, the grantees and other partners. Some views indicate that the reductions are reflective of what is possible to achieve from a cost of goods sold (COGS) perspective, and there were confirmatory views that the reduction in GeneXpert price has happened earlier than otherwise expected on account of the grants. But, test prices remain higher than laboratory based, centralised platform test prices which is an ongoing barrier to take up.
- **Pricing agreements:** Looking at affordability more widely for molecular diagnostics (i.e. both POC and non-POC), there have been improvements in manufacturer agreements, especially in terms of the all-inclusive agreement with Hologic. This deal has significantly contributed to the sensitisation of manufacturers and global and country stakeholders on the need for an all-inclusive price and move to long term agreements. For example, the project has been linked to PEPFAR’s 2019 RFP which stakeholder feedback indicates reflected a lot of what was included in Hologic’s agreement. In addition, all-inclusive pricing arrangements have been obtained with GeneXpert and m-PIMA and other progress has been made with regards to service and maintenance agreements for both the GeneXpert and m-PIMA POC devices.
- **Cost-effectiveness:** Evidence relating to the cost-effectiveness of POC testing and cost-per-test result returned was developed by EGPAF and CHAI which some stakeholders considered to be a significant achievement; and the WHO guidelines now state that EID testing is cost-effective. However there have been some limitations with

² For this access barrier in particular, our assessment adopts a wide evaluation lens that considers the overall implications and indirect impacts of the grants. Also our assessment is at the portfolio rather than grant-specific level, which necessitates this wider lens of assessment. We specifically note that although the grants did not directly target the innovation access barrier, their work has had an indirect impact on the supply base for POC diagnostics for EID and VL by facilitating the availability of these products in countries and therefore the innovation and availability access barrier as a whole.

this evidence influencing take up due to an ongoing focus on the ‘sticker price’ as well as funding envelopes being unable to accommodate higher overall infant testing costs related to POC use.

- **Integration and affordability:** The grants have focused belatedly on integration which has been useful and important for affordability, however much more progress needs to be made.

Demand and adoption – EID largely achieved; VL moderately achieved

- **Introduction and adoption:** Both grants catalysed the introduction and adoption of POC EID, and to a lesser extent POC VL (noting the different contexts for each type of testing), through procurement of commodities and introduction of testing services. POC EID was non-existent or extremely limited before the grants but successful procurement of devices/ cartridges and incorporation of POC EID into infant testing programmes through the grants has resulted in durable commitments to substantial POC EID testing in many countries. POC VL use has increased in some countries, especially for specific populations, but this was not achieved in all countries, and in many countries scale up has been limited and long-term commitments remain uncertain.
- **Evidence base and guidelines:** Generation of high-quality evidence has been one of the grants’ most significant achievements and grantees successfully disseminated findings at the national, regional, and global levels to inform policy and implementation. The evidence base generated has been instrumental in updating of global normative guidance by WHO, funder guidance such as the PEPFAR COP guidance, and in the revision of national EID guidelines and VL guidelines to a lesser extent. However, the evidence generated for routine use of POC and near-POC EID was much stronger than for VL, due to some extent to the later market entry of this product in comparison to POC EID. Several stakeholders noted that the data on POC VL is sparse and the latest WHO guidelines state that there are “multiple research gaps” for VL.
- **Demand creation:** Demand creation efforts were undertaken, although belatedly for the UCPOC grant. More progress was made with regards to clinicians and laboratory staff than with beneficiaries/ community level which could have been further enhanced.
- **Integration:** Grant activities played an important role in introducing and normalising the concept of integration. This included emphasising the complementarity of POC and centralised testing and multiplexing (which has also been leveraged under the ongoing COVID-19 pandemic), but this is an area where further work is needed.

Supply and delivery – largely achieved

- **Health systems:** The projects effectively facilitated the introduction of POC technologies within country health systems including with regards to supply chain and procurement processes, training, data systems and waste management – all with important strides through the project work, although some gaps remaining particularly with regards to robust data systems that align with existing national systems and developing waste management systems.
- **Delivery models:** EGPAF demonstrated the hub and spoke model for POC testing which has been a key contribution. In relation to sample transport, the EGPAF grant focused on transport between hub and spoke sites and the UCPOC grant focused on sample referrals via integrated referral systems and expansion of dried blood spot. Although the models used were largely successful, concerns remain about sustainability after grant closure given implementation challenges and need for continued funding.
- **Network optimisation:** The grants incorporated a more holistic view of diagnostics networks and development of network optimisation plans. The shift in approach to diagnostics network optimisation through the UCPOC grant was appropriate and useful, albeit belated, although countries need to conduct further planning and implementation to reach this goal.

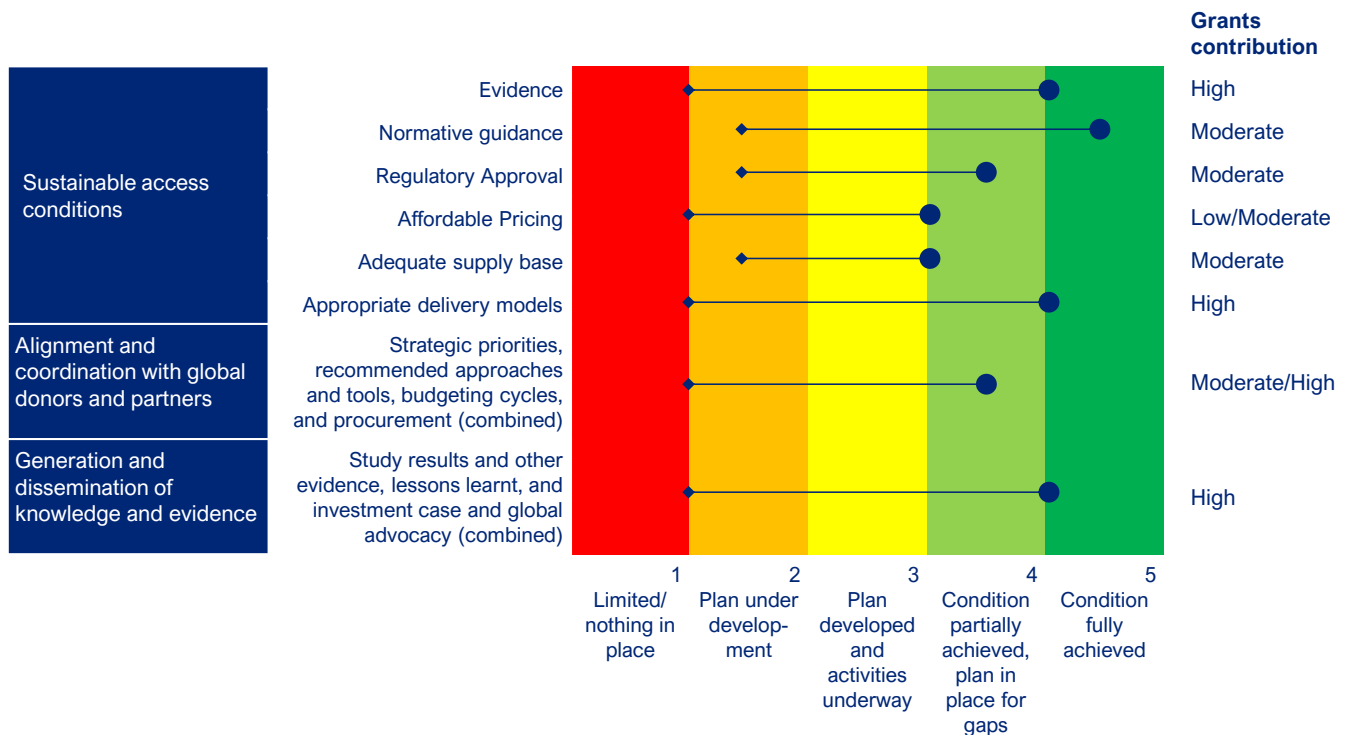
Pillar 3: Sustainability and scalability

Funding **transition** has been secured for the most part (more so for EID, than VL), with the key challenge being Kenya where future funding for POC testing is under review especially for VL.³ The transition process for the EGPAF grant in particular has been challenging resulting in gaps in services during the transition period. Transition for the portfolio was fundamentally hindered by the limited upfront dialogue and engagement with large funders such as PEPFAR and Global Fund by Unitaid and the grantees (as discussed above under Pillar 1), although has been resolved for the most part as described above. The UCPOC grant fared better than the EGPAF grant overall as it also had the benefit of a few more years' implementation and associated changes to PEPFAR COP guidance, WHO recommendations etc. In some cases, transition was hampered by the belated implementation of transition plans and there was also the challenge that the grants were not well aligned with donor funding cycles and there was limited provision for bridging of supplies over this transition period. In addition, some of the country case study examples highlighted the fact that the grants were implemented into 'well established ecosystems' (e.g. laboratory and PMTCT programme governance issues etc.) which created additional challenges for sustainability and financing decisions. Another key challenge for sustainability is that it is not fully clear if funding secured post grants will cover the supporting health systems aspects such as with regards to sample transport, development and management of data systems, management of waste, ongoing training needs, etc.

In terms of progress made against the Unitaid framework of **global scalability conditions**, Figure E.1. shows a summary of the mean score for global scalability conditions across the two grants. Important contributions have been made by both grants in terms of the various conditions deemed relevant to support global scale up of POC molecular diagnostics for HIV, which have progressed further for POC EID than for POC VL. There has been a lot of good evidence generated supporting the development of normative guidance from WHO, however donor/ partner support is tenuous (although increasing over time for POC EID) and the supply base and pricing issues continue to present challenges.

³ As of April 2021.

Figure E.1: Global scalability conditions and scores for baseline to end of project (2020 for UCPOC grant) at the portfolio level



◆ Shows the baseline rating, ● shows the rating to date. Where markers are in the center of a box, this shows a 0.5 rating, due to the averaging of the scores across the two grants.

The column on the right hand side indicates the grants contribution which is different from the scalability scores presented in the colour ratings.

Source: CEPA analysis

With regards to the Unitaid framework for **country conditions for scale up**, overall, there has been some good progress in furthering key country scale up conditions, especially with regards to supporting the development of POC-related policies and guidelines in countries. However, the biggest barrier is the limited donor funding to scale up use beyond what has been achieved through the grants, although there are some early indications from PEPFAR on increasing country support for POC in the coming year. In addition, community driven demand remains an area of weakness. In particular:

- **Political and financial support:** There are several aspects to note here:
 - There has been good country level political engagement and advocacy with a range of stakeholders through the grants that has helped secure their buy-in, although there has been some resistance from laboratory stakeholders due to concerns with quality of testing and services, particularly if POCs are not fully integrated within the laboratory network.
 - POC EID and VL testing remains heavily dependent on donor funding with domestic funding for POC testing being negligible across project countries.
 - The majority of project countries have managed to secure funding to sustain the same level or to moderately increase POC EID testing after grant closure, at least for the short-term, with a good level of scale up being achieved by the projects themselves (e.g., in Mozambique, Uganda and Zimbabwe). As shown in Table E.2. below, for POC EID, nine countries had confirmed funding to maintain or increase the POC EID coverage levels when compared to the 2020 levels.

- For POC VL, there have been more challenges to secure funding with some countries experiencing funding shortfalls for the anticipated POC need (e.g., Kenya) or not having confirmed funding, beyond a year (e.g., Tanzania).
- While maintaining, or moderately increasing, the POC EID and VL coverage gains made during the grant period is an achievement in itself, limited further donor funding acts as a barrier to achieve significant scale up going forward. This is not expected to change in the short-term with donors focusing on optimising existing platforms rather than supporting significant further scale up, although there is some early indication from PEPFAR on providing some funding.

With regards to the percentage of EID testing which is currently done with POC versus conventional and the targets for years to come, the data available is variable across project countries and the estimated POC EID coverage varies to a large degree too. For example in Kenya it is estimated that POC testing is currently less than 10% and there is a target of 50% of POC EID testing whilst it is currently 76% in Lesotho, with a target of 95%. POC EID coverage targets for future years are around half for a number of countries (Cameroon 55%, Ethiopia 50%, Zimbabwe 40%). However whilst a number of countries have targets which aim to increase the use of POC EID testing, this is subject to available funding. Table E.2. below shows the expected trends in POC EID and VL testing coverage for 2021 (and where available 2022) based on funding commitments to date compared to actual testing coverage in 2020.

Table E.2: Trends in POC EID and VL testing coverage based on funding commitments compared to 2020

Type	Trend	Number of countries	Project countries
POC EID	Increase	4	Nigeria (significant increase); Tanzania (significant increase); Senegal (moderate increase); Ethiopia (moderate increase)
	Decrease	1	Kenya (at least in short-term due to transition challenges)
	Stable	5	Eswatini; Lesotho; Malawi; Mozambique; Uganda
	Unconfirmed	5	Cameroon; Côte d'Ivoire; Rwanda; Zambia, Zimbabwe
POC VL	Increase	3	Malawi (significant increase); Senegal (moderate increase); Cameroon (moderate increase)
	Decrease	1	Kenya
	Unconfirmed	2	Tanzania; Zimbabwe

- **Programmatic and operational readiness:** While there has been some progress with regards to country programmatic and operational readiness for introduction and scale up of POC technologies in terms of supportive policies and integration into national programmes (being a key achievement), ongoing support is needed to ensure effective supply chains, data systems, and other aspects of health systems capacity.
- **Community driven demand:** In general demand creation was relatively limited at the community level, partly as it was introduced quite belatedly, especially in the UCPOC grant.

Pillar 4: Impact

Overall, the impact of the portfolio is significant, especially with regards to the public health benefit of POC EID and, to a lesser extent, VL testing. The most important impact from EID testing has been from the reduction in turnaround time (TAT) of results (in the majority of countries reducing TAT to within one day). This is particularly due to the positive impact that a faster returned result has on HIV exposed child morbidity and mortality through the enabling of faster management of infants who require treatment quickly. The impact of VL POC testing is less than for EID as quick result return is less critical for VL, although its value is enhanced for priority population groups to allow for a shorter time to clinical action of adherence counselling or second line treatment switching.

Table E.3. below provides an overview of the **measurable public health and economic impact** of the POC portfolio, including both the direct impact (achieved during the grant) and indirect impact (achieved in the five and a half years after grant closure):

Table E.3: Public health and economic impacts of POC within Unitaids HIV molecular diagnostic portfolio

KPI	Indicator	POC EID			POC VL		
		Direct	Indirect	Total	Direct	Indirect	Total
Public health impacts (KPI 4.1)	Deaths averted	~1,300 [1,100 - 1,600]	~6,800 [5,100 - 11,500]	~8,100 [6,200 - 13,100]	~290 [170 - 400]	~1,600 [680 - 3,000]	~1,900 [850 - 3,400]
	Transmission averted	N/A	N/A	N/A	~260 [160 - 350]	~1,450 [600 - 2,700]	~1,700 [760 - 3,050]
Economic impacts (KPI 4.2)	Treatment costs averted	US\$ 0.8m [0.8 m – 0.9 m]	US\$ 5.1 m [4.1m – 6.2m]	US\$ 5.9 m [4.9 m – 7.0 m]	US\$ 0.8m [0.5 m – 1.1 m]	US\$ 4.6 m [1.9m – 8.7m]	US\$ 5.4 m [2.4 m – 9.8 m]

The measurable public health impacts are predominately driven by POC EID which is due to the fact that more POC EID tests are being conducted, as well as the higher importance that a reduction in turnaround of testing results has on the mortality and morbidity of infants. Economic impacts in the form of direct cost-savings to the health system include a total of ~US\$ 5.9 million [4.9 m – 7.0 m] in treatment costs averted for opportunistic infections for infants and a total of ~US\$ 5.4 million [2.4 m – 9.8 m] in HIV treatment costs averted due to the reduction of HIV transmission.⁴ Importantly, evidence generated by the grantees has shown that the use of POC EID instead of laboratory based, centralised EID can be cost-effective. This is illustrated by lower costs per test returned within 30 days under POC EID, as well as cost per life year saved that is below the GDP per capita threshold.

Conclusions and recommendations

While the Unitaids HIV molecular diagnostics portfolio has faced several challenges and its results have not been as successful as originally anticipated, there have been important contributions and value from the grants. Indeed, the foundation for country uptake and scale up for POC EID has been laid through the work of these grants, although there continue to be some key gaps for POC VL. This progress has been through evidence generation that has led to updated WHO guidance and supportive guidance from PEPFAR, as well as the development of national policies and guidelines on POC. The grants have played a pivotal role in encouraging countries to adopt these technologies, through awareness raising, evidence generation and site demonstrations, procurement and implementation of testing services and working directly with stakeholders. Key challenges remain with regards to access and scale up of POC testing in HIV (some of which are issues beyond the possible influence of the grants), with tenuous and at best moderate support from donors for scale up due to relatively higher pricing of POC technologies as well as a bid to first optimise networks, in addition to challenges with the market structure and supply base. The work of the portfolio, along with PEPFAR, has helped mainstream optimisation and integration of diagnostics systems, however these aspects are yet to progress further and more work remains. Going forward, the potential benefits for countries are large with more of a strategic approach to POC testing within overall diagnostics systems and greater multi-stakeholder engagement to support its effective use.

⁴ These are relatively modest when compared to total project costs due to the fact that they only include direct cost-savings to the health system and not wider benefits such as aversion of productivity losses.

Strategic

1. Unitaid should ensure **upfront, timely and continuous engagement with the range of relevant stakeholders** at the global and country levels for its grants, to ensure appropriate product positioning, sustainability and scalability. This could be facilitated at several levels for Unitaid such as key partner involvement during development of Areas for Intervention (Afls) and participation in design related discussions between Unitaid and its grantees. A common understanding on what “success looks like” or what conditions need to be met to bring about partner scale up funding should be agreed upfront (and revised during the course of grant implementation, if appropriate). With regards to country stakeholders, a clear mapping should be done for new products/ delivery approaches that reflects enabling and inhibiting factors determining stakeholder demand/ interest within a country’s health systems, and project designs should be closely cognisant of these.
2. Unitaid should **adopt more of a portfolio approach** across its diagnostics grants, ensuring synergies in design in terms of objectives and approaches as well as coordination during implementation. A portfolio approach for Unitaid should not be limited to specific diseases where possible, but transcend across diseases, as appropriate to optimise investments and impact. Further, Unitaid should introduce mechanisms in the next Unitaid Strategy that **consider impact at the level of the portfolio** e.g. developing a TOC from the outset, defining clear and objective parameters on the success of the portfolio and not just individual grants, impact modelling that considers the combined effects of grants, etc.
3. Unitaid should continue to **emphasise diagnostics integration and network optimisation** through its grants. Whilst recognising that these aspects are complex and beyond the role of Unitaid alone and indeed require efforts from multiple funders and stakeholders, at a minimum, Unitaid’s investments should support integration and optimisation principles and thereby adopt a “country-focused approach”. While designing and reprogramming its grants, Unitaid should engage with key stakeholders, especially at the country level to understand the challenges to effective integration and DNO, and innovatively consider how these can be applied to its grant programming. The importance of this recommendation cannot be undermined in the context of Unitaid’s strategic expansion to consider multiple diseases as well as the global effort to support resilient and sustainable systems that can better support countries’ epidemic preparedness and responses.
4. Unitaid should **emphasise the development of data systems in its grants to facilitate collection of much needed data**, as integral to the introduction of any new technology. We view this as a critical recommendation given the opportunity for additional data collection that is presented with the introduction/ adaptation of a new technology. The experience of this evaluation in terms of limited data for some aspects as well as limitations with impact modelling reflect the need for greater efforts at data collection (e.g., there has been no clear data on testing coverage pre and post the investments as well as the remaining testing gap).
5. A range of **demand creation activities** need to be included in grants from the outset with clear demand creation plans. These should target a range of stakeholders, including patients/ beneficiaries, CSOs and community representatives.
6. Unitaid should ensure that **cost-effectiveness assessments** are included in grants when introducing a new technology/ product/ delivery approach. These studies should be reflective of what would provide a compelling case for global and country level stakeholders e.g. it is important to ensure that the studies are highly applicable (i.e. not undertaken in controlled environments which are unlikely to be reproduced outside of the grant). Therefore consultation particularly with donors, WHO and country stakeholders would be key early on in the design stage. In addition, grants should include a range of activities to disseminate evidence and facilitate demand creation based on the findings to help facilitate more of a focus on this evidence rather than the product sticker price. This could include workshops, South to South sharing of information etc.
7. Unitaid should include considerations regarding **waste management/ environmental impact** in their grants. This is an important area for the introduction of new technologies and so should receive the deserved attention from Unitaid in their grant tenders, grant proposals and then grant implementation and monitoring.

Operational

8. Unitaid should be **bold in its reprogramming efforts for relevant grants** by clearly defining red-flags or hard-stops for its grants as well as any needed changes in approach. This is particularly the case with larger and longer-term grants. Consideration should be given for new processes that take into account continually changing technologies, guidelines updates (i.e. two year cycle), and alignment with funding and programming priorities by key stakeholders and funders (e.g. COPs). While our evaluation findings do not indicate any issues per se with the technical content of the reprogrammings, the several challenges that these grants have faced over time form the basis for this recommendation. In addition, Unitaid should consider **streamlining its reprogramming processes** with a more appropriate balance between rigour/ scrutiny and level of effort.
9. Unitaid should be **clearer in its communication and engagement with grantees** – clearly setting out drivers for changes and reprogramming to its grantees and wider stakeholders.
10. Unitaid may consider **better aligning its grants with donor funding cycles** to support transition, or else continue to include provisions for bridge funding where needed, and ensure that these are of sufficient value.

PART A: INTRODUCTION AND PORTFOLIO LEVEL FINDINGS

1. INTRODUCTION

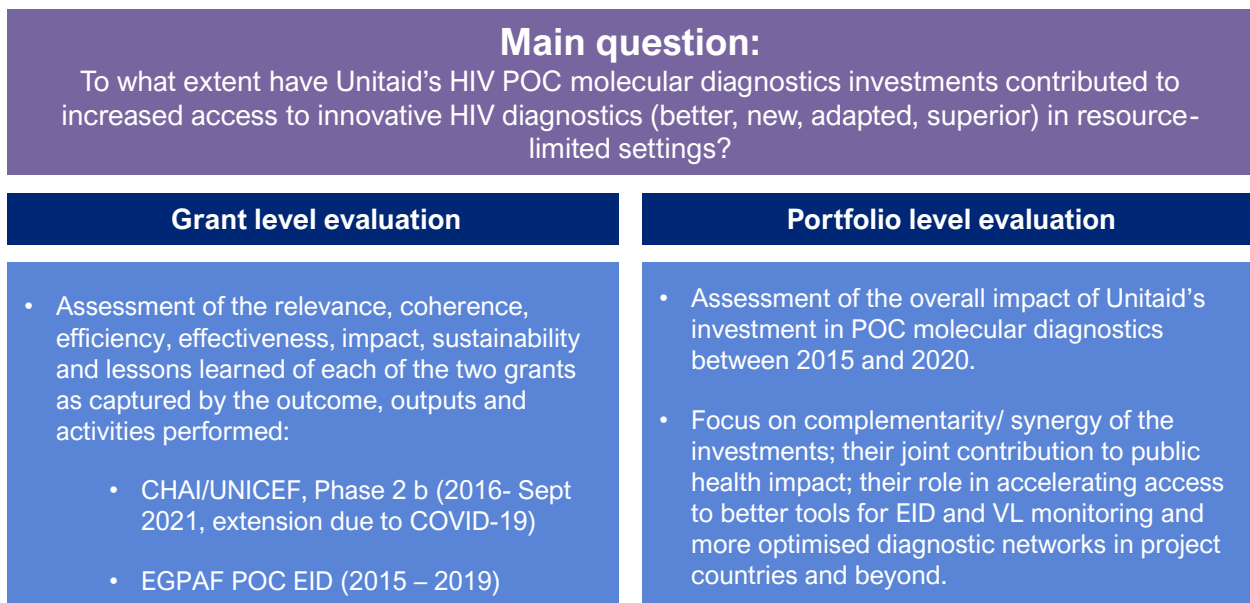
Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct a joint end-of-grant evaluation of its investments in Point of Care (POC) molecular diagnostics for HIV implemented by the Clinton Health Access Initiative (CHAI) and United Nations International Children's Emergency Fund (UNICEF) (UCPOC) (2016-21) and the Elizabeth Glaser Paediatric AIDS Foundation (EGPAF) (2015-19). This report presents CEPA's evaluation findings, conclusions and recommendations.

The introduction section presents the evaluation scope and objectives (Section 1.1), a high-level summary of the two grants included in the review as well as a portfolio-level theory of change (ToC) outlining the objectives and impact pathways for the grants (Section 1.2) and the evaluation framework and methodology (Section 1.3).

1.1. EVALUATION SCOPE AND OBJECTIVES

Figure 1.1. summarises the evaluation scope and objectives. The terms of reference (ToR) is included in Appendix I.

Figure 1.1: Evaluation scope and objectives



The scope of work involves a consideration of the OECD DAC evaluation criteria (relevance, coherence, efficiency, effectiveness, impact and sustainability), alongside a consideration of performance against Unitaid's Key Performance Indicators (KPIs) and scalability framework.

1.2. GRANT BACKGROUND AND THEORY OF CHANGE

This section sets out a brief background to the grants as well as the ToC for the two grants combined.

1.2.1. Summary of grants

The goal of the four-year, multi-country EGPAF POC early infant diagnosis (EID) project was to introduce new-to-market, innovative POC diagnostic technologies into the laboratory network systems of nine sub-Saharan African countries in order to increase the number and percentage of infants and caregivers receiving HIV test results; decrease the turnaround time (TAT) from sample collection to return of result to caregivers; decrease the number of days from HIV diagnosis to ART initiation for HIV-infected infants; and increase the number of children on life-saving

treatment. It also aimed to increase the POC EID market share and decrease the cost of POC testing within project countries, making HIV testing and diagnosis of infants more accessible.

The UCPOC project had a longer history from 2012 when it was launched to focus on POC CD4 test introduction and then reprogrammed to include EID and subsequently to focus on Viral Load (VL) testing with the changing World Health Organisation (WHO) guidance. From October 2016, Phase 2b of the grant commenced (which is the focus of this review) which aimed to utilise the availability of long-awaited POC technologies to speed clinical decision-making (especially through reducing TAT), improving patient outcomes and improving programme efficiency. The aims of this grant were to be achieved through accelerating market entry and uptake of POC EID/VL products, and strengthening centralised laboratory systems to optimise the national EID and VL networks. The grant also aimed to build more efficient and sustainable systems and to create a healthier market place – defined as competitive market - where multiplexing testing solutions are available and used across all tiers and interlinked via an optimised integrated network.

Table 1.1. below provides further details for the two grants.

Table 1.1: Description of grants in review⁵

Aspect	UCPOC grant ⁶	EGPAF grant
Outputs (which describe the main activity areas)	<ul style="list-style-type: none"> • Multiple competing POC/ near-POC products approved for routine use • Routine POC EID and VL testing established • Systems for both POC and laboratory based, centralised EID and VL programs strengthened • Global access pricing established for POC/near-POC EID and VL products • Catalytic commodity procurement of POC and laboratory based, centralised EID and VL testing • Procurement support of POC and laboratory based, centralised testing responsibly transitioned 	<ul style="list-style-type: none"> • Ensure conditions for use of POC EID are met in beneficiary countries • Procurement of POC EID platforms and tests • Placement and scale up of POC EID under the direction of Ministries of Health (MOHs) and according to the national EID network plans • Transparent generation and sharing of data and evidence with WHO and other relevant partners • Implementation of transition plans in each country • Create a market for affordable, effective and equitable HIV testing of exposed infants
Timeframe	Five-year project period: October 2016 to September 2021 ⁷ (extended from original four-year time frame from October 2016 to September 2020)	Four-year project period (August 2015 – July 2019)
Countries	Cameroon, Democratic Republic of the Congo, Ethiopia, Kenya, Malawi, Mozambique, Nigeria (from September 2019) Senegal, ⁸ Tanzania, Uganda, and Zimbabwe ⁹	Cameroon, Côte d'Ivoire, Kenya, Lesotho, Mozambique, Rwanda, Swaziland, Zambia, and Zimbabwe

⁵ Details taken from project plan unless otherwise noted (CHAI, UNICEF (2015), UCPOC Ph2b Accelerating access to innovative point of care HIV diagnostics Phase 2b. Annex 1 Project Plan and EGPAF (2016), POC EID Introduction of POC EID in decentralized settings: creating a market for affordable, effective and equitable HIV testing of exposed infant. Annex 1 Project Plan)

⁶ Partnered with African Society for Laboratory Medicine (ASLM)

⁷ Unitaid (2020), UCPOC Ph2b Annex 1 Project Plan Amendment

⁸ Senegal was added later with pilot commencing in May 2019

⁹ South Africa was also included for a small EID pilot in 2019 but the activities have been limited to this pilot and as such it is not included in the list of 11 countries.

Aspect	UCPOC grant ⁶	EGPAF grant
Budget	US\$ 74 million (this was reduced in the 4 th Amendment from an original budget of US\$ 94.3 million) ^{10,11}	US\$ 63.1 million

1.2.2. Portfolio level theory of change

The evaluation has adopted a ToC based approach, which means that the evaluation has been grounded on a theory of what the different areas of work/ activities were seeking to achieve, considering the conceptual pathways of change along the results chain from inputs and activities to outputs, outcomes (access barriers as defined by Unitaid) and finally impacts (as measured by the Unitaid KPIs). The main objective of the ToC is to serve as a base for understanding the planned impacts of the projects i.e. what they set out to do and how, in order to critically assess the extent to which these aims were met as well as guide the analysis around which factors contributed to their achievement and non-achievement.

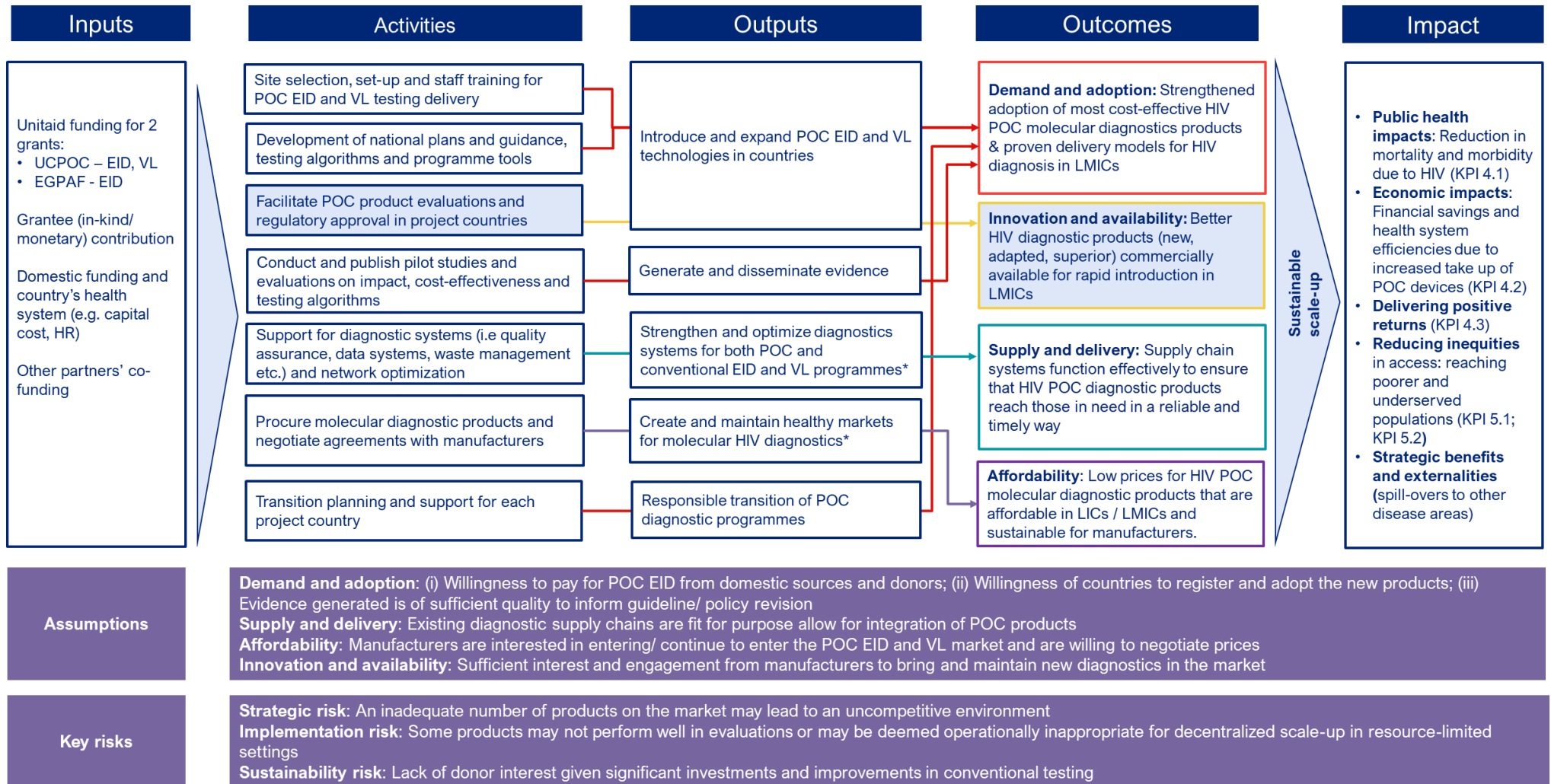
At the time of grant design, neither grant used a ToC approach to consider intended impact as this was not yet the approach required by the Unitaid Secretariat. Therefore, the ToC has retrospectively been developed by CEPA (alongside discussion with Unitaid) for these grants for the purpose of this evaluation at a portfolio level over 2015-2020.

Figure 1.2 presents the ToC, representing key activities and outputs only, rather than all details of the grants (e.g. all activities, objectives etc). Annex H provides a full list of all activities conducted under the two grants mapped against the five key outputs identified in the ToC.

