



UNITAID

**END-OF-PROJECT EVALUATION – MSF GRANT ON IMPLEMENTATION OF
CD4 AND VIRAL LOAD TESTING IN RESOURCE-LIMITED SETTINGS**

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FINAL REPORT

Submitted by:

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ACRONYMS AND ABBREVIATIONS

Acronym	Full description
ART	Antiretroviral Therapy
BM	BioMérieux
CAG	Community ART Group
CCM	Country Coordinating Mechanism
CHAI	Clinton Health Access Initiative
CSO	Civil Society Organisation
DRC	Democratic Republic of the Congo
DRW	Diagnostics for the Real World
EAC	Early Adherence Counselling
EID	Early Infant Diagnosis
ERPD	Expert Review Panel for Diagnostics
HCW	Healthcare worker
ITPC	International Treatment Preparedness Coalition
KPI	Key Performance Indicator
LTFU	Lost to Follow-Up
M&E	Monitoring and Evaluation
MOH	Ministry of Health
MOU	Memorandum of Understanding
MSF	Médecins Sans Frontières
OCB	MSF Operational Centre Brussels
OCG	MSF Operational Centre Geneva
OCP	MSF Operational Centre Paris
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PLHIV	People living with HIV/AIDS
POC	Point-of-Care
TAT	Turnaround Time
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV and AIDS
VL	Viral Load
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification

EXECUTIVE SUMMARY

This report presents Cambridge Economic Policy Associates' (CEPA's) findings, conclusions and lessons learnt from an end-of-project evaluation of the Unitaid grant to Médecins Sans Frontières (MSF) on "Implementation of CD4 and viral load testing in decentralised, remote and resource-limited settings in MSF HIV programmes".

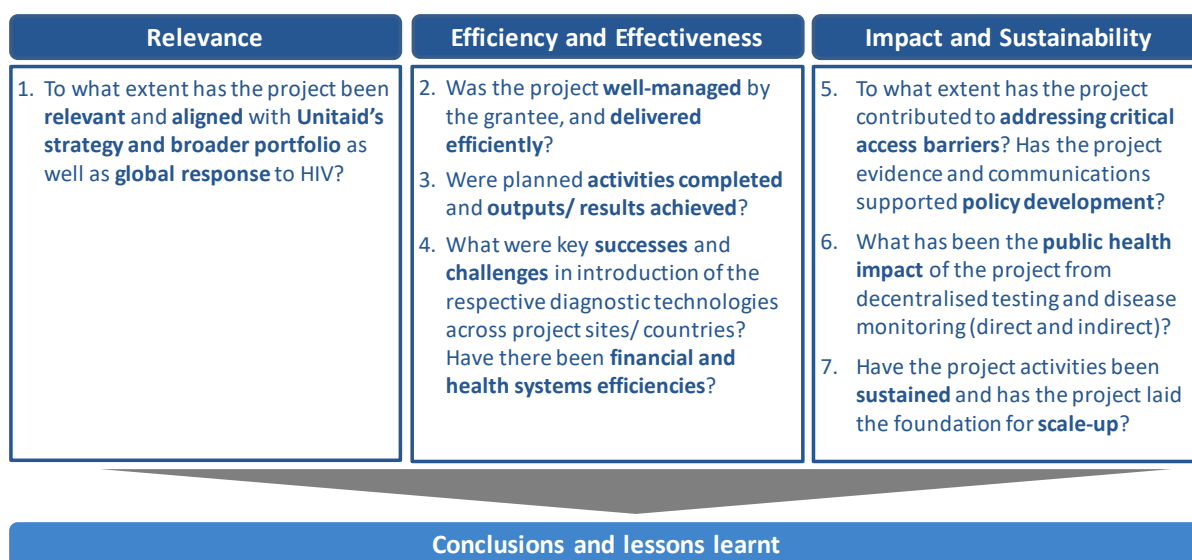
Project background

The project was commissioned by Unitaid in December 2012, with the objective of improving clinical outcomes for people living with HIV through the development and delivery of models of care for the optimal use of: (i) point of care (POC) CD4 testing; (ii) laboratory-based viral load (VL) testing; (iii) POC VL testing; and (iv) early infant diagnosis (EID). This was an operational research project with the aim to evaluate the feasibility of emerging technologies, and identify optimal strategies for the delivery of HIV treatment monitoring and diagnostic services. The total budget for the project was US\$28.7m, with an implementation period until December 2015, later extended to April 2017. Seven countries were initially targeted: Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda and Zimbabwe; and the Democratic Republic of the Congo (DRC) and Kenya were added in 2014 and 2015 respectively.

Evaluation objectives and methodology

The objective of the evaluation was to assess the programmatic implementation of the project, with a focus on its contribution to public health impact and in catalysing access to diagnosis and linkage to care in project countries. Figure A sets out the evaluation framework, structured along the OECD DAC evaluation criteria, highlighting the main areas of review.

Figure A: Evaluation framework



A mixed-methods approach was employed for the evaluation including document review, data analysis, stakeholder consultations with Unitaid, MSF, other donors and partners, as well as with country government officials, partners and beneficiaries through field visits to two of the nine project countries namely Zimbabwe and Malawi (Chiradzulu and Thyolo). Key evaluation limitations include limited generalisability of findings as there has been an in-depth assessment for two of the nine project countries only (although our global-level consultations have supported wider corroboration of country-specific findings) and challenges with the M&E data due to frequent updates to the logframe indicators and targets, discrepancies between annual reporting.

Key findings by evaluation dimension are presented below, followed by overall conclusions and lessons learned.

Relevance

We considered the relevance of the project in terms of its need for countries and in relation to the broader HIV policy landscape as well as its alignment with Unitaid’s mandate and diagnostics portfolio. Our findings are as follows:

The project was approved at a time when there was limited commitment, funding and policy progression on VL monitoring across countries, thereby highlighting its strong need and relevance. None of the project countries (except South Africa) had access to routine VL monitoring through a government or donor-sponsored programme, highlighting the significance of the MSF project in initiating and feasibility testing of alternative models of care in this area. Further, the project evolved over time with changing WHO guidelines – and particularly the change in the WHO Antiretroviral Therapy (ART) guidelines to “treat all” resulting in a reduced need for CD4 testing – thereby maintaining its ongoing relevance. The significance of the project is also brought out by the introduction of the UNAIDS 90-90-90 targets in 2014, including 90% of people on ART having viral suppression by 2020.

The project has been directly relevant and aligned with Unitaid’s strategy and market mandate; and while the operational research nature of the grant is not typical for Unitaid funding, its feasibility establishment and therefore demand creation role is fully aligned with Unitaid’s objectives. There has also been good complementarity with Unitaid’s other HIV diagnostics grants, with each having their own objectives and specific niches, but together covering a plethora of relevant issues for improved HIV diagnostics and monitoring. Importantly, the MSF project has been viewed as “seminal” and a “trailblazer” within this portfolio of grants, with our consultations with the other grantees indicating that the MSF project set the base for the work conducted by these other grants.

The relevance of the project could have been enhanced through better coordination with other Unitaid grants and wider partners – which was mostly ad hoc, and although improved over time at the global level through Unitaid-organised synergy meetings, continued to vary in efficacy in countries. Also, looking forward, the project’s relevance is undermined by the

greater interest and emphasis on polyvalent platforms and integrated approaches to health today, although it is noted that this grant focused on single-use platforms due to these not being available early on in the project.

Efficiency and effectiveness

With regards to efficiency and effectiveness, we considered the extent to which the project was well managed by MSF, as well as overall achievement of planned activities and outputs, alongside country case studies that reviewed the implementation experience of different diagnostic platforms and models of care.

Efficiency of budget, timelines and overall project management

The MSF project was an ambitious project to be implemented in highly resource-constrained settings, with several uncertainties relating to product availability and timing alongside evolving WHO guidelines. MSF has approached these challenges well, nimbly adapting and revising its country programme and diagnostic platform selection to best suit the needs of the specific context, although the product delays have resulted in limited testing (and therefore demonstration) of POC VL and EID by the project (with the predominant focus being on laboratory-based VL testing).

These aspects have contributed to some variances in planned versus actual project expenditures as well as created challenges in effective monitoring (with targets and budgets being constantly revised). Project monitoring was also weak on the whole with poorly defined indicators (e.g. relating to sustainability of MSF programmes in country), absence of key indicators that could measure project results (e.g. on policy uptake, which was an important result of the project) and limited ownership of the results framework by the grantee. Further, to the extent that we have been made aware, formal risk management processes were not adopted until the end of the project by Unitaïd, which may have detracted from engaged risk management.

MSF-Unitaid engagement has generally worked well, although there were some initial teething issues as a result of a first-time engagement for both institutions. Project management in terms of coordination amongst the different MSF offices could have been better done, with for example, MSF units working in Malawi advocating for different approaches to VL testing.

Efficacy of planned activities and related targets

We have assessed the extent of delivery of planned activities and targets, as set out in the project plan and logframe, considering both country-level activities relating to planned versus actual testing as well as at the global level in terms of the research and advocacy/ dissemination work conducted by the project. With continually revised logframe targets and several key activities not been monitored through the logframe (as noted above), we do not have clear benchmarks to assess progress against and rather have based some of the assessment on stakeholder feedback.

In terms of testing, the following was achieved under the project: 540,690 VL tests (79% of the final agreed target), 65,659 POC CD4 tests (exceeding the final agreed target by 8%) and 5,875 EID tests (48% of the revised target).¹ As such, the project had a much larger impact in terms of VL testing (which is viewed as the main contribution of the project), as compared to EID and CD4 testing. While not directly evident from this data, and as noted previously, the project had a larger impact in terms of laboratory-based VL testing as compared to POC VL testing, primarily due to product availability.

With regard to operational research and advocacy, MSF published 40 peer-reviewed studies on diagnostic validation and ART adherence, and delivered the MSF Access 'Undetectable Campaign', including a nine-volume series of publications advocating for scale up of VL, EID and CD4 monitoring. The clinical, technical and operational findings from the project have been widely disseminated by MSF, with all of our global-level consultees noting the utility of the research work and different publications (particularly WHO) as well as dissemination through several global fora. Advocacy and dissemination work by MSF has also been well-received at the country level, through regular engagement with Ministry of Health (MOH), donors and partners (e.g. PEPFAR, Global Fund, CHAI) to facilitate hand-over and scale-up of VL testing, and with civil society organisations (CSOs) and patient groups for demand creation, although the extent of engagement has varied by country (discussed further below). For example, MSF collaborated with the International Treatment Preparedness Coalition (ITPC) on advocacy campaigns, and while the feedback was positive for some countries, in others we understand that the advocacy messaging was delayed and only introduced towards the end of the project, reducing its value.

Country case studies and efficacy of implementation

Country case studies were conducted on the MSF programme in Malawi (encompassing two different programmes in Chiradzulu and Thyolo) and Zimbabwe to evaluate successes and challenges. The following were the main findings:

- **Malawi Chiradzulu:** MSF led the way in demonstrating the feasibility and benefits of POC VL testing using the SAMBA platform, including high VL testing coverage (62% to 81% across sites), rapid test turnaround times (one day), low rate of loss of results (<1%), associated health system efficiencies, and high rates of switching to second-line regimens (68%) relative to other project sites.² The specific diagnostic platform employed has not been taken forward by the government due to high costs; however, the government is supportive of POC VL testing drawing on the experiences of this project, although in a targeted rather than routine manner at present on account of costs. The MSF work has also paved the way for near-POC VL testing through alternative platforms being implemented by other partners.

¹ MSF (2017) End of Project Report.

² MSF (2017) End of Project Report and consultations with MSF OCP.

- **Malawi Thyolo:** MSF introduced the use of dried blood spot (DBS) testing at a district level through the BioMérieux (BM) platform, and then the Abbott platform. The project worked well, demonstrating the feasibility of lab-based routine VL testing at the district level (achieving a VL testing coverage rate of 56%), and the adaptability of the MSF programme in changing diagnostic platforms paved the way for hand-over and government ownership which was completed in 2015.³ The demonstration work for DBS sample collection and linkages with community ART groups worked particularly well in this case. MSF also pioneered the rental agreement model, which can improve flexibility, transparency and maintenance services.
- **Zimbabwe:** The MSF programme worked particularly well in Zimbabwe, where MSF was a front-runner and primary supporter for VL testing, pioneering a number of VL cascade activities, including DBS sample collection, and increasing the number of diagnostic platforms in country to support competition between manufacturers. Through these initiatives, the VL testing coverage was 91% in Buhera and 74% in Gutu district.⁴ The MSF project was well integrated with the work of the MOH at both the district and national level with regard to testing, capacity building and information-sharing, which facilitated hand-over of project activities to the government. Significantly, respondents unanimously attributed much of the VL scale up plan (2015-2018) to the work of MSF.

In summary, the case studies exhibit varying experiences across countries, based on their specific circumstance, and while particularly pivotal in the case of Zimbabwe with direct linkages with the VL scale-up plan, the MSF work has also made useful contributions in Malawi where the demonstration work has shown that routine VL testing can be feasible and is much needed in countries. One driving factor for results has been the the degree to which MSF has engaged with government stakeholders as well as with CSOs and other community bodies (such as the CAGs) which have supported demand creation and efficiency, which was noted as a particular focus in Zimbabwe.

These varying country experiences have been due to differing country contexts and the suitability of the diagnostic technology and testing plan within these settings, and therefore lack of full hand-over at the end of the MSF project need not be viewed as an issue per se (as also discussed further below). Indeed, the main benefit of the MSF project across all three countries has been its demonstration work that has shown that routine VL testing can be feasible and is much needed in countries.

Impact and sustainability

We consider the extent to which the project has contributed to addressing critical access barriers as defined in Unitaids' latest strategy including with regards to policy development,

³ MSF (2016) Vol. 8: Making Viral Load Routine: Part 1 Programmatic Strategies.

⁴ MSF (2016) Vol. 8: Making Viral Load Routine: Part 1 Programmatic Strategies, p.10.

the public health impact (direct and indirect), sustainability of project sites and overall prospects for scalability.

Addressing access and policy barriers

Unitaid's latest strategy defines the main attributes of an effective market in relation to the following – innovation and availability, quality, affordability, demand and adoption, and supply and delivery. Barriers to access relate to those that impede these attributes. In our assessment of the project's impact, we view its main contribution as having been towards reducing the barriers related to demand specifically, and also to some extent with regards to the supply and delivery of diagnostic platforms and models of care, albeit on a pilot basis.

With regards to encouraging demand, the project has made an important contribution to global policy development in terms of supporting the development of WHO guidelines, as intimated directly by WHO. In particular, the project contributed to the WHO guidelines for ART treatment and monitoring through its provision of clinical data and examples of best practice on laboratory work and programmatic considerations relating to routine VL monitoring. MSF's studies looking at the performance of DBS specimens contributed to WHO's understanding of the best threshold for that specimen type and created a consistent threshold across specimens, and MSF's consistent review of the WHO algorithm has assisted the consideration of changes by WHO. The project also provided valuable evidence to the WHO on the importance of CD4 testing for complex and advanced HIV cases.

With regards to demand generation by supporting national policy development, the impact of the MSF project has also been important, although varied in significance by country. Following on from the country case studies described above, the policy significance of MSF's work in Zimbabwe has been particularly strong. In particular, in Zimbabwe, evidence generated through the project provided significant input for both the National HIV Viral Load Scale-Up Plan (2015-2018) and the VL component of the Operational and Service Delivery Manual for the Prevention, Care and Treatment for HIV (2015). There have also been important specific policy influences in Malawi, where for example evidence generated through the project supported the adoption of national level finger-prick DBS testing for routine VL testing and POC targeted testing for patients at higher risk of virological failure; influenced the revision of the national VL threshold for second-line regimen switching to >1000ml/copies; encouraged task-shifting for DBS sample collection and second-line initiation to lower cadres; and promoted the community ART group treatment model for improved adherence, efficiency and community empowerment.

The project has also supported demand generation through working with CSOs, health workers (especially regarding capacity building) and beneficiaries, although this varied by country (as also noted previously).

With regards to enabling supply and delivery, the MSF project has had an impact through procuring and delivering HIV diagnostic and monitoring platforms in countries, albeit on a

small/ pilot scale. In terms of other access barriers, affordability continues to be a major challenge, with persistently high prices for VL consumables, in particular.

Public health impact

The MSF project has had an important public health impact by increasing access to VL monitoring in resource-constrained settings. Across seven sites with 2016 available data, the percentage of coverage of VL testing was 44% overall, of which 33% was covered by MSF.⁵

Notwithstanding the many benefits of the increased coverage, the rate of switch to second-line treatment has not been as extensive as expected with 4,839 (30% of target) ART patients being switched.⁶ This reflected a number of factors, including insufficient confidence among clinicians, centralisation of decision-making on switches, and the limited availability and relative expense of second line drugs. Whilst strategies were employed by MSF to combat the low switching rate, the lower than planned achievement has reduced the ultimate public health impact of the project. Further, switching to second-line treatment was not a direct focus of the project, and consultations indicated that it might have been helpful to have this focus at the outset for greater linkages with results.

Based on the available project data and drawing on key research studies, we have also estimated the public health impact of the VL monitoring component of the project in terms of deaths averted – both direct (i.e. through the project) and indirect (i.e. assuming scale up on routine VL coverage in project countries). This estimation should be interpreted with caution as it is based on crude data and assumptions.⁷ Regarding direct impact, we estimate that: (i) through the impact of switching patients to second line regimen, an additional 363 deaths were averted after one year; and (ii) through the impact of increasing VL coverage testing (i.e. beyond just switching to second line regimen), we estimate that 2,579 (CI 2,192 – 2,708) deaths will be averted after three years, in comparison to VL testing coverage not having been scaled up. Regarding the indirect impact of the project, it is estimated that if VL testing is scaled up to the level of South Africa's routine VL coverage in project countries (i.e. as a proxy for high coverage levels), 82,000 (CI 69,700 - 86,100) additional deaths will be averted in three years, in comparison to not having routine VL testing. Furthermore, assuming that PLHIV on ART in project countries receive routine VL testing, it was estimated that an additional 2,700 deaths may be averted after one year due to switching to second line treatment.

Finally, we note that the project has also impacted health outcomes through EID and CD4 testing, although to a lesser extent than planned given the product delays (EID) and revised WHO guidelines (CD4).

Sustainability and scalability

⁵ MSF (2017) End of Project Report.

⁶ MSF (2017) End of Project Report.

⁷ Please refer the main report and annexes for more details on the data, references and calculations.

The MSF project was a demonstration and feasibility assessment project, and hence the expectation is that not all approaches will be taken forward by the government and other partners. Further, there may be varying experiences ranging from full hand-over of the diagnostic platform and ART cohort to the government with or without supporting donor funding, to take over of a specific service or adoption of a particular approach that may have been piloted by MSF, to a continuation of diagnostics and monitoring by MSF themselves. This last aspect does not necessarily suggest a poor outcome given MSF's role in several countries of managing ART cohorts. However, ultimately for longer term sustainability one would expect hand-over to the government, which might be particularly risky for project sites where MSF activities have not been well-integrated with the government.

A review of the programmes supported by MSF under the project, suggests there have been highly successful country programmes that have seen full take-over by the government and other donors (e.g. Zimbabwe, Mozambique, Malawi Thyolo), alongside others in which selected services have been handed over or particular approaches adopted (e.g. Malawi Chiradzulu). Where full take-over has not happened, this has been on account of limited government funding and capacity as well as preference for alternate technologies other than those piloted by MSF, reflecting the complex context for MSF operations where the work of multiple players and funders influences MOH decision making. Finally, some operations such as in Kenya and South Africa have not been taken up by the government, although with their operational research focus, this was not the core objective of the MSF work.

Generally it is recognised that ensuring the sustainability of the MSF programmes is challenging given the resource-limited settings in which that they are operating and some respondents commented that the project has been very ambitious with too short a timeframe to ensure integration with governments and others. In many instances, such as Zimbabwe, MSF's work has been seminal in terms of demonstrating feasibility of routine VL testing with other partners and the government increasing their work in this area based on MSF's demonstration. In other instances, MSF's work was alongside other partners working in country but some of MSF's demonstration work has been taken forward such as using DBS in Malawi. However, overall, the main contribution of the MSF programme has been its clear demonstration of the feasibility of routine VL testing and presentation of "proof of concept" has set the stage for longer term scalability of routine VL monitoring.

Conclusions and lessons learnt

In conclusion, the MSF project has been highly relevant and timely, and helped create a strong body of evidence and experience, serving as a trailblazer to pave the way for uptake, adoption and scale-up in countries. The project has been extremely complex, with an ambitious goal of demonstrating the feasibility and use of routine VL testing in countries that are largely resource-constrained, alongside several pipeline diagnostic product delays; MSF has approached these challenges well, nimbly adapting and revising its country plan and diagnostic platform selection to suit the needs of the specific and evolving context.

The project has made a significant contribution to laboratory-based VL monitoring, less so for POC VL testing and EID mainly on account of timing of availability of technologies and CD4 testing with changing WHO guidelines. Its significance has been greater in countries like Zimbabwe where MSF's work played a key role in the government's scale-up plan, but also important in many other countries like Malawi. While coordination with other partners and between MSF units as well as active working with CSOs and patient groups was well done in some countries, this has been variable in nature across other countries and represents an area where greater coordination/ engagement could have been beneficial. Also, looking forward, the project's relevance is undermined by the greater interest and emphasis on polyvalent platforms and integrated approaches to health today, although it is noted that this grant focused on single-use platforms due to these not being available early on in the project.

While recognising that Unitaid has updated its project design and management approach, especially under the new strategy, lessons from the experience of the implementation of the MSF project suggest the need for: (i) more realistic timeframes for projects, recognising the complex and uncertain environment that Unitaid projects operate in; (ii) project design to be carefully supported by scenario assessment, aided with a clear and continually updated risk assessment; (iii) a critical consideration of what really defines the measures of success for a project and developing suitable M&E indicators, with an emphasis on project site data collection especially given the weak data that exists; (iv) greater emphasis on coordination with other partners, through for example, measurable indicators to ensure this is done; and (v) close monitoring of impact metrics to ensure continued efficiency in terms of increased benefits for increased costs.

Finally, as an end note, we highlight that the landscape for VL testing remains challenging. Not only do VL testing coverage rates remain very low, there is also much to be improved in terms of test TATs and treatment regimen switching rates. Challenges persist with available technologies in terms of high prices, ineffective maintenance and the issue of waste management. As such, the path to scale-up requires further work, although noting that the MSF contribution through this project has made a positive contribution to setting the stage for scale-up.

2. INTRODUCTION AND EVALUATION APPROACH

Cambridge Economic Policy Associates (CEPA) was appointed by Unitaid to conduct an end of project evaluation of the grant to Médecins Sans Frontières (MSF) on “Implementation of CD4 and viral load testing in decentralised, remote and resource-limited settings in MSF HIV programmes” (“the project”). This report presents our evaluation findings, conclusions and lessons learnt.⁸

In this introduction, we provide a brief background to the project (Section 1.1), the evaluation objectives and methodology (Section 1.2) and the structure of the report (Section 1.3).

2.1. Project background

The rapid rollout of antiretroviral therapy (ART) has not been matched by a comparable increase in access to diagnostic support for optimal compliance with case management protocols. Limited access to virological monitoring in these settings has led to a reliance on immunological and clinical criteria for the purposes of diagnostic support, which has been shown to perform relatively poorly as predictors of ART treatment failure and the need for second-line treatment.⁹ In this context, the goal of the Unitaid-MSF project was to improve clinical outcomes for people living with HIV (PLHIV) in resource-constrained settings through the development and delivery of models of care for the optimal use of: (i) Point of Care (POC) CD4 testing; (ii) laboratory-based viral load (VL) testing; (iii) POC VL testing; and (iv) early infant diagnosis (EID). The project had an operational research focus, and aimed to evaluate the feasibility of new technologies and identify optimal strategies for different resource-poor settings.

The project grant agreement between Unitaid and MSF was concluded in December 2012, with a total budget of US\$28.7m and an implementation period until December 2015, later extended to April 2017. Seven countries were initially targeted: Lesotho, Malawi, Mozambique, South Africa, Swaziland, Uganda and Zimbabwe, and the Democratic Republic of the Congo (DRC) and Kenya were added in 2014 and 2015 respectively.¹⁰ The project was implemented in MSF-supported sites within these countries and targeted ART cohorts between 3,000 to 46,000 in size.¹¹ Table 1.1 outlines the project goal and purpose, as per the logical framework (logframe).

⁸ This report benefits from input and review from CEPA Associate, Debi Boeras.

⁹ Ferreyra et al. (2012)

¹⁰ Unitaid funding represented 19% of the expected MSF budget for three years across the original set of countries (Project Plan, p.84).

¹¹ MSF (2016) Vol. 8: Making Viral Load Routine Part 1: Programmatic strategies

Table 1.1: Project goal and purpose

Result level	Description
Goal	Improved clinical outcomes for People Living with HIV/AIDS (PLWHA) in resource-constrained settings through models of care for optimal use of POC CD4, laboratory-based and POC viral load and EID testing
Purpose	Increased POC CD4, laboratory-based and POC VL and EID testing according to evidence-based recommendations

The scope, focus and logframe went through a number of revisions, with certain indicators and/ or targets removed and amended, and additional indicators included. These revisions were due to various reasons including changing policy and operational factors as well as challenges with measurement of indicators. For example, there was a shift from CD4 to VL monitoring in most countries on account of the new WHO guidance (resulting in reduced emphasis of CD4 related monitoring targets), recognition of the limited feasibility of same-day initiation on ART following CD4 testing (and consequent revision of related targets), etc.^{12,13}

In 2016, Unitaid and MSF agreed a no-cost extension until December 2016 on account of the delayed availability of pipeline diagnostic technologies as well as the delayed start of activities in countries.¹⁴ In 2017, a second extension was agreed until 30 April 2017 to complete planned operational research, procurement and close-out activities.

2.2. Evaluation objectives and methodology

2.2.1. Scope and objectives

Based on the Terms of Reference (TOR), the objective of the end-of-project evaluation is to assess the programmatic implementation of the project with a particular focus on its contribution to public health impact and in catalysing access to diagnosis and linkage to care in project countries. The following are the main areas of assessment:

- Progress made against the project’s goal, outcomes and outputs as well as the range of activities contributing to each output, including a summary assessment of the value of Unitaid’s investment in this grant, also using the Key Performance Indicator (KPI) framework under Unitaid’s new 2017-21 Strategy;
- Potential public health impact (direct and indirect) from decentralised testing services and disease monitoring;¹⁵

¹² MSF (2017) End of Project Report, p.10.

