

# EVALUATION OF OPP-ERA PROJECT PHASE II

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Unitaid-funded grant on “Open Polyvalent Platforms For Sustainable Access To Quality And Affordable Viral Load Testing In Resource-Limited Settings”

Report of the final evaluation of Phase II of the OPP-ERA project, commissioned by Unitaid, and carried out by Procela Partners Ltd.

8 December 2019

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## List of Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANRS	Agence Nationale de Recherche sur le Sida et le Hépatites Virales
ANSS	Association Nationale de Soutien aux personnes vivant avec le VIH et le Sida
ASLM	African Society for Laboratory Medicine
CBO	Community-Based Organization
CeDReS	Centre de Diagnostic et de Recherches sur le SIDA
CE/IVD	Conformité Européenne/in vitro diagnostics
CePReF	Centre de Prise en Charge et de Formation
CHAI	Clinton Health Access Initiative
CHU	Centre Hospitalier Universitaire
CHUK	Centre Hospitalo-Universitaire de Kamenge
CNLS	Conseil National de Lutte contre le Sida
EID	Early Infant Diagnosis
Esther	Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau
FDA	Food and Drug Administration
FHI360	Family Health International 360
GF	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHSC-PSM	Global Health Supply Chain – Procurement and Supply Chain Management
HIV	Human Immunodeficiency Virus
HLD	Hôpital Laquintenie de Douala
HQ	Headquarters
ICASA	International Conference on AIDS and Sexually Transmitted Infections in Africa
INSP	Institut National de Santé Publique
KPI	Key Performance Indicator
LMIC	Low and Medium Income Country
LOD	Level of Detection
MOH	Ministry of Health
MOU	Memorandum of Understanding
MSF	Médecins Sans Frontières
NGO	Non gouvernemental Organisation
OECD/DAC	Organization for Economic Co-operation and Development/Development Assistance Committee
OPP	Open Polyvalent Platform
OPP-ERA	Open Polyvalent Platforms (OPP) for sustainable and quality access to VL in resource limited settings
PCG	Central Pharmacy of Guinea (Pharmacie Centrale de Guinée)
PCR	Polymerase Chain Reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PNLS	Programme National de la Lutte contre le Sida
PNLSH	Programme National de la Lutte contre le Sida et l'Hépatite
POC	Point-of-Care
PQR	Price and Quality Reporting
PSI	Population Services International
PSM	Procurement and Supply Management
QA	Quality Assurance
RCI	Republic of Ivory Coast
RFP	Request For Proposals

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SMART	Specific, Measurable, Attainable, Realistic/Relevant and Time Bound
Solthis	Solidarité Thérapeutique et Initiatives pour la Santé
TA	Technical Assistance
UPS	Uninterruptible Power Supply
UNDP	United Nations Development Programme
US FDA	United States Food and Drugs Administration
VLT	Viral Load Testing
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification Programme

## Acknowledgements

Procela Partners would like to thank all those who assisted us in the compilation of this report, in particular:

Vincent Bretin, Smiljka de Lussigny, Nargiza Mazhidova, Ombeni Mwerinde, Philippe Duneton, Anna Laura Ross, Matthieu Vittot, at Unitaïd, Geneva.

Jeanne Roussel and Sophie Ouvrard, at Solthis, Paris.

Laurent Malato, at Expertise France, Paris.

Olivia Sylla, at Sidaction, Paris.

Anthony Billaud, at Solthis, Guinea.

Prof Kokou André Inwoley and his team at CeDReS, Dr Dialo Karidiatou, and her team at CePReF, in Ivory Coast.

Mbangue Madeleine, project coordinator, Dr Djubgang Mbadie Rina Estelle, CNLS and Eyoum Bille Bertrand, Hôpital Laquintenie Laboratory, in Cameroon.

Penda Maladho Diallo, INSP laboratory, Dr Zakari Moluh, Médecins Sans Frontières, and Pascal Tiapacoura Bonimy, UNAIDS, in Guinea.

Stakeholders from CHAI, WHO, PEPFAR, and ASLM, with a big thank you to Isabel Benloch and Paula Hacopian of the Global Fund for their invaluable inputs.

A big thank you to Tordjeman Marc, of Biocentric for his inputs and flexibility.

A special thank you goes to Kouadio Agaman and Aka Konin Mathias of Expertise France, for their personable attention to the evaluators while in Ivory Coast, and Penda Maladho Diallo, who helped out the evaluators with the incredibly complicated rush hour traffic in Conakry.

All those who have given us their time and answered our sometimes relentless questions by telephone, questionnaires or in person, thank you.

## Disclaimer

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## EXECUTIVE SUMMARY

The goal of the OPP-ERA was “to contribute to the scaled-up access to viral load testing (VLT) in low and middle income countries (LMICs)”. The project intended to show that “Open Polyvalent real-time PCR Platforms (OPPs) can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs, in complementarity to other technologies” and “create a market for OPPs in LMICs, by encouraging new generic suppliers to increase competition with beneficial impacts on price and volume of supplies”. Its objectives were to improve HIV-1 monitoring by increasing access to routine, affordable HIV-1 viral load testing and HIV-1 Early Infant Diagnosis (EID) in low and middle income countries, specifically through the deployment of OPPs capable of diagnosing or monitoring treatment for a range of infections e.g. HIV-1 and -2, TB, and hepatitis B virus (HBV), and the use of dried blood spot type samples (DBS).

It was implemented by a consortium of organizations, in 2 phases. Phase 1 was led by France Expertise Internationale, but coordination for Phase II was transferred to Solthis, a NGO based in France, a consortium partner which in phase 1 of the project had already provided technical assistance in Guinea. The project was scientifically supported and co-funded (for infrastructure development) by France’s National Agency for Research on AIDS and Viral Hepatitis (ANRS). The project supported field activities in four countries in francophone sub-Saharan Africa: Burundi, Cameroon, Guinea and Ivory Coast. At country level technical assistance was provided by teams from Sidaction in Burundi, Solthis in Guinea, and Expertise France (the new name of France Expertise Internationale) in Cameroon and Ivory Coast.

Phase II intended to increase access to VLT by increasing the throughput of the seven labs opened during Phase I of the project, and then to support national health departments to scale up VLT through the OPP approach in seven new sites. Its intent was to also offer access to HIV-1 Early Infant Diagnosis and co-infection (TB, HBV) diagnostics. Compared to Phase I, Phase II of the project was to:

- **Increase demand** for VLT services
- **Engage with new suppliers** to ensure uninterrupted and sustainable supply
- **Increase dissemination of project evidence**
- **Increase engagement with global stakeholders** to review project evidence and potential for scale-up the (*OPP*) approach in order to achieve global targets.

Phase II of the project, which is the focus of this evaluation, started on 1 August 2016 and ended on 31 July 2019, with some closure activities ongoing until end of December 2019. In Phase I the OPP-ERA project had rehabilitated, equipped and made operational seven molecular biology laboratories in the four countries. By the end of Phase II, the OPP-ERA project had opened four additional laboratories, and prepared an additional two for opening. It had trained over 300 health professionals (clinicians, Procurement and Supply Management (PSM) experts, laboratory staff), including 25 laboratory staff certified to perform HIV viral load testing on an OPP. Between 2013 and 2019, the labs supported by the project carried out more than 230.000 viral load tests, including over 150.000 during Phase II of the project.

In November 2018, when there were only seven months left to the end of the project, progress was much slower than anticipated. The project had been unable to motivate additional suppliers of OPP equipment and reagents to enter the VLT market in LMICs, had not started any field evaluations of the polyvalent use of OPPs for DBS, EID, TB or HBV, and its economic assessment deliverables were delayed. The expansion of laboratory capacity in the four countries was also lagging behind: while it was making progress towards the opening of two additional labs in Cameroon and one in Burundi, only two of the seven new laboratories that should have been opened in early 2017 had been opened in the second half of 2018 (in Burundi). The likelihood that the two remaining laboratories

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(one in Ivory Coast and one in Guinea) would be opened was considered small. In reprogramming, the project was refocused to ensure sustainability of achievements so far, thus by focusing on 1) finishing the work on lab expansion that could be completed by the end of the project, 2) ensuring that the project infrastructure, skills and financing be sustained and ownership be transferred to the national counterparts, and 3) increasing dissemination of project results. The intent to demonstrate that the OPPs could be used for HIV-1 EID and co-infection diagnosis (TB, HBV) and with DBS was abandoned because – given delays in protocol development and obtaining the necessary project approvals – there was very limited progress made, and because the reagent supplier – Biocentric – was reportedly doing its own validation work for EID and DBS. Work on the development of a business case for OPPs and outreach to new suppliers was stopped.

The present evaluation focuses on the programmatic performance and outcomes of Phase II of the grant. It uses the OECD/DAC evaluation framework to structure the evaluation, to which we added, a header on learning/risk mitigation, and a header to accommodate a specific evaluation area, namely Procurement and Supply Management.

Our findings are that the project was not successful in “creating a market for OPPs in LMICs”, which linked to its goal “to contribute to the scaled-up access to VLT in LMICs”, as the project failed to show that “OPP can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs, in complementarity to other technologies”, because:

- 1) The OPP-ERA was unable to document that the use of OPPs results in better scalability of VLT than the use of integrated real time PCR platforms.
- 2) The OPP-ERA project failed to demonstrate the feasibility to use OPPs with DBS-type samples, with limits their utility for VLT, and failed to demonstrate that OPPs can be used for EID.
- 3) The OPP-ERA project did not show that the OPPs can be used to scale up the diagnosis of HIV-related conditions (even if the ability of diagnosing HBV infection on the platform used by the project is well documented in the literature and in the field),
- 4) The OPP-ERA project failed to make the economic case for using OPPs for VLT, as it did only state, but did not publish a peer reviewed assessment of, the full cost of using OPPs in comparison to other VLT platforms, and as the price differential between using an OPP and using other approaches (integrated real time PCR platforms and POC technologies) decreased considerably during Phase II of the OPP-ERA project,
- 5) While the OPP-ERA project identified, in addition to its existing suppliers and one supplier for thermocyclers, more manufacturers of equipment and reagents useable within OPPs, it was unable to entice them to start supplying Global Fund supported programmes or obtain the necessary approvals to start supplying PEPFAR.

That no market for the use of OPPs in VLT was created is based on the following facts:

- 1) Other than Biocentric, the supplier of HIV-1 RNA Amplification reagents used by the OPP-ERA project, there are only two suppliers of HIV-1 RNA amplification reagents listed as HIV-1 RNA amplification reagent suppliers to the Global Fund, none of which is truly present in Global Fund procurement as neither did supply any products to Global Fund supported programs after 2014.
- 2) Unlike the increasing uptake of Point of Care (POC) tests, the share of Biocentric reagents in Global Fund procurement for VLT was and remained very limited. Whereas Guinea Bissau, Madagascar and DRC were identified as new OPP users in our interview with Biocentric (beyond the 25 countries listed in 2016 as users of OPPs in the OPP-ERA project plan), there is, outside the four project countries, no evidence of increased uptake of OPPs for VLT in procurement by the Global Fund or in reports by OPP-ERA.
- 3) The use of HIV-1 RNA amplification reagents requires the availability of matching equipment. The matching equipment offered by Biocentric/Brucker is not on the list of the Global Fund



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list of approved suppliers. Potential new users of the Biocentric's reagents that are supported by the Global Fund need to identify the matching equipment on the list of eligible suppliers first, and obtain them from other vendors. This complicates their procurement and maintenance.

- 4) PEPFAR requires that its suppliers of VLT technology have WHO prequalification or FDA approval. There are presently no suppliers HIV-1 RNA amplification reagents usable on OPPs with such approval. The OPP-ERA project's attempts to support Biocentric with obtaining WHO prequalification were not successful. This makes it impossible for PEPFAR to fund or procure their products.
- 5) PEPFAR is presently requiring, in its tender for VLT, the offer of all-in reagent lease contracts. While OPP suppliers like Biocentric/Brucker are or should be able to propose such contracts, their lack of FDA or WHO prequalification precludes their access to PEPFAR funding.
- 6) The WHO prequalification program will not give prequalification to HIV-1 RNA amplification reagents, unless paired with a well characterized set of extraction technology and thermocyclers. In practice this means that it will only approve the equivalent of an integrated PCR system.

Apart from the few labs with OPP equipment in LMICs that can continue to use their OPPs for VLT with support from the Global Fund, the market for OPPs in LMICs is therefore limited to laboratories with access to funding from donors other than the Global Fund or PEPFAR, or domestic sources, or that are self-financed.

The reasons why no significant market for OPPs was created were beyond the control of the project. In addition to the facts cited above, this includes that the price of VLT on integrated platforms decreased, which decreased the financial appeal of the OPP, and that a POC platform was introduced in 2015, which enabled VLT without having to use highly skilled laboratory technicians. The leading integrated platforms and the POC platform are in addition polyvalent, require less technician time as they are more automated, and can, unlike the OPP used by the OPP-ERA project, be used with DBS type samples.

However, it should be recognized that the late delivery or failure to deliver on several outputs by the OPP-ERA project made it more difficult for the project to argue for the use of OPPs. Its slow delivery on its scale up targets meant that it could not well argue for the scalability of the OPPs. The ability to argue in favour of the OPPs on the basis of their lower cost was limited by the failure to publish a peer reviewed assessment of their cost. While suggesting that the extractor used by the project is more robust and can be maintained more easily than that of other PCR platforms, it has not published data to corroborate this assertion. Finally, the project did not, until the release of its "operational guide", provide a quantification of the amount of human resources and operational requirements of OPPs. Those are similar (and where human resources are concerned, likely higher) than those of integrated PCR platforms. In spite of its outreach and presence in international conferences, web, and media, the project failed to convince major funders and opinion leaders about the merit of OPPs in VLT in LMICs.

The main impact of the OPP-ERA project was at the level of its four supported countries. It was most visible in Guinea and Burundi, where the project provided a sizable proportion of the number of VLTs carried out in the country. The impact was such that in policy development in Burundi and Guinea, the project set the foundation for their VLT programmes, increased access to VLT, and it strengthened the health system. In its four target countries, the project strengthened the operation of its supported laboratories, of which the ability to ensure quality was greatly improved, and led to some improvement of health supply chain management. The project made major contributions to the national planning to scale up access to VLT. This enabled the project to anchor the use of the OPPs within the national action plans, ensured their successful transition to national ownership, and

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de-risked their financing, as the Global Fund took over the responsibility for the supply of the reagents and the maintenance of equipment used by the OPPs.

At country level, the project performed well against the indicator for laboratory Quality Assurance: it ensured consistent high quality performance when measured through external EQA programmes, and thus demonstrated a robust setup in supported laboratories. While facing considerable delay in the scaling up the number of labs in Phase II, the project increased access to VLT in all four countries, providing a substantial proportion of the VLT in all four countries, especially in Burundi and Guinea, where over half of all VLTs in the country were performed on OPPs.

However, the public health impact of the OPP-ERA project was limited, as, in addition to a less than anticipated output of its OPPs, the project did not have sufficient ability to influence the rational use of VLT results. The project recognized the challenge to improve the public health impact of VLT early, in 2017, and has invested time and effort in education for prescribers and community outreach to address this problem. However, its ability to work with civil society organizations was limited, as the project did not have sufficient funding to support CS activities to the extent that they would be meaningful.

Phase II of the project faced challenges in the start-up phase, when the coordinating team at Solthis was not fully constituted. This led to delays in the signature of agreement with the technical assistance partners in countries, the consortium agreement and the convention with ANRS, and likely escalated through to the slow signature of agreements with the Ministries of Health in three countries and the absence of such a convention in Cameroon (also explained by the national political situation). In addition, work plan and budget reviews with Unitaid took a long time. The coordination team described that in the first two years of Phase II this led to a strained relationship with Unitaid, which later improved. However, it resulted in uncertainties about project implementation, which might partly explain the slow opening of the Phase II labs. Delayed contributions from national counterparts in renovation, of which the scope was larger than anticipated, and the security situation and time needed inform planning by Global Fund (in Burundi) also played a role. The local teams have worked well with the national authorities. They might have neglected to formalize their collaborations with some implementing organizations, but in the end the technical collaborations were constructive. As the project also worked well with the Global Fund country teams, the transition of the project to national ownership was successful: the OPPs were fully integrated in national planning, and the Global Fund committed to cover the cost of their reagents and maintenance in all four countries until the end of 2020. This renders their operation sustainable in the short term. In the medium term the risk for the sustained use of the OPPs increases somewhat, as their continued funding requires that they are included in the next grant cycle of the Global Fund, and other factors, such as equipment wear, or optimization and standardization of technologies, might interfere too.

The procurement and supply management system was well designed, though the division of responsibilities between the Paris and local PSM managers limited the opportunity for the latter to develop relationships with the suppliers. This lack of engagement with the suppliers (primarily Biocentric) may be less significant as Global Fund procurement uses a procurement agent in its pooled procurement mechanism, but may present challenges when procuring direct with own funding. The project did not establish key performance indicators to assess and manage the PSM activities, which we consider a missed opportunity. All countries experienced challenges in handling sub-zero commodities, which the OPP-ERA project managed through direct delivery to the operational laboratories. The quantification and forecast strategy was strong, even though only Ivory Coast had sufficient capacity and data availability to use best practice tools such as FORLAB and Pipeline. The PSM transition arrangements are robust in Ivory Coast, and, while the PSM risk is higher in other countries, it is managed adequately in the short term. Whether they will be able to sustain their PSM arrangements in the longer term is unknown.

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Our economics assessment found that the output of this work – which was expected to include three costing studies, a costing tool, the development of a business case, and market surveys, was less than expected. A waste management costing tool, which was added in reprogramming in 2017, was considered informative by ASLM. According to ASLM, a key opinion leader, it is the only tool so far addressing the issue of waste management in VLT lab settings. The viral load costing tool, released in November 2019, would be useful for VLT costing, if its limitation to OPPs could be addressed and problems in the module calculating staff costs can be fixed. The market watch report was considered useful, but would have been more so if it had also addressed the interest of the suppliers in the LMIC market, the demand side in LMICs, including the procurement preferences of the donor community, and the compatibility between reagents and different pieces of equipment.

Taking into account the experience of the OPP-ERA project, our specific recommendations for future work in diagnostics are the following

**We recommend to Unitaid that the consideration for OPP models for VLT in LMIC not be explored further**, as OPPs have lost their relevance for increasing access to VLT and HIV-related diagnosis. The main buyers (Global Fund, PEPFAR), opinion leaders (ASLM, CHAI, WHO), and the WHO prequalification program are all coalescing around the concept that LMICs are best served by integrated polyvalent platforms, which could be located either in central labs or (near) POC. However, if Unitaid wanted to explore the open platform further, it could consider using its convening power to brief the manufacturers of PCR reagents and equipment identified by the OPP-ERA project about the LMIC market prospects. We make this recommendation because, possibly executed in collaboration with the Global Fund, it would be a low cost venture, increase the visibility of Unitaid's investment, and might motivate one or more of them to start developing competitive offers for the LMIC market. The OPP-ERA project identified the manufacturers, but did not inform manufacturers of the evolution of the LMIC market and its entry requirements.