¹⁰ CHAI, UNICEF (2017), UCPOC Ph2b 3rd Amendment to Tri-Partite Agreement

¹¹ CHAI, UNICEF (2019) UCPOC Ph2b 4th Amendment to Tri-Partite Agreement

Figure 1.2: ToC for Unitaid's investments in HIV POC molecular diagnostics for the period 2015-2020



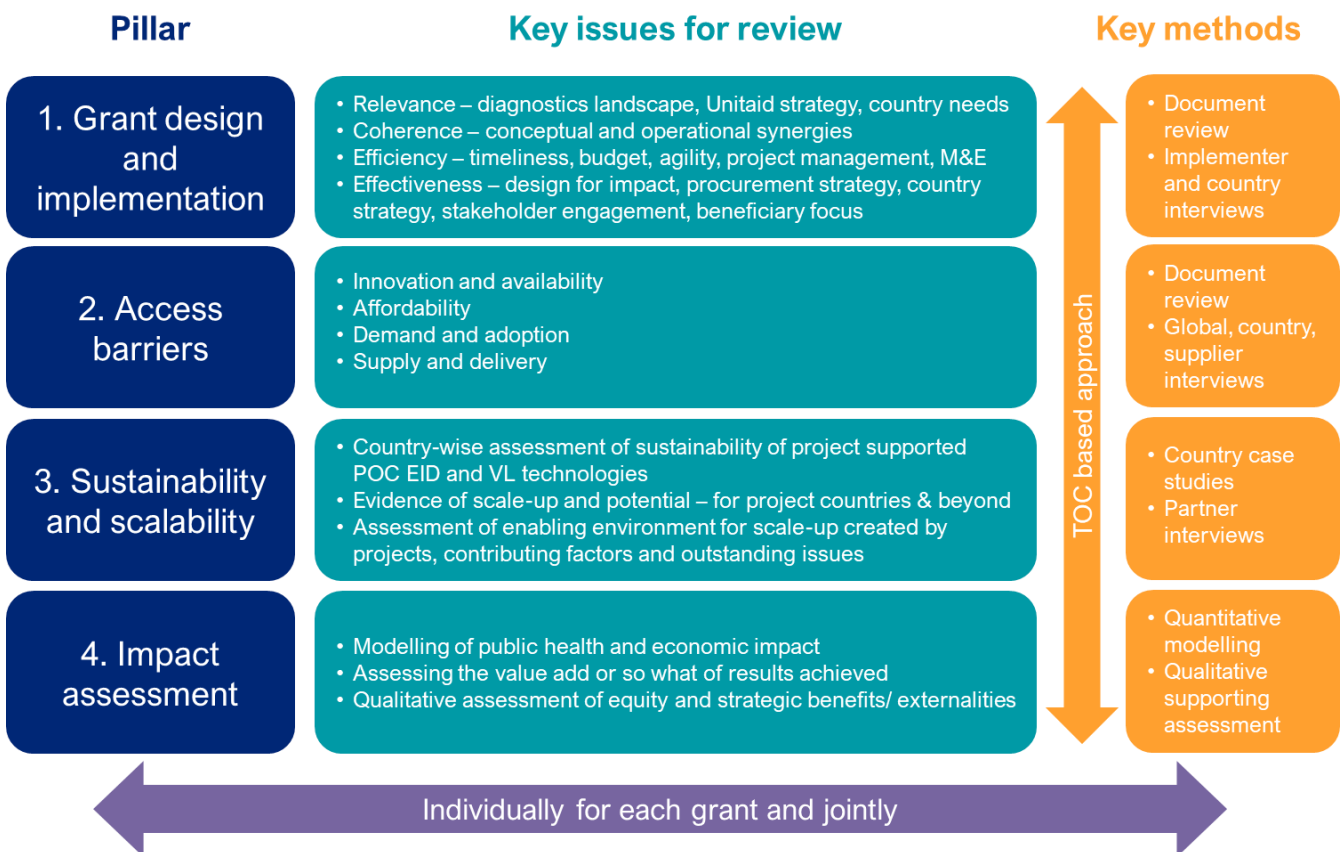
Legend: Blue boxes = UCPOC grant only; white boxes = both UCPOC grant and EGPAF grant; purple boxes = assumptions and risks. Outputs market with "*" signal that EGPAF grant contributed to these, but to a smaller degree than the other outputs. In addition, the access barriers and associated pathways have been colour-coded.

1.3. EVALUATION FRAMEWORK AND METHODOLOGY

1.3.1. Evaluation framework and approach

The evaluation framework presented below in Figure 1.3 brings together the priority issues for this review across four key pillars of focus. These include: (i) grant design and implementation; (ii) access barriers; (ii) sustainability and scalability and (iv) impact assessment. The key issues explored within each of these are demonstrated in Figure 1.3 below.

Figure 1.3: Evaluation framework



1.3.2. Methodology

Description of evaluation methods

This section summarises the methods we employed for this evaluation. Table 1.2 below provides a summary.

Table 1.2: Evaluation methods

Method	Detail
Desk-based review of relevant documentation	<p>This has included:</p> <ul style="list-style-type: none"> • Project documentation such as Project Plans, logframes, Annual and Semi-Annual Reports, evaluation reports and other grant-related material (e.g. tools developed). • Wider Unitaid documentation including synergy meeting notes, evaluation on molecular diagnostics, Unitaid’s Strategy 2017-2021, scalability framework, relevant landscape reports. • Data and documents from partners such as United States President’s Emergency Plan For AIDS Relief (PEPFAR), Global Fund, World Health Organisation (WHO) (e.g. guidelines). • Select relevant academic and grey literature regarding HIV POC diagnostics. • Country level documents (e.g. policies, guidelines).

Method	Detail
	Appendix A includes an initial bibliography.
Key stakeholder and focus-group interviews	<p>Semi-structured key informant interviews comprised an important methodological tool for the evaluation and have been used to gather a range of perspectives and insights. Respondents included: Unitaid Secretariat, lead grantees (EGPAF, CHAI, and UNICEF - as well as African Society of Laboratory Medicine (ASLM) as a subgrantee within the CHAI-UNICEF grant), manufacturers, donors (e.g. Global Fund, PEPFAR, technical partners (WHO, MSF others) and in-country stakeholders. Appendix B includes a full list of consultees.</p> <p>Stakeholder interviews have been supported by semi-structured interview guides which are presented in Appendix D. These have been conducted remotely except some interviews conducted in Cameroon.</p>
Country studies (detailed and less-detailed)	Detailed country studies have been undertaken for five countries: Cameroon, Lesotho, Kenya, Uganda and Zimbabwe. In addition, a less-detailed country study has been undertaken in Mozambique, where a smaller number of interviews were undertaken. All the country case studies have included desk research, data analysis and remote phone interviews (with the exception of Cameroon where it was possible to undertake some in-person interviews).
Impact modelling	The public health and economic impacts of the grants and portfolio have been modelled against Unitaid's KPIs (4.1, 4.2, and 4.3) using bespoke-Excel based impact models. The model design and input assumptions leverage on the work previously conducted by the grantees. A full overview of the model design, updates to the grantee's approaches and input assumptions varied across sensitivities is provided in Appendix J.
Data and quantitative analysis	<p>The main quantitative analysis is the impact modelling which is described above.</p> <p>Other data analysis has included an analysis of project data (e.g. examining the logframe and progress reports) as well as product and market data. Appendix E and F provide a mapping a progress against targets for each grant as per the logframes.</p>

Strength of evidence assessment

Evidence has been collated across the range of methods described above. In line with good evaluation practice, we have assessed the strength of the evidence by assessing both the "quality" as well as triangulation/"quantity" of the evidence. Bringing together these aspects of quality and quantity, ratings describing this assessment as well as an explanation of the rating is shown in Table 1.3. All robustness rankings are *relative* robustness rankings, based on careful consideration and are ultimately judgement-based.

Table 1.3: Robustness rating for emerging themes/main findings

Rating	Assessment of the findings by strength of evidence
Strong (1)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> 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)	<ul style="list-style-type: none"> The finding is supported by various data and/or documents of poor quality; or The finding is supported by some/few reports only and not by any of the data and/or documents being used for comparison; or The finding is supported only by a few consultations or contradictory consultations

1.3.3. Limitations

There are a number of key limitations of the above-noted evaluation methods that were encountered during the evaluation. These are presented in Table 1.4 alongside mitigating measures employed.

Table 1.4: Key limitations and mitigating measures

Limitations	Mitigating measures
Consultation limitations including respondent bias, staff turnover and possible political sensitivities.	Triangulation of data sources, sourcing alternative consultees, anonymising of comments and informed respondents as such.
Challenges with attribution of impact, recognising the role of multiple factors that may contribute to project outcomes and broader impact. In particular, it has been difficult to distinguish the impact between the two grants especially at the country level.	Theory of change based approach which outlines impact pathways, stakeholder consultations
Data limitations including (i) availability challenges with regard to UCPOC project data for 2020 and end-of-project data; (ii) the large number of grant reprogrammings made it difficult to apply a retrospective evaluation of progress; (iii) uncertainty in the data quality of modelling input assumptions; and (iv) country level data availability.	Triangulation of data sources, sensitivity testing and scenario development, qualitative assessment. We have used preliminary UCPOC 2020 data made available on the 8 th of March 2021. Where no updated data has been available, we have used 2019 data.
Extent of generalisability of findings, especially relating to findings from countries given that every country situation is unique, and case studies have been conducted in a subset of project countries.	Mitigated through purposive sampling of countries to ensure a representation from both grants as well as countries where aspects have worked well and countries where aspects have worked less well.
Limited insight from the remote country assessments due to Covid-19, given the more limited scope of key respondent enquiry	Use of in-country team members where possible, pre-testing of interview guides.

2. GRANT DESIGN AND IMPLEMENTATION

The first pillar of the evaluation framework considers the relevance, coherence and efficiency of the Unitaid HIV molecular diagnostics portfolio. Less emphasis has been placed on the findings within this on request from Unitaid. In addition, findings relating to effectiveness have been incorporated into the access barriers or sustainability and scalability sections.

A summary assessment is provided below, followed by a more detailed discussion on each aspect.

Aspect	Findings	Strength of evidence
Relevance	<ul style="list-style-type: none"> The Unitaid HIV molecular diagnostics portfolio has been extremely relevant given the important public health need. However its initial design heralded POC in its own regard, although rightfully evolved to a more holistic approach and consideration of integration and optimisation priorities over time. An important lesson for Unitaid is to ensure upfront and ongoing engagement with the range of global and country level stakeholders when helping to introduce a new technology and delivery approach. 	Strong
	<ul style="list-style-type: none"> It is unclear if the portfolio represented the right approach from a market shaping perspective, given the continuing challenging supply situation. While the demonstration/ introduction role of the projects cannot be undermined, with the limited availability of POC technologies and the lack of a level playing field for existing technologies, some have questioned whether alternate approaches such as direct supplier engagements would have had better results. While it is challenging to predict what approach might have yielded desired results, the experience of this portfolio suggests the need for Unitaid to continually review the appropriateness of their investment approaches in relation to desired end goals. 	Moderate
Coherence	<ul style="list-style-type: none"> The individual grant designs played to the strengths of each implementing organisation and were complementary but did not represent a coherent whole for internal and external stakeholders for a number of reasons. Coherence with other Unitaid molecular diagnostics grants and other funders has also been relatively weak. Coordination between the grantees was generally sufficient but there was room for improvement. Engagement with donors was belated in the case of both grants, also due to the need to first generate data, but this ultimately impacted transition and scale up. Stakeholder coordination at the country level worked well, especially the extensive national level engagement and alignment through the UCPOC grant. 	Strong
Efficiency	<ul style="list-style-type: none"> Grant reprogrammings were largely appropriate in terms of content but inefficient in terms of process. 	Moderate

2.1. RELEVANCE

The Unitaid HIV molecular diagnostics portfolio has been extremely relevant given the important public health need. However its initial design heralded POC in its own regard although rightfully evolved to a more holistic approach and consideration of integration and optimisation priorities over time. A key learning for Unitaid has been the need for upfront assessment and engagement on product positioning with the range of relevant global and country level stakeholders.

The public health case for POC diagnostics for EID and VL monitoring is strong:

- EID:** The proportion of HIV-exposed infants receiving a timely virological test for HIV by two months of age was below 50% from 2010-16, and during the same period, while the number of EID tests nearly doubled, the long

turn-around time (TAT) of the laboratory based, centralised system and high proportion of results not returned have remained problematic, with only 51% of HIV-infected children on ART in 2017.¹² Studies have shown that POC can diagnose more HIV-positive infants faster, reduce TAT and initiate treatment faster.¹³

- **VL:** There are 26 million people living with HIV (PLHIV) receiving ART and requiring treatment monitoring, mostly in low- and middle-income countries (LMICs) and 14% on treatment not yet having suppressed VL.¹⁴ Studies have shown that, for example, there has been a 14% improvement in virological suppression and retention in care in a public clinic due to same-day provision of results from POC VL.¹⁵

Each of our country studies for this evaluation have emphasised the big testing gap and strong need for POC diagnostics for HIV (see Section 8). While donors such as PEPFAR and the Global Fund were investing in large scale diagnostics laboratory infrastructure and testing to meet the target numbers needed, further emphasis was needed on decentralising access to reach more people in need, and improving the quality of testing (e.g. timeliness, linkage to faster clinical action). As such, from a public health perspective, the relevance of Unitaids' work in this area is undeniable.

The challenge with the Unitaids portfolio however was with the initial approach – Unitaids' overall initial approach, and thereby the initial design of the two grants, was set up to champion POC technologies on their own merit, without adequate consideration of the network and environment within which they are to be placed, the broader issues impacting use of these technologies (e.g., maintenance, waste management, etc.), and integration with diagnostics for other diseases. However, over time and based on learnings, this approach evolved to be better reflective of the system within which laboratory based and POC diagnostics function, and several reprogrammings and course-corrections of both grants have sought to better reflect these aspects. Some have argued that this initial 'POC-siloed' approach was much needed given the significant investments in laboratory based, centralised testing until that time and the need to focus on POC as well as to steer the priorities of large donors to move beyond a focus on increasing the "quantity" of testing to the "quality" of testing through better reach of POC. But, on the other hand, the initial "POC as a panacea" approach that was adopted, and advocated for, has in a sense set the scene for more challenging prospects for the wider adoption and scale up of these technologies – given a degree of resistance at both the global (donor) and country (e.g. laboratory personnel) levels – thereby ultimately impacting the overall relevance of the grants. It is noted that the grants have however successfully transitioned at project close, as discussed further in Section 4.1.

Limited dialogue and engagement with other stakeholders supporting diagnostics in the initial grant design and implementation period, and particularly PEPFAR and the Global Fund that have been supporting laboratory based, centralised systems and laboratory quality improvements for several years, has created a disconnect between the catalytic objectives of this portfolio and what has been feasible in terms of scale up (given misalignment between the priorities of these funders that focused on laboratory based, centralised large-scale testing numbers and the agenda that Unitaids was trying to take forward in terms of improving the quality of testing). As emphasised in our consultations with Unitaids, but also the grantees and other stakeholders, one of the key lessons learnt from this portfolio has been the need for a clearer mapping and dialogue on product positioning (i.e., fit of the product within donor objectives, country systems, market structures, etc.) from the very start of Unitaids grants.

It is unclear if the portfolio represented the right approach from a market shaping perspective, given the ongoing challenging supply situation.

¹² Global AIDS monitoring 2017, UNAIDS 2017 estimates.

¹³ For example: Jani, I., et al. (2018), Effect of point-of-care early infant diagnosis on antiretroviral therapy initiation and retention of patients. AIDS, July.

¹⁴ UNAIDS (2020) PLHIV data, June

¹⁵ Girdwood, S., et al. (2020), Cost-effectiveness of adoption strategies for point of care HIV VL monitoring in South Africa. EClinicalMedicine.

In addition to the above finding, considering portfolio relevance holistically, there is a question as to whether the grants represented the right approach to market shaping, given the ongoing challenging supply context.

The challenge with the market at the start of the grants was the limited number of innovations/ technologies and suppliers as well as high price, but there was a potential pipeline of products to come to market. In this context, both the EGPAF and UCPOC grants were set up as demonstration projects to support the development of global normative guidelines as well as country introduction, adoption and learning, with the UCPOC grant in particular to support market competitiveness and procurement. However, the pipeline of products did not materialise, and the market remains concentrated and “asymmetric” – in that: (i) technologies are not similar with a mix of near and true POC platforms so products cannot be directly compared (i.e. differentiated products); and (ii) products are at different level playing fields, also due to their history and donor support e.g. GeneXpert has a longer history with its tuberculosis (TB) footprint and pricing impacted by the original buy-down, Diagnostics of the Real World (DRW) received market entry support for SAMBA, etc. This is discussed in more detail in Section 3.1 on the assessment against the innovation and availability access barrier.

As such, and with the benefit of hindsight, it is not clear as to whether the substantial monies invested through the grants on procuring diagnostic equipment represented the right market shaping approach.^{16,17} Some consultees at Unitaid have commented on whether more “direct” supplier focused engagements would have represented better value for money, although acknowledge that this has been very challenging. However, others at Unitaid and a range of external stakeholders have also commented that such approaches can be market distorting and create precedence for other suppliers/ markets, and that in general, there is limited donor appetite for such approaches. While it is challenging to predict what approach might have yielded desired results, the experience of this portfolio suggests the need for Unitaid to continually review the appropriateness of their investment approaches in relation to desired end goals.

2.2. COHERENCE

The individual grant designs played to the strengths of each implementing organisation and were complementary but did not fully represent a coherent whole for internal and external stakeholders for a number of reasons. Coherence with other Unitaid molecular diagnostics grants (both for HIV and other diseases) and other funders has also been relatively weak.

It is recognised that both grants were developed on their own, with their respective histories – for UCPOC in particular which has a longer history in terms of Unitaid funding. While both grants played to the strengths of each implementing organisation, together as a portfolio they represented quite different approaches in that:

- The EGPAF grant focused on service delivery at lower health levels in terms of introducing and demonstrating the delivery and use of POC EID.¹⁸
- The UCPOC grant adopted a national-level systems approach, engaging closely with country governments on their diagnostics policies and systems as a whole, with a focus on network optimisation.

¹⁶ Indeed, we understand that Unitaid was keen to limit procurement a few years into the projects, but this was not fully understood by the grantees, leading to lack of clarity; and manufacturers were also not clear on the signals being sent by Unitaid in relation to their business opportunity. Further, there was also an issue of over-estimating the quantities of tests needed, which contributed to unrealistic quantities required to achieve price breaks from manufacturers.

¹⁷ Note that this is a qualitative assessment and not based on a quantitative value for money assessment of the market shaping approach which is not within scope for this assignment.

¹⁸ It is recognised that there was engagement at the national level as well, and implementation plans at facility level were developed in collaboration with national stakeholders through participation in the relevant national TWGs.

Our consultations, both with global and country stakeholders indicated confusion as to the overall objective of Unitaid in terms the balance of support for POC and laboratory based, centralised technologies. Perhaps this is indicative of the evolving approach in this regard within Unitaid and the grantees themselves (as discussed previously). Indeed, the several reprogrammings/ budget realignments of the grants changed/ diluted different areas of focus and most stakeholders consulted - at the country level as well as global partners and manufacturers - have claimed that this unhelpfully created confusion (see Section 2.3 below on the efficiency of the reprogrammings more generally). For example, with regards to the UCPOC grant, the reprogrammings have not been fully reflected in the logframe goals, outcomes and outputs which do not capture and communicate the scope of the grant well. Not all the grantees themselves were always aware of the approach and focus of each other, as indicated in some of our interviews with grantees at the global level. As such, given all of these issues, our assessment is that there is scope to develop a more coherent diagnostics portfolio.

While a review of other Unitaid grants in molecular diagnostics is not within scope for this review, we note that Unitaid has diagnostics grants across diseases (e.g., TB and Hepatitis C Virus (HCV)) using the same/ similar platforms with limited coordination and integration between the approaches and grantees. This is in terms of the different approaches to market shaping adopted by some grants (as discussed in Section 2.1. and 3.1), but also limited harnessing of synergies for diagnostics integration (for example, some grantees for this portfolio were not aware of other Unitaid POC diagnostics investments in other diseases). More generally however, these investments do fit well with Unitaid's strategy for diagnostics as well as broader aspects such as investments in paediatric HIV treatment – while one of the aims of Unitaid's work was to increase the percentage of children living with HIV on ART between 2015 and 2020, they simultaneously invested in these grants to increase the percentage of infants born to HIV-positive mothers who are tested for HIV.¹⁹

Some of our consultees also commented that the upstream work of Unitaid in terms of bringing suppliers/ products to market is not well coordinated with the research and development (R&D) work of the Gates Foundation and other R&D funders. While there are issues of confidentiality and it is noted that R&D investments are high risk-high failure in nature, it was noted that greater coherence was needed between the work of Unitaid and other partners in this regard.

Coordination between the grantees was generally sufficient but there was room for improvement.

In addition to the design issue discussed in the previous finding, our review has found that in actual practice/ implementation, there was mixed feedback on the degree of coordination between the two grants/ grantees with some key stakeholders considering this to be appropriately done and others of the opinion that more could have been done in this regard. CHAI and EGPAF coordinated well in terms of global procurement of platforms and cartridges,²⁰ as well as aspects such as regular progress meetings, donor engagement and working together on the Integrated Diagnostics Consortium (IDC). However, some of the grantees have also commented that coordination was challenging in the absence of a joint implementation plan, including in countries where both grantees were active. In-country coordination was pursued, but this was done better in some countries than others. Some good examples include strong efforts to collaborate in Zimbabwe where the grantees had monthly meetings where they shared on progress and ongoing activities, as well as in Mozambique. One of the main ways that the two grants collaborated in several countries was that the implementing organisations sat on technical working groups (TWG) with the MoH and other key country stakeholders.

Stakeholder coordination at the country level worked well, especially the extensive national level engagement and alignment through the UCPOC grant.

All country case studies highlight good engagement and alignment at the country level with government/ policymakers and a range of other stakeholders. This was the case for both grants at their respective levels, and CHAI

¹⁹ Unitaid (2021), Thematic Discussion: Unitaid's paediatric portfolio.

²⁰ There was a global procurement strategy developed for the two grants and there was coordination between the grants on procurement.

in particular, given the scope and nature of the grant and CHAI's general approach to working in countries, worked closely with government on guidelines development and network optimisation issues. EGPAF also engaged with governments through their roles on country TWGs and this was particularly impactful in countries where EGPAF worked on its own. With regards to other government stakeholders, some issues are noted in the sections below with regards to the balance between laboratory and programmes departments as well as limited engagement with communities for demand creation.

2.3. EFFICIENCY

Grant reprogrammings were largely appropriate in terms of content but inefficient in terms of process.

The UCPOC grant underwent several reprogrammings and the EGPAF grant underwent one reprogramming and several budget realignments. These were on account of the evolving landscape and priorities such as changing WHO guidelines, delays in product pipeline, and a more holistic approach to POC and laboratory based, centralised testing (details provided in Section 7 on grant level assessments). In general, these have been viewed as appropriate and responsive to the changing external environment and dynamic for POC diagnostic testing. However, one challenge with the reprogrammings is that certain manufacturers noted that this reduced their incentives to lower prices (which links to the finding above on whether the right market shaping approach was adopted by the portfolio given the status today). The reduction in procurements also implied revision of country implementation plans that had been agreed with MOH, causing some confusion and lack of clarity on project scope and impact amongst government. Also, as noted above, successive reprogrammings caused confusion amongst stakeholders as to the main objectives of the grants.

Importantly however grantees in particular have highlighted that the reprogramming processes by Unitaïd are extremely arduous and time-consuming and would merit efforts at greater efficiency. They noted that in contrast to other donors, Unitaïd's processes are considered to be much more time consuming.

3. ACCESS BARRIERS

The second pillar of the evaluation framework seeks to assess progress made through the Unitaïd HIV molecular diagnostics portfolio against the Unitaïd framework of access barriers. Given the portfolio focus, this effectiveness review encompasses four of the five barriers namely, innovation and availability, affordability, demand and adoption, and supply and delivery (i.e. excludes quality). Different from the Unitaïd Secretariat's assessment of the access barriers which considers the direct achievements of the specific activities funded under the two grants, this evaluation adopts a wider lens that considers the context and implications of the grant activities and overall progress made.

A summary assessment is provided below, followed by a more detailed discussion by access barrier.

Barrier	Progress ²¹	Evidence	Contribution of grants	Strength of evidence
Innovation and availability ²²	Slightly achieved	<ul style="list-style-type: none"> • The POC molecular diagnostics market remains challenging and asymmetrical with only (differentiated) GeneXpert and m-PIMA being available, with the former having a much larger footprint. • Progress has been made on in-country product registrations. 	<ul style="list-style-type: none"> • Not a direct/ large focus of the grants and Unitaid’s market shaping approach through this portfolio. • Both grants facilitated suppliers by supporting POC product introductions and availability. • UCPOC grant in particular helped facilitate availability of products in countries through supporting registration of products and creating clearer and faster processes for product registration. 	Moderate
Affordability	Moderately achieved	<ul style="list-style-type: none"> • Some test price reductions were achieved, including through more inclusive pricing, for m-PIMA and GeneXpert. Some views indicate that the reductions are reflective of what is possible to achieve from a cost of goods sold (COGS) perspective. • Looking at affordability more widely for molecular diagnostics, there have been improvements in manufacturer agreements, especially in terms of the all-inclusive agreement with Hologic. • POC cost-effectiveness evidence made available through the grants although focus of stakeholders continues to be on the sticker price. 	<ul style="list-style-type: none"> • Contribution by UCPOC grant on price reductions. • Contribution by both grants on pricing agreements. • EGPAF and UCPOC grants contributed to cost-effectiveness evidence base. 	Moderate

²¹ The scale is as follows: fully achieved, largely achieved, moderately achieved, slightly achieved, not achieved (N/A).

²² For this access barrier in particular, our assessment adopts a wide evaluation lens that considers the overall implications and indirect impacts of the grants. Also our assessment is at the portfolio rather than grant-specific level, which necessitates this wider lens of assessment. We specifically note that although the grants did not directly target the innovation access barrier, their work has had an indirect impact on the supply base for POC diagnostics for EID and VL by facilitating the availability of these products in countries and therefore the innovation and availability access barrier as a whole.

Barrier	Progress ²¹	Evidence	Contribution of grants	Strength of evidence
Demand and adoption	<p>EID - Largely achieved</p> <p>VL - Moderately achieved</p>	<ul style="list-style-type: none"> • Project countries introduced POC EID and VL through procurement of commodities. Adoption of POC VL less certain than POC EID. • Evidence base for EID POC much stronger than pre-grants. Evidence base for POC VL is stronger but this is an area still requiring further work. • Upgrading of WHO recommendation for POC EID in guidelines to 'strong recommendation/high certainty of evidence' from conditional. Upgrading of WHO recommendation on POC VL in the latest guidelines is 'conditional recommendation/ moderate certainty of evidence'. • Updating of Country Operational Plan (COP) guidance to include POC EID and POC VL for certain population groups. • Project country policies include POC EID and VL although more so for POC EID. • Demand creation efforts undertaken, although belatedly for the UCPOC grant. More progress was made with regards to clinicians and laboratory staff, than beneficiaries/ community level which could have been further enhanced. • Integrated diagnostics become more mainstream but this is an area requiring more work. 	<ul style="list-style-type: none"> • Both grants catalysed the introduction and adoption of POC EID but to a lesser extent POC VL through procurement of commodities. • Both grants significantly contributed to evidence base for POC including influencing the COP guidance. UCPOC grant particularly contributed to updating of WHO guidelines. • Both grants contributed to the updating of country policies. • Both grants, but more so UCPOC grant, contributed to helping integrated diagnostics becoming more mainstream. 	Moderate
Supply and delivery	Largely achieved	<ul style="list-style-type: none"> • Integration of POC EID VL commodities into national supply chain systems. • Demonstration of hub and spoke networks for use of POC technologies with sample transport between sites mostly being successful. • More holistic view of diagnostics networks and development of network optimisation plans. • Further improvements needed on data and waste management systems. 	<ul style="list-style-type: none"> • Largely through the CHAI grant, but also some aspects covered through the EGPAF grant. • EGPAF demonstrated hub and spoke model for POC testing which has been a key contribution. • The approach to diagnostics network optimisation (DNO) through UCPOC has been useful and is also supported by donors. 	Moderate

3.1. INNOVATION AND AVAILABILITY

Box 3.1: Pre-grant status – innovation and availability

- No POC/ near POC products for EID or VL with WHO Pre- Qualification (WHO PQ) in 2015.
- Pipeline of promising POC products.
- A number of countries without in-country authorisations for POC EID and VL use.
- No/ very limited instances of availability and/ or use of POC EID and VL.

The Unitaid Strategy 2017-21 defines the access barrier on innovation and availability as having been met when “there is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply-chain managers. It means that new and/or superior, evidence-supported, adapted products are commercially available and ready for rapid introduction in low-income countries and lower-middle-income countries”. We note that while the grants themselves were not aimed at supporting the development of new innovations,²³ their work has had an indirect impact on the supply base for POC diagnostics for EID and VL by facilitating the availability of these products in countries and therefore the innovation and availability access barrier as a whole (an aspect which is not reflected in the conceptual ToC included in Section 1.2). Further, the grants also made some direct contributions specifically with regards to fostering availability, namely through supporting country registrations and procedures as well as product adaptations (or what might be considered as incremental or implementation-related innovations). With these aspects in mind, we consider the progress made and contributions of the portfolio on the innovation and availability access barrier, contextualising for the other Unitaid grants in the molecular diagnostics space that have also had an impact in this area. This is also linked to an assessment of the validity of the market shaping approach employed by the portfolio, as discussed in Section 2.1.

A summary of findings for these aspects is presented below, followed by a more detailed discussion of each aspect in turn.

Table 3.1: Summary of findings – innovation and availability access barrier

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
Product availability and supply base	<ul style="list-style-type: none"> • Facilitated suppliers to make their product available in the market for POC EID and VL and thereby contributed to initiating the POC market in countries. • Signalling effect for other manufacturers and some useful product adaptations have been introduced such as e-health solutions. 	Low: Supply base is complex and asymmetrical on account of a range of factors including the original pipeline of products not materialising but also potentially due to the wider Unitaid investments in the area.	Low: Given the extent of challenges in the supply side.	Moderate
	<ul style="list-style-type: none"> • In the context of the evolution of the market, partnerships-based approach and focus on all-inclusive pricing have been useful market shaping tools. 	Moderate: Good progress achieved, and some work ongoing.	High: Portfolio has been at the forefront of this work.	Moderate

²³ It is recognised that the wider work of CHAI involves engagement with manufacturers on new technology development in a number of different ways and capacities.

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
Product registration	<ul style="list-style-type: none"> Clearer and faster processes for product registrations in countries, contributing to product availability. 	Moderate: POC products have been registered in all focus countries, however in general, registration of products in countries remains an ongoing issue for manufacturers.	High: Both grants, and particularly UCPOC played an active role in this regard.	Strong

Product availability and supply base

The UCPOC and EGPAF grants have facilitated suppliers to make their product available in the market for POC EID and VL. Together with other Unitaid grants covering molecular diagnostics, they have initiated the POC EID and VL diagnostics market on the supply side, although also potentially contributed to its asymmetry and challenges.

It is recognised that there was a pipeline of products at the start of the grants which has not materialised, but prior to the grants there were no/ very limited instances of availability and/ or use of POC EID and VL and the two grants have made POC EID and VL available in countries. In particular:²⁴

- GeneXpert POC had been successfully introduced in TB programmes. The UCPOC and EGPAF grants leveraged the Xpert market to introduce EID/VL POC in countries.
- In terms of m-PIMA, the EID Consortium brought together data from the various evaluations to expedite completion of a harmonised evaluation, and the work of the two Unitaid grants helped facilitate product entry in several Sub-Saharan African countries.

By the end of the grants, all nine EGPAF countries had POC EID available and out of the 11 UCPOC countries, 11 now have POC EID available (recognising an overlap with four countries that the EGPAF grant also supported) and nine UCPOC project countries for POC VL now have POC VL testing available²⁵. POC EID and VL testing is also now available in some non-project countries but it is not possible to accurately state which ones given confidentiality of information between grantees and manufacturers. With these achievements, the portfolio of grants has kick started/initiated the POC EID and VL diagnostics market in countries.

In addition to the two grants of focus for this review, Unitaid has also made a number of other investments in the molecular diagnostics space that have impacted the market and supply base for POC diagnostics. In particular: (i) DRW SAMBA POC was brought to market through Unitaid although this product has had limited-to-no uptake; and (ii) Open Polyvalent Platform (OPP-ERA) is an innovative modular VL testing platform and played a key role in establishing and expanding access to VL testing in four African countries, although did not progress further. While Unitaid's investments in DRW SAMBA and OPP-ERA overcame some access barriers, the projects failed to establish a viable business model. DRW had a sub-optimal commercialisation plan, and SAMBA remains more expensive than its competitors. DRW was not in a position to compete effectively and further investments would have been needed to de-risk the commercialisation plan. The OPP-ERA model, while innovative, was complex by design and neither succeeded in demonstrating its open system by bringing new suppliers nor its polyvalence.

Our assessment is that the range of these grants alongside a number of other wider issues and developments (such as the original pipeline of products not materialising, the small size of the EID market and hence limited number of manufacturers), the supply side for POC diagnostics has become fairly asymmetrical in that not only are the

²⁴ While not POC, the UCPOC grant aided the introduction of the Hologic Panther platform to a number of countries, and thereby its availability.

²⁵ This includes all six focus countries for POC VL under the UCPOC grant: Cameroon, Kenya, Malawi, Senegal, Tanzania and Zimbabwe. In addition, DRC, Ethiopia and Mozambique had POC VL conducted at least at the pilot stage with only Uganda and Nigeria not using POC VL at all.

technologies fairly differentiated with a mix of near and true POC platforms, there is also no level playing field for the different products. In particular, GeneXpert has a longer history with its TB footprint and pricing impacted by the original buy-down which was supported by Unitaid, the Gates Foundation and others, DRW and OPP-ERA received market entry support for SAMBA from Unitaid, and there has been no direct Unitaid support for m-PIMA.

Some stakeholders consider that the support for m-PIMA (through procurements under the UCPOC and EGPAF grants) has helped maintain at least two products in the market given GeneXpert's large footprint and thus prevented the situation of a true monopoly. However a number of stakeholders think that efforts might have been better focused on further expanding the use of GeneXpert given it is cheaper, has a larger number of assays and is already well established in many countries. In addition some stakeholders consider that there is a relatively large degree of uncertainty as to whether the m-PIMA may remain in the market, especially due to its relatively high cost and currently lower multiplexing ability (notwithstanding its several unique features not offered by other technologies).

While not the direct objective of the UCPOC or EGPAF grants, new POC diagnostic platforms have not yet been brought to the market through a market/ demand creation role of these grants. However, the UCPOC grant worked closely with suppliers to inform new technology development, mainly through signalling the expected stronger future market for POC testing. In particular this relates to Lumira Dx and SD Biosensor Standard F technologies which are currently expected to enter the market soon. Further, it is also important to highlight that the grantees have contributed to the development of product adaptations or implementation-related innovations through digital solutions. For example, primarily through the work of EGPAF m-PIMAs now have modems with simcards to support an e-health solution. Further, an SMS printer system with m-PIMAs is now available at hub sites which can be used as functional solution for sharing results from decentralised platforms.

While industry cited a lot of engagement with CHAI around new innovations, and driving new programmes, at country and global levels, they also noted it is becoming more challenging to implement new innovations. Further, there are the compounding challenges of low EID testing volumes, implying limitations on the number of suppliers that can maintain a viable business²⁶ (alongside limited progress with integration of diagnostics – even though there have been some advances with multiplexing over time). This is also discussed further in Section 3.2 on affordability.