¹³ MSF (2017) 2016 Logframe.

¹⁴ Unitaid (2016) First No Cost Extension: Letter of Agreement and Annexes.

¹⁵ This assessment is based on data availability under the project.

- Contribution of the project to addressing barriers to access, using the Unitaïd framework that considers aspects such as demand and adoption, innovation and availability, amongst others;
- The catalytic effect on patient access to services attained through a combination of an improved policy environment (at the global and country levels) and increased evidence of feasible implementation of complementary testing technologies;
- Experience of transitioning of project sites to governments and other donors, also within the context of potential for scalability of testing services (recognising that scale-up was not a specific project objective); and
- To consider the above in terms of not only of what can be attributed to the project, but also its complementarity with Unitaïd’s broader portfolio in HIV diagnostics and monitoring.

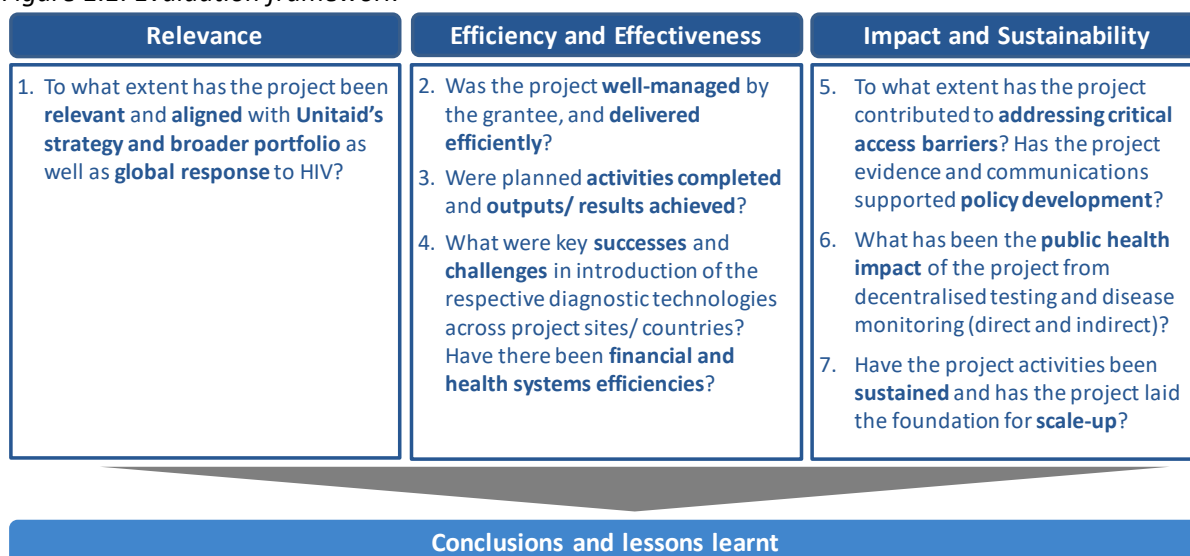
2.2.2. Evaluation framework

Figure 1.1 provides the evaluation framework, encompassing the range of OECD DAC evaluation criteria, and including a review of:

- **Relevance:** focusing on a review of the alignment with Unitaïd’s strategy and HIV diagnostics portfolio as well as the global priorities and response to HIV.
- **Efficiency and effectiveness:** focusing on project management by the grantee (e.g. budget efficiency and timeliness) and the implementation of project activities, and its successes and challenges.
- **Impact and sustainability:** focusing on the extent to which the project has addressed access barriers, public health impact and potential for sustainability and scalability.

Findings across the evaluation questions have supported the development of conclusions, and lessons learnt.

Figure 1.1: Evaluation framework



2.2.3. Evaluation methods and their limitations

A mixed-methods approach has been employed for the evaluation, comprising:

- **Document review:** including a review of project documents (e.g. project plan, annual reporting), key publications (e.g. the MSF Southern Africa Medical Unit (SAMU) Viral Load Toolkit, the 2016 Making Viral Load Routine publication) and broader relevant documents (e.g. the 2017-21 Unitaid Strategy). Annex A provides the list of key references.
- **Data analysis:** including an analysis of project data such as data on project results and impacts, budgets and expenditure, procurement, etc.
- **Stakeholder consultations:** including with the Unitaid Secretariat, MSF project team (globally and in country) as well as other relevant stakeholders (e.g. WHO, donors, other Unitaid grantees) Annex B provides the list of consultees and interview guides.
- **Country field visits:** to Zimbabwe and Malawi, where we have consulted with the MSF country office and project representatives, government, donors and relevant partners (e.g. WHO, USAID, Global Fund representatives, CHAI), civil society organisations (CSOs), etc. Annex B also includes a list of consultees for the country visits and corresponding interview guides.

Key **evaluation limitations** include: (i) limited generalisability of findings as there has been an in-depth assessment for two of the nine project countries only (although our global-level consultations have supported wider corroboration of country-specific findings); (ii) challenges with the M&E data due to frequent updates to the logframe indicators and targets, discrepancies between annual reporting); and (iii) stakeholder bias, especially given that

consultations have been a key evidence source (although we have attempted to minimise the impact of this by triangulating views across stakeholders and other sources of evidence).

2.3. Structure of the report

The report is structured as follows:

- Sections 2-4 present analysis and findings across each of the three evaluation dimensions of relevance, implementation efficiency and effectiveness and impact and sustainability.
- Section 5 presents the evaluation conclusions and lessons learnt.

The main report is supported by the following annexes:

- Annex A lists the bibliography;
- Annex B includes the list of consultations and interview guides;
- Annex C presents a mapping of Unitaid 2013-16 Strategy objectives and the focus of the MSF project;
- Annex D is a summary analysis of the linkages of the MSF project with Unitaid's broader diagnostics portfolio;
- Annex E provides the project logframe and summary progress;
- Annex F offers some key points on project procurement based on the annual reports;
- Annex G includes a summary of project experiences across countries based on the annual reports;
- Annex H shares details on the experiences across countries with hand-over of MSF programmes at project close;
- Annex I includes the evaluation conclusions using the framework of the Unitaid 2017-21 Strategy KPIs; and
- Annex J presents an analysis of the public health impact of the project.

3. PROJECT RELEVANCE

The starting point of the evaluation has been to assess project relevance, which we consider in terms of the extent to which the project has been aligned with Unitaid’s strategy, mandate and diagnostics portfolio as well as the broader HIV context and international and national response to the epidemic.

The evaluation question is as follows:

1. To what extent has the project been relevant and aligned with Unitaid’s strategy and broader portfolio as well as global response to HIV?

3.1. Alignment with Unitaid strategy and diagnostics portfolio

Alignment with Unitaid strategy and mandate¹⁶

Unitaid has had a **long-standing commitment** on HIV diagnostics and monitoring, from 2008, when discussions on VL were commencing at the global level. As such, with the grant objective of improving clinical outcomes for PLHIV through improved diagnostics and monitoring, this project strongly emphasises Unitaid’s long term (and continuing) focus in the area.

A review of the project goal and activities suggests close alignment with the overall framework, strategic objectives and defined Unitaid role along the commodity value chain, as set out in its **2013-16 Strategy**. In particular, the grant is highly relevant in terms of Strategic Objective 1 to “increase access to simple, point-of-care diagnostics for HIV/TB...”, especially in terms of addressing the market barriers noted in the strategy on the “acceptability/adaptability” and “delivery” of diagnostics.¹⁷ We note that Unitaid’s overall aim within this Strategic Objective is to increase CD4, VL and EID coverage, which is the basis of this grant.¹⁸ Further, the 2013-16 Strategy presents Unitaid’s role within the commodity value chain in terms of a “push” and “pull” role, serving as a “market catalyst”, “market creator” and “market fixer”; and while Unitaid’s larger grants have focused on the market creator function, the current grant emphasises its market catalyst role, serving to demonstrate the feasibility of primarily VL but also CD4 and EID testing.¹⁹ The operational research nature of the project, while not the core focus of Unitaid funding, and representing one of the few operational research grants within Unitaid’s grant portfolio, aims to establish feasibility and create demand, and hence is very much in line with Unitaid’s overall market mandate.

¹⁶ The grant was delivered over the period 2013-17, and hence it is appropriate to evaluate the relevance of the project in the context of the Unitaid Strategy for 2013-16. However, we also provide some comments on the continued relevance of the project in light of emerging priorities in the new 2017-21 Unitaid Strategy.

¹⁷ Unitaid (2013) Unitaid strategy 2013-2016, p.44

¹⁸ Further, although not the primary objective, the project goes some way to addressing Strategic Objectives 2 and 3 on access to paediatric medicines and emerging regimens to improve treatment, given its scope includes EID testing, as well as understanding the need and feasibility of switching to second-line treatment respectively.

¹⁹ Unitaid (2013) Unitaid strategy 2013-2016, p.29

The strong relevance and alignment of the project also holds with the new **2017-21 Unitaid Strategy**. However we note that in this new strategy, there is a larger focus on integrated approaches to health, which for example include “enabling access to a health product that addresses more than one disease or condition (e.g. polyvalent or multi-disease diagnostic platforms)”.²⁰ As the platforms used within the MSF project were primarily single platforms (as polyvalent platforms were not as easily available at the time), and the project exclusively focused on HIV, its relevance is slightly less in terms of the priorities of this new strategy.²¹

Fit with Unitaid’s broader diagnostics portfolio

While a full review of the complementarity of the Unitaid HIV diagnostics portfolio is beyond the scope of this evaluation, we provide some salient points by way of assessing the fit of the MSF grant with other related diagnostics grants, including:²²

- The **CHAI/UNICEF grant**, which is a much larger grant of US\$149.3m and serves as a market creator grant with proposed large procurement volumes and implications on market demand, supply and prices. As such, this grant is very different from the MSF project which is more about demonstration/ feasibility, and thereby complementary in nature.²³ In addition, we understand that the CHAI/UNICEF project had a global market and national policy-level focus, whereas the MSF project, in most instances, focused on demonstrating lessons at the clinic/ district level.
- Other related grants include the **OPP-ERA project**, testing open polyvalent platforms, the **EGPAF project** on EID testing, and the **Diagnostics for the Real World (DRW) project** on the SAMBA technology. While the MSF grant has several areas of similarity with these grants (including common countries), their focus is on specific components, with the OPP-ERA project focusing on the feasibility of multi-sourced platforms (which formed a smaller component of the MSF project, as noted above), the EGPAF project focusing on infants and children (where the MSF project did not end up focusing as much) and the DRW project being a grant to support product development.

As such, there are some areas of overlap across the grants. However each has its respective intended objective and area of focus, and thereby the portfolio can be viewed as largely complementary.

²⁰ Unitaid (2016), Unitaid 2017-2021 Strategy

²¹ While multi-platforms were used under the grant, the focus was on single platforms, or at least using multi-platforms for single use. For example, the grant piloted the Abbott technology which could be used for both VL and EID, but the focus was very much on VL for this grant with the exception of EID testing using the Abbott in DRC. Further GeneXpert was not used extensively within this grant (some use in DRC, Kenya, Malawi and Zimbabwe, mainly for research).

²² Additional details are provided in Annex D.

²³ Our review of the project documentation for the MSF grant suggests that the objectives and scope were somewhat ill-defined, with earlier project documentation referring to a degree of emphasis on impacting market suppliers and prices, whilst later documentation focused on operational research and evidence generation. This difference/ shift in emphasis however seems appropriate in line with the rest of Unitaid’s grant portfolio.

Consultations indicated that the **MSF project was a “pioneer and trailblazer grant”**, establishing the feasibility of VL testing and kick-starting the process of emphasising routine VL monitoring in countries, thereby serving as a starting point for the other grants.

A key challenge however has been in terms of **coordination amongst grantees**, which has been mostly ad hoc with room for improvement, as recognised by all stakeholders consulted included Unitaid, MSF and other partners. For example, there are some references to MSF-CHAI coordination in the annual progress reports for the MSF grant (e.g. the 2013 report makes reference to monthly phone calls between partners as well as plans for a common tender exercise for procurement of platforms which was later dropped), but this does not appear to be systematic or long term.

We understand that coordination improved over the life of the project, with “synergy meetings” being organised by Unitaid which brought together a number of stakeholders to discuss key issues in the diagnostics landscape (e.g. research gaps, WHO PQ related issues, programmatic discussions on VL scale-up and clinical considerations, EID next steps, integration of diagnostic technologies and cost-effectiveness, etc.). However, this has largely been at the global level with only informal engagement outside of these meetings; and as discussed further in Section 3.3, country-level coordination between grantees has been driven more by individuals, than at an organisation level. As such, the lack of good coordination presents a missed opportunity across the grants.

3.2. Relevance in context of HIV needs and guidance

The project was highly relevant in relation to **supporting the needs of the HIV epidemic**. At the start of the project, CD4 and VL testing were recommended to maximise the benefits of ART and improve transition from first- to second-line regimens. Whilst there were a number of factors accounting for the low switching rates, one of these was the unavailability of VL monitoring to inform treatment switching. Estimates in 2013 indicated that the proportion of existing demand that had been met for CD4, VL, and EID testing was only ~60%, ~25%, and ~26%, respectively²⁴. Therefore the focus of this grant on these aspects was much needed.

As emphasised in our review, and highlighting by our consultees for the evaluation, the project was also very relevant in relation to the **limited commitment/ funding and policy progression** on VL monitoring at the start of the project. Whilst ARV coverage varied between 35%-85% in the project countries, none of the target countries had government or donor-sponsored access to routine VL monitoring except South Africa.²⁵ At the time of grant initiation, the only funding for routine VL in the region (apart from South Africa) came from Unitaid. In terms of national guidelines, a number of countries recognised VL monitoring but had low coverage, and did not have operational plans.

²⁴ Unitaid (2013) Unitaid strategy 2013-2016

²⁵ MSF (2012) Project Plan

Further, the grant also **evolved to remain relevant with changing WHO guidelines and global goals**. The change in the WHO ART guidelines to ‘treat all’ meant that there was less need for CD4 monitoring, and with the introduction of the UNAIDS 90-90-90 targets in 2014 including 90% of people on ART having viral suppression by 2020, the importance of VL monitoring was further emphasised.²⁶ The project adapted to these changes to place less emphasis on CD4 monitoring and focus on VL in all project countries, thereby emphasising its continued relevance.

Summary findings:

Our review confirms the strong relevance and need for the project in the face of limited commitment, funding and policy progression on VL monitoring.

The project was well-aligned with Unitaids’s mandate and complemented its other investments in HIV diagnostics. Indeed, the project is viewed as a pioneer grant, setting the ground for much of the work conducted in this area by other partners.

The relevance of the grant may have been enhanced through better coordination with other Unitaids grants, although this has improved over time mainly at the global-level.

Also, in terms of its relevance looking forward, it is noted that this grant had focused on single-use platforms while there is greater availability and emphasis today on polyvalent platforms and integrated approaches to health.

²⁶ UNAIDS (2014) 90-90-90 An ambitious treatment target to help end the AIDS epidemic.

4. EFFICIENCY AND EFFECTIVENESS

The second dimension of the evaluation is on efficiency and effectiveness. We consider these evaluation criteria from the lens of overall project management on the one hand (e.g. whether planned budgets and timelines were adhered to) and in terms of the implementation of the project activities in country on the other (e.g. whether planned activities and targets were completed, what worked well and less with the MSF country programmes, etc.). The former aspect is discussed in Section 3.1 and the latter in Sections 3.2 and 3.3.

4.1. Budget, timelines and project management

The evaluation question is as follows:

2. Was the project well-managed by the grantee, and delivered efficiently?

We consider budgets, timelines, project management structure, as well as the approach to measuring results and managing risks.

4.1.1. Budget management

Of the total project budget of US\$28.7m, US\$27.3m (96%) had been spent by the end of the project in April 2017. Comparing total expenditure over the lifetime of the project with the original budget presented in the 2012 Project Plan, we note the following variances:^{27,28}

- Commodity expenditure was lower than planned, with 77% of the budget spent by the end of the project. US\$17m was spent compared with a budget of US\$22m.
- Staff expenditure was 1.2x greater than planned, with US\$6.5m spent against US\$5.4m budgeted.
- There was a large overspend with regard to operating expenditure, with a total spend over the lifetime of the project of US\$3.6m, which is almost 2.8x larger than the original budget of US\$1.3m.²⁹

We understand that these variances were on account of several changes that took place during the course of the project, including delayed pipeline product availability and commencement of country activities (discussed below). The overall longer timeframe for implementation with the project extension as well as addition of countries implied greater staff and operating expenditure.

²⁷ There were significant revisions to the budget throughout the project period, which reflected the re-alignment of the grant with changing technologies/ country plans and timelines.

²⁸ There was an overspend with regard to audit expenditure, with US\$236,000 spent as compared with US\$40,000 budgeted, i.e. 5.9x higher expenditure than planned, although it is noted that this represented a small proportion of the total value of the grant.

²⁹ Operating expenditure as per the 2012 Project Plan, and budget revision document, comprises consulting, travel, training, meetings and publications costs.

We note that the budget updates and expenditure reports provided alongside annual progress reports have been difficult to follow, with some discrepancies across years due to the frequent need to change budgets with technology/ country updates. We understand from Unitaid that budget tracking and management for this grant was more of a challenge in comparison to its other grants. This was because this grant represented a new approach for MSF funding (i.e. an external donor with a earmarked project), which required new budget management and reporting approaches by MSF. There were also added complexities given the involvement of multiple MSF offices. We also understand that the high turnover of the Unitaid Finance Manager position also created challenges for continuity and consistency in requirements for MSF.

4.1.2. Planned versus actual timelines

Many consultees noted that the project timeline was extremely ambitious, given the challenging nature of the grant and complex environments in which it was being delivered. The project further suffered from two key delays from plan:

Lengthy country MOU processes

As a condition of the grant, Unitaid requested MSF to have project-specific MOUs with the government in all project countries.³⁰ Table 3.1 includes the date of signature of the MOUs for the project countries, noting project start in late 2012 (and DRC and Kenya were added in 2014 and 2015 respectively).³¹ As is noted from the table, there were considerable delays in agreeing the MOUs, which had a knock-on impact on commencement of country activities.

Table 3.1: Date of signature of project-specific MOUs with country governments³²

Country	MSF operational section	Date of signature
Lesotho	OCB	30 April 2013
Malawi	OCB and OCP	13 February 2013
Mozambique	OCB and OCG	7 June 2013
South Africa	OCB	3 March 2014
Swaziland	OCG	18 March 2013
Uganda	OCP	18 June 2013
Zimbabwe	OCB	28 March 2013
DRC	OCB	30 October 2014

³⁰ MSF (2013) Annual Report

³¹ In certain project countries, difficulty in reaching agreements with MOH authorities on project-specific MOUs created additional challenges for implementation. For example, in South Africa, in KwaZulu Natal, MSF encountered barriers when attempting to discuss an MOU with the health authorities, which meant that no MOU had been signed by the end of 2013. As a result, MSF re-considered the South Africa activities planned through the grant, with a change in province.

³² MSF (2013) Annual Report, p.12; MSF (2014) Annual Report, p.35.

Country	MSF operational section	Date of signature
Kenya	OCP	n/a

We note that these MOUs may not have been necessary given that MSF had MOUs with governments for their HIV cohort programmes. In light of this, and the recent update to Unitaid policy on not requiring country-specific MOUs for a project, these delays may have been avoidable.

Delays in diagnostic technologies

The project was significantly affected by delays in the availability of pipeline diagnostic technologies. Table 3.2 below lists the years in which the diagnostic technologies employed in the project became available for use in the project.

Table 3.2: Availability of diagnostic platforms

Manufacturer	Device	POC or Lab-based	Type	Year first used in project ³³
BioMerieux	NucliSENS	Lab-based	VL	2013
Biocentric	Platform	Lab-based	VL	2013
DRW	SAMBA I	POC	VL	2013
	SAMBA II	POC	VL and EID	2016
Alere	PIMA	POC	CD4	2013
	Alere Q	POC	VL and EID	2015
Abbott	RealTime	Lab-based	VL and EID	2015 (for DBS)
Cepheid	GeneXpert	POC	VL and EID	2016

Sources: End of Project Report, Annual Report 2016, Annual Report 2015 and Annual Report 2013

As such, MSF had to revise its country plan on an ongoing basis, as technologies became available, resulting in later than planned commencement of activities in many cases. The project activities that were most impacted by the delays in technologies coming on-stream related to POC operational research for EID and VL.

4.1.3. Project management structure

The project is structured within MSF with MSF Belgium: Operational Centre Brussels (OCB) as the lead partner in charge of coordinating the project, along with three other MSF entities as sub-partners: MSF France: Operational Centre Paris (OCP); MSF Switzerland: Operational Centre Geneva (OCG); and MSF International Access Campaign. Field operations are delivered by MSF OCB (DRC, Lesotho, Mozambique, Malawi, South Africa, Zimbabwe), MSF OCP (Kenya, Malawi, Uganda) and MSF OCG (Mozambique, Swaziland), alongside technical, operational

³³ As referenced for first time in Annual Reports.

research and M&E support from the South African Medical Unit (SAMU) and EpiCentre as well as the MSF Access Campaign for issues relating to cost-effectiveness and market analysis.

As such, the project structure within MSF is complex, involving multiple entities with overlapping (although discrete) functions. We consider implications for MSF-Unitaid engagement and project implementation more generally below.

Implications for MSF-Unitaid engagement

We understand that this complex project structure resulted in a lengthy process for project sign-off to establish agreed ways of working and reporting between Unitaid and MSF, with this project being Unitaid's first project engagement with MSF and hence lack of familiarity with their structure for operations. This was also a first-time engagement with a donor like Unitaid for MSF, and hence had its own implications for management within the existing structures of MSF. For example, the 2013 progress report noted the heavy reporting burden (also confirmed by country offices during our field visits). The report also notes the start-up time required to formalise relationship with Unitaid. (e.g. establish SOPs, etc.), highlighting frequent changes within Unitaid as a challenge.

MSF country offices noted that Unitaid engagement during the course of the project was supportive and the flexibility from Unitaid was much appreciated to accommodate the complex nature of the project. A consideration from MSF's perspective was regarding the relative merits of 100% independence versus the added merits of engaging with a donor such as Unitaid. Their view was that positives included the global access achieved through Unitaid funding, while negatives were additional transaction costs on reporting.

Implications for project implementation

In-country respondents including government, health facility staff, and partners noted that the project has been managed well in country, however:

- Whilst the project has improved coordination between MSF units, it seems a missed opportunity that further learnings were not shared between the units. There were only some select examples of evidence sharing such between Malawi (Chiradzulu) and Uganda on use of the SAMBA II and between Malawi and Mozambique on the Community ART Groups (CAGs) – further discussed in Section 3.3.
- Different MSF offices had different approaches (e.g. in Malawi where OCB supported a centralised approach and OCP supported a decentralised POC approach), and there was lack of synchrony in approach.
- The structure of multiple MSF units appeared mostly to have worked well, however there were instances in which it was considered that inefficiencies were caused through ultimate approvals required from head offices.

4.1.4. Approach to measuring results

There were a number of challenges with the logframe and reporting, including the following:

- **Poor development:** MSF noted that the initial logframe was not developed in close consultation with them, resulting in limited ownership and buy-in. The logframe did not adequately capture the diversity of the grant's objectives, and in particular MSF did not believe that the chosen indicators offered a meaningful 'measure of success'. As a result, there was limited use of the logframe as a management tool by Unitaid.
- **Multiple revisions:** There was a constant revision of targets and indicators with the most significant revision in August 2015 (mainly on account of changing WHO guidelines and country work plans, as discussed previously). Key revisions to the logframe included:³⁴
 - The CD4 goal on linkage to ART following POC CD4 testing was removed after 2015.³⁵ This reflected the revision to the WHO normative guidance on ART monitoring published in 2013.³⁶
 - The EID goal was changed from: (i) the number of EID-testing HIV-positive infants initiated on ART; to (ii) the number of calendar days from EID sample collection to initiation on ART.
 - Nineteen of 24 output indicators were removed in 2015 and only five output indicators were reported against in the End of Project Report.
- **Technical weaknesses:** There were also a number of technical weaknesses including the following
 - there was a wide mix of indicators at the same level, although they have different levels of significance, e.g. "number regularly scheduled meetings conducted" (undertaking activities) and "percentage pre-ART patients lost to follow-up (LTFU) after POC CD4 testing confirmed treatment eligibility (an output based on activities);
 - there were a number of indicators that MSF was not able to fully impact such as "new quality-assured, resource-adapted products available for implementation in MSF-type settings";
 - there were no indicators to track policy update, a key measure of success for the grant
 - the tracking of donor or government support was weak with indicators such as 'percentage of national funding available annually for each country' and "%

³⁴ Annex E includes the revised logframe, as well as the indicators that were dropped during the project.

³⁵ The initial goal was the number and percentage of patients initiated on ART after same-day PoC CD4 testing.

³⁶ WHO (2013) Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, p.26.

international funding available annually for each country”, rather than a tracking of whether the project activities were included in Global Fund and PEPFAR grants, etc. post project close, which are more in line with the results of this project.

4.1.5. Approach to measuring risks

An initial risk matrix was developed with the project plan which identifies a number of key risks such as lack of uptake by government, challenges with product availability, etc., although there is no update in terms of review and management of evolving risks overtime (at least not been made available for this evaluation).

A Unitaid risk matrix for the project shared with us presents the following risks: research not being completed in time (high); dissemination not being optimal (medium); inadequate service provision when sites are handed over the government (medium); waste management issues (high); and transition issues (medium). We understand that this was developed towards the end of the grant and hence focuses more on sustainability as compared to other issues. While the latter three risks are relevant issues, we view the first two risks as being very simply defined i.e. the risk is essentially stated as the planned work not being completed. We assess that a more strategic approach to assessing these risks e.g. considering planned technologies for certain sites and implications of their delays on a case by case basis would be more effective.