In view of the evolution of demand for VLT in HIV programs in LMICs, **we recommend to manufacturers** interested in the VLT market in LMICs to:

- offer competitive all-in reagent lease contracts,
- seek WHO prequalification for their integrated suites of equipment and reagents,
- ensure the compatibility of their systems with DBS-type samples,
- offer equipment that is minimally dependent on highly qualified lab personnel,
- ensure that their systems are able to diagnose or manage HIV-related morbidities and morbidities of particular concern in LMICs (including HCV, HBV, and TB).

**We recommend that Solthis** or the authors of the viral load costing model developed under the OPP-ERA project include the possibility to assess the cost of alternative VLT techniques, review the human resource module, and continue publicizing it, as we agree with the OPP-ERA project that it is important to assess the full cost of ownership of VLT platforms, and that the OPP-ERA project developed a useful model to assess it.

Our recommendations on general project management include:

**We recommend that projects aiming to effect major changes in market behaviour** be grounded in an in-depth market analysis, including identification of implementation bottlenecks and demand side constraints likely to influence its impact. Such projects should include or ensure that specific demand creation plans are in place, ideally developed with local organizations. This would limit the impact of problems encountered in the OPP-ERA project, in which the need to deal with infrastructure problems and demand creation was insufficiently anticipated.

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The experience of the OPP-ERA project demonstrated the superiority of direct delivery to point of use of reagents that need to be kept at -30 C, which the central medical stores in the countries could not ensure. We **recommend that projects or programs with a limited number of final destination delivery points**, e.g. public health laboratories or referral hospitals, and/or for commodities that require special handling, direct delivery to point of use be considered, in preference to central warehouse delivery.

As the OPP-ERA project suffered delay at the start of Phase II, when the coordination team had critical staff shortages, we recommend that, when projects are extended or have a change in management arrangements during their implementation, the grantees should ensure that the necessary staff is/remains in place (or is made available on loan) to keep the project running without interruption.

We **recommended that projects involving**, beyond national authorities, also **local technical partners**, involve those local technical partners also in project development, and that their role in the project be agreed in writing at the start of the project. This will improve collaboration and avoid frictions, such as those identified with one of the local technical partners in Ivory Coast.

For **projects in which significant procurement challenges are anticipated**, or with major allocations for procurement and supply management, we recommend that PSM Key Performance Indicators (KPIs) be defined at the beginning of the project, and reported on at least annually.

Either during grant design, or during project initiation, we recommend that grantees should assess whether the national health system is capable of providing the necessary data and reports to enable quantification and ordering of supplies, and more generally support reporting on the grant, negotiating access to the data as needed. When this is not the case, **we recommend** that they should undertake **data system strengthening efforts** in collaboration with their national counterparts **to complement (rather than replace) existing data systems**.

## INTRODUCTION

In August 2019 Unitaid issued a Request for Proposals (RFP) Reference No. 2019.14 to conduct an end of project evaluation for OPP-ERA Grant to Solthis. Procera Partners Ltd were successful in their bid to undertake this work and were duly awarded the contract, commencing work on October 7<sup>th</sup>, 2019 with a launch meeting at the Unitaid offices in Geneva, Switzerland.

In accordance with Unitaid instructions to Procera given during the launch meeting on the evaluation, while taking due account of the history of the Grant, the evaluation did focus on Phase II of the OPP-ERA project, which commenced on 1 August 2016, and ended on 31 July 2019 (with some closure activities continuing until the end of Dec 2019).

## PROJECT BACKGROUND

The goal of the OPP-ERA was “to contribute to the scaled-up access to VLT in LMICs”. The project intended to show that “OPPs can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs, in complementarity to other technologies” and “create a market for OPPs in LMICs”, by encouraging new generic suppliers to increase competition with beneficial impacts on price and volume of supplies.<sup>(1)</sup>

The objectives of Unitaid’s grant to the OPP-ERA consortium were to improve HIV-1 monitoring by increasing access to routine, affordable HIV-1 viral load testing (VLT) and HIV -1 Early Infant Diagnosis (EID) in low and middle income countries (LMICs), specifically through the deployment of Open Polyvalent real-time PCR platforms (OPPs) capable of diagnosing or monitoring treatment for a range of infections e.g. HIV 1 and 2, TB, and HBV, and capable of using DBS.<sup>(1)</sup>

The grant supported field activities in four countries in francophone sub-Saharan Africa; Burundi, Cameroon, Ivory Coast and Guinea. Phase I was led by a consortium coordinated by France Expertise International. In Phase II, the responsibility to coordinate the consortium moved to one of the technical assistance partners, Solthis, a NGO based in France. It continued to be supported by the original technical assistance partners at country level, namely Sidaction in Burundi, Solthis in Guinea, and Expertise France (the new name of France Expertise International) in Cameroon and Ivory Coast, with scientific support and co-funding from ANRS.

In Phase I, the OPP-ERA project resulted in the installation of OPPs and the start of VLT on OPPs in a total of seven labs in the four target partner countries.<sup>(2)</sup> Phase II of the project started on 1 August 2016 and ended on 31 July 2019, with some closure activities ongoing until end of December 2019. By the end of Phase II, the OPP-ERA project had rehabilitated, equipped and made an additional four molecular biology labs operational, and had prepared an additional two for opening. It had trained over 300 health professionals (clinicians, PSM experts, laboratory staff), including 25 laboratory staff certified to perform HIV viral load testing on OPP. Between 2013 and 2019, the labs supported by the project carried out more than 230.000 viral load tests, including over 150.000 performed during Phase II of the project.<sup>(3)</sup>

Phase II intended to “**increase access** to VLT within existing sites by scaling up throughput of test in the existing labs, and then to support national health departments to **scale up** the OPP VLT approach in new sites and offer access to HIV-1 Early Infant Diagnosis (EID) or co-infection (TB, HBV) diagnostics. Compared to phase 1, the project was to:

- **Increase focus and investment in creating and increasing demand** for services
- **Engage with new suppliers** to ensure uninterrupted and sustainable supply to match demand
- **Increase dissemination of project evidence**

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- **Increase engagement with global stakeholders** to review project evidence and potential for scale-up the (*OPP*) approach in order to achieve global targets.”<sup>(1)</sup>

In November 2018, when there were only seven months left to the end of the project, progress was slower than anticipated. The project had been unable to motivate additional suppliers of OPP equipment and reagents to enter the VLT market in LMICs, had not started any field evaluations of the polyvalent use of OPPs for DBS, EID, TB or HBV, and was lagging behind on its economic assessment deliverables. The expansion of laboratory capacity in the four countries was lagging behind: while there was progress towards the opening of two additional labs in Cameroon and one in Burundi, only two of the seven new laboratories that should have opened in early 2017 had opened in the second half of 2018. The likelihood that the two remaining laboratories (one in Ivory Coast and one in Guinea) would be opened was considered small. In reprogramming, the project was refocused to 1) finish the work on lab expansion that could be completed by the end of the project, 2) ensure that the project infrastructure, skills and financing be sustained and ownership be transferred to the national counterparts, and 3) increase dissemination of project results.<sup>(3)</sup>

## EVALUATION APPROACH AND METHODOLOGY

The evaluation team carried out four main activities:

- a) **Review of project documentation**, including project plans, contracts, progress reports, results and assessments by Solthis and Unitaid,
- b) **Stakeholder interviews**, in person where practical, and otherwise by telephone or conference call,
- c) **In-person visits to Ivory Coast and Guinea** to meet local implementation teams, national government agencies and other relevant local stakeholders,
- d) **Assessment and analysis of the findings** from activities a), b) and c) to prepare the final report and presentation to Unitaid

This evaluation report is based on data received, information provided, Procela Partners' internal research and analyses, and the responses to the various questions posed to stakeholders. It focuses on the programmatic performance, impact and outcomes of the grant. The report is constructed around the main evaluation parameters of the OECD/DAC evaluation framework <sup>(4)</sup>, namely:

- Relevance
- Effectiveness
- Efficiency
- Impact
- Sustainability

To those we added a header on learning/risk mitigation, and headers to accommodate specific evaluation areas, namely Procurement and Supply management, and Tools for scale-up advocacy.

Together with the progress reports, which contain detailed reporting on the performance against the log frame, and its amendments over time, the report provides a qualitative evaluation of the project and an assessment of reasons why some originally planned deliverables were cancelled.

The limitations of this evaluation include that it is sensitive to the quality of the written documentation on the project, that the ability to interview staff involved in Phase II of the project was limited, as many staff left the project before it ended. In particular, this affected the coordination team in Solthis, the project manager in Expertise France, and the country teams in Cameroon and Cote d'Ivoire. Further limitations are that interviews are subject to recall bias on the part of the respondents. Delays in reporting on procurement of diagnostics by the Global Fund and the unavailability of data on diagnostics procurement by PEPFAR limited our ability to fully characterize the development of the VLT market in LMICs. Our partial dependence on members of the OPP-ERA consortium for the selection of respondents for this evaluation also might have introduced a bias in their favour. We were able to assess grant performance on the ground in Guinea and Ivory Coast, but our assessment of grant performance in Burundi and Cameroon was solely through document review and a limited number of informant interviews, and therefore less comprehensive. Finally, our assessment of sustainability was made on the basis of information available to us, but, like all judgements, is somewhat subjective.

## RESULTS

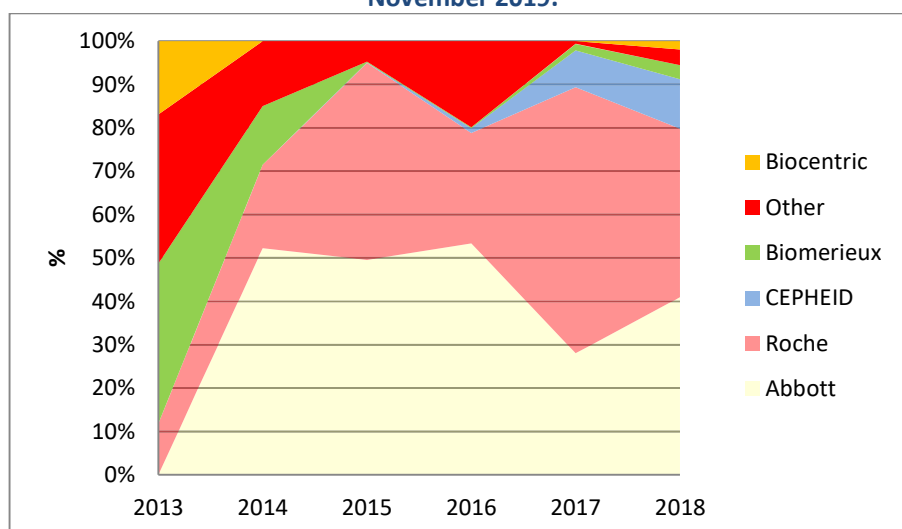
### RELEVANCE

Relevance refers to the extent to which the intervention objectives and design respond to beneficiaries, and partner/institution needs, policies, and priorities, and continue to do so if circumstances change.<sup>(4)</sup> This section addresses whether the outcomes and impact of the grant were and remained aligned with and relevant for Unitaid’s overall mission.

At the start of Phase II OPPs still presented a potential opportunity to expand access to VLT for a population in need at potentially lower cost than other existing technologies. In particular, development of a market for OPP through Phase II would be consistent with Unitaid’s market-based approach: at that time access to VLT was limited (<30%), which offered an opportunity for Unitaid to intervene.<sup>(2)</sup> As the reagents used by the OPP-ERA project were still competitive in price (see Annex 1 for details), the project had been well received in the four pilot countries, and had begun to show some results, the rationale for its continuation remained intact.

However, the VLT landscape was changing rapidly. Following an announcement by the Global Fund and Roche in 2014<sup>(5)</sup>, and discussions between Global Fund and additional suppliers in 2015<sup>(6)</sup>, the price of HIV VLT reagents for countries supported by the Global Fund started dropping. In addition, in 2015 Cepheid had obtained CE IVD approval and WHO prequalification for its “Point of Care” VLT cartridges.<sup>(7)</sup> Figure 1 shows how these changes altered that market share of different producers in procurement by the Global Fund, as reported in its Price & Quality Report (PQR) up to 4 November 2019.<sup>(8)</sup> The POC VLT test from Cepheid was introduced in 2015, and rapidly increased its market share in Global Fund procurement. The suppliers of integrated systems retained their position. Biocentric, the only supplier of HIV VLT amplification reagents for OPPs after 2016, remained a marginal supplier.

**Figure 1: Market participation of HIV VLT reagents by volume of tests reported in PQR as of 4 November 2019.**



(“Other” includes SACACE and VectorBest ZAD – of which no sales were reported after 2014, Cavidia Exavir – of which no sales were reported after 2016, and QUIAGEN Artus HIVirus, which after 2015 provided the bulk of the sales in the “other” category)



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Biocentric's share in procurement for Global Fund supported programmes remained very limited (less than 2% in 2018, last year for which a reasonable amount of data is available in the PQR). The number of countries reported in PQR as buying Biocentric test kits did not increase (one in 2013 [Burkina Faso – 45 kits of 220 tests, no repeat orders], one in 2017 [Togo – 10,000 tests, no repeat orders], two in 2018 [Myanmar – 15 kits - and Senegal – seven kits]. No transactions were reported for 2014, 2015, and 2016. Early users (Burkina Faso and Togo) appear not to have placed repeat orders. The Project plan for Phase II of the OPP-ERA project <sup>(1)</sup> stated (on page 15) that OPPs were used in 25 countries, which were listed in a footnote. Our interview with Biocentric <sup>(15)</sup> added DRC, Guinea Bissau and Madagascar to the list of present clients – without indication of the volumes bought. As the latter two countries have very small numbers of people on antiretroviral treatment, and as DRC is on record in PQR as buying important quantities of HIV-1 RT amplification reagents from Abbott, we conclude that there is limited or no increased uptake of OPPs for VLT in LMICs.

Among the reasons for the limited uptake of OPPs for VLT in LMICS is that to date no amplification reagent suppliers have obtained WHO Prequalification or FDA approval, which precludes their procurement by PEPFAR <sup>(10)</sup>, the second major donor for HIV programs in LMICs. More recently, the GHSC-PSM, which manages PEPFAR commodity procurement, launched a Request for Proposals (RFP) for VLT (and EID) tests over the next three years <sup>(11)</sup>, which intends to move all PEPFAR testing procurement to an “all inclusive” pricing model, and documents a strong preference for integrated systems. This pricing model will include the rent and routine maintenance of equipment, training, and QA, in the price of the reagents.

The Global Fund is less explicit about its preference or the choice of VLT platforms, because, as a matter of policy, it will support the approach favoured by the countries it supports. However, the data in Figure 1 show that in practice it has been buying nearly exclusively integrated PCR systems, at least one member of the sourcing team mentioned a preference for rental lease agreements <sup>(12)</sup>, and the Global Fund's preference for integrated systems is also stated in the 2015 Unitaid HIV Diagnostics Landscape Report. <sup>(13)</sup>

WHO's HIV experts confirmed the tendency in the LMC VLT market towards integration and simplification. <sup>(14)</sup> Evaluators were informed by both Biocentric <sup>(15)</sup>, members of the OPP-ERA coordination team <sup>(16)</sup>, and members of the staff at Unitaid <sup>(17)</sup> that WHO would prequalify HIV RNA amplification kits only in combination with a well characterized set of extractor and thermocycler/analyser equipment. The WHO prequalification program informed us that to date, and with the exception of Biocentric, which applied for prequalification but subsequently withdrew its application, no other suppliers of assays that can be used on open platforms have approached it. <sup>(18)</sup>

Those preferences interplay with the way country decision makers approach the issue of increasing access to VLT. In Ivory Coast, the head of the National AIDS Control Programme (PNLS) expressed this as follows: *“Cost is not the main determinant in the choice of VLT platforms: more important considerations are the availability of funding to make them operational and cover the recurring costs (reagents and maintenance), logistics, and for outlying regions whether they can be used with DBS.”* <sup>(19)</sup>. Taken together, this reduced the window of opportunity for OPPs to make a major contribution toward access to VLT in LMICs to next to none. As such they have lost their relevance for the Unitaid mission <sup>(20)</sup> “to increase access to treatment for HIV/AIDS, TB and malaria for people in developing countries”.

A window of opportunity for open PCR systems remains in settings that are not dependent on the main HIV donors. In our interview with Biocentric, we learnt that the company has continuing interest from around 20 countries <sup>(15)</sup>, and that it has an optimistic outlook on the future. We also learnt that VLT is not the main driver behind the growth of the market for PCR systems – hepatitis B

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and C, HPV and other pathogens are far more important. Biocentric also offers (and claims to be the only company offering) a test kit for HIV-2 viral load (which at the time of writing of this report was not CE IVD approved). As using the HIV-2 kit requires access to an open PCR platform, we learnt in our interview with the PNLs in Ivory Coast that, given the prevalence of HIV-2 in the country, they consider it important to continue using OPPs.<sup>(19)</sup>

The OPPs will also likely remain relevant for the countries that were supported by OPP-ERA project, because they provide a significant share of the VLTs performed in each country, and because the OPP-ERA project successfully integrated the OPPs in the countries' planning and funding landscape.<sup>(3)</sup> As the OPP-ERA project started additional laboratories with OPPs in 2018 and 2019, and facilitated the recent or imminent opening of an additional 2, it is even possible that their will increase in those countries.

The relevance of the OPP labs for VLT would increase if the Biocentric test kit were validated for use with dried blood spot type samples. This was mentioned to us by the OPP-ERA project coordinator at Sidaction<sup>(21)</sup>, the PNLs in Ivory Coast<sup>(19)</sup>, and by an expert at the Global Fund.<sup>(12)</sup> Unpublished data on the use of the Biocentric test kit with DBS in two labs in France, carried out by the OPP-ERA project, suggest that this should be possible.<sup>(22)</sup> Reasonable performance with DBS has been documented in the peer review literature.<sup>(23, 24)</sup> Biocentric has started marketing a DBS sample collection kits for use with its amplification reagents.<sup>(25)</sup> However, as its website does not indicate that it has CE IVD approval, we assume that this was not obtained so far.