Given the absence of a level playing field and how the market has evolved, the work of the grants through partnerships and on all-inclusive pricing have been useful market/ supply shaping approaches and tools.

The grants focused on trying to reduce prices through strong negotiations and advocacy at all levels including collective negotiations with PEPFAR/USAID. This has helped to lower prices (discussed further in the next section 3.2 on affordability) and been somewhat effective as a market shaping approach.

More generally, looking at molecular diagnostics as a whole, Unitaid supported the introduction of a more sustainable and preferable all-inclusive pricing through the Hologic Global Access Initiative. That price point was made available through a volume guaranteed by MedAccess, which would have not been awarded had Unitaid not agreed to de-risk it by supporting the introduction of the product in four early-adopter countries.²⁷ This effort has increased the emphasis on all-inclusive pricing agreements where possible, by countries and large global purchasers such as PEPFAR.

Product registration and related procedures

Both grants, and particularly the UCPOC grant, helped facilitate the availability of products in countries through supporting the registration of products and creating clearer and faster processes for product registration.

²⁶ Halteres Associates (2017), Landscape Assessment of the HIV Viral Load and Early Infant Diagnosis Point of Care Market Opportunity.

²⁷ Unitaid (2019), Lessons learned from implementation: The example of Molecular Diagnostics.

In a number of countries product registrations was a barrier to availability of products. In particular, many countries require evaluations even though products had WHO PQ. Both grants supported the registration of products as follows and as a counterfactual, without this work, the registration of products would have been slower.

In 2020, all 11 project countries for UCPOC had at least one EID assay approved, and seven countries had both m-PIMA and GeneXpert assays approved.²⁸ All nine UCPOC countries targeted for POC VL assay approval had at least one VL assay approved, and five countries had both m-PIMA and GeneXpert assays approved. In particular:

- The UCPOC grant supported evaluations and regulations with overall success. The UCPOC grant assessed a range of products but initially leveraged the GeneXpert footprint, so evaluations and approvals for use of this technology was the fastest. In turn, many of the CHAI studies then provided evidence for PQ and contributed to WHO policies. The grant also leveraged pooled data by the EID Consortium to try and reduce number of evaluations required across project countries where national regulatory agencies would accept the consortium data.
- EGPAF urged national authorities in project countries to accelerate, reduce or eliminate national regulatory studies in light of WHO PQ approval and the positive field evaluation results reported by the EID Consortium. EGPAF also particularly supported registration in countries where there was no overlap with CHAI (e.g. Cote d'Ivoire, Rwanda, Eswatini, Lesotho and Zambia).
- In addition, and importantly, the UCPOC grant helped outline the regulatory pathway for other products. In particular ASLM advocated through their networks for a reduction of in-country evaluations. The grant also supported countries in updating their policies to accept WHO PQ for regulatory approvals. Whilst country sovereignty remains an issue and there is still a trend towards local evaluations in countries, there were a number of successes. One example is Zimbabwe where through the work of both grants, updates have been made to streamline the approach for all products being registered in the country. EGPAF and CHAI engaged the Zimbabwean MoH and the Lab Council successfully to accept pooled results from a number of evaluation pilots conducted in Southern Africa to register platforms in-country and allow its use in public health facilities. Zimbabwe can now accept data from multi country evaluations and just a feasibility study looking at operational studies is sufficient for adoption. This work helped change the policy and products are now introduced faster with stakeholders noting *“it paved the regulatory pathway for introduction of other products”* and *“the documents, pathways, procurement etc is all much clearer – there is a policy document to point you towards that”*. These successes notwithstanding, country stakeholders and manufacturers highlighted the overall challenge with country level registrations in terms of the range of requirements and time taken.

3.2. AFFORDABILITY

Box 3.2: Pre-grant status - affordability

- POC platforms (m-PIMA and GeneXpert) had high platform and test prices, with test prices being considered unaffordable in comparison to laboratory based, centralised platform test prices.
- Manufacturers were not offering favourable agreements with regards to aspects such as service and maintenance, or more generally all-inclusive pricing.
- There was a lack of evidence regarding cost-effectiveness of POC.

A summary of findings is presented below, followed by a more detailed discussion of each aspect in turn.

²⁸ UCPOC (2021) Consolidated Logframe 23-03-2021

Table 3.2: Summary of findings – affordability access barrier

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
Pricing and agreements	<ul style="list-style-type: none"> Reduction in GeneXpert test price, especially that it happened earlier than otherwise might have been expected. GeneXpert all-inclusive pricing agreement reached. m-PIMA all-inclusive pricing agreement reached (subject to volumes). 	<p>Moderate: Some reductions in m-PIMA and GeneXpert POC tests and a reduction in price for the m-PIMA platform, including through more inclusive pricing, with some views indicating the reductions are reflective of what is possible to achieve from a COGS perspective. But test prices remain higher than laboratory based, centralised platform test prices which is an ongoing barrier to take up.</p>	<p>Moderate: Both grants facilitated some reduction in prices. However these reductions have not yet facilitated significant take up.</p>	Moderate
	<ul style="list-style-type: none"> Expansion of Hologic all-inclusive pricing agreement to project countries through UCPOC grant. Sensitisation of manufacturers and stakeholders of benefits of all-inclusive pricing. 	<p>High: All-inclusive pricing being undertaken by more manufacturers as well as being included as a requirement by global purchasers such as PEPFAR.</p>	<p>High: UCPOC grant facilitated the expansion of the Hologic agreement which directly affected uptake and sensitisation of Hologic agreement and indirectly affected all-inclusive agreements with other manufacturers.</p>	Moderate
	<ul style="list-style-type: none"> EGPAF and the UCPOC grantees negotiated improved service and maintenance agreements with m-PIMA and GeneXpert. 	<p>Moderate: Manufacturers engaged through the project now have documented service and maintenance agreements.</p>	<p>Moderate: EGPAF grant negotiated improved service and maintenance agreements alongside improvements in warranty agreements. The UCPOC grant's work on all-inclusive agreements also contributed.</p>	Moderate
Cost-effectiveness	<ul style="list-style-type: none"> Cost-effectiveness and cost-per-test result returned evidence developed through EGPAF. 	<p>Moderate/low: Some stakeholders note this evidence has been key to shifting thinking on pricing but others disagree.</p>	<p>Moderate/low: EGPAF grant presented new evidence but 'sticker price' remains key to a number of stakeholders.</p>	Moderate
Integration	<ul style="list-style-type: none"> The portfolio of grants have focused more belatedly on integration, which while useful and important for affordability, much progress remains to be made. 	<p>Moderate: This is an area where a lot of work remains to be done especially at the country level.</p>	<p>Moderate/ Low: This aspect was introduced later in the grants. However the UCPOC grant in particular did help to put this issue higher up on the agenda at the global and country levels.</p>	Moderate

Pricing and agreements

There have been some reductions in prices for the m-PIMA and GeneXpert tests and the m-PIMA platform. However, the test prices remain higher than laboratory based, centralised platform test prices, and this is

considered to be one of the important factors affecting take up. The evolution and structure of the market has made it very difficult to achieve meaningful price reductions, alongside the challenge that it will be more difficult for POC devices to achieve price parity with laboratory based, centralised devices given the higher COGS and lower test volumes.

Table 3.3 below shows the change in price per test and platform during project implementation years.²⁹ As the table shows:

- The price per EID and VL test for **GeneXpert** has reduced over the course of the grants, especially considering the shift to all-inclusive pricing (although stakeholder consultations indicate this is not as comprehensive as the all-inclusive pricing offered by Hologic can be considered ‘more inclusive’, similarly this applies to m-PIMA too). This reduction from US\$25.00 has been attributed to work undertaken by Unitaid and the grantees (as well as with other key partners).^{30,31} The cartridge price alone is now US\$12, a 33% decrease from US\$17.95. Overall stakeholders noted the positive progress in relation to a reduction in this price.
- In addition, progress has been made in relation to the **m-PIMA** device with an all-inclusive pricing agreement being reached in 2018 and this agreement was attributed to discussions with the grantees, Unitaid and USAID.³² The price therefore decreased from US\$25 per test and US\$25,000 per device to US\$20 per test inclusive of the device. However this offer is a tiered pricing plan contingent on volume commitments which stakeholders think many countries may not be able to meet. In Zimbabwe, stakeholders consider that the larger procurement volumes obtained through the grants were an influencing factor for the decrease in the m-PIMA test price. Stakeholders in Lesotho considered the m-PIMA test price to be particularly high, especially given that they have a shorter shelf life with a higher risk of wastage due to expiration. As one stakeholder said, *“In future maybe we will switch to one analyser (GeneXpert) because of the price, unless the vendor agrees to come down”*.

Some progress has been made with regards to POC testing costs, especially considering POC devices are considered to have higher COGS and lower test volumes making it more difficult to achieve price parity with laboratory based, centralised testing. However, overall, many stakeholders highlighted that the price of the POC platforms and tests are considered to be one of the important factors affecting take up, especially the m-PIMA tests and platform costs. In particular, a key issue is that the price per test for both of these POC devices is still higher than laboratory based, centralised platform testing, especially Roche which is under \$10 per test and Hologic at \$12 which is an all-inclusive price. While there has been some take up at these prices, feedback from consultations indicates that if the price per test was closer to the price of laboratory based, centralised tests then take up would be increased by donors and others. However the fact that all-inclusive pricing agreements have been reached has been positive in particular as it is expected that this will support further procurements from PEPFAR (discussed further Section 4). Country stakeholders also highlighted that there may be additional setup costs to support diagnostic testing at lower-level facilities which are not required for laboratory based, centralised testing in existing laboratories such as electricity connections and waste disposing costs, e.g. the cost for disposing GeneXpert cartridges in Zimbabwe varied between 23 to 25 cents per cartridge (however CHAI negotiated lower prices for reagents inclusive of waste management which is a positive achievement).

²⁹ It is recognised that given the differences between the technologies and what aspects are included in the platform and/ or cartridge prices, one cannot conduct a like-for-like comparison. But the figures are indicative of the top line numbers that stakeholders consider in their decision-making.

³⁰ EGPAF (2018) Annual Report for 2017.

³¹ We note that in consultations it was shared that there may be further reductions and a more inclusive pricing for Cepheid testing (potentially at \$12-13 per test) based on current discussions with Cepheid but these have not been confirmed as of March 2021.

³² UCPOC (2019), Annual Report for 2018.

Table 3.3: Price per EID and VL tests and device³³

Manufacturer	Earliest year for data ³⁴	2020 ³⁵
Abbott m-PIMA/ Alere Q (true POC)	Test: \$25.00 ³⁶ (2016)	\$19.40-\$30 all-inclusive, price dependent on instrument placement and test volume
	Device: \$25,000 (2016)	\$15,000
Cepheid GeneXpert (near POC)	Test: \$17.95 ³⁷ cartridge only (2016)	\$14.90 all-inclusive or US\$12.00 ex works
	Device: \$17,500 (incl. laptop) ³⁸ (2016)	\$17,500
DRW SAMBA I (near POC) and SAMBA II (true POC)	Test: \$17.80 - \$37.40 (2017)	\$28.80
	Device: \$56,000 (I) Device: \$18,000-\$24,000 (II) (2017)	\$26,550 (II)
Hologic Panther (laboratory based, centralised)	Test: \$12 all-inclusive ^{39,40} (2018)	\$12 all-inclusive
	Device: \$150,000-\$175,000 but a rental model is used so no cost is incurred by users (2018)	Device: included in all-inclusive price
Roche CoBAS AmpliPrep/ TaqMan system (laboratory based, centralised)	Test: \$9.40 Roche GAP pricing (2014) Device: \$150,000 (2017)	Not available (consultation feedback indicates it has not changed since 2017 following a decrease in that year)
Abbott m2000rt (laboratory based, centralised)	Test: \$11-\$23 Device \$170,000 (2017)	Not available

The evolution and structure of the POC market has implied that achieving any meaningful price reductions has been very challenging. As outlined in the ToC, the achievement of the affordability access barrier assumes supplier/product entry as well as willingness to negotiate on price reductions which has not been the case. More specifically:

- As noted previously, many stakeholders highlighted that the number of products available on the market did not materialise as expected over the course of the grant as there are only three POC, or near POC products available for VL and EID. These include GeneXpert, m-PIMA (the m-PIMA only had the EID assay until the VL assay was

³³ We note that the price per test and per machine is not directly comparable across the three POC platforms as different aspects such as the instrument, internal batter, external battery, printer etc are included in some and not others. Work was undertaken under the grants to support countries to understand these differences and a fuller assessment of the total cost.

³⁴ Data from MSF (2017), Putting HIV and HCV to the test – 3rd Edition unless otherwise stated.

³⁵ Data from UCPOC (2021), Preliminary data for 2020.

³⁶ EGPAF (2015), Project Plan.

³⁷ EGPAF (2017), Annual Report for 2016.

³⁸ EGPAF (2015), Project Plan.

³⁹ UCPOC (2019), Annual Report for 2018 programmatic.

⁴⁰ CHAI (2018), Website [CHAI website](#): with no upfront costs or capital expenditure. US\$12 price includes the full set of supplies and services needed to generate a patient result, including reagents, instrument placement, service and maintenance, consumables and controls, as well as full freight and logistics delivered to the laboratory.

approved in 2019.⁴¹) and DRW's SAMBA. However only a minimal number of SAMBA I and II cartridge kits were procured within this project and most stakeholders do not consider it to be a competitive product given the high price and lack of WHO PQ. Therefore whilst the grants had initially intended to support the introduction of a number of products, and reduce the price through increased competition, this did not materialise as expected as there is limited competition.

- The existing asymmetric structure of the market also makes it very difficult to achieve price declines, with the products being at very different supply base levels in countries – e.g. GeneXpert's large existing footprint and greater success in multiplexing.
- Further, demand side market dynamics with limited (and assumed to be declining) EID test volumes implies there can be limited impact on POC prices through EID. A study conducted by Halteres Associates reviewed the Total Addressable Market (TAM)⁴² and the Served Available Market (SAM)⁴³ estimates for all VL and EID testing, considering both the centralised laboratory and POC applications.⁴⁴ This study states that no more than two HIV POC companies would be comfortably supported in a SAM scenario, the more likely of the two scenarios modelled. In addition, some have commented that with higher COGS, further declines in POC testing may not be achievable.

The expansion of the Hologic all-inclusive pricing agreement to project countries is a key positive outcome from the UCPOC grant. The grants significantly contributed to a strong sensitisation of manufacturers and global and country stakeholders on the benefits of an all-inclusive price and move to long term agreements.

Hologic planned to introduce the Panther using an all-inclusive pricing agreement which incorporates the price of the device as well as the vast majority of the costs associated with testing.⁴⁵ The agreement was through MedAccess, supported by the UCPOC project and the key value add was (i) to facilitate take up of the Hologic Panther in project countries as this was a new device being introduced; and (ii) to expand the uptake of the all-inclusive pricing approach and 'helped to get message across' to stakeholders regarding the benefits of an all-inclusive agreement.

Overall the grants have significantly contributed to the sensitisation of manufacturers and global and country stakeholders and purchasers on the need for an all-inclusive price and move to long term agreements. In particular, global purchasers such as PEPFAR are now requiring all-inclusive pricing in their agreements with manufacturers. For example, the project has been linked to PEPFAR's 2019 RFP which stakeholder feedback indicates reflected a lot of what was included in Hologic's agreement. Therefore, Roche and Abbott's agreements now have more inclusive pricing and this is applied to a number of assays.⁴⁶ As one stakeholder said, *"it would be hard for countries to move back now give the evidence generated on all-inclusive pricing"*. Country level stakeholders confirmed this in Zimbabwe where they noted how valuable the Hologic all-inclusive agreement was, as one stakeholder said, *"the introduction of Hologic revolutionised the testing space with a significant decrease in price... and it has challenged other manufactures to have all-inclusive pricing"*.⁴⁷

⁴¹ EGPAF (2020), End of Project Report. Appendix 2.

⁴² A potential market which assumed the execution of additional market growth drivers and other market shaping activities.

⁴³ Describes what the market fulfilment opportunity is most likely to be today and into the near future given competitive and other limiting factors.

⁴⁴ Halteres Associates (2017), Landscape Assessment of the HIV Viral Load and Early Infant Diagnosis Point of Care Market Opportunity.

⁴⁵ The all-inclusive testing price consists of all supplies and services needed to generate a patient result, including: instrument placement, reagents and consumables, service and maintenance, freight and logistics and replacement tests (for one set of controls and calibrators and documented instrument errors). [source: Hologic (2018) All-inclusive Pricing FAQ. Available at: https://www.hologic.com/sites/default/files/MISC-06024-001_001_01.pdf]

⁴⁶ UCPOC (2020), Annual Report for 2019.

⁴⁷ In Kenya, Hologic HPV testing pilots faced delays due to registration and importation challenges; discussions with Hologic are ongoing to find a more permanent solution

Improvements have been made with regards to service and maintenance agreements for POC devices of which some aspects can be attributed to work undertaken under the grants.

Apart from the Hologic all-inclusive pricing agreement, other progress has been made with regards to service and maintenance agreements (as well as all-inclusive agreements) for both the GeneXpert and mPIMA POC devices. In particular:

- *m-PIMA*: In 2017, EGPAF negotiated an improved service and maintenance agreement (2017) which included Abbott installing and verifying the instrument, repair and replacement clarification, transfer of warranty ownership and other clarifications.⁴⁸ In 2018, an all-inclusive price was established following work undertaken within the grants, especially the UCPOC grant. The all-inclusive price included instrument, data services, connectivity, service and maintenance for EID and VL assays and has built in costs associated with the instruments and support.^{49, 50} In addition, EGPAF negotiated a warranty extension which was longer than originally proposed in order to match GeneXpert.
- *GeneXpert*: in 2017, EGPAF negotiated improved service and maintenance package including installation of instruments by Cepheid, repair/replacement improvements, transfer of warranty ownership, and clarified areas previously without explicit language.⁵¹ In 2018, Cepheid announced a service level agreement for a surcharge of \$1.50 maximum per test. This negotiation was attributed to Global Drug Facility (through the Stop TB partnership), Unitaid and the Global Fund through the IDC workstream.⁵² In addition, the UCPOC grant aided the introduction of the Access Care agreement which has improved the service and maintenance agreements with Cepheid.

Overall an impact of the project included documented service and maintenance agreements which were previously lacking. Stakeholders consider that this will help to keep manufacturers accountable. It also reflects greater value for money in the face of no big price declines in the platform and cartridge prices. Another aspect that is considered positive in encouraging manufacturers to respond to maintenance issues is that both the Global Fund and PEPFAR have shifted to rental agreements in the past few years (this shift has not been attributed to either of the projects but will support the aims of obtaining more favourable service and maintenance agreements).

Cost-effectiveness

Evidence relating to the cost-effectiveness of POC testing and cost-per-test result returned was developed by EGPAF which some stakeholders considered to be a significant achievement and WHO guidelines state that EID testing is cost-effective. However there have been some limitations with this evidence influencing take up due to an ongoing focus on the 'sticker price' as well as funding envelopes being unable to accommodate higher overall infant testing costs related to POC use.

EGPAF developed two significant papers on the costs of POC EID testing. The first paper, measured cost-effectiveness of POC EID in terms of life expectancy and mortality, based on the case study of Zimbabwe. The cost-effectiveness study showed use of POC assays for EID improved projected undiscounted life expectancy to 25.5 years among infants with HIV and 62.6 years among HIV-exposed infants at a cost of \$690 per HIV-exposed infant.⁵³ EGPAF also advanced a more nuanced view of POC costs by generating data on cost-per-result returned versus the

⁴⁸ EGPAF (2018), Annual Report for 2017.

⁴⁹ UCPOC (2019), Annual Report for 2018.

⁵⁰ EGPAF (2019), Annual Report for 2018.

⁵¹ EGPAF (2019), End of Project Report.

⁵² UCPOC (2020), Annual report for 2019.

⁵³ Frank et al., (2019), Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study.

more simplistic price per test that is traditionally cited.⁵⁴ This cost-per-result returned study demonstrated that POC is more efficient than laboratory based, centralised testing when cost per test returned at 30 days is compared between the two.⁵⁵ Specifically, the study found that for results returned within 30 days of sample collection, POC EID costs \$27.24 at optimal throughput (\$37.89 at actual throughput) compared to \$131.02 for laboratory based, centralised EID. This cost-effectiveness approach promotes a more cascade-centric focus by highlighting the importance of the post-test steps in the clinical cascade (i.e., a test result has no value if clinical action (e.g., ART initiation, adherence counselling, etc.) is not taken). This showed that decentralised testing can be more efficient which a number of stakeholders noted to be key. Some stakeholders highlighted that this evidence helped programmes to make decisions regarding different models to employ whilst others stated it helped to persuade them regarding the value of POC testing when they were previously unsure (global level and country level). In addition, WHO guidelines released in March 2021 state that POC EID is cost-effective.⁵⁶

In addition, under the UCPOC grant, evidence was generated to show that POC testing was cost-effective using methodologies other than classical models. In Zimbabwe, CHAI piloted the price per result concept in 2018 in three sites (Kadoma, Bindura and Marondera) using the Hologic Panther Viral load (VL) platform.⁵⁷

However, a number of stakeholders remained unconvinced for the following reasons:

- Sticker price remains important despite appreciation of the concept of cost-effectiveness;
- Partners find it challenging to accommodate the higher absolute funding required for POC EID testing scale up in the face of flat or decreasing prevention of mother to child transmission (PMTCT) programme budgets (discussed further in Section 4);
- Stakeholders consider that some operational questions remained unanswered such as (i) where POC devices should be placed; (ii) integration with other disease testing; and (iii) utilisation of the machines;⁵⁸
- Other country stakeholders considered that more comprehensive costing needed to be done to further understand cost drivers – e.g., lab testing requires specialised lab workers doing the test (which requires training etc), the sample testing, costing to factor in transportation etc;⁵⁹
- Perceived risk of replacing laboratories: i.e. perception that the focus was on POC *versus* the laboratory network rather than POC *within* a laboratory network.

In hindsight, some stakeholders noted that perhaps more could have been done at the start of the project to ensure that this evidence focused on what partners wanted/ needed. While the successive course corrections and

⁵⁴ Bianchi et al., on behalf of EGPAF (2019), Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries.

⁵⁵ Bianchi et al., on behalf of EGPAF (2019), Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries.

⁵⁶ World Health Organization (2021), Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring, March. Accessed: <https://apps.who.int/iris/rest/bitstreams/1336192/retrieve>

⁵⁷ UCPOC (2019), Grant Brief Analysis for 2018.

⁵⁸ The study advocates for the hub and spoke model as an efficient way to extend facility access to POC, but does not address further issues of placement or around integration with other diseases. In addition, the cost per test calculations do not include human resource costs for running the tests, sample transport costs, lab facility costs and other costs, and the study admits that further work is needed to analyse full programme costs.

⁵⁹ One such bit of evidence generated late in the project is the evaluation in Zimbabwe at EGPAF sites. This study addresses cost per EID test based on number of EID tests performed on each machine per day, while taking into consideration the various cost drivers e.g. materials, equipment, labour, training, facility upgrades and monitoring (reference: Mukherjee et al., (2020), Estimating the Cost of Point-of-Care Early Infant Diagnosis in a Program Setting: A Case Study Using Abbott m-PIMA and Cepheid GeneXpert IV in Zimbabwe. J Acquir Immune Defic Syndr Volume 84, Supplement 1, July 1, 2020.)

reprogrammings sought to address a number of issues, the continued focus of stakeholders on the sticker price and overall view that the POC technology is more expensive could not be subverted through these grants.

Integration

An important aspect that can influence affordability is integration, where the grants have focused more belatedly and much progress remains to be made.

An important factor that can influence affordability is integration and the associated utilisation of platforms. In particular USAID has increasingly been focusing less on how much a platform costs and more around how well it is integrated within a health system. One of the aspects that is a benefit for GeneXpert over the m-PIMA is its relatively extensive multiplexing capacity. One stakeholder reported that manufacturers are increasingly aware of this as they said “an influence of the project is that it helped manufacturers to realise that EID volumes were too low for countries to justify a \$25,000 piece of equipment”. In addition, global and country level stakeholders noted the importance of EID yield of the test results and therefore it makes sense to also use the platforms in alternative entry points outside of PMTCT clinics (e.g. paediatric and nutrition wards).

However, as noted in Section 2.1, the Unitaid HIV molecular diagnostics portfolio came to focus on integration as a priority belatedly, and this was not a strong emphasis in approach from the start. However, the grants did contribute to helping put integration further on the agenda at the global and country levels (discussed further in Section 3.3).

In general, integration is a complex issue, much beyond the diagnostics platforms themselves (where differing test prices are also problematic, for example), and also relates to the structuring of the country’s health system (e.g., linkage with different disease treatments) and requires an all-encompassing and comprehensive approach (where equipment throughout needs to be carefully considered alongside multiplexing capacity). This aspect is also discussed further in the assessment of the demand and adoption barrier (Section 3.3).

3.3. DEMAND AND ADOPTION

Box 3.3: Pre-grant status – demand and adoption

- No project countries implementing POC testing for EID or VL in any significant way.
- Very limited evidence regarding POC VL and EID.
- WHO normative guidance not available for POC VL and conditional for EID.
- Country policies and guidelines not reflective of POC use.
- Limited experience/ demand for POC at global or country levels.
- Donor funding guidance unsupportive of POC EID and VL.
- Concept of integrated diagnostics not mainstream.

A summary of findings across key areas is included in the table below, followed by the details and evidence base supporting the findings. POC EID and VL has been addressed separately and it is fully recognised that the context for both testings is very different in terms of size of populations and intended use/ scale of use (amongst other factors).

Table 3.4: Summary of findings – demand and adoption access barrier

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
POC introduction/ adoption	Introduction and adoption of POC	High (EID): POC EID was non-existent or extremely limited but successful procurement of devices/ cartridges and incorporation of	High (EID) & Low (VL): given the adoption	Strong

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
	technologies for EID and VL	POC EID into infant testing programs has resulted in durable commitments to substantial POC EID testing in many countries. Low (VL): POC VL use was not achieved in all countries and was targeted at specific population groups (as intended overtime). However, in many countries scale up was limited and long-term commitments remain uncertain.	and scale up context for both	
Evidence and guidelines	Evidence generation to inform global and national guidance	High (EID); Moderate (VL): Grantees conducted numerous high-quality studies related to operational aspects and impact of POC EID and POC VL. These were instrumental in updating of global normative guidance and in revision of national EID guidelines and VL guidelines to a lesser extent due to some extent to the later market entry of this product in comparison to POC EID.	High (EID); Low (VL): given progress and contributions	Moderate
Demand creation	Creation of demand for POC EID and VL	Moderate (EID); Low (VL). Demand creation efforts were undertaken, although belatedly for the UCPOC grant. More progress was made with regards to clinicians and laboratory staff, than beneficiaries/ community level which could have been further enhanced.	Moderate (EID); Low (VL)	Moderate
Integration	Integration in diagnostics	Low: Grant activities played an important role in introducing and normalising the concept of integration. This included emphasising the complementarity of POC and centralised testing but this is an area where further work is needed, especially with regards to integration with diseases other than HIV.	Moderate	Moderate

Introduction and adoption of devices

The grant portfolio was instrumental in catalysing the introduction and adoption of POC EID and VL technologies through procurement of essential commodities as well as via development of new service delivery models, with greater success for POC EID as compared to POC VL (noting the different contexts for each type of testing).

At the start of the grant, no project countries were implementing POC testing for EID or VL in any significant way, so support from the portfolio had a significant impact on introduction and adoption. Table 3.5 below shows a summary of procurement and delivery over the projects' duration (four years for EGPAF grant and five years for UCPOC grant).

Table 3.5: Procurement and delivery summary for EGPAF and UCPOC grants

	EGPAF ⁶⁰ (2019)	UCPOC (2020) ⁶¹
EID	259 devices procured 217,620 cartridges procured 147,147 EID tests run 1,668 sites with access to POC EID	59 devices procured by UCPOC June 2020 ⁶² and 408 GeneXpert devices used in project countries 258,752 tests procured by UCPOC 318,363 EID tests run at Unitaid supported sites ⁶³ 492 sites with access to POC EID
VL	N/A	16 EID/VL devices procured by UCPOC June 2020 ⁶⁴ and 273 GeneXpert devices used in project countries 159,000 tests procured by UCPOC 121,926 VL tests run at Unitaid supported sites 208 sites offering POC VL

Both grantees used systematic and comprehensive approaches to site selection that considered country context, existing POC devices in use (e.g., GeneXpert platforms placed by the TB programmes), and laboratory based, centralised testing to create networks of sites that optimised use of the POC platforms. Global and country level stakeholders generally agreed that site selection and platform placement was well thought out and successful.

For POC EID, grant activities resulted in a significant proportion of EID being conducted on POC devices and appeared to have generated a durable commitment to continuation of testing as a substantial proportion of overall EID testing. In particular, POC EID has become the preferred testing method in many countries over the last few years taking over a substantial market share. Examples from countries include the following:

- Cameroon: the national scale up target is to have 55% of EID testing conducted using POC platforms.⁶⁵
- Ethiopia: 45% of EID tests were conducted on POC devices in 2020 and the national target for EID tests on POC is 50%.⁶⁶
- Kenya: Current EID POC testing is estimated to account for <10% of all testing,⁶⁷ but the government plans to have 50% of EID tests by POC, targeting select settings experiencing issues with access and slow TATs.
- Lesotho (EGPAF only): 76% of EID testing was being done on POC devices at the end of the grant.⁶⁸ This may potentially be expanded to 100% if resources allow according to stakeholders. The Country Operational Plan (COP) 2020 explains that by the end of 2020, the split is expected to be 95% POC EID, and 5% laboratory based, centralised testing.⁶⁹

⁶⁰ EGPAF (2019), End of Project Report.

⁶¹ Data from UCPOC (2021) consolidated Logframe 23-03-2021 unless otherwise stated.

⁶² UCPOC (2020), Semi-annual Report for 2020.

⁶³ Note that tests run is at Unitaid sites, where as tests procured is just by the UCPOC project.

⁶⁴ UCPOC (2020), Semi-annual Report for 2020.

⁶⁵ CHAI, UNICEF (2021), Cameroon UCPOC Factsheet 2018-2020, February.

⁶⁶ UCPOC 2020 Annual Report.

⁶⁷ Informants in Kenya were not at all in agreement on the percentage of EID tests that were using POC technology. The figure of less than 10% was based on a consensus of views across stakeholders rather than strong quantitative data.

⁶⁸ EGPAF (2019), End of Project Report.

⁶⁹ PEPFAR (2020), Country Operational Plan 2020 Strategic Direction Summary.

- Malawi: 69% of EID tests were conducted on POC devices with a national goal of 100%.⁷⁰
- Mozambique: 39% of EID tests were conducted on POC devices.⁷¹
- Uganda (UCPOC EID only): Scale up of POC EID has already started, with 100 new sites added to the original 33 pilot sites; the target is to shift 30% of all EID testing to POC technology.
- Zimbabwe: By 2019, 25% of its EID need was conducted on POC platforms⁷² and it is expected to be 40% for 2020-2023.

With many countries using none to very little POC EID prior to the Unitaids grants, these are valuable achievements despite the UCPOC grant not fully realising all the POC EID coverage targets that they set (see Appendix E for tests conducted against the project plans).

Whilst recognising the different context for POC VL testing, it was noted that demand and adoption of POC VL was less successful and multiple stakeholders expressed doubts about its potential for scale up. This was due to some extent to the later market entry of this product in comparison to POC EID. In addition, the market share for POC VL is considerably smaller with market share most often being in the single digits. Factors contributing to these issues included less well-defined indications for use of POC VL over laboratory based, centralised testing and programmatic complexity in targeting only specific patient populations. However, several stakeholders considered that the UCPOC grant was helpful in exploring whether POC VL should be pursued or taken up. We note the progress over the course of the grant implementation as follows:

- At the start of the grant, indications for POC VL and its use were not well-defined and minimal guidance existed advocating its use (e.g., by WHO, Global Fund, or PEPFAR). During grant implementation, there has been some useful trialling of POC VL.
- However there has been a preference for trialling POC EID over POC VL in some countries. Not all UCPOC project countries (e.g., Uganda) agreed to pilot POC VL, but in those who did initiate POC VL activities, its use was primarily targeted to HIV-positive pregnant and breastfeeding women (PBFW), serodiscordant couples, PLHIV with advanced disease, and/ or suspected cases of HIV treatment failure. Within the UCPOC grants in many countries, EID testing was prioritised over VL testing; for example, in Cameroon, VL testing was given only 2% of the share of testing on POC devices, although this is expected to increase to 8% with the transition and 2% of the market share of VL testing in Malawi was conducted using POC.
- Looking forward, multiple stakeholders noted that POC VL is not expected to play a large role in VL testing given the significant volume of VL tests required for routine monitoring of PLHIV on ART and the low throughput of POC VL platforms. However, it can play a role in more isolated settings or inpatient populations in which timely results are more important (e.g., PBFW, children, advanced HIV disease (AHD)). As a result, while not an unexpected outcome at the end of the grant, almost all interviewees agreed that centralised VL testing will remain the backbone.

Zimbabwe's experience is illustrative in highlighting the challenges of POC VL implementation. In-country stakeholders noted that a relatively high number of POC VL tests were conducted for patients not eligible per the country guidelines (e.g., for routine monitoring or for follow-up of patients outside the targeted groups). Table 3.6 below shows further details.

⁷⁰ UCPOC 2020 Annual Report.

⁷¹ UCPOC 2020 Annual Report.

⁷² EGPAF (2019), End of Project report.

Table 3.6: Split of POC VL and laboratory based, centralised VL testing across the implementation years (2018-2020) in Zimbabwe⁷³

Type of test	Number of laboratory based, centralised tests ⁷⁴	Number of POC tests ⁷⁵	Total number of tests	% laboratory based, centralised out of total number of tests	% POC out of total number of tests
Routine	52,284 (88%)	3,503 (19%)	55,787	94%	6%
Targeted tests ⁷⁶	7,130 (12%)	14,842 (81%)	21,972	32%	68%
Follow up VL	2,377 (4%)	182 (1%)	2,559	93%	7%
Targeted (Children)	594 (1%)	2,782 (15%)	3,376	18%	82%
Targeted (Pregnant/lactating mother)	594 (1%)	2,794 (15%)	3,388	18%	82%
Targeted (Suspected failure)	1,782 (3%)	8,706 (47%)	10,488	17%	83%
Other	1,783 (3%)	378 (2%)	2,161	83%	17%
Total	59,414 (100%)	18,345 (100%)	77,759	76%	24%

Evidence generation

It is widely acknowledged that generation of high-quality evidence has been one of the grants' most significant achievements and grantees successfully disseminated findings at the national, regional, and global levels to inform policy and implementation.