As such, to the extent that we have been made aware, formal risk management processes were not adopted until the end of the project by Unitaid, which may have detracted from engaged risk management. We note however that this was an ambitious project with several risks such as changing WHO guidelines, availability (including timeliness) of technologies, effective demand creation within countries, effective coordination with country systems in terms of linkage with the supply chain and treatment cascade, adequate coordination amongst MSF implementing offices and other partners, as well as in relation to the expected impact of the project such as demonstrated feasibility of the models being employed (i.e. they could have been proven infeasible), poor switch rates to second-line treatment, etc. MSF has nimbly adapted to a number of these risks during the course of project implementation (e.g. changing focus away from CD4 with the new guidelines, constantly revising country plans based on feasibility and availability of technologies, etc.), and as such can conclude that MSF has responded to risks well.

Summary findings:

The MSF project was an ambitious project, being implemented in resource-poor settings, and with several uncertainties relating to pipeline product availability alongside evolving WHO guidelines. This has resulted in some variances in planned versus actual project expenditures, country work plans as well as created challenges in effective monitoring (which was also impeded by poor M&E design). The project has generally been well managed, although there was room for improvement in terms of information sharing within MSF and in some instances, synchrony in approaches between different MSF units. Key risks appear to have been dealt with nimbly, but not managed in a formalized manner until the end of the project. An avoidable delay was with regards to the country MOU requirement, which has since been removed for Unitaaid projects.

4.2. Delivery of planned activities and related targets

This section provides an assessment of the extent of delivery of planned activities and targets, as set out in the project plan and logframe, noting that these have evolved over time with the changing circumstances for the project. The evaluation question is as follows:

3. Were planned activities completed and outputs/ results achieved?

We focus on a “top-level/ global” grant picture rather than country details, which is the subject of the next section. The focus is also on activity delivery, rather than assessment of results which is covered under Section 4.

Specifically, we review: (i) the overall planned versus actual procurement and related testing for POC CD4, laboratory and POC VL and EID; and (ii) supporting operational research and advocacy work. Note that for (i) there are logframe targets to review project performance (although revised a number of times), but for (ii) there are no benchmarks/ suggested performance and so our conclusions have been based on consultation feedback, which have, for the most part, provided more generic responses to the performance in the area.

4.2.1. Procurement and related testing for POC CD4, laboratory and POC VL and EID

As noted above, pipeline delays and revisions to country programmes implied a change from plan to actual procurement of devices and tests. Table 3.3 provides details on the planned versus actual device procurement.

Table 3.3: Planned and actual procurement

Manufacturer	Device Name	Type	# Devices Planned	# Devices Purchased	# Tests Planned ³⁷
BioMerieux	NucliSENS	Lab-based VL	5	7	302,500

³⁷ It has been difficult to track actual tests procured by device from the available progress reports and hence this information is not presented below.

Manufacturer	Device Name	Type	# Devices Planned	# Devices Purchased	# Tests Planned ³⁷
Biocentric	Platform	Lab-based VL	<i>n/a</i>	0	<i>n/a</i>
DRW	SAMBA I	POC VL ³⁸	14	8	121,800
	SAMBA II	POC VL and EID	0	2	0
Alere	PIMA	POC CD4	22	15	365,145 ³⁹
	Alere Q	POC VL and EID	24		59,203
Abbott	RealTime	Lab-based VL and EID	0	1	0
Cepheid	GeneXpert	POC VL and EID	2	9	10,800
Zyomix	MyT4	POC CD4	10	0	4,500
Sysmex Partec	CyFlow miniPOC	POC CD4	2	0	42,720

Source: MSF/Unitaid Purchasing and Procurement Approach, Draft v4, pp.13-14 and MSF Annual Procurement Reports.

With regards to **VL testing**, the original project plan notes the intention to conduct 371,129 laboratory-based VL testing, alongside 52,429 POC VL tests and 122,480 simplified VL test through the SAMBA. These targets changed substantially during the course of the project, with increased need for VL testing given the new WHO guidelines but also considerable re-planning on account of pipeline product delays and country-specific issues. The end of project progress report highlights an achievement of 426,181 against a revised target of 540,690 VL tests, representing a 79% achievement. The majority of these tests, a total of 304,827 representing 72% of all VL tests, were performed in 2015 and 2016. The initial years of the grant had lower number of tests conducted with pipeline delays, but despite a substantial increase in testing, these could not be made up for in the latter years of the grant. However, despite a lower than planned achievement, this was the main contribution of the MSF grant, namely to establish and demonstrate the feasibility of VL testing.

In terms of **POC CD4 testing**, the original project plan target was to conduct a total of 362,100 tests across Lesotho, Mozambique, South Africa, Swaziland and Malawi. With the change in WHO guidelines in 2013 the demand for CD4 testing declined, and as such the overall target for CD4 testing under the project dropped to 65,659 tests as per the August 2016 revision of the logframe. As reported in the end of project report, this final target was exceeded by 8%, with a total of 71,125 tests conducted. According to the 2016 project logframe, the majority

³⁸ SAMBA I would ultimately become validated for EID, but by Jan 2016 (first NCE) it was yet to be validated, according to device summary in the annex to the agreement.

³⁹ MSF (2012) Project Plan notes this to be 362,100 tests.

of these tests, a total of 49,430, were performed in Swaziland, comprising 69% of total CD4 tests performed over the lifetime of the grant.⁴⁰

Finally, with regards to **EID testing**, the project plan indicates 12,300 EID tests will be conducted in Swaziland under the project alongside 9,610 EID tests through SAMBA in Malawi and Uganda. These were revised to a cumulative target of 12,261 tests as per the end of project report, with a noted achievement of 5,875 tests or 48%, the majority of these were driven by the EID tests conducted in Kenya through GeneXpert in support of intense EID research related efforts, rather than routine EID testing.

A focus on the numbers, in terms of planned versus actual devices and tests procured is not instrumental to assess the performance of the grant alone (also noting the changing targets over time). Rather, a qualitative assessment is useful, which was provided through our interviews, both global and country-level, where the feedback has largely been that MSF made an important contribution to demonstrating VL testing in particular, amidst complex settings and challenges such as delayed technologies, although to a lesser extent in terms of EID, CD4 and POC VL testing.

4.2.2. Operational research and advocacy activities

The project plan identifies a number of areas of research and topics of interest (pp 13-14, 18-22) alongside a plan for communications at the country level (in terms of liaison with country stakeholders such as the Ministry of Health (MOH) as well as creation of educational material and sharing at appropriate fora) and at the global level (in terms of publications and meetings; and at the wider community level, in terms of coordinating with WHO, other Unitaid grantees and stakeholders) (pp 121-122). Further, while not operational research per se, there was also a plan to develop market assessment reports (pp 22-23).

While it has not been possible to review all research outputs and communications from the project, we note the following in terms of progress highlighted in successive annual reports as well as feedback from our consultations:

- A wide-ranging set of **scientific publications** have been produced, with 40 peer-reviewed articles disseminated in scientific and policymaker arenas, including validation studies for new diagnostic platforms and sample types, such as DBS, and studies on adherence to ART. The value of these studies is reflected in their citing in

⁴⁰ We note here that there is a discrepancy in the total number of CD4 tests performed between the End of Project report and the 2016 Logframe, which provides the latest possible data on the number of tests performed by country. The total figure in the End of Project report is 71,125. In the 2016 logframe, the total figure is 70,097. The 69% percentage figure uses the 2016 logframe figure for the figure of 49,430 CD4 tests performed in Swaziland as the numerator, and the End of Project report figure of 71,125 for total tests performed as the denominator.

other academic literature e.g. the article by Roberts et al (2016) on scale-up of Routine Viral Load Testing in Resource-Poor Settings has been cited 56 times to date.⁴¹

- The **MSF Access ‘Undetectable’ campaign** was delivered, a coordinated advocacy and communication campaign to push for early ART initiation, routine VL monitoring, enhanced adherence support and community models of care with increased community involvement and patient self-management in low-income settings.⁴² This campaign produced a nine-volume series of publications advocating for scale up of VL, EID and CD4 monitoring. It included the *Making Viral Load Routine* report launched at the 2016 IAS meeting in Durban, and market assessments showcasing data on prices for VL and CD4 tests, plans for country scale-up and barriers to implementation in project countries. Consultations, including with WHO, have indicated how useful these reports have been.
- At the **global level, specific advocacy and dissemination activities** have included: (i) direct support to WHO through data-sharing and technical advice which informed the 2013 and 2017 revisions to the ART guidelines as well as engagement with WHO to facilitate the PQ process for new diagnostics (more in Section 4.1); and (ii) regular dissemination of results and lessons learned through the grant at a wide range of international fora, with MSF progress reports highlighting the IAS 2013, 2015 and 2016, CROI 2013 and ICASA 2013 conferences in particular. Consultations have indicated that these have been well delivered and received.
- A number of **evidence sharing, advocacy and dissemination activities** have been conducted at the **country level**, including regular engagement mainly with: (i) MOH staff, donors and partners (e.g. PEPFAR, Global Fund, CHAI) to facilitate hand-over to MOH and scale-up of VL testing; and (ii) CSOs and patient groups for demand creation. However, the extent of this work has varied across countries as presented in our country case studies described in Section 3.3. “Traction” of this work in terms of supporting national policy development has also varied by country as described in Section 4.1. MSF also collaborated with the International Treatment Preparedness Coalition (ITPC) to implement the ‘Be Healthy, Know Your Viral Load’ campaign which provides networks of PLHIV and community activists in nine countries with knowledge to demand VL scale-up and resources to run advocacy campaigns. Feedback has indicated that this was helpful in some countries. However, we understand that this advocacy messaging was delayed and only introduced towards the end of the project, reducing its value to a certain degree. We understand that part of this delay was due to Unitaids’ approach to funding CSOs which we understand has since evolved.

⁴¹ Roberts et al. (2016) Scale-up of routine viral load testing in resource-poor settings: current and future implementation challenges, *Clinical Infectious Diseases*, 2016, <https://doi.org/10.1093/cid/ciw001>

⁴² MSF (2013) Annual Report, p.54.

Summary findings:

The procurement of diagnostic devices and tests was different from what was planned, reflecting delays in pipeline product availability and the complex environment in which the grant was conducted, however feedback is very positive in terms of the important role of the project in demonstrating lab-based VL monitoring in particular, and POC VL, CD4 and EID testing in a more limited manner.

The project has had produced a substantial evidence-base and engaged well at the global level in terms of advocacy and dissemination of results, noted by stakeholders as having been well done. The extent of country level sharing of evidence/ advocacy and dissemination has however varied by country, and the ITPC campaign may have had a larger effect had it been introduced earlier.

4.3. Country case studies and summary experience

This section focuses on an assessment of the MSF work in country – what was done, what were areas of success and key challenges, and issues remaining. The evaluation question is as follows:

4. What were key successes and challenges in introduction of the respective diagnostic technologies across project sites/ countries? Have there been financial and health systems efficiencies?

The focus of our review is on the two field visit countries – Malawi (encompassing two different MSF programmes in the Chiradzulu and Thyolo districts) and Zimbabwe. We present each of the experiences in turn below, before summarising the overall experience, also selectively considering other project country experiences described in the annual progress reports and shared during our telephone consultations (particularly with MSF). Annex F collates progress reported in the annual reports across the nine project countries.

4.3.1. MSF programme in Malawi – Chiradzulu

The MSF programme in Malawi Chiradzulu was implemented by MSF OCP from 2013 and encompassed POC CD4 and VL testing in health centres and the district hospital.

With regards to **CD4 testing**:

- This was conducted using the PIMA machine until 2016. A total of 11 machines were purchased under the project, with 16,084 tests conducted as per the 2016 annual report, representing the second largest testing for CD4 under the project.⁴³
- Thereafter, Malawi moved to a “test and treat” protocol and phased out routine CD4 testing. MSF performed CD4 tests until the implementation of the new guidelines was completed and the machines are still kept at disposal for research purposes and

⁴³ Malawi stakeholders informed us that there are 121 PIMA in the country, of which CHAI has bought 70 machines.

targeted CD4 tests. Three machines have been retained at the sites, with the plan to potentially shift the others to Uganda.

The main emphasis of the MSF programme was however **VL testing**, where the work conducted in the Chiradzulu site represented one of the few near-POC VL testings under the project. This was conducted using the SAMBA I platform, which was the first POC platform for VL testing available on the market. Six SAMBA I machines were purchased and deployed across five locations within MOH centres in the district with the following key activities in support of the testing programme:

- **Provision of supporting infrastructure** – in addition to the diagnostic equipment itself, MSF support included related laboratory infrastructure support such as back-up power supply.
- **Training and related task shifting** – MSF supported training, refresher courses and paid for examinations for MOH clinical staff to become approved second line providers. MSF also trained MOH community workers and MSF lab technicians and demonstrated that community workers could be trained to conducting the testing. Further, MSF also trained Health Surveillance Assistants to conduct counselling.
- **Demand generation/ awareness campaigns** were conducted by MSF, working alongside CSOs who support PLHIV in the district.
- **Provision of EAC and psychosocial counselling** – also providing mentorship to PLHIV who were responding well to treatment.

Table 3.4 presents the feedback received from country stakeholders on the working of the SAMBA I platform in Chiradzulu, in terms of positive and negative attributes.

Table 3.4: Positive and negative attributes with the SAMBA I POC device in Chiradzulu, Malawi⁴⁴

Positive attributes	Negative attributes
<ul style="list-style-type: none"> • Public health impact: Rapid availability of results, which can be provided within two hours • Public health impact: Simple clinical decision making • Use: Good quality platform, which is easy to use and requires little maintenance • Use: Less need for sample transport in comparison to laboratory-based devices as the platforms were POC • Use: No need for cold-chain transport, as reagents are stable for 9 months at 2-37°C 	<ul style="list-style-type: none"> • Public health impact: Could only test for VL, with results indicating < or > 1000 copies/ml • Public health impact: Cannot be used for children < age 7 • Use: Sample collection required is plasma • Use: Labour intensive testing, with three separate stages to manage within two hours • Use: Maximum capacity of 30 tests per day • Market: Risk and inefficiencies with small manufacturer, e.g. reagent supply delays, sent in batches which each incur transport fees

⁴⁴ Based on Ritchie et al. (2016) Performance evaluation of the point-of-care SAMBA I and II HIV-1 Qual whole tests as well as in-country consultations.

Positive attributes	Negative attributes
	<ul style="list-style-type: none"> • Costs: Costly testing approach – initial costs per test were US\$45, and then reduced to US\$38⁴⁵

Our consultations in Malawi indicated that the programme as a whole worked well.

The main aim of the project was to prove the feasibility and benefits of POC VL testing, which was well achieved. Country stakeholders noted that “MSF contributed significantly to showing the feasibility of POC testing” and that “they were pioneers”. Indeed, the POC VL testing programme had the following noted benefits in Malawi Chiradzulu:

- **High VL testing coverage:** The programme served a cohort of around 19,000 ART patients for routine VL, and VL coverage ranged from 62% to 81% across health centres using the SAMBA platform in Chiradzulu. In addition, testing services were provided for suspected treatment failure for an additional 17,000 ART patients from six further health facilities.⁴⁶
- **Rapid turnaround of tests and low loss of results:** Before the project, the average turnaround time (TAT) for VL test was three months, however by the end of the project, the TAT for results was one day, which was the result of steady improvement over the course of the project.⁴⁷ There was also low loss of results (<1%), facilitated through the rapid test TAT.⁴⁸ As such, there was generally quick management of patients, with consequent implications on public health impacts. This also made a six-monthly model of appointments possible for those patients that required that level of review.
- **Relatively high switching rates to second line:** The Chiradzulu district performed the best among all grant sites in terms of switching-rate to second line ART, with 68% of eligible ART patients changed to a second-line regimen, due in part to the quick availability of test results.⁴⁹ The district represented the biggest second line treatment cohort in Malawi in which 2,129 patients were put on second-line treatment. This represented a high proportion (17%) of the 12,000 patients on second-line treatment in the country.⁵⁰ Further, there were studies conducted on adolescents which highlighted particular benefits for this population group of VL testing, recognising that

⁴⁵ Country consultations provided this figure which is less than that stated in the End of Project Report (US\$43).

⁴⁶ MSF (2017) End of Project Report

⁴⁷ Initial TAT is based on consultations with MSF and health facility staff; end of project TAT based on End of Project report.

⁴⁸ Based on consultations MSF OCP

⁴⁹ MSF (2017) End of Project Report

⁵⁰ Based on consultations with MSF OCP

disclosure and adherence is a challenge and therefore faster time to switching is helpful.⁵¹

Box 3.1 presents several areas of financial and health systems efficiencies that were afforded through the project.

Box 3.1: Observed health systems efficiencies in Malawi Chiradzulu resulting from use of POC VL testing with the SAMBA platform

- With the rapid TAT (most tests results reviewed within the same day), there were fewer patient visits to clinics.⁵²
- Fewer than 1% of samples were lost using the SAMBA platform, compared with 15% of samples lost with sending tests to a laboratory-based platform based at a referral tertiary hospital, implying a reduction in leakages along the treatment cascade. There were also reduced number of re-tests needed given a lower frequency of lost samples.⁵³
- More control for clinicians over patient outcomes given greater proximity to diagnostic platforms and the ability to visit laboratories directly to request results.⁵⁴
- Faster identification of virologically stable patients to be placed on the fast track refill. Patients on the fast track refill visit clinics less frequently, typically four clinic visits a year, of which two are full clinical appointments and two ART refill visits in which services are provided by a lower level cadre health professional, thereby lessening the burden on clinics.⁵⁵ 14,000 patients were placed on fast track, representing 74% of the ART cohort.⁵⁶

However, the most significant challenge was that the MOH decided not to take routine VL testing through POC forward, primarily due to the high cost of the test.⁵⁷ The SAMBA platform in particular was not taken forward by the government, with their preference being for other POC platforms (such as the GeneXpert piloted by the MOH and CHAI). Some stakeholders in country commented that MSF could have done more to share findings within Malawi and lobby the government, as well as the manufacturer on price, which may have helped the government to accept the SAMBA technology.⁵⁸

⁵¹ Schramm, B. (2017) Understanding Virological Failure Among Adolescents Living with HIV: a cross-sectional assessment and a qualitative study.

⁵² MSF (2017) End of Project Report

⁵³ Based on consultations with MSF OCP

⁵⁴ Based on consultations with health facility staff and MSF OCP

⁵⁵ CHAI (2016) Assessing Implementation of Models of Differentiated Care For HIV Service Delivery in Malawi: Evidence Brief, September 2016, p.1.

⁵⁶ Based on consultations with MSF OCP

⁵⁷ It was also noted that turnover of MSF country directors created challenges in the programme implementation and traction. Further, MSF had challenges with lab staff retention, and had to offer higher than market rate for salaries in order to retain them.

⁵⁸ Within Malawi, MSF coordinated with other Unitaid grantees, especially between CHAI and OCP with regards to POC devices. Duplication was avoided through the following ways: (i) CHAI focused more on EID than VL through conducting evaluations and pilots on Alere, as well as the GeneXpert platform. In contrast, MSF focused more on VL testing on the SAMBA, and shared lessons with CHAI. MSF asked CHAI to conduct an independent evaluation of POC devices (GeneXert, SAMBA and Alere) in order to assist partners regarding which one to use. In addition, OCP coordinated with DRW and they both shared evidence, publications, and worked together to a certain degree to lobby the government. However, as noted above, further lobbying could possibly have been done.

Further, the full ART cohort in Chiradzulu was not handed over to the MOH, therefore MSF are still supporting targeted VL testing. The plan to hand-over, and then not to hand-over resulted in some missed opportunities, e.g. trialling of the SAMBA II platform which was not undertaken because it did not seem beneficial to introduce a new device close to hand-over.

As per the government's VL scale up plan, all health centres will switch to a strategy where routine DBS VL samples are sent to a centralised laboratory using the Abbott platform. Accordingly, MSF supported this through: (i) providing training on DBS sample collection, sample result management, documentation; (ii) have phased out routine POC VL testing and are now supporting only targeted VL testing. Within this as well, it was not possible to hand-over the operation of the platforms to community workers (i.e. the task shifting pioneered by MSF) because of the legal constraints of the MOH.

In conclusion, the MSF OCP POC VL testing programme in Malawi Chiradzulu demonstrated the many positive benefits of POC testing, however the specific technology employed could not be sustained due to high costs. Indeed the government is supportive of POC VL testing drawing on the experiences of this project, although in a targeted rather than routine manner at present on account of costs. The MSF work has also paved the way for near-POC VL testing through the GeneXpert being conducted by CHAI and other donors.

Further, an indirect benefit of the MSF OCP SAMBA programme in Chiradzulu was that lessons were transferred to the Uganda operations, where SAMBA-based VL monitoring was conducted.

4.3.2. MSF programme in Malawi – Thyolo

The MSF programme in Malawi Thyolo was implemented by MSF OCB from 2013 and encompassed laboratory-based VL testing in the MOH district hospital and health centres.

At the start of the project, VL testing was being conducted in Malawi but not at the district level, nor using DBS. MSF chose to pilot the BM platform with DBS, in a district model and this platform was replaced with the Abbott m2000 platform in 2015, in response to the MOH scale-up plan that had a preference for this device.

In support of the piloting of the new VL testing approach, MSF undertook the following:

- **Provision of infrastructure and related support** – including needed renovations to incorporate the BM and then the Abbott machine, the equipment itself but also reagents, etc., laboratory infrastructure support such as back-up power supply and additional materials, stationary, etc. We understand that MSF provided prompt support to ensure smooth running of service in terms of reagents provision, maintenance, calibration, etc.
- **DBS introduction** including a sample transport system.
- **Training, supervision and support for task shifting** – including the following:

- Trained Health Surveillance Assistants (HSAs) and provided guidelines on sample collection.
- Trained and mentored MOH healthcare workers (HCWs) on a range of aspects around VL testing, and use of platforms (lab technicians).
- MSF initially set up second-line committees to decide which patients should be switched. Subsequently, MSF advocated and provided training for task shifting beyond medical doctors to other second line prescribers.
- **Demand generation/ awareness campaigns** were conducted by MSF, working alongside CSOs in the district, although we did not get a sense from our consultations that this was not extensively prioritised as much as in some other settings beyond the experience with CAGs mentioned below.

Table 3.5 summarises the feedback received from country stakeholders on the working of the BM and Abbott platforms in Thyolo, in terms of what worked well and less well.

Table 3.5: Positive and negative attributes of the BM device in Thyolo, Malawi

Positive attributes	Negative attributes
<ul style="list-style-type: none"> ● Use: Sample collection can be DBS (as well as plasma) ● Use: Results provided for specific copies/ml 	<ul style="list-style-type: none"> ● Market: Delays for BM with reagents and maintenance support from manufacturer ● Use: BM requires substantial amount of maintenance ● Comparison: BM much more labour intensive than the Abbott machine (requiring manual labour), producing more waste, and can run fewer samples.

Given that routine VL testing had not previously been undertaken at the district level, the main contribution of the MSF project in Thyolo helped **demonstrate the feasibility of lab-based routine VL testing at the district level**. In particular, use of DBS, and an effective ‘whole cascade’ approach (e.g. sample collection, transport of samples to and from Laboratory etc) proved that this was possible. Notable successes include:

- **Public health successes** in terms of improvement in switching rate to second line⁵⁹ and validation of DBS sample collection, therefore allowing more remote health posts to conduct testing.⁶⁰
- While diagnostics platforms were changed during the course of the project, these were well managed and **MSF adapted their work to the needs and requirements of the government**. For example, MSF negotiated a rental agreement for the Abbott product to help better manage costs and also transferred the BM machine to Zimbabwe for use.

⁵⁹ Annual Report 2013

⁶⁰ Annual report 2013 and consultations

- The **rental agreement** with the Abbott platform was particularly noted as an important initiative to circumvent high outright purchase prices for countries, especially in circumstances of uncertainty on continued use.
- The work by MSF was well documented and shared at the national level in terms of lessons learnt for **policy impact**. The good relationship between MSF and the DHO also helped reach policy makers at national level.

We understand that **MSF has handed over the whole ART cohort to the MOH** at the end of 2015. They had been providing support in 26 health facilities to an ART cohort of approximately 46,000 patients. VL testing was handed over as part of the broader hand-over of the MSF ART cohort and the core of the Unitaid funding was terminated.⁶¹

A key aspect of the MSF work was the **management of the DBS approach**, which demonstrated its effectiveness for broader scale-up by the government which according to consultations is estimated to now be used for at least 90% of the testing. The MSF work demonstrated the finger-prick test for DBS, and together with the important work around task shifting mentioned above, supported a relatively high testing coverage of 56%.⁶²

Another key aspect, while not exclusive to the MSF work, was the effective functioning of the CAGs, which contributed to overall successes/ results during the pilot. Box 3.2 provides some details on their functioning, which worked across a number of countries in addition to Malawi.

Box 3.2: Bringing treatment closer to home and empowering patients: Lessons learnt from implementing the CAG model in Malawi, Mozambique and Zimbabwe

The CAG model was originally piloted in Mozambique for ART distribution, whereby groups of PLHIV rotate for clinic visits and drug refills at the clinic while dispensing drugs to their peers in the community and ensuring peer support.⁶³ Through this project, this model has been particularly beneficial for supporting VL monitoring, adherence, reducing access barriers and introducing health system efficiencies. Through our consultations in Thyolo, and Zimbabwe, we learnt the following:

In terms of supporting **access**, using PLHIV volunteers as ‘champions’ has helped to spread the word about the importance of VL testing. One beneficiary in Thyolo noted how they had obtained their understanding of the need for VL testing, as well as interpretation of the result, from being part of a CAG. In Thyolo, the CAG model has enabled VL testing interventions to reach people in areas that could not otherwise have been reached. In terms of **adherence support and VL monitoring**, the CAG model reinforces peer support to PLHIV, through which adherence is encouraged, at the community level. Furthermore, the individual who collects ART, also gets their VL test conducted during that visit, this encouraging take up of VL monitoring. In terms of **health system efficiencies**, the CAG model provides an example of decongesting over-burdened health facilities by reducing the number of clinic visits as individuals collect ART for group members.

While the programme as a whole worked well in country, aspects flagged by stakeholders where there was room for improvement included:

⁶¹ MSF (2017) End of Project Report

⁶² MSF (2016) Vol. 8: Making Viral Load Routine: Part 1 Programmatic Strategies.

⁶³ Decroo et al (2013) Scaling Up Community ART Groups in Mozambique.