A threat for the future relevance of the OPPs is that the limit of detection of the Biocentric kit is rather high – 390 RNA copies per ml. Concerns about this have been expressed in interviews with laboratory staff at CEPREF in Ivory Coast<sup>(26)</sup> and the CNLS in Cameroon.<sup>(27)</sup> In addition we learnt from WHO that the organization intends to review its guidance on the threshold for diagnosis of viral failure.<sup>(14)</sup> In view of concerns about HIV transmission and the development of resistance at low levels of viral replication, it might decide to lower it. A further threat is, according to remarks by a Unitaid staff member, the absence of WHO prequalification.<sup>(28)</sup> Reportedly this was an issue for the inclusion of the OPPs in the national planning in Ivory Coast. In our interview with PSI Burundi, this was also raised as an issue.<sup>(29)</sup> A final threat for the continuing use of OPPs used by the OPP-ERA project for VLT is their dependence on one supplier for its reagents.<sup>(30)</sup>

Considering the continued relevance of OPPs, it is significant to note that Biocentric, the only supplier of amplification reagents in the OPP-ERA project, has now started offering rental lease agreements (it did so already in Ivory Coast)<sup>(3, 15)</sup>. We also heard from Biocentric that it plans to re-apply for WHO prequalification of its reagents, in association with the equipment on which it should run, in the first quarter of 2020.<sup>(15)</sup> These two developments signal a de-facto shift in its marketing model towards integrated platforms.

Finally, the relevance of OPPs for EID is also rapidly decreasing, as POC platforms are increasingly preferred to central labs (whether using IPs or OPPs), as the latter are considered to have a too long turn-around time to be used effectively in antenatal care.<sup>(31, 32)</sup>

## Conclusion

While, at the start of Phase II of the OPP-ERA project, there was still the possibility that OPPs might play a role in increasing access to VLT in LMICS, their relevance for VLT in LMICs quickly diminished over the course of the project. This is explained by the inability of OPP suppliers to access funding from PEPFAR, the preference of global level stakeholders for integrated systems, the need of donor-dependent countries to minimize the risks for their VLT approaches, and the fact that WHO would prequalify HIV-1 RNA amplification reagents only in association with well-defined equipment.

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Additional factors include that from 2014 the price of competing technologies with similar or less logistical requirements decreased considerably, and that POC technology has become available at an affordable cost. A window of opportunity for OPPs remains in settings that are not dependent on the main HIV donors, but this means that OPPs are longer relevant as a lever to increase access to VLT in LMICs globally. This makes supporting the use of OPPs for VLT irrelevant for Unitaids' mission "to increase access to treatment for HIV/AIDS, TB and malaria for people in developing countries".

OPPs will likely remain relevant for VLT in the countries where they have been installed, provided their recurring costs can be covered, as would likely be the case in the four countries targeted by the OPP-ERA project.

## EFFECTIVENESS

This section assesses the extent to which the project achieved its objectives and its results.

Annex 2 lists the project indicators as stated in the project log-frame<sup>(33)</sup>, with their targets in consecutive years and their performance at that point in time, from consecutive annual reports by the project.<sup>(3, 34-36)</sup> The results are colour coded: green stands for "good", defined as "exceeds, or meets at least 90% of the value of the performance target", orange for "insufficient", defined as "meets 50% to up to 90% of the performance target, and red for "poor", defined as "meets less than 50% of the performance target". Indicators that could not be scored are not colour coded, except when data problems make the assessment impossible, when the cells are coloured grey.

### Outcome indicators

No targets were stated for any of the five outcome indicators for 2016 and 2017. The original log-frame states that "*Targets will be defined when orders will be planed more precisely (dates), in the procurement plan (by dec 2016)*"<sup>(33)</sup>. For the first outcome indicator "Proportion of VLT performed on OPPs compared with integrated platforms, per target country" no target was ever set during Phase II. Targets for the other indicators were set in 2017, presumably during the first budget and work plan review. We could not assess why the targets for the indicators were set late in the course of Phase II, but the inability to state targets earlier in the course of the project suggests discontinuity in its conduct between its Phases I and II.

At the end of the project the **proportion of VLTs performed on OPP compared to integrated platforms (P1)**, reached 52% in Burundi and 87% in Guinea (including the VLTs done on the OPP installed in the lab of MSF), but low in Cameroon (12%) and Ivory Coast (7%). The relatively high uptake in both Guinea and Burundi is explained by the fact that the OPP-ERA project started offering VLT when the offer of VLT was very limited (in Burundi only the INSP offered VLT, but not routinely, and in Guinea it was non-existent in the public sector). In Cameroon and Ivory Coast the lower uptake is explained by the presence of other organizations performing VLT. As no targets were set for this indicator, no performance level could be assigned for this indicator.

No results could be reported against indicator "**proportion of EID performed on OPP**"(P2), as the OPP had not been validated for EID at the start of Phase II. The validation of the OPP for EID was cancelled in reprogramming in November 2018.

The remaining three outcome indicators report on the efficiency of the service delivery cascade with VLT, which is of immediate relevance to Unitaids KPI 1.1 "Increasing public health impact".

The **proportion of patients benefiting from a control after a detectable first VL (P3)** reached the 2019 50% target performance level in Guinea (50%), but not in the other countries (Cameroon (40%), Burundi (32%) and Ivory Coast (25%). The **proportion of patients benefiting from a control VLT 3 to 6 months after a detectable first VL (P4)** reached the 2019 target performance level of 30% in Guinea and Ivory Coast, but not in the two other countries (Burundi 14%, Cameroon 4%). The **proportion of patients with a second detectable VLT benefiting from a treatment switch after their first VLT in the supported sites (P5)** reached the 2019 performance target of 30% in Guinea (30%), but not in Burundi (25%), Cameroon (24%) or Ivory Coast (5%). Over time, those three indicators did show a tendency to improve in all four countries, but in 2019 only one country (just) met the performance level for all three of them. The other three countries did have at least two indicators with “insufficient” performance, of which one had one indicator with “good” performance, and two had one indicator with “poor” performance.

Among the reasons for weak performance were that practitioners and clients were not, and are still not, well informed of the significance of VLT for patient management. Compared to an earlier project by Médecins Sans Frontières (MSF) in Southern and East Africa supported by Unitaid <sup>(37)</sup> (Table 1), the performance of the OPP-ERA project against these indicators is less. The discrepancy in performance between the OPP-ERA project and that reported by MSF might be explained by the fact that, unlike MSF, the OPP-ERA project had no control over the implementation of the treatment program.

**Table 1: Comparison of OPP-ERA to MSF performance in re-testing and switch to second line treatment in Southern and East African sites.**

Indicator	OPP-ERA (2019) Arithmetic average across countries (range)	MSF (2016) Arithmetic average across sites (range)
Proportion of patients benefiting from a control after a detectable first VL	37% (25-50%)	47% (23-71%)
Proportion of patients with a second detectable VLT benefiting from a treatment switch	21.5% (7-30%)	33% (10-68%)

### Output Indicators

Outputs produced on time and in keeping with the project plan include the **deployment of laboratory QA procedures (O1.7), delivery of HIV VL amplification reagents to supported laboratories (O1.1)** (in two countries), and **inclusion of OPPs in the strategy and plans (O4.1)** of all four countries. **Price of purchased HIV VL amplification reagents (O1.5)** is also rated as having good performance, even though their price did not decrease over the course of Phase II of the project. However, in the 2019 annual report by the OPP-ERA project we noted a decrease in the price of the extraction reagents, which up until then had been on the high side (see Annex 1).

Considering the **deployment of laboratory QA procedures (O1.7)**, the project needs to be credited for bringing all of its opened labs up to Good Laboratory Practice standards, and certifying their performance in External Quality Assurance systems. This momentous achievement is likely explained by the strong grounding of the staff implementing the project in laboratory operation. The **HIV VL amplification reagents were delivered to supported laboratories as planned (O1.1)**, but deliveries fell short of the originally set targets in Guinea and Ivory Coast, as GF started supporting reagents in Guinea, and demand in Ivory Coast increased slower than expected. The project was successful in **integrating the OPPs in the national planning for VLT (O4.1)** in all four countries, as the technical

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collaboration with the Ministry of Health (MOH) and other stakeholders in VLT was excellent in all four countries. This secured funding for their continued operation up to the end of 2020 from the Global Fund. In addition, the project successfully put out a significant number of communication and media products, according to a strategy developed in collaboration with Unitaid, of which the milestones were included under this indicator.

Other outputs were less than expected or delayed. **The number of HIV VLTs performed on OPP-ERA platforms in supported laboratories (O1.4)** turned out to be much less than expected, especially in 2018 and 2019. While the project managed to increase the output of the Phase I labs in 2017, the output remained next to stagnant in Cameroon and Burundi or decreased in Ivory Coast and Guinea, at a time when the targets increased in anticipation of the opening of additional laboratories. In addition, the indicator **“Average number of calendar days between sample collection and results returned to clinicians” (O1.6)** did show insufficient to poor results most of the time, except in 2018 in Burundi. As a consequence, the output of the project is rated “insufficient” to “poor” for those two indicators.

The targets for the number of VLTs performed were missed because of the delayed opening of Phase II labs in Cameroon and Burundi and the failure to open them in the two others countries. A slow start of the activities at the coordinating team in Solthis<sup>(34,35)</sup>, delay in the signature of the agreements between Solthis and the country level providers of technical assistance, slow disbursement of Unitaid grant support to the country teams<sup>(35)</sup>, slow signature of the country level conventions with the MOH<sup>(35,36)</sup>, and a long reprogramming process in 2017<sup>(3)</sup>, all possibly contributed.

In Burundi, the project was run by only one staff member from August 2016 to April 2017, which likely did not help with opening the Phase II labs. An additional contributing factor to the slow opening of the Phase II labs was the slow decision making process between the Global Fund and the PNLS on whether and which PCR platforms to install. Started in 2016, the Global Fund had, by the end of 2017, after on-site assessment which was delayed by security concerns, not committed to install additional PCR platforms.<sup>(34,35)</sup> In early 2018 it was finally decided to install three OPPs, which were funded by OPP-ERA. Their deployment was delayed until September 2018 because of the need to refurbish the laboratories and the need to train the technical staff<sup>(36)</sup>. The initial plan to install an OPP at INSP (one of the three laboratories originally identified as a site for the installation of an OPP) was abandoned by the MOH in 2018<sup>(3, 36)</sup>, which decided to install the planned OPP in Gitega instead. The project supported readying the lab, including installation of the equipment, and training of the technicians, and secured support for its opening after the project ended<sup>(3)</sup>, but the lab could not be opened during the project.

In Cameroon, two new labs were to be opened in early 2017. Their opening was reprogrammed (in mid-2017) to early 2018.<sup>(3)</sup> The delivery of small equipment and renovation (under government responsibility) were completed only between September and November 2018. Political instability and the unavailability of reagents then precluded opening the labs until March 2019.<sup>(3)</sup>

In Guinea, while the OPP-ERA project provided lots of technical assistance and partly supported refurbishment of a laboratory at Kankan (with ANRS support), the main reason for not opening the lab was that the MOH experienced long delays with its part of the refurbishment.<sup>(39, 40)</sup> At the end of October 2019, the MOH had not managed to install sufficient electricity supply in the laboratory in Kankan, which therefore could not open.<sup>(40,41)</sup>

In Ivory Coast, the renovation of the Daloa hospital laboratory led to long delays<sup>(43)</sup>, which led to the cancellation of technical assistance from the OPP-ERA project to the site in November 2018. The

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laboratory was finally handed over to the MOH on 22 July 2019 <sup>(43)</sup>, and subsequently started working under MOH management.<sup>(3)</sup>

Other issues explaining the limited output include supply side issues, such as:

- human resource limitations: the Biocentric web site <sup>(25)</sup> and the OPP-ERA “Operational Guide”<sup>(44)</sup> suggest that a test run (including extraction and amplification) would take three hours only, meaning that two test runs per day should be possible on an OPP. Detailed reporting on lab activities in the 2016 and 2017 annual reports and the annual report 2018, respectively, document that in the CEDRES and Laquintinie laboratories, and suggest that in laboratories in Guinea, more than one test run was done per day for a limited time period. This documents that the nominal throughput can be attained. However, most OPP-ERA supported labs carried out well under one test run per day most of the time. As reported by the coordinator for the OPP-ERA project at Sidaction <sup>(45)</sup>, the number of laboratory technicians and the working hours as well as the presence of people to record the results (i.e. human resources) combined with access to equipment limited throughput.
- unavailability of reagents (the annual reports mention stock out episodes in Burundi in March-April 2018), in Cameroon in January 2017, May-June 2017, and October 2018-March 2019, in Guinea in March 2017 and September-October 2018, and in Ivory Coast in January to February 2017; and March 2018).
- occasional equipment outages (Reported in annual reports for Burundi, August-September 2016; Ivory Coast – CEPREF May 2017)
- technical issues (software problems in Cameroon in Laquintenie laboratory in November 2016 and December 2016; and in Guinea in September 2016, and April to July 2017).

Demand side issues include the limited awareness of the prescribers and patients of the importance of using VLT as a tool to monitor treatment <sup>(43, 44)</sup>. The project tried to deal with this through its education program for prescribers, and through community outreach. In addition, financial disincentives discouraged patients in Cameroon, where a co-payment of 5000 CFA was required to access VLT<sup>1</sup>. Our interview with stakeholders in Burundi and Cameroon also identified the inability to use the kit with DBS as a critical constraint for access to VLT.<sup>(12, 27, 29,45)</sup>

When considering demand, one also needs to realize that inability of providing VLT testing and the inability to provide VLT results in a timely manner has impact on the willingness of prescribers to ask for VLT. This was most clearly documented in Cameroon, where the inability to do VLT’s in Garoua between October 2018 and March 2019 led to the near disappearance of VLT demand <sup>(3)</sup>, but also in Burundi, where prior to the start of the OPP-ERA project there was little demand from the prescribers when the INSP was not providing access to VLT on a routine basis, and prescribers could not access the results in a timely manner.<sup>(29)</sup>

In Cameroon and Ivory Coast, the existence of labs offering VLT with IPs likely also limited demand for VLT on OPPs. <sup>(19,27,43)</sup>

Finally, the OPP-ERA project reported that interference of unplanned VLT campaigns also explained why the average turn-around time was long (and established a temporal association between such campaigns and turn-around time in their “Operational Guide”<sup>(44)</sup>). We learnt, in interviews with the lab technicians <sup>(26,46-49)</sup> and clinicians <sup>(29,32)</sup>, that the turn-around time was 2 weeks or slightly less when such campaigns did not interfere.

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<sup>1</sup> The requirement of co-payment will disappear in 2020.

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Beyond administrative concerns, the fact that the opening of new labs took a long time for technical reasons (infrastructure not ready, staff not trained) document that scaling up the availability of operational real time PCR platforms – be they OPPs or integrated platforms – is not easy. Both types of PCR platforms have similar heavy infrastructure requirements<sup>(13, 44)</sup>, even though the staffing requirements of integrated platforms are less, as they are to a much larger extent automated. The OPP-ERA project reported<sup>(44)</sup> that the time required, from the decision to install in OPP to the start of routine viral load testing, was 12 to 18 months. In addition, the VLT output by Phase I labs increased slowly between 2016 and 2017, and when opened, the availability of Phase II labs did not lead to rapid increases in the number of VLTs performed. This illustrates that scaling up output within labs is not an easy process, even if it cannot be disentangled from the difficulty of increasing demand for VLT.

Under **“Cost of VL test per type of OPP site”**, the project did present on costing of VLT at ICASA 2017 and AFRAVIH 2018, and stated the full cost of VLT in its “HIV viral load testing operational guide”, but did not publish a peer reviewed estimate of its costing. The three papers in the peer review literature expected under this output by December 2018 were drafted, but had not yet been submitted for publication in November 2019.<sup>(50)</sup> The delay in work on costing delayed also the development of the business case for OPPs. Different drafts of the business case read more like an advocacy piece for the use of OPPs, and were not structured along the lines of a business case.<sup>(51-54)</sup> Unitaid did provide detailed instructions on its structure in July 2017, and again in January 2018.<sup>(55)</sup> As the grantees and Unitaid did not come to an agreement on the purpose and structure of the business case, its development was stopped in January 2019.<sup>(36)</sup>

The output under **“Increased number of suppliers are engaged in the market”** was less than projected. The assessment of two suppliers, started during phase 1, was completed in 2017, as was the assessment of a 3rd VLT reagent supplier in Phase II.<sup>(36)</sup> One supplier was considered unsuitable for use in the OPP-ERA project because it had difficulty quantifying VL levels for the HIV subtypes prevalent in West Africa, and a second one was found to have problems with the controls included in the test package. A third supplier had left the market by the time new amplification reagents were to be ordered.<sup>(36)</sup> Further assessment of HIV-1 RNA amplification reagent suppliers was cancelled in discussion with Unitaid prior to the issue of the 2017 RFPs, which were thus limited to extractors (August 2017) and thermocyclers (September 2017).

To prepare the 2017 RFP, a market survey of OPP suppliers was done.<sup>(9)</sup> This identified 14 suppliers of extractors and 12 suppliers of thermocyclers with CE IVD approval. In the RFP for extractors, only three (Bedia Genomics, Biocentric, Thermo Fisher Scientific) submitted bids, of which only one satisfied the technical requirements. In the RFP for thermocyclers only four manufacturers were invited to bid, of which only one (Thermo Fisher Scientific) provided an offer.<sup>(36)</sup> The objective of increasing the number of suppliers in the market for OPPs through OPP-ERA has therefore not been met.

The reasons for this less than hoped for performance relates less to the unavailability than to the willingness of producers to invest in marketing them to LMICs. While the 2018 market watch report (which reported on the survey carried out in 2017) points out that more suppliers are entering the market, it failed to recognize the different dynamics of high-income and donor-supported LMIC markets.<sup>(9)</sup> While the report correctly identified that high income market is very dynamic, the low income market is dominated by two donors (PEFFAR and the Global Fund) and buyers (like the government of South Africa) which for reasons of convenience and concern for the quality of the results in their supported labs prefer integrated PCR systems or POC systems. Their concern for quality also leads to their enforcement of high regulatory standards. For the Global Fund this is

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minimally approval by a regulatory authority from the Founding Members of GHTF<sup>2</sup> or the WHO Expert Review panel<sup>(56)</sup> – which in practice comes down to CE/IVD certification, and for PEPFAR minimally WHO Prequalification or FDA approval.<sup>(10)</sup> Few suppliers of OPP equipment or reagents can or are willing to meet those high standards. In addition there is high price pressure (which increased after 2015) and high demand for technical assistance in the LMIC market. Their limited interest in the LMIC market likely explains why, other than Biocentric, the Global Fund list of approved suppliers of 29 Dec 2019 lists only two other suppliers with HIV-1 amplification reagents usable on OPPs: Bioneer and Sacace Health Technologies Srl. It also likely explains why, after 2014, no sales of HIV-1 RNA amplification reagents other than Biocentric's were reported in the PQR of the Global Fund.<sup>(8)</sup> Of note is that, while both Bioneer and Sacace also sell extractors and thermocyclers, neither responded to the 2017 OPP-ERA tenders for those products.