The studies included data and implementation experiences on a wide range of aspects related to POC/ near-POC testing, including operational aspects (e.g., hub and spoke models), cost-effectiveness (discussed in Section 3.2), connectivity solutions, diagnostic network optimisation (DNO), and multiplexing. In addition, significant efforts were put into the dissemination of the evidence as the grantees presented and published evidence in a wide variety of levels and venues, including health facilities, district health offices, local civil society organisations (CSOs), TWGs,

⁷³ CHAI (2021), program data.

⁷⁴ Brackets indicate the percentage of conventional tests conducted within the specific category out of all conventional tests conducted.

⁷⁵ Brackets indicate the percentage of POC tests conducted within the specific category out of all POC tests conducted.

⁷⁶ Targeted test total is made up of the following categories: (i) Follow up VL, (ii) Targeted (Children), (iii) Targeted (Pregnant/lactating mother), (iv) Targeted (Suspected failure), (v) Other.

local news articles, academic journals and large global conferences.⁷⁷ This laudable approach maximises engagement of stakeholders at all levels, maintains demand, and builds capacity for data-driven decision making and planning. Grantees also collaborated to develop and disseminate a wide range of high-quality guidance documents and tools related to POC diagnostics, particularly for EID; they are still in use by a variety of stakeholders (e.g., PEPFAR) and widely available for other non-project countries.

The evidence generated for routine use of POC and near-POC EID was much stronger than for VL. Several stakeholders noted that the data on POC VL is sparse and the latest WHO guidelines state that there are “multiple research gaps” for VL and that additional studies are currently ongoing. The emerging consensus is that POC VL is best targeted at certain priority population groups, and indeed the UCPOC grant has helped establish this, but there continues to be uncertainty and ambiguity as to which are these targeted priority groups.

Policy and guideline updates

The grants played a pivotal role in influencing global and national guidance for POC testing for EID, thus paving the way for increased donor investment and accelerating adoption and scale up. The impact of the grant on guidelines and policies related to POC VL has been much more limited.

At the **global** level:

- The evidence from the grants was foundational to the global evidence base for POC EID and the strength of some of the findings prompted an upgrading of the WHO recommendation for POC EID in the new 2021 guidelines to ‘strong recommendation/ high certainty of evidence’ from conditional in 2016.^{78,79} In particular, it was noted that CHAI worked closely with WHO to identify the type of POC evidence needed to inform WHO global policy and the studies from Mozambique and Zimbabwe were particularly influential. Some studies undertaken by EGPAF were incorporated into the systematic review but WHO also indicated that some could not be included due to issues with applicability and representativeness.
- For POC VL, the grant activities were less influential, and the WHO recommendation on POC VL in the latest guidelines on limiting to specific priority populations (examples provided include pregnant and breastfeeding women to prevent transmission, people with advanced HIV disease, infants and children and people suspected of having drug resistance)⁸⁰ is ‘conditional recommendation/ moderate certainty of evidence’ due to lack of high-quality evidence comparing POC to the current standard of care which is largely based on centralised testing.
- Because of the Unitaid grants, PEPFAR and Global Fund also now recommend the use of POC EID and, for specific population groups, POC VL.⁸¹ This occurred prior to the change in WHO guidance due to the compelling evidence generated during the grant period. PEPFAR COP guidance in 2021 endorses the use of POC EID (complementary to the laboratory based, centralised system) as well as POC VL for PBFW and in infants and children as an aspect of family centered testing and improved optimisation and effective instrument use.⁸² This is an important achievement indeed, on account of the successful work of the grantees of both projects, although as mentioned above there is still some ambiguity as to the target priority population groups for POC VL, and is

⁷⁷ UCPOC (2020), Summary of 2019 Joint UCPOC Communication Activities: Achievements, Lesson Learned, and Priorities for 2020.

⁷⁸ The 2016 guidelines: World Health Organization (2016), Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Available at: <https://www.who.int/hiv/pub/arv/arv-2016/en/>

⁷⁹ World Health Organization (2021), Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring, March. <https://apps.who.int/iris/rest/bitstreams/1336192/retrieve>

⁸⁰ Ibid.

⁸¹ PEPFAR (2020), Country Operational Plan. Guidance for all PEPFAR Countries, January. <https://www.state.gov/wp-content/uploads/2020/01/COP20-Guidance.pdf>

⁸² PEPFAR (2021), PEPFAR 2021 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR Countries

largely based on expert opinion to date than hard data. It is also noted that this falls short of the initial “panacea approach” proposed by the grants, which was appropriately balanced over time to focus on network optimisation.

- CHAI, UNICEF, ASLM and EGPAF advocated for a broader endorsement and uptake of POC EID as a cost-effective approach progressing towards UNAIDS’ StartFree – StayFree – AIDSFree Framework.⁸³ UNAIDS reference evidence generated through the grant through academic publications as evidence for use of POC EID in their 2017, 2019 and 2020 Annual reports.^{84,85,86} POC EID has now been included in the 2021 Strategy to help close the testing gaps.⁸⁷

At the **country** level:

- Grant activities were integral in accelerating the development of policies and guidelines in project countries related to POC EID and, to a lesser extent, POC VL. These policy shifts were made possible by the accompanying evidence. As one country stakeholder stated, “*Had we not produced that evidence, I don’t think we would have been able to come up with shifts in policy*”.
- In all case study countries, grantees collaborated with the MOH to develop or amend policies, strategies and guidelines to include POC EID and, to a lesser extent and where applicable, POC VL. In particular, the work of ASLM through their platform of sharing information across countries was noted to help with “*the persuasion to get the laboratory on side*”.
- In addition to clinical guidance, the work and evidence from the grants also played significant roles in developing policies and guidelines that support the use and adoption of other diagnostics and help strengthen overall laboratory systems. A Zimbabwe stakeholder noted that “*the grant was able to put in place different policy COGS that even beyond the POC project will benefit the country*”. This shows the impact of the grants on POC testing but also on broader aspects (e.g., waste management guidelines).

Box 3.4 provides examples from country case studies of policies and guidelines which have been updated due to the grants.

⁸³ UCPOC (2020), Summary of Joint UCPOC Communications Activities.

⁸⁴ UNAIDS (2017), Start Free Stay Free AIDS Free 2017 report.

⁸⁵ UNAIDS (2019), Start Free Stay Free AIDS Free 2019 progress report.

⁸⁶ UNAIDS (2020), Progress towards the Start Free, Stay Free, AIDS Free targets.

⁸⁷ UNAIDS (2021), End Inequalities. End AIDS. Global AIDS strategy 2021-2026.

Box 3.4: Examples from country case studies of policies and guidelines which have been updated

- Cameroon: Draft National HIV Diagnostic Guidelines, a National DNO plan, National Guidelines for HIV Treatment, and External Quality Assessment (EQA) policies and plans;
- Kenya: Roadmap for roll-out of POC, a guide to optimization of diagnostic platforms, and a national strategy on utilisation of POC devices;
- Lesotho: Medical Laboratory Service Policy, POC Implementation Guide;
- Mozambique: National Mother-to-child transmission (MTCT) Elimination Plan, National EID POC Implementation Guideline, and Manual for Training of Trainers on POC EID; Monitoring and Evaluation (M&E) reporting tools;
- Uganda: National POC policy and implementation guideline, National HIV Consolidated Guidelines; EID Request Form; M&E reporting tools.
- Zimbabwe: Zimbabwe Health Laboratory Plan, Laboratory Waste Management Guidelines, VL Scale up Plan and POC testing guidelines. CHAI/ UNICEF and EGPAF also collaborated to generate concrete data on multiplexing of machines which demonstrated that using POC platforms for TB and HIV did not undermine TB testing. This data helped convince policy makers that multiplexing was effective and desirable.

Demand creation

Demand creation efforts were incorporated into both grants, although belatedly for the UCPOC grant. Whilst some progress was made with regards to clinicians and laboratory staff, beneficiaries/ community level demand remains an area requiring further efforts.

The EGPAF grant undertook demand creation activities through engaging with civil society and stakeholders and partners of the project in the majority of countries and they undertook grassroots advocacy activities in a smaller number of countries.⁸⁸ The UCPOC also had demand creation activities through the Diagnostics Community Advisory Board (Dx CAB) in seven countries, UNICEF worked with the Global Network of People Living with HIV (GNP+) to jointly develop a strategic framework and resource pack to promote civil society engagement and community demand creation for POC EID and ASLM's LAbCop work brought together a range of stakeholders, including CSOs.⁸⁹ However, many of these activities for the UCPOC grant (especially the work within the Dx CAB) were introduced belatedly. Numerous interviewees at both global and country levels noted that the grant portfolio progress on implementation was limited by lack of consideration of, and funding for, demand creation. It is notable that despite UNICEF's expertise in advocacy, even within the UCPOC grant it was felt this capacity was not leveraged sufficiently and was considered only near the end of the grant funding. As one stakeholder stated, "*it is great to have the grant and buy the equipment but it would not be effective without the demand creation*". Due to a lack of emphasis, especially initially in the UCPOC grant, our finding from the majority of case study countries is that countries were not able to implement comprehensive and holistic demand creation campaigns; the approaches were ad hoc and varied considerably.

We have considered demand creation from the perspective of three groups of stakeholders – clinicians, laboratory staff and beneficiaries/ patients. Overall the activities were more successful with the first two groups than with beneficiaries as follows:

- **Clinicians:** There were some examples where demand creation activities worked well, especially within the EGPAF grant. For example, in Lesotho CSOs were engaged to train health care workers (HCWs) on advocacy and demand creation and the HCWs then emphasised the benefit of reduced TAT and in Kenya, EGPAF utilised a multidisciplinary approach to sensitise facility staff, including mentor mothers and peer educators to create demand which had the effect of raising awareness from both clinicians and to a lesser extent beneficiary

⁸⁸ EGPAF (2019), End of Project Report.

⁸⁹ UCPOC 2019 Annual Report

populations. In Zimbabwe, clinicians were included from various entry points (e.g., maternity, children’s ward, outpatient department), which was especially laudable given the high yield in alternative entry points. However, stakeholders at the global and country levels noted that grantee activities in some countries failed to adequately address buy-in and demand creation among HCWs. This is especially problematic in the POC testing space, as in many sites, it is the HCWs themselves who are conducting the tests as part of their clinical responsibilities. As a result of this oversight, progress in some areas lagged until clinical staff were engaged. For example, in Uganda the grant was initially rolled out as a lab-centred project through the laboratory staff within health facilities until it was realised that the HIV care and treatment team needed to be involved to generate demand for POC EID testing amongst health workers. After the implementation approach was changed to bring on board clinicians, identification of eligible infants improved significantly. In addition programme managers express hesitation about POC VL scale up due to programmatic challenges and the weaker recommendations for POC VL use over laboratory based, centralised VL testing.

- **Laboratory staff:** The grant’s initial focus on POC and the perceived risk of replacing laboratories created resistance among laboratory staff. Under the UCPOC grant, ASLM facilitated discussions to break down resistance from lab teams, but more focused messaging at the beginning on POC complementarity with laboratory based, centralised testing could potentially have avoided the extent of resistance from this group. The evolution of the message during the grant period that framed POC within the lab network has helped considerably and has benefitted roll-out of other POC tests such as for HPV and COVID. There were a range of experiences across countries. In Lesotho and Mozambique, strong buy-in was obtained from both laboratory and programmatic stakeholders. However, in Zimbabwe this was more mixed, especially as engagement was perceived to be better done by CHAI but given EGPAF mostly worked with the national HIV programme and at lower health levels, there was limited engagement with lab stakeholders directly. Conversely, a number of stakeholders in Kenya suggested that because the project was introduced through the laboratory system, there was some initial resistance from the clinical side in the MoH, and the project had to bring the National Laboratory and MoH staff together to obtain buy-in and support.
- **Beneficiary/ patient demand:** There were mixed experiences in countries but in general efforts targeted at beneficiaries/ the community level were not considered to be substantial enough and this is an area requiring further efforts. Examples include:
 - In Cameroon, external resources from outside the grants had to be utilised for community engagement through the use of network of the association of PLHIV to create demand. Due to these challenges, stakeholders suggested that the support should have dedicated a budget to finance activities to create awareness for POC among community members.
 - In Uganda and Mozambique, few community-level demand activities were conducted during the grant period, which was noted to be a missed opportunity to increase demand amongst communities.
 - In Zimbabwe, CHAI worked with Zimbabwe National Network of PLHIV (ZNNP+) to create demand for EID and VL through young mentor mothers and support groups and training sessions. This enabled word to spread about POC EID and VL amongst PLHIV including pregnant mothers.

Integration

The concept of integrated diagnostics has become more mainstream and normalised contributed to by the Unitaid grants along with PEPFAR. However, substantial work remains in the actual execution of diagnostic integration especially outside of HIV and into other disease areas as progress has been limited to date.

As one stakeholder noted, “*Integration was a learning process during the grant*”, but overall, stakeholders agreed that ultimately the grant activities were pivotal in advancing the notion that optimal placement of POC technologies should be considered within the context of the overall health system and that diagnostics cannot be done in isolation with a focus on a specific disease or specific type of technology.

The shift in focus during the grant period also underscored the importance of considering diagnostic tests within the cascade of care (as that is where the real impact lies) and using a patient-centric approach. However, several stakeholders noted that further work on delineation and documentation of impact is needed.

The work undertaken within the grants were successful in integrating HIV POC technologies into the larger laboratory networks as well as the existing healthcare systems.

Although initially the grants were perceived by country and global level stakeholders as pitting POC testing vs. laboratory based, centralised testing, the shift in work undertaken through the grants was eventually effective in emphasizing the complementarity of POC and centralised testing and the unique mixes needed for each country context.

Stakeholders appreciated that grantees worked within the existing healthcare delivery systems and PMTCT programmes for introduction of POC EID (and, where applicable, POC VL). Within project countries, use of existing staff, infrastructure, sample transport, etc. improved efficiency and effectiveness and increased the chances for sustainability after grant closure.

The focus on diagnostic network integration was an invaluable contribution, as it encouraged countries to utilise existing investments/ platforms and leverage opportunities for multiplexing, helping to break down silos in disease programs and encourage integration.

Multiple country-level stakeholders noted that the advancement of these principles during the grant period, including through the DNO exercises undertaken by CHAI. This advancement has been of significant benefit during the COVID-19 pandemic and has helped to launch a more rapid response to COVID-19 diagnostic testing. However in general, there is a need to progress integration especially outside of HIV and into other disease areas.

Despite long-standing hesitation on the part of TB programs to allow utilisation of existing GeneXpert platforms for HIV testing, multiple stakeholders noted that grantees were successful in overcoming these issues in many countries by coordinating with TB counterparts and leveraging underutilised platforms. Several examples from case study countries include:

- In Cameroon, EGPAF and UCPOC coordinated with the MoH to enable use of seven GeneXpert platforms procured prior to the grant by the Global Fund for the National TB control programme.
- In Uganda, it was agreed with TB programme managers that any GeneXpert machines with a utilisation below 50% could be used for HIV testing.
- In Kenya, all 34 CHAI sites were also multiplex sites (TB and HIV), and two of these sites are also part of the ongoing HPV Pilot (integrating TB, HIV and HPV).⁹⁰ Stakeholders noted, however, that *“the absence of collaboration between TB and HIV programmes remains a risk.”*
- In Lesotho, EGPAF piloted HPV integration together with EID testing, resulting in 91% platform utilisation rates.⁹¹
- In Zimbabwe, the pilot demonstrated that offering TB, EID and targeted VL integrated testing increased the utilisation rate of all devices without exceeding capacity and without negatively impacting provision of TB testing and treatment services. This was highly influential in overcoming hesitation among relevant stakeholders. Through the UCPOC grant, Zimbabwe was the first country to generate concrete data on multiplexing of machines. This work was presented at a number of international conferences. More recently in 2020, Zimbabwe was also part of a multi country study to develop a publication on multiplexing.

⁹⁰ UCPOC (2020), Semi-annual report over first 6 months of 2020.

⁹¹ EGPAF (2019), End of project Report.

3.4. SUPPLY AND DELIVERY

Box 3.5: Pre-grant status – supply and delivery

- POC EID and VL commodities not included in supply chain and procurement processes.
- Service delivery models for POC VL and EID testing not demonstrated including sample transport models.
- DNO approach not adopted.

Table 3.7: Summary of findings – supply and delivery access barrier

Aspect	Key areas of contribution	Progress made	Scale of importance of grants	Strength of evidence
Supply chain/ procurement	Incorporation of POC commodities into supply chain processes	High: Successful integration of POC EID, and POC VL where applicable, commodities into national supply chain systems.	High: Both grants facilitated the incorporation of POC commodities into supply chain processes.	Moderate
Delivery models and sample transport	Implementation of new service delivery models for POC EID	High: Development of hub and spoke networks for use of POC technologies improved equity and access and optimised utilisation of POC platforms.	High: EGPAF grant demonstrated use of hub and spoke model for POC testing.	Strong
	Sample transport networks for centralised and POC EID and VL testing	Moderate: Sample transport between hub and spoke sites largely successful although sustainability is uncertain in many countries. Focus and impact of UCPOC on strengthening of national sample transport varied considerably but with some positive country examples.	Moderate/ low: sample transport was not a major component of either grant but there are some positive country examples.	Moderate
Network optimisation	DNO	Moderate: Grant helped encourage a more holistic view of diagnostics networks and development of network optimisation plans.	Moderate/high: the approach to DNO through UCPOC has been useful in furthering the DNO agenda.	Moderate
Data and waste management	Supporting development of data systems and approaches to waste management	Moderate: Processes and results were successfully incorporated into national data capture tools and systems	Low: Ongoing challenges remain	Moderate

Supply chain/ procurement processes

Supply chain and procurement processes were generally considered to be a successful component of the projects, and grantees integrated POC commodities into national supply chain systems.

Despite the potential for significant logistical and supply chain challenges with decentralisation of diagnostics to many clinics, supply of commodities was largely continuous and smooth once initial regulatory hurdles were overcome.⁹² This was particularly noteworthy given the relatively short POC cartridge shelf-life, which necessitated close monitoring of distribution to avoid expiries.

Among the case study countries, all reported that POC EID commodities were successfully integrated in the national supply chain management systems and that responsibility for procurement was transitioned to national government systems prior to the EGPAF grant end (although there were some teething issues within this in some countries such as Lesotho). The integration of POC VL commodities into the supply chain systems was not as widespread given varying levels of buy-in and adoption by MOHs.

Two case study countries experienced stockouts after closure of the grants: Firstly, Cameroon's stockouts stemmed from multiple causes, including lack of funding and COVID-related shipping delays, but one stakeholder noted that the limited capacity of the MoH to procure and distribute POC supplies according to national priorities may have contributed to the stockout of cartridges in high volume testing EID testing centres following the closure of the EGPAF grant. Secondly, Lesotho also experienced post-grant stockouts, but these were considered to be due to challenges related to ordering at the site and district levels and the issues were not prolonged.

Models of delivery and sample transport

The hub and spoke model implemented by grantees (primarily EGPAF) for POC EID in project countries (except Mozambique) was agreed by most stakeholders to be a noteworthy advancement.

It improved equity and access to timely EID testing and also helped leverage capacity of the platforms, which several stakeholders noted was much more feasible than a higher number of instrument rollouts. The hub and spoke model also expanded the concept of POC by generating two levels of use – onsite/'true' POC (hubs) and near-POC (spokes). This approach was important in that it demonstrated how attention to practical models of care that are integrated into the existing health delivery system can accelerate scale up of new diagnostics while also addressing gaps in the cascade of care. In addition, the approach increased the throughput for POC instruments and therefore contributed to the decreased cost per test. EGPAF used a comprehensive and pragmatic approach to POC EID site selection and roll-out that considered patient pathways, feasibility, burden of POC for clinical staff, TAT, time to treatment, quality assurance, and cost.

In several project countries, grantees also helped establish use of POC EID in alternative entry points (e.g., maternity wards, nutrition wards, outpatient departments, etc.), a significant and critical step for advancing identification of infants who are not enrolled in PMTCT programs and thus would be missed at PMTCT service locations. For example, in Uganda within the UCPOC grant, the reach of POC was improved when access to EID testing was increased beyond the traditional Mother Baby Care Point through the laboratory based, centralised system to include alternative entry points (e.g. paediatric and nutritional wards), which were found to be high yield entry points for HIV positive infants.

In Mozambique, based on initial feasibility studies and facility mapping led by the National Health Institute, MoH and partners decided that a pilot within the UCPOC grant would implement a model with stand-alone POC sites in primary health care facilities, using a "real" POC approach in EID testing, with nurses in Mother and Child Health (MCH) wards conducting the tests and reporting the results. The m-PIMA device was selected as it was considered to facilitate this real POC approach. Results of this pilot led to the country adopting the real POC approach in 2017 and allowing CHAI and EGPAF to further scale it up to additional stand-alone sites. The MoH and partners consider the standalone POC site model to be appropriate in Mozambique's context of high HIV prevalence, large distances between health facilities and weak transport links. They are also satisfied with the performance of the real POC approach and find that nurses

⁹² For the UCPOC grant, one global stakeholder noted that the relationship and coordination between UNICEF and CHAI was strained in some countries given differing institutional processes and approaches and lack of clarity about specific roles; however, no country level stakeholders interviewed mentioned this issue so the significance is unclear.

are capable of conducting quality testing and results reporting, which is why the EID POC approach is included in the recent national plan for eliminating HIV, syphilis and Hepatitis B.^{93,94}

In relation to sample transport, the EGPAF grant focused on transport between hub and spoke sites and the UCPOC grant focused on sample referrals via integrated referral systems and expansion of dried blood spot (DBS) testing. Although the models used were largely successful, concerns remain about sustainability after grant closure given implementation challenges and need for continued funding.

One global stakeholder noted that in some countries, there was a feeling that investment in optimising sample transport networks could be more cost-effective in the long-term than POC as they said “*If the sample transport issue is fixed, countries can reach very high gains at low cost. Countries will be asked the question as to whether they invest in sample transport or POC and it’ll be a lot cheaper to invest in sample transport*”. This sentiment was less common among other stakeholders, especially country level clinical staff, who value the fast turnaround time for results.

The UCPOC grant did work in several countries to optimise sample transport between sites and molecular laboratories to improve DBS collection procedures and strengthen the central VL and EID systems. For example, in Cameroon CHAI mapped the VL sample transport and the procurement and management systems of molecular laboratories and supported development of data collections tools for VL sample transport and storage. However, sample transport within the laboratory based, centralised system generally appeared to be less of a focus in all countries despite the need to strengthen laboratory based, centralised systems, particularly for VL. Box 3.6 includes an example from Zimbabwe where CHAI piloted an integrated sample transportation system which can be noted to be a best practice example.

Box 3.6: CHAI integrated sample transportation system pilot in Zimbabwe

CHAI piloted an integrated sample transportation system that is integrated across disease areas (HIV, TB). This has been considered to be a key success of the grant as the evidence from the pilot in 68 health facilities using 5 centralised laboratories using a regular transportation system (ZimPost). This was to demonstrate feasibility of providing such a service and assess impact of an integrated sample transport service on TAT, number of patients tested and ART initiation rates. CD4, EID and TB were the tests carried on the pilot. Results showed that sample collection increased by 70% with the highest increase in CD4 samples (121%). There were increased ART initiation rates (baseline 66.2%, post-pilot 76.4%). EID turnaround time (TAT) decreased by 24 days between baseline and post pilot implementation within the pilot districts. A 44% per sample cost reduction and 35% per facility cost reduction was observed. Cost-savings were driven by a decrease in the number of courier service providers and trips required as a result of combining different sample types.⁹⁵ Following the pilot, the Global Fund is now supporting the national scale up of this pilot.

In the case study countries, the sample transport issues primarily focused on issues of sample and result delivery between the hubs and spokes. Of the five case study countries that utilised the hub and spoke model (Mozambique used only stand-alone POC sites), two noted issues with sustainability of the sample transport bikers. In particular, in Cameroon, they noted low biker motivation and high turnover due to low payment rates as an issue, as well as lack of funding to sustain the hub and spoke transport model beyond the grant period. In Lesotho, the sample transport between hub and spokes is done by Riders for Health, an MoH partner. Although this has worked well during the grant and to date, financial sustainability is unclear. In Kenya, however the hub and spoke model was already established and the projects were able to integrate their activities into the existing system, with the result that transport issues were not viewed by respondents as a major issue.

⁹³ Meggi, B. et al., (2018), Performance of point-of-care birth HIV testing in primary health care clinics: An observational cohort study. PLoS ONE, Eduardo Mondlane University.

⁹⁴ MISAU (2020), Plano Nacional de Tripla Eliminação da Transmissão Vertical do HIV, Sífilis e Hepatite B em Moçambique 2020-2024 (MoH (2020), National Plan for Triple Elimination of Vertical Transmission of HIV, Syphilis and Hepatitis B, 2020-24).

⁹⁵ CHAI (2018), Program data.

Use of the sample transport system for return of results was also an issue; in Uganda, they noted that return of results to spoke sites is a challenge because spokes are visited only once or twice a week. Leveraging online solutions may be necessary but is not always possible in more remote sites. In Lesotho (and other EGPAF countries), in m-PIMA facilities with internet connectivity, 45 SMS printers were rolled out to improve time for results return and mitigate the need for return trip for bike riders in some cases.⁹⁶

Overall, the hub and spoke sample and return transport may be insecure in some countries so will need further donor attention and support to ensure continued operation.

Diagnosics network optimisation

The shift in approach to diagnostics network optimisation through the UCPOC grant was appropriate and useful, albeit belated, although countries need to conduct further planning and implementation to reach this goal.

Both global and country stakeholders were in general agreement on this aspect. Although this broader diagnostics lens was not in place at the beginning of the grant and may have generated mixed signals on the importance and emphasis on POC during the grant period, it is generally considered that the approach has shown country and global level stakeholders the importance of strategic placement of POC, near-POC, and centralised laboratory based systems to increase coverage and efficiency. This has also included thinking beyond the 'conventional wisdom' about POC (e.g., that POC is only for remote geographic locations when in fact POC may be helpful anywhere that a quick result has positive patient impact). Global stakeholders highlighted the benefit of the evidence shared, including through the IDC to help garner support for DNO. ASLM has worked to capitalise on this momentum especially through the network of country level laboratory stakeholders and donors such as PEPFAR and Global Fund are now encouraging countries to use available data to develop network optimisation plans prior to scale up of POC to determine the correct mix of technologies and ensure optimal utilisation of existing devices. Overall the DNO work went a long way in aiding countries to determine the most efficient testing, sample transport, placement of devices etc. However further work is needed to implement the DNO findings.

The network optimisation work during the grant period also laid the groundwork for successful COVID-19 platform placement, as countries were primed to approach diagnostics placement more strategically. These exercises also help better define where the issues are (e.g., sample transport, sample collection, etc.).

As the grant activities progressed and evolved, there was more of an emphasis on the need for both laboratory based, centralised testing and POC/ near POC testing being complementary. The shift from a larger emphasis on POC to being more clearly advocating for the complementary testing of both is considered by some stakeholders to have created mixed messaging about the role and importance of POC, especially for POC VL, although on balance the shift was considered appropriate including the focus on DNO.

Forecasting and quantification

As a result of grantee support, POC commodities forecasting and quantification generally functioned well and POC EID (and VL, where applicable) was integrated into the national quantification system in all case study countries, although continuing to require ongoing support.

Both grantees provided technical assistance in forecasting and quantification, with CHAI providing particularly intensive support and capacity-building at the central level as part of health system strengthening since accurate forecasting is a common weakness among national programmes. As a result of grantee support, POC commodities quantification and forecasting generally functioned well and POC EID (and VL, where applicable) was integrated into the national quantification system in all case study countries. It was noted in most countries, however, that these activities required substantial support from partners and there was concern about capacity of many MoH's to have accurate forecasting without grantee support. For example, in Lesotho and Zimbabwe, there were challenges

⁹⁶ Of note, grant reports did not delineate turnaround times in hub sites versus spoke sites, so it is unclear the impact and significance of these hurdles.

transitioning from the EGPAF procurement system to MoH procurement systems, and since the MoH has taken over, several stockouts have occurred that stakeholders attributed to problems of quantification and to ordering at the site level.

Health care system issues, data management/ M&E and waste management

The grants included a significant focus on collection and reporting of quality data on grant activities, particularly POC testing, and processes and results were successfully incorporated into national data capture tools and systems (e.g., DHIS2) in most countries. However, significant challenges remain with connectivity of POC devices and alignment with existing MOH data systems and dashboards.

Prior to the grants, policies in countries often prohibited the use of POC testing by “non-laboratory” personnel, which limited the availability of POC. The grant supported trainings of non-laboratory personnel to be able to operate POC. In Kenya, Lesotho, Mozambique and Zimbabwe nurses can now conduct POC testing. In Lesotho and Zimbabwe, lab personnel and HCWs reported receiving good quality training and were enthusiastic about the POC work after the grant closure. In particular this worked well in Lesotho where a pool of trainers from MoH were trained to train and mentor future POC EID platform operators and one stakeholder commented “*Often other partners ignore the ministry, but EGPAF were an exception, it was an integrated team, supervising and training together*”.

Both grantees worked to support case study countries on collection and reporting of data from POC testing sites, including development of POC registers, testing forms, and inclusion of POC testing into existing M&E systems. By the end of the grant, EGPAF supported countries had an operational connectivity solution. CHAI expended particularly intensive efforts to assist countries with data collection and management issues. This has worked well in some countries: In Cameroon, CHAI helped develop a LIMS dashboard to support data visualisation across POC and laboratory based, centralised platforms. In Zimbabwe, a new national LIMS system for all laboratory results was established in 2018, including but not limited to VL, EID, TB and chemistry and CHAI designed the LIMS programme. Centers for Disease Control and Prevention (CDC) joined around 2019 and are now expanding it. This is being roll-out in a step-by-step process, and thus far TB and laboratory based, centralised VL data has been integrated while EID data integration is currently being trialled in one lab and will be rolled out to ten more in the short-term if the trial is successful. In Lesotho, there were challenges experienced in terms of incorporating the results from EGPAF POC testing in DHIS2 initially post the grant, however this has now been resolved and data from POC devices is incorporated into DHIS2.

However there are some ongoing challenges in relation to data systems: In Uganda, relaying POC EID results to the central dashboard was creating challenges, as the POC devices were not interfacing well with the laboratory based, centralised LIMS. The project installed a supplementary information management system in most pilot sites, but data entry and connectivity remain persistent challenges. In Kenya, stakeholders reported similar challenges with data transmission and integration into the MOH data system.

Waste management, especially of GeneXpert cartridges that require incineration, was a key issue in project implementation that was not sufficiently anticipated at the beginning of activities and continues to pose significant challenges.

The grants highlighted the importance of the waste management issue and brought it to attention of stakeholders. ASLM was particularly active in discussing the issue and underscoring the important of waste management policies and inclusion of waste management costs in funding. As a result of the grants, the Global Fund now includes waste management plans as part of required documentation from countries. One stakeholder noted that waste management issues may have also negatively impacted volumes of tests procured as countries were not prepared to deal with GeneXpert cartridges.

While grantees were cognisant of these issues during platform selection, most of the six case study countries noted that waste management systems were not well thought-out during initial planning, requiring development of solutions during grant implementation – although it is recognised that waste management in molecular diagnostics was a new area and learnings occurred during the grants. These approaches varied among countries. In Cameroon, a private company was contracted; in Uganda and Lesotho, used cartridges are transported to sites with incinerators. In all six

case study countries except Uganda and Mozambique, stakeholders noted that waste management is a significant issue post-grant and is unclear how it will be addressed without donor support.

4. SUSTAINABILITY AND SCALABILITY

The third pillar of the evaluation framework focuses on an assessment of the sustainability/ transition (Section 4.1) and potential for scale up, where we examine the global conditions (Section 4.2) and country level conditions (Section 4.3) as per Unitaid’s Scalability Framework. The scalability assessment is contextualised for this grant portfolio, and specifically cognisant of the priority of network optimisation for both POC EID and VL (as compared to large scale/ 100% scale up that may be more applicable for some of Unitaid’s other investments) and the more focused scale up for POC VL in terms of use with specific priority population groups only. Summary findings are presented below followed by the detailed assessment.

Aspect	Findings	Strength of evidence
Sustainability/ transition	Funding transition has been secured for the most part (more so for EID, than VL), however the transition process for the EGPAF grant in particular has been challenging for a number of reasons.	Strong
Global conditions for scale up	Important contributions have been made by both grants in terms of the various conditions deemed relevant to support global scale up of POC molecular diagnostics for HIV, which have progressed further for POC EID than for POC VL. There has been a lot of good evidence generated supporting the development of normative guidance from WHO, however donor/ partner support is tenuous and at best moderate (although increasing overtime for POC EID) and the supply base continues to be challenging.	Moderate
Country conditions for scale up	Overall, there has been some good progress in furthering key country scale up conditions, especially with regards to supporting the development of POC-related policies and guidelines in countries. However, the biggest barrier is the limited donor funding to scale up use beyond what has been achieved through the grants. Community driven demand remains an area of weakness.	Moderate

4.1. SUSTAINABILITY/ TRANSITION

Funding transition has been secured for the most part (more so for EID, than VL), however the transition process for the EGPAF grant in particular has been challenging for a number of reasons.

Positively, across the majority of our country case studies, stakeholders indicated that the EGPAF project has been sustained and there is a high likelihood that the same will be the case for the UCPOC project when it concludes, especially given the progress with transition to date in almost all countries. The key challenge has been in Kenya where future funding for POC testing is under review, especially for VL.⁹⁷

Sustainability is supported through the development and adoption of POC testing within overall testing guidelines by governments (as discussed in Section 3.3). An important supporting factor to this has been the close engagement of grantees throughout the projects with country MoH and other relevant stakeholders. This was done through TWGs, where evidence was presented and consensus/ buy-in was obtained early on and throughout the grant period.

However the transition process for the EGPAF grant (and for UCPOC in one country) has faced some issues. The following are noted from project countries:

⁹⁷ As of April 2021.

- Cameroon faced stock-outs at EGPAF project close, stemming from lack of funding and COVID-related shipping delays. It is expected that the funding secured from the Islamic Development Bank and the multi-donor Lives and Livelihood Fund (see below) will help address these challenges soon.
- In Eswatini, partner funding was not secured to sustain activities at project close, although Eswatini had drafted an integrated diagnostics network plan for review by the Global Fund. EGPAF committed to continue to support transition for Eswatini until January 2020, under the EGPAF project's no-cost extension.^{98,99} Funding has now been secured with the Global Fund reportedly providing funding to sustain current POC EID coverage levels for 2021 and 2022.
- In Kenya, lack of stakeholder buy-in with the transition plan had resulted in disruption of POC services at all EGPAF sites, with CHAI picking these up following closure of the EGPAF grant until September 2020. However the transition of procurement from the UCPOC grant has also not yet been secured and these are now unfunded until the ongoing negotiations around Global Fund support are concluded.¹⁰⁰
- Lesotho experienced post-grant stockouts, due to challenges related to ordering at the site and district levels but the issues were not prolonged. It was assumed by country stakeholders three months before grant closure that the Global Fund would finance some of the procurement but the Global Fund had not been informed of this highlighting an issue with transition planning.