- Need for training of additional health workers to undertake DBS sample collection, as there was a limited number post project.
- Hand-over was affected by lack of motivation from MOH laboratory technicians. A missed opportunity was not to have employed MOH staff earlier to conduct testing.
- Recommendations from the *INCLUSIVE* report (which proposed specific national VL landscape with a (semi-) centralised management of high volume of routine VL samples plus POC as a complementary strategy, provided through private-public trusts), were not taken up by other VL actors/ donors, in part because the report was produced very late.⁶⁴

More broadly, both OCP and OCB coordinated with partners through technical working groups (TWGs) and directly with partners working in their respective districts, such as Riders for Health regarding transport and with Baobab regarding data handling. Whilst not directly attributable, we note that quite a few aspects that MSF were advocating for, were also not encouraged by partners suggesting that possibly evidence sharing and/or coordination could have been improved, for example rental agreements for platforms (other than the platform rented by OCB); and the *INCLUSIVE* report recommendations (OCB). We also note that MSF OCB and OCP advocated for different approaches to VL testing and whilst these were complementary, this may have been better coordinated, particularly in terms of engagement with the government.

4.3.3. MSF programme in Zimbabwe

MSF Brussels provided VL and EID testing in Zimbabwe. **VL testing** was performed through: (i) centrally located platforms; and (ii) decentralised testing with tests being conducted in health centres, initially in three MSF supported districts (Buhera, Chikomba and Gutu) and later also in Gweru, Mutare and Nyanga.

Regarding **EID** support, this was provided under the PMTCT programme in three sites within two districts. Studies were also conducted on the **integration of EID and VL**. These included:

- Study assessing VL and EID testing on the GeneXpert platform and received approval from MOH to continue it for VL and EID in MSF supported districts.
- An economic evaluation of VL testing and EID including on the viability in a rural district.

In terms of VL testing, 169,897 samples were processed over the course of the grant from MSF-supported and non MSF-supported sites.⁶⁵

⁶⁴ Unfortunately, MSF was unable to generate sufficient commitment among VL actors in the country to develop a concrete business plan in line with the *INCLUSIVE* recommendations. The concept will remain an important advocacy tool for MSF, though, both in Malawi and in neighbouring countries where the setting up of a well-functioning VL landscape encounters similar challenges.

⁶⁵ MSF (2017) 2016 Annual Logframe.

- **Buhera:** a total of 64,577 VL tests from 28 ART sites were performed over the lifetime of the grant, representing 55% of all the VL tests performed in MSF-supported sites in Zimbabwe. The number of patients in the ART cohort was 19,289, with a VL coverage rate of 91%.⁶⁶
- **Gutu:** a total of 36,489 VL tests from 19 ART sites were performed. The number of patients in the ART cohort was 11,944, with a VL coverage rate of 74%.⁶⁷
- **Chikomba:** a total of 16,680 VL tests were performed.⁶⁸

The majority of the VL testing was conducted using centrally located BM platforms, with DBS (venous blood samples) taken from decentralised clinics. The Buhera (2015) and Chikomba (2015/2016) cohorts were handed over but MSF have continued to provide mentoring support in Gutu (not for VL specifically). Furthermore, during the course of the project, MSF provided additional support to other districts, particularly to support scale up.

In terms of **activities undertaken for VL testing**, these included:

- **Central laboratory infrastructure support:** renovation of the National Microbiology Reference Laboratory (NMRL) was conducted, including to accommodate the BM platform.
- **Deployment, and support of platforms:** This included **centrally located BM platforms:** one installed in the NMRL Harare Central Hospital, in 2013 and one installed in Beatrice Road Infectious Diseases Hospital (BRIDH), Harare (December 2015). Support was also provided for servicing equipment and calibration, provision of reagents and a waste management system was introduced. With regards to **deployment of POC VL platforms**, GeneXpert was trialled in Mutare.
- Introduction of **decentralised DBS sample collection** and **supply system support for VL testing:** This included introduced tracking forms for patients with high VL results, introduction of M&E tools, provision of transport systems and training.
- **Training:** At the **decentralised level** this included training for: (i) sample collection (venous blood DBS, not finger-prick as per MOH decision); (ii) task shifting and training on second line switching; (iii) implementation of VL protocol. In addition, a mentoring model was adopted. At the **centralised level**, this included (i) use of instrumentation/platform (specialist training for a month) and (ii) training for staff at lower level laboratories to refer to central laboratories.

⁶⁶ The figure for the number of viral load tests is drawn from MSF (2016) Annual Logframe. The figures for the number of ART sites, the size of the ART cohort and the coverage rate are drawn from MSF (2016) Vol. 8: Making Viral Load Routine: Part 1 Programmatic Strategies, p.10.

⁶⁷ Ibid.

⁶⁸ No data was available for the Chikomba site from 2016 on the size of the ART cohort, coverage rate and number of ART sites. Figures provided for 2015 in the 2015 Annual report present the following: 6,015 viral load tests performed out of an estimated number of 8,216 viral load tests, amounting to a coverage rate of 73%.

- **Demand/ awareness raising activities** through HCWs and worked alongside CSOs in the districts, with feedback indicating that the direct collaboration and data sharing from the project was beneficial. The CAGs model was used as a flagging system for when patients needed VL testing.
- **General scale up support** was provided in Mpilo District Hospital, Mutare and Bulawayo. This included plasma testing/ Roche VL testing through support such as provision of reagents (very limited), materials, stationary, maintenance; training and mentoring. Support was also provided to completed rehabilitation works to three laboratories (BRIDH, Chinoyi and Mutare).

The **additionality of the project** is reflected in the fact that prior to MSF introducing VL testing, testing was only conducted in expensive private facilities. MSF therefore led the way in terms of introducing routine VL testing and were viewed as pioneers. MSF remained the only partner with a platform in country until mid-2016, and as such undertook a “hugely ambitious project” (as stated by several stakeholders) in an extremely challenging setting.

There were a **number of successes** achieved in this project and aspects that worked well. These included:

- **Relevance for policy:** Respondents unanimously attributed much of the VL scale up plan (2015-2018) to the work of MSF. In addition, their work supported guideline and algorithm development, and buy in from MOH and donors.
- **Introducing a “new system”:** As MSF were the pioneers, a high number of supply chain, demand/ awareness activities, health system strengthening aspects were introduced, importantly including DBS testing. Many of these form the basis of what is now being scaled up in country, supported by partners and the government.
- **Integration with MOH:** MSF work was well integrated with the district and national level MOH. This included (i) conducting tests for MSF supported sites as well as MOH sites; (ii) placement of platforms within MOH. As one respondent said, “MSF could have put the BM machine in their district but they didn’t, they put it centrally and also let MOH use their platforms”; (iii) training and capacity building (noted further below); (iv) provided database for VL information system which helped the NMRL. National and district level MOH respondents were highly appreciative of MSF work. This is a particularly strong aspect that worked well with this project.
- **Training and capacity building:** This worked particularly well through (i) mentoring model; (ii) training of trainers model (centralised and decentralised levels). Respondents in a decentralised location reported being capacitated in conducting testing, training and adherence counselling with comments such as “we are well versed in VL testing because of MSF”. Training resulted in capacity building for staff at NMRL too, and it was noted, “when MOH handed over their machines, the lab staff had been capacitated so they could take it on”.

- **Introduction of diversity of platforms** which created market competition. This is considered to be one of the successes of the programme in Zimbabwe, due in part because of the high training that MOH staff received, as well as the support provided to introduce multiple platforms such as BM, Abbott, Roche for VL; PIMA vs BD FACSPresto for POC CD4, and GeneXpert for EID (and VL). Maintenance delays experienced with BM also helped to inform the country to consider models that mitigate this such as rental agreements, as well as decision to adopt more than one platform.
- A key respondent noted that this project “had a huge **public health impact**”. In 2016, 42% of VL testing in Zimbabwe was performed by MSF. In terms of national VL testing coverage of PLHIV on ART, Zimbabwe achieved 14% VL coverage in 2016, up from 5% at the end of 2015 and respondents reported the most recent coverage to be 23%. Of particular benefit to the MOH was the assessment of viral suppression, and that the project showed a need to invest in adherence counselling and capacitate counsellors. MOH reported that studies showed that 22-40% were suppressing with Early Adherence Counselling (EAC), thus also providing an efficiency in terms of savings from not needing to switch patients to second-line treatment. However, other consultations noted that there were still delays in switching patients to second-line treatment which reduced the public health impact of the project.

Box 3.3 elaborates on partner coordination and MOH integration by MSF in Zimbabwe.

Box 3.3: Partner coordination and MOH integration in Zimbabwe

Within Zimbabwe, MSF coordinated well with partners as well as the MOH, particularly through their involvement in a number of TWGs with which evidence from the project was shared. Respondents noted that “information sharing was a strength of MSF” that they were well aware of MSF’s work.

In addition, a smaller Unitaid grantee partner TWG was established between EGPAF, CHAI/UNICEF and MSF. This group had separate monthly meetings with one of the aims being to avoid duplication and facilitate partners to work to their respective strengths. For example, decisions as to which organisation would take something forward depended on which one was working in a specific setting, or perhaps had already engaged with the MOH on a particular issue, or had the most appropriate technical capacity. In particular, MSF led on the clinical side, and helped to lay the foundation for scale up and the work of the MSF project laid the foundations in other ways such as the GeneXpert study enabled CHAI not to have to do their own evaluation on the GeneXpert.

In addition, CHAI, UNICEF and MSF worked together to assist the MOH to develop VL scale-up plan. It was noted however, that this synergy was more because of personal relationships, and could have been better structured/ coordinated.

In addition, stakeholders noted a missed opportunity to be the lack of pooled procurement between these grants.

At the same time, there were some **challenges** as well:

- Ongoing **transport challenges** were experienced throughout the project such as fuel, break downs, maintenance, and coordination of transport among partners. However

this was not specific to MSF, and transport is an ongoing challenge that other partners are still experiencing.

- **Ongoing long TAT.** TAT remained high due to a number of factors such as transport, samples being sent without reagents, a high backlog of tests (from demand being stimulated before having the capacity to meet the demand) etc.; maintenance delays etc.
- **Delays** were experienced regarding the national scale up due to: (i) technology development, particularly regarding platforms able to do VL on DBS and/or VL POC technology; (ii) implementation of the plan in terms of building laboratory capacity; (iii) writing and finalising the national VL roll out plan; (iv) selection of the platforms and agreements with the companies by MOHCC/ UNDP. There was also a delay within the project with regards to UNDP procurement for the second BM platform in which it took two years for this information to be communicated to the government. This resulted in MSF providing the only one laboratory-based platform in country until late 2015, and being the only partners supporting any platforms in country until approximately mid-2016 when CDC and PEPFAR supported platforms.
- Whilst many positives regarding sustainability were noted during consultations, a few respondents noted that the transition period was too short and **transition was too abrupt**. This may have been in part due to delays in hand-over to UNDP, and their procurement system which caused delays. However, respondents noted that the transition could have been communicated earlier, in particular because of the significance of the grant before hand-over.

4.3.4. Summary findings across countries

As a conclusion to this section, we summarise the main findings and lessons learnt from the country case studies, alongside a broader consideration of the contribution of the MSF project across countries. Finally, the section ends with a summary of the key remaining challenges with regards to VL monitoring across countries, as also noted in the *Making Viral Load Routine* publication.

Summary of country case studies, lessons learnt and project contributions

As described above, the experiences have varied substantially by country and project site. The MSF programme in Zimbabwe has worked particularly well, with good linkages with the government and hand-over, alongside support for scale-up. The project has also worked reasonably well in Malawi Thyolo, where the adaptability of the MSF programme paved the way for a greater degree of hand-over/ government commitment, and the DBS demonstration work and linkages with the CAGs worked particularly well. Malawi Chiradzulu has seen lesser results at project close with the SAMBA not being taken over by the government due to high costs, but the demonstration of the many positive benefits of POC

testing has been useful, supporting the government's decision to take forward targeted rather than routine manner at present.

These varying country experiences have been due to differing country contexts and the suitability of the diagnostic technology and testing plan within these settings, and therefore lack of full hand-over at the end of the MSF project need not be viewed as an issue per se (as discussed further in Section 4.3 on sustainability and scalability). Indeed, the main benefit of the MSF project across all three countries has been its demonstration work that has shown that routine VL testing can be feasible and is much needed in countries.

This demonstration has and will set the way for further roll out and scale-up in the future. Certain features of MSF's work that have served as success factors for hand-over/ scale-up have included the degree to which they have engaged with government stakeholders (from the beginning, continuously and on an ongoing basis, as was the case in Zimbabwe) as well as with CSOs and other community bodies (such as the CAGs) which have supported demand creation and efficiency. On this latter aspect, there have been some good examples, although this has varied between settings and potentially more could have been done if there had not been delays with the work of ITPC, as noted in Section 3.2.

Several examples of health system efficiencies demonstrated through the project. Box 3.4 presents experiences with regards to health system efficiencies across Malawi and Zimbabwe.

Box 3.4: Health system efficiencies from VL testing across Malawi and Zimbabwe

A number of observed health systems efficiencies were noted during our consultations in Malawi and Zimbabwe, other than those already mentioned in Box 3.1 specifically noted with regards to POC in Chiradzulu and the CAG model in Box 3.2. Examples include the following:

- Although VL testing has been a 'new type of monitoring', in general it has not added to the workload of HCWs as previously facilities were conducting six monthly CD4 testing. In comparison, if VL testing shows they are virally suppressed, then patients only need to be tested annually, bi-annually.
- Through DBS, demonstrated that VL sample collection could be easier to manage than plasma with regard to cold chain, storage system needs etc.
- Through task shifting, it is possible for sample collection, second-line treatment decision making (Thyolo) and counselling (Chiradzulu, Thyolo) to be made lower cadres.
- If patients receive EAC post VL testing, and become virally suppressed, this can save on patients unnecessarily being switched to second-line treatment, which is more costly.
- VL testing provided clinicians with information regarding which patients can be 'fast-tracked' if found to be virally suppressed.
- In Zimbabwe, systems for data and forms were introduced by MSF, as these were a big bottleneck.
- Multi-platforms (such as use of the GeneXpert in Zimbabwe) have the benefits of reducing under-utilisation if a platform is only used for testing for one disease.

Looking across the nine project countries, the focus of MSF's work has been more on laboratory-based VL testing as compared to POC testing.⁶⁹ This has largely been on account of the delayed pipeline of POC products, but also based on country acceptability and context viability for introduction of POC testing. As such, a number of the lessons learnt through this work by MSF are based on models adopted for laboratory-based VL testing and further work is needed on evidence-base and demand creation for POC testing. Our conclusion from the MSF project work however is that its demonstration has been more successful at the laboratory rather than POC level.

That said, the models employed have considered decentralised testing approaches more generally – most notably through the DBS approaches which have been extensively piloted and tested through the range of MSF projects across the countries. Indeed, there has been much good learning with regards to the use of DBS in routine VL testing through this MSF project, noting in the *Making Viral Load Routine* report, “While plasma remains the gold standard, use of DBS and near POC helps overcome the challenges of sample transport”.

Key ongoing issues in countries

Key issues, some of which are also outlined in the end of project report as well as MSF's flagship publication on *Making Viral Load Routine*, are as follows:

- **Continued low and varying coverage rates across countries:** While the project sites have demonstrated an improvement in coverage rates, VL testing coverage as a whole within the project countries is very low. As noted in the *Making Viral Load Routine* publication, coverage is low and varies considerably (32-91% in MSF supported sites), with the probability of having a second VL test following an initial high VL being even lower (23-71% in MSF project sites).
- **Maintenance challenges and supply chain as ongoing issues:** Maintenance challenges have been fairly extensive across project countries, for example as noted in the case studies presented above. Further, poor supply chain functioning in countries also creates further challenges. For example, the MSF annual report states that the Abbott platform arrived June 2015 in DRC, but was only operational for 72 days out of 191 in 2015 due to lack of consumables, a small broken bolt, and a cold chain rupture resulting in the reagents being put in quarantine.
- **Varying TATs and great need to reduce:** Experiences with improvements in test TATs have varied substantially by country/ technology/ setting, but in general, there is considerable scope to reduce TATs across the board.

⁶⁹ Also recognized in the 2013 MSF progress report which states that majority of the sites focus on VL testing in central labs with high throughput (BM, Roche and Abbott) while fewer sites were using POC VL - Samba (Malawi-C and Uganda)

- **Challenge with low switching rates:** In a similar vein, while some successes have been achieved on switching rates within the project sites (albeit noted as challenging), this continues to be a major issue in countries as discussed further in Section 4.2.
- **Challenge with waste management:** Unfinished work also remains with regards to waste management. This particularly relates to cyanide which is produced by most of the platforms. Country consultations highlighted waste management as an outstanding issue that requires further work in terms of technical guidance, regulation and funding, and if not addressed, poses an important risk.

Summary findings:

The MSF programme in Zimbabwe has worked particularly well, with good linkages with the government and hand-over, alongside support for scale-up. The project has also worked reasonably well in Malawi Thyolo, where the adaptability of the MSF programme paved the way for a greater degree of hand-over and government commitment, and the DBS demonstration work and linkages with the CAGs worked particularly well. Malawi Chiradzulu has seen lesser results at project close in terms of the SAMBA platform not being taken over by the government due to high costs. However the demonstration of the many positive benefits of POC VL testing has been useful, supporting the government's decision to take forward targeted rather than routine manner at present.

These varying country experiences have been due to differing country contexts and the suitability of the diagnostic technology and testing plan within these settings, and therefore lack of full hand-over at the end of the MSF project need not be viewed as an issue per se. Indeed, the main benefit of the MSF project across all three countries has been its demonstration work that has shown that routine VL testing can be feasible and is much needed in countries. Certain features of MSF's work that have served as success factors for hand-over/ scale-up have included the degree to which they have engaged with government stakeholders as well as with CSOs and other community bodies (such as the CAGs).

Looking across the nine project countries, the focus of MSF's work has been more on laboratory-based VL testing as compared to POC testing. As such, a number of the lessons learnt through this work by MSF are based on models adopted for laboratory-based VL testing and further work is needed on evidence-base and demand creation for POC testing. That said, the models employed have considered decentralised testing approaches more generally – most notably through the DBS approaches which have been extensively piloted and tested through the range of MSF projects across the countries.

Challenges persist with low VL coverage rates, high TATs, low switching rates to second-line treatment and with regards to waste management.

5. IMPACT AND SUSTAINABILITY

The final evaluation dimension on impact and sustainability seeks to **assess the overall results/ benefits of the investment made by Unitaid on the project**. We consider the extent to which the project has contributed to addressing critical access barriers including with regards to policy development (Section 4.1), the public health impact from disease monitoring and decentralised testing (Section 4.2) and the extent of sustainability of project sites and overall prospects for scalability (Section 4.3).

5.1. Addressing access and policy barriers

The evaluation question is as follows:

5. To what extent has the project contributed to addressing critical access barriers? Has the project evidence and communications supported policy development?

One of the key objectives of Unitaid's 2017-21 Strategy is to overcome market barriers to catalyse equitable access to better health products (Strategic Objective 2). The strategy defines an effective market as one with the following attributes, which we have further defined in the context of the market for this project:

- **Demand and adoption:** Countries, programmes, providers and end users rapidly introduce and adopt the most cost-effective products within their local context.
- **Supply and delivery:** Supply chain systems including quantification, procurement, storage and distribution function effectively. Adequate and sustainable supply exists to meet global needs.
- **Innovation and availability:** Availability of new/ adapted diagnostic products for improved clinical efficacy, reduced cost, or better meeting of the needs of end users, providers or supply chain managers.
- **Quality:** Quality-assured diagnostic technologies, with reliable information on the quality of the product.
- **Affordability:** Lowest sustainable price for the technology that does not impose an unreasonable financial burden on governments, donors, individuals or other payers, with a view to increasing access for the under-served.

We consider the extent to which the project has contributed to addressing each of these access barriers, focusing on VL monitoring, which has been the main basis of this project. We present the evidence base for all of the above-noted access barriers, noting that the project may have impacted some more than others. Further, we highlight that several aspects presented below have been discussed in previous sections of the report, so here we bring the analysis together to present our overall findings.

Our conclusion is that while the MSF project has contributed to addressing all of these access barriers, its fundamental contribution has been in terms of supporting demand for VL monitoring, and also supply and delivery of diagnostic platforms on a pilot scale.

5.1.1. Demand and adoption

The project has had an important impact in terms of fostering demand, through contributions to global and national policy development (although the extent has varied by country), alongside working with CSOs, health worker and beneficiaries on ground. We consider each in turn below.

Global policy development

Our discussions with WHO have indicated that the project has contributed to the development and updates to the WHO guidelines for ART treatment and monitoring, alongside contributions from a range of other sources.⁷⁰ MSF is viewed as the first implementer to progress with VL testing (“trailblazers”), particularly from the clinical perspective, and hence have had an important contribution to global policy development.

In particular, data generated through the project was helpful for WHO in identifying strategies to tackle ART failure and revising their ARV guidelines accordingly (these were updated in 2015, published in 2016). This included MSF’s work reviewing the performance of DBS specimens which contributed to WHO’s understanding of the best threshold for DBS and created a consistent threshold across specimens. In addition, WHO noted MSF’s work with regards to reviewing the WHO algorithm. This included MSF’s programmatic implementation work and studies which reviewed the following: (i) reducing the threshold for VL failure; (ii) switching patients to second-line after a first elevated VL test result; (ii) implementation of POC VL to determine if it is supportive of faster clinical decisions and switching to second-line treatment; and (iii) determining if a more rapid second VL test supports more efficient switching to second-line. WHO also noted that MSF’s work contributed to best practices, both related to laboratory work on VL and to programmatic considerations in routine VL monitoring.

Another point flagged by WHO was the important contribution of the project in flagging the drastic reduction in CD4 testing services after the change in WHO guidelines, to the detriment of complex HIV cases that still require this testing.

National policy and guideline development

As noted in Section 3.1.2, a number of stakeholders viewed the project timeline as very ambitious to impact national policy and guidelines. That said, MSF has played an important role in national policy development relating to VL testing, through participation in the TWGs and engagement with policymakers. For example, the End of Project Report notes policy

⁷⁰ MSF (2017) End of Project Report

influence by MSF in terms of shaping national or provincial HIV treatment guidelines and/or VL scale-up plans in DRC, Malawi, Mozambique, Western Cape/ South Africa on EID, Zimbabwe.⁷¹

Our review suggests that the impact of MSF’s work has varied by country, depending on the extent of engagement by MSF with policymakers. Table 4.1 presents the main aspects of policy that were impacted through work in Malawi and Zimbabwe. While there were several aspects demonstrated in the project sites that were incorporated into national policy, the impact has been much more substantial in Zimbabwe, where MSF was a front runner and primary supporter for VL testing for a number of years and worked closely with government. More limited engagement with government in Chiradzulu has been cited as one of the reasons for the lack of uptake of the routine testing model from the MSF project in that site.

Table 4.1: Policy impact in Malawi and Zimbabwe

Malawi (Chiradzulu)	Malawi (Thyolo)	Zimbabwe
<ul style="list-style-type: none"> • POC targeted testing in the instances when clinical or virological failure is suspected for PLHIV, for adolescents and children (draft)⁷² • Fast track refills model 	<ul style="list-style-type: none"> • Finger prick DBS testing for routine VL testing⁷³ • CAGs model • Task shifting for DBS sample collection to lower cadres and for second line initiation beyond medical doctors (2015) 	Significant input for: <ul style="list-style-type: none"> • National HIV VL Scale up Plan (2015-2018)^{74 75} • VL component in Operational and Service Delivery Manual for the Prevention, Care and Treatment for HIV (2015)
<ul style="list-style-type: none"> • Regimen switch to second-line treatment to be made after two, instead of three high VL test results, and for the cut off to be >1000ml/copies • Expected that VL testing to be changed from every two years to yearly in 2018 		

With regards to Zimbabwe, respondents noted, “when the project started, there were a lot of gaps. The lessons learnt and innovative ideas from MSF enabled the production of the National VL Scale-up Plan” and “their data and results have given the government the confidence to say that we, the Government, can also implement this programme”. In Malawi, the direct influence of the MSF project has not been as pronounced as in Zimbabwe given that other partners were working in VL during the project and also a degree of limited engagement by MSF. We also note that in some instances, recommendations by MSF have

⁷¹ MSF (2017) End of Project Report

⁷² MOH Malawi (2015) Malawi HIV Viral Load Scale up Strategic and Implementation Plan 2015 to 2018, it notes that this will be scaled up in “support to balanced VL testing platforms between conventional and POC, if POC devices are considered beneficial to the Malawian VL Program”. Our understanding is that there is a draft plan for this to be scaled up.

⁷³ MOH Malawi (2015) Malawi HIV Viral Load Scale up Strategic and Implementation Plan 2015 to 2018

⁷⁴ MOHCC Zimbabwe (2015) Zimbabwe HIV Viral Load Scale-up Plan 2015-2018

⁷⁵ It is noted however that the plan has been for the period 2015-18, although scale-up and donor funding is yet to happen.

not been taken forward in policy such as (i) preferential rental agreement procurement model; (ii) public-private semi-centralised model as recommended in the *INCLUSIVE* report; (iii) routine POC testing (although targeted POC testing was taken forward).

In addition, in both Malawi and Zimbabwe, various tools designed by MSF have been adopted such as high VL alerts, VL forms, and various M&E tools to support the government during and following project hand-over and this has contributed to enhanced national capacity.

Demand creation through engagement with CSOs, health workers and others

Through our global and country level consultations, we understand the following work of the project helped facilitate demand amongst different stakeholders:

- As previously discussed with regards to engagement with **CSOs**, MSF has worked directly with CSOs and community groups (such as through establishing the CAGs) as well as through ITPC's advocacy work. The degree and impact of this work has varied by country.
- A key finding of the project was the need to work with clinicians, health workers, and PLHIV in order to create awareness and stimulate demand.⁷⁶ The project has supported capacity building and training of **health workers**, lab technicians and clinical staff across health centres, reference laboratories, district hospitals, etc., which has enabled countries to introduce VL testing, and stimulate demand amongst HCWs.⁷⁷
- Demand has been stimulated amongst **beneficiaries** through the activities noted above. In addition, demand has been stimulated because VL testing services have been brought closer to PLHIV, and services have been provided quicker due to reduced TAT, especially in POC sites such as Chiradzulu.