The **outputs related to demonstrating the polyvalence of the OPPs** for EID, DBS, TB and HBV were cancelled in reprogramming with Unitaid in November 2018.<sup>(36)</sup> The only output produced by the project under “demonstrating polyvalence” is an initial evaluation of the use of the Biocentric test kit with dried blood spots in two laboratories in France.<sup>(22)</sup> Unfortunately this evaluation was not presented publicly or published.

The cancellation of the outputs demonstrating polyvalence of the OPPs is explained by delays in protocol development and obtaining the necessary project approvals, which made it unlikely that the outputs could be produced prior to the close of the grant. In addition, there was the expectation that Biocentric was about to obtain CE/IVD mark for its kit for DBS and EID. This made pursuing the validation of the kit for DBS and EID by the OPP-ERA project less relevant.<sup>(36)</sup> As of December 2019, Biocentric did not obtain this approval. In our interview with Biocentric we learnt that the company intends to request WHO Prequalification for VLT (using plasma) and EID in the first quarter of 2020, but will not pursue WHO prequalification of its VLT kit with DBS in the near future.<sup>(15)</sup>

A final note on effectiveness is that project was unable to report on several output indicators in Ivory Coast. This was due to the refusal of the laboratories to install the OPP-ERA database, because they considered that the database duplicated their existing data system, of which the data were aggregated at national level. The OPP-ERA coordinator at EF for Ivory Coast considered this a failure of the project.<sup>(16)</sup> However, in our assessment of the PSM system we found that the national system worked satisfactorily. We suggest that future projects assess what nationally owned data they need to access to enable grant reporting, and negotiate access to such data, and strengthen the nationally operated system if needed, rather than demand that their data systems be installed and used by their local technical partners. In the three other countries the data system proposed by OPP-ERA was installed without problems. We could not verify whether this was explained by the weakness or absence of a national system in the other countries.

## Conclusions

OPP-ERA project was not successful in building a market for OPP reagents and equipment. It did not demonstrate that the platform could be used for other HIV-related diagnosis or with DBS. However, as part of its laboratory strengthening and supply management work it did produce a number of tools that could be useful to inform planning of VLT roll out. Those outputs were released at the very end of the project.

The output of the laboratories it supported was less than planned, partly because the project suffered long delays in the expansion of laboratory capacity in all four countries. The heavy

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<sup>2</sup> The GHTF founding members are the European Union, the United States, Canada, Japan and Australia.



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infrastructure demands of the OPPs and need to train staff to high skill levels were key constraints. Then human resource constraints, the occasional interruptions of reagent supply, machine outages and technical problems then limited the output of the laboratories. The long delays in expanding the number of labs operating OPPs document that the OPP approach is not easily scalable, or not more scalable than integrated real time PCR platforms, which have similar infrastructure requirements. When they were opened, the Phase II labs did not clearly increase the number of VLTs performed, and between 2016 and 2017 it took time to increase throughput in the Phase I laboratories. This additionally points to difficulties to scale up the testing operations in the laboratories, but cannot easily be disaggregated from the difficulty of increasing demand for VLT.

The OPP-ERA project was successful at introducing advanced laboratory technology, building laboratory infrastructure and strengthening their management with quality assurance procedures and skills. It supported human resource development in the laboratories and in supply management in the four supported countries, and introduced awareness and skills in biosafety. This infrastructure and the skills operate it was successfully transitioned to national ownership at the end of the project.

Expressed against the KPI's of the Unitaid 2013-2016 strategy<sup>(38)</sup>, the OPP-ERA project delivered well against KPI 5.1 "Securing funding", as, through integration with the national planning process and collaboration with the Global Fund country teams, it secured funding for the continued use of the OPPs until the end of 2020. It delivered reasonably well against KPI 5.2 "Scaling up coverage" in Burundi and Guinea, but less so in the other two countries. Its success in KPI 4 "Overcoming market barriers", which, in the Unitaid framework of market effectiveness<sup>(38)</sup>, is assessed for "Supply and Delivery", and for "Demand and Adoption", was limited. It failed to increase "Supply and Delivery", as the project did not increase the number of suppliers of OPP reagents and equipment. Its outcome in "Demand and Adoption" – which was not part of the project log-frame – was limited, as the uptake of OPPs did increase only in a limited manner in the project countries. Beyond the project countries, we found that only three new countries (Guinea Bissau, Madagascar and DRC) had started using an OPP, but could not ascertain whether this was for VLT and how many tests were performed by them, and the result was not reported by or attributed to the project. There was a decrease in the price of extraction reagents in 2019, which could count as limited performance against Unitaid KPI 1.2 "Generating Efficiencies and Savings", but it was not claimed that it came about because of the work of the project.

### EFFICIENCY

The OECD/DAC framework defines efficiency as "the extent to which the intervention delivers, or is likely to deliver, results in an economic and timely way".<sup>(4)</sup> As part of efficiency we assess the extent to which implementers and national authorities collaborated in grant activities, and collaboration between Unitaid and the grantees.

#### Collaboration with the national authorities

In all four countries, the project had good collaboration with the national level authorities. In Burundi, the project was the main contributor to the ongoing development of the national VLT strategy. In Guinea, a very strong collaboration with the PNLISH was evident, as the project led the development of the national HIV VLT strategy. In Cameroon and Ivory Coast, the project participated in the development of the national VLT strategy.<sup>(3)</sup>

This good technical level collaboration is in contrast with the slow formalization of the collaboration with the MOH's (discussed earlier, under "Effectiveness"). The slow signature of the MOU's with the MOH could have contributed to delays in project implementation, but none of our interviewees mentioned it as a reason for it.

### Collaboration of grantees with the Unitaid secretariat

The communication link between the project and the Unitaid secretariat was with the coordination team at Solthis in Paris. Country implementing teams had no direct link with the Unitaid secretariat.

At the start of Phase II, the coordination team at Solthis had difficulties managing the multiple partners and governance levels of the project, which resulted in “permanent emergencies” and the perception in the field that the project was managed in a top down manner.<sup>(3)</sup> Communication between the coordination team at Solthis and the Unitaid secretariat was not always smooth. The Final report 2019 states this situation as *“in a context where the degree of autonomy (of the coordination team) was not explicit enough, .../... (it) caused quite a distrust between Unitaid and the consortium”* in the first years of Phase II. According to the coordinating team, slow decision making in the Unitaid secretariat also contributed. The first budget review in 2017 was first submitted on 20 June 2017, and formally validated on 20 September 2017 in its 5th version.<sup>(3)</sup> This slow validation was according to Solthis partly responsible for delayed start of the activities in Phase II.<sup>(59)</sup> For the 2018 reprogramming, proposals were first submitted by the coordinating team to the Unitaid secretariat in June 2018. Agreement on the re-programmation was reached in November 2018 in an inclusive meeting which involved, in addition to Unitaid and the grantees, participation from the Global Fund. However, it took until February 2019 to agree on the practical implementation arrangements.<sup>(16, 59)</sup> This held up budget re-allocations in the field.

Communication also held up protocol development for the polyvalence studies. It was initially not known, and came as a surprise to the coordinating team, that the protocols to document polyvalence needed to be validated by the Unitaid secretariat.<sup>(3, 16)</sup> In addition, there was lack of clarity about who was responsible for protocol development – initially the assumption was that ANRS would do so, but the final report mentions “ANRS did not support Solthis on research development”, while Solthis did have limited experience in R&D and technology development.<sup>(3, 60)</sup> This led to slow protocol development. The need of the Unitaid secretariat to seek input on the draft protocols contributed further to the delays that ultimately led to the cancellation of the outputs related to polyvalence of the OPPs.<sup>(36)</sup> Finally, the development of a business case for OPP was cancelled after a lengthy back and forth between the grantees and Unitaid, “without being able to agree with Unitaid on a shared vision of what the document should be”.<sup>(3)</sup>

The relationship between the coordination team and technical assistance (TA) providers was not always easy. The delay in signature of the contracts with the TA providers, delay in the signature of the consortium agreement, delay in work planning and allocation of funds following the 2017 and 2018 budget review, led to delays in implementation and difficulties to deliver on the commitments that the TA partners had made to national counterparts.<sup>(3)</sup> A case in point is the situation in Guinea, where the local team disagreed with the decision to stop technical assistance to the laboratory in Kankan. This decision was felt to have been made between the coordinating team and the Unitaid secretariat, and was considered insufficiently sensitive to the local situation.<sup>(39)</sup> While acknowledging that one joint country visit by Unitaid and Global Fund staff to Guinea took place, the local team considered this insufficient to acquaint the decision makers with the local situation.<sup>(39)</sup> Additionally, the coordination team was considered insufficiently sensitive to local VLT demand when it exceeded initially agreed targets and available budget.<sup>(39,46)</sup>

The communication improved in the last year of the project, possibly because of the clarifications brought about by the November 2018 reprogramming. Of note is that the final report describes the OPP-ERA project as “the objectives of the project and its logic of intervention were far too ambitious” and “the resources identified were not always right”. Reprogramming in 2018 (with the addition of a project closure period after the main grant was closing) shifted the focus of the project towards transitioning the project to national ownership and public health impact, and had, according to the final report, a beneficial effect on communication at all levels in the project.

### Implementation arrangements and coordination with local implementing partners

The project had technical assistance (TA) partners in country, Solthis in Guinea, Expertise France in Cameroon and Ivory Coast, and Sidaction in Burundi. The TA partners worked with local implementing partners: for laboratory testing those were laboratories owned/operated by local institutions. They also reached out to civil society organizations for community awareness activities. The staff of the local teams provided hands on support to the training of prescribers (demand creation), supply management, and laboratory strengthening. The local teams reported to and were supported by the coordination team in Paris.

In our interviews with the implementing lab CEDRES in Ivory Coast we learnt that, unlike a previous project with GIP Esther from France, the project did not include them in the design of the project, and did not have a written agreement signed with it <sup>(46)</sup>. To the extent that this was the case with other implementing organizations, this identifies an important omission, which, however, might need to be attributed more to the conduct of Phase I than to Phase II of the project.

#### INTERVIEW NOTES

CeDRes was approached by France Expertise to participate in the OPP-ERA project because in the past they had worked with GIP Esther successfully. They were not involved in the planning or operational level discussion. OPP-ERA project management did not know the situation of VLT access in RCI very well. The project was designed in Paris, and lessons learnt from CEDRES' collaboration with GIP Esther was apparently not taken into account. Unlike the project with GIP Esther, which also had a MOU with the MOH, OPPERA did not have a written agreement with CEDRES. At the onset of the project, the roles of collaborating partners were never clearly defined. Whenever a concern was raised, the CeDRes team was told by Expertise France that "they will ask Paris". This inefficient communication caused delays, e.g when there was a shortage of reagents, which led to increased turn-around time, and a loss of reputation for the OPPs. <sup>(46)</sup>

In each of the countries the project had a steering committee, which involved comprehensive participation of the local implementing organizations, the National AIDS Control Programme (PNLS, PNLSH, or CNLS), and a variable number of other stakeholders (including civil society organizations in Guinea). In Guinea this steering committee evolved to become the national steering committee for VLT expansion. In other countries it enabled close linkage with the national planning process, which eventually led to the integration of the OPP-ERA activities in national planning.

The main activities with Community Based Organizations (CBOs) were workshops, support for the development of community mobilisation materials, and collaboration in the logistics of sample transportation.

Except in Burundi, where the project was implemented by ANSS, a civil society organization, the collaboration with civil society organizations in other countries was limited. In the progress reports from Burundi there is however no mention of the involvement of other civil society organizations in the activities of the project.

In Guinea, Solthis supported the inclusion of REGAP+ and REFIG (the two biggest CSO networks of PLWH) in the National Steering Committee for VLT in 2017. A demand creation workshop in February 2017 involved both networks. A workshop was organised with REGAP+ and REFIG in October 2018, and two workshops were organized in May 2019 with civil society organizations (REGAP+, REFIG, FEG, ASFEGMASSI) in Conakry.

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In Cameroon, the project participated in 2017 in a meeting on CBO coordination with the Principal Recipient of the Global Fund for national community response. Integrated supervision missions were conducted to empower CBOs in their operations, in Douala (July 2017; three associations), Ngaoundere (September 2017; four associations) and Garoua (October 2017; four associations). In 2018, following a meeting with national level trainers, the responsibility of community mobilisation was shifted to Health District Committees, and a budget was allocated within the project to help the latter holding meetings. A workshop co-chaired by CNLS for community actors was held in Bertoua in November 2018. However, negotiations with local CBO network "Treatment Access Watch" which monitors access to HIV services, and "Positive Generation", failed because their budget expectations were beyond the means of the project. According to the OPP-ERA project manager at Expertise France, the ability to reach out to civil society in Cameroon was rather limited, and was not given a strong focus <sup>(59)</sup>. However, he felt it hard to judge whether this was a critical setback.

In Ivory Coast, in 2017 a workshop was held to validate a manual for community actors on the importance of the VLT for patients under ARV treatment, originally developed by ICHANGE <sup>(57)</sup>. Additional collaborations were concentrated on the South Comoé health region, where the project organised meetings with community advisors from NGO's coordinated by RIP+ <sup>(58)</sup>, the national umbrella organization for civil society organizations and PR of the Global Fund. This led to the civil society organization Alliance CI (sub-recipient of the GF) contributing to sample transport from the region to OPP labs.

The limited scope of the activities with CBOs is explained by the limited funds available in the OPP-ERA budget to meet demand from the CBOs. As the CBOs are also recipients of GF support, lack of clarity about what is already funded within the CBOs possibly also made it difficult to develop increased synergies.

### Conclusion

Implementing Phase II of the OPP-ERA project was quite challenging, as its coordination moved to Solthis, which at the time it needed to take responsibility for coordinating the project was not staffed to take over the project. This, the complexity of the project, and a perceived lack of autonomy at the coordination team, combined with close oversight over the project by Unitaid, led to a situation of permanent emergency at the coordination team and was considered partly responsible for the inability of the country level TA providers to deliver on their planning in a timely manner. The focus on laboratory output and expansion, and attempt to document polyvalence by a consortium that did not have the necessary experience to do so, likely led to less attention for the higher level impacts that were not stated at a high level of visibility in the project log-frame. Reprogramming in November 2018 refocused the project on consolidation of lab capacity and quality, transitioning the project to national ownership, and external communication, and improved the project's efficiency. However, it resulted in a de facto abandonment of attempts to advocate for OPPs as a global level solution to increase access to VLT in LMICs.

### IMPACT

Impact is defined as the extent to which the intervention has generated or is expected to generate significant positive or negative, intended or unintended, higher-level effects.<sup>(4)</sup> This section deals first with higher level impacts and then with the impact of the grant in beneficiary countries.

#### Higher level effects

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The plan for OPP-ERA stated as the goal for the project that it was “to contribute to the scaled-up access to VLT in LMICs”,.../... “show that “OPPs can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs”, and “create a market for OPPs in LMICs”, by encouraging new generic suppliers to increase competition with beneficial impacts on price and volume of supplies. (Reference: Project plan)

The design of the project did not include provision for estimating public health impact in terms of lives saved and infections averted. The log-frame did not include indicators for those higher level pursuits among its “impact” indicators.

The indicators useful to assess “impact” partly in the log-frame are outcome level results, included in the outputs “Increased number of suppliers are engaged in the market” (with indicators “No. of reagents suppliers supported in their “go-to-market” process (including WHO-PQ)”, and “Price of purchased HIV VL amplification reagents”), “Demonstrate polyvalent use of OPPs for EID, DBS, TB and HBV”, and “Shared generated knowledge amongst key national and international stakeholder on OPP solutions”. As mentioned earlier, the outputs under “Demonstrate polyvalent use of OPPs for EID, DBS, TB and HBV” were all cancelled in November 2018.

As discussed under “Effectiveness”, the efforts to **engage with new suppliers** in Phase II (and create a market for OPPs) failed, except for the selection of one new equipment supplier (of thermocyclers) for the OPP-ERA project. The OPP-ERA project had identified earlier that of the four suppliers of HIV-1 RNA amplification reagent with CE-IVD certification available in 2015, three did not satisfy the performance criteria required.<sup>(60-62)</sup> When in 2017 a new tender for HIV-1 RNA amplification reagents was to be published there was less than one year left up to the end of the grant. As this was insufficient time to evaluate additional reagent suppliers it was decided, in agreement with Unitaid, not to put out a tender for reagents and continue working with Biocentric, even if this limited the ability of the project to show that the PCR platform used was “open” to others.

After a price decrease for HIV-1 RNA amplification reagents in Phase I, the OPP-ERA project did not obtain a decrease in the “**Price of purchased HIV VL amplification reagents**” in Phase II. However, a price decrease for extraction reagents was reported in 2019 by the project.<sup>(3)</sup> The project did not claim that this price decrease was due to its actions. Compared to the price of reagents used on integrated platforms, those used on the OPPs remained slightly less expensive. (Annex 1)

Under output “**Share generated knowledge amongst key national and international stakeholder on OPP solutions**” the OPP-ERA project did advocate and communicate on its work in an array of fora. During Phase II of the project this included, among other activities <sup>(3, 34-36)</sup>:

- Regular web communication on OPP-ERA activities on OPP-ERA website and Social networks
- Publication of a brochure on OPP-ERA in French and English
- Production/screening and web publication of videos (“Measuring HIV treatment success”, Interview with Jeanne Gapiya )
- Participation in international conferences:
  - ASLM 2016 (symposium on reaching 3<sup>rd</sup> 90 in W and C Africa)
  - IAS 2017 (satellite symposium, two posters, and presentation, video and brochure at the Unitaid booth)
  - ICASA 2017 (symposium on sustainability of HIV VLT, oral presentation of costing tool, five posters)
  - AFRAVIH 2018 (participation in Unitaid symposium, poster, presentation and presence in Unitaid booth)

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- AIDS 2018 (satellite symposium on scaling up VLT in resource limited settings – video on webpage, poster)
- ASLM 2019 (two oral presentations)
- WHO AFRO workshop on “Laboratory systems and the fast track target”(presentation)
- ICASA 2019 (1 oral presentation, four posters)
- Media coverage: paper in Le Monde Afrique, two broadcasts on Radio France Internationale “\*Priorité Santé” in December 2017, and a paper on [scidev.net](https://www.scidev.net/afrique-sub-saharienne/vih-sida/actualites/afrique-systemes-virologie.html) on the OPP-era project (<https://www.scidev.net/afrique-sub-saharienne/vih-sida/actualites/afrique-systemes-virologie.html>)
- Release of the OPP-ERA toolkit and “HIV Viral Load Testing Operational Guide” on the OPP-ERA website in November 2019.