In addition, it is not fully clear if funding secured post grants will cover the supporting health systems aspects such as with regards to sample transport, development and management of data systems, management of waste, ongoing training needs, etc. For example, in Zimbabwe and Mozambique the high staff turnover and a rotational system may disrupt the flow of activities and as such there is need for constant retraining and awareness raising. Similarly the hub and spoke model relies on strong functioning sample delivery with one stakeholder noting that “*gaps are starting to show now that funding from EGPAF is not there anymore*”.

Transition for the portfolio was fundamentally hindered by the limited upfront dialogue and engagement with large funders such as PEPFAR and Global Fund by Unitaid and the grantees (as discussed in Section 2.1), although has been resolved for the most part as described above. The UCPOC grant fared better than the EGPAF grant overall as it also had the benefit of a few more years' implementation and associated changes to PEPFAR COP guidance, WHO recommendations etc. In some cases, transition was hampered by the belated implementation of transition plans and there was also the challenge that the grants were not well aligned with donor funding cycles in that the EGPAF grant ended in the middle of the Global Fund funding cycle and therefore the only option to include POC EID into grants was to reprogramme existing Global Fund grants. Grant planning also only accounted for limited bridging of supplies over this transition period. In addition, some of the country case study examples highlighted the fact that the grants were implemented into ‘well established ecosystems’ (e.g. laboratory and PMTCT programme governance issues etc.) which created additional challenges for impacted sustainability and financing decisions.

4.2. GLOBAL CONDITIONS FOR SCALE UP

We have undertaken an assessment of the global conditions for scale up based on Unitaid's Scalability Framework. As part of this assessment, we have analysed the status of each of the 13 global conditions for scale up included in the framework which are structured across three domains and include:

⁹⁸ EGPAF (2019), End of Project Report.

⁹⁹ The EGPAF grant's NCE changed in aim away from testing and towards developing and implementing solutions to overcome critical access barriers to delivery of paediatric antiretrovirals. Some activities for Eswatini's transition from the main grant were also undertaken during this NCE.

¹⁰⁰ As of April 2021.

- **Create sustainable access conditions**, which includes: (i) evidence; (ii) normative guidance; (iii) regulatory approval; (iv) affordable pricing; (v) adequate supply base; and (vi) appropriate delivery models.
- **Align and coordinate with global partners and donors**, which includes: (vii) strategic priorities/ needs; (viii) recommended approaches/ tools; (ix) planning/ budgeting cycles; and (x) procurement.
- **Generate and disseminate knowledge and evidence**, which includes: (xi) study results/ other evidence; (xii) project progress/ lessons learned; and (xiii) investment case/ global advocacy.

This is CEPA's independent assessment, drawing on the assessments submitted by grantees on the Scalability Framework and stakeholder interviews (and as such, may differ from the assessments submitted by the grantees).¹⁰¹ The grant-specific evaluations consider the contribution of each grant in more detail and Appendix C presents our assessment by grant. The assessment by domain and overall is presented below.

Create sustainable access conditions

Sustainable access conditions have improved over the grant periods, especially in relation to normative guidance for POC EID and evidence generation. Progress in some of the other areas has been limited.

We note the following key points in terms of progress and contribution of the portfolio grants:

- **Evidence:** There was a need for evidence as WHO guidelines for POC EID were conditional and not available for POC VL and national guidelines were not supportive of POC EID or VL. Through the grants, a large amount of useful and quality evidence has been produced to demonstrate impact and feasibility of POC testing and this has been used to influence normative guidance and donor and country policy.
- **Normative guidance:** Some of the evidence generated through the projects contributed to the upgrading of the WHO recommendation for POC EID in the new 2021 guidelines to 'strong recommendation/ high certainty of evidence' from conditional in 2016.^{102,103} The WHO recommendation on POC VL in the latest guidelines is 'conditional recommendation/ moderate certainty of evidence' due to continued research gaps in the area, highlighting that less progress has been made in this regard.
- **Regulatory approval:** At the start of the grants neither GeneXpert nor m-PIMA had WHO PQ for EID and VL and were not registered in countries. In June 2016, the m-PIMA and GeneXpert platforms received WHO PQ for their EID assays, and the VL assays followed with WHO PQ in July 2017 for GeneXpert and in 2019 for m-PIMA.¹⁰⁴ By 2021, a majority of project countries that were targeted for regulatory approval had registered the products (see Section 3.1 for further details), mainly with contribution from the UCPOC grant.
- **Affordable pricing:** Although there has been a decrease in the GeneXpert price and to a lesser extent the m-PIMA price and some argue that this is close to COGS, the relatively higher price per test of POC in comparison to laboratory based, centralised testing remains one of the important factors affecting uptake and expansion (despite evidence on cost-effectiveness produced by EGPAF and also indicated in the WHO guidelines). However, important progress has been made with regards to obtaining more transparent and all-inclusive pricing arrangements which has been due in part to work under both grants, especially the Hologic deal within the UCPOC.

¹⁰¹ Given the portfolio context, we have considered domains two and three as a whole rather than detailed consideration of each of the concomitant conditions,

¹⁰² The 2016 guidelines: World Health Organization (2016), Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Available at: <https://www.who.int/hiv/pub/arv/arv-2016/en/>

¹⁰³ World Health Organization (2021), Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring, March. <https://apps.who.int/iris/rest/bitstreams/1336192/retrieve>

¹⁰⁴ WHO (2019), HIV molecular diagnostics toolkit to improve access to viral load testing and infant diagnosis.

- **Adequate supply base:** At the start of the grant periods there was a strong pipeline of POC and near POC devices. However, this has not materialised, and the market is concentrated and asymmetric with differentiated products and footprint. In addition, there is a risk that m-PIMA may not stay in the market given its current lower competitiveness in comparison to GeneXpert. Overall, the supply context continues to be very challenging.
- **Appropriate delivery models:** At the start of the grants, there was a need for new service delivery models to strengthen key diagnostics systems and maximise the impact of testing services. The hub and spoke model is considered by the majority stakeholders to be a good model and to have helped increase access to testing significantly – a key contribution of the EGPAF grant given it expanded the use of this model.

Align and coordinate with global partners and donors

While the portfolio has solidly progressed the visibility of POC, the biggest challenge to global scale up is tenuous and at best moderate donor/ partner support for funding expansion of POC testing, especially for POC VL.

Most stakeholders including Unitaid, donors and technical partners highlighted that POC testing is much more on the agenda than it was at the start of the grants, although more so for EID than VL. Overall, this is noted to be a success of the grants which have driven the POC agenda forward through introducing POC in countries, obtaining evidence and learnings and disseminating information. In particular the dissemination of information to other partners through the IDC has been noted to be a strength as a large number of partners have been brought together through the IDC and concepts have been socialised and normalised within these.

As evidence of donor support, the COP guidance from 2017 and 2018 endorsed the use of POC EID (complementary to the laboratory based, centralised system) and COP guidance from 2021 endorsed selected strategic use of POC VL for PBFW, infants and children and the Global Fund is supporting POC EID and VL through national requests. However, in general despite POC being more on the agenda than before, stakeholders noted that they do not consider POC to be used beyond specific circumstances (e.g., EID, VL for specific population groups) largely due to the relative cost as compared to laboratory based, centralised testing. More recently, consultation with a US government representative has intimated that there have been indications through 2021 country applications to PEPFAR that there may be more take up by countries (although this cannot be confirmed until country grants are approved). This increase is considered to be due to (i) changes in the 2021 COP guidelines as noted above and (ii) the all-inclusive pricing agreements with GeneXpert and m-PIMA. These agreements have enabled savings due to (i) the reduced prices which have enabled more tests to be procured within the same budget envelopes and (ii) machines do not need to be purchased anymore and for the past three years PEPFAR had not supported the procurement of new machines and therefore this had been a barrier for countries to receive support for POC testing through PEPFAR.

More generally, partners consider that the emphasis should be on increasing utilisation of existing platforms through (i) improving integration and use of the platforms for multiple diseases and (ii) ensuring adequate optimisation of the platform placement within the overall laboratory network including laboratory based, centralised and POC testing. In addition, a number of stakeholders highlighted that belated engagement with donors/ partners has also contributed to the limited scale up interest. This was particularly relevant for the EGPAF grant as the UCPOC grant has had a longer implementation period and discussions could be further progressed with the additional evidence collected to date.

Generate and disseminate knowledge and evidence

Both grants have contributed significantly with regards to the generation and dissemination of knowledge and evidence. It is considered that further evidence would be beneficial is in relation to cost-effectiveness as well as for POC VL more generally.

At the start of the grant there was very limited/ no data regarding (i) patient impact of POC testing; (ii) operational feasibility of POC testing; and (iii) cost and affordability of POC testing. As noted in Section 3.3, both grants contributed evidence which has been viewed as extremely useful and well disseminated (at both the global levels through the IDC and international conferences as well as in countries especially through the TWGs). A number of stakeholders consider that while some countries would likely have been using POC without the grants by now, things

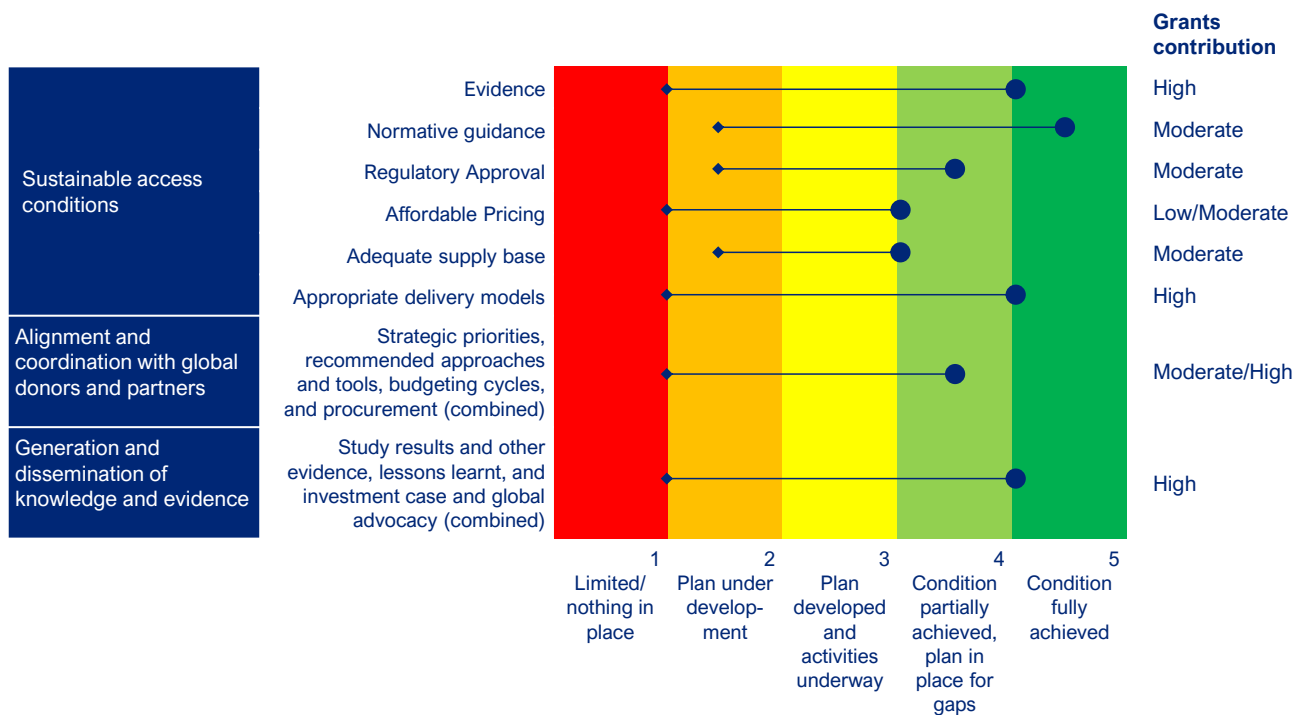
would not have progressed as much as they have, and this is especially due to the guidelines and tools developed through the grants. Stakeholders noted further evidence would be beneficial in relation to cost-effectiveness (discussed in detail previously Section 3.3) as well as further evidence to support POC VL.

Overall assessment

Important contributions have been made by both grants in terms of the various conditions deemed relevant to support global scale up of POC molecular diagnostics for HIV, which have progressed further for POC EID than for POC VL. There has been a lot of good evidence generated supporting the development of normative guidance from WHO, however donor/ partner support is tenuous (although increasing over time for POC EID) and the supply base continues to be challenging.

Figure 4.1 shows a summary of the mean score for global scalability conditions across the two grants.¹⁰⁵

Figure 4.1: Global scalability conditions and scores for baseline to end of project (2020 for UCPOC grant) at the portfolio level across the two grants.¹⁰⁶



◆ Shows the baseline rating, ● shows the rating to date. Where markers are in the center of a box, this shows a 0.5 rating, due to the averaging of the scores across the two grants. The column on the right hand side indicates the grants contribution which is different from the scalability scores presented in the colour ratings.

Source: CEPA analysis

¹⁰⁵ For sustainable access conditions, at the end point, the rating given for evidence, adequate supply base and appropriate delivery models were the same across the two grants. ‘Normative guidance’ was rated more highly in the EGPAF grant and ‘regulatory approval’ was rated more highly in the UCPOC grant, as was ‘affordable pricing’. For the UCPOC grant, ‘normative guidance’ for EID was rated at 5 (condition fully achieved), but at 3 for VL (plan under development).

¹⁰⁶ With regards to normative guidance, the difference in 'After' status as presented in project documentation: the EGPAF project reported “Condition fully achieved”, UCPOC reported “Plan under development” for VL, “Condition fully achieved” for EID.

4.3. COUNTRY CONDITIONS FOR SCALE UP

Similar to the assessment of the global conditions for scale up, as part of this review, we have also assessed the country conditions for scale up using the Unitaid Scalability Framework, which encompasses three key readiness domains and component conditions:

- **Secure political and financial support**, which includes: (i) political engagement and buy-in; (ii) donor funding; (iii) domestic funding; and (iv) national advocacy.
- **Ensure programmatic and operational readiness** which includes: (v) supportive policies; (vi) integration into national programmes; (vii) effective supply chain systems; (viii) adequate health systems capacity; and (ix) timely registration of products.
- **Create community driven demand**, which includes: (x) civil society demand; and (xi) grassroots advocacy.

Key findings by domain and overall, based on the country case studies, are as follows:

Secure political and financial support

There has been good country level political engagement and advocacy with a range of stakeholders through the grants that has helped secure their buy-in, although there has been some resistance from laboratory stakeholders. For the next few years sufficient funding has been secured to maintain or moderately increase POC EID and VL testing levels (although this is less certain for POC VL) but donor funding is expected to be limited in terms of significant further scale up beyond what has already been achieved during the grants.

Political engagement and buy-in and national advocacy: In general, country-level engagement has been strong across stakeholders, particularly with regards to the sharing of evidence. Country stakeholders recognise the public health impact of POC, particularly for EID, and therefore are supportive of it, and in a number of countries policies and guidelines now include EID and VL POC testing (as discussed in Section 3.3). However, one challenge was the resistance from laboratory stakeholders, and while this has improved over time, there has been some disconnect between programmes and laboratory staff with regards to POC value and use (as described in Section 3.3). More broadly, the DNO work undertaken within the UCPOC grant has aided political buy in (and funding) as it has helped to legitimise the role of POC within the broader ecosystem and has helped to aid the scalability of POC testing.

Donor and domestic funding: POC EID and VL testing remains heavily dependent on donor funding with domestic funding for POC testing being negligible across project countries. Table 4.1 below provides an overview of the progress made by countries in securing POC EID and VL funding, the key funding sources as well as the expected testing coverage trend for 2021 and 2022 (where data is available) compared to 2020 coverage levels. Key findings include:

- **The majority of project countries have managed to secure funding to sustain the same level or to moderately increase POC EID testing after grant closure, at least for the short-term, with a good level of scale up being achieved by the projects themselves.** While there have been some aberrations to a seamless transition of funding for the EGPAF grant (discussed above), all countries supported by the UCPOC grant except Kenya secured commodity funding for POC EID testing in the short run. As shown in Table 4.1 below, for POC EID, nine countries had confirmed funding to maintain or increase the POC EID coverage levels when compared to the 2020 levels. Only Nigeria which currently is still implementing the UCPOC project, as well as Tanzania, had funding commitments to ensure a significant scale up. For other countries, it is not possible to obtain reliable funding data but consultations suggests that these are also countries that likely maintain or moderately increase their POC EID coverage. Maintaining or moderately increasing the existing POC EID coverage also should be considered within the context of the significant scale up in coverage that has been achieved in project countries

during the grant periods (outlined further in Section 3.3 above).¹⁰⁷ While maintaining or moderately increasing these coverage gains is an achievement in itself, limited further donor funding acts as a barrier to achieve significant scale up going forward.

- **The funding challenges have been more pronounced for POC VL.** Whilst a majority of UCPOC countries managed to secure sufficient funding (Cameroon, DRC, Malawi and Senegal), other countries are reporting funding shortfalls for the anticipated POC need (e.g., Kenya) or have not secured funding yet (Mozambique).¹⁰⁸ Tanzania which considerably increased its POC VL coverage through funding from the Global Fund in 2020 (partly due to a shortage of laboratory based, centralised VL) also has not yet confirmed whether there are sufficient funds from the Global Fund for 2021-22.
- **Funding commitments beyond commodity purchases have been more challenging** with several countries (e.g., Malawi, Tanzania) reporting funding needs for programmatic activities such as trainings, mentorship, supervision data collection and general operational support.
- **Donors are currently focusing on optimising existing platforms rather than purchasing of additional platforms.** While the PEPFAR COP guidance has recognised the use of POC EID since 2017 (in conjunction with laboratory based, centralised testing) as well as a strategic use of POC VL for select populations from 2020 (as discussed in Section 4.2 above), the expectation is that these guidelines will not translate into significant additional scale up beyond what has been achieved during the grants as donors are at this stage more focused on first optimising existing platforms (laboratory based, centralised and POC), and the cost of POC technologies is still viewed as prohibitive in the context of overall funding envelope constraints.^{109, 110, 111} Only a few countries (e.g., Senegal and Malawi) managed to secure additional funding for new platforms. For grant countries, this may be due to the fact that a large number of platforms were procured within the grants.
- **In relation to non-project countries, stakeholders were not aware of many examples of support for POC testing and it has not been possible to obtain a full list given confidentiality of information between grantees and manufacturers.** However, there are a few examples provided through stakeholder consultations including from West and Central African countries (e.g. Cape Verde) who have procured POC testing for EID as well as Burkina Faso where they were able to learn lessons from the implementation to date of POC testing in Cote d'Ivoire. In addition, a few non-project PEPFAR countries have also expanded use of POC as a result of grant activities and the associated PEPFAR COP guidance that endorses use of POC EID and VL testing (e.g., Haiti, Namibia).

¹⁰⁷ We understand that under Unitaids' current strategy, scale up to the extent funded under these grants is not done, and only pilot procurement is funded.

¹⁰⁸ It was not the aim of the UCPOC project to secure POC VL funding for Mozambique or DRC.

¹⁰⁹ PEPFAR (2017) Country/Regional Operational Plan (COP/ROP) Guidance, January.

¹¹⁰ PEPFAR (2018) Country/Regional Operational Plan (Country Operational Plan Guidance for Standard Process Countries).

¹¹¹ PEPFAR (2020) Country Operational Plan Guidance for all PEPFAR Countries.

Table 4.1 Confirmed external funding for POC EID and VL post 2020 and analysis on testing coverage trends compared to 2020 coverage

Country	Secured funding (yes / no)		External funding details	Trend in testing coverage ¹¹²	
	POC EID	POC VL		POC EID	POC VL
Cameroon	Yes	Yes	US\$40 million has been secured to support the POC EID and VL system during the coming three to four years: 70% will be provided through a loan from the Islamic Development Bank (ISDB) and 30% through a grant from the Multi-donor Lives and Livelihoods Fund.	Unconfirmed	Unconfirmed
DRC	Yes	(Yes – but not focus country) ¹¹³	All GeneXpert commodities have been financed by in-country HIV donors (Global Fund and PEPFAR) for both POC EID and VL testing.	Unconfirmed	Unconfirmed
Ethiopia	Yes	(Yes – but not focus country)	POC EID and VL cartridges have been included in the national procurement system supported by the Global Fund and, to a lesser extent, PEPFAR. The committed funding should help to reach that national target of a 50% market share for POC EID compared to 45% in 2020.	Moderate increase	Moderate increase
Eswatini	Yes (after delay)	N/A ¹¹⁴	After initial delays in securing funding, the Global Fund has financed POC EID in 2020 and 2021.	Stable	N/A
Kenya	Delayed	No	Funding for POC EID and VL testing is part of the Global Fund grant proposal which is still currently being negotiated and not yet confirmed. Funding shortfalls are more likely to impact VL with only 10% of the total funding needed for POC VL testing among pregnant and lactating women and suspected treatment failures has been identified.	Decrease in short-term due to delay	Decrease (at least in short-term)

¹¹² Trend refers to the comparison of expected testing coverage in 2021 (and 2022 where data is available) based on secured funding commitments with the actual tests conducted in 2020.

¹¹³ DRC, Ethiopia and Mozambique were not one of the six countries that were initially targeted for POC VL scale up by the UCPOC grant.

¹¹⁴ N/A refers to countries that were not supported by the grants to scale up POC VL and that currently do not use any POC VL.

Country	Secured funding (yes / no)		External funding details	Trend in testing coverage ¹¹²	
	POC EID	POC VL		POC EID	POC VL
Lesotho	Yes	N/A	POC EID had been incorporated into the Lesotho COP 2019 and COP 2020, as well as in the Global Fund NFM3 grant proposal. This is to maintain the existing POC testing which is 76% of EID testing.	Stable	N/A
Malawi	Yes	Yes	POC EID and VL commodity procurement has been successfully transitioned to the Global Fund in 2020 and the funding also covers 15 new GeneXpert platforms. However, there have been challenges with securing funding for the transition of programmatic activities.	Stable	Significant increase
Mozambique	Yes	(Likely – but not focus country)	PEPFAR has committed to supporting 100% of all POC EID reagent and supplies and maintenance needs for the immediate years.	Stable	N/A
Nigeria	Yes	N/A	Transition is expected in 2021 following supported activities through the UPOC grant on POC EID scale up and demand generation for integrated HIV EID / HPV testing. POC EID and HCV commodities have been included in the PEPFAR COP20 and COP21.	Significant increase (still in transition)	N/A
Senegal	Yes	Yes	Funding has been confirmed from the Global Fund and PEPFAR. It is likely that the government will also provide some funding for POC tests directly.	Moderate increase	Moderate increase
Tanzania	Yes	Unconfirmed	POC test procurement has been transitioned with POC EID tests procured by PEPFAR and POC VL tests procured by Global Fund in 2020. For 2021-22, PEPFAR has committed to fund POC EID but has not included POC VL in COP21. Funding for POC VL for 2022 is not confirmed and will depend on Global Fund funding availability. Operational transition is still ongoing with not all funding secured for programmatic activities.	Significant increase	Unconfirmed
Uganda	Yes	N/A	Currently 30% of EID testing is conducted on POC and the Global Fund and PEPFAR have committed to sustain this.	Stable	N/A

Country	Secured funding (yes / no)		External funding details	Trend in testing coverage ¹¹²	
	POC EID	POC VL		POC EID	POC VL
Zimbabwe	Yes	Yes	POC EID and laboratory based, centralised VL has been incorporated into the Zimbabwe COP 2019/20, and included in the Global Fund NFM3 grant proposal. This is to maintain the 40% POC EID market share across 2020-23.	Unconfirmed	Unconfirmed

CEPA analysis based on data provided by EGPAF and CHAI and data from the country case studies; no reliable data could be sourced for Côte d'Ivoire, Rwanda and Zambia

Ensure programmatic and operational readiness

While there has been some progress with regards to country programmatic and operational readiness for introduction and scale up of POC technologies, ongoing support is needed to ensure effective supply chains, data systems, and other aspects of health systems capacity. An important achievement of the grants has been facilitating countries to have supportive policies and guidelines in place.

Supportive policies: Before the start of the grants, there were virtually no policies in place at the country level for POC VL and EID testing. However as noted in Section 3.3, a number of countries now have policies which include EID and VL POC testing, and in addition, there have been changes to some other policies such as waste management guidelines (e.g. Zimbabwe) and quality assurance. Stakeholders consider that the grants played an important role in terms of laying the foundation of policy development in countries across country case studies.

Integration into national programmes: Prior to the grants, POC EID and VL testing was not integrated into national programmes as countries were only using laboratory based, centralised testing. With the grants, there are some good examples from countries where EID and/ or VL POC testing has been integrated into national supply networks, data management and health systems, quantification etc such as in most of our country case studies and for EID in Uganda and Mozambique. However, VL testing has not been incorporated in Uganda (it was not trialled under the grant) and Mozambique (where it is still being piloted), and in Kenya the EID testing is no longer being undertaken due to lack of funding. There is a larger issue of integration of the diagnostic platforms across diseases (i.e. multiplexing) where there is a need for further progress.

Effective supply chains and adequate health systems capacity: Substantial work was undertaken through the grants in terms of supporting effective supply chain and building health systems capacity, however in general this is an area which may pose challenges regarding sustainability going forward. Some examples raised were (i) having adequate and trained human resources to undertake testing on POC devices (Lesotho, Uganda, Zimbabwe, Mozambique), (ii) ensuring that there is adequate power to run the testing (Cameroon, Zimbabwe), (iii) requiring ongoing technical assistance to assist with quantification (Zimbabwe), (iv) support with quality assurance programmes, and (iv) being able to adequately address waste management (Cameroon). In addition, stakeholders noted that an ongoing area of need is in relation to integration and optimisation of platforms. The work undertaken through the UCPOC grant to support DNO has been positive in this regard. However, the fact that not all countries have done network optimisation planning is considered to be one of the reasons delaying the scale up of POC in some countries.

Timely registration of products: As outlined in Section 3.1, the majority of UCPOC countries targeted for regulatory approval managed to register two assays for POC VL and POC EID respectively. Beyond the progress made through the grants for POC devices, the process and timeliness of registration varies by country. In Cameroon, Lesotho and Uganda, WHO PQ is sufficient for country registration; however, in Kenya this is an ongoing challenge with country registration posing delays across products. In Zimbabwe, the UCPOC grant has been noted to have had a positive effect in addressing this barrier as not only did the grant help with the registration of devices but it also helped to simplify the registration process for other products being introduced in the future as discussed in Section 3.1.

Create community driven demand

In general demand creation was relatively limited at the community level, partly as it was introduced quite belatedly, especially in the UCPOC grant.

As noted in Section 3.3, demand creation activities relating to beneficiaries/ community level demand were undertaken belatedly and with insufficient activities with CSOs or grassroots advocacy. Stakeholders consider this to be an area requiring further efforts as the grants are not considered to have had much impact.

Overall

Overall, there has been some good progress in furthering key country scale up conditions, especially with regards to supporting the development of POC-related policies and guidelines in countries. However, the

biggest barrier is the limited donor funding to scale up use beyond what has been achieved through the grants. In addition, community driven demand remains an area of weakness.

Figure 4.2: Summary of progress towards country readiness for scale up from baseline (2015) to end of grant evaluation (2021) based on the country conditions for scale up (number in parentheses against each domain refers to number of conditions within each domain)

	Baseline (2015/2016)			End of grant evaluation (2021)		
	Political & financial support (4)	Programmatic & operational readiness (5)	Community driven demand (2)	Political & financial support (4)	Programmatic & operational readiness (5)	Community driven demand (2)
Cameroon		●		●●●	●●●	
Kenya	●			●●	●●●●●	●
Lesotho				●●	●●●●	●
Mozambique				●●●	●●●●	●
Uganda				●●	●●	●
Zimbabwe				●●●	●●●	●
Average scalability assessment	0.2	0.2	0.0	2.5	3.5	0.8

Source: CEPA case studies for Cameroon, Kenya, Lesotho, Mozambique, Uganda and Zimbabwe

The blue dots represent the status for each country for the 11 conditions for scale up according to Unitaids Scalability Framework,¹¹⁵ estimated based on the assessment of country readiness at the time of the baseline (corresponding with pre-grant situations in 2015 or 2016) and at the time of the end-of-grant evaluation in early 2021. The status at the end of grant evaluation is based on the scalability rating given by the evaluators for each of the 11 conditions, with a rating of fully achieved or partially achieved with a plan in place to address the gap corresponding to a dot. The average scalability represents the average number of dots per condition category and was calculated by summing the total number of dots and then dividing this by the number of countries (six).

5. IMPACT ASSESSMENT

This section provides an overview of the estimated public health and economic impacts of Unitaids HIV molecular diagnostic portfolio as measured against Unitaids KPI 4.1, 4.2 and 4.3. Section 5.1 presents findings from the impact modelling and Section 5.2 presents findings from the document review, consultations and country case studies.

Key theme	issue/	Findings	Strength of evidence
Public health impact (KPI 4.1)	health (KPI 4.1)	<ul style="list-style-type: none"> Higher public health impact has been achieved by the POC EID component of the grant than the POC VL component. In total within the grants and five years post the grants: <ul style="list-style-type: none"> The POC EID component is estimated to avert 8,066 [6,352 - 13,176] deaths, equivalent to 257,047 [182,130 – 372,085] life years. POC VL is estimated to avert 1,931 [856 - 3,470] deaths and 1,710 [758 – 3,074] transmissions, equivalent to 53,397 [23,682 – 95,973] DALYs 	Moderate

¹¹⁵ Unitaids (2020), Unitaids Scalability Framework – Guidance for Implementers, draft, October 8 2020.

Key theme	issue/ Findings	Strength of evidence
	<ul style="list-style-type: none"> ○ Laboratory based, centralised VL is estimated to avert 736 [397-1,383] deaths and 652 [352 -1,225] transmissions, equivalent to 20,369 [10,979 -38,262] DALYs. ● POC EID has been critical in reducing the turnaround time of EID testing, leading to a substantial increase in infants that received their results and are initiated on ART within 60 days. POC VL has also enabled reduction in turnaround time leading to an increase in people with high viral load to receive adherence counselling or a switch to second line treatment. 	
Economic impact and cost-effectiveness (KPI 4.2)	<ul style="list-style-type: none"> ● Evidence generated by the grantees showed that the use of POC EID instead of laboratory based, centralised EID can be cost-effective. This is illustrated by lower costs per test returned within 30 days under POC EID as well as cost per life year saved that is below the GDP per capita threshold. The cost-effectiveness of POC VL is less well evidenced but recent research suggests POC VL can be cost-effective when targeted at key populations with higher risks of viral failure. ● Economic impacts in the form of cost-savings to the health system are modest with quantified cost-savings include a total of US\$5.9 million [4.9 m – 7.0 m] in treatment costs averted for opportunistic infections for infants and a total of US\$ 7.5 million [3.5m – 13.7m] in HIV treatment costs averted due to the reduction of HIV transmission. 	Moderate

5.1. FINDINGS FROM THE IMPACT MODELLING

Impact figures have been estimated by developing bespoke-Excel based models that leverage the existing work done by the grantees, in particular on the robust assessment through the Cost Effectiveness of Preventing AIDS Complications (CEPAC) model for POC EID.¹¹⁶ At the portfolio-level, the impacts have been estimated in three areas in line with the grants: POC EID (combined EGPAF and UPCOC), POC VL (UCPOC only) and laboratory based, centralised VL (UCPOC only). Following Unitaids' impact modelling approach, the impact estimates provided state only additional impact achieved through the supported interventions and, thus, ensure that gains that would have also been made in the absence of the Unitaids projects are taken into consideration. Appendix J provides a detailed overview of the model design for each of the components as well as input assumptions that have been varied for the three scenarios modelled: conservative, central and best-case scenario. Detailed impact estimates for EGPAF and UCPOC specifically are outlined in Appendix K.

Table 5.1 below provides a summary of the public health and economic impacts by grant against Unitaids' KPIs. The key findings from the impact modelling include the following:

- **Higher public health impact has been achieved by the POC EID component of the grant than the POC VL component.** To date, the POC EID component of the portfolio has achieved a direct impact of 1,306 [1,239 - 1,642] deaths equivalent to 41,615 [4,924 - 46,367] life years saved.¹¹⁷ The POC VL component had a lower direct impact of 290 [178 – 395] deaths averted and 257 [158 -350] transmissions averted, equivalent to 8,031 [4,924 – 10,934] DALYs averted. Laboratory based, centralised VL through the use of Hologic platforms could avert an additional 430 [292-588] deaths and 381 [259 - 521] transmissions, equivalent to 11,904 [8,079 - 16,270] DALYs

¹¹⁶ The CEPAC model and its application to POC EID have been explained in detail in the following paper: Frank, Simone C., et al. "Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study." *The Lancet HIV* 6.3 (2019): e182-e190.

¹¹⁷ As outlined in the grant specific impact in Appendix K, as well as in Appendix J, the POC EID impact figures compare the outcomes and impacts of POC EID to a scenario in which every tested infant would have otherwise had access to the laboratory based, centralised EID testing. This is a very cautious assumption and as such the presented impact numbers for POC EID in this section present a conservative assessment approach.

averted. The higher values from the POC EID component are expected given the higher number of POC tests conducted as well as the fact that timely clinical action is more critical in the case of an infant than for PLHIV with an elevated VL. The direct impact captures health benefits from infants tested directly through the projects during the grant duration which is reportedly around 418,000 infants tested for POC EID and ~ 122,000 tests conducted for POC VL.