5.1.2. Supply and delivery

In terms of supply and delivery, the project has had an impact on a pilot basis as was not set up as a "market creator" project with substantial procurement volumes and price impact.⁷⁸ In particular:

- The main thrust of the project has been pilot testing and demonstration of a range of lab-based and POC approaches to VL testing that have required procurement and delivery of the diagnostic platforms to countries.
- Alternate procurement strategies were demonstrated for countries, such as negotiating rental agreements for the Abbott platform in Malawi.

⁷⁶ MSF (2016) Vol. 8: Making Viral Load Routine Part 2: The Viral Load Laboratory

⁷⁷ The project has also demonstrated the need for counsellors (including for EAC). Our consultations in Malawi and Zimbabwe suggested that, seeing the success in terms of adherence among PLHIV utilising MSF facilities where counselling is provided, has encouraged governments to make greater use of counsellors.

⁷⁸ As noted in Section 2, this was the predominant focus of the CHAI/UNICEF project rather than the MSF project.

5.1.3. Innovation and availability

Whilst not the main area of impact of the project, the project has made a contribution to supporting innovation and availability of diagnostic technologies and models of care for VL monitoring. This has primarily been through piloting innovative models of care.

5.1.4. Quality

With the objective of the project being to pilot diagnostic technologies, quality checking and assurance was core to the project. We understand that most technologies used under the project were either WHO pre-qualified or ERP-D approved. Further, certain technologies were piloted in country for expanded purposes (e.g. use of the Abbott platform for DBS) and other platforms have been validated in country such as the GeneXpert for VL and EID testing in DRC and the SAMBA II for use in Uganda.

Whilst challenges with maintenance support from manufacturers and its availability (especially for POC technologies) has been an ongoing constraint, some improvements have been made during the course of the project such as an increase in in-country engineer presence, after having been highlighted by MSF.

5.1.5. Affordability

Affordability continues to be a challenging access barrier for the diagnostic technologies, contributing to its limited sustainability and scalability, as discussed in Section 4.3.

The End of Project Report notes that while some manufacturers (e.g. Abbott, BM and Biocentric) have somewhat reduced prices for VL reagents, prices for VL consumables continue to be very high. For example, MSF noted that the manufacturing costs of commonly used laboratory and POC VL tests would be between US\$2 (BM) and US\$7 (Alere), assuming that 1m tests were produced annually; however prices today range from US\$6-20, with the SAMBA POC tests being exceptionally expensive at US\$38.⁷⁹ The report further notes reasons for these high prices as lack of demand/ international funding, lack of pooled procurement arrangements and lack of bundled pricing discounts across multi-disease testing platforms.

Indeed, an issue flagged on the project performance was in terms of whether Unitaid or the Unitaid grantees directly may have set up some arrangement for pooled procurement for efficiency and better pricing. The 2013 annual progress report makes reference to some attempts between MSF and CHAI, but we understand these were not taken forward. This can be viewed as somewhat of a missed opportunity, given that all of these grantees are purchasing the same technologies and working in the same countries. Further, the MSF *How Low Can we Go* report emphasised that the cost of reagents was usually the most significant costs, with quite a large degree of flexibility, and that better informed negotiations and/or pooled procurement could assist with price reductions.

⁷⁹ Country consultations provided this figure which is less than that stated in the End of Project Report (US\$43).

Notwithstanding this issues, we note that as this is was an operational research project, procurement was less relevant for this grant in comparison to other larger commodity grants. Further we understand from Unitaid that there has been an improvement over time with regards to procurement coordination with the introduction of strategic engagement with manufacturers and Unitaid grantees, Global Fund and PEPFAR.

Finally, we note that MSF contributed to price transparency through the Access Campaign such as in the *How Low Can We Go* publication.

Summary findings:

While the MSF project has contributed to addressing all access barriers, its fundamental contribution has been in terms of supporting demand for VL testing. At the global level, the project has contributed to WHO global policy and guidelines development. At the country level, there has been greater impact on national policies in Zimbabwe as compared to Malawi, reflecting varying degrees of engagement with policymakers and the number of partners simultaneously supporting VL testing in the respective countries. Demand has also been facilitated by bringing the technologies closer to PLHIV, capacity building of health workers and engagement with civil society. The project has also contributed to the supply and delivery of HIV monitoring for patients at a pilot scale, however affordability remains an important access barrier that remains.

5.2. Public health impact

The evaluation question is as follows:

6. What has been the public health impact of the project from decentralised testing and disease monitoring (direct and indirect)?

We consider the public health impact of the project work on VL, EID and CD4 testing below. The analysis is based on progress reported against logframe indicators relating to public health impact, supplemented by additional quantitative analysis and consultation feedback, especially from the country visits to Malawi and Zimbabwe.⁸⁰

5.2.1. VL monitoring and public health impact

The project contributed significantly to the increase in VL coverage that reached 80% and above in some rural sites and MSF helped to increase VL coverage to approximately 30% of the tests needed in cities.⁸¹ Whilst no target was set for the logframe indicator O5.1a on “percentage of coverage of VL testing based on annual HIV caseload estimates”, across seven sites with 2016 available data, the percentage of coverage of VL testing was 44% overall, of

⁸⁰ The project goal of “improved clinical outcomes for PLHIV in resource-constrained settings through models of care for optimal use of PoC CD4, laboratory-based and PoC viral load and EID testing” has associated indicators of (i) improved switching to second-line regimen treatment; and (ii) median/average number of calendar days from EID sample collection to treatment initiation.

⁸¹ MSF (2017) End of Project Report

which 33% was covered by MSF.⁸² Given that many sites did not have routine testing before the start of the project, this is good progress, but more will need to be done to achieve required scale up.

One of the benefits of the VL testing in the project is that it highlighted the lack of coordination in the VL cascade, and the high need for switches to second-line treatment. Table 4.2 shows the number of enrolled ART patients changed per protocol to a second-line regimen by VL testing, revealing a much lower than planned achievement and considerable variation by project site.⁸³ Switching to second-line treatment was not a direct focus of the project, and consultations indicated that it might have been helpful to have this focus at the outset for greater linkages with results. However while the project target was not met, it needs to be noted that the absolute number of switches to second-line treatment has increased significantly as this was below 1% at the time of grant proposal.⁸⁴

Table 4.2: Number and percentage of enrolled ART patients changed per protocol to a second-line regimen by VL testing (Indicator G2)⁸⁵

Select countries	Target	Result ⁸⁶
Overall	16,030	4,839 (30%) ⁸⁷
DRC (Kinshasa)		8%
Malawi (Chiradzulu)		68%
Mozambique (Maputo)		57%
Swaziland (Shiselweni)		24%
Zimbabwe (Gutu)		25%

Box 4.1 provides barriers to switching and particular strategies that have worked under the project.

⁸² Ibid

⁸³ The progress reports also present average number of calendar days between VL sample collection and results being ready to be sent from the laboratory. The experience has varied by project site (e.g. around 1.5 days in Malawi Chiradzulu on account of POC but 46 days in Zimbabwe) but generally been poor.

⁸⁴ MSF (2017) End of Project Report

⁸⁵ MSF (2017) End of Project Report

⁸⁶ The country results refer to the number of patients switched to second-line treatment as a proportion of those patients identified in need of switching.

⁸⁷ This result refers to the achievement of the number of patients switched to second-line treatment as a proportion of the project target.

Box 4.1: Switching to Second Line Drugs – Barriers and Potential Solutions

Barriers to switching

The End of Project report notes a number of reasons why the switch to second-line regimens did not happen as much as expected. This included: (i) clinicians confidence; (ii) delaying switching, and requesting multiple VL tests due to expected lack of adherence causes; (iii) second-line treatment prescription decisions being centralised and/or a lack of task-shifting to enable lower cadres second-line treatment prescribers; (iv) lack of access to second line drugs (i.e. stock-outs) and (v) perceptions that second line drugs are expensive and should be a ‘last resort’.

Some of this was echoed in our country visits where we heard that previously MOH perceived that the switch was happening too fast; second line drugs are more toxic and more expensive and that patients do not like to switch (Zimbabwe); challenges regarding second-line regimen quantification and associated supply (Malawi) and insufficient task shifting to lower cadres (Malawi and Zimbabwe).

Strategies to improve switching

The End of Project report summarises the interventions MSF undertook to increase the second line switch rates which included: (i) M-health tools to aid information sharing and discussions to facilitate remote decision making; (ii) training of doctors at district level to make switch decisions (Lesotho); (iii) ongoing training, mentorship, and provincial- and facility-level ART committees (Mozambique) and (iv) integration of treatment reporting into routine M&E to sensitise staff and strengthen approach to switching (Swaziland).

As reported in the End of Project report, and from our country visits, we learnt the following with regards to strategies for switching to second-line treatment:

- In Zimbabwe, providing training and mentoring increased the number of nurses who can be tasked with switching. For example. One nurse stated, “if you are knowledgeable, you are confident. It’s easy to switch patients because we have the information”. Engagement, and obtaining support from the District Medical Officer has significantly impacted switching rates.
- In Malawi, MSF developed a mentorship programme and a national second line examination which if passed, enables clinicians and nurses to be certified, thus enabling task shifting. Systems alerting HCWs to high results were also utilised to prompt switching.
- In Chiradzulu, POC testing contributed significantly to achievement of the highest switching rate in the project because of “the quick, and high coverage of VL testing, able to highlight the high need for switching to second line”, and as noted for further reasons noted Section 3.3.
- In both Malawi and Zimbabwe, the project helped with quantification for second-line drugs.

Despite the relatively low achievements in second line switching, for those patients who did receive second-line treatment, or who were able to achieve viral suppression after EAC, the following benefits were noted:

- Viral suppression has numerous benefits including improving morbidity, mortality and quality of life.
- In addition, viral suppression, particularly to a lower than detectable level, significantly reduces the likelihood of HIV transmission (a particularly important consideration for discordant couples who want to have children).
- In the case of children and adolescents, the positives were particularly pronounced given the higher needs for closer monitoring and treatment (as noted above).

Box 4.2. further notes positive feedback from HCWs.

Box 4.2: Select quotes from HCWs on benefits of VL monitoring

Health facility staff in Malawi and Zimbabwe were very positive about the effects of VL testing and VL suppression. The following comments were made:

- “The public health impact of the MSF project is significant. To a large extent, the MOH used to use immunological and clinical monitoring to switch patients to second-line treatment. Learning from MSF’s experiences in remote districts, we discovered that we switched patients unnecessarily; and then we had problems with their adherence. VL testing ensures that patients are ready to be switched – after all, second line medicines are very expensive compared to first line so we don’t want to prescribe them unnecessarily”
- “We now see children looking well”
- “We now rarely seeing very sick patients or patients with opportunistic infections”
- “Patients are not just living longer but also have a better quality of life”

In addition, consultations have indicated that VL scale up has also provided important clinical data on HIV treatment in project countries, identifying problems and research needs. For example, Mozambique has the highest proportion of PLHIV with a detectable VL (27-40% in certain districts compared to 9-21% in other project countries).⁸⁸ Across nine MSF sites, all sites, except Swaziland, children less than 15 years had the highest percentage of viral failure, with adolescents and young adults (15-25 years) experiencing the next highest level, followed by adults.^{89,90} Without increased VL testing, this discovery would not have been made, and it has led to research into whether this is attributable to a drug-resistant HIV strain. Furthermore, whilst not common, in select instances in Zimbabwe, VL testing also shed light on when patients were being switched unnecessarily.

Finally, feedback indicates that if MSF had not initiated routine VL testing, it is probable that VL testing would have arrived in those districts at a later stage, thus resulting in higher morbidity and mortality for those PLHIV with persistent viraemia, and increased number of infections during that time.

Estimations regarding direct and indirect impact of the project

Based on available project data and drawing on key research studies, a brief indication of the public health impact of the VL testing component of the project has been provided regarding the direct impact (through the project) and indirect (assuming scale up on routine VL coverage in project countries). We note that this data should be interpreted with extreme caution as it is based on crude data and assumptions. Annex J provides further details.

With regards to the **direct impact** of the project, using a study by Keiser et al. (2010) assessing the mortality at one year of patients switching to second-line regimen (4.2%), in comparison to those who remained failing first-line regimen (11.7%) in sub-Saharan Africa, it can be

⁸⁸ MSF (2016) Vol. 8: Making Viral Load Routine Part 1: Programmatic strategies

⁸⁹ In Shiselweni, Swaziland, the proportion of those tested with VL >1000copies/ml was as follows: 25% (<15 years); 28% (15-25 year olds); 12% (>25 years)

⁹⁰ MSF (2016) Vol. 8: Making Viral Load Routine Part 1: Programmatic strategies

estimated that there were 363 deaths averted at one year due to 4,839 people switching to second-line treatment during the project.^{91, 92}

Keiser et al (2011) note the benefits from routine VL monitoring beyond just switching to second-line treatment, and that at three years post routine VL coverage, 4.3% (CI 3.9 – 4.8%) had died in comparison to 6.3% (CI 6.0 – 6.5%) who died in settings without routine VL coverage.⁹³ Therefore the estimated direct impact of the project at three years post increasing VL testing coverage is that an estimated 2,579 (CI 2,192 – 2,708) deaths were averted, in comparison to VL testing coverage not having been scaled up.⁹⁴

Given the nature of the project being focused on demonstrating feasibility of VL testing, the potential indirect impact may be seen as being of more of particular relevance, rather than the direct health impact through the project. Regarding the **indirect impact** of the project, it is estimated that if VL testing is scaled up to the level of South Africa's routine VL coverage in project countries, then 82,000 (CI 69,700 - 86,100) additional deaths will be averted in three years, in comparison to not having routine VL testing.⁹⁵ Furthermore, assuming that PLHIV on ART in project countries receive routine VL testing, it was estimated that an additional 2,700 deaths may be averted after one year due to switching to second line treatment.⁹⁶

5.2.2. EID testing and public health impact

As noted previously, the work on EID POC testing was much delayed and majority of the testing was for research rather than routine purposes. As such, the project has not had much impact in the area. Notwithstanding this, EID was introduced in DRC, Kenya and South Africa and Table 4.3 shows the average number of calendar days from EID sample collection to treatment initiation for that year. As early initiation of treatment has significant impacts on morbidity and mortality on infants, the fact that targets were met, or exceeded for Kenya and

⁹¹ Keiser et al, (2010). Mortality after failure of antiretroviral therapy in sub-Saharan Africa. *Trop Med Int Health*. 2010; 15(2): 251–258.

⁹² Cumulative mortality at one year was 4.2% (95% CI 2.2 - 7.8%) in patients who switched to a second-line regimen and 11.7% (7.3% - 18.5%) in patients who remained on a failing first-line regimen. We have assumed that the MSF project sites are similar in nature to the sub-Saharan sites participating in this study by Keiser et al but this study may not be representative of all sites providing ART in these countries, or to other sub-Saharan African countries.

⁹³ Keiser et al (2011). Outcomes of Antiretroviral Treatment in Programmes with and without Routine Viral Load Monitoring in Southern Africa. *AIDS* 25(14): 1761–1769.

⁹⁴ Data for ART cohorts and viral load coverage has been based on the Making Viral Load Routine Part 1: Programmatic Strategies document. As such, data has not been available for DRC, and has been taken from 2015.

⁹⁵ This estimate assumes that the project countries achieve routine VL testing for PLHIV on ART to a degree which is the same as that which was achieved in South Africa within a study by Keiser et al (2011). Estimates regarding the number of PLHIV on ART have obtained from UNAIDS 2016 estimates (UNAIDS 2016: http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf)

⁹⁶ This was derived through applying assumptions regarding the number of PLHIV on ART who are failing first line treatment as well as an assumed increase in switching rate of 8.9% from routine VL testing instead of CD4 testing (based on a study by Haas et al 2015) and assuming a reduction in mortality from switching to second line regimen, as per Keiser et al (2010).

South Africa is significant. The reasons for delay in DRC are due in part to the fact that the team only operates the Abbott platform twice per month.⁹⁷

Table 4.3: Average number of calendar days from EID sample collection to treatment initiation^{98, 99}

Country	Target	Result
DRC	7	30
Kenya	15	10
South Africa	1	1

5.2.3. CD4 testing and public health impact

With regards to CD4 testing, we note that this was not a key component after the 2013 guideline changes. However, during the course of the project, as number of CD4 tests were conducted. In addition, MSF has advocated for the ongoing monitoring of CD4 in specific instances. This has ongoing relevance for patients who benefit from these tests. It has been recognised through consultations that the speed with which CD4 testing was dropped has been problematic, particularly for complex HIV cases where CD4 measurement is more relevant. The continued focus by the project was helpful (including in establishing the risks with de-emphasising CD4 measurement).

Summary findings:

The project has made an important contribution to increasing VL testing, which has had a number of public health benefits. However, the ultimate impact on switching to second-line treatment has not been as much as expected.

In terms of EID TAT, while project monitored targets have mostly been achieved but due to the delays in the devices being available, the public health impact of the project in this area has been limited.

5.3. Extent of sustainability and potential for scalability

The final evaluation question considers the extent of sustainability of the MSF programmes and potential for scalability. The specific evaluation question is as follows:

7. Have the project activities been sustained and has the project laid the foundation for scale-up?

The MSF project was a demonstration and feasibility assessment project, and hence the expectation is that not all approaches will be taken forward by the government and other partners. Further, there may be varying experiences ranging from full hand-over of the diagnostic platform and ART cohort to the government with or without supporting donor funding, to take over of a specific service or adoption of a particular approach that may have

⁹⁷ MSF (2017) End of Project Report

⁹⁸ MSF (2017) End of Project Report

⁹⁹ Malawi, Uganda and Swaziland EID testing was not implemented, data from 2016.

been piloted by MSF, to a continuation of diagnostics and monitoring by MSF themselves. This last aspect does not necessarily suggest a poor outcome given MSF's role in several countries of managing ART cohorts. However, ultimately for longer term sustainability one would expect hand-over to the government, which might be particularly risky for project sites where MSF activities have not been well-integrated with the government.

A review of the total of ten programmes supported by MSF under the project (considering two separate programmes in Malawi and a total of nine countries covered), indicates this varying experience.¹⁰⁰ In particular:

- **Three programmes have seen good hand-over to the government and follow-up funding by donors.** These include: (i) Zimbabwe, where the MSF work has been particularly successful, with strong MOH interest in scale-up and crowding-in by other donors (PEPFAR, Global Fund, UNDP); (ii) Mozambique, where there has been a hand-over to the government in early 2017, including take-over of both the BM and Abbott platforms and support for reagents from PEPFAR; and (iii) Malawi Thyolo, where MSF has proactively revised its programme to ensure government take-over.
- **Four programmes are being largely continued by MSF, with some services and/ or approaches being taken forward by the government.** This includes DRC, where the government has taken over certain services such as sample transport and donors are funding reagent costs, however VL testing continues to be provided by MSF. There are some indications of the government funding certain aspects in Swaziland, but MSF continues operations for now. In Uganda as well, MSF notes that the government sees the value of POC testing but is unable to cover the costs. Finally, as noted in Section 3.3, MSF's programme in Malawi Chiradzulu on routine POC VL testing including the SAMBA platform has not been taken up by the government, although the government is taking forward targeted POC VL testing through other platforms.
- **The remaining three programmes had somewhat of a mixed/ limited hand-over experience.** In Lesotho, there was hand-over to EGPAF, however there were challenges with MSF closing its operations in the country. In Kenya, although the GeneXpert platform was validated, the government is not planning to roll out GeneXpert EID as part of its national strategy. In South Africa, the Alere Q platform supported by MSF has been discontinued as there is a good central laboratory system with good TATs. Whilst we note that this may be appropriate from the country's perspective, the platforms utilised under the operational research have not been taken forward.

As such, there have been highly successful country programmes that have seen full take-over by the government and other donors (being driven by MSF's close alignment and working with government), alongside others where selected services have been handed over or

¹⁰⁰ Annex H provides country specific details.

particular approaches adopted. This has been on account of limited government funding and capacity as well as preference for alternate technologies other than that piloted by MSF, reflecting the complex context for MSF operations where the work of multiple players and funders also influences MOH decision making. Finally, some programmes such as in Kenya and South Africa have not been taken up by the government, which reflects the feasibility of alternative approaches, although with their operational research focus, hand-over was also not the core objective of the project.

Generally it is recognised that ensuring the sustainability of the MSF programmes is challenging given the resource-limited settings that they are operating in. Even for the more positive experiences of hand-over, there have been ongoing challenges with a decline in certain services post-hand-over (e.g. in Zimbabwe and Malawi Thyolo), including longer TAT and lower switch rates (e.g. in Mozambique and Zimbabwe). Further, some have also commented that the project has been very ambitious with too short a timeframe (even with extensions) and that integration with governments and others takes more time, especially given the nature of the intervention which requires not only financial commitment but also revisions to the approach to HIV diagnosis and monitoring.

The main contribution of the MSF programme however has been its clear demonstration of the feasibility of routine VL testing and presentation of “proof of concept” that this can work and is much needed. As such, the policy-making and demand creation “leverage” facilitated by the project is considerable and should not be under-estimated. As such, this baseline of MSF contributions will go a long way in ensuring future scalability of VL monitoring, which is of increasing importance to country governments and large donors such as PEPFAR and the Global Fund. We also note that donors are already supporting country governments with regards to testing platforms, as well as reagents, consumables, transport etc., both for the new platforms and Unitaid-procured platforms that have been handed over (for example in Malawi and Zimbabwe), thus emphasising the positive groundwork laid by this project towards scalability.

While scalability was not a direct objective of the project, we have examined current VL testing coverage rates and policy implementation in project and non-project countries to analyse if there has been any further impact (Table 4.4). Not unexpectedly, there isn’t a direct correlation between project countries and progress, with varied and slow experience across both project and non-project countries – primarily reflecting the complexity of scaling of VL monitoring in these resource-limited settings. This does not undermine the significance of the MSF project work, rather emphasising the challenging nature of the intended ultimate outcome. A first step to the pathway is however noted in the increased implementation of national policy on VL testing across a number of countries.

Table 4.4: Viral load testing coverage and policy implementation¹⁰¹

Country	Viral load testing coverage (2016) ¹⁰²	Implementation of national policy on routine viral load testing for adults and adolescents
DRC ¹⁰³	<50%	Partially implemented
Kenya	<50%	Fully implemented
Lesotho	No data	Fully implemented
Malawi	50-74%	Fully implemented
Mozambique	No data	Partially implemented
South Africa	50-74%	Fully implemented
Swaziland	<50%	Fully implemented
Uganda	No data	Fully implemented
Zimbabwe	<50% ¹⁰⁴	Partially implemented
Eastern and Southern Africa (21 countries)	1 country with 75% and above (Comoros) 3 countries with 50-74% (Malawi, Seychelles and South Africa) 8 countries with less than 50% 9 countries – no data	13 countries have fully implemented policies 8 countries have partially implemented policies 0 countries have only targeted testing or no policy

Summary findings:

There has been varying experience across the MSF programmes in terms of extent of hand-over to the government and other donors, with some programmes still continuing to be delivered by MSF, although with certain services or approaches being adopted by the government. Sustainability of programmes continues to be a challenge in resource-limited settings, with some evidence of declining service provision post MSF hand-over. The main contribution of the project however has been its demonstration of proof of concept which has helped set the stage for longer term scalability of routine VL monitoring.

¹⁰¹ Data taken from UNAIDS (2017) UNAIDS Data 2017

(http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf)

¹⁰² Percentage of people living with HIV on antiretroviral therapy who received a viral load test

¹⁰³ DRC is included in Western and central Africa statistics, not Eastern and Southern Africa

¹⁰⁴ During our consultations in country, Zimbabwe has reportedly increased VL testing coverage from 5% at the end of 14% in 2016 and approximately 23% in 2017.

6. CONCLUSIONS AND LESSONS LEARNT

The MSF project has been a highly relevant project, initiated in a context where there was limited commitment, funding and policy progression on VL monitoring. The project is recognised as timely and important, given the significant changes with regard to the global HIV guidelines on VL testing and the related international targets of 90-90-90. With the project objective of developing and delivering optimal models of care for HIV diagnosis and monitoring, it has helped create a strong body of evidence and experience that will pave the way for uptake, adoption and scale-up in countries. Indeed, our consultations at the global and country levels have emphasised the seminal role of MSF in the field of VL testing.

The project has been extremely complex, with an ambitious goal of demonstrating the feasibility and use of routine VL testing in countries that are largely resource-constrained. MSF's task has been further complicated by pipeline diagnostic product delays and the high prices at which these platforms have been made available. MSF has approached these challenges well, nimbly adapting and revising its country plans and diagnostic platform selection to suit the needs of the specific and evolving context.

While lower than planned, MSF has conducted substantial VL testing across a number of countries and through the application of a wide-range of technologies and models of care. The project has demonstrated a number of successes, including the feasibility of high VL coverage in project sites (e.g. Buhera, Zimbabwe (91%), Shiselweni, Swaziland and Arua, Uganda (85%)); the value of POC testing through experiences of very rapid test TAT (one day), low loss of results (<1%) and relatively high switching rates to second line regimens (68% of eligible ART patients changed to a second-line regimen (Malawi Chiradzulu)); decentralised approaches, including DBS, which reduced a number of access barriers (e.g. in Zimbabwe and Malawi (Thyolo), where DBS is used for 90% of VL testing); developing of laboratory strategies for VL testing; amongst others. Further, while CD4 testing was also lower than planned, appropriately reflecting the changing WHO guidelines, the project made an important contribution by highlighting of the risk of the dramatic decline in this testing.

These demonstrations and engaged working with governments have contributed to hand-over of a number of MSF programmes to the government and other donors, particularly in the case of three of ten MSF programmes in Zimbabwe, Mozambique and Malawi Thyolo. Other MSF country programmes have not been as successful in terms of full hand-over, but select services and/ or approaches have been taken over by the government (e.g. targeted POC VL testing in Malawi Chiradzulu). MSF continues to support these projects in country through their ongoing programmes, which is understandable in a time of high competition for diminishing donor resources and static or declining government health budgets. However, ultimately the programmes need to be handed over to the government and sustainability risks remain post MSF handover, especially for MSF projects sites that are not fully integrated with government services. The main contribution of the project however has been its

demonstration of proof of concept which has set the stage for longer term scalability of routine VL monitoring.

There has been good progress in generating operational research outputs in terms of 40 peer-reviewed publications alongside advocacy and dissemination efforts at several international fora. Indeed, the project's evidence-base has informed the development of WHO guidelines on HIV testing and treatment.