As the toolkit <sup>(64)</sup> and the “Operational Guide” <sup>(44)</sup> have just been released, their effect on the impact of the communication effort cannot yet be fully appraised. However, to date global level impact of the project and its communication effort appears negligible. In particular, the use of OPPs has not been endorsed by key opinion leaders in the area of VLT.

### FACTS

While two WHO publications mention the use of the Biocentric Generic HIV Charge Virale test kit, they do not mention the existence of OPPs.<sup>(65, 66)</sup>

OPPs are not mentioned on the website of the African Society for Laboratory Medicine (ASLM)<sup>(67)</sup> on which there is in addition no mention of participation of any of the OPP-ERA consortium members or Biocentric in any of its activities. In our interview with ASLM, the interviewee mentioned that OPP-ERA advocacy was not very effective. The only lasting impact from OPP-ERAs presentations (at IAS) was the waste management tool.<sup>(68)</sup>

On the CHAI website there is no mention of OPPs. In the description of the negotiations which led to price decreases for HIV VLT in 2015, the only discussions with manufacturers mentioned are with those that produce closed VLT platforms (Cepheid, Abbott, Roche, Hologic, and BioMerieux).<sup>(69)</sup> In our interview with CHAI, the interviewee indicated that CHAI does not consider the Solthis’s advocacy for OPP and generic supply very effective. As the market has changed to inclusive per test pricing the existing advantage to the incumbent integrated platform players has increased.<sup>(70)</sup>

The Unitaid HIV/AIDS Diagnostics Technology Landscape, October 2015, does not include mention the use of OPPs for VLT.<sup>(13)</sup>

Finally, the OPP-ERA project intended to **increase engagement with global stakeholders.**

The above description of the interaction between OPP-ERA consortium members with WHO, ASLM and CHAI suggests that its outreach to those global level stakeholders was minimal or failed to generate impact.

Among the reasons are that, as the project failed to deliver on its scale up targets, it could not well argue for the scalability of its technology. Also, the project did to date not publish a peer reviewed assessment of the cost of VLT on OPPs, which, combined with the price decrease of other VLT approaches, impeded its ability to argue for OPPs on the basis of their cost. While in its documentation <sup>(1, 44)</sup> it suggests that the extractors it used are more robust and can be maintained more easily than that of other PCR platforms, it has not published data to corroborate that assertion. In addition, the project did not, until the release of its “operational guide”, provide a quantification

of the amount of human resources needed to operate the OPP. While the project also had limited engagement with global level stakeholders the lack of supporting data, rather than the lack of engagement, is the more likely explanation for its inability to convince.

Different stakeholders outside the project team stated higher expectations for the global level impact of the project. For example, the spokesperson of Biocentric told us that the purpose of the OPP-ERA project was to decrease the price of VLT testing, and create a situation that would force the main sellers of VLT testing technology to decrease theirs.<sup>(15)</sup> An interviewee in Unitaid mentioned that the purpose of the grant was to break through the duopoly that Abbott and Roche had in the LMIC market for VLT.<sup>(17)</sup> The project did not, or only in a very limited way, deliver on those expectations. This might have to do with the fact that those expectations were not stated as the high level impacts in the log-frame, with measurable impact indicators to assess progress towards them. The limited time available for the formulation of the project<sup>(3)</sup> might have contributed, as at the end of Phase I there was an overriding concern to protect service delivery by the Phase I labs. Also, the original OPP-ERA project was designed and approved in 2013, when Unitaid-funded projects had much more latitude in defining their strategy than is currently the case. From 2013, Unitaid introduced a much more directive approach to grant making<sup>(38)</sup> which continues to this day, and guarantees that higher level impact is maximized.

### Local level impacts

The indicators for impact in the OPP-ERA log-frame all related to local level impacts.

Performance against indicator **“Proportion of people on ART receiving an undetectable viral load result on OPP-ERA supported platforms”(G1)** did improve in Cameroon and Guinea. At the end of the project between 80% and 88% of those tested in the four countries had undetectable viral load. However, as many factors beyond the control of the project contribute to these results, the improving performance cannot reliably be attributed to the project.

Performance against the second impact indicator **“Proportion of people on ART in the four project countries receiving a VLT on OPP-ERA supported platforms”(G2)** documents poor performance against this indicator. However, the targets for this indicator might be unrealistic: they were set taking into account the “evolution of the case load in each of the countries, and an assessment of the rate at which the supplies of the OPPs could be increased”.<sup>(70)</sup> The targets are referenced in the log-frame as “Source: OPP ERA Phase II GAD 3 Targets.xls”<sup>(72)</sup>, and were, according to Solthis, not informed by a market assessment in any of the countries.<sup>(71)</sup>

Until the annual report 2019, the OPP-ERA project did not report on the **“Proportion of patients with a second detectable VLT benefitting from a treatment switch less than 6 months after their first VLT”**, and no targets were set, which precludes assessing project performance against this indicator.

The project did not document how the use of VLT influenced outcomes in the national treatment programme – which could be to retain people on ART suspected to present with potential failure longer on first line treatment following adherence intervention, or a decrease lost to follow up rate, or a better survival experience of people with treatment failure when switched to second line treatment. However, with the limited proportions of people retested and switched to second line treatment when treatment failure is confirmed, the impact on survival of treated patients (Relevant to Unitaid KPI 1.1 “Increasing public health impact”) was likely very limited.

In the absence of an impact metric attributable to the project we review the impact of the OPP-ERA in the countries where the project was implemented, and its global level impact in an informal manner. We consider the **policy impact** and **amount of impact on access to VLT** in the four target countries.

### Burundi

The main impact of the OPP-ERA project in Burundi was that it introduced for the first time a viable approach to VLT in the country. It had major influence on the national policy on VLT scale up, made a major contribution to the increased coverage of VLT among people on treatment, and, through its training activities, the project also had health system strengthening impact.

Before the start of the project, in 2012, the capacity to do VLT had been created in the country at the lab of INSP.<sup>(73)</sup> However, the very long turn-around time at INSP made the use of this platform impractical<sup>(29)</sup>. A second Abbott platform had been installed at the regional hospital in Ngozi, but started working only in 2016, with support from FHI360.<sup>(45,74)</sup>

The operationalization of a VLT lab at the laboratory of the National Association for the Support of HIV-positive and AIDS patients (ANSS) established the OPP-ERA project and civil society as important stakeholders with significant **policy impact** in the development of the **national VLT scale up plan**. Its weight increased after the opening of additional labs in the Regional Hospital at Muyinga in June 2018 and Kamenge University Hospital (CHUK) in September 2018), and because of its support to the laboratory at the Regional Hospital at Gitega. The policy impact of the project will likely be sustained, as the national project coordinator and the medical officer previously employed by the project have been taken over by the PNLs in senior positions.

As the project carried out 52% of all VLT in the country in 2019, it made a major contribution to the increased coverage of VLT among people on ART, which increased from next to 0% in 2013 to 45% in 2019. It might be able to contribute more in the future when and if the laboratories it supported at Muyinga and CHUK start operating at full capacity. During the project, this was not yet the case: after opening in 2018, the Phase II labs tested on average 55 samples (less than a full test run) per week.<sup>(75)</sup>

### Cameroon

The impact of OPP-ERA on VLT access in Cameroon was limited, which is explained by the limited number of labs it supported.<sup>(27,59)</sup> However, it appears to have created a momentum that made VLT more accessible by making VLT less costly<sup>(49,76)</sup>. The other impacts were mainly through the laboratories that it strengthened with lab technical skills and support for Quality Assurance, improved supply management skills and improved infrastructure.<sup>(59,76)</sup> The project provided support to the creation of demand for and rational use of VLT in the areas in which it operated.<sup>(27)</sup>

The OPP-ERA project introduced OPPs in four labs, of which three did not have VLT capacity prior to the start of the project. Two of those were opened in 2019. Between 2016 and 2019, those labs performed 11% of all VLTs in the country. The project was an active participant in the development of the national VLT strategy, which enabled successful transition of the project to national ownership in 2019.

Laquintinie Hospital, Douala:

“Very positive is the human resource development (lab techs, PSM capacity) via the accreditation process, and the development of infrastructure. Also, thanks to the OPP-ERA project, VLT has become a routine test – no longer a luxury.”<sup>(49)</sup>

### Ivory Coast

The OPP-ERA project was not the main driver for scaling up access to VLT in Ivory Coast.<sup>(16,19)</sup> In Abidjan, the coverage of VLT was around 20% because “projet Retro-CI” and CEDRES had started doing VLT prior to 2014, when OPP-ERA started.<sup>(19)</sup> The WHO recommendations were very important



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in driving the national discussion about VLT, and the decision to make VLT available as a routine test for all people on ART was made in 2015.<sup>(19)</sup> However, according to staff at one of the OPP-ERA supported laboratories, the project created a competitive challenge in the VLT space, which might have motivated other implementers to do more VLT outside Abidjan.<sup>(46)</sup>

The OPP-ERA project worked closely with the national authorities, which led to the inclusion of its OPPs in national planning. The PNLS bought into the OPP concept, at least for the laboratory that it installed with help of OPPERA in Daloa.<sup>(16)</sup> The PNLS concluded a three year reagent lease contract with Biocentric for the continuation of the activities on the OPPs following negotiations facilitated by OPPERA.<sup>(3)</sup>

### CITATIONS

#### PNLS Ivory Coast:

“The main impact of OPP-ERA was to scale up access to VLT in the geographical areas covered by the project, and to have strengthened the capacity of the labs that it supported. A positive aspect is that it also successfully transitioned its project to national management in the last phase of the project. The development of a sample transport system for VLT testing was also a key impact of the project.”<sup>(19)</sup>

#### OPPERA Project supervisor at Expertise France:

“OPP-ERA managed to increase the offer of VLT and decentralize it a bit, but was not a driving factor in the scale up of VLT in the country. Other partners had VLT offer at the onset of the project, and have been increasing it over time. However, there was appropriation of the OPP concept for specific settings by the national counterpart, the PNLS, for Daloa.”<sup>(16)</sup>

#### CEDRES:

“One of the successes of the project was that OPP-ERA managed to penetrate with an OPP in a market of VLT dominated by other players, in spite of its limited funding. Other players in the VLT space – in particular PEPFAR - did not abandon their reservations about the OPPs, and continued to resist the collection of samples in Abidjan for use on the open platforms. Another impact of the OPP-ERA project was that its competitive challenge in the VLT space motivated other implementers to do more VLT outside Abidjan.”<sup>(46)</sup>

## Guinea

The main impact of the OPP-ERA project was that it introduced for the first time a viable approach to VLT in the public sector in the country<sup>(39, 40)</sup>. It also had a significant **policy impact**, acting as the lead agency supporting the development and implementation of a 4-year national VLT scale up plan.<sup>(77, 78)</sup> It had some health system strengthening impact through its training activities for laboratory staff, prescribers and people on ART, and the organization of a transport system for samples for VLT.

### CITATIONS

#### MSF Guinea

“Beyond its contribution to scale up of VLT in Conakry and lab capacity in Guinea, OPP-ERA was the driving force behind the development of the 2019-2022 expansion plan for VLT in Guinea.”<sup>(32)</sup>

UNAIDS Guinea: “OPP-ERA/Solthis stimulated the development of the national plan for the expansion of access to VLT. .../...OPP-ERA/Solthis has been the convener of the 3rd “90” technical working group, charged with supporting the implementation of the VLT expansion plan, and the quantification of the VLT commodities.”<sup>(78)</sup>

INSP Guinea: “The biggest achievement of the OPP project was that it introduced VLT in routine ART management in Guinea. This was achieved in a manner that included not only development of lab capacity, but also demand creation through outreach to prescribers and community organizations.”<sup>(48)</sup>

### Conclusion

The global level impact of the OPP-ERA project was very limited, as the project was unable to convince the main opinion leaders and the donor community that OPPs could make a critical contribution to the scale up of VLT and HIV related diagnosis in LMICs. It was unable to mobilize significant interest from the producers of OPP equipment and reagents in the LMIC market, which consequently did not obtain the necessary regulatory approvals and marketing strategies to become competitive in the LMIC market. OPP-ERA’s inability to convince other stakeholders in the VLT space is partly explained by the price decrease of other VLT platforms, which eroded the financial attractiveness of the OPP proposition. In addition, OPPs proved to be no more scalable than integrated centralized PCR platforms, while requiring higher expenditure on human resources and more sophisticated supply chain management.

The main impacts of the OPP-ERA project were at the level of its four supported countries. They were most visible in Guinea and Burundi, where the project provided a sizable proportion on the VLTs carried out in the country and laid the foundation for the national strategy for VLT scale up. The impacts were in policy development for VLT expansion, increased access to VLT, and strengthening of the health system. The latter were mainly in the operation of its supported laboratories, of which the ability to ensure quality was greatly improved. However, in all four countries, the public health impact of the OPP-ERA project was limited, as, in addition to a less than anticipated output of its OPPs, the project did not have sufficient ability to influence the rational use of VL testing results.

### SUSTAINABILITY

Sustainability assesses the extent to which the net benefits of an intervention continue, or are likely to continue. Adapted from the risk management matrix for the OPP-ERA project <sup>(1)</sup>, the risks for sustainability that will likely play out differently in each country include:

1. OPP not being competitive/other solutions more appropriate
2. Insufficient buy-in from and alignment with major stakeholders (like GF, USG, PNLS)
3. Risk of machine breakdown
4. Procurement and supply chain risks
5. Human resource risks: Availability and motivation of staff to carry out VLTs
6. Financial risks
7. Security risks

The risk for supply security due to reliance on a single reagent supplier (an 8<sup>th</sup> risk category) would affect all countries equally. The supplier indicated that it will have no problems scaling up its production of reagents and that its recent take-over by Brucker will not create a threat for their continued availability. The change in the commercial approach of Biocentric, which now can offer reagent lease contracts, indicates that it is adapting to market conditions.<sup>(15)</sup> Therefore the risk is considered “very low” at present. It might increase to “medium” in the future.

We rated each risk mentioned as Very low (0 –  $p < 0.25$ ) – Low (1 –  $0.26 < p < 0.50$ ) – High (2 –  $0.50 < p < 0.75$ ) and Very high (3 –  $p \geq 0.75$ ), for the short term (up to end 2020) and medium term (2021-2024), summed up the risk scores across the 8 risk categories, and divided the result by 32 (the highest possible risk score) to yield a probability of discontinuation.

## Evaluation of OPP-ERA Project Phase II

The country sections below discuss ratings for each of the risks identified, which are summarized in a table in which the aggregate risk for discontinuation is calculated.

### Burundi

Given the inclusion of the OPPs in the national planning and the large share of OPPs in VLT in the country the risk “OPP not being competitive/other solutions being considered more appropriate” is considered “Very Low” in the short term. Going forward, the inability to use DBS <sup>(45)</sup> and some competition from POC instruments for EID will increase the risk somewhat, but it will likely remain “Low”.

The risk “Insufficient buy-in from and alignment with major stakeholders (like GF, USG, PNLS)” is considered “Very Low” in the short term as there is good collaboration with FHI360 – the only other major player in the VLT space in the country. The relationship with Global Fund and PNLS is supportive and has been consolidated. In the medium term it might increase to “Low”.

The “Risk of machine breakdown” is considered “Low” in the short term, as the machines are either new or have been serviced, and have low probability of breakdown. As they wear out, this risk increases to “Medium”.

In the short term “PSM risks” are “Low” as PSM is presently supported by UNDP, with a remaining risk for the scheduling of the delivery of 2020 reagents which requires timely ordering from Global Fund funds. Even though the transition of the procurement and logistics component was ensured by involving the national parties in skills transfer workshops organized by the OPP-ERA PSM manager, the medium term risk is rated “Medium” as it might require transition of the PSM support role to a new PR if UNDP is not selected as PR for the new Global Fund grant.

OPP-ERA project has thoroughly trained all laboratory staff and documented their proficiency, and has successfully secured transition of the salary of the ANSS laboratory technicians to Global Fund funding. However, the staff in the other laboratories is on government salaries, and might be less motivated to do VLTs when the incentives from the OPP-ERA project (such as training abroad, networking and encouragement from project staff) disappear. Therefore the human resource risk is considered “Medium” in the short and medium term.

The “financial risk” is rated “Very Low” for the short term, as Unitaid committed to fund a buffer stock of reagents until the end of 2019 and the Global Fund committed to support the supply of reagents and consumables and maintenance for the OPP-ERA platforms, as well as part of the medical activities of the OPP-ERA project until the end of 2020. The local coordinator and the medical officer of the OPP-ERA project have been integrated in the PNLS with GF funding to support the implementation of the national strategy for scaling up VLT, which is being developed, and help with writing the next concept note for the GF in 2020. This limits the financial risk in the medium term to “Low”.

Even though the security situation in the country improved recently, the risk remains fairly high (i.e. “Medium”) in both the short and medium term.

**Table 2: Risks for sustainability in Burundi**

RISKS	Short term	Medium term
OPP not being competitive/other solutions more appropriate	Very Low (0)	Low (1)
Buy-in from and alignment with major stakeholders (like GF, USG, PNLS).	Very Low (0)	Low (1)
Risk of machine breakdown	Low (1)	Medium (2)

## Evaluation of OPP-ERA Project Phase II

Supply chain risks	Low (1)	Medium (2)
Human resource risks	Medium (2)	Medium (2)
Financial risks	Very Low (0)	Low (1)
Security risks	Medium (2)	Medium (2)
Reliance on a single reagent supplier	Very low (0)	Medium (2)
	Very Low 6/32 (0.18)	Low 13/32 (0.40)

### Cameroon

The risk of “OPPs not being competitive/other solutions being more appropriate” is presently “Low”, even though the CNLS and private sector providers - which are very influential in Cameroon - already have reservations about the LOD of the OPPs<sup>(27,49)</sup>. It might increase to “Medium” if the LOD problems cannot be solved.

The risk for “Buy-in from and alignment with major stakeholders” is presently “Low”, as there is good collaboration with Chemonics/PEPFAR in quantification. If there is a push towards harmonization of the VLT equipment fleet, the risk will increase to “Medium”.

The “Risk of machine breakdown” is considered “Medium” as there is uncertainty about the state of the aging thermocyclers in the phase 1 laboratories, in particular for the HLD lab.<sup>(27,49)</sup> It was repaired twice in 2019. Going forward the risk will increase, but remain “Medium” as the maintenance of the machines has been funded through the Global Fund.

The “PSM risk” is presently considered “Low”, as the PSM activities continue now with support from Chemonics and Expertise France (until end of December 2019). In the medium term it increases to “Medium”, because of concerns about the chronic weakness of the CNLS and uncertainty about the ability to maintain the sub-zero supply chain for reagents.