The indirect impact captures the health benefits of additional POC EID and VL tests conducted in the five years after grant closure as well as tests financed by partners during the grant period in countries that transitioned. The scale up of POC EID and VL tests has been based on the latest available evidence around the funding commitments for POC EID and VL presented in Section 4.3 above. The analysis showed that POC EID and VL coverage is expected to be maintained or to moderately increase in most project countries. Thus, projected scale up has been based on tests conducted in 2020 (including tests conducted through the project as well as tests financed by partners for countries that have transitioned) adjusted by a growth rate which has been varied across conservative, central and best scenarios to account for the underlying uncertainty.¹¹⁸ Additionally, different scenarios were developed to also estimate potential usage of POC in non-project Sub-Saharan African countries. Appendix J provides a detailed breakdown of the used scale up assumptions and the variation between scenarios to capture the underlying uncertainty. Based on these scale up assumptions, POC EID tests conducted during the five years after grant closure are estimated to be 2.1 million [1.8m - 2.8m] (with above 95% of those conducted in EGPAF and UCPOC project countries) and 1 million [0.7m-1.3m] for POC VL (with around 77% in UCPOC project countries). The health benefits of these additional tests include 6,760 [5,184 - 11,534] deaths averted equivalent to 215,432 [148,616 – 325,718] life years saved for POC EID. POC VL is estimated to avert 1,640 [678 - 3,075] deaths and laboratory based, centralised VL 306 [105 – 795] deaths.¹¹⁹

In total, between the impact during the grant period (i.e. direct impact) and the five years following grant closure (i.e. indirect impact), the POC EID component is estimated to avert 8,066 [6,352 - 13,176] deaths equivalent to 257,047 [182,130 – 372,085] life years saved and the POC VL component 1,931 [856 – 3,470] deaths and 1,710 [758 – 3,074] transmissions, equivalent to 53,397 [23,682 – 95,973] DALYs. Laboratory based, centralised VL is estimated to avert 736 [397 – 1,383] deaths and 652 [352-1,225] transmissions, equivalent to 20,369 [10,979 – 38,262] DALYs. While these overall figures are moderate when compared directly to some other disease interventions supported by Unitaids, this is particularly due to the nature of the intervention with diagnostic tools often not achieving very high public health impact numbers (as compared to direct treatment programmes for example). In addition, key benefits from diagnostics relate to equity aspects with the vast majority of the interventions being focused on vulnerable populations which is not possible to capture quantitatively.

- **Economic impacts in the form of cost-savings to the health system are modest** with quantified cost-savings estimated to be US\$ 5.9 million [4.9m – 7.0m] in treatment costs averted for opportunistic infections for infants and US\$ 7.4 million [3.5m – 13.7m] in HIV treatment costs averted due to the reduction of HIV transmission. While there are no direct significant cost-savings to the health system, POC EID is still considered to be cost-effective when considering the health impacts achieved for the additional costs required (see Section 5.2 below for more details).
- **The return of investment (RoI) of the portfolio as defined under Unitaids' KPI 4.3 is positive with the achieved health impacts being monetised.**¹²⁰ The return of investment has been determined by estimating the

¹¹⁸ Growth rates across scenarios have been based on the CHAI market report 2020 as well as historic growth rate in project countries. Detailed assumptions are provided in Appendix J.

¹¹⁹ The impact of laboratory based, centralised VL testing through Hologic is more limited after grant closure as it is assumed that countries with funding for laboratory based, centralised VL testing could have also chosen a competitor product. The additionality in terms of laboratory based, centralised testing was estimated based on the costs savings that could be made using Hologic vs purchasing a new platform from Roche / Abbott and that these savings are used to increase laboratory based, centralised VL testing coverage.

¹²⁰ We note though that the results highly depend on chosen methodology and input assumptions.

additional costs compared to the additional benefits of the projects. Additional costs included the project costs, differentials in testing costs between using POC technology compared to laboratory based, centralised testing as well as additional treatment and care costs for additional patients identified. Additional benefits included the cost-savings to the health system but also monetised the health outcomes using the approach endorsed by the Lancet Commission (Jamison et al. (2013) Global health 2035: a world converging within a generation).^{121, 122} Using this approach, the RoI for the EGPAF grant is around 3.6 [1.2-7.0] and 6.7 [2.1 – 11.3] for the UCPOC grant. The higher RoI of the UCPOC grant is driven by the higher number of POC EID as well as POC VL and laboratory based, centralised testing relative to the project costs.

¹²¹ The calculation is sensitive to input assumptions which have been aligned with work for previous Unitaid projects. Key inputs include: (i) life value co-efficient; (ii) population weighted average GNI per capita and (iii) discount rate.

¹²² While our approach is based on the approach set out in the Lancet, there remains a debate in the health economic landscape as to what is the most appropriate approach to monetising public health impacts.

Table 5.1: Public health and economic impacts in Unitaid's HIV molecular diagnostic portfolio

KPI	Indicator	POC EID			POC VL			Laboratory based, centralised VL		
		Direct	Indirect	Total	Direct	Indirect	Total	Direct	Indirect	Total
Public health impacts (KPI 4.1)	Deaths averted [conservative – best case]	1,306 [1,169 - 1,642]	6,760 [5,184 - 11,534]	8,066 [6,352 - 13,176]	290 [178 - 395]	1,640 [678 - 3,075]	1,931 [856 - 3,470]	430 [292 – 588]	306 [105 - 795]	736 [397- 1,383]
	Life years gained [conservative – best case]	41,615 [33,515 - 46,367]	215,432 [148,616 – 325,718]	257,047 [182,130 – 372,085]	N/A	N/A	N/A	N/A	N/A	N/A
	DALYs averted [conservative – best case]	N/A	N/A	N/A	8,031 [4,924 - 10,934]	45,366 [18,758 – 85,039]	53,397 [23,682 – 95,973]	11,904 [8,079 - 16,270]	8,464 [2,901 - 21,992]	20,369 [10,979 - 38,262]
	Transmission averted [conservative – best case]	N/A	N/A	N/A	257 [158 - 350]	1,453 [601 – 2,724]	1,710 [758 – 3,074]	381 [259 - 521]	271 [93 – 704]	652 [352 - 1,225]
Economic impacts (KPI 4.2)	Treatment costs averted [conservative – best case]	US\$ 0.8m [0.8 m – 0.9 m]	US\$ 5.1 m [4.1m – 6.2m]	US\$ 5.9 m [4.9 m – 7.0 m]	US\$ 0.8m [0.5 m – 1.1 m]	US\$ 4.6 m [1.9m – 8.7m]	US\$ 5.4 m [2.4 m – 9.8 m]	US\$ 1.2m [0.8 m – 1.7 m]	US\$ 0.8 m [0.3m – 2.2m]	US\$ 2.0 m [1.1 m – 3.9 m]

Source: CEPA analysis

5.2. FINDINGS FROM THE CONSULTATIONS AND DOCUMENT REVIEW

Public health impacts (KPI 4.1)

In addition to the impact modelling, key impacts highlighted in grant logframes are presented in Table 5.1.

Table 5.1: Key public health impacts presented in grant logframes

Grant	EID/ VL	Indicator	Baseline (start of grant)	Achievement (2019 EGPAF/ 2019 or 2020 - UCPOC)
EGPAF	EID	Median number of calendar days (including range and inter-quartile range) from POC EID blood sample collection to initiation on ART for all HIV-infected infants	Median: 50 days (2015)	0 days (IQR:0-1) ¹²³
UCPOC	EID	Testing coverage in each of the 10 target countries	40% (2014)	48% ¹²⁴
	VL		7% (2014)	57% ^{125, 126}
	EID	Median number of calendar days from sample collection to treatment initiation (POC EID, referral EID)	29-52 days where EID testing prior to POC (2014)	0 days (Cameroon DRC) 1 day (Ethiopia, Zimbabwe) 12 days (Malawi) 38 days (Senegal) ¹²⁷
	VL	Median number of calendar days from sample collection to adherence counselling or 2L switching (POC VL, referral VL)	34-63 days where VL testing prior to POC (2014)	< 7 days (DRC, Malawi, Senegal, Zimbabwe) 29 days (Kenya) 45 days (Tanzania) ¹²⁸

Other key qualitative impacts highlighted include:

EID POC testing: The most important impact from EID testing has been from the rapid TAT of results. This is particularly due to the positive impact that a faster returned result has on HIV exposed child morbidity and mortality through the enabling of faster management of infants who require treatment quickly. As one stakeholder said “*The increase in coverage of POC EID means we’re able to identify children as early as possible and have interventions to help them to survive.*” As an example, stakeholder consultations indicate that the impact has contributed to having more children start on ART in 60 days of diagnosis and 90% children living with HIV get started on treatment.¹²⁹ The improvement of tests returns and clinical action taken has also been clearly shown in project data and the subsequent journal publications. Data from the EGPAF grant showed that return of results to caregivers within 30 days was much higher (98.3% POC vs 18.7% laboratory based, centralised EID) and quicker (median time of 0 days for POC vs 55

¹²³ EGPAF (2019) POC EID 2019 End of Project Report.

¹²⁴ CHAI, UNICEF (2021) Preliminary data for progress up to 2020 end.

¹²⁵ CHAI, UNICEF (2021) Preliminary data for progress up to 2020 end.

¹²⁶ The increase in VL testing coverage compared to the Baseline in 2014 is driven by predominately by the expansion of laboratory based, centralised VL testing rather than POC VL testing supported under the grant.

¹²⁷ UCPOC (2021) Consolidated Logframe 23-03-2021.

¹²⁸ UCPOC (2021) Consolidated Logframe 23-03-2021.

¹²⁹ UNAIDS (2019), Start Free- Stay Free- 2019 Progress report.

days for laboratory based, centralised testing).¹³⁰ This is also reflective of the number of infants with HIV initiating ART within 60 days of sample collection with 92.3% for POC EID vs 43.3% for laboratory based, centralised EID. Data from the UCPOC grant illustrated similar strong improvements with regard to increasing the number and speed of infants with tests returns and initiation of ART.¹³¹

In addition, EID has been noted to help in the following ways based on country case study findings:

- Helped to more appropriately manage infants who are HIV negative.
- In some countries it has facilitated a shift in coverage of EID testing:
 - Lesotho: Overall the EID coverage has increased from 55% to 70% from 2015 to 2019¹³²
 - Zimbabwe the EID testing coverage increased less substantially from 54.9% to 56%¹³³
- It has helped to gain the trust of beneficiaries. As one stakeholder said, *“Because laboratory based, centralised testing has been failing mothers and children for so long, especially due to lost results or delayed results, this has had an effect on trust from patients/ communities. It’s a fragile relationship and so the project helping to build trust again was important.”* Another country level stakeholder said, *“the promise of quick results means parents are encouraged to come for more testing”*.
- Anxiety for caregivers has reduced as results have been able to be returned more quickly and therefore they know the child’s status more quickly.

Box 5.1: Public health benefits example – Uganda (UCPOC grant)

In Uganda, before the start of the pilot, 5,426 exposed infants were tested in the 33 pilot sites during six months.¹³⁴ During the pilot, the same sites tested 13,298 exposed infants during six months, which is a 245% increase. From the same facilities, 80 HIV positive infants were identified during six months before the pilot, compared to 196 identified in the same sites in six months during the pilot phase, a 245% increase in recovery of positive infants. In addition, the overall positivity rate increased from 1.2% to 2.5% and the percentage of babies initiated on ART in 14 days of sample collection increased from 26% to 49%.¹³⁵ In relation to the positive yields, stakeholders in Uganda consider that having the testing conducted in PMTCT, paediatric and nutrition wards (especially the latter) provided the missing link between the expected and identified HIV positive infants.

VL POC testing: The impact of VL POC testing is less than for EID as quick result return is less critical for VL although its value is enhanced for priority population groups such as pregnant and breastfeeding women, people with advanced HIV disease etc. The three main benefits of improved access to VL testing and being able to obtain results more quickly has been (i) shorter time to clinical action and initiation of adherence counselling; (ii) improvement in adherence as PLHIV are kept more up to date with their VL status and (iii) ability to switch to second line treatment when needed. As an example, in Kenya, the median number of calendar days from sample collection to adherence counselling or second line treatment switching (integrating POC VL into the standard system) was reduced from 55 to 29 days.¹³⁶

¹³⁰ Bianchi et al., on behalf of EGPAF (2019), Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries.

¹³¹ Boeke, Caroline E., et al. (2021), "Point-of-care testing can achieve same-day diagnosis for infants and rapid ART initiation: results from government programmes across six African countries." *Journal of the International AIDS Society* 24.3

¹³² EGPAF (2018), Updated Log Frame and EPGA (2019), End of Project Report for Lesotho.

¹³³ Ministry of Health and Childcare, Zimbabwe (2019) PMTCT Program data (sourced via phone call to MoH directly).

¹³⁴ MOH, Uganda (2018), EID POC Implementation Report in Partnership with CHAI and UNICEF.

¹³⁵ MOH, Uganda (2018), EID POC Implementation Report in Partnership with CHAI and UNICEF.

¹³⁶ UCPOC (2019), Annual report.

VL Hologic testing: The grant had managed to improve TAT for results from 47 days to 7 days for VL for laboratory based, centralised platforms in Zimbabwe.

Economic impact (KPI 4.2)

As outlined in Section 5.1 above, POC technology offers only modest direct cost-savings to the health system. However, POC EID in particular is considered to be cost-effective when assessing the additional health benefits against the additional costs. The EGPAF grant has supported publications on the topic of cost-effectiveness of POC EID using the CEPAC model to examine clinical benefits, costs and cost-effectiveness of replacing laboratory based, centralised EID with POC EID.¹³⁷ In a detailed modelling study for Zimbabwe, the researchers found that POC EID has been cost-effective with US\$ 680 needed per year of life saved when compared against Zimbabwe's GDP per person (US\$ 1,010).¹³⁸ The change to POC EID remained cost-effective for the majority of sensitivities which took account of POC assay costs, the probability of ART initiation and the probability of return of the results of POC testing. The cost-effectiveness of POC EID was also supported by another publication supported by EGPAF which showed that the costs per test returned within 30 days was less for POC EID at US\$ 27.24 [21.39 – 33.10] than for laboratory based, centralised testing at US\$ 131.02 [96.26 – 165.76] in eight African countries.¹³⁹ The recent WHO guidelines which found that POC EID testing was more cost-effective than the standard of care defined in each study included in the review.¹⁴⁰ The evidence on the cost-effectiveness of POC VL has been more limited with the latest WHO guidelines identifying this as a research gap.¹⁴¹ The findings of recent studies suggest that POC VL can be cost-effective when targeted at key populations or facilities with higher risks of viral failure.¹⁴²

In addition to the impact modelling, key qualitative impacts highlighted during the review include **reduced opportunity costs and out of pocket payments**. Prior to the introduction of POC testing, beneficiaries - particularly those in remote areas – often had to make long journeys to the clinic/ hospital for samples to be taken, and then return later to receive results. With POC, a number of these patients now only have to take the one trip. This has helped them both in terms of opportunity costs as well as out of pocket payments for aspects such as transport and was highlighted across country case studies. In Zimbabwe, stakeholders highlighted that beforehand clients would go the health facility at least three times before they received a result and action was taken on the result. Therefore, there have been savings in terms of travel costs and opportunity costs.

Equity impact (KPI 5.1 and KPI 5.2) and strategic benefits and positive externalities

The main beneficiaries of the grant have been infants and their families, as stakeholders anticipate the reduction in morbidity and mortality. Country case studies demonstrated a number of ways in which the testing has had an impact on equity. In particular the following population groups have benefited: (i) infants (who a number of stakeholders noted have not received equitable access to care in the past in comparison to adults); (ii) populations living in remote areas, including in tough terrain (Lesotho, Mozambique, Uganda); (iii) PBFW (all case studies where VL testing was used) and some population groups such as religious populations (Zimbabwe) and adolescents (Lesotho) who do not

¹³⁷ The model took account of factors including (i) testing costs; (ii) treatment costs of infants initiated on ART and (iii) treatment costs of comorbidities in the absence of ART treatment.

¹³⁸ Frank et al., (2019), Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study.

¹³⁹ Bianchi et al., on behalf of EGPAF (2019), Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries.

¹⁴⁰ World Health Organization (2021), Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring, March. <https://apps.who.int/iris/rest/bitstreams/1336192/retrieve>

¹⁴¹ World Health Organization (2021), Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring, March. <https://apps.who.int/iris/rest/bitstreams/1336192/retrieve>

¹⁴² Girdwood, Sarah J., et al, (2020) "Cost-effectiveness of adoption strategies for point of care HIV viral load monitoring in South Africa." *EClinicalMedicine*

wish to be seen attending health facilities, including for HIV, have particularly benefited from the reduced number of health facility visits.

Key positive externalities outlined across the portfolio include:

- **Improved access to testing for other diseases including COVID-19** through utilising the POC platforms. With regards to the EGPAF grant, this is particularly in relation to VL testing which was not undertaken under the grant. For both grants, this relates to other diseases too such as HPV. Indirectly this is also considered to have helped to break down barriers across silo'd disease approaches and helped to use diagnostics more efficiently and this was found in a number of countries. In Zimbabwe, there was support for laboratory multiplexing to increase access to diagnostics using existing platforms and one stakeholder expressed the unanticipated benefit that POC platforms brought, “no one *anticipated that that we would use them for multiplexing like during COVID. We have managed to use it for COVID testing and we are riding on the machines for other tests like HPV and cervical cancer*”. Zimbabwe was able to respond quickly to COVID-19 since there were platforms able to run tests. Similarly the platforms have been used for COVID-19 testing in Cameroon and Kenya.
- **Lower reagent prices for other diseases:** Stakeholders reported that CHAI lobbied for lower prices for reagents prices and this influenced costing for COVID-19 commodities through the same processes in Zimbabwe.
- **Placement of platforms for use for other diseases:** The network optimisation work during the grant period also laid the groundwork for successful COVID platform placement in some countries, as they were primed to approach diagnostics placement more strategically.
- **Reduction in patient out-of-pocket costs:** In Cameroon in April 2020, the government declared that VL testing would become free of charge. Stakeholders revealed that this was motivated by an increased capacity to meet demands for POC VL testing.

Key strategic benefits have been noted to include: (i) the introduction of the hub and spoke model which is considered to have helped to leverage the use of the platforms and (ii) where the grant has helped to change registration processes beyond the molecular testing devices, these are considered to long-lasting positive effects (e.g. for Zimbabwe noted in Section 3.1 above).

6. CONCLUSIONS AND RECOMMENDATIONS

The HIV POC molecular diagnostics landscape is complex and dynamic, with a challenging supply situation where there are limited number of suppliers offering different types of products (i.e. “differentiated products”) and there is a need for careful consideration of POC use within the wider diagnostics system in terms of fit with laboratory based centralised testing, leveraging of multiplexing capacity and overall optimisation of device use and placement. In addition, the stakeholder arena has proven to be complex particularly in terms of coordination with the strategic priorities of PEPFAR and the Global Fund. Notwithstanding this challenging context, the Unitaid HIV POC molecular diagnostics portfolio has served an important need to increase testing coverage and patient access to testing, and thereby potentially covering the remaining gaps in the 90/95 targets as well as improving patient outcomes. In this context, the two grants have been very relevant investments by Unitaid.

The grants have made important contributions in establishing and furthering global awareness and guidance for POC EID and VL including key contributions to WHO and funder guidelines, initiating and encouraging country demand and adoption of POC testing supporting improved service delivery, negotiating improved pricing agreements, and normalising/ mainstreaming diagnostics integration and network optimisation including through the Integrated Diagnostic Consortium (IDC) coordinated by Unitaid. However, key challenges remain in terms of access, where there continues to be a largely monopolistic and asymmetric market for POC technologies with products that have relatively higher pricing, and where donor support for scale up is tenuous, or moderate at best, particularly so for POC VL. Whilst the grants have aided progress with regards to diagnostic network optimisation and integration (with the benefits accruing for COVID-19), more progress is needed in this regard.

In general, the fundamental value-add of the portfolio has been the shift they have brought about from a situation where countries did not have experience with POC testing (including knowledge regarding the benefits of POC testing and the best means to introduce these technologies optimally) to one where countries have adopted POC EID and VL in their national policies, guidelines and service delivery models. In addition, global-level discussions have evolved from one where there were differing views on the role of POC within the diagnostic landscape to one where donors and partners are considering and supporting their use.

Key aspects that these grants have enabled are the following:

- **Contributed evidence to the updated WHO recommendations and supportive guidance from PEPFAR, particularly for POC EID:** The most recent 2021 WHO guidelines provide a strong recommendation with high certainty of evidence for POC infant HIV virologic testing, alongside a conditional recommendation with moderate certainty of evidence for use of POC VL for treatment monitoring in select populations. This achievement for POC EID establishes the base for country uptake, although in the case of POC VL there continue to be some key research gaps that need to be fulfilled for a solid recommendation. The 2020 PEPFAR COP guidance (which preceded the WHO guidelines) endorsed the use of POC EID (complementary to the laboratory based, centralised system) as well as POC VL for PBFW, which has been further expanded under the 2021 COP guidance. Not only the evidence-generation but also the momentum created by both grants have been important contributory factors to these updated guidelines.
- **Development of national policies and guidelines on POC EID, and to a lesser extent POC VL, and initiating the availability and adoption of these technologies in countries:** Across our case study countries, national policies and guidelines have been updated to include use of POC EID and to some extent POC VL. The grants have played a pivotal role in encouraging countries to adopt these technologies, through awareness raising, evidence generation and site demonstrations, and working directly with government and laboratory and HIV programme stakeholders. CHAI in particular facilitated and fast-tracked country registrations of the products, and both grants procured and implemented POC EID and VL testing in countries, from a situation where there were no POC products and at best only research-focused testing. This included supporting health systems with regards to supply chain and procurement processes, training, data systems and waste management – all with important

strides through the project work, although some gaps remaining particularly with regards to robust data systems that align with MoH and developing waste management systems. Different delivery models have been piloted through the grants such as the hub and scope model and use of alternate entry points, which further the system optimisation priority, although with some challenges especially with regards to sustaining systems for sample transport and scaling up nationally.

- **Within the context of a very challenging product/ supplier base, negotiated better pricing agreements:** Some price declines for GeneXpert and m-PIMA were achieved, and while the price is still considered a barrier to scale up, some argue that realistic declines in relation to COGS have been achieved. In addition, and importantly, through the work of the UCPOC grant, the Hologic all-inclusive pricing agreement was expanded to project countries. In addition, more inclusive pricing for GeneXpert and the m-PIMA were negotiated, together with improved service and maintenance agreements for m-PIMA and GeneXpert. All of these achievements have been significant as they have contributed to the sensitisation of manufacturers, funding partners/ donors and countries on the benefits of all-inclusive pricing.
- **Furthered the agenda on integration and diagnostics network optimisation alongside PEPFAR:** Although these were aspects that were brought in later into the grants, both grantees together with Unitaid have helped mainstream and normalise the importance of integrated diagnostic testing and optimisation of diagnostics networks. Some progress has been made in this regard in countries (particularly with the advent of COVID-19), although more continues to be needed.

Despite the important progress outlined above, **key challenges remain with regards to access and scale up of POC testing in HIV, as follows:**

- **While increasing, tenuous support for scale up from donors, especially for POC VL:** The latest PEPFAR guidelines have been updated for greater support for POC EID and VL, however the extent to which these are implemented in practice remains to be seen – in the face of defined budget envelopes for countries and the higher sticker price of POC technologies relative to laboratory based, centralised technologies, as well as the priority for network optimisation in the first instance. This also applies for Global Fund funding for countries, where country CCMs face similar questions that determine their inclusion in country funding requests. Our review of select project countries as well as insights into some non-project countries has revealed that a significant level of POC EID testing has already been achieved through the two grants with some/ modest scaling up is planned for the in the coming years. More limited POC VL testing has been scaled up through the duration of the grants and not much further scale up anticipated, especially with a core donor and country focus on optimising existing instruments and networks in the first instance.
- **A largely monopolistic market, with pricing still considered to be one of the important factors affecting large scale take up:** While at the start of the grants there was a pipeline of products expected to enter the market, this has not materialised (as they have not yet received WHO PQ), also because the market size implies business feasibility for a limited number of suppliers. While a near-POC product, the GeneXpert has developed a substantial footprint through TB over the years and as such has a monopoly in the market at present, with what stakeholders (donors, countries) continue to consider as unaffordable pricing despite the declines achieved during the grants period, especially in comparison to laboratory based, centralised testing. Other competitors – Abbott m-PIMA and DRW SAMBA – have faced challenges with regards to footprint and pricing in comparison with the GeneXpert. This challenging supply situation is expected to perpetuate with limited funding for new platform purchases, as noted above.
- **Further need for country-level assessment for diagnostic network optimisation:** While network optimisation was factored into the UCPOC grant, albeit belatedly, there is a need for further assessments at the country level on how best to optimise the diagnostics network. Progress has been achieved in terms of mainstreaming the complementarities of laboratory based, centralised and POC testing at the country level, encouraging thinking beyond conventional wisdom for POC, highlighting where the issues are (e.g. sample transport), and there has

been recent leveraging for COVID-19 as well. However, scale up of POC needs to take place in the context of better defined networks for diagnostics in countries. This is a larger issue in terms of similar needs across a range of diagnostics such as for CD4 as well.

- **Limited progress with regards to integration:** Again, an aspect that was incorporated belatedly into the grant portfolio, and some gains have indeed been secured through the work of the grants as noted above – however substantial work remains in the actual execution of diagnostic integration within countries. This is with regards to developing guidelines and systems for use of multiplexing capacity of instruments, but also, realising the benefits of this through developing country health systems that provide the needed linkages from diagnosis to treatment for a range of diseases.
- **Need for greater community awareness:** This was an aspect that was incorporated belatedly in the grant portfolio, and while some activities were conducted in this regard, more work is needed to generate community awareness in order to facilitate uptake of POC testing where it is most needed.
- **Further evidence and dissemination on cost-effectiveness:** There was some useful work done by EGPAF with regards to cost-effectiveness of POC testing, but this was not “picked-up” adequately by stakeholders as the emphasis remains on the sticker price of POC products. Further, there is a need to engage with stakeholders to carefully understand how cost-effectiveness assessments could be useful, especially to drive decision-making.

While a number of these challenges such as with regards to the supply situation are external to the grants i.e. are beyond the control of Unitaid and the grantees, **there have been some issues and missed opportunities with the portfolio, as follows:**

- First, the grants’ initial “panacea approach” to POC set the scene for some resistance from stakeholders and a competitive rather than complementary environment for POC and laboratory based, centralised diagnostics, with its concomitant implications on the prospects for scale up. However it is considered a positive that changes were made during the grant demonstrating Unitaid and the grantees flexibility.
- Second, the difference in approaches between the grants in terms of a “bottom-up”/ service delivery POC approach (EGPAF) versus a national-level systems optimisation approach (CHAI) and the mix of emphasis in the UCPOC grant between POC and laboratory based, centralised platforms, whilst intended to be complimentary, contributed to confusion/ lack of clarity amongst some global and country level stakeholders. Further, the grants were reprogrammed/ had budget realignments several times, and while for appropriate reasons, they created further confusion and lack of clarity amongst stakeholders (e.g. country stakeholders and manufacturers) as to the main objective of the grants/ portfolio. There was also some room for improvement in grant coordination, with some grantees professing lack of clarity on the others’ scope and focus of work.
- Third, there was limited consultation and engagement with stakeholders at the start and during key reprogrammings – particularly with donors who were expected to assume funding after grant closure (at the global level overall, and in some countries), but also with in-country groups such as the laboratory community – which impacted product positioning, sustainability and scale up potential. Overall though stakeholders consider that lessons were learnt during the grant in this regard and have been integrated.
- Finally, together with other Unitaid grants on molecular diagnostics across diseases and a range of external factors such as the pipeline of POC products not materialising to date, the grants may have contributed to the observed asymmetry on the supply-side with highly differentiated products and no level playing field. For example, some stakeholders consider that the procurement of m-PIMA through the UCPOC and EGPAF grants has helped maintain at least two products in the market, however others think that efforts might have been better focused on further expanding the use of GeneXpert.

In sum, while the Unitaid HIV molecular diagnostics portfolio has faced several challenges, there have also been important contributions and value from the grants. Indeed, the foundation for country uptake and scale up for POC

EID has been laid through the work of these grants, although there continue to be some key gaps for POC VL. Going forward, the potential benefits for countries are large with more of a strategic approach to POC testing within overall diagnostics systems and greater multi-stakeholder engagement to support its effective use.

The above achievements, challenges and lessons learnt from this portfolio of grants indicate the following recommendations below at both the strategic and operational level.

Strategic

1. Unitaid should ensure **upfront, timely and continuous engagement with the range of relevant stakeholders** at the global and country levels for its grants, to ensure appropriate product positioning, sustainability and scalability. This could be facilitated at several levels for Unitaid such as key partner involvement during development of Areas for Intervention (Afls) and participation in design related discussions between Unitaid and its grantees. A common understanding on what “success looks like” or what conditions need to be met to bring about partner scale up funding should be agreed upfront (and revised during the course of grant implementation, if appropriate). With regards to country stakeholders, a clear mapping should be done for new products/ delivery approaches that reflects enabling and inhibiting factors determining stakeholder demand/ interest within a country’s health systems, and project designs should be closely cognisant of these.
2. Unitaid should **adopt more of a portfolio approach** across its diagnostics grants, ensuring synergies in design in terms of objectives and approaches as well as coordination during implementation. A portfolio approach for Unitaid should not be limited to specific diseases where possible, but transcend across diseases, as appropriate to optimise investments and impact. Further, Unitaid should introduce mechanisms in the next Unitaid Strategy that **consider impact at the level of the portfolio** e.g. developing a TOC from the outset, defining clear and objective parameters on the success of the portfolio and not just individual grants, impact modelling that considers the combined effects of grants, etc.
3. Unitaid should continue to **emphasise diagnostics integration and network optimisation** through its grants. Whilst recognising that these aspects are complex and beyond the role of Unitaid alone, and indeed require efforts from multiple funders and stakeholders, at a minimum, Unitaid’s investments should support integration and optimisation principles and thereby adopt a “country-focused approach”. While designing and reprogramming its grants, Unitaid should engage with key stakeholders, especially at the country level to understand the challenges to effective integration and DNO, and innovatively consider how these can be applied to its grant programming. For example, given countries are at a spectrum in terms of progress with regards to integration, and as such, for countries with limited progress it may make sense to fund country assessments on network optimisation, while for others with greater progress there may be more focused interventions aimed at harnessing synergies between the laboratory and decentralised testing network. The importance of this recommendation cannot be undermined in the context of Unitaid’s strategic expansion to consider multiple diseases as well as the global effort to support resilient and sustainable systems that can better support countries’ epidemic preparedness and responses.
4. Unitaid should **emphasise the development of data systems in its grants to facilitate collection of much needed data**, as integral to the introduction of any new technology. We view this as a critical recommendation given the opportunity for additional data collection that is presented with the introduction/ adaptation of a new technology. The experience of this evaluation in terms of limited data for some aspects as well as limitations with impact modelling reflect the need for greater efforts at data collection (e.g., there has been no clear data on testing coverage pre and post the investments as well as the remaining testing gap).
5. A range of **demand creation activities** need to be included in grants from the outset with clear demand creation plans. These should target a range of stakeholders, including patients/ beneficiaries, CSOs and community representatives.

6. Unitaid should ensure that **cost-effectiveness assessments** are included in grants when introducing a new technology/ product/ delivery approach. These studies should be reflective of what would provide a compelling case for global and country level stakeholders e.g. it is important to ensure that the studies are highly applicable (i.e. not undertaken in controlled environments which are unlikely to be reproduced outside of the grant). Therefore consultation particularly with donors, WHO and country stakeholders would be key early on in the design stage. In addition, grants should include a range of activities to disseminate evidence and facilitate demand creation based on the findings to help facilitate more of a focus on this evidence rather than the product sticker price. This could include workshops, South to South sharing of information etc.
7. Unitaid should include considerations regarding **waste management/ environmental impact** in their grants. This is an important area for the introduction of new technologies and so should receive the deserved attention from Unitaid in their grant tenders, grant proposals and then grant implementation and monitoring.

Operational

8. Unitaid should be **bold in its reprogramming efforts for relevant grants** by clearly defining red-flags or hard-stops for its grants as well as any needed changes in approach. This is particularly the case with larger and longer-term grants. Consideration should be given for new processes that take into account continually changing technologies, guidelines updates (i.e. two year cycle), and alignment with funding and programming priorities by key stakeholders and funders (e.g. COPs). While our evaluation findings do not indicate any issues per se with the technical content of the reprogrammings, the several challenges that these grants have faced over time form the basis for this recommendation. In addition, Unitaid should consider **streamlining its reprogramming processes** with a more appropriate balance between rigour/ scrutiny and level of effort.
9. Unitaid should be **clearer in its communication and engagement with grantees** – clearly setting out drivers for changes and reprogramming to its grantees and wider stakeholders.
10. Unitaid may consider **better aligning its grants with donor funding cycles** to support transition, or else continue to include provisions for bridge funding where needed, and ensure that these are of sufficient value.

PART B: GRANT LEVEL FINDINGS AND COUNTRY CASE STUDIES

In this Part B of the report we first present our grant level assessments and evaluation findings for the EGPAF and UCPOC grants separately, against the same sections/pillars as the portfolio level assessment (Section 7), followed by summary findings from the country case studies (Section 8).

7. FINDINGS – GRANT LEVEL ASSESSMENT

In this section we present the grant-specific evaluations. These are more focused than the portfolio level finding section above as they aim to not be duplicative, and as such bring out key grant-specific aspects, approaches and contributions. As in the portfolio level section, the assessment of grant design and implementation is only at the high level. We present findings for the EGPAF grant followed by the UCPOC grant.

7.1. EGPAF GRANT

Table 7.1: Summary of grant specific evaluation for EGPAF

Area	Findings	Strength of evidence
Grant design and implementation		
Relevance	<ul style="list-style-type: none"> The EGPAF grant has been very relevant given the strong public health need. However its relevance has been somewhat compromised on account of limited upfront engagement with key donor partners on POC product positioning by both Unitaid and EGPAF. There are compelling statistics on the limited reach of laboratory based, centralised testing for EID as well as the long TAT and loss to follow up (the median number of calendar days from POC EID blood sample collection to initiation on ART for all HIV-infected infants reduced from 50 days in 2015 to 0 days in 2019),¹⁴³ thereby making a strong public health case for investing in POC EID. However, one of the limitations of the EGPAF project is that more should have been done upfront to contextualise its work in terms of the funding plans and priorities of key donors, namely PEPFAR and the Global Fund, to ensure the grant would have more a catalytic impact in support of scale up, including for non-project countries. 	Strong

¹⁴³ EGPAF (2019), POC EID 2019 End of Project Report.