Notwithstanding the range of positives and benefits from the project, it is noted that its contribution has been more limited for POC VL and EID testing, mainly on account of delayed availability of technologies. Looking forward, it is also recognised that while the project demonstrated single-use platforms, multi-disease or polyvalent platforms are becoming increasingly more available and important in the context of integrated approaches to health.

In addition, while the project well-complimented other Unitaid-funded HIV diagnostics grants in terms of scope and objectives, there was relatively poor actual coordination between these grants. At the country-level, this has varied (being more coordinated in Zimbabwe as compared to Malawi for example), and represents a missed opportunity to harness the respective strengths and efficiencies across grants. Information sharing and coordination was also lacking amongst MSF units, with for example, two differing approaches being advocated for in Malawi. Alignment or coordination in this respect may have helped present a stronger evidence base for governments.

Another area where there was room for improvement was with regards to engagement with CSOs to support broader demand creation. While there were some good examples (e.g. the working with CAGs in countries), this was not uniformly well done across project countries.

While recognising that Unitaid has updated its project design and management approach, especially under the new strategy, lessons from the experience of the implementation of the MSF project suggest the need for: (i) more realistic timeframes for projects, recognising the complex and uncertain environment that Unitaid projects operate in; (ii) project design to be carefully supported by scenario assessment, aided with a clear and continually updated risk assessment; (iii) a critical consideration of what really defines the measures of success for a project and developing suitable M&E indicators, with an emphasis on project site data collection especially given the weak data that exists; (iv) greater emphasis on coordination with other partners, through for example, measurable indicators to ensure this is done; and (v) close monitoring of impact metrics to ensure continued efficiency in terms of increased benefits for increased costs.

Finally, as an end note, we highlight that the landscape for VL testing remains challenging. Not only do VL testing coverage rates remain very low, there is also much to be improved in terms of test TATs and treatment regimen switching rates. Challenges persist with available technologies in terms of high prices, ineffective maintenance and the issue of waste management. As such, the path to scale-up requires further work, although noting that the

MSF contribution through this project has made a positive contribution to setting the stage for scale-up.

ANNEX A LIST OF REFERENCES

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ANNEX B CONSULTATIONS AND INTERVIEW GUIDES

This annex provides the list of consultations undertaken in support of this evaluation.¹⁰⁵

B.1. Consultee lists

Table B.1: Global consultee list

Stakeholder	Organisation	Name	Position
Unitaid	Unitaid Secretariat	Robert Matiru	Operations Director
		Smiljka de Lussigny	Programme Manager
		Lorenzo Witherspoon	Procurement Officer
		Carmen Perez	HIV Strategy Manager
		Philippe Duneton	Deputy Executive Director
		Jemmy Dopas	Finance Manager
		Vincent Bretin	Team Lead, Results
		Gauri Khanna	M&E Manager
Project Grantee	MSF	Stephan Grosserueschkamp	Grant Manager (from January 2017 to October 2017)
		Mikhael de Souza	Grant Manager (2013-2016)
		Camille Baillat	Grant Finance Manager (from October 2016)
		Teri Roberts	Diagnostic Advisor
	MSF-Belgium	Marc Biot	Program Manager
	MSF-Switzerland	Javier Goiri	Deputy Program Manager
	MSF-Southern African Medical Unit (SAMU)	Tom Ellman	Director
	MSF-Supply	Eric Morel	Field Procurement Expert
Global Partners	WHO	Lara Vojnov	HIV Diagnostics Advisor
		Meg Doherty	WHO Coordinator, HIV Treatment and Care
	USAID	Dianna Edgil	Senior Laboratory Adviser
	CHAI	Trevor Peter	Head of CHAI Laboratory Team
		Zach Katz	Former Head of CHAI Laboratory Team

¹⁰⁵ Representatives of the Global Fund were contacted for an interview, however there was no response, and as such it has not been possible to gain their feedback for this evaluation. Other donors and global partner have however been interviewed.

Stakeholder	Organisation	Name	Position
	CDC	Debi Boeras	Former Head of the VL/EID Section of The International Laboratory Branch
	IPTC	Solange Baptiste	Executive Director, IPTC

Table B.2 Country level consultee list

Stakeholder group	Organisation	Name	Position
Zimbabwe			
Other donors	WHO	David Okello	WHO Resident Representative
		Simbarashe Mabaya	HIV Prevention Officer
	CHAI	Phibeon Mangwendeza	Manager
	Global Fund CCM	Oscar Mundida	CCM Executive Secretary
	USAID	Kathy Webb	Health Officer
Government	NMRL, MOH	Ellen Munemo	Coordinator, NMRL
CSO	Jointed Hands Welfare Organisation	Jessie Sukuta	Programmes Coordinator
		Melody Mukundwi	Communications and Liaison Officer
	ZNNP+	Rumbidzai Matewe	Programmes and Training Manager
Government	MOH	Regis Choto	National ART Coordinator
Implementing partner	MSF	Daniela Garone	Medical Coordinator
		Bjorn Nissen	Country Director
		Abraham Mapufo	Medical Doctor, Deputy Field Coordinator (Gutu)
		Dominique Kouadio	Field Coordinator (Gutu)
Health facilities	Gutu Facility Staff	Agustus Chikwati	Nurse in Charge
		Tafadzwa Kupfavira	Opportunistic Infection Nurse
Malawi			
Government	MOH	James Kandulu	Director of Diagnostics Department
		Dr Arnold Jumbe	DHO Thyolo
Other donors	CHAI	Andrews Gunda	CHAI Country Director and Lab Team

Stakeholder group	Organisation	Name	Position
	Global Fund CCM		Chairman of the Oversight Committee of the CCM
	USAID	Anteneh Worku	USAID HIV Treatment Advisor
	CDC	Henry Mbah	Laboratory Advisor
		Alice Maida	Medical Officer
Implementing partner	MSF Operational Centre Brussels (OCB)	Jacob Pidini	Thyolo, Activities Manager
		Ilse Casteels	Head of Mission
		Dr Reinaldo Ortuno	Medical Coordinator
	MSF Operational Centre Paris (OCP)	Cyrus Paye	Project Coordinator
		Adriana Palomares	Head of Mission
		Robert Keango	Medical Coordinator
		John Sekibibi	Medical Focal Point
		Natalia Castgon	Point of Care Manager
		Rachel Masinga	HC Laboratory Manager DBS-TB
	Health facilities	Thyolo District Hospital	Lameck Mkuntha
Nancy Kayenda			Laboratory Technician
Jones Mhango			Laboratory Technician
Clinic, Thyolo District		Celina Kamankdola	Medical Assistant, clinic in Thyolo District
			Beneficiary
Chiradzulu District Hospital		Rachel Kamba	Clinical Officer
		Tambudzai Misasa	Laboratory technician
		Euster Maluza,	Laboratory clerk
		Lidia Moyo,	Laboratory Manager
		Patricia Zaunda,	Psychosocial Counsellor

B.2. Interview Guides

Key interview guides are included below. Further interview guides were adapted for specific consultees (especially at the country level) and have not been included here for the sake of brevity.

B.2.1. MSF

1. Please provide an overview of the project in terms of the main objectives, areas of work/ main activities and aspects that worked well and less well.

Key questions

2. What was the basis for selection of the project countries and project sites? What were the main types of models employed across project countries/ sites and how were these planned for (considering aspects such as level of facility, diagnostic technology in use, engagement with government, forward and backward linkages, etc., across the VL, CD4 and EID components of the project)?
3. What were key successes and challenges in introduction of the respective diagnostic technologies across project sites/ countries? What has been the key learnings in terms of what has worked well and less well?
4. What learning is there on more efficient and effective testing? For example, has there been financial and health systems efficiencies and/ or more effective targeting/ reach of key populations?
5. What has been the public health impact of the project from decentralised testing and disease monitoring (direct and indirect) and is this aligned with expectations?
6. To what extent has the project contributed to addressing critical market barriers in terms of facilitating demand and adoption, including updating of global and country level policy? Has the project evidence and communications supported policy development?
7. Have the project activities been sustained since project closure? Has the project laid the foundation for scale-up of HIV monitoring and testing?

Other questions

8. To what extent has the project been relevant and aligned with the global guidelines and policies for HIV as well as the work of other actors (including other related Unitaids grants on POC diagnostics)?
9. Has the project been efficiently delivered, considering aspects such as adherence to planned budgets, procurement activity and timelines as well as overall project management and coordination?

Lessons learnt and recommendations

10. What are the main lessons learnt from the implementation of the grant and related recommendations including with respect to Unitaids funding, grantee performance, further work required in the POC HIV diagnostics space and any other aspects?

B.2.2. Global Partners (USAID, CDC, CHAI)

1. To what extent has the Unitaid-MSF project on implementation of viral load, CD4 and EID testing been relevant/ needed intervention in relation to the global goals/ needs for HIV?
2. What do you view as the key learning from the Unitaid-MSF project on the use and implementation of different diagnostic/ monitoring technologies? Has the project adequately demonstrated use as well as challenges to facilitate uptake/ increased coverage and what remain as key challenges?
3. What has been the main benefit/ value add of the Unitaid-MSF project? Have there been any missed opportunities?
4. To what extent has the project contributed to developing and updating global and country level policy on HIV diagnosis and monitoring? Have the results from the project been adequately disseminated?
5. Has the Unitaid-MSF project been adequately coordinated with the work of other organisations working in the HIV diagnostics space?
6. Do you view the Unitaid-MSF project to have successfully laid the foundations for scale-up by government and other partners? What more could the project have done to support scale-up of viral load testing?

B.2.3. WHO

1. To what extent has the Unitaid-MSF project on implementation of viral load, CD4 and EID testing been relevant/ a much needed intervention in relation to the global goals/ needs for HIV?
2. What do you view as the key learning from the Unitaid-MSF project on the use and implementation of different diagnostic/ monitoring technologies? Has the project adequately demonstrated use as well as challenges to facilitate uptake/ increased coverage and what remain as key challenges?
3. What has been the main benefit/ value add of the Unitaid-MSF project? Have there been any missed opportunities?
4. To what extent has the project contributed to developing and updating global and country level policy on HIV diagnosis and monitoring? Have the results from the project been adequately disseminated?
5. Has the Unitaid-MSF project been adequately coordinated with the work of your organisation?

B.2.4. Government and Policymakers (Zimbabwe and Malawi)

1. What was the situation regarding (i) POC CD4 testing; (ii) laboratory-based VL testing; (iii) POC VL testing; and (iv) EID testing at the start of the Unitaid funded MSF project (i.e. around 2013)?
2. How have the activities of the MSF project linked to other HIV initiatives in the country, including other POC diagnostics, laboratory-based testing, as well as prevention and treatment activities?
3. What were key successes and challenges in introduction of the respective diagnostic technologies in the project sites? What has been the key learnings in terms of what has worked well and less well?
4. How efficient and effective have the (i) POC CD4 testing; (ii) laboratory-based VL testing; (iii) POC VL testing; and (iv) EID models been in terms of improving HIV monitoring (e.g. targeting of key/ vulnerable population groups, simplification of testing, faster turnaround times for testing, more effective access to test results, etc.)?
5. What have been the various demand (e.g. community awareness) and supply side (e.g. procurement, supply chain, equipment maintenance, training of health workers) factors determining results and how have these factors worked in practice?
6. Have the new approaches to testing contributed towards any financial or health systems efficiencies?
7. What has been the public health impact of the project from decentralised testing and disease monitoring (direct and indirect) and is this aligned with expectations? What do you believe has been the impact of this project in terms of i) increased levels of HIV monitoring; ii) switching to second line regimens and improved clinical outcomes?
8. To what extent has the project contributed to addressing barriers regarding HIV monitoring and to updating country level policy? What have been the lessons learned from the operational research? Have these been communicated to country stakeholders and what actions have subsequently been taken, including regarding policy?
9. Have the project activities been sustained since project closure? Has the project laid the foundation for scale-up of HIV monitoring and testing? What more is required for countries to increase uptake of VL monitoring and EID?
10. What do you view as the key value add of the Unitaid-MSF project in country? Have there been any key missed opportunities?

ANNEX C MAPPING OF UNITAID 2013-16 STRATEGY OBJECTIVES WITH GRANT FOCUS

Table C.1: Unitaid 2013-2016 Strategic Objectives and grant relevance¹⁰⁶

Strategic objective	Market shortcoming sought to be addressed through the project	Description of project aims and alignment with Strategic Objective/ market shortcoming
1: Increase access to simple, point-of-care diagnostics for HIV/AIDS, TB, and malaria	<p>Affordability: Traditional HIV diagnostics performed in sophisticated laboratory settings are unaffordable for resource-limited settings.</p> <p>Quality Absence of information on quality of newer POC diagnostics.</p> <p>Acceptability/ Adaptability: Traditional, laboratory-based products are ill-adapted for low-resource settings because they are complicated to use and maintain, and require sophisticated infrastructure and skilled technicians. Newer POC diagnostics currently on the market allow for more decentralized testing but many are still too complicated for use in remote settings by unskilled workers.</p> <p>Delivery: Slow and insufficient uptake of both traditional laboratory-based and newer POC diagnostics.</p>	Within the project aims, operational research was to be conducted on feasibility, acceptability, sustainability, and affordability of POC testing and laboratory-based tools to determine optimal implementation approaches across a range of settings. In addition, informal assessments on the quality of the products were to be conducted. As such, the focus of the project was on acceptability/ adaptability and delivery, although it also touched upon affordability and quality.
2: Increase access to affordable, adapted paediatric medicines to treat HIV/AIDS, tuberculosis, and malaria	<p>Delivery: Few children are initiated on HIV treatment prior to 18 months of age as recommended.</p>	Project indirectly contributed towards this objective by aiming to improve access to EID.
3: Increase access to emerging medicines and/or regimens as well as new formulations, dosage forms, or strengths of existing medicines that will improve treatment of HIV/AIDS and coinfections such as viral hepatitis	<p>Affordability: High prices of existing products</p> <p>Delivery: Low uptake of second-line regimens; almost no uptake of third-line regimens in LICs.</p>	Project indirectly contributed to this objective by increasing the understanding of the need for second and third line treatment, and feasibility of testing and switching in LICs. The project aimed to provide lessons learned and best practices to WHO for incorporation into Treatment 2.0 guidance.

¹⁰⁶ Unitaid (2013), Unitaid Strategy 2013-2016

ANNEX D COMPLEMENTARITY OF THE MSF GRANT WITH UNITAID’S BROADER PORTFOLIO

Table D.1: Key Unitaïd diagnostics grants during the MSF project timeframe and areas of complementarity

Grant overview	Primary aim/s	Complementarity/ synergy with MSF grant
<p>CHAI/UNICEF Project</p> <p>2012-2020, US\$149.3m</p>	<ul style="list-style-type: none"> • Organise demand • Ensure low prices • Coordinate with suppliers, scale-up POC HIV diagnostics. 	<ul style="list-style-type: none"> • MSF project provided lessons learnt to inform market, CHAI-UNICEF focused on healthy market through procurement volumes • CHAI/UNICEF focused on POC, MSF focused on laboratory and POC • Some overlap in project countries (Malawi, Mozambique, Uganda, and Zimbabwe)
<p>DRW project</p> <p>2013-2017</p> <p>US\$8.8m</p>	<ul style="list-style-type: none"> • Prepare the HIV diagnostic market for use of the SAMBA platform for PoC VL and EID in six countries • Designed to accelerate the product’s market entry through supporting regulatory approvals and field studies in the target countries 	<ul style="list-style-type: none"> • Focus on the SAMBA technology, serving as a grant to support the manufacturer with product entry • Some overlap in project countries
<p>EGPAF</p> <p>2015-2019</p> <p>US\$63m</p>	<ul style="list-style-type: none"> • Using innovative POC EID, aim to demonstrate public health impact and impact the market 	<ul style="list-style-type: none"> • Some overlap in project countries • EID uptake was slow during MSF project years
<p>OPP-ERA Project</p> <p>Phase 1: 2013-2016, US\$6.4m</p> <p>Phase 2 2016-2019, US \$14.7m</p>	<ul style="list-style-type: none"> • Implement Open Polyvalent Platform in countries • New manufacturers and suppliers enter the market • Ensure lower price and increase access for diagnostic 	<ul style="list-style-type: none"> • Focus on different countries • Focus on open polyvalent platforms, MSF project focused on single-platforms (Multiplex platforms were an innovation that came out during the MSF project and budget is larger for Phase 2 of OPP-ERA project)

ANNEX E PROJECT LOGFRAME AND ACHIEVEMENTS

This annex includes the full logframe with achievements. Indicators that were dropped following the 2015 annual report have been included with their most recent target, and are highlighted in grey.

Table E.1: Revised logframe, as agreed between Unitaid and MSF in 2016, and cumulative project results

Result level	Description	Revised Target	Result	% Achievement
Goal	Improved clinical outcomes for PLWHA in resource-constrained settings through models of care for optimal use of PoC CD4, laboratory-based and PoC VL and EID testing			
G1	Number and percentage of patients initiated on ART after same-day PoC CD4 testing	10,000	Dropped after 2015 annual report	
G2	Number and percentage enrolled ART patients changed per protocol to a second-line regimen by VL testing	16,030	4,839	30%
G3	Median/Average number of calendar days from EID sample collection to treatment initiation	DRC: 7	30	Not achieved
		Kenya: 15	10	Achieved
		South Africa: 1	1	Achieved
Purpose	Increased PoC CD4, laboratory-based and PoC VL and EID testing according to evidence-based recommendations			
P1	Number of PoC CD4 tests done per MSF country project	65,659	71,125	108%
P2	Number of VL tests done per MSF country project	540,690	426,181	79%
P3	Number of EID tests done per MSF country project	12,261	5,875	48%
Output 1	Use of PoC CD4 testing in resource-constrained settings to generate evidence-based recommendations			
O.1.1	% pre-ART patients LTFU after PoC CD4 testing confirmed treatment eligibility	<15%	Dropped after 2015 annual report	
O.1.2	% patients receiving PoC CD4 results from their provider during same medical visit	>90%	Dropped after 2015 annual report	
Output 2	Use of district/regional laboratory-based VL testing in resource-constrained settings to generate evidence-based recommendations			
O.2.1	# newly-initiated ART patients district/regional lab-based VL tested for early adherence	10,000 total for all countries	Dropped after 2015 annual report	
O.2.2	# stable ART patients tested by routine district/regional lab-based VL follow-up	70,000	Dropped after 2015 annual report	
O.2.3	Average number of calendar days between VL sample collection and results are ready to be sent from the laboratory	Malawi: 1	1.5	Not achieved
		Mozambique: 30	44	Not achieved

Result level	Description	Revised Target	Result	% Achievement
		Swaziland: 15	36	Not achieved
		Uganda: 0	0	Achieved
		DRC: no target	45	Not defined
		Zimbabwe: no target	46	Not defined
O.2.4	% Lab based VL tested ART patients adherent to treatment 1 year after initiation	>85%	Dropped after 2015 annual report	
Output 3	Use of peripheral health facility VL testing (PoC/simplified) in resource-constrained settings to generate evidence-based recommendations			
O.3.1	# newly-initiated ART patients peripheral facility VL tested for early adherence	25,000	Dropped after 2015 annual report	
O.3.2	# stable ART patients tested by routine peripheral facility VL follow-up	50,000	Dropped after 2015 annual report	
O.3.3	% peripheral facility VL-tested ART patients adherent to treatment 1 year after initiation	>85%	Dropped after 2015 annual report	
Output 4	Use of EID testing platforms in resource-constrained settings to generate evidence-based recommendations			
O.4.1.	Percentage of HIV-exposed infants tested between 6 to 12 weeks of age ¹⁰⁷	DRC: 90%	95%	Achieved
		Kenya: 100%	65%	Not achieved
		Malawi: 60%	64%	Achieved
O.4.2	Number and percentage of children tested positive with PoC technology receiving result within one week	75%	Dropped after 2015 annual report	
Output 5	Strategy document to guide scale up of PoC CD4, lab-based, PoC and simplified VL and EID technologies in resource-constrained settings			
O.5.1.a	Percentage of coverage of VL testing based on annual HIV caseload estimates	No target	44% covered by all actors, of which 33% covered by MSF	Not defined
O.5.1.b	Coverage of EID	No target	No data	Not defined
O.5.2	% project-specific technology and supply prices included in pricing report	>85%	Dropped after 2015 annual report	
Output 6	Report on economic evaluation of CD4 and VL platform use in resource-constrained settings to inform policymaking			

¹⁰⁷ We note here a few points with regard to the data on coverage of EID testing. In the DRC, coverage of 95% is the figure for 2016. In 2015, the coverage rate was 90%. In Kenya, data are reported from 2016 only. In Malawi, a coverage of 64% is taken from 2014 only, and is based on MOH services and MOH data.

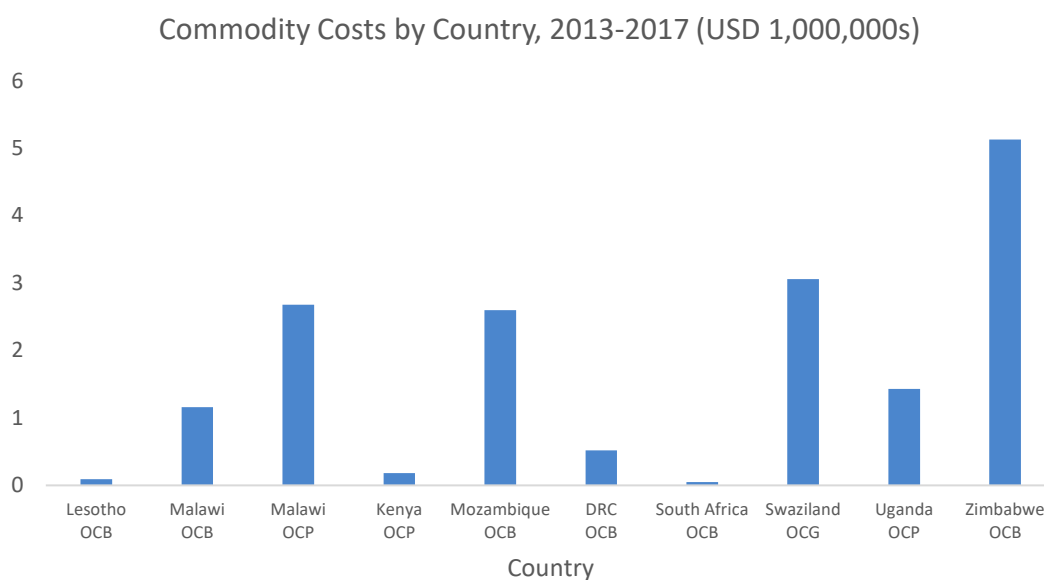
Result level	Description	Revised Target	Result	% Achievement
O.6.1	# MSF field sites participating in costing evaluation	6 countries/sites	Dropped after 2015 annual report	
O.6.2	Median price test/ patient (range and IQ)	No target	Multiple	Not defined
Output 7	List of specifications for resource-adapted, end user needs-driven product development			
O.7.1	% relevant manufacturers presented with specification list in the final year of this project	100%	Dropped after 2015 annual report	
O.7.2	# new quality-assured, resource-adapted products available for implementation in MSF-type settings	10	Dropped after 2015 annual report	
Output 8	Report on evidence-based recommendations on resource-appropriate CD4, VL and EID testing for normative guidance and country policy			
O.8.1	# of LSHTM-led collaboration meetings attended for development of generic new diagnostics field evaluation protocols	3 meetings during the course of the LSHTM-Unitaid project	Dropped after 2015 annual report	
O.8.2	# collaboration meetings with partners between mid-2013 and the end of the project	5 (1 in 2013, 2 each in 2014 & 15)	Dropped after 2015 annual report	
Output 9	Plan for sustainable transition			
O.9.1	% national funding available annually for each country		Dropped after 2015 annual report	
O.9.2	% international funding available annually for each country		Dropped after 2015 annual report	
Output 10	Plan for synergy with other Unitaid diagnostics projects			
O.10.1	% action points from initial synergy list with documented follow-up	100%	Dropped after 2015 annual report	
O.10.2	# regularly scheduled meetings conducted	Quarterly meetings	Dropped after 2015 annual report	

ANNEX F PROJECT PROCUREMENT OVERVIEW

This annex provides an overview of the procurement activities conducted under the grant, based on the information included in the annual progress reports.

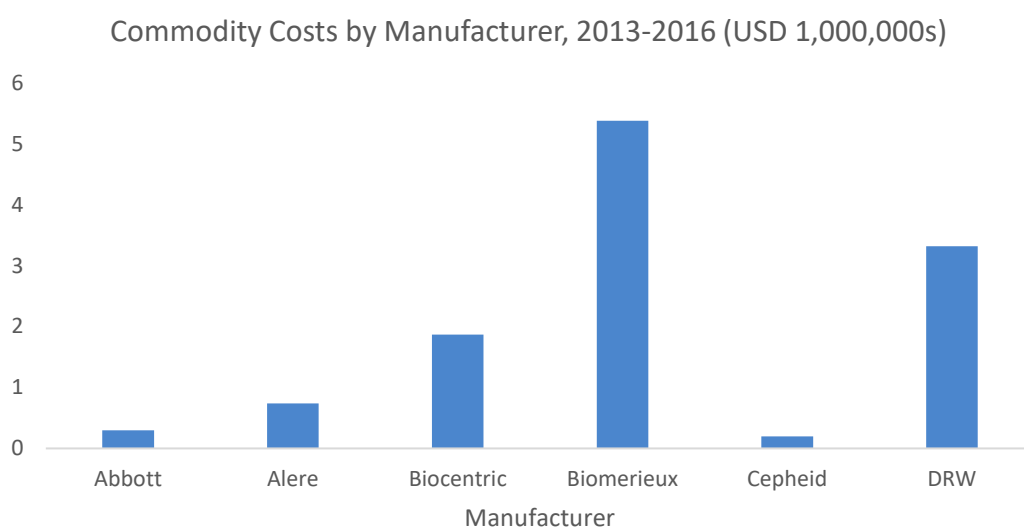
F.1. Commodity Costs By Country

Figure F.1: Commodity costs (including freight, maintenance and rehabilitation costs, USD)



F.2. Commodity Costs By Manufacturer

Figure F.2: Diagnostics Expenditure, by Manufacturer



F.3. Areas of Success and Challenges

Delays

- Procurement delays were explained by: (i) delays in certification (specifically, slow-processed ERPD), (ii) commercial unavailability, and (iii) technical issues with platforms.¹⁰⁸
- In 2013 and 2014:
 - **POC VL devices** were more affected by delays than lab-based VL platforms in the early stages of the grant.¹⁰⁹
 - These delays were further impacted by the update of Unitaids' quality policy, restricting procurement to products with Stringent Regulatory Authority approval, WHO PQ or ERPD quality certification only.¹¹⁰
- In 2015:
 - The Annual Report reported delays in 2015 with regard to certain technologies (notably the Abbott platform and Alere Q platform), but overall it attributed missed targets on VL testing (150,000 VL tests delivered in 2015 vs. 170,000 VL tests planned for 2015) to **delays in 2013 and 2014**.¹¹¹
 - The large delays with the Abbott platform (SAMBA and SAMBA II), partly caused by delays in receiving WHO PQ¹¹², significantly affected programme activities in Mozambique, Uganda and the DRC.¹¹³
 - The installation of an Abbott platform in Mozambique had been planned for June 2015 but was delayed beyond 2015 due to delays in receiving the platform from the manufacturer.¹¹⁴
- In 2016:
 - With the exception of POC EID (described further below), there were no major reported procurement delays in 2016, although there were other operational challenges (insufficient HR, technical problems) which led to sub-optimal use of the project VL and EID platforms.¹¹⁵
 - Testing of POC EID in South Africa was delayed by more than a year, mainly because manufacturers were unable to provide POC EID platforms. It was

¹⁰⁸ MSF (2014) Annual Report, p.31.