The “Human resource risk” is presently and in the medium term considered “Low” as the OPP-ERA project has trained the laboratory staff and documented their proficiency, and staff has been performing well without incentives.

The “Financial risk” is presently considered “Low” because Unitaaid committed to funds a buffer stock of reagents until October 2019, and the Global Fund committed to support the supply of reagents and consumables as well as the maintenance of the machines until the end of 2020. But difficulties between the Global Fund and Cameroon around counterpart financing increase the risk in the medium term to “Medium”.

The security risks related to the political situation in the country are presently “Low”, but might escalate in the future to “Medium”.

**Table 3: Risks for sustainability in Cameroon**

RISKS	Short term	Medium term
OPP not being competitive/other solutions more appropriate	Low (1)	Medium (2)
Buy-in from and alignment with major stakeholders (like GF, USG, PNLs).	Low (1)	Medium (2)
Risk of machine breakdown	Medium(2)	Medium (2)
Supply chain risks	Low (1)	Medium (2)
Human resource risks	Low (1)	Low (1)

## Evaluation of OPP-ERA Project Phase II

Financial risks	Low (1)	Medium (2)
Security risks	Low (1)	Medium (2)
Reliance on a single reagent supplier	Very low (0)	Medium (2)
	8/32 (0.25) - Very Low	15/32 (0.47) - Low

### Ivory Coast

OPP-ERA project activities were taken over by the PNLs with the support of the Global Fund. The PNLs has committed to buy reagents for all OPPs in a 3-year rental lease agreement with Biocentric<sup>(3)</sup> and intends to use the unique ability of the OPPs to assess HIV-2 viral load.<sup>(19)</sup>

In the national planning, frank collaboration between sites using OPPs and the closed platforms supported by PEPFAR/Chemonics was evident, even if implementers of integrated VLT platforms still question the value of the OPPs<sup>(46)</sup> – this makes the risk “Low” for both short and medium term.

The “Risk of Machine Breakdown” is presently “Low” as equipment has been partly renewed, and is well maintained, but will increase to “Medium” as time goes by.

The “PSM risk” is considered “Low” in the short and medium term as Ivory Coast has the necessary data systems and competence in place to manage supplies.

The “Human resource risk” is “Low” now, but might increase to “medium” as some uncertainty will arise when the incentives (training, support from project staff) provided by OPP-ERA will disappear.<sup>(26)</sup>

The “Financial Risk” is “Low” as Unitaid provided a buffer stock on HIV VL intrans for the period August-October 2019, and the gap for November and December 2019 will be filled by PNLs on Global Fund procurement. Beyond, the supply of OPP reagents is guaranteed for the next 3 years (including for the lab in Daloa) through a reagent rental contract between the PNLs and Biocentric, which includes the maintenance of the extractors and thermocycler of the Daloa lab.

The “Security risk” related to the political situation in the country are presently “Low”, but might escalate in the future to “Medium”.

**Table 4: Risks for sustainability in Ivory Coast**

RISKS	Short term	Medium term
OPP not being competitive/other solutions more appropriate	Very Low (0)	Very Low (0)
Buy-in from and alignment with major stakeholders (like GF, USG, PNLs).	Low (1)	Low (1)
Risk of machine breakdown	Low (1)	Medium (2)
Supply chain risks	Low (1)	Low (1)
Human resource risks	Low (1)	Medium (2)
Financial risks	Low (1)	Low (1)
Security risks	Low (1)	Medium (2)
Reliance on a single reagent supplier	Very low (0)	Medium (2)
	6/32 (0.19) Very Low	11/32 (0.34) Low

## Guinea

The risk of “OPP not being competitive/other solutions more appropriate” is considered “Very Low” in the short term as PNLISH appreciates OPP-ERA’s effort of introducing VLT in the public sector in the country and has fully integrated OPPs in the national VLT plan.<sup>(77)</sup> It is proceeding with the operationalization of an additional OPP lab in Kankan. However, in the medium term the risk will increase to “Medium” because for the rural areas the PNLISH is rolling out the use of DBS. DBS samples will be tested on Abbott equipment in the labs were up-lifted to GLP compliance by the OPP-ERA project. The presence of Abbott platforms in the same labs as OPPs creates a risk for the continued use of the if/when staff preference shifts to using the Abbott platform instead of the OPP.

The short term “Risk of lack of acceptance by other players” is “Very Low”, as 87% of all VLTs in the country are done on OPPs, and as the one project using an IP (Dream) is not closely integrated in national planning.<sup>(39)</sup> In the medium term the risk might increase to “Medium” because the preference of the OPP-ERA supported labs might shift to IPs and because of the increased use of POC devices.

The present “Risk of machine breakdown” is “Low”, as the equipment in both phase 1 laboratories benefits from maintenance contracts. It will increase to “Medium” with time. The lab in Kankan might not become operational – in which case the deployment of an OPP there might be abandoned.

In spite of our assessment that the PSM situation in Guinea is fragile, the short term “PSM risk” is rated “Low”, because Solthis informed us<sup>(60)</sup> that it will provide the PNLISH with TA to manage the supply chain. In the medium term the PSM risk is rated “Medium”, as it might not be possible to continue supporting the PNLISH indefinitely.

The “Human resource risk” is presently “Low”, as training and QA are in place. Going forward it might increase to “Medium” if staff is less motivated when the OPP-ERA incentives (training, support from project staff) disappear.<sup>(47)</sup>

Presently the “Financial risk” is “Very Low” as up to end 2020 Global Fund funding has been committed, and Global Fund is already supporting the reagents now. The new concept notes need to include funding for the OPPs, but the risk that this will not happen is “Low”.

The “Security risk” is rated “Medium” in both the short and medium term in view of the tense political situation in the country.

**Table 5: Risks for sustainability in Guinea**

RISKS	Short term	Medium term
OPP not being competitive/other solutions more appropriate	Very Low (0)	Medium (2)
Buy-in from and alignment with major stakeholders (like GF, USG, PNLIS).	Very Low (0)	Medium (2)
Risk of machine breakdown	Low (1)	Medium (2)
Supply chain risks	Low (1)	Medium (2)
Human resource risks	Low (1)	Medium (2)
Financial risks	Very Low (0)	Low (1)
Security risks	Medium (2)	Medium (2)
Reliance on a single reagent supplier	Very low (0)	Medium (2)
	5/32 (0.16) Very Low	15/32 (0.47) Low

## Conclusion

The risk that the OPPs will no longer be used or supported is rated “Very Low” in the short term, and increases with time to “Low” in all four target countries.

**Table 6: Summary of sustainability risk assessment**

Country	Short term risk	Medium term risk
Burundi	6/32 (0.18)	13/32 (0.40)
Cameroon	8/32 (0.25)	15/32 (0.47)
Ivory Coast	6/32 (0.19)	11/32 (0.34)
Guinea	5/32 (0.16)	15/32 (0.47)

The countries where medium risk is greater are Cameroon, where reputational risks, supply chain risk and financing risks are at play, and Guinea, where supply chain risks, the inability to use DBS, and the ready availability of integrated platforms in the laboratories supported by the OPP-ERA project create a fairly high discontinuation risk. In Burundi the risk is low because there is no push back from other opinion leaders, the transition of OPP-ERA staff to the PNLs, and because the OPPs ensure a large proportion of the VLT in the country. The risk also appears low in Ivory Coast, because of the reagent lease contracts for the OPPs concluded by PNLs, and its recognition of the unique ability of the OPPs to detect VIH-2.

## LEARNING AND RISK MITIGATION

### Dissemination of lessons learnt

The grantees have presented about their project on several occasions, and have followed the guidance of Unitaid in the communication plan which they jointly developed. As mentioned in the section on Impact, we consider that their effort did not result in increased adoption of OPPs.

The “HIV viral load testing operational guide”<sup>(44)</sup>, which is currently posted on the Solthis website, states, in its subtitle “60 lessons learned from the OPP-ERA project”, and supposedly comprehensively reports on the lessons learnt by the project. It identifies the important challenges associated with demand creation and the rational use of VLT. However, the operational guide ignores how the offer of VLT evolved outside of their project, which limits its usefulness in the changed landscape of VLT in LMICs.

Sections that deal with patient care, strategy/planning and costing would be useful regardless of the laboratory technology used, and the section on laboratory would apply to integrated platforms too, but other sections are focussed on the operational characteristic of the open platforms only.

Clear omissions from the operational guide are that POC instruments and the use of DBS for sample collection are not mentioned. In addition, the implications of the evolution of the VLT landscape in LMIC towards integrated platforms and reagent lease approaches are not mentioned. The failure to “learn” of those important developments precludes briefing of potential buyers or users of VLT technology users about how they can de-risk and simplify their operations.

### Risk management

The consecutive progress reports by the OPP-ERA project include a comprehensive risk management matrix, which includes the actions taken and agreed on with the Unitaid secretariat to manage the risks identified.

Risks identified from the onset of the project and insufficiently addressed include:

### *Risk that OPPs solution not being competitive*

The OPP-ERA project tried to manage this risk through the development of cost-effectiveness analysis and the development of a business case, and through additional focus on communication. The first strategy failed, as the outputs were not produced in a timely manner, and the communication effort did not have the hoped-for impact in the absence of data demonstrating the superiority of OPPs compared to other VLT platforms.

The OPP used by the project is vulnerable because of its inability to use DBS (which links to its relatively high limit of detection). The project tried to address this vulnerability, but failed to validate the Biocentric test kit for use with DBS. The project also tried to support Biocentric with TA for WHO prequalification, but the company did not avail itself of the offer.<sup>(36)</sup> The project asked Unitaid to reach out to Biocentric to motivate the company to fast track DBS validation and WHO prequalification<sup>(16)</sup>, but was not successful at this: Biocentric confirmed that it never had any significant contact with Unitaid<sup>(15)</sup>. As the vulnerability related to DBS has to date not been addressed, countries are shifting to platforms that are able to use DBS. In Guinea, the two labs supported by OPP-ERA were equipped with an Abbott system to enable them to use DBS, and POC machines are being readied for VLT outreach in rural areas.<sup>(39,40)</sup> In Cameroon the lab at Laquintenie hospital also uses an Abbott system – and CNLS stated that, when it has the option to use either an integrated platform or an OPP, it uses the OPP as a back-up solution given concerns about the limit of detection of the latter.<sup>(27)</sup>

### *Risk of insufficient buy-in from other major stakeholders*

The OPP-ERA project secured buy in from national level stakeholders, but was not successful in its outreach to global level stakeholders. Unitaid tried to help with global level engagement, in particular with the Global Fund. With the Global Fund at HQ the main topic of discussion was transition (in the November 2018 reprogramming meeting), which likely made it difficult to focus on strategic alignment. With WHO there was no significant discussion on strategy, and the discussion on prequalification of the Biocentric test kit was mainly between Biocentric and the prequalification programme.<sup>(18)</sup> While consecutive drafts of the business case document that the OPP-ERA project was aware of the increasing tendency of integration of the VLT offer<sup>(52, 53)</sup>, it did, until the November 2018 reprogramming exercise, not result in adaptations to the project's strategy.

## **PROCUREMENT AND SUPPLY MANAGEMENT ASSESSMENT**

Effective procurement and supply management was an essential prerequisite to the success in achieving the goals of the OPP-ERA grant. In 2017 and 2018 the primary focus of PSM was directly on the grant needs, procuring the equipment needed and establishing a regular supply of reagents and other consumables from international suppliers. In 2019 the focus shifted to a more intensive effort on transitioning the PSM activities to country stakeholders, primarily government entities, to ensure the continuation of the VLT testing levels in the focal countries.

PSM under Phase II of the grant was led and managed from Solthis HQ in Paris, with country-based PSM managers in each of the four focal countries of the grant. Solthis was responsible for establishing the procurement and supply management strategies, primary supplier relationships, and for all international tendering. The country-based PSM managers were responsible for local procurement of smaller scale laboratory equipment that could be sourced locally. Equipment needs that could not be satisfied locally were transferred to Solthis in Paris to launch international calls for bid or international shopping dependent on value.<sup>(79)</sup>

Solthis Paris was responsible for managing the international supply chain to point of entry in the country of destination, with the local PSM manager responsible for all local supply chain movements.



## Evaluation of OPP-ERA Project Phase II

In general this division of labour worked well, although all countries experienced some levels of challenge with maintaining the reagents at sub-zero temperatures. The majority of international shipments were received on time, and any minor delays in arrival did not lead to in-country stock outs.

In May 2018 Cardno Consultants reported on a review of the PSM status of OPP-ERA <sup>(79)</sup>, and produced a number of recommendations for Solthis as the new Grant Managers. These recommendations were particularly pertinent for the transition of procurement responsibility to country ownership

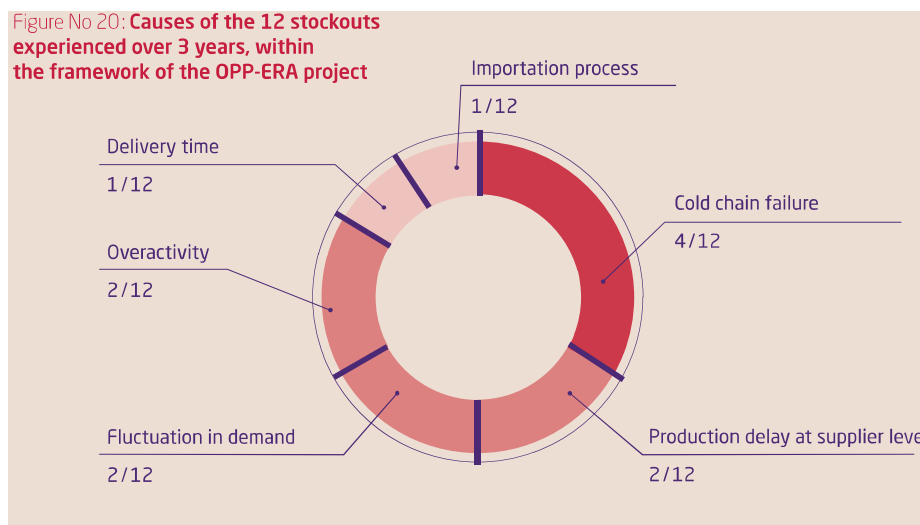
### Findings

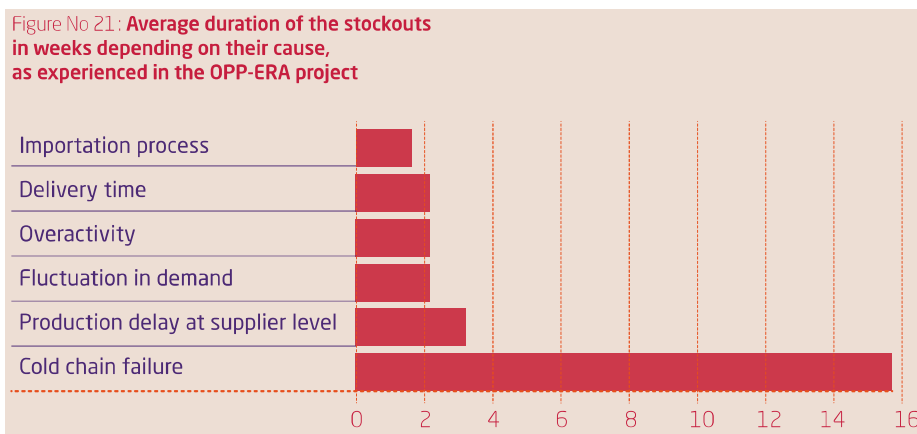
#### Procurement

The procurement process followed best practice in seeking open competitive bids of appropriately qualified equipment and commodities. Annual ordering ensured competitive pricing, with quarterly deliveries that could be adjusted as needed to provide flexibility to react to changes in demand.

However, as reviewed under “Effectiveness” a key objective of the project to expand the range of generic suppliers was not achieved despite outreach by Solthis.

Solthis did not establish procurement key performance indicators. As a result we were not able to evaluate the relative success of the procurement process other than the evidence that pricing was within normal market expectations, and the programme did not suffer any significant stock outs as a result of procurement failures. In the Operations Guide <sup>(44)</sup>, Solthis published the following graphics based on stock outs incurred showing that the major cause was breakdown in cold storage or cold chain, resulting in product damage from temperature excursion. The country PSM managers reported to the evaluators that the programme was able to take measures to ensure that VLT continued using the availability of integrated platforms despite the OPP stocks outs. In practice, there were interruptions, including a 3-month interruption of OPP testing on OPP in Laquintenie Hospital and a 6 month interruption in CPAG, both in Cameroon, and a 2 month interruption in Guinea.





Additionally, Solthis did not establish a routine process of supplier assessment and relationship management. Relationship management is routine best practice for all regular suppliers, and is particularly important when managing a sole supplier situation, without assessment of performance the supplier can exploit the privilege of the sole supplier relationship and create a dependency and imbalance of power between buyer and supplier.

### Forecasting and Quantification

Each of the four countries had an established process of annual quantification of reagents. Solthis supported the countries in this activity, and aggregated the needs of the four countries at the central level in Paris to inform their procurement and ordering process with Biocentric. The actual process and tools used varied between countries. In Ivory Coast, influenced by PEPFAR, the laboratory service used the FORLAB tool, a comprehensive quantification and demand management tool originally developed with PEPFAR funding, but in the other countries the level of data available and the supply chain capacity in the country was insufficient to support use of FORLAB.<sup>(80,81)</sup> In those countries Solthis and the local PSM managers developed tailored Excel spreadsheet solutions, which operated satisfactorily, but may not be as robust as a tool like FORLAB in the longer term. In all countries the annual quantification process was a multi-stakeholder effort including the governments.

The demand indicated from the annual quantification was revisited on a quarterly basis to take account of actual demand/usage, and current stock levels to inform the level of quarterly orders. This ensured that deliveries were flexible to actual demand rather than being rigidly controlled by a single annual process. This was successful in ensuring no stock outs, and minimal wastage, even as demand fluctuated and grew. Solthis did not, however, conduct a formal process to retrospectively assess the forecast accuracy to be able to track trends in deviation from forecast, or to assess and learn from reasons for any inaccuracies in the quantification and demand forecasts.

### Supply Chain Management

As indicated above Solthis took responsibility for arranging international transport, with the local PSM manager responsible for in-country delivery. The process to country worked well, and Solthis kept the in-country PSM managers informed of progress, providing the necessary advices and documentation to enable goods to be received and moved through customs without undue delay. In each case the host governments expected that initial delivery would be to a central medical stores or similar entity, and from there local delivery would be made to the actual laboratories. In all countries this proved to be a misassumption, as the stores were not well equipped to manage laboratory commodities that must be kept at sub-zero temperatures, neither was there sufficient refrigerated transport and dry ice to quickly moved the products to the laboratories. Solthis and the in-country PSM managers were able to persuade their counterparts that the centralised approach was

## Evaluation of OPP-ERA Project Phase II

impractical, and in each case delivery was managed direct to the laboratories. This is a practice the evaluators support for these products to reduce the risk of damage and subsequent wastage due to temperature excursions. (Detailed experiences are briefly reported by country below).