Area	Findings	Strength of evidence
Coherence	<ul style="list-style-type: none"> • The EGPAF and UCPOC grants played to the strengths of each implementing organisation and were complementary. However, the grant approaches were not in full coherence, causing some stakeholder uncertainty and confusion. The EGPAF grant emphasised the POC approach within a service delivery context, while the UCPOC grant gradually evolved to consider POC within the context of the wider diagnostics system. With several reprogrammings (especially for the UCPOC grant) some country stakeholders and manufacturers expressed a degree of confusion as to the overall approach and positioning of Unitaid with regards to the overall objective of Unitaid in terms of balance of support for POC and laboratory based, centralised testing. • EGPAF generally aligned and coordinated well with in-country stakeholders. This was highlighted in Cameroon, Kenya, Lesotho and Mozambique in particular where stakeholders noted that EGPAF engaged actively with MoH and health sector partners. This also aided sustainability of activities post the grant. In Zimbabwe, EGPAF engaged well with stakeholders but was reported to work more with the HIV programme and not as well with the labs which caused some challenges. 	Strong/ Moderate
Efficiency	<ul style="list-style-type: none"> • The grant reprogramming and budget realignments were mostly viewed as useful and supporting achievement of overall objectives. • The experience of the EGPAF grant has highlighted key inefficiencies with Unitaid's grant management model in terms of lengthy and arduous process for reprogramming and lack of clarity in communication. Consultations indicate there was a lack of clarity on certain requirements/ guidance from Unitaid to EGPAF during grant implementation such as the decision to not procure further m-PIMA machines. Reprogramming efforts were also viewed as time-consuming, including in comparison to other donors that EGPAF engages with. 	Moderate
Access barriers		
Innovation and availability	<ul style="list-style-type: none"> • While not a key area of focus nor exclusively attributable to EGPAF, the project's work in introducing POC technologies at the country level has contributed to initiating the market for these diagnostics, albeit with some challenges. The EGPAF grant has introduced both GeneXpert and m-PIMA technologies in countries and thereby contributed to these technologies being available in countries. By the end of the grants, all nine EGPAF-supported countries had POC EID available. • EGPAF has made useful contributions with regards to facilitating implementation-related innovations in existing products and product registrations. EGPAF urged national authorities in project countries to accelerate, reduce or eliminate national regulatory studies in light of WHO PQ approval and the positive field evaluation results reported by the EID Consortium and also facilitated product registrations in some countries. In addition, through the work of EGPAF, m-PIMAs now have modems with simcards to support an e-health solution. Further, an SMS printer system with m-PIMAs is now available at hub sites which can be used as functional solution for sharing results from decentralised platforms. 	Strong/ Moderate

Area	Findings	Strength of evidence
Affordability	<ul style="list-style-type: none"> ● The EGPAF grant has particularly added value through its work on generating evidence on the cost-effectiveness of POC EID as well as negotiating for all-inclusive pricing and improved service and maintenance agreements. In particular: <ul style="list-style-type: none"> ○ A multi-country study demonstrated that POC is more efficient than laboratory based, centralised testing when measuring cost per test returned.¹⁴⁴ In addition, the Zimbabwe study into cost-effectiveness shows use of POC EID improved projected undiscounted life expectancy to 25.5 years among infants with HIV and 62.6 years among HIV-exposed infants at a cost of \$690 per HIV-exposed infant.¹⁴⁵ However the stakeholder focus remains on the sticker price, especially given overall budget envelope constraints. ○ Despite the link with volumes and continued high price, EGPAF (together with other stakeholders such as the Vatican Initiative) played an important role in negotiating an all-inclusive price for the m-PIMA. EGPAF also negotiated improved service and maintenance terms for both m-PIMA and GeneXpert, thereby increasing the value for money for consumers, as well as negotiated improved warranty arrangements. 	Strong
Demand and adoption	<ul style="list-style-type: none"> ● The EGPAF grant has helped lay the foundation for POC EID in countries, especially through procurement of commodities and introducing and demonstrating use of POC testing as well as evidence generation. In particular: <ul style="list-style-type: none"> ○ The EGPAF grant, together with the UCPOC grant, has catalysed the introduction and adoption of POC EID through procurement of commodities and introduction of testing services. Given the extremely limited use of POC EID in countries before the grants, coverage for EID in countries has increased over the course of grant implementation (as discussed in more detail in the portfolio section of the report). ○ EGPAF's work contributed significantly to the evidence base for POC EID and to raising global level (i.e. partner, guidelines related) awareness and interest. One of the primary papers from the EGPAF grant was the efficiency paper by Bianchi et al., demonstrating the that the cost per-test result returned is lower for POC EID for those returned within 30 days, and the cost-effectiveness paper by CEPAC demonstrating how POC EID use extends life expectancy. In addition, EGPAF contributed to a wide range of evidence that has been disseminated and used at global and country levels, including joint publications with CHAI, an impact study, one cost-effectiveness study, two small birth-testing studies, and two small pilot studies in Lesotho on HPV testing and discordancy testing. In addition guidance documents and training materials, job aids and tools, case studies and other documents have been developed. 	Moderate

¹⁴⁴ Bianchi et al., on behalf of EGPAF (2019) Evaluation of a routine point-of-care intervention for early infant diagnosis of HIV: an observational study in eight African countries.

¹⁴⁵ CEPAC Frank et al., (2019), Clinical effect and cost-effectiveness of incorporation of point-of-care assays into early infant HIV diagnosis programmes in Zimbabwe: a modelling study.

Area	Findings	Strength of evidence
	<ul style="list-style-type: none"> ○ Evidence from the grant has been used to support updating of PEPFAR COP guidance and some evidence prompted an upgrading of the WHO recommendation for POC EID in the new 2021 guidelines to ‘strong recommendation/ high certainty of evidence’ from conditional in 2016. ● Work through the EGPAF grant contributed to national policy making and updating of guidelines. In all country case studies, the work undertaken through the grant contributed towards policy and guidelines on POC testing for EID. ● The EGPAF grant contributed to demand creation largely through its support to the training of health care workers (HCWs) and supervisors but less so in terms of community mobilisation/ engagement. The EGPAF grant undertook demand creation activities through engaging with civil society and stakeholders and partners of the project in the majority of countries and they undertook grassroots advocacy activities in a smaller number of countries. Consultations at both global and country levels suggest that further efforts are needed for community mobilisation. ● Grant activities played an important role in introducing and normalising the concept of integration with regards to diagnostics. This included emphasising the complementarity of POC and centralised testing and multiplexing (which has also been leveraged under the ongoing COVID-19 pandemic), but this is an area where further work is needed. 	
Supply and delivery	<ul style="list-style-type: none"> ● The hub and spoke model implemented by grantees for POC EID in project countries was generally agreed by stakeholders to be a noteworthy advancement, although with potential challenges in sustaining sample transport. This model improved equity and access to timely EID testing and also helped leverage capacity of the platforms, which several stakeholders noted was much more feasible than a higher number of instrument rollouts. The hub and spoke sample and return transport may be insecure in some countries so will need further donor attention and support to ensure continued operation. ● In case study countries, POC EID commodities were successfully integrated in the national supply chain management systems and responsibility for procurement was transitioned to national government systems prior to the EGPAF grant end (although there were some teething issues within this in some countries). In addition, EGPAF supported project countries to establish a connectivity solution whereby they could monitor instrument performance as well as consumption of cartridges, which ensure timely and accurate quantification and supply planning as well as tracking of instrument utilisation and down time.¹⁴⁶ ● The grant contributed to training, data systems and waste management – all with important strides through the project work, although some gaps remaining particularly with regards to robust data systems that align with MoH and developing waste management systems. 	Moderate

¹⁴⁶ <https://www.pedaids.org/resource/point-of-care-connectivity-issue-brief-2/>

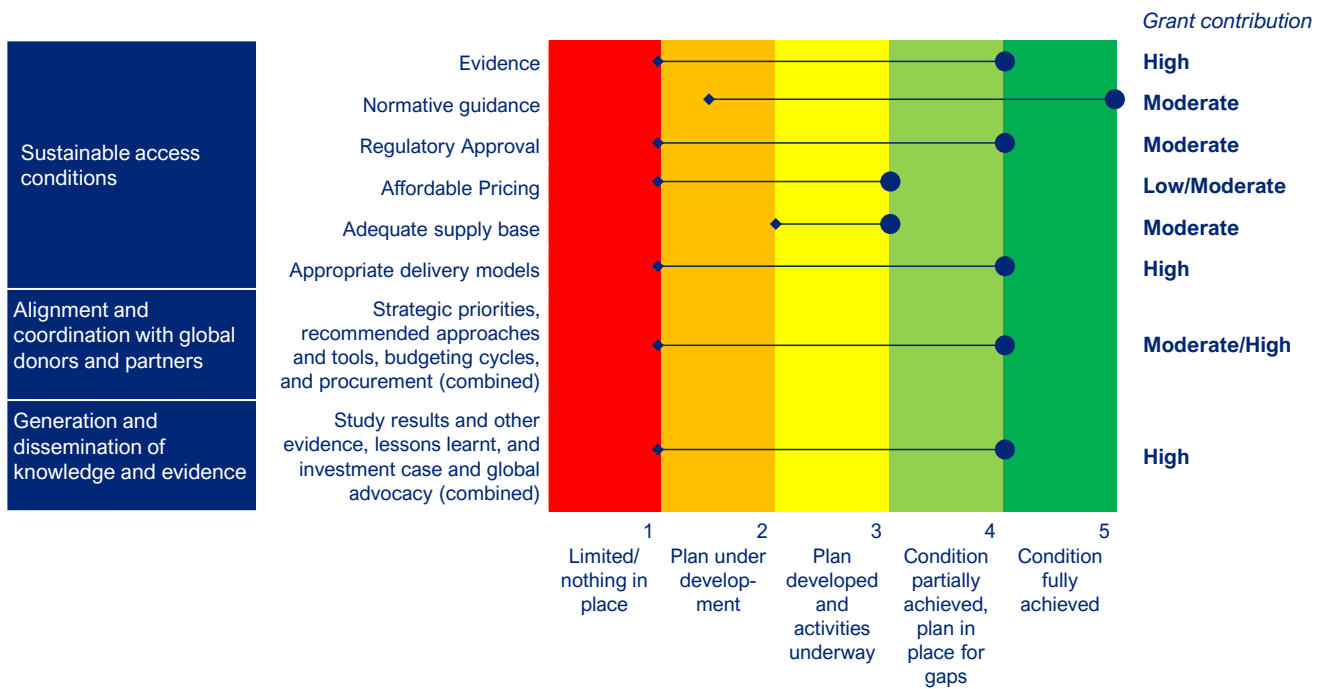
Area	Findings	Strength of evidence
Sustainability and scalability		
Sustainability	<ul style="list-style-type: none"> • EGPAF activities have for the most part been sustained through supporting country policies for EID and effective engagement with government, however there have been some transition challenges with belated donor engagement and transfer to “real-world” settings. Ultimately, EGPAF activities have been sustained given country supporting policies for POC EID. Engagement of stakeholders, particularly at the country level, was generally done well to aid sustainability, especially the MoH (e.g. Kenya, Lesotho, Mozambique, Zimbabwe). Currently the funding for procurement of POC EID for eight out of nine countries has been secured with funding for Kenya being delayed but likely to be secured through the Global Fund. Eswatini also had challenges with regard to the transition and a budget extension had to be obtained, but funding has now been secured through the Global Fund for 2021 and 2022.¹⁴⁷ • However, the transition/ handover process has not been smooth on account of insufficient transition planning with belated donor engagement, misalignment of EGPAF project timelines with scale up partner funding cycles without substantial provision of bridging funding and also the challenge of moving from well-resourced and governed EGPAF sites to the “real-world” situation. • While there are commitments for donor funding for POC across most countries, there is a need to ensure that supporting health systems aspects (e.g., sample transport, data systems, waste management systems) are also funded as otherwise these can pose a risk to sustainability (as discussed further in the portfolio section of the main report). 	Moderate
Scalability	<ul style="list-style-type: none"> • For the next few years sufficient funding has been secured to maintain or moderately increase POC EID testing levels but donor funding is generally expected to be limited in terms of significant further scale up beyond what has already been achieved during the grants. For EGPAF supported countries, five out of nine had confirmed funding to maintain or increase the POC EID coverage levels when compared to the 2020 levels with the exception of Kenya which is not confirmed and data was not available for Cote d'Ivoire, Rwanda and Zambia (although for these three countries it is expected that funding will at least be maintained). Maintaining or moderately increasing the existing POC EID coverage should also be considered within the context of the significant scale up in coverage that has been achieved in project countries during the grant period. However, limited additional donor funding acts as a barrier to achieve further significant scale up going forward. The recent updates to PEPFAR guidelines, and the all inclusive pricing arrangements obtained for m-PIMA and GeneXpert platforms may result in an increase in PEPFAR support for POC testing but in general it is not expected that there will be a significant change to funding in the short-term given the current donor focus on optimising existing platforms as well as the viewpoint that POC technologies are still prohibitively expensive for significant scale up given overall constrained funding envelopes. 	Moderate

¹⁴⁷ Further country specific details are provided in the portfolio level section.

Area	Findings	Strength of evidence
	<ul style="list-style-type: none"> <li data-bbox="315 328 1930 547"> The main contribution of the EGPAF grant in terms of the catalysing scale up has been in terms of developing the evidence base for POC EID as well as demonstrating different delivery models. The EGPAF grant has helped generate substantial evidence for POC EID which has been viewed as useful by the range of global and country level stakeholders. The cost-effectiveness work in particular has been critical, although has not been able to generate substantial buy-in from funders on account of the overall unaffordability of POC in comparison to laboratory based, centralised testing. EGPAF’s work at the country level in demonstrating and delivering POC testing successfully has been instrumental in catalysing country interest and adoption, including updating of policies and guidelines. 	

Figure 7.1 below shows a summary of the scalability assessments of the EGPAF grant. They are based on the assessments submitted by the grantees themselves in the Scalability Framework, supplemented by stakeholder interviews for this evaluation and includes CEPA’s independent assessment. The full table of detail can be found in Appendix C. Where ratings here differ from what is presented in the portfolio level assessment, this is because the EGPAF grant focused only on POC EID whilst the portfolio level assessment incorporates POC EID and VL, alongside the portfolio level assessment being for both grants.

Figure 7.1: Global scalability scores for baseline to end of project for the EGPAF grant



◆ shows the baseline rating, ● shows the rating to date. Where markers are in the center of a box, this shows a 0.5 rating, due to the averaging of the scores across the two grants.

7.2. UCPOC GRANT

Table 7.2: Summary of grant specific evaluation for UCPOC

Area	Findings	Strength of evidence
Grant design and implementation		
Relevance	<ul style="list-style-type: none"> • The UCPOC grant, with its wide scope in relation to the needs for HIV molecular diagnostics and system-wide approach, has been very relevant and significant, although its initial design heralded POC in its own regard but rightfully evolved to a more holistic approach and consideration of integration and optimisation priorities over time. The grant has highlighted the need to engage upfront and closely with the range of relevant stakeholders on POC product positioning, including donors for scale up. The overall approach of the UCPOC grant has been on diagnostics systems optimisation, thereby considering the need for POC in relation to the laboratory based, centralised system. Further, the UCPOC grant has been multi-faceted in nature, encompassing national level policy engagement, structuring of pricing deals, considering the full supply chain and health system issues in relation to POC introduction, etc. Given the context of the state of the diagnostics systems in countries, the UCPOC grant has encompassed a range of relevant aspects. The challenge however has been with regards to the initial approach of the grant, wherein POC was heralded in its own regard, although this has been expanded for an appropriate consideration of optimisation and integration issues over time. A large number of stakeholders consider that the UCPOC project should have done more upfront to contextualise its work in terms of the funding plans and priorities of key donors namely PEPFAR and the Global Fund to ensure the grant would have a catalytic impact in support of scale up. 	Strong
Coherence	<ul style="list-style-type: none"> • The design of the UCPOC and EGPAF grants were not in full coherence, including within the UCPOC grant design itself (although the grants played to the strengths of each implementing organisation and were complementary). Some country stakeholders and manufacturers expressed a degree of confusion as to the overall approach and positioning of POC across the two grants. In addition, the UCPOC grant did not adequately define the individual roles of CHAI and UNICEF upfront, with UNICEF being unclear of its precise role in terms of procurement and initially lacking programmatic budget in countries. • The work of ASLM has been a valuable component, especially in terms of sharing evidence and information with members of their network. • Stakeholder coordination at the country level worked well, including national level alignment through the UCPOC grant. In all country case study countries, UCPOC grantees coordinated actively with MoH and key health sector partners for aligned approaches to POC EID and VL implementation. 	Moderate

Area	Findings	Strength of evidence
Efficiency	<ul style="list-style-type: none"> • Although very relevant and useful in terms of content, the experience of the UCPOC grant highlighted inefficiencies with Unitaids grant management model in terms of lengthy and arduous process for reprogramming. Reprogramming resulted in the UCPOC grant's reduced focus on procurement and move to 'proof of concept' and shift to POC and laboratory based, centralised testing including work on the Hologic deal, etc). All of these aspects were very much in line with the evolving landscape and environment for POC and helped re-focus and improve the potential impact of the grant. Whilst grantees generally reported a good working relationship with Unitaids, this was an aspect which was considered to create inefficiencies given the time taken to reprogramme activities. In addition, the reprogrammings reduced the emphasis on POC testing and sent mixed messages regarding POC, as perceived by a large number of external stakeholders, especially manufacturers and country governments. 	Moderate
Access barriers		
Innovation and availability	<ul style="list-style-type: none"> • While not a key area of focus, nor exclusively attributable to the UCPOC grant, the project's work in introducing POC technologies at the country level has contributed to initiating the market for these diagnostics, albeit with some challenges. The UCPOC grant has introduced both GeneXpert and m-PIMA in countries. Out of the 11 UCPOC countries, 11 have POC EID available and nine have POC VL testing available. With these achievements, the grants has contributed to kick starting/ initiating the POC EID and VL diagnostics market in countries. • The supply context remains very challenging for POC technologies, and it is not clear if the market shaping implications of the project were appropriate and most efficient – e.g. expanding monopoly of GeneXpert, supporting m-PIMA when its sustainability is uncertain, etc. • The UCPOC grant worked closely with suppliers to inform new technology development, mainly through signalling the expected stronger future market for POC testing. In particular this relates to Lumira Dx and SD Biosensor Standard F technologies which are currently expected to enter the market soon. • The UCPOC grant played a useful role in fast-tracking and facilitating product registrations in countries. <ul style="list-style-type: none"> ○ The UCPOC grant supported evaluations and regulations with overall success. UCPOC initially leveraged the GeneXpert footprint, so evaluations and approvals for use of this technology was the fastest. In turn, many of the UCPOC grant studies then provided evidence for PQ and contributed to WHO policies. The grant also leveraged pooled data by the EID Consortium to try and reduce number of evaluations required. In 2020, all 11 project countries for UCPOC had at least one EID assay approved, and seven countries had both m-PIMA and GeneXpert assays approved.¹⁴⁸ All nine UCPOC countries targeted for 	Strong/moderate

¹⁴⁸ UCPOC (2021) Consolidated Logframe 23-03-2021

Area	Findings	Strength of evidence
	<p>POC VL assay approval had at least one VL assay approved, and five countries had both m-PIMA and GeneXpert assays approved.</p> <ul style="list-style-type: none"> ○ Beyond the purposes of availability of products being used within these grants, the UCPOC grant helped outline the regulatory pathway for other products. In particular ASLM advocated through their networks for a reduction of in-country evaluations. An example is Zimbabwe where through the work of both grants, updates have been made to streamline the approach for all products being registered in the country. 	
Affordability	<ul style="list-style-type: none"> ● The UPOC grant has played a lead role in terms of improved affordability of diagnostics in terms of the m-PIMA and GeneXpert test prices. In particular, these manufacturers now offer more inclusive agreements and the work under the grant aided the introduction of the Access Care agreement which has improved the service and maintenance agreements with Cepheid. ● Price reductions have been achieved to some extent, although the price point still remains high, especially in comparison to laboratory based, centralised testing, partly due to the COGS and limited procurement volumes. ● The expansion of the Hologic all-inclusive pricing agreement to project countries is a key positive outcome from the UCPOC grant. The key value add of the agreement was (i) to facilitate take up of the Hologic Panther in project countries as this was a new device being introduced; and (ii) to expand the uptake of the all-inclusive pricing approach in countries. The grant significantly contributed to a strong sensitisation of manufacturers and global and country stakeholders on the benefits of an all-inclusive price and move to long term agreements, which is now a requirement for large global purchasers such as PEPFAR. In particular, the project has been linked to PEPFAR’s 2019 RFP which stakeholder feedback indicates reflected a lot of what was included in Hologic’s agreement, ultimately contributing to cost savings. Therefore, Roche and Abbott’s agreements now have more inclusive pricing and this is applied to a number of assays.¹⁴⁹ 	Strong/moderate
Demand and adoption	<ul style="list-style-type: none"> ● The UCPOC grant was instrumental in catalysing the introduction and adoption of POC EID and VL technologies through procurement of essential commodities and work on network optimisation, with greater success for POC EID as compared to POC VL. ● There has been a strong contribution from the grant on evidence generation and informing development of global and country guidelines, more so for POC EID than POC VL. <ul style="list-style-type: none"> ○ CHAI disseminated findings through presentations for the IDC covering topics such as all-inclusive pricing, data systems, KPIs, waste management, laboratory network optimisation, and diagnostics integration, among other topics. 	Strong/moderate

¹⁴⁹ UCPOC (2020), Annual Report for 2019.

Area	Findings	Strength of evidence
	<ul style="list-style-type: none"> ○ Country level examples include: In Zimbabwe, CHAI collaborated with MOH to generate data and evidence for products and interventions introduced including through multi country studies. Evidence was shared in country through the TWGs, regional and global platforms and this played a big role in adoption of POC EID and VL. In Mozambique, during the piloting phase of the UCPOC grant, CHAI worked with the National Health Institute to generate evidence on the feasibility of implementing the real POC approach in primary health care facilities. This resulted in publication of a number of international scientific articles demonstrating that nurses in MCH clinics were able to conduct EID POC testing and produce quality results quickly. In Uganda, the UCPOC grant generated evidence on the impact of POC on increasing access, reducing TAT and improving early ART initiation which compelled MOH and partners to adopt POC for EID into the national system. ○ WHO guidelines: The evidence from the grants was foundational to the global evidence base for POC EID and the strength of some of the findings prompted an upgrading of the WHO recommendation for POC EID in the new 2021 guidelines to 'strong recommendation/ high certainty of evidence' from conditional in 2016. For POC VL, the grant activities were less influential, and the WHO recommendation on POC VL in the latest guidelines is 'conditional recommendation/ moderate certainty of evidence' due to lack of high-quality evidence comparing POC to the current standard of care which is largely based on centralised testing. In addition, the new WHO guidelines recommend that POC VL should be limited to specific priority populations. ○ Country policies: Grant activities were integral in accelerating the development of policies and guidelines in project countries related to POC EID and, to a lesser extent, POC VL. ● Demand creation efforts were incorporated in the grant, albeit belatedly. Whilst some progress was made with regards to clinicians and laboratory staff, beneficiaries/ community level demand remains an area requiring further efforts. The UCPOC grant included demand creation activities through the Diagnostics Community Advisory Board (Dx CAB) in seven countries, UNICEF worked with the Global Network of People Living with HIV (GNP+) to jointly develop a strategic framework and resource pack to promote civil society engagement and community demand creation for POC EID and ASLM's LAbCop work brought together a range of stakeholders, including CSOs.¹⁵⁰ However, many of these activities for the UCPOC grant (especially the work within the Dx CAB) were introduced belatedly. Many interviewees at both global and country levels noted that progress on grant implementation was limited by insufficient consideration of, and funding for, demand creation activities. In addition, despite UNICEF's expertise in advocacy, even within the UCPOC grant it was considered this capacity was not leveraged sufficiently. ● Grant activities played an important role in introducing and normalising the concept of integration. This included emphasising the complementarity of POC and centralised testing and multiplexing (which has also been leveraged under 	

¹⁵⁰ UCPOC 2019 Annual Report

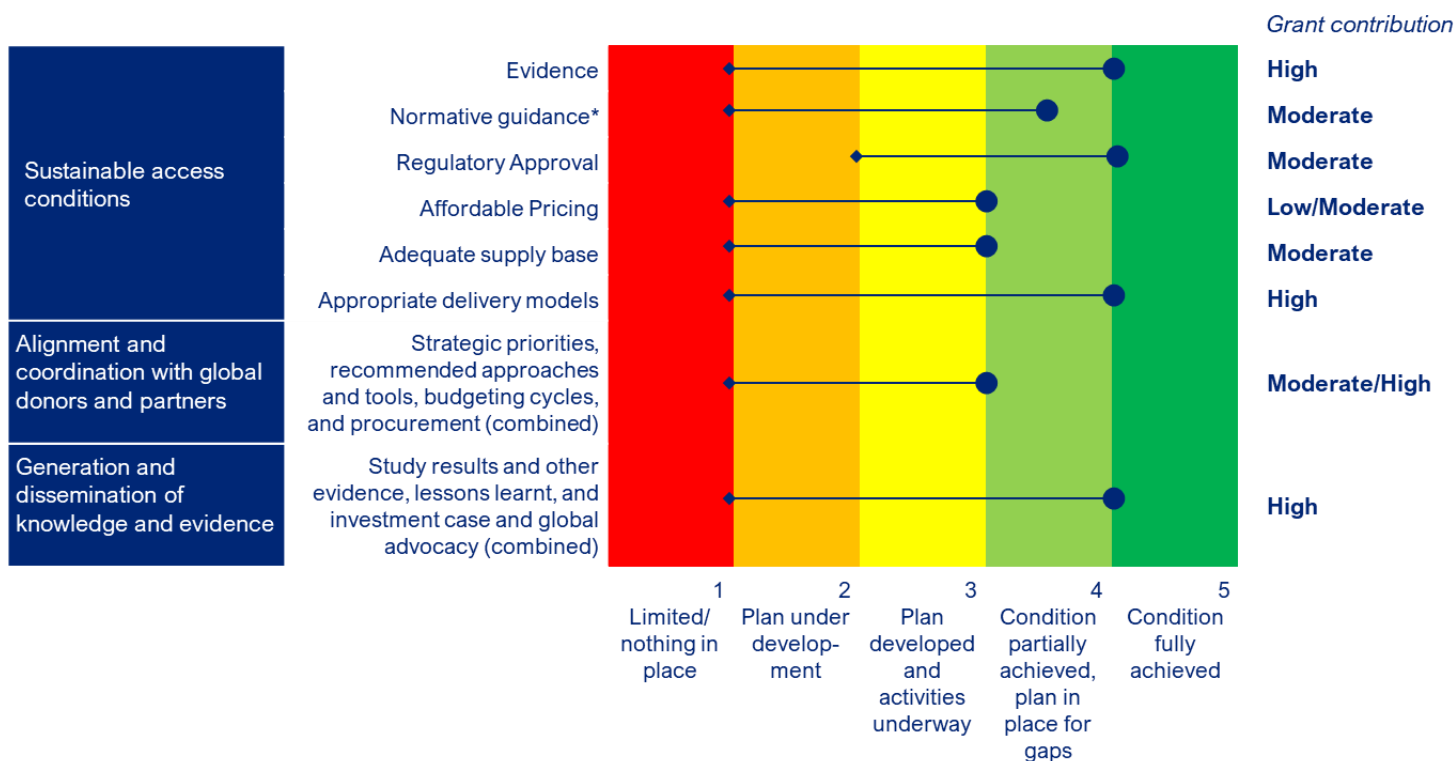
Area	Findings	Strength of evidence
	<p>the ongoing COVID-19 pandemic), but this is an area where further work is needed. In particular, the focus on diagnostic network integration was an invaluable contribution, as it encouraged countries to utilise existing investments/ platforms and leverage opportunities for multiplexing, helping to break down silos in disease programs, although more needs to be done in countries with regards to effective integration.</p>	
Supply and delivery	<ul style="list-style-type: none"> • The grant supported the integration of POC commodities into national supply chain and procurement processes. For example, in Uganda and Mozambique, UNICEF and CHAI assisted MoH in the development of POC EID quantification and forecasting tools and protocols and supported the development of POC data management systems. In Zimbabwe, CHAI utilised the existing system which is mostly funded by USG to deliver commodities to sites. This worked well as the grant did not create a parallel system. • The UCPOC grant worked in several countries to optimise sample transport between sites and molecular laboratories to improve DBS collection procedures and strengthen the central VL and EID systems. The models used were largely successful, although concerns remain about sustainability after grant closure given implementation challenges and need for continued funding. A positive example is from Zimbabwe where CHAI piloted an integrated sample transport system which is now being scaled up nationally with support from the Global Fund. • The UCPOC grant's increased focus on DNO was appropriate and useful as it resulted in countries progressing towards reaching the DNO targets. Overall the DNO work within the UCPOC grant went a long way in aiding countries to determine the most efficient testing, sample transport, placement of devices etc. However further work is needed to implement the DNO findings. • Work under the grant integrated data systems from the grant into country data systems. By end of 2020, across project countries, 456 (93%) EID and 162 (78%) VL sites were connected to the national LIMS. For example, in Zimbabwe, a new national LIMS system for all laboratory results was established in 2018, including but not limited to VL, EID, TB and chemistry and CHAI designed the LIMS programme. In Tanzania, CHAI supported the linkage of data from GxAlert to the national database while PEPFAR supported the installation of routers in all GeneXpert sites. Some countries such as Cameroon did not achieve connectivity targets, in this case due to technical difficulties in configuration with local servers. • The grant helped establish use of POC EID in alternative entry points (e.g., maternity wards, nutrition wards, outpatient departments, etc.), a significant step for advancing identification of infants who are not enrolled in PMTCT programs. For example, in Uganda the reach of POC was improved when access to EID testing was increased beyond the traditional Mother Baby Care Point through the laboratory based, centralised system to include alternative entry points (e.g. paediatric and nutritional wards), which were found to be high yield entry points for HIV positive infants. 	Moderate
Sustainability and scalability		

Area	Findings	Strength of evidence
Sustainability	<ul style="list-style-type: none"> ● UCPOC activities are likely to be sustained post grant given a focus on integrating activities into national processes and engagement so far with donors. So far procurement funding for POC EID has been secured for ten out of 11 countries post the UCPOC grant with some uncertainty around funding only in the Kenya as of April 2021. In addition, procurement funding for four out of the six countries that received POC VL has been secured, with Kenya having reportedly a funding shortage and Tanzania POC VL funding remaining unconfirmed for 2021-22 (after a high procurement from the Global Fund in 2020). Some specific countries examples include: <ul style="list-style-type: none"> ○ In Zimbabwe, sustainability was considered from grant inception and this was demonstrated by plans. CHAI managed to secure commitments for certain activities through Global Fund and PEPFAR. There is general consensus from all stakeholders on the UCPOC grant working with closely with the MoH from grant inception to ensure sustainability. ○ In Mozambique, CHAI and UNICEF worked closely with MoH and main health sector HIV partners from grant inception to optimise buy-in to the POC EID approach. This resulted in a smooth transition to the MoH national PMTCT programme taking over responsibility for training and certification of health workers and in the supervision and mentoring of POC sites, and PEPFAR taking over procurement for POC supplies and maintenance of devices. ○ In Uganda, CHAI and UNICEF worked closely with other donors which has resulted in PEPFAR and Global Fund having committed to supporting 30% of Uganda’s EID testing on POC (with the Global Fund supporting 60% and PEPFAR 40%), on top of their support for laboratory based, centralised EID and VL testing in Uganda. ● While there are commitments for donor funding for POC across countries, there is a need to ensure that supporting health systems aspects (e.g., sample transport, data systems, waste management systems) are also funded. 	Moderate
Scalability	<ul style="list-style-type: none"> ● For the next few years sufficient funding has been secured to maintain or moderately increase POC EID and VL testing levels (although this is less certain for POC VL) but donor funding is expected to be limited in terms of significant further scale up beyond what has already been achieved during the grants. POC EID and VL testing remains heavily dependent on donor funding with domestic funding for POC testing being negligible across project countries. For POC EID, nine countries had confirmed funding to maintain or increase the POC EID coverage levels when compared to the 2020 levels. Only Nigeria which currently is still implementing the UCPOC project, as well as Tanzania, had funding commitments to ensure significant scale up. The funding challenges have been more pronounced for POC VL. Whilst a majority of UCPOC countries managed to secure sufficient funding (Cameroon, DRC, Malawi and Senegal), other countries are reporting funding shortages (e.g., Kenya) or have not secured funding yet (Tanzania). Maintaining or moderately increasing the existing POC EID coverage should be considered within the context of the significant scale up in coverage that has been achieved in project countries during the grant periods. More broadly, the DNO work undertaken within the UCPOC grant has aided political buy in (and funding) as it has helped to legitimise the role of POC within the broader ecosystem and has helped to aid the scalability of POC testing. However, limited 	Moderate

Area	Findings	Strength of evidence
	<p>additional donor funding acts as a barrier to achieve further significant scale up going forward. The recent updates to PEPFAR guidelines, and the all inclusive pricing arrangements obtained for m-PIMA and GeneXpert platforms may result in an increase in PEPFAR support for POC testing but in general it is not expected that there will be a significant change to funding in the short-term given the current donor focus on optimising existing platforms as well as the viewpoint that POC technologies are still prohibitively expensive for significant scale up given overall constrained funding envelopes.</p> <ul style="list-style-type: none"> • The UCPOC grant has made several contributions towards building the environment for scale up, but key challenges remain in terms of limited donor funding and the complex supply base. Some of the main contributions from the UCPOC grant have been the systems wide approach employed in countries and the active working with governments on system optimisation and POC placement within this. The end-to-end working in terms of engaging with governments on policies and guidelines for POC testing, procurement of platforms and delivery/ demonstration of POC testing approaches, and working on the ancillary health systems aspects such as supply chain, waste management and data systems have all been critical to facilitate the introduction and adoption of POC testing for HIV in countries. The grant has also been able to generate substantial and useful evidence, which has directly contributed to updating of WHO guidelines. However perceived high prices within limited donor funding and a limited supply base (while not a direct objective of the grant) remain challenges for significant scale up. 	

Figure 7.2 below shows a summary of the scalability assessments of the UCPOC grant. They are based on the assessments submitted by the grantees themselves in the Scalability Framework, supplemented by stakeholder interviews for this evaluation and includes CEPA’s independent assessment. The full table of detail can be found in Appendix C. Where ratings here differ from what is presented in the portfolio level assessment, this is because the EGPAF grant focused only on POC EID whilst the portfolio level assessment incorporates POC EID and VL, alongside the portfolio level assessment being for both grants.

Figure 7.2: Global scalability scores for baseline to end of project for the UCPOC grant



◆ shows the baseline rating, ● shows the rating to date. Where markers are in the center of a box, this shows a 0.5 rating, due to the averaging of the scores across the two grants.

*Difference in 'After' status. UCPOC reported “Plan under development” for VL, “Condition fully achieved” for EID

8. COUNTRY CASE STUDIES

8.1. CAMEROON (BOTH GRANTS)

Country context: Prior to the start of the Unitaïd supported grants, EID and VL testing in Cameroon were accessible only via the centralised laboratory testing system. Laboratory based, centralised EID and VL testing were only conducted in three central/ regional laboratories covering testing for all the ten regions of Cameroon. National EID coverage was 26.4% with average EID results turnaround time at 35 days, while data on the coverage of VL testing was scarce.¹⁵¹ Long turnaround time for EID and poor linkages to ART initiation were associated with poor paediatric HIV outcomes.