¹⁰⁹ MSF (2014) Annual Report, p.29.

¹¹⁰ MSF (2014) Annual Report, p.29.

¹¹¹ MSF (2015) Annual Report, p.29.

¹¹² MSF (2015) Annual Report, p.15

¹¹³ MSF (2015) Procurement Plan, p.2.

¹¹⁴ MSF (2015) Annual Report, p.18.

¹¹⁵ MSF (2016) Annual Report.

eventually completed in 2016 and involved an assessment of the advantages of **POC EID** with the Alere Q platform compared to lab-based VL with the MOH's Roche technology.

- In 2017:
 - Although MSF had planned to investigate the use of **POC devices for EID** from the start of the project, delays with the availability and approval of EID devices led MSF to postpone some EID research beyond the grant period into 2017: one study in Uganda on the SAMBA II platform and a second study in Swaziland on the Biocentric platform.¹¹⁶

Technical Problems

- There were reported instances of **technical problems** leading to less-than-efficient use of testing platforms. Examples included:
 - The BM platform suffered from numerous breakdowns in Mozambique. In 2014, these problems impacted the uptake of VL testing in Maputo to such an extent that MSF advised clinicians not to test patients, creating significant negative publicity.¹¹⁷
 - In Zimbabwe, problems with the BM service company in 2016 reportedly led to delays with maintenance activities for the platform, reducing VL capacity and resulting in an annual average TAT of 46 days by the end of the year.¹¹⁸

Price Savings

- Overall, the MSF grant **did not exert significant downward pressure on prices** for VL platforms.¹¹⁹ In September 2014, MSF estimated that the manufacturing costs of commonly used laboratory and POC VL tests were between US\$2 (BM) and US\$7 (Alere) per test, assuming that 1m tests were produced annually. However, prices in 2017 ranged from US\$6 to around US\$20 per test, and SAMBA POC tests were particularly expensive at US\$43 per test.
- The reasons for this lack of price reduction included:
 - The number of VL tests provided through the grant (a total of 420,000 tests) was insufficient to affect global procurement volumes or the number of manufacturers.
 - Lack of demand for VL testing (partly through lack of international funding).
 - Limited use of pooled procurement.

¹¹⁶ MSF (2017) End of Project Report, p.5.

¹¹⁷ MSF (2014) Annual Report, p.29.

¹¹⁸ MSF (2016) Annual Report, p.15.

¹¹⁹ MSF (2017) End of Project Report, p.5.

- Lack of bundled pricing discounts across multi-disease testing platforms (TB, HIV, HCV etc.).
- There were **isolated examples of success** in pushing prices downward:
 - In Kinshasa in the DRC, the Abbott VL test fell from US\$65 per test to US\$15 (excluding transport costs) over the grant implementation period, due to (i) direct procurement from Abbott Germany and (ii) negotiations by MSF and other actors, such as the Global Fund. This triggered **further price drops at the national level.** ¹²⁰

Market competition/monopoly:

- Through the grant, MSF has consistently advocated for competition between manufacturers, and its choice of technologies across the project countries was informed by this priority.¹²¹
- In Malawi, MSF believe the MOH are at risk of being 'locked in' with the Abbott platform. The MOH has bought the Abbott platforms rather than renting them, and MSF changed to an Abbott platform in Thyolo in order to be aligned with the MOH to improve project hand-over.¹²²
- In Zimbabwe, MSF credit the Unitaid grant for maintaining competition between several technologies: i.e. BM vs Roche for VL; and PIMA vs BD FACSPresto for POC CD4.

¹²⁰ MSF (2017) End of Project Report, p.17.

¹²¹ MSF (2017) End of Project Report, p.19.

¹²² MSF (2017) End of Project Report, p.19.

ANNEX G SUMMARY OF COUNTRY PROGRAMMES AND PROGRESS

This annex provides a high-level summary of progress and issues by project country and site, drawing on the information contained in the Annual Progress Reports for 2013-16.

Table G.1: Progress and key issues by country and site

Country	2013	2014	2015	2016
DRC OCB		<p>No tests completed on Unitaids funds due to delay in delivery of VL Abbott Machine (originally Oct 2014).</p> <p>Essential VL outsourced, continuing with CD4 for the Health Centres.</p> <p>Lab rehabilitation to include VL equipment adaptability.</p> <p>The PNLs (National Program to Fight Aids) to offer VL testing 6 months after ART initiation and afterwards repeat annually.</p>	<p>The Abbott platform arrived June 2015, but was only operational for 72 days out of 191 in 2015 due to lack of consumables, a small broken bolt, and a cold chain rupture resulting in the reagents being put in quarantine. Some tests outsourced.</p> <p>A GeneXpert was ordered to start POC VL and EID analyses, and as a back-up in case of further Abbott defects. Will consider whether GeneXpert may be better suited to a relatively small and concentrated cohort.</p>	<p>DBS EID testing on the Abbott platform started in early 2016</p> <p>Significant scale-up of VL and EID activities.</p> <p>Samples pooled from MSF and partner sites.</p> <p>Conducted a study to validate VL and EID testing on GeneXpert together with TB diagnosis.</p>
Kenya OCP			<p>Ethical approval for GenXpert HIV-Qual validation study obtained in France and Kenya.</p> <p>Labs ready, staff recruited and trained.</p>	<p>Study started on January 2016.</p> <p>Study results were positive and shared with MOH and other partners to support national validation of GeneXpert EID in Kenya.</p> <p>Validation not completed by end 2016.</p> <p>Once approval is received MSF plans to roll out GeneXpert as part of its routine testing (with MSF funding).</p>
Lesotho OCB	<p>PIMA CD4 installed, Roche VL not installed but VL testing through Durban lab, EID not included</p> <p>Triggered VL supported initially, and MOH willingness to change to routine also on account of advocacy of the</p>	<p>VL sample processing started in August 2015.</p> <p>Back-log of EID samples resolved by end of July.</p>	<p>Operations at 9 facilities handed over to MOH/EGPAF according to original plans. MSF withdrawal from Lesotho.</p> <p>MOH reportedly lacked HR capacity and appropriate molecular platform to perform routine VL DBS monitoring for</p>	<p>In-country presence ended, but MSF used Unitaids grant funds for expenses related to the shipping and processing of DBS samples in a laboratory in Durban, South Africa.</p>

Country	2013	2014	2015	2016
	<p>project; routine VL guidelines to be implemented from April 2014; CD4 and VL monitoring done concomitantly</p> <p>catchment moved from plasma sample for VL to DBS samples, transport issues resolved</p> <p>2nd line drugs available</p>	<p>Majority of 2014, Roche platform in national research laboratory only used for EID (ie not sufficiently processing EID and VL).</p> <p>PoC CD4 Alere PIMA continue to run in all 9 clinics.</p> <p>Supply of PIMA CD4 for Semonkong transferred to MOH supply chain system; transfer of Roma catchment delayed by gap in including the forecast at national level.</p> <p>Routine VL incorporated into national ART guidelines, though country only able to provide routine VL monitoring for targeted groups.</p> <p>Supply chain for 2nd line weak (and centralised), posing risks to scalability.</p> <p>Health-workers trained on cold chain maintenance for plasma transport.</p>	<p>all the MSF HIV cohort, but declined to sign a renewed MOU with MSF [which the author attributes to obstruction from NGO Partners in Health]. An agreement was negotiated end-2015 for EGPAF to continue providing direct support as MSF had done previously, with partial funding from Unitaid. Leftover PIMA cartridges & devices donated to MOH.</p> <p>MOH up-dated its national routine VL roll-out plan, but next platform to be installed at NRL expected to be a Roche device, rather than DBS for VL.</p>	
Malawi OCB	<p>BM VL operational, scale up on DBS samples, VL monitoring algorithms developed and implemented</p> <p>lab based VL testing for all ART patients (MOH algorithm) using whole blood and DBS samples, training material developed, 2nd line initiations only in district hospital</p> <p>2011 Malawian HIV National guideline: VL routine monitoring at 6M, 24 M 48M years after ART initiation. New guidelines expected in Q2 2014.</p> <p>Finger prick DBS was endorsed by the National MOH in June/July 2013. MSF finger-prick study supporting evidence. Implemented Q4/2013</p>	<p>Requirement for quality certification slowed down ability to roll out VL testing on DBS on Abbott platforms.</p> <p>Change of procurement strategy: from purchase to rent of the Abbott machine.</p> <p>Pooling (for transport) implemented in January 2014.</p> <p>Active communications & advocacy - e.g. local media covered a VL play that MSF created with Community ART Group members to encourage enrolment.</p> <p>Thyolo District Hospital achieved VL target.</p>	<p>Hand-over to MOH on 31st December 2015.</p> <p>VL platform in Thyolo changed from BM to Abbott through a rental agreement plan as MOH staff were trained in Abbott.</p> <p>Rental agreement plan not yet signed.</p> <p>MSF requested Unitaid for feasibility analysis of setting up VL provision in the shape of a not-for-profit trust in response to MOH reagent stock-outs.</p>	<p>Operational activities ended.</p> <p>Unitaid funds used to support Queens lab with an additional lab technician and to temporarily process VL samples from Nsanje at Durban laboratory, SA.</p> <p>Commenced a study to assess feasibility of EID and very early EID testing in a district hospital. A one-year enrolment period began in May 2016. Results expected H2 2017.</p> <p>Advocated for a public-private trust approach, but dropped business plan following lack of interest.</p> <p>Engaged with patient awareness campaigns.</p>

Country	2013	2014	2015	2016
	<p>national VL database adapted to use with the BM platform.</p> <p>Sustainability: meetings held between MSF and MOH, including lab TWGs, results of the DBS-FP roll out pilot provided evidence for national guidelines</p>			
Malawi OCP	<p>First POC VL SAMBA and POC CD4 PIMA installed</p> <p>Low uptake of VL; MOH guidelines still being determined regarding 2nd line switch threshold;</p> <p>CD4 uptake higher than VL</p> <p>EID not done (SAMBA not yet validated)</p>	<p>Implementation of SAMBA 1 devices for VL and EID still on hold, pending ERPD feedback.</p> <p>Requirement for quality certification slowed down ability to roll out VL testing on DBS on Abbott platforms.</p> <p>POC CD4 and VL testing started in Namadzi and Mbulumbuzi Health centres in November - total of 6 Facilities with POC activities.</p> <p>Decision at Middle Annual plan in October 2014 not to implement POC tools in 4 of the 10 HCs (Nkalo, Thumbwe, Ndunde, Mauwa).</p> <p>Milepa HC POC implementation still unclear depending on ERPD feedback for SAMBA 1, and safety of the building.</p> <p>Task-shift PIMA CD4 study ongoing. Task-shift study SAMBA 1 planned for Q1 2015.</p> <p>MOH opted for centralized VL monitoring using DBS, not supporting of POC VL anymore. MSF granted some flexibility, to continue to use SAMBA.</p>	<p>SAMBA 1 component of Task-Shift Study completed at two health centres.</p> <p>Two community workers from each health centre trained in SAMBA-1.</p> <p>Roll-out of the MOH centralised routine VL testing service began in Chiradzulu district in Q2 2015 at the six health centres that do not have POC VL facilities.</p> <p>DBS system is struggling with current sample load, resulting in long VL TAT (range from 2-4 months).</p>	<p>MSF has started to prepare the hand-over by strengthening the MOH's capacity in terms of DBS VL. For instance, a VL alert and tracking system was developed and MOH staff was trained in managing DBS samples and results.</p> <p>In 2016, Malawi moved to a "test and treat" protocol and phased out routine CD4 testing. MSF performed CD4 tests until the implementation of the new guidelines was completed and keeps the machines at its disposal for research purposes and targeted CD4 tests.</p>
Mozambique OCB and OCG	<p>Finalisation of lab site rehabilitation; validation of VL platform, initiation of VL operations in Maputo & Tete</p> <p>BioMérieux VL platform installed in laboratory; reagents, sample collection,</p>	<p>MOH decision for only one standardized platform in the country (Abbott)</p>	<p>Abbott platforms have been installed, but MOH is struggling to make them function consistently due to lack of maintenance capacity, and supply and storage of reagents.</p>	<p>MOH has agreed to include BM technology in its roll-out plans and MSF has incorporated an Abbot platform into the lab of Jose Macamo hospital in Maputo.</p>

Country	2013	2014	2015	2016
	<p>transportation, counselling procured by MOH (part of MOH VL “Acceleration Plan”. MSF platform only VL platform. VL lab technicians & data encoders on MOH payroll</p> <p>Technical problems (e.g. lab electrics) caused delays</p> <p>National algorithm to be decided upon in Jan 2014</p>	<p>Requirement for quality certification slowed down ability to roll out VL testing on DBS on Abbott platforms.</p> <p>Introduction of routine VL in all MSF-supported sites.</p> <p>Hand-over to MOH for one site.</p> <p>VL uptake not increased due to multiple breakdowns of BM platform which stopped testing for almost 2 months, shortage of second line drugs, and resistance to implementation in some HCs.</p> <p>Following difficulties, targets revised in July 2014.</p>	<p>Reagent stock-outs in August and December.</p> <p>MSF’s plans (June 2015) to install an Abbott platform in Maputo delayed [author attributes this to Abbott] till May 2016.</p> <p>Implementation of RVL remains slow and below the original targets.</p> <p>Operational support to Mavalane District wound down, but VL lab scale-up support extended to aide transition.</p>	<p>PEPFAR funding secured for Abbott and BM reagents to be integrated into MOH system.</p> <p>During first semester of 2016, the BM platform was temporarily out of service (stock-out of reagents and DBS kits; technical breakdown) and samples were sent to Durban/South Africa.</p>
South Africa OCB	<p>Change of approach from KZN site to Western Cape and IQUUM’s LIAT chosen for pilot EID study</p>	<p>Received two Alere Q POC devices, laboratory validation ongoing. Delays in receiving cartridges. Delays with the Stellenbosch Ethics Review Board. Awaiting approval for amendment to allow change from Liat to Alere Q (received March 4 2015).</p> <p>EID pilot underway, clinical guidelines being written by Western Cape Department of Health and Southern African Clinician’s Society in consultation with MSF.</p> <p>All EID done in 2014 were done on Lab platform (Roche), as the POC EID devices had not arrived in the country.</p> <p>Birth PCR started on all HIV exposed babies on 15/11/2014.</p> <p>Training done on new PMTCT guidelines to the DOH staff.</p>	<p>Began using the two RUO- Alere Q POC devices following validation in July 2015. Due to supply/regulatory issues with Alere, had to change the RUO devices for CE/IVD approved devices: started using the latter in October 2015 (after laboratory validation).</p> <p>Extension request for POC EID past June 2016 until December 2017. Approved until December 2016.</p> <p>Published short article in Southern African Journal of HIV Medicine on the MSF experience of testing infants at birth.</p>	<p>Study completed on advantages of POC EID with Alere Q platform over lab-based VL with MOH’s Roche technology. Conclusion of low need in developed setting (SA). Birth VL on Alere Q therefore discontinued after end of study.</p> <p>Study results widely shared.</p>

Country	2013	2014	2015	2016
Swaziland OCG	<p>CD4 POC done in minilabs; Routine VL monitoring conducted; delays in EID role out</p> <p>Break downs/ stock out of centralised CD4 Fascalibur meant MSF CD4 POC assisted to fill gap; POC CD4 PIMA devices required repairs</p> <p>MSF agreed to support CHAI with VL testing in 2014 with aim to roll out VL nationwide, only targeted VL monitoring in 2013;</p> <p>MSF lead integration of VL algorithm into protocol of new 2013/13 treatment guidelines</p> <p>MSF OCG support for CHAI VL (MaxART project) expected to start mid 2014</p>	<p>Routine VL monitoring and CD4 POC continuing. VL support for CHAI started in September 2014.</p> <p>In Jan 2015, it was decided to drop EID POC ALEREQ.</p> <p>Development of LIMS database not supported anymore by MSF (budget to be reduced by 30,000 USD).</p> <p>Pre-ART Genotyping study on halt (MOH may do a national drug resistance survey in 2015).</p> <p>MOH commitment to roll out routine VL monitoring in all of Swaziland.</p>	<p>MOH/CHAI committed to integrate the Biocentric platform into the NRL with MSF support (expected functional, under MOH management, by mid-2016). Lab in the MSF project will continue under Unitaaid funding in 2016, and MSF funding in 2017.</p> <p>Routine VL testing funded by Unitaaid will continue in 2016, except external support to CHAI/OCA/Baylor.</p>	<p>MOH received a Biocentric platform at NRL with own funds and CHAI support.</p> <p>MSF assisted staff training.</p> <p>Study to validate Biocentric platform for plasma VL, DBS VL and DBS EID underway. Late completion expected by Q3 2017 due to delays from ethics boards; delivery of reagents; and recruitment of patients. Will be finalised post-grant with MSF funds.</p>
Uganda OCP	<p>Delays including MSF lab requiring change of location</p> <p>SAMBA VL activities started</p> <p>Hospital director decision for SAMBA results to be used to make switch to 2nd line</p> <p>Sustainability most important aspect: MOH will take over ART clinic and MSF to remain in charge of PoC VL/EID activities.</p>	<p>VL monitoring started Sept 2013.</p> <p>SAMBA II validated for use in Uganda.</p> <p>Plan to support PMTCT unit of Arua Regional Referral Hospital with EID. Must be run under a research protocol until SAMBA 2 EID receives quality certifications.</p>	<p>MOH rolled out a national VL testing program using DBS, but demand from MOH sites is still low.</p>	<p>Study assessing POC EID did not start in 2016 due to delays in procuring devices and cartridges. The study will be implemented as of Q1 2017 with MSF covering costs that occur after closure of the grant.</p> <p>Evaluation study for the VL platform SAMBA II has started: expected completion by end 2017, and funded by MSF beyond grant end.</p>
Zimbabwe OCB	<p>BM VL platform and technique of VL on DBS validated by MOH; VL routine activities launched at NMRL; introduced VL data base at NMRL</p> <p>Difference in access to VL due to (i) later introduction and (ii) MSF presence in districts Buhera>Gutu>Chikomba</p> <p>Routine VL put into GF budget for 2014-16 – accepted by then removed except</p>	<p>Number of VL sites trained and supported increased from 7 to 12. Further sites not added attributed to lack of push from MOHCC and delay in placing order for additional platforms with GF funding.</p> <p>Due to continuous delay between UNDP and MOHCC the order for 2 BM machines on GF was not signed by end</p>	<p>Delays cited to explain continuous but slow progress: writing & finalizing national VL roll out plan; platform selection and purchase by MOHCC/UNDP; building lab capacity; device breakdown; etc.</p> <p>Zimbabwe VL roll out plan (2015-2018) approved by the highest level of MOHCC in May 2015.</p>	<p>Completed a study assessing VL and EID testing on the GeneXpert platform and received approval by the MOH to use GeneXpert for VL and EID testing in districts where MSF is operating.</p> <p>Mitigated results in terms of VL TATs (beyond MSF control as lab service handed over to MOH).</p>

Country	2013	2014	2015	2016
	<p>VL equipment; GF also stopped funding incentives for counsellors</p> <p>CD4 monitoring stopped since VL intro but MOH remains with CD4 monitoring (on paper)</p> <p>EID guidelines for infants to receive DNA PCR testing or RNA-based tests at 6weeks.</p> <p>MSF participation in Laboratory Partnership forum and GF CCM</p> <p>Support from PEPFAR for 'on the job' mentoring</p>	<p>2015 (although MSF gave all specifications end 2013).</p> <p>Low number of VL tests attributed to 'HR management issues, WHO accreditation requirements and some machine breakdowns'.</p> <p>Technical Working Group formed.</p> <p>Delays attributed to laboratory department not taking a clear stand on choice of high throughput platform.</p> <p>"VL pooling" received ERB (MSF) approval – study run in December but had to be stopped as plasma sample coming from MUR suffered from a cold chain breakdown.</p> <p>Good BM reagent price negotiated.</p>	<p>Continued training of health facilities for VL.</p> <p>Rehabilitation of 3 laboratories.</p> <p>EasyMag platforms acquired from MSF Malawi / bought using OCA funding, now fully functional.</p> <p>VL delays expected in 2016 following UNDP inability to procure BM products.</p> <p>New agreement negotiated by MSF-Supply with BM for 2016 for Zimbabwe for \$14.50 / test for a volume of 30.000 tests (includes maintenance).</p>	<p>Rates of switch to second-line ART remained lower than expected.</p> <p>MSF did an economic evaluation of VL testing and EID in Gutu as a showcase for a rural Zimbabwean district. Conclusions were widely shared with MOH.</p>

ANNEX H SUSTAINABILITY OF COUNTRY PROGRAMMES

This annex provides a summary of key activities undertaken to support hand-over of MSF projects in country and the current status as per the End of Project Report. It includes a rating of the progress made towards sustainability of project activities, as follows:

- A **green rating** indicates that a good degree of progress has been made on sustainability in terms of hand-over to the government and other donors.
- An **amber rating** indicates that some progress has been made on sustainability e.g. continued funding/ programmes by MSF, hand-over of specific components or aspects of the MSF work, etc.
- A **red rating** indicates that less progress has been made on sustainability i.e. the diagnostic platform and approach have not been taken forward for a number of reasons included limited feasibility.

Please note that this is based on CEPA’s subjective assessment drawing on a desk review of MSF progress reports, and may not present the full picture as our consultations have not covered all countries.

Table H.1: Activities undertaken by MSF to support hand-over of project activities, and the current status as per the End of Project Report.

Country	Activities undertaken to support hand-over	Status after project close
DRC OCB	<ul style="list-style-type: none"> • Capacity building and support for in-country VL and EID networking between key actors, with a VL taskforce of all implementing partners in Kinshasa established and measures to improve sharing of resources in place (e.g. better use of Abbott platform capacities through pooling of samples of several partners). MSF organised a programmatic VL/EID workshop in early 2016, attended by key stakeholders. • Research on optimal technology use. MSF, in collaboration with the country’s AIDS and TB programs, has started a study to validate VL and EID testing on GeneXpert together with TB diagnosis. MSF will complete the study with its own funds in 2017 and the validation is expected in the second half of 2017. • Advocacy with MOH and key donors and partners (including GF and CHAI). 	<ul style="list-style-type: none"> • Limited funding and capacity for MOH to take over project activities. • MSF to continue providing VL testing after grant closure through MSF facilities, with some very limited hand-over of certain services to MOH (e.g. sample transport). • VL and EID reagents are expected to be funded through GF and PEPFAR. • The national TB program operates more than 90 GeneXpert platforms in the country which represent great potential for VL and EID scale-up, should the multiplex-use of the platform be validated by the MSF study.

Country	Activities undertaken to support hand-over	Status after project close
Kenya OCP	<ul style="list-style-type: none"> Continuous HIV testing at all prevention of mother-to-child transmission (PMTCT) entry levels of care (maternal and child health care, out-patient- and in-patient-departments, etc.) was handed over in summer 2016 and is part of the national protocol. Advocacy within the National Lab POC Technical Working Group and with the National HIV Program to advocate for inclusion of POC VL and EID in the national testing strategy. Research on POC EID in Ndhiwa, with GeneXpert, which generated positive results and were widely shared with MOH and other partners, contributing to national validation of the GeneXpert platform in spring 2017. 	<ul style="list-style-type: none"> The MOH is so far not planning to roll out GeneXpert EID as part of its national EID strategy despite MSF study validating use for EID. There is limited clarity about future MOH funding sources for EID and VL but these will likely include PEPFAR and the GF. MSF is supporting maintenance, procurement of commodities (especially cartridges) both for targeted VL and EID and contributes to some of the VL-related MOH staff costs. MSF supports the supervision of laboratory activities and an MSF advocacy officer is part of the GF oversight committee. A hand-over of the remaining MSF activities to the MOH or other partners is not currently planned. MSF hopes to be allowed to pilot roll out of GeneXpert EID routine testing in its intervention zone (with MSF funding). MSF teams are in contact with EGPAF (which supports PMTCT in Ndhiwa) to avoid duplication of services.
Lesotho OCB	<ul style="list-style-type: none"> During 2015 MSF handed over VL activities in 9 health facilities in the Roma region of Maseru to EGPAF. MSF did not receive government permission to open a new project in the neighbouring district during the grant period and therefore closed all operations in Lesotho. 	<ul style="list-style-type: none"> Given the lack of MOH HR and technical capacity for routine VL, MSF supported EGPAF in processing about 2,800 VL DBS samples with Unitaid funding in 2016 after hand-over. The MOH is adopting a centralised VL system. With regard to CD4 testing, MSF donated 11 PIMA devices to the MOH in 2015, as these were to be used by the MOH in areas where VL was not available and provided the MOH with a buffer stock of PIMA cartridges.
Malawi OCB, Thyolo	<ul style="list-style-type: none"> MSF-B created Technical Working Groups in Thyolo and Nsanje (called 'Second-line committees'), which helped with (i) programmatic decisions on VL and (ii) reporting practices. 	<ul style="list-style-type: none"> The MSF-B Abbott platform was handed over to the MOH (note that this was the Abbott platform installed in 2015 to align with the MOH strategy); while the BM platform was transferred to Zimbabwe. Overall, Malawi's HIV treatment performance is good, with 90% viral suppression among adults on ART reported in the End of Project report. Reduction of MSF support to VL monitoring has led to some declines in the operation of the service. For example, in Nsanje, samples are now sent to the central MOH laboratory in Blantyre (where previously they relied on the Thyolo VL lab). There has been a need for MSF to step in again to (i) provide support to the lab with staff and (ii) process some samples in South Africa. This was due to capacity problems and long TATs from the central MOH laboratory in Blantyre.