The country PSM managers were able to apply their local knowledge and existing networks to overcome the majority of the cold chain supply challenges, with only one significant out of temperature incident (on a Global Fund consignment) that led to wastage and destruction of product affecting the performance of the labs in Cameroon for several months. Considering that handling these commodities was new to many stakeholders this is a good outcome, as wastage due to temperature excursion is common in resource limited settings.

A key challenge and objective in the supply of temperature sensitive reagents to de-risk the supply chain for the purchaser. In the case of lab supplies this would require the supplier to be responsible for delivery door-to-door (factory to lab), with evidence provided to the buyer of no temperature excursions from monitoring devices. This extends the supplier's responsibility from factory gate delivery point (the least risk for the supplier, and highest risk for the buyer), to the buyer's place of use (reversing this risk profile). Generally speaking, the fewer nodes in the supply chain where product custody changes the less inherent risk in the supply chain. To address this challenge, under Phase II Solthis shifted the scope of the risk from buyer to supplier by use of Incoterm DAT (Delivery at Terminal, or place of destination), although the exact place of delivery varied by country, with the local PSM manager managing the local transportation process to maintain the cold chain. In addition Q-tags were placed in each cold box to monitor temperature, and were examined as part of the goods reception procedure.

### Transition to Country Ownership

Phase II of the OPP-ERA grant was relatively short, from August 1, 2016 to July 31, 2019 (3 years) plus five months of closure activity, mainly to support four labs opened in Phase II. As a result the usual stages of start-up, steady state and transition out were all compressed, especially when considering the delays experienced at the outset of Phase II as discussed earlier in this report. Country-ownership/transition workshops were held in early 2019 to agree timetables and responsibilities, which in most countries only allowed around 6 months for the changeover. Time will tell if the transition arrangements were sufficiently robust, but the evaluators would have preferred to see a full annual cycle of quantification, forecasting and commodity delivery led by country actors before closure of the country projects. Although, in the main the country counterparts to whom responsibility was transitioned had been engaged in the forecasting and quantification process throughout Phase II. Unitaid agreed to supply buffer stocks of reagents up to the end of 2019. Solthis informed us during the review of the preliminary version of the present report on 13 December 2019 that it is making technical assistance available in Burundi and Guinea to assist in addressing unforeseen challenges, or weakness in local capacity during the early stages of full country ownership. Similar technical assistance can also be requested by the other countries.

Funding has primarily been transferred to Global Fund grants, although VLT commodities were not included in the original grant applications and had to be addressed retrospectively. Local funding is very limited.

### PSM Advocacy and International Stakeholder Engagement

The major advocacy legacy from the grant is the Operations Guide published by Solthis in November 2019. <sup>(44)</sup> As regards PSM, in this document the lessons learned, best practice, programmatic advice and tips, are consistent with established practice, but do not add significantly to the current body of knowledge. There is value in bringing this advice together into a single document in French, but continued relevance will depend on how well it is publicised, and whether it remains readily available by download, with updates as practice develops.

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The evaluation team reached out to major influencers of the diagnostics market, including the Clinton Health Access Initiative, the African Society for Laboratory Medicines (ASLM)<sup>(68)</sup>, PEPFAR's Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) project<sup>(10)</sup>, WHO<sup>(14)</sup>, and the Global Fund.<sup>(12)</sup> None of the people interviewed at the stakeholders reported major direct engagement from Solthis, although all were aware of the OPP-ERA project and the objectives to promote generic supply and open polyvalent platforms. However, with support from Unitaid, Solthis did engage with the Global Fund country teams, and as reported elsewhere the Global Fund will provide funding for OPP commodities after closure of the OPP-ERA grant.

As reported, each of these global level stakeholders was more in favour of the use of bundled supply from the major integrated platform solutions. Bundling being defined as, bundling not only all supplies needed for individual tests in one supply package, but also including training and routine maintenance of the diagnostic platform. This was considered to be a simpler and more robust solution for both the procurement process and laboratory operations in resources constrained environments, and would better support programme goals to rapidly increase levels of viral load testing. Global Fund have long-term supply contracts in place with the major integrated platform suppliers, and at the time of this evaluation GHSC-PSM is close to completing a major RFP to also appoint, probably three, integrated suppliers for bundled procurement on a reagent lease basis.<sup>(11)</sup> PEPFAR is not supportive of generic supply in diagnostic market for public health laboratories.<sup>(10)</sup>

As reported elsewhere, ASLM were impressed by a waste management costing tool developed by OPP-ERA, and presented at IAS. ASLM consider the tool provides the most granular analysis of waste management costs they have seen. ASLM were not aware of the situation in the focal countries as a result of the OPP-ERA project.<sup>(68)</sup>

### Country Level - Burundi

Annual quantification, with quarterly review of usage and stock levels worked well, and the local team felt able to influence the international procurement and delivery schedules. The PSM manager had advance sight of shipping documents that enabled pre-clearance of import authorisation prior to shipment, thus ensuring prompt clearance through customs, usually with only one night storage at the airport, before direct delivery to the laboratories. The project used East Africa Cargo as their local freight forward who respected timetable and product care. An earlier provider did not respect the timelines and kept product in conditions that risked temperature control. Shipments were generally on time, and complete, with just one incidence of incomplete supply of gloves, that was corrected and did not cause operational problems.<sup>(80)</sup>

A local transition plan was developed in early 2019. Responsibility has been transferred to UNDP, the principal recipient of the Global Fund grant. Government of Burundi does not have the current capacity or capability to manage the PSM activities for the OPP-ERA commodities. There is, therefore, a vulnerability going forward that if UNDP does not continue as the GF PR after their current appointment ends in December 2020 requiring a further transition.<sup>(80)</sup> As far as we are aware there are no current plans to build Ministry of Health capacity in this area.

### Country Level – Cameroon

Quantification was managed through annual multi-stakeholder workshops, including all key local actors from Government, and local representatives of the international stakeholders e.g. PEPFAR, GF PR, CHAI and OPP-ERA (Unitaid). There were occasions when quantities available did not match commitments, and required cooperation between the parties. Specifically, a Global Fund consignment experienced a temperature excursion, and had to be destroyed, although the final incident report could not establish whether the excursion happened at the central store, or in transit. Local cooperation ensured that testing operations were not interrupted at the HLD lab (which also has an Abbott platform), but at the CPAG lab, which has only an OPP, no VLT could be done from Sept 2018 to mid-March 2019, when OPP reagents could be re-supplied.<sup>(81)</sup>

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The quantification results were translated into demand forecasts by Excel templates developed by the Cameroon office of OPP-ERA project. Solthis Paris had a more complex model requiring weekly data inputs that did not prove practical or acceptable to local counterparts. The locally developed Excel option has since been adopted by the Ministry of Health for other lab areas (e.g. Abbott, EID), and is now being introduced in the Democratic Republic of Congo. At PEPFAR's recommendation they also tried to migrate to the FORLAB tool, but could not provide all the data the model requires.<sup>(81)</sup>

Supply chain to the country was managed by Solthis, and then taken over by the country. The main challenges were with the cold chain, particularly the limited local supplies to recharge the packaging with dry ice to maintain the sub-zero temperatures. It was also very challenging to transport the supplies to distant local labs, some had no air links, and would take over two days by land transport. It was sometimes necessary to hold consignments overnight in Yaoundé, where temperature monitoring at night and over weekends was limited or non-existent, and power supply unreliable. This is a common challenge in large countries with constrained transport infrastructure, but a widespread epidemic. We were unable to ascertain why the decision was made to hold overnight consignments in Yaounde, but were informed that the project bought an alternative power supply for lab fridges.<sup>(81)</sup>

For transition OPP-ERA capacitated CNLS (laboratory unit) from the outset, with four different training workshops with follow-ups to assess how well the training had been adopted and if best practices were applied. At the end of 2018 a wider transitioning workshop developed a country-owned and designed transition plan. The national central medicines store CENAME was initially resistant to being involved as the agency is unfamiliar with lab commodities, and was only empowered for essential drugs. They also lacked the capacity to handle and store frozen product. After advocacy and persuasion, CENAME became involved in 2019, although this was rather late to get full buy-in and experience. A new cold store is under construction, and there is ongoing good collaboration with PEPFAR and the Global Fund.<sup>(81)</sup> As a result of this initial reluctance and lack of experience in CENAME, the evaluators would assess the PSM transition in Cameroon as fragile.

### Country Level – Ivory Coast

The tendering and procurement of extractors, thermocyclers, viral load reagents and consumable were all managed by Solthis in Paris, but the local project felt able to influence purchasing decisions to ensure local requirements were met.<sup>(82)</sup> There was strong cooperation between the purchasing manager in Paris, the freight forwarder and the local team. The main challenge experienced was to get the product through airport customs in time to avoid temperature excursions. It appears the Customs Authority in Ivory Coast is more challenging and less flexible in appreciating the demands of sub-zero shipments than elsewhere. Orders arrived in good time and condition, with one exception of a one month delay, but due to good local stock management this did not affect the project.

The lab system in Ivory Coast has benefited from investment by PEPFAR. As a result data systems were in place that enabled more sophisticated quantification and forecasting efforts than the other three countries who had not received such investment. Ivory Coast therefore could use the FORLAB and Pipeline tools to build up national demands from a per lab and per platform basis at each laboratory and HIV care site. The local team reported no stock out or wastage due to forecasting errors.<sup>(82)</sup>

All PSM activities have been fully transitioned to local teams in a well-planned process that started in sufficient time for the team to report feeling confident that they can manage the required processes.

### Country Level –Guinea

During Phase II of OPP-ERA procurement and supply management functioned satisfactorily, complaints from Phase 1 that the Paris HQ did not respect changes of demand as the programme grew were not experienced in Phase II, showing this lesson was learned. Shipments were funded by

both OPP-ERA and GF, a good preparation for transition. Quantification was undertaken in a 3<sup>rd</sup> 90 quarterly working group, convened by OPP-ERA. <sup>(39, 72)</sup> However, since OPP-ERA ended in July this workshop has not been convened. <sup>(32, 78)</sup> Quantification was difficult due to a lack of consistent processes in treatment and care sites across the country (MSF was critical of the methodology as it does not take into account needs to retest, and of patients that may be failing on their treatment<sup>3</sup>). Reagents have been secured until the end of October 2019 by an OPP-ERA buffer stock supplied before closure. The GF has committed to take over supplying the reagents from 2020, but at the time the evaluators visited there was no indications when fresh supplies may be received.

Transition arrangements have been difficult to establish. The National AIDS control Programme (PNLSH) is responsible for procurement, but without a quantification or forecast it is unclear as to the quantities they may secure. The central medicines store of Guinea (“Pharmacie Centrale de Guinée” (PCG)) demanded that they should be responsible for storage, despite the fact that their sub-zero room, financed by Global Fund, was not yet functional.<sup>(39)</sup> As an interim solution PNLISH installed freezers and UPS at the laboratories<sup>(40)</sup>, although there is concern that local power supply is unreliable, and local systems do not always appreciate the vulnerability of reagent supplies to even small temperature excursions.

At the time of this evaluation the status of PSM in the transition in Guinea is considered highly fragile. However, Solthis informed us (on 13 December 2019) that it will make technical assistance available to the PNLISH to help deal with the PSM and other challenges.<sup>(60)</sup>

### PSM Conclusions

1. Procurement and supply management was well-designed for the project to ensure that supplies and equipment needs of OPP-ERA in conducting viral load tests in the four focal countries were received in good time and condition and appropriate prices. The division of responsibilities between Paris and local PSM managers made sense for the project, although it did limit local stakeholders’ opportunities to establish relationships with the major international suppliers, ready for transition. However, as the immediate future funding of commodities will be from the Global Fund, and possibly PEPFAR later if the Biocentric reagents receive WHO prequalification, both of whom use procurement agents, the lack of direct relationships with the supplier may be less significant.
2. All countries experienced challenges in handling sub-zero commodities. Country government counterparts pressed for use of central medical stores, or similar entities, as the first point of delivery, despite inadequate cold storage capacity. This adds an unnecessary node in the supply chain, and creates a potential vulnerability to temperature excursions. As each country had only a limited number of final delivery points, adopting a policy of direct delivery to the operational laboratories was correctly considered preferable and implemented by Solthis. Despite the success of this approach, it is a concern that local counterparts are still pressing to return to the use of a central storage node.
3. Detailed performance of the PSM system was difficult to assess due to the lack of detailed key performance indicators. The only KPI mentioned to the evaluators was whether stock outs were experienced, but this is a very basic, and crude KPI, as it does not give any indication as to cause and effect, trends or opportunities. Additionally, there was no formal system of supplier relationship management.
4. The quantification and forecast strategy of annual quantification and quarterly review of usage and demand was strong, although, due to local capacity constraints, detailed operations differed in each country. Only one country, Ivory Coast, had sufficient capacity and data availability to

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<sup>3</sup> OPP-ERA has assured the evaluators that quantification did take account of retesting and patients failing on treatment.

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use best practice tools such as FORLAB and Pipeline. The other countries used locally developed Excel spreadsheets, which are vulnerable to error over time.

5. Despite assessment of potential additional suppliers, and efforts to encourage these suppliers to respond to OPP-ERA RFPs, the project was not able to expand and develop the market for generic reagents and equipment, which was a key objective of the original OPP-ERA grant.
6. Of necessity, transition arrangements varied for each country, and due to the relatively short timescale of OPP-ERA Phase II only started in earnest in 2019, giving just 6 months for handover. As a result the timetable did not allow a full annual cycle of quantification, forecasting and commodity delivery led by country actors before closure of the country projects during which time weaknesses could be identified, lessons learned and any necessary adjustments made. However, local actors were included in the quantification and forecasting efforts throughout Phase II, and will be familiar with the process, albeit not as the leadership of the exercise.
7. The evaluators consider the transition arrangements in Ivory Coast to be robust, reflecting the greater capacity in the country due to investment by PEPFAR, transition in Burundi is sound, but reliant on UNDP the Global Fund PR, in Cameroon we consider the transition to be fragile due to limited local facilities to handle sub-zero laboratory commodities, and in Guinea we consider the transition to be highly fragile due to weak local system capacity and problems in managing sub-zero laboratory commodities. While in the short term the PSM risk is controlled in the 4 countries, it is unknown whether the countries will be able to sustain their PSM arrangements in the longer term.

### PSM Recommendations

1. Grants with major allocations for procurement and supply management should be required to establish PSM KPIs during project start up, and be required to report on these KPIs at least annually.
2. Direct delivery to point of use is recommended for products that require special handling (e.g. cold storage) which may not be appreciated in a large centralised multi-product store. Initial delivery to a central national or regional depot is not recommended as good logistics practice for the most efficient and cost effective supply chain solution on grants with a limited number of final destination delivery points, e.g. public health laboratories or referral hospitals.
3. The option for direct local delivery post Customs by suppliers should be considered, and compared for cost and risk reduction.
4. Either during grant design, or during project initiation the capacity of the health system to provide necessary data and reports should be assessed to see if systems strengthening is required to support the objectives of the grant. In the case of OPP-ERA in three of the four countries data necessary to support state of the art quantification and forecasting using the FORLAB tool, or similar, was not available. As OPP-ERA was not a system strengthening project per se, it did not have the funding or mandate to intervene to build data collection and management systems.

## TOOLS FOR SCALE UP ADVOCACY

Under output O1.8 of the log frame, the project developed two important tools: the waste management costing tool, and the viral load costing model. Other products developed under this output – the business case and the market survey – were discussed under “Effectiveness”.

The waste management tool <sup>(83)</sup> is a very detailed instrument, but it works as expected. We agree with ASLM, which indicated in its interview with us that this is an important product.<sup>(68)</sup>

The viral load costing tool <sup>(84)</sup> was due in the first quarter of 2017, but, after several rounds of field evaluation, was released only in November 2019. It uses a micro-costing methodology: all costs that contribute to the total cost of a viral load test carried out on an OPP are considered. We found this

tool quite interesting because its use potentially would provide implementers to assess the trade-offs between different VLT technologies, and it is relatively easy to use. This would however require that the modules “cost of laboratory reagents” and “the cost of laboratory equipment” be arranged or slightly modified to accommodate the specific information of the other VLT platforms. While an expert could modify the content of those two modules to calculate the lab costs and reagent costs of other VLT platforms, in their present configuration, they are pre-filled with information relating to the OPPs only. As the tool was used for comparative analysis of OPP and integrated PCR platforms in at least one abstract presented by the project <sup>(85)</sup>, we dare hope that this feature can be added in the future. Presumably the costing tool was used to develop the cost estimates for VLT published in the OPP-ERA toolkit, but the estimates were not published in the peer reviewed literature. As the cost estimates for VLT on integrated platforms posted on the website of the Global Fund <sup>(86)</sup> were also not published in the peer review literature, the publication of the OPP-ERA estimates would fill an important knowledge gap.

We found only one problem with the tool, in the “human resource” module. When several staff categories are used for the same task, e.g. sample collection, it underestimates the cost of human resources. This error seems to be due to the inability to split, within each task, the workload assigned to each staff category. The grantees were informed of this finding, and informed the evaluation team that they will address this problem in the first quarter of 2020.

## CONCLUSIONS

Regarding the **goal** of the grant “to contribute to the scaled-up access to VLT in LMICs” and the project’s intent to show that “OPPs can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs .../...” and “create a market for OPPs in LMICs”, the OPP-ERA project was not successful. This conclusion is based on the following findings:

- 1) The OPP-ERA was unable to document that the use of OPPs results in better scalability of VLT than the use of integrated real time PCR platforms.
- 2) The OPP-ERA project failed to demonstrate the feasibility to use OPPs with DBS-type samples, with limits their utility for VLT, and failed to demonstrate that OPPs can be used for EID.
- 3) The OPP-ERA project did not show that the OPPs can be used to scale up the diagnosis of HIV-related conditions (even if the ability of diagnosing HBV infection on the platform used by the project is well documented in the literature and in the field),
- 4) The OPP-ERA project failed to make the economic case for using OPPs for VLT, as it did only state, but did not publish a peer reviewed assessment of, the full cost of using OPPs in comparison to other VLT platforms, and as the price differential between using an OPP and using other approaches (integrated real time PCR platforms and POC technologies) decreased considerably during the lifetime Phase II of the OPP-ERA project.
- 5) While the OPP-ERA project identified, in addition to its existing suppliers and one supplier for thermocyclers, more manufacturers of equipment and reagents useable within OPPs, it was unable to entice them to start supplying Global Fund supported programmes or obtain the necessary approvals to start supplying PEPFAR.