Grant design and implementation:

- Both the EGPAF POC EID and the UCPOC EID and VL grants were highly relevant as they addressed the challenges of limited access, long turnaround time and poor linkages to ART initiation.
- The hub and spoke model improved access to POC EID and VL testing for many health facilities, by establishing a network of 154 sites, including 31 hubs and 121 spokes sites and two standalone sites, with bikers transporting EID samples from spokes to the hub sites on a daily basis.
- Even though the grant reprogramming and lack of budget for community engagement were reported to have affected grant implementation, the Unitaïd grant investments in Cameroon are considered to have addressed a 'major public health issue' by demonstrating that POC technologies can provide better HIV diagnostic testing outcomes and earlier treatment initiation.
- Implementation of the grants was conducted in a participatory manner with involvement of the MoH and engagement of a range of other stakeholders.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

Table 8.1: Summary of progress against access barriers in Cameroon

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> • The grant supported the registration for in-country use of GeneXpert and m-PIMA devices for EID and VL testing. 		Fully achieved
Affordability	<ul style="list-style-type: none"> • EGPAF and CHAI negotiated the prices of Alere q devices and cartridges at \$25,000 and \$25.0 respectively, and GeneXpert devices and cartridges at \$17,000 and \$14.9 respectively. • Grantees also arranged with manufacturers on other marketing options for procurement of devices and cartridges, for countries to 	<ul style="list-style-type: none"> • Stakeholders consider prices of POC devices to be high. • Despite concerns over the cost of the devices and cartridges, the government is committing to making POC EID and VL user-fee free in Cameroon. The cost of POC technologies will therefore have to be borne by external donors or domestic funding. 	Moderately achieved

¹⁵¹ NACC (2017), Rapport annuel 2016 des activites de lutte contre le VIH, le SIDA et les IST au Cameroun.

Access barrier	Key progress	Remaining challenges	Assessment of progress
	<p>choose from, e.g. placement deals in which the manufacturer agrees to provide the devices for free and maintain it for free in exchange for the buyer agreeing to regularly procure a minimum volume of cartridges.</p>		
Demand and adoption	<ul style="list-style-type: none"> • POC EID and VL have been integrated into the national HIV diagnostic/ treatment guidelines and into the national HMIS/ DHIS and monitoring systems and EQA systems. • National Diagnostic Network Optimisation guidelines have been developed and endorsed by the MoH to guide placement of POC devices and referral networks. • The grants supported evidence generation and dissemination on the impact of POC, such as articles and conference abstracts. • POC has been well accepted among HCWs and communities. 	<ul style="list-style-type: none"> • Weak community engagement due to lack of budget for community demand creation. 	Largely achieved
Supply and delivery	<ul style="list-style-type: none"> • The grants enabled the integration of POC EID and VL commodities into the national quantification system. • A coordinated platform for pooled procurement of POC commodities has been created, and is managed by the National AIDS Control Committee (NACC). • The use of bikers is considered to have been effective in facilitating rapid transport of results from spokes to hub sites. • Grantees negotiated to obtain government waivers for customs duty-free importation of WHO-prequalified POC EID and VL testing devices. 	<ul style="list-style-type: none"> • Post-grant stockouts of cartridges occurring at most sites previously supported by EGPAF. COVID-19 caused delays in international commodity shipments. • Lack of POC waste collection and incineration systems in facilities. • Low financial incentivisation of bikers transporting samples and results resulted in low motivation of bikers to provide transport services and therefore high turnover. 	Moderately achieved

Sustainability and scalability: MoH and partners have agreed on scale up plan for EID and VL testing. The Government secured \$40 million in external funding comprised of a loan from the Islamic Development Bank (ISDB) (70%) and a grant from the multi-donor Lives and Livelihoods Fund (30%). These funds will be used to sustain testing in the current POC EID sites (standalone, hubs and spokes) for 3 - 4 years and scale up POC EID and VL. Under the ISDB loan, 45 additional platforms purchased have already arrived in the country. The government's high

dependence on external funding for procurement of devices and cartridges and device maintenance is a major challenge, in addition to the fact that at the current market prices of POC platforms, POC EID and VL technologies will remain unaffordable to the government without external donor support. Other key remaining scalability challenges include unstable electrical supply in health facilities, need for air conditioning rooms for GeneXpert devices (a requirement that many health facilities cannot fulfil), the lack of waste management systems and the unstable transport bikers pool which depends on external funding.

Summary and conclusion: The Unitaid investments addressed a significant public health issue in Cameroon and demonstrated that POC EID and VL testing systems contribute to achieving the targets of national HIV strategies. However, there are concerns about the high set-up costs of the POC technology as well as ongoing costs regarding testing and the government's reliance on external funds to scale up and sustain POC activities.

8.2. KENYA (BOTH GRANTS)

Country context: At the start of the grants, identification of HIV positive children remained low, while linkage to ART for HIV positive infants was suboptimal with significant results not being returned to the caregivers. Only 50% of infants received a timely virologic test and ART coverage of infants was 41% due to limited access to diagnosis, especially in hard to reach areas within the country.¹⁵² In 2014, only two research centres were using POC technology for VL.

Grant design and implementation:

- The grants were relevant in terms of VL and EID testing as they assisted the country to address the marked gaps in EID and VL testing, as well as health system delivery and infrastructure challenges that could potentially be overcome by POC technology (e.g. problems with transmitting results to the caregiver/ patient especially in more remote areas). An improved understanding and awareness of POC technology was needed and UNICEF was in a position to raise awareness of the need for/relevance of POC interventions, especially for child health programs.
- Initiation of POC testing for EID and VL was aligned with national plans and policies. The grants were designed in close collaboration with the MoH and the National HIV Reference Laboratory and aligned with stakeholders through the establishment of a POC TWG, including: Kenya MOH National AIDS and STI's Control Programme (NAS COP), the National HIV Reference Laboratory (NRL), grantees, PEPFAR, the Global Fund CCM, the Kenya Medical Supplies Authority (KEMSA), county governments and CSOs.
- Overall CHAI, UNICEF and EGPAF collaborated well together, illustrated by the joint production of a toolkit to assist counties in evaluating the criteria for making site selection decisions.
- The POC model for most of Kenya, and which was also adopted by both EGPAF and CHAI, is the hub and spoke model. The result of the two systems operating together is the widespread availability of EID and VL testing by either centralised or POC platforms.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

¹⁵² EGPAF (2019), End of Project Report

Table 8.2: Summary of progress against access barriers in Kenya

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> GeneXpert was registered and authorised by the national program and the m-PIMA was registered. However only the GeneXpert was authorised because of the high cost of the mPIMA device, equipment and supplies. 	<ul style="list-style-type: none"> Product registration in Kenya is time consuming due to national processes requiring in-country product evaluations. 	Moderately achieved
Affordability	<ul style="list-style-type: none"> The average cost of a test has reduced from \$25 to \$16-18. 	<ul style="list-style-type: none"> The cost of the devices are considered to be expensive and a barrier to further uptake. 	Slightly achieved
Demand and adoption	<ul style="list-style-type: none"> Only two research sites using POC in 2014 now expanded to 500 POC sites in the country. Progress from no demand to high demand for POC as evidenced by acceptance by HCWs and reaction from community when services were terminated. Testing coverage continued to increase over the course of the project. Inclusion of POC for EID and VL within elimination of MTCT Guidelines, roadmap to roll out POC for both EID and VL, guide to optimise diagnostic platforms. Formation of a POC TWG. 	<ul style="list-style-type: none"> Need to work with CSOs to maintain momentum regarding demand generation, create advocacy and awareness Need to expand TWG to include labs, clinics, CSOs especially to facilitate demand creation. 	Moderately achieved
Supply and delivery	<ul style="list-style-type: none"> Delays of clearance of goods and supplies including for POC somewhat reduced. Integration of national network and the hub and spoke model has reduced number of stockouts through improvements of the HMIS and linking the systems. 	<ul style="list-style-type: none"> More work needed to reduce supply delays which affects a range of products including POC. Processes still need more improvement for monitoring of POC stock supplies. 	Moderately achieved

Sustainability and scalability:

- Grantees managed to obtain interest from external donors to support POC EID and VL POC. In addition, there are some discussion of options for government domestic funding support but continued high donor dependency (currently 100%) of the POC commodities.
- EGPAF supported the development of a multiplexing policy to guide the country on multiplexing. All 34 sites supported by CHAI were also multiplex sites (TB and HIV), and two of these sites are also part of the ongoing HPV Pilot (integrating TB, HIV and HPV). This multiplexing may support continued uptake and funding through other programs.

- There was an issue with EGPAF project transition and funding. Delay in start-up led to an early closing of the project before a transition plan could be operationalised. With no other source of funding immediately available, POC testing at the EGPAF study sites ceased (covered for some months by CHAI but that ceased in September 2020).
- Funding for POC EID and VL testing is part of the Global Fund grant proposal which is still currently being negotiated as of April 2021 and not yet confirmed. Funding shortfalls are more likely to impact VL with only 10% of the total funding needed for POC VL testing among pregnant and lactating women and suspected treatment failures has been identified.
- Management and administration of the CHAI programme has been handed over to the MoH. Within the MoH, opportunities are being sought to leverage resources from other existing or emerging programmes to support POC.
- Trainings and quality management are areas that will require continuous support and attention in order to maintain and continue to scale up quality POC testing.

Summary and conclusion: POC testing for EID and VL now exists in Kenya where it did not exist six years ago. This has contributed to increased coverage and access, reduced test turn-around times, and more infants initiated on treatment. Most respondents agreed that without the grants, POC would not be on the Kenya national health agenda. Furthermore, the majority of interviewees consider that POC is now “*engrained*” in the national programme, with enough advocates at a high level to ensure that support will be found to sustain the programme.

A challenge is that POC testing in Kenya is entirely donor-dependent and Kenya would like to see less dependency on donors to ensure sustainability. While it promising that both PEPFAR and the Global Fund are likely to provide some support to POC interventions in the next few years, it will not be sufficient to guarantee future sustainability.

It is broadly recognised that a major lesson learned from the project is the need to develop a workable transition plan early on and included in discussions with country and other stakeholders during the project life cycle.

8.3. LESOTHO (EGPAF GRANT ONLY)

Country context:

Prior to the implementation of the EGPAF project, EID testing was only available through laboratory based, centralised testing, in the National Reference Laboratory in Maseru, on only one existing platform according to stakeholders. With the second highest HIV prevalence in the world at 23.5%,¹⁵³ low EID testing coverage of 55%,¹⁵⁴ and a combination of difficult terrain and backlog of tests at the central lab causing a median turn around time of 63 days,¹⁵⁵ Lesotho had an urgent need for POC EID.

Grant design and implementation:

- The EGPAF grant was highly relevant given (i) long TATs for EID in the central laboratories and low coverage rates for EID and (ii) POC EID had not previously been piloted.
- Engagement and alignment with the MoH and other partners was mostly successful with regards to collaboration during the grant and support to develop strategies and plans. This was aided by the sharing of

¹⁵³ In adults over age 15. UNAIDS epidemiology estimates (2020) for 2015 – People living with HIV All ages

¹⁵⁴ EGPAF (2019) End of Project Report - Original Baseline for 2014/15 Global AIDS Response Progress Report

¹⁵⁵ EGPAF (2018) Updated Logframe (November 2018)

information in the TWG and engaging the MoH in the project from the start. Engagement with donors was considered to be weaker in terms of collaboration and alignment.

- There were only minor issues in relation to efficiency such as some reported stockouts and cartridge wastage during project implementation, and a delay in the pilot project implementation but these did not jeopardise the success of the project.
- Overall the grant activities were well designed. Stakeholders expressed that the hub and spoke model with staggered roll out was effective, that platforms were appropriately placed and the sample transport system worked well through a collaboration with MoH partner, Riders for Health. EGPAF’s approach has worked well for sustainability, particularly due to the inclusion of the MoH early in the project and training MoH staff. The grant achieved its targets for TAT, number of tests and proportion of HIV positive infants initiated on treatment.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

Table 8.3: Summary of progress against access barriers in Lesotho

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> • National approval of POC devices was straightforward as Lesotho accept WHO PQ as sufficient for regulatory approval in country.¹⁵⁶ 		Fully achieved
Affordability	<ul style="list-style-type: none"> • EGPAF negotiated prices on a global level. Nothing of note on country level for pricing. 	<ul style="list-style-type: none"> • Stakeholders in Lesotho view commodities as still too expensive, especially the m-PIMA cartridge price. 	Moderately achieved
Demand and adoption	<ul style="list-style-type: none"> • EGPAF worked closely with MoH to share information, data and programmatic lessons learned about POC EID throughout the project, resulting in national support for POC EID. • In 2019, at the end of the grant, overall EID testing coverage had improved from 55% to approximately 70%.¹⁵⁷ • POC EID accepted into policies and strategies. • EGPAF collaborated with CSOs to raise the visibility of POC EID activities amongst HCWs which was considered to work well. 	<ul style="list-style-type: none"> • Still room for increase in EID coverage from 70% at end of project. The COP 2020 explains that by the end of 2020, the split is expected to be 95% POC EID, and 5% laboratory based, centralised.¹⁵⁸ • POC VL is to be rolled out for PBFW (POC VL was not an aim of the grant, but the grant has influenced this).¹⁵⁹ 	Fully achieved

¹⁵⁶ EGPAF (2019) End of project Report

¹⁵⁷ EGPAF (2019) End of Project Report for Lesotho

¹⁵⁸ PEPFAR (2020), Country Operational Plan 2020 Strategic Direction Summary.

¹⁵⁹ PEPFAR (2019) Country Operational Plan for 2019

Access barrier	Key progress	Remaining challenges	Assessment of progress
	<ul style="list-style-type: none"> • POC integrated well into national system. Devices were well placed, and use of Riders For Health for sample transportation is working well. 		
Supply and delivery	<ul style="list-style-type: none"> • POC testing procurement integrated into the national supply chain. • EGPAF aided sites with quantification, forecasting and procurement ordering. • Hub and spoke design for POC, and site selection criteria were well done. • EGPAF aided the collection of site data, registers, logbooks and testing forms for infants. These have now been adopted by MoH. • EGPAF engaged staff for data collection and monitoring and trained MoH staff to train machine operators. 	<ul style="list-style-type: none"> • MoH require ongoing capacity building for quantification and forecasting. • Concerns regarding the sustainability of health system aspects if POC testing if volumes increase (e.g. sample transport, availability of HCWs) • POC wastage policy still to be designed. 	Largely achieved

Sustainability and scalability:

- Project activities have been sustained post grant closure and in general there was a smooth transition of activities. This is attributed in particular to the close working with the MoH from the start of the project. In addition, the project has had a particularly strong impact on the demand and adoption of POC EID.
- Through donor support, there is financial sustainability for commodities and supporting activities which were undertaken within the grant. However, this financial support was secured only close to the end of the grant (three months before project close) which risked a smooth transition. In particular the Global Fund was engaged late in the process. EGPAF helped to facilitate donor funding from PEPFAR and Global Fund for reagents and consumables for after the grant.
- The long term financial sustainability of POC activities is uncertain given Lesotho's reliance on donor support. At this stage there are no plans for further POC scale up in relation to the number of platforms, however there are plans to scale up the testing coverage subject to funding. With PEPFAR support, the COP 2019 guidance, VL will be rolled out for PBFW, and COP 2020 explains that by the end of 2020, the split is expected to be 95% POC EID,¹⁶⁰ and 5% laboratory based, centralised testing.¹⁶¹

Summary and conclusion:

Stakeholders were overwhelmingly positive regarding the work undertaken under within the project. Lesotho is considered to be a best practice example of involvement of the MoH early in the project process and throughout the grant activities. The project is also considered to have been a success due to the significant public health impact, especially in relation to the reduction in TAT and an improvement in EID testing coverage from 55% to 70%.¹⁶²

¹⁶⁰ PEPFAR (2019) Country Operational Plan for 2019

¹⁶¹ PEPFAR (2020) Country Operational Plan 2020 Strategic Direction Summary

¹⁶² EGPAF (2019) End of Project Report

8.4. MOZAMBIQUE (BOTH GRANTS)

Country context: Mozambique has a high general HIV prevalence of 13.2%; 2.2 million PLHIV, of which 1.2 million on ART; PMTCT coverage is still low at 85% with 16,000 infants are born to HIV-infected women annually, representing 11% of all new infections in the country.¹⁶³ Before the Unitaid investments, EID and VL testing in Mozambique only took place using the laboratory based, centralised system, with samples being sent to five regional reference laboratories covering large distances.

Grant design and implementation:

- The UCPOC and EGPAF grants were highly relevant in Mozambique as they allowed the MoH and partners to test and roll out POC technologies to improve EID testing coverage and accelerate ART initiation for HIV exposed infants (HEIs), addressing the high turnaround time of EID results with only 63% of HEIs receiving their EID results within 6 weeks, and 33% of HEIs not receiving test results within 18 months.¹⁶⁴
- The National Health Institute, MoH and partners opted for the standalone POC site model in view of Mozambique’s high HIV prevalence, large distances between health facilities and weak transport links. They furthermore preferred the real POC approach of nurses in MCH wards operating the testing in a ‘one-stop’ service and found nurses capable of conducting quality testing and results reporting.¹⁶⁵
- The results of the initial pilot conducted by CHAI and the National Institute for Health in 12 sites during 2016-2017 influenced policy making at national level and resulted in the government adopting the POC approach for EID testing in 2017 as complementary to the laboratory based, centralised EID testing system. This then laid the foundation for the UCPOC and EGPAF grants to support scaling up the EID POC sites to 130.
- The participatory approach used by CHAI in the implementation of the UCPOC grant with early and intensive engagement with the MoH, National Institute for Health and key partners contributed to the success of the pilot phase (supported by the UCPOC grant) and the scale up phase (supported by both UCPOC and EGPAF) and the translation of evidence into policy making at national level.
- Mozambique is seen by stakeholders as a best practice example in the Southern African region in quickly rolling out and scaling up its “real” POC approach in EID testing undertaken by nurses in the MCH / paediatric HIV services in primary health care facilities.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

Table 8.4: Summary of progress against access barriers in Mozambique

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> • Through the grant, the registration of m-PIMA devices was supported. 	<ul style="list-style-type: none"> • VL POC products not yet registered as pilot still ongoing and 	Moderately achieved

¹⁶³ MISAU (2020), Plano Nacional de Tripla Eliminação da Transmissão vertical do HIV, Sífilis e Hepatite B em Moçambique 2020-2024 (MoH (2020), *National Plan for triple elimination of vertical transmission of HIV, Syphilis and Hepatitis B in Mozambique 2020-2024*).

¹⁶⁴ MISAU (2020), Plano Nacional de Tripla Eliminação da Transmissão vertical do HIV, Sífilis e Hepatite B em Moçambique.

¹⁶⁵ Meggi, B. et al., (2018), Performance of point-of-care birth HIV testing in primary health care clinics: An observational cohort study. PLoS ONE, Eduardo Mondlane University.

MISAU (2020), Plano Nacional de Tripla Eliminação da Transmissão vertical do HIV, Sífilis e Hepatite B em Moçambique 2020-2024

Access barrier	Key progress	Remaining challenges	Assessment of progress
		decision on national adoption not made yet.	
Affordability	<ul style="list-style-type: none"> • Costing study of EID POC system conducted by National Health Institute supported by the UCPOC grant considers costs of technology justified in view of benefits obtained. • EID POC testing is free for users. 	<ul style="list-style-type: none"> • Country fully dependent on donor funding for procurement of devices and reagents, and maintenance and therefore affordability considerations need to be made in this regard despite country stakeholders currently of the opinion that the devices are affordable especially given the public health benefit. 	Moderately achieved
Demand and adoption	<ul style="list-style-type: none"> • Rapid piloting of EID POC technology, preceded by feasibility assessments led by the National Health Institute and MoH. • POC EID has been adopted in Mozambique's national HIV guidelines and national EID implementation plan. • The POC system increased the proportion of HIV exposed infants tested for EID within 6 weeks of birth to 85% in 2020 in POC sites.¹⁶⁶ • VL POC is being tested in pilot study. 	<ul style="list-style-type: none"> • Community demand creation is an area noted to require further attention. It was not a priority in the grants due to limited funding. • VL POC still being piloted and therefore not adopted yet. 	Moderately achieved
Supply and delivery	<ul style="list-style-type: none"> • Standalone POC site model considered to work well as providing immediate results to infants and parents. Real POC approach also found effective in reducing loss to follow up as the same nurse is providing mother and child health consultations and conducting the EID test. • Supply and delivery of cartridges (including quantification) has been fully integrated with country system. • The grants supported the strengthening of the M&E system with regards to POC. 	<ul style="list-style-type: none"> • Continuing challenges with HR capacity in Mozambique. • System still dependent on provincial health sector partners for distribution of EID POC supplies from provincial warehouses to POC facilities and transport of faulty devices to Maputo for maintenance. 	Largely achieved

¹⁶⁶ Data communicated by the grantees.

Access barrier	Key progress	Remaining challenges	Assessment of progress
	<ul style="list-style-type: none"> The MoH PMTCT programme is now taking charge of training and certification of health workers. Waste management systems in health facilities are considered adequate for dealing with m-PIMA cartridges. 		

Sustainability and scalability:

- There is no indication of long-term financial sustainability of the POC system. Mozambique is entirely dependent on external donor funding for procurement of POC devices and reagents and for device maintenance.
- MoH would like to scale up to and have another 100 devices. However the priority is currently to sustain the current system of 130 EID POC sites and further domestic or external funding has not been secured to support further scale up. Given the approach that Mozambique would like to adopt for ‘true POC’ and the cost of the devices, this may be particularly challenging.

Summary and conclusion:

Mozambique is considered a best practice example of quick government-led testing and roll-out of a “real” POC approach in EID testing conducted by nurses in Mother and Child Health wards and in stand-alone sites. Unitaïd investments enabled pilot testing EID and VL POC technology and facilitated the national adoption and scale up of EID POC diagnostics in the country, leading to reducing EID result turnaround times (the average EID TAT was reduced from 80 to 14 days) and accelerating ART initiation for infants (with 95% of identified infants initiated on ART).¹⁶⁷ However, a challenge is that no domestic or external funding has been secured to enable further scale up the EID POC system to additional sites so that additional facilities can benefit.

The strong early engagement of CHAI with national stakeholders contributed to the success of the EID POC pilot, the fast national adoption of the technology and the transition to PEPFAR taking on supporting 100% of the procurement and maintenance for the POC EID system in the country.

8.5. UGANDA (UCPOC GRANT ONLY, EID ONLY)

Country context: The MoH has implemented centralised EID testing using DBS samples since 2007, with marked improvement in access to 2,425 (over 95%) health facilities and 115,000 annual tests by 2016.¹⁶⁸ However, despite this marked growth health in facility access and test numbers, access to HIV exposed infants still remains sub-optimal at only 56% of HIV-exposed infants receiving tests (despite nearly 10 years of EID implementation), and only 35% receiving the test by 8 weeks of age. Only EID testing was conducted under this grant, not VL testing.

Grant design and implementation:

- The UCPOC grant was highly relevant and much needed in Uganda given the limited access to EID testing using the laboratory based, centralised system.

¹⁶⁷ Data communicated by the grantees.

¹⁶⁸ Central Public Health Laboratories (2018), EID programme data.

- CHAI and UNICEF engaged actively with the MOH, and project planning was done in conjunction with a range of stakeholders. A challenge was belated engagement with donors and implementing partners in the country, which delayed the national adoption of the POC technology by the country and its integration into the laboratory based, centralised EID programme.
- The project was initially rolled out as a laboratory-centred approach, and then expanded to include the HIV programme teams due to challenges with the initial roll out. This was an important learning from the project and the revision in approach to have both laboratory and programmes teams working in conjunction at all levels was important to support improved access to HIV exposed infants and action on results. The reach of POC was improved when access to EID testing was increased beyond the traditional Mother Baby Care Point (MBCP) through the laboratory based, centralised system to include alternative entry points (e.g. paediatric and nutritional wards), which were found to be high yield entry points for HIV positive infants.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

Table 8.5: Summary of progress against access barriers in Uganda

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> • The grant employed multiple devices in country (GeneXpert, m-PIMA and SAMBA) to assess suitability for country needs. • CHAI strongly advocated for use of WHO PQ to reduce country registration requirements but were not successful. 	<ul style="list-style-type: none"> • The Central Public Health Laboratories (CPHL) continues to conduct in country validations for each new device used in country, to which CHAI and UNICEF provided assistance. 	Moderately achieved
Affordability	<ul style="list-style-type: none"> • The CHAI/UNICEF grant negotiated cartridge price reduction of Alere q from \$30 to \$25, and of GeneXpert from \$17.95 to \$14.90. 	<ul style="list-style-type: none"> • Stakeholders expressed concern over the high price of POC versus laboratory based, centralised testing. 	Slightly achieved
Demand and adoption	<ul style="list-style-type: none"> • POC EID has been adopted in Uganda's HIV consolidated guidelines and in the national EID implementation plan. • The pilot showed a 245% increase in EID testing using POC and a 245% increase in identification of HIV positive infants using EID POC.¹⁶⁹ • The grant supported training of health workers, supervisors and of policy makers for demand creation. • The EID POC networks have been well integrated with the laboratory 	<ul style="list-style-type: none"> • No national policy developed yet on POC VL (as MoH decided not to pilot test POC VL approaches and the grant therefore did not include support to POC VL). • Demand creation within the community and CSOs is still lacking. 	Moderately achieved

¹⁶⁹ MOH (2018), EID POC Implementation Report in Partnership with CHAI and UNICEF.

Access barrier	Key progress	Remaining challenges	Assessment of progress
	based, centralised EID system as one programme.		
Supply and delivery	<ul style="list-style-type: none"> • Supply and delivery of cartridges (including quantification) has been fully integrated with country system. • A sample transport system was established using motorbikes. • Waste management systems were established with cartridges transported to sites with incinerators. • In order to address the device interface challenges, the grant assisted the introduction of the ALIS laboratory information management system. 	<ul style="list-style-type: none"> • Data entry and connectivity still pose challenges with regards to the POC system and further strengthening of the LMIS is needed in relation to the integration of POC. • Continuing challenges with HR capacity due to high turnover of health workers in facilities which results in requirement to continuously train newly arrived health workers on operating the POC system. • Immediate return of results from the hubs to the spoke sites is a challenge because spokes are visited only once or twice a week. 	Moderately achieved

Sustainability and scalability:

- MoH and partners have agreed on a scale up plan in order to shift 30% of all EID testing in country to POC technology. Scale up has already started and 100 additional new sites have been added to the 33 pilot sites. In order to achieve this, the existing 133 devices will be optimised before bringing in any additional POC devices.
- Stakeholders consider that given the high unit cost per test for POC EID, and the intensive health systems demand POC EID puts on the already weak health system in Uganda, the use of POC EID should be reserved for high yield stations like paediatric and nutrition wards - which the laboratory based, centralised EID system does not cover – and where it still makes sense. There is still no agreed position on the introduction of POC VL for PBFW.

Summary and conclusion:

This grant contributed to identifying the HIV positive infants which the laboratory based, centralised testing would not have been able to identify. It helped the laboratory based, centralised EID programmes to discover the cause of the gap between the numbers of identified HIV positive infants and the expected numbers, and to develop the tools/strategies to narrow that gap of the 25% of HIV exposed infants not captured in the Mother and Baby Care Points.¹⁷⁰ If the POC EID intervention is taken to scale in that context, it will help the national EID programme to increase coverage for the HIV exposed and positive infants and support meeting the national and global targets of ending PMTCT and paediatric HIV.

Stakeholders consider that POC should be supported because it is impactful in EID by enabling the reaching of babies in alternative entry points which the laboratory based, centralised system cannot adequately reach, while considering that laboratory based, centralised testing should remain the backbone of the national EID programme complemented by POC.

¹⁷⁰ MOH (2018), EID POC Implementation Report in Partnership with CHAI and UNICEF

Grant implementation showed that to establish a functional POC system requires not only the procurement of the device but also significant health systems strengthening investments, including human resource capacity building, logistics and equipment management system, quality assurance systems, data management and M&E systems etc. Stakeholders observed that POC should not be rolled out as a vertical programme, but as part of the national laboratory network with proper integration with the national laboratory based, centralised EID programme, and recommended that since POC exerts a lot of burden to the already weak health system, its scale up in Uganda should be undertaken consciously and thoughtfully, with proper prior planning for the required health system investment.

8.6. ZIMBABWE (BOTH GRANTS)

Country context: Prior to the Unitaid grants, samples for EID and VL were centrally processed at three central labs. EID experienced challenges with sample transportation, long TAT for return of results, rejected samples, lost samples and loss to follow up of HIV exposed infants. VL testing was also lagging behind and by 2014, a total of 28,211 patients (3.3% of PLHIV on ART) had received VL testing, and CD4 testing was still the preferred monitoring method. EID and VL testing coverage were at 54.9% and 3.3% respectively.¹⁷¹

Grant design and implementation:

- Both grants were considered to be highly relevant and much needed. Stakeholders agreed that the grants were implemented well, introduced interventions that were timely to make significant positive shifts and aimed to address health systems issues such as sample transport.
- Use of POC for CD4 testing before both grants had provided an enabling environment for POC VL and EID introduction.
- The grant made use of existing national level platforms for communication, and hence were well aligned with national systems. Information and updates regarding the grants were shared through existing platforms which worked well especially through engagement with the Ministry of Health and Child Care (MOHCC) who provides strong leadership for the TWGs and HIV diagnostics more broadly.
- The two grants generally were well synergised with CHAI focusing more on upstream aspects and EGPAF focusing more on site-specific work and trialling a new model. However, there were some internal differences with different proposed approaches which caused some challenges at times.
- There were some delays which affected implementation of the grants, especially relating to when the POC products became available. As one stakeholder said, “*we have to make it work even if a product is actually near POC and not actual POC*”.
- The UCPOC grant was considered to have been appropriately reprogrammed to shift towards the inclusion of laboratory based, centralised testing.

Access barriers: The table below outlines key progress at the country level with regards to the access barriers.

¹⁷¹ Ministry of Health and Child Care (2016) Zimbabwe VL scale up Plan (2015-2018)

Table 8.6: Summary of progress against access barriers in Zimbabwe

Access barrier	Key progress	Remaining challenges	Assessment of progress
Innovation and availability	<ul style="list-style-type: none"> • UCPOC grant facilitated registration of POC VL and EID devices. • UCPOC grant helped to create a clearer and faster process for product registration utilising evidence from pooled results from other counties for registration. 		Largely achieved
Affordability	<ul style="list-style-type: none"> • Reduction in price and negotiation of all-inclusive price per test, brought prices down at the global level. This has led to Zimbabwe seeking more inclusive pricing arrangements with other manufacturers for POC and laboratory based, centralised testing prices.¹⁷² • Cepheid: \$17,000 (device), and \$14.90 (test). for near POC. Abbott: \$15,000 (device) and \$20 (test) for POC EID. • Hologic: all-inclusive pricing achieved at \$12.00 per patient test for laboratory based, centralised testing. 	<ul style="list-style-type: none"> • Stakeholders consider the cost of POC to be still expensive, especially the m-PIMA cartridge price. 	<p>Moderately achieved for POC</p> <hr/> <p>Largely achieved for Hologic</p>
Demand and adoption	<ul style="list-style-type: none"> • EGPAF and CHAI work supported a number of pilots, assessments to generate evidence and shared evidence, locally and globally. • CHAI, UNICEF, and EGPAF worked with MoH and other stakeholders to have policies around POC EID/ VL updated or developed and accepted into policy and strategies. • CHAI collaborated with a civil society to raise the visibility of POC EID activities. • Laboratory based, centralised testing and POC well integrated. • HIV and TB programme both utilising GeneXpert devices following an influential study undertaken by CHAI demonstrating that the platforms have enough capacity to be utilised by both programmes without compromising delivery. • POC VL has been earmarked for pregnant and breastfeeding women, Children, and “urgent” VL needs 		Largely achieved

¹⁷² In Zimbabwe, CHAI negotiated for an all-inclusive price of \$12 price for MOH against established developers who were pegged at \$17.80 for Roche and \$19.90 for Abbot for laboratory based, centralised VL/EID testing. This allowed competition and developers reduced their process. Also, m-PIMA was offered at \$20 all-inclusive (including service and maintenance) down from \$25 per cartridge and \$1,000 per year for service and maintenance.

Access barrier	Key progress	Remaining challenges	Assessment of progress
Supply and delivery	<ul style="list-style-type: none"> • Both grants integrated procurement of POC EID/ VL into the national supply chain system, and commodities were distributed from the central warehouse. • CHAI provided technical expertise for quantification and forecasting. • EGPAF piloted hub and spoke in a phased approach, and worked with DHE to optimise existing resources • EGPAF trained MoH staff to train machine operators. • CHAI piloted an integrated sample transport network which is now being scaled up nationally by the Global Fund. • The MOHCC have accepted roll out of connectivity for all of EGPAF's platforms to monitor real time machine performance and consumption. All the platforms are now connected either to GxAlert or DataPoint connectivity solutions. 	<ul style="list-style-type: none"> • Post-grant stockouts of cartridges occurring at most sites previously supported by EGPAF. • Sample transport challenges starting to emerge post grant support due to gaps in funding. • High staff turnover and retention of HCWs is an ongoing concern. • Waste disposal of Cepheid cartridges is still a challenge that needs to be resolved. 	Largely achieved

Sustainability and scalability: In the immediate future, there are financial commitments through donor support. Global Fund will support: (i) integrated sample transportation; maintenance and service of devices and (iii) procurement of cartridges for GeneXpert, Samba, and m-PIMA. PEPFAR has committed to support (i) decentralisation of laboratory based, centralised EID platforms, (ii) integrated specimen transport system, (iii) EID cartridges for POC machines, (iv) support and procurement of five Hologic platforms which has been fully integrated into the PEPFAR programme and (v) QA for POC in 2021, although there is limited funding for reagents. However, it is not sustainable for the long term and stakeholders would like to see the government of Zimbabwe take on some of these costs. The cost of POC remains high, proving to be a threat to its sustainability. At this stage there are no plans for further scale up in terms of procuring devices but rather to continue with the existing testing levels using existing devices.

Summary and conclusion:

The grant facilitated the development and updating of policies and guidelines for POC and laboratory based, centralised machines and successfully introduced the complementarity of POC and laboratory based, centralised systems, strengthening the lab systems to improve efficiencies of both systems. The projects are considered to have had a significant public health impact, especially in relation to the reduction in TAT time and ART initiation from 36 days to one day and to a lesser extent, an improvement in EID testing coverage from 54% to 56%.¹⁷³ The grant managed to negotiate for reduced costs for both cost per test and service and maintenance bringing cost savings to the system and the Hologic all-inclusive pricing agreement is considered to be a significant achievement. However, stakeholders expressed the cost of POC still remains expensive which is the main barrier to further scale up.

¹⁷³ Zimbabwe PMTCT Program data (2019)



UK

Queens House
55-56 Lincoln's Inn Fields
London WC2A 3LJ

T. **+44 (0)20 7269 0210**

E. **info@cepa.co.uk**

www.cepa.co.uk

 **cepa-ltd**  **@cepaltld**

Australia

Level 20, Tower 2 Darling Park
201 Sussex St
Sydney NSW2000

T. **+61 2 9006 1307**

E. **info@cepa.net.au**

www.cepa.net.au