Country	Activities undertaken to support hand-over	Status after project close
Malawi OCP, Chiradzulu	<ul style="list-style-type: none"> MSF demonstrated the benefits of the POC VL through the SAMBA platform, in terms of patient management, efficiency and TAT. It conducted a task-shifting study which demonstrated that accurate results could be obtained when the SAMBA was used by trained community workers and lab technicians. MSF has prepared for hand-over by strengthening the capacity of the MOH in terms of DBS VL, including: <ul style="list-style-type: none"> (i) The development of a VL 'alert and tracking' system; and (ii) Training for MOH staff on the management of DBS samples and results. 	<ul style="list-style-type: none"> OCP will operate three POC VL 'hubs' (using the SAMBA platform) that offer targeted VL with a focus on vulnerable populations (children, adolescents, patients on second or third line regimen). This support will be funded by MSF. OCP have exerted some policy impact with regard to the benefits of POC VL testing, with inclusion of POC in the Malawi scale-up strategy and some 'signs' that MOH will adopt the GeneXpert POC technology. This being noted, Malawi is prioritising centralised DBS VL on the Abbott platform, due to cost. Recognising that Malawi has phased out routine CD4 testing, MSF has kept CD4 machines at its disposal for research purposes and targeted CD4 tests.
Mozambique OCB and OCG	<ul style="list-style-type: none"> MSF's routine and targeted VL services were fully aligned with the MOH's diagnostic and treatment guidelines. MSF successfully advocated for the implementation of one MOH M&E system, with the MOH implementing DISA since 2016. Collaboration between MSF, MOH and a local cement factor to develop a solution for waste disposal and a suitable national policy. 	<ul style="list-style-type: none"> MOH hand-over occurred in spring 2017, with a donation of the Unitaaid-funded BM and Abbott platforms from MSF to the MOH. In Chamanculo, partial hand-over of VL activities in five health facilities occurred in 2016, with continued MSF support. Overall, VL coverage is low as is viral suppression and only a small percentage of patients with virological failure switch to second line and do so with long TATs. 73% and 60% of patients have a VL below 1,000 copies/ml in Maputo and Tete respectively (data from 2015). MOH has incorporated BM into its VL rollout plans. Procurement of reagents for the BM and Abbott machines to be covered by PEPFAR, and supply integrated into the MOH procurement system. In Chamanculo, MSF continues to provide support in terms of HR (data clerks and a lab supervisor) and logistics (platform maintenance) until summer 2017 (using MSF funds).
South Africa OCB	<ul style="list-style-type: none"> Advocated for the introduction of VL tests at birth for all HIV-exposed babies, which helped to shape new guidelines on the ART initiation of newborns in Western Cape province (released in November 2015). MSF conducted a study of POC EID using the Alere Q platform, which demonstrated good TAT and enabling treatment initiation within hours of a positive diagnosis. MSF disseminated the results widely at national and international fora. 	<ul style="list-style-type: none"> The new ART guidelines in Western Cape province (which were implemented as of April 2016) require a VL test at birth, VL at 10 weeks of age, at 6 weeks post cessation of breast feeding, and rapid tests at 9 months and 18 months of age for all babies. Birth VL on Alere Q has been discontinued after the end of the study. This is because Western Cape province has a good, centralized laboratory system with relatively rapid TATs (2 to 3 days for VL), decent infrastructure and patient follow-

Country	Activities undertaken to support hand-over	Status after project close
		up and a very low mother-to-child transmission rate at two months after birth. In this context, the Alere Q was not cost-effective.
Swaziland OCG	<ul style="list-style-type: none"> MSF succeeded in introducing a Biocentric high-throughput platform on regional level, in Shiselweni. This helped to advocate for a somewhat decentralized VL technology landscape in a country where no POC VL technology is so far available. MSF had supported the MOH with training central reference laboratory staff in the capital (while the training on the platform itself was done by Biocentric). CD4 POC activities were handed over to the MOH in 2015 and the PIMA machines have been donated to the MOH in 2016. 	<ul style="list-style-type: none"> The MOH is committed to rolling out VL as an ART monitoring tool but lacks the funds needed for widespread implementation. Since the government currently focuses its resources on providing an increasing number of tests in its national reference lab, MSF will continue to provide the reagents for the VL machine in Shiselweni during 2017. In 2018, the MOH plans to take over parts of the reagent-purchases for Shiselweni.
Uganda OCP	<ul style="list-style-type: none"> No hand-over of MSF activities.¹²³ MSF has ensured the alignment of its activities with MOH policies: the MOH ART guidelines recommend VL at a threshold of 1,000 copies/ml as the tool for diagnosing treatment failure and MSF's clinical and psychosocial management of patients follows MOH protocols. MOH laboratory staff have been trained to operate the SAMBA platform and VL data from Arua is being imported into the national database. MSF has shared results on the benefits of the POC SAMBA technology in terms of patient management, simplification of treatment and short TATs. 	<ul style="list-style-type: none"> The MOH has recognised the use of POC VL and the SAMBA specifically. However, the MOH currently has no plans to include the SAMBA POC platform in its national VL technology landscape, possibly due to cost. MSF will continue to provide the following services on its own funds after the closure of the grant: POC VL testing for ART patients; POC EID testing for exposed infants; HIV drug resistance testing in case of suspected second line ART failure; and management of failing patients, including provision of third line treatment.
Zimbabwe OCB	<ul style="list-style-type: none"> Advocated for (i) routine VL with MOH through technical working groups, partnership forums, and meetings with the national AIDS and TB programmes (routine VL adopted by Zimbabwe MOH in 2013) and (ii) optimal use of existing VL platforms, helping to accelerate scale up of VL through an existing Roche platform. Study on feasibility and cost-effectiveness of POC VL and EID through GeneXpert to inform policy on optimal use of POC technologies. 	<ul style="list-style-type: none"> Most MSF-led activities at project sites have been handed over to the MOH. This includes: donation of VL machines and 3 months' worth of BM VL reagents; laboratory services HR; reagent supply; machine repair and maintenance. Clinical management has been 'fully' handed over in two project sites (Chikomba and Buhera) but not in Gutu.

¹²³ We note here that MSF staff in Malawi had suggested that some handover of activities in Uganda had occurred, which may indicate that certain activities have been handed over after the submission of the End of Project report.

Country	Activities undertaken to support hand-over	Status after project close
	<ul style="list-style-type: none"> Development of a sample transport system offers a template for the MOH system, once funds have been secured. 	<ul style="list-style-type: none"> Overall VL coverage is low, estimated at 14% by closure of the project. VL TATs are very high, estimated at 46 days in 2016. VL coverage is estimated to have increased since 2016. In Buhera, VL coverage declined from 91% in 2014 (during MSF direct support) to 80% in 2015 (after MSF withdrew direct support) Grant helped to catalyse MOH interest in VL scale-up and crowd in other donors (PEPFAR, GF and UNDP). Reagent supply now includes machine service and maintenance (it is currently managed by Chemonics with funding from GF). Grant helped to foster competition between platforms in-country, specifically with regard to (i) BM and Roche for VL and (ii) PIMA and BD FACSPresto for PoC CD4. Management: MSF will keep a 'mentoring' and 'coaching' role in Gutu, to support clinicians with 'special cases' and an emphasis on switching patients to second-line ART. Transport: MSF will continue to support sample transportation (from clinics to district level). A GF-funded transport system is in the pipeline, but MSF will maintain transport support until the GF system has been established. Technical Support: MSF will continue its participation in the VL Technical Working Group. Advocacy: MSF will continue its VL advocacy activities towards (i) the MOH and (ii) donors (e.g. GF).

ANNEX I PRESENTATION OF CONCLUSIONS AS PER UNITAID’S 2017-21 STRATEGY KPIS

Table I.1 presents a mapping of the progress made by the project against Unitaid 2017-2021 KPIS.

Table I.1: Assessment of progress in terms of Unitaid 2017-2021 KPIS¹²⁴

KPI	KPI description	Progress
1.1	Increasing public health impact (Number of lives saved - Number of infections or cases averted)	<p>VL testing</p> <p>VL testing: Total of 426,181 tests conducted. % of coverage of VL testing was 44% overall, of which 33% was covered by MSF.¹²⁵</p> <p>4,839 patients have been moved to second-line regimen.¹²⁶</p> <p>At repeat VL test for those who previously had viraemia, 22-50% of patients had suppressed to <1000 copied/ml¹²⁷</p> <p>Through improving viral suppression (either through EAC, or changing to second-line regimen), mortality and morbidity are reduced. In addition, viral suppression, particularly to a lower than detectable level, significantly reduces the likelihood of HIV transmission.</p> <p>The average number of calendar days between VL sample collection and results ready to be send from the lab: DRC (45 improving), Malawi Chiradzulu (1, improving); Mozambique (44, worsening), Swaziland (36, worsening), Uganda (0, improving), Zimbabwe (46 stable)¹²⁸</p> <p>Based on a study by Keiser et al. (2010) assessing the mortality at one year of patients switching to second-line treatment (4.2%), in comparison to those who remained failing first-line regimen (11.7%) in sub-Saharan Africa, it can be estimated that there were 363 deaths</p>

¹²⁴ Unitaid (2017), Strategy 2017 – 2021.

¹²⁵ Across seven sites with 2016 available data

¹²⁶ MSF (2017) End of Project Report

¹²⁷ Making Viral Load Routine Part 1: Programmatic Strategies

¹²⁸ MSF (2017) End of Project Report

KPI	KPI description	Progress
		<p>averted at one year due to 4,839 people switching to second-line treatment during the project.^{129, 130}</p> <p>Keiser et al (2011) note the benefits from routine VL monitoring beyond just switching to second-line treatment, and that at three years post routine VL coverage, 4.3% (CI 3.9 – 4.8%) had died in comparison to 6.3% (CI 6.0 – 6.5%) who died in settings without routine VL coverage.¹³¹ Therefore the estimated direct impact of the project at three years post increasing VL testing coverage is that an estimated 2,579 (CI 2,192 – 2,708) deaths were averted, in comparison to VL testing coverage not having been scaled up.¹³²</p> <p>Additional estimations on indirect public health impact of the project are provided in Annex J.</p> <p>CD4 testing: Total of 71,125 tests conducted¹³³</p> <p>EID testing: Total of 5,875 tests conducted. The average number of calendar days from EID sample collection to treatment initiation decreased throughout the project to 30 days (DRC); 10 days (Kenya), 1 day (South Africa).¹³⁴</p>
1.2	Generating efficiencies & savings (Financial savings (\$) + Health System Efficiencies (\$))	<p>Financial savings: in some instances price reductions for reagents were achieved (Abbott VL test fell from US\$65 per test to US\$15; SAMBA I reagent cost was reduced from US\$45 to US\$38.</p> <p>Health System Efficiencies: (i) DBS sample collection and transport easier than plasma (ii) task-shifting to lower cadres with regarding to sample collection and second-line regimen switching; (iii) patients becoming virally suppressed post EAC reduces patients unnecessarily being switched to second-line treatment, which is more costly; (iv) ability to ‘fast-track’ patients if found to be virally suppressed; (v) reduces underutilisation of multi-platforms (e.g</p>

¹²⁹ Keiser et al, (2010). Mortality after failure of antiretroviral therapy in sub-Saharan Africa. *Trop Med Int Health*. 2010; 15(2): 251–258.

¹³⁰ Cumulative mortality at one year was 4.2% (95% CI 2.2-7.8%) in patients who switched to a second-line regimen and 11.7% (7.3%-18.5%) in patients who remained on a failing first-line regimen. We have assumed that the MSF project sites are similar in nature to the sub-Saharan sites participating in this study by Keiser et al but this study may not be representative of all sites providing ART in these countries, or to other sub-Saharan African countries.

¹³¹ Keiser et al (2011). Outcomes of Antiretroviral Treatment in Programmes with and without Routine Viral Load Monitoring in Southern Africa. *AIDS* 25(14): 1761–1769.

¹³² Data for ART cohorts and viral load coverage has been based on the Making Viral Load Routine Part 1: Programmatic Strategies document. As such, data has not been available for DRC, and has been taken from 2015.

¹³³ Ibid

¹³⁴ Ibid

KPI	KPI description	Progress
		GeneXpert); (vi) with regards to POC, reduction in TAT fewer samples are lost, and results can be acted upon more quickly. For beneficiaries: cost and time savings through (ii) same day results in POC testing; (ii) CAGs and ART refill
1.3	Delivering positive returns (Return on Investment = \$ Benefits / \$ Costs)	Limited cost-effective analyses were conducted in this project.
2.1	Investing for the poorest (Total number (or \$) of active grants designed to benefit people living in LICs and LMICs / Total number of active grants (or \$))	This project fits within Unitaids' portfolio through reaching populations in LMICs
2.2	Investing for the underserved (Total number (or \$) of active grants designed to benefit the underserved / Total number of active grants (or \$))	This project has benefited population groups that have been underserved including PLHIV in rural and hard-to-reach areas. It has improved access for populations, particularly through the POC and decentralised approach.
3	Catalysing innovation (Total number of Unitaids-supported products for which product development activities have been successfully completed)	The project has pilot-tested a number of new and innovative diagnostic platforms through new and innovative models of care.
4	Overcoming market barriers (Total number of critical access barriers overcome during the strategic period)	While the MSF project has contributed to addressing all access barriers, its fundamental contribution has been in terms of supporting demand for VL testing. At the global level, the project has contributed to WHO global policy and guidelines development. At the country level, there has been greater impact on national policies in Zimbabwe as compared to Malawi, reflecting varying degrees of engagement with policymakers and the number of partners simultaneously supporting VL testing in the respective countries. Demand has also been facilitated by bringing the technologies closer to PLHIV, capacity building of health workers and engagement with civil society. Whilst this last aspect was an important part of the project, the extent of engagement has varied by country and may have been further enhanced had there been earlier engagement with CSOs through ITPC. The project has also contributed to

KPI	KPI description	Progress
		the supply and delivery of diagnostic platforms albeit on a pilot basis. Affordability remains an important access barrier.
5.1	Securing funding (Proportion (%) of project countries where future funding has been secured at grant closure through partners and countries)	There has been varying experience across the MSF programmes in terms of extent of hand-over to the government and other donors, with some programmes still continuing to be delivered by MSF, although with certain services or approaches being adopted by the government. Sustainability of programmes continues to be a challenge in resource-limited settings, with some evidence of declining service provision post MSF hand-over. The main contribution of the project however has been its demonstration of proof of concept which has helped set the stage for longer term scalability of routine VL monitoring.
5.2	Scaling-up coverage (Additional number of people who benefit from a better health product or approach)	

ANNEX J PUBLIC HEALTH IMPACT ANALYSIS: RESULTS AND BACKGROUND NOTES

This annex presents the public health impact analysis including our approach and limitations as well as background data.

J.1. Approach and limitations

On the request of Unitaaid, a brief indication of the direct and indirect public health impact of the project has been provided as part of this evaluation. In terms of the direct impact, this refers to the impact due to the project. The indirect impact is based on assumptions that project countries scale up VL testing to reach routine VL testing. This is a rough estimation based on academic sources and with limited project data (Section 3 presents the numerous challenges with the project M&E data). It has also been conducted through a rapid desk-based review and may not comprehensively reflect all relevant academic sources and approaches to estimation. **As such, this data should be interpreted with caution as it is based on crude data and assumptions.**

Although VL testing is recommended for ART monitoring by the WHO, the evidence regarding the effect on mortality is not conclusive.¹³⁵ A systematic review conducted by Tucker et al (2014) concluded that VL monitoring was associated with shorter duration of viremia and higher rates of switching to more effective second line treatment, but an impact on mortality was not consistently shown.¹³⁶ Essentially, VL monitoring as a quality of care monitoring intervention can, but may not, lead to improved clinical outcomes directly, but rather indirectly, dependent on follow up actions based on VL test results. In addition, due to the recent scale up of VL testing, few studies have been able to estimate the health impact. That said, one of the few studies which compared mortality with and without routine VL testing by Keiser et al (2011) found a mortality benefit following three years of intervention at ART sites that used VL monitoring.¹³⁷

As such, there are significant challenges in the applicability of both the metrics available in the literature (e.g. due to its inconclusive nature, not being up to date) and in the use of project data. These limitations, together with considerable assumptions that have been applied in our analysis are summarised in Table J.1.

¹³⁵ WHO (2016). Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach (2nd ed.) Accessed at: http://apps.who.int/iris/bitstream/10665/208825/1/9789241549684_eng.pdf

¹³⁶ Tucker et al (2014) Optimal strategies for monitoring response to antiretroviral therapy in HIV-infected adults, adolescents, children and pregnant women: a systematic review

¹³⁷ Keiser et al (2011). Outcomes of Antiretroviral Treatment in Programmes with and without Routine Viral Load Monitoring in Southern Africa. *AIDS* 25(14): 1761–1769

Table J.1.: Data challenges and assumptions

Limitation/ challenge with data	Assumption/ response
Literature Data	
<p>Limited evidence available, both in terms of quantity and scale of studies, which may also be reflective of the only recent change (2013) in WHO guidelines to specify VL monitoring. There is a limited generalizability of the existing study findings.</p>	<p>Metrics taken from the literature have been noted in the data sources and some have been applied crudely in our analysis.</p>
<p>Varying level of routine VL coverage achieved in the studies, varying definitions of “VL coverage” used, and in the level of specific data provided e.g. percentage of VL coverage assumed under ‘routine testing’; number of VL test patients receive in specific settings.</p>	<p>We have assumed ‘routine viral load coverage’ to mean 100% of the PLHIV on ART, unless stated otherwise, and that the number of tests received to be similar to those in South Africa as noted in the Keiser et al (2011) study.</p>
<p>Health outcome data on morbidity and mortality is very limited, due in part because of the short timeframe following routine VL coverage that has been achieved in some LMIC settings. It is also particularly difficult to accurately measure mortality rate given the high rates of patients lost to follow up, and due to a range of confounding factors such as urban/ rural location, gender, age etc. which may affect both morbidity and mortality. Second line regimen is evolving and therefore studies showing impact on mortality may also be outdated.</p>	<p>We consider the Keiser et al (2011) study to provide the most appropriate metrics for the basis for our mortality estimates.</p> <p>Where the specific health impact is known through project data (e.g. through changing from first to second line regimen, this impact has been calculated.</p>
<p>A number of factors that are not possible to control for including the changing nature of the epidemic (e.g. ART resistance); HIV response (e.g drugs available, treatment regimens in place) and broader health system factors</p>	<p>We have not factored these aspects into the analysis.</p>
Project data	
<p>Baseline coverage rates have not been provided (except for South Africa) and ‘current’ VL coverage rates vary depending on project site (e.g. Thyolo the latest data was 2015, other sites may have more recent data).</p>	<p>We have assumed baseline coverage to be 0%. We have assumed the 2015 coverage rates from the <i>Making Viral Load Routine</i> report to be ‘at project close’</p>
<p>The total number of tests conducted over the course of the project does not stipulate the number of tests conducted per PLHIV.</p>	<p>Data from <i>Making Viral Load Routine</i> report has been used as it stipulates coverage of routine VL testing within ART cohorts. However, it is noted this data is slightly outdated (2015).</p>
<p>Tests are not disaggregated by (i) children/ adults or by (ii) POC vs not POC which has implications on the public health impact.</p>	<p>We have assumed impact on morbidity and mortality to be consistent across population</p>

Limitation/ challenge with data	Assumption/ response
	receiving VL monitoring and device used for the monitoring.
Baseline and endline data on deaths and new infections has not been measured.	Additional deaths averted has been estimated where possible; it has not been possible to confidently estimate new infections averted.
Regarding indirect impact, scale up of VL testing, as well as follow up actions based on the VL testing will vary considerably by country, and within countries with timeframes being extremely uncertain.	We have assumed 'scale up' to be equal to that achieved in routine VL coverage in South Africa.

J.2. Direct impact estimates

Direct impact estimates are presented below in terms of deaths averted from: (i) switching to 2nd line treatment; and (ii) due to increasing VL coverage more generally. Please note that the estimates are not comparable as we are using different data sets.

Number of additional deaths averted at one year from switching to 2nd line treatment

Based on a study by Keiser et al. (2010) assessing the mortality at one year of patients switching to second-line treatment (4.2%), in comparison to those who remained failing first-line regimen (11.7%) in sub-Saharan Africa, it can be estimated that there were 363 deaths averted at one year due to 4,839 people noted in the end of project report as switching to second-line treatment during the course of the project.¹³⁸ This estimate has been derived by multiplying the number of people switched to second-line treatment by the difference in mortality of remaining on first-line treatment (11.7%) and switching (4.2%).

Number of additional deaths averted due to increasing VL testing coverage

Keiser et al (2011) note the benefits from routine VL monitoring beyond just switching to second-line treatment, and that at three years post routine VL coverage, 4.3% (CI 3.9 – 4.8%) had died in comparison to 6.3% (CI 6.0 – 6.5%) who died in settings without routine VL coverage.

Using project data (specifically from the MSF flagship publication on “Making Viral Load Routine” (2015)) regarding the number of people reached through MSF VL monitoring, the estimated direct impact of the project at three years post increasing VL testing coverage is that an estimated 2,579 (CI 2,192 – 2,708) deaths were averted, in comparison to not having routine VL testing. This estimate has been derived by multiplying: (i) the country ART cohort

¹³⁸ Keiser et al, (2010). Mortality after failure of antiretroviral therapy in sub-Saharan Africa. Trop Med Int Health. 2010; 15(2): 251–258. Cumulative mortality at one year was 4.2% (95% CI 2.2-7.8%) in patients who switched to a second-line regimen and 11.7% (7.3%-18.5%) in patients who remained on a failing first-line regimen. We have assumed that the MSF project sites are similar in nature to the sub-Saharan sites participating in this study by Keiser et al but this study may not be representative of all sites providing ART in these countries, or to other sub-Saharan African countries.

size by the coverage achieved in that MSF site and (ii) by the difference in mortality due to increasing routine VL coverage (6.3% CI 6.0% - 6.5% -subtract 4.3% CI 3.9% - 4.8%).

J.3. Indirect impact estimates

Number of deaths averted due to increasing VL testing coverage after 3 years assuming reaching SA coverage rates

This estimate assumes that the project countries achieve routine VL testing, to a degree which is the same as that which was achieved in South Africa within the study by Keiser et al (2011).¹³⁹ Using UNAIDS data regarding the estimated number of PLHIV on ART from these countries¹⁴⁰, it is estimated that if VL testing is scaled up to the level of South Africa’s routine VL coverage, then 82,000 (CI 69,700 - 86,100) additional deaths will be averted in three years in comparison to not having routine VL testing. This estimate has been derived by multiplying (i) the number of PLHIV on ART in project countries by the by the difference in mortality due to increasing routine VL coverage (6.3% CI 6.0% - 6.5% subtract 4.3% CI 3.9% - 4.8%).

Table J.2. Country Data¹⁴¹

Country	Number of PLHIV on ART in 2016 ¹⁴²	Number of deaths averted due to increasing VL testing coverage
DRC	160,000	3,200
Lesotho	180,000	3,600
Malawi	680,000	13,600
Mozambique	990,000	19,800
Swaziland	170,000	3,400
Uganda	940,000	18,800
Zimbabwe	980,000	19,600
Total		82,000

Number of additional deaths averted due to switching to second line treatment

Assuming that PLHIV on ART in project countries receive routine VL testing, we estimate how many additional deaths may be averted due to switching to second line treatment. This was derived through applying assumptions regarding the number of PLHIV on ART who are failing first line treatment¹⁴³ as well as an assumed increase in switching rate of 8.9% from routine

¹³⁹ Keiser et al (2011). Outcomes of Antiretroviral Treatment in Programmes with and without Routine Viral Load Monitoring in Southern Africa. AIDS 25(14): 1761–1769.

¹⁴⁰ UNAIDS 2017: http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf

¹⁴¹ Kenya and South Africa have not been included as increasing VL coverage was not an aim of the project in these countries.

¹⁴² UNAIDS 2017: http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf

¹⁴³ Optima model 1.0 input assumptions assume first line treatment failure rate of 10% (CI 8% - 12%)

VL testing instead of CD4 testing.¹⁴⁴ Through applying these assumptions and assuming a reduction in mortality from switching to second line regimen, as per Keiser et al (2010) it is estimated that an additional 2,700 deaths will be averted after one year through switching patients to second line regimen, in comparison to not having routine VL testing. This estimate has been derived by multiplying (i) the number of PLHIV on ART in project countries¹⁴⁵ by the proportion of PLHIV assumed to be failing first-line treatment (10%) and (ii) by the number of PLHIV switched to second-line treatment (assumed to be 8.9%)¹⁴⁶ and (iii) by the reduction in mortality due to switching to second-line treatment (11.7% subtract 4.2%).¹⁴⁷

While we cannot compare the two sets of numbers, the relatively smaller number of deaths averted through switching could be reflective of the challenges in switching, as was also observed under the MSF project.

¹⁴⁴ Haas et al (2015). Monitoring and switching of first-line antiretroviral therapy in adult treatment cohorts in sub-Saharan Africa: collaborative analysis. *Lancet HIV*. 2015 Jul;2(7):e271-8

¹⁴⁵ UNAIDS 2017: http://www.unaids.org/sites/default/files/media_asset/20170720_Data_book_2017_en.pdf

¹⁴⁶ Haas et al (2015). Monitoring and switching of first-line antiretroviral therapy in adult treatment cohorts in sub-Saharan Africa: collaborative analysis. *Lancet HIV*. 2015 Jul;2(7):e271-8

¹⁴⁷ Keiser et al (2010)