That no market for OPPs was created is based on the following facts:

- 1) Other than Biocentric, the supplier of HIV-1 RNA Amplification reagents used by the OPP-ERA project, there are only two suppliers of HIV-1 RNA amplification reagents listed as HIV-1 RNA amplification reagent suppliers to the Global Fund, none of which is truly present in Global Fund procurement as neither did supply any products to Global Fund supported programs after 2014.



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- 2) Unlike the increasing uptake of Point of Care (POC) tests, the share of Biocentric reagents in Global Fund procurement for VLT was and remained very limited. Whereas Guinea Bissau, Madagascar and DRC were identified as new OPP users in our interview with Biocentric (beyond the 25 countries listed in 2016 as users of OPPs in the OPP-ERA project plan), there is, outside the 4 project countries, no evidence of increased uptake of OPPs for VLT in procurement by the Global Fund or in reports by OPP-ERA.
- 3) The use of HIV-1 RNA amplification reagents requires the availability of matching equipment. The matching equipment offered by Biocentric/Brucker is not on the list of the Global Fund list of approved suppliers. Potential new users of the Biocentric's reagents that are supported by the Global Fund need to identify the matching equipment on the list of eligible suppliers first, and obtain them from other vendors. This complicates their procurement and maintenance.
- 4) PEPFAR requires that its suppliers VLT technology have WHO prequalification or FDA approval. There are presently no suppliers HIV-1 RNA amplification reagents usable on OPPs with such approval. The OPP-ERA project's attempts to support Biocentric with obtaining WHO prequalification were not successful. This makes it impossible for PEPFAR to procure their products.
- 5) PEPFAR is presently requiring, in its tender for VLT, the offer of all-in reagent lease contracts. While suppliers like Biocentric/Brucker (or Sacace or Bioneer) are or should be able to propose such contracts, their lack of FDA or WHO prequalification precludes them from accessing PEPFAR funding for their systems.
- 6) The WHO prequalification program will not give prequalification to HIV-1 PCR amplification reagents, unless paired with a well characterized set of extraction reagents and equipment and thermocyclers. In practice this means that it will only approve integrated PCR systems.
- 7) Leading opinion leaders in the VLT space, such as WHO, ASLM, and CHAI, prefer integrated systems because of the relative simplicity of their procurement from a single provider and the ability of their suppliers to offer reagent lease contracts.

The main impact of the OPP-ERA project was at the level of its four supported countries. It was most visible in Guinea and Burundi, where the project provided a sizable proportion of the number of VLTs carried out in the country, and laid the foundation for their VLT programmes. In all four countries, the impact was in policy development for VLT expansion, increased access to VLT, and in strengthening of the health system. The project strengthened the operation of its supported laboratories, of which the ability to ensure quality was greatly improved, and led to some improvement of health supply chain management. However, the public health impact of the OPP-ERA project was limited, as, in addition to a less than anticipated output of its OPPs, the project did not have sufficient ability to influence the rational use of VL testing results.

While the OPP-ERA project was still relevant when Phase II of the project was started in 2016, the global level relevance of the OPPs for VLT and EID in LMICs eroded quickly thereafter, as the decrease in price of VLT on integrated platforms decreased the financial attractiveness of the OPP, and a POC platform was introduced that enabled the use of less highly skilled staff to do VLT. The project was unable to address some of the drawbacks associated with its OPP platform, such as the inability to use the Biocentric test kit with dried blood spots and validate it for EID.

While the decreasing relevance of OPPs for VLT in LMICs is explained by factors beyond the control of the project, it should be recognized that the late delivery or failure to deliver on several outputs by the OPP-ERA project made it more difficult for the project to argue in favour of OPPs. As the project failed to deliver on its scale up targets, it could not well argue for the scalability of its technology, and the ability to argue in favour of the OPPs on the basis of their lower cost was limited by the fact that the project did to date not publish a peer reviewed assessment of their cost. While, in its communication, it suggested that the extractor used is more robust and can be maintained more

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easily than that of other PCR platforms, it has not published data to corroborate those assertions. In addition, the project did not, until the release of its “operational guide”, provide a quantification of the amount of human resources needed to operate the OPP. In spite of its outreach and presence in international conferences, web, and media, the project failed to convince major funders and opinion leaders about the merit of OPPs in VLT in LMICs. The project also had limited engagement with global level stakeholders such as ASLM, CHAI, the Global Fund (at HQ level), and WHO, but the lack of supporting data is the more likely explanation for its inability to convince.

The OPP-ERA project did demonstrate that OPPs can be used, and that their share in VLT testing can be increased considerably in two countries (Burundi and Guinea), provided the conditions for their successful deployment can be met. Those include that the infrastructure, human resources, and finances are available to sustain the system, that a transport system to ensure the rapid transport of samples is in place, and that a supply management system is in place to operate a centralized real time PCR platform. Among the advantages are a somewhat lower reagent cost, a lower equipment cost, and possibly a somewhat smaller footprint of the equipment. Compared to integrated platforms, the infrastructure requirements are similar, and their use requires more hands on time of highly skilled technicians.

OPP-ERA project supported implementing partners in Burundi, Cameroon, Ivory Coast and Guinea by creating or supporting the realization of the conditions for the deployment of the OPPs, and then with increasing access to HIV viral load testing. Over 300 health professionals (clinicians, PSM experts, laboratory staff) were trained, the competence of 25 laboratory staff to do VLT on the OPP was certified, and from the start of the project in 2013 to mid-2019, over 230.000 VLTs were carried out, of which 150.000 during Phase II of the project. In the 14 laboratories in which the OPP-ERA project planned to support the installation of an OPP, 7 OPPs started during Phase I of the project, and four during Phase II (two in 2018 and two in 2019). In addition, two more labs were rehabilitated, equipped with an OPP, and prepared to start offering VLT using an OPP, but a last laboratory in which the project intended start an OPP was not opened. Through its technical assistance and investment in infrastructure, equipment and staff development, it contributed to the strengthening of the health system in the countries.

In each country, the project was carried out in close collaboration with the Ministries of Health and the National HIV/AIDS Programs, the HIV care units, the laboratories and partners from the civil society. This enabled the project to have considerable impact on the planning of access to VLT in Guinea and Burundi, and to successfully transition the ownership of the OPPs to national management at the end of the project.

In spite of its dependence on one reagent supplier, and the dependence of the OPPs on a highly qualified workforce, the project remained relevant in its target countries because OPPs continued to provide a significant share of the VLTs performed in each country, and because the OPP-ERA project ensured integration of the OPPs in their planning and funding landscape. We assessed the risk that the use of OPPs will cease in each of the countries, and concluded that in the short term that risk is very low in all four, and low in the medium term.

Coming to project performance, the OPP-ERA project shows mixed performance against its impact and outcome indicators. The “proportion of VLTs performed on OPP as compared to IPs” was high in Burundi and Guinea, and much lower in the two other countries. However, as no target was identified for this indicator, this does not allow direct assessment of project performance. The same is the case for the indicators reporting on the VLT service delivery cascade (proportions of people with detectable VL retested and proportion switched to alternative treatment regimens), for which mixed, but generally insufficient performance was reported.

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Given the goal of the project “to contribute to the scaled-up access to VLT in LMICs” and the project’s intent to show that “OPPs can significantly contribute to the scaled-up access to key HIV-related diagnostics in LMICs .../...” and “create a market for OPPs in LMICs”, we found it somewhat surprising to see that the log frame did not include indicators to assess the project’s market impact. The limited time available for the formulation of the project might have contributed, as at the end of Phase I there was an overriding concern to protect service delivery by the Phase I labs. Also, the original OPP-ERA project was designed and approved prior to 2013, when the initiators had much more latitude in defining the strategy of Unitaid funded projects. In 2013 Unitaid introduced a much more directive approach to grant making which guarantees that higher level impact is maximized.

The project performed well against several output indicators, but most noticeably against the indicator for laboratory QA: : it ensured consistent high quality performance when measured through external EQA programmes, and thus demonstrated a robust setup in supported laboratories. Performance against the other output indicators, which covered the increasing laboratory output and expansion of the number of laboratories operating OPPs was insufficient. The demonstration of the polyvalence of the OPPs was cancelled because of slow delivery and decreased need for the project to deliver the output, as Biocentric was reportedly doing parallel evaluations for DBS and EID (which at the end of 2019 had not been completed).

Considering implementation efficiency, Phase II of the project faced challenges in the start-up phase, when the coordinating team at Solthis was not fully constituted. This led to delays in the signature of agreement with the TA partners in countries, the consortium agreement and the convention with ANRS, and likely escalated through to the slow signature of conventions with the MOH in 3 countries and the absence of such a convention Cameroon (also explained by the national political situation). In addition, work plan and budget reviews took a long time. The resulting uncertainties about project implementation partly explain the slow opening of the Phase II labs, but delayed contributions from national counterparts and the security situation and time needed inform planning by Global Fund (in Burundi) also played a role. While the project planning was perceived too “top down” by one of the implementing partners and a national coordinator; the local teams have worked well with the national authorities, but might have neglected to formalize their collaborations with some implementing organizations. Fortunately, in balance, the technical collaborations with the local authorities and national stakeholders were good. As a result the transition of the project to national ownership was successful.

We noted that in Ivory Coast the project was unable to report on several log-frame indicators, as the laboratories refused to install the OPP-ERA project database. We suggest that future projects assess what data nationally owned data need to be accessed to enable grant reporting, negotiate access to such data, and strengthen the nationally operated system if needed, rather than demand that their data systems be installed and used by their local technical partners.

While the local teams have reached out and included civil society input in their planning and conducted some joint activities, their contracting of collaboration with civil society organizations was limited, as it did not have sufficient funding to support CS activities to the extent that they would be meaningful.

The procurement and supply management system of the OPP-ERA project was well-designed. The division of responsibilities between Paris and local PSM managers made sense for the project. However, detailed performance of the PSM system was difficult due to the lack of detailed key performance indicators. Additionally, there was no formal system of supplier relationship management. All countries experienced challenges in handling sub-zero commodities, but the OPP-ERA project managed this challenge through direct delivery to the operational laboratories, which we agree is preferable to delivery to a large general medical supply store for projects or commodities

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that have few final users and specific supply management requirements. The quantification and forecast strategy of annual quantification and quarterly review of usage and demand was strong, although, due to local capacity constraints, detailed operations differed in each country. Only one country, Ivory Coast, had sufficient capacity and data availability to use best practice tools such as FORLAB and Pipeline. The PSM transition arrangements in Côte d'Ivoire are robust, in Burundi sound, but reliant on UNDP the Global Fund PR, in Cameroon fragile, due to limited local facilities to handle sub-zero laboratory commodities. In Guinea they are highly fragile, due to weak local system capacity and problems in managing sub-zero laboratory commodities, but will be supported in the transition by Solthis.

Our economics assessment found the waste management tool informative and noted that it was appreciated by others in the field. The viral load costing tool would be useful for VLT costing, if its limitation to OPPs could be addressed and problems in the module calculating staff costs can be fixed. We found the market watch report useful, but consider that it would have been stronger if it had probed the manufacturers about their interest in the LMIC market, assessed the compatibility between different reagents and the equipment identified, and if it had also considered the demand side in the LMIC market, in particular the procurement behaviour of the Global Fund, as it would have offered the OPP-ERA project an opportunity to align itself with the Global Fund.

## RECOMMENDATIONS

### Recommendations relating to the market development goal of the project

**We recommend to Unitaid that the consideration for OPP models for VLT in LMIC not be explored further**, as OPPs have lost their relevance for increasing access to VLT and HIV-related diagnosis. The main buyers (Global Fund, PEPFAR), opinion leaders (ASLM, CHAI, WHO), and the WHO prequalification program are all coalescing around the concept that LMICs are best served by integrated polyvalent platforms, which could be located either in central labs or (near) POC. The demand for VLT that cannot be addressed by real-time PCR platforms, is shifting to POC platforms, which by design are integrated. The reasons for their preference include that those platforms became more affordable after 2015, and allow consolidation of all procurement with a single vendor. The latter makes reagent lease contracts possible, and shifts major parts of the risk of operating VLT to the suppliers. In addition, the technology offered by the suppliers of integrated platforms (including POC systems) is polyvalent (i.e. can be used to diagnose other HIV-related conditions), most can be used with dried blot spots, and require less hands on time from qualified staff to operate.

However, if Unitaid wanted to explore the open platform further, it could consider using its convening power to brief the manufacturers of PCR reagents and equipment identified by the OPP-ERA project about the LMIC market prospects. We make this recommendation because, possibly executed in collaboration with the Global Fund, it would be a low cost venture, increase the visibility of Unitaid's investment, and might motivate one or more of them to start developing competitive offers for the LMIC market. The OPP-ERA project identified the manufacturers, but did not inform manufacturers of the evolution of the LMIC market and its entry requirements.

**We recommend to manufacturers** interested in the VLT market in LMICs should be prepared to

- offer competitive all-in reagent lease contracts,
- seek WHO prequalification for their integrated suites of equipment and reagents,
- ensure the compatibility of their systems with sample collection on DBS-type of samples,
- offer equipment that is minimally dependent on highly qualified lab personnel,
- ensure that their systems are able to diagnose or manage HIV-related morbidities and morbidities of particular concern in LMICs (including HCV, HBV, and TB).

Considering the importance of assessing the full cost of ownership of VLT platforms, and that the OPP-ERA project developed a useful model to assess it, **we recommend that Solthis** or the authors of the viral load costing model include the possibility to assess the cost of alternative VLT techniques, review the human resource module, and continue publicizing it.

### General recommendations

As the OPP-ERA project was not grounded in an in depth market analysis, realistic and flexible targets could not be set at its start, and challenges (like infrastructure problems and demand creation) encountered during its implementation were insufficiently anticipated and budgeted for. To avoid this situation in future project we recommend that projects aiming to effect major changes in market behaviour be grounded in an in-depth market analysis, including identification of implementation bottlenecks and demand side constraints likely to influence its impact. Such projects should include or ensure that specific demand creation plans be in place, ideally developed with local organizations.

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This would limit the impact of problems encountered in the OPP-ERA project, in which the need to deal with infrastructure problems and demand creation was insufficiently anticipated.

Because the experience of the OPP-ERA project demonstrated the superiority of direct delivery to point of use of reagents that needed to be kept at -30 C, which the central medical stores in the countries could not ensure, we recommend that projects or programs with a limited number of final destination delivery points, e.g. public health laboratories or referral hospitals, direct delivery to point of use, instead of delivery to a central warehouse, in particular where products require special handling which may not be appreciated in a large centralised multi-product store.

As the OPP-ERA project suffered delay at the start of Phase II, when the coordination team had critical staff shortages, we recommend that, when projects are extended or have a change in management arrangements during their implementation, the grantees should ensure that the necessary staff is/remains in place (or is made available on loan) to keep the project running without interruption.

We recommended that projects involving, beyond national authorities, also local technical partners, involve those local technical partners also in project development, and that their role in the project be agreed in writing at the start of the project. This will improve collaboration and avoid frictions, such as those identified with one of the local technical partners in Ivory Coast.

For projects in which significant procurement challenges are anticipated, or with major allocations for procurement and supply management, we recommend that PSM KPIs be defined during project start up, and reported on at least annually.

Either during grant design, or during project initiation, grantees should assess whether national health system is capable to provide the necessary data and reports to enable quantification and ordering of supplies, and more generally support reporting on the grant, negotiating access to the data as needed. When this is not the case, they should undertake data system strengthening efforts in collaboration with their national counterparts to complement (rather than replace) existing data systems.

## REFERENCES

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## ANNEX 1: Evolution of the price of VLT reagents in the PQR of the Global Fund

The table below shows, in part A, average prices of individual HIV-1 RNA amplification and extraction reagents reported in the Price & Quality Reporting (PQR) of the Global Fund as of 4 November 2019, and prices for Biocentric reagents and extraction reagents (for Diasorin Arrow extractor) from OPP-ERA progress reports. Both types of reagents are needed for real-time PCR systems, but Cepheid's POC technology has both included in its cassette, and the Cavid Exavir test does not need amplification or extraction reagents, as it is not based on PCR. Therefore, their prices are not shown in the first part of the table. Part B shows the sum of the cost of amplification and extraction reagents from different manufacturers of PCR platforms, the price of the Cepheid VLT cassette, and the price of the Cavid Exavir reagents.

Because of reporting delays in PQR (1.5 to 2 years), some information on 2015 prices might have been in the public domain in 2016, when Phase II of the OPP-ERA project started. Until then, the reagents supplied by Biocentric were less expensive than those of other manufacturers, but in 2016 the reagent cost of Roche and Cepheid was less, and in 2017 Roche's were less expensive than Biocentric's. In 2018, Biocentric became the least expensive reagent supplier again, but the cost difference with other suppliers was small.

Year	2014	2015	2016	2017	2018	2019
<b>A) Individual reagents</b>						
Abbott RT HIV-1 (m2000sp)	29.32	22.99	20.98	20.13	16.46	16.46
Abbott mSample Preparation system RNA (4x24 preps)[04J70-24]	6.02	5.12	5.12	5.12	5.12	5.12
Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 test quantitative and COBAS TaqMan HIV-1 test, V 2	34.63	18.1	11	10.99	11.08	11.08
Roche High Pure System Viral Nucleic Acid Kit – 03502295-001-48T	NA	3.74	3.74	3.74	3.74	3.74
Biomerieux Nuclisens EasyQ HIV-1 V2.0 test kit	31.75	13.86	18.37	15.79	16.39	10
Biomerieux Easy Mag Magnetic Silica 384 extractions [280133]	5.45	4.22	4.22	4.22	4.22	4.22
Biocentric Generic HIV Charge Virale	9.87	9.87	NSR	8.55	8.48	8.59
Extraction reagents (Diasorin Arrow extractor, to use with Biocentric kit) *	6.12	6.12	NSR	NSR	6.12	3.30
<b>B) Complete set of reagents (extractor + amplification for PCR systems, cassettes for Cepheid, test kit for Cavid)</b>						
Abbott	35.34	28.11	26.10	25.25	21.58	21.58
Roche	NA	22.84	14.74	14.73	14.82	14.82
CEPHEID Xpert HIV-1 Viral Load	NA	16.80	16.80	16.80	17.69	17.16
Biomerieux	37.20	28.08	22.59	20.01	20.61	14.22
Cavida Exavir Load V3	18.63	19	12	12	12	12
<b>Biocentric</b>	<b>15.99</b>	<b>15.99</b>	<b>16.84</b>	<b>15.20</b>	<b>14.60</b>	<b>11.89</b>

Legend: In part A of the table, prices in orange are prices carried forward from the previous year, and prices in green are prices carried backwards from later procurement. Totals (in part B of the table) including such prices are in italics. NSR = not separately reported.