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Accelerating Access to Innovative Point-of-Care HIV Diagnostics

Lessons learned from UNICEF

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Acronyms List

ACRONYM	MEANING
ART	antiretroviral therapy
ARV	antiretroviral (drugs)
ASLM	African Society for Laboratory Medicine
CHAI	Clinton Health Access Initiative
CSO	civil society organization
CO	country office
COP	Country Operational Plan
DBS	dried blood spot
DNO	diagnostics network optimization
DRC	Democratic Republic of the Congo
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
EID	early infant diagnosis
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
M&E	monitoring and evaluation
MoH	Ministry of Health
MoU	memorandum of understanding
PEPFAR	United States President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother-to-child transmission
POC	point-of-care
RO	regional office
TWG	technical working group
UAV	unmanned aerial vehicle
UCPOC Project	UNICEF-CHAI Point-of-Care Project
UN	United Nations
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

1. Introduction

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Without antiretroviral therapy (ART), up to 50 per cent of children living with HIV die by their second birthday, with a peak mortality at two to three months of age[1]. The urgent need for them to start treatment as soon as possible is a main reason that the World Health Organization (WHO) recommends that all HIV-exposed infants be tested before two months of age[2]. However, although a decade of investments in conventional laboratory networks has expanded access to HIV early infant diagnosis (EID), huge gaps remain. In 2019, only 60.3 per cent of 1.21 million HIV-exposed infants globally were tested within two months of birth. In that year alone, lack of early diagnosis delayed or prevented access to treatment for at least 480,000 HIV-positive infants, leaving them at a greater risk of death.

Ensuring access to EID is a logistical, programmatic and systems challenge in much of the world. Point-of-care (POC) HIV EID is an innovative technology that is proved to be a game changer in global efforts to address these challenges and end paediatric AIDS. It offers a more convenient and accessible testing option that allows for rapid return of HIV test results to caregivers and timely initiation of ART and care for the youngest and most vulnerable children[3].

Efforts to introduce and scale up POC HIV EID include the Unitaid funded UNICEF-CHAI Point-of-Care Project (UCPOC Project) implemented over the last seven years (2013–2020) in sub-Saharan Africa. The Clinton Health Access Initiative (CHAI), the African Society for Laboratory Medicine (ASLM)

and the United Nations Children's Fund (UNICEF) are joint partners in implementation efforts in 10 countries (Cameroon, Democratic Republic of the Congo [DRC], Ethiopia, Kenya, Malawi, Mozambique, Senegal, Uganda, United Republic of Tanzania, Zimbabwe). The Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) is a partner with those institutions in four of the countries (Cameroon, Kenya, Mozambique, Zimbabwe) and also implemented in five others (Côte d'Ivoire, Eswatini, Lesotho, Rwanda, Zambia).

Based on work to date in the countries, this document is intended to provide some useful knowledge and recommendations for countries to consider when implementing, introducing, and scaling up POC diagnostics. It is based on input from UNICEF project focal points in country offices involved in the UCPOC Project (Annex 1), who identified and reflected on lessons learned based on their experiences during project implementation. The aim of this document was to capture reasons for success, identify where improvement is needed, and indicate which interventions and ideas did not work. A detailed set of questions (Annex 3 and Annex 4) was used to guide discussions. For context, the latest relevant HIV response statistics for each country are presented in Annex 2.

[1] Newell ML, Coovadia H, Cortina-Borja M, et al. 2004. Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. Lancet. 364: 1236–1243.
[2] https://data.unicef.org/resources/hiv-estimates-for-children-dashboard/
[3] https://www.childrenandaids.org/poc-toolkit-page

Due to the diversity of experiences, this is not a prescriptive, one-size-fits-all document. Not all lessons will be relevant to every country, but the depth and richness of the compilation make it likely that useful recommendations and observations for each country are included. UCPOC Project stakeholders and others engaged in this work in different countries will determine which recommendations might be followed and how.

It is important to point out that this document avoids duplicating information and is meant to complement resources previously published under the UCPOC Project. Key lessons up to 2017 are compiled in the 'Key Considerations for Introducing New HIV Point-of-Care Diagnostic Technologies in National Health Systems'[4], and information up to 2019 is presented in EGPAF's 'Lessons Learned from Integrating Point-of-Care testing Technologies for Early Infant Diagnosis of HIV into National Diagnostic Networks'[5]. The lessons presented here build on these two resources by adding UNICEF's experience and perspective up to September 2020 (Figure 1). Readers are encouraged to use this entire set of three complementary resources for a comprehensive, multi-faceted perspective on the challenges, alternative strategies, and lessons learned in the course of integrating POC diagnostics in national health systems.
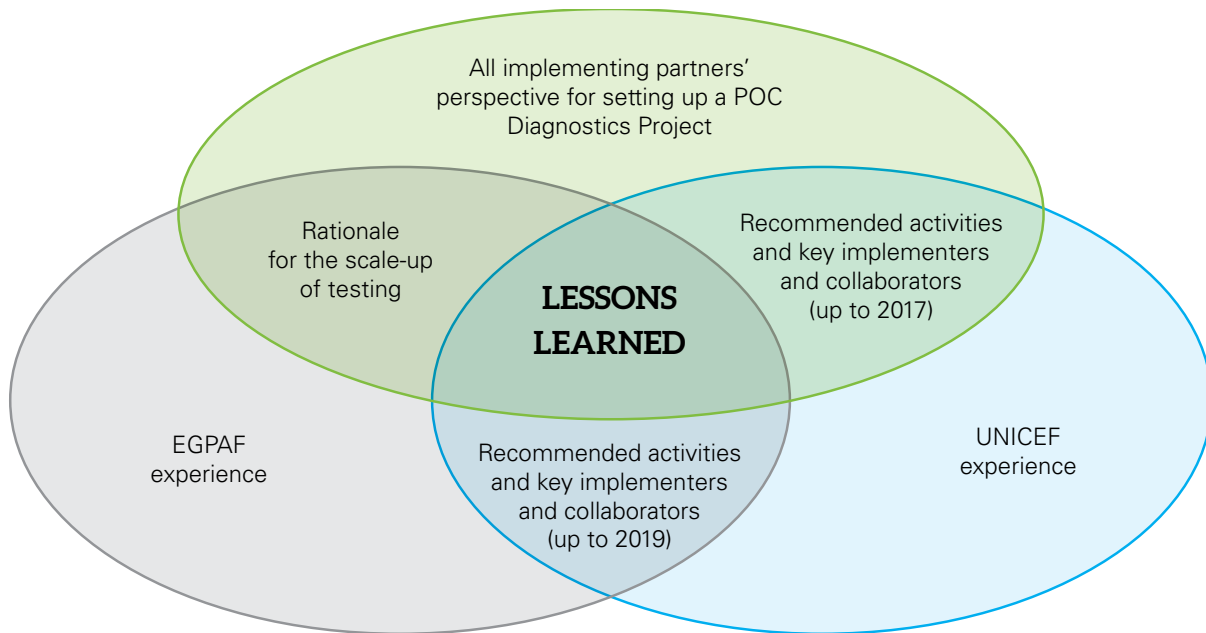
Figure 1: The diagram shows the scope of lessons learned and recommendations compiled in three resources produced under the UCPOC Project through December 2020. The circles highlight unique contributions and intersections identify converging topics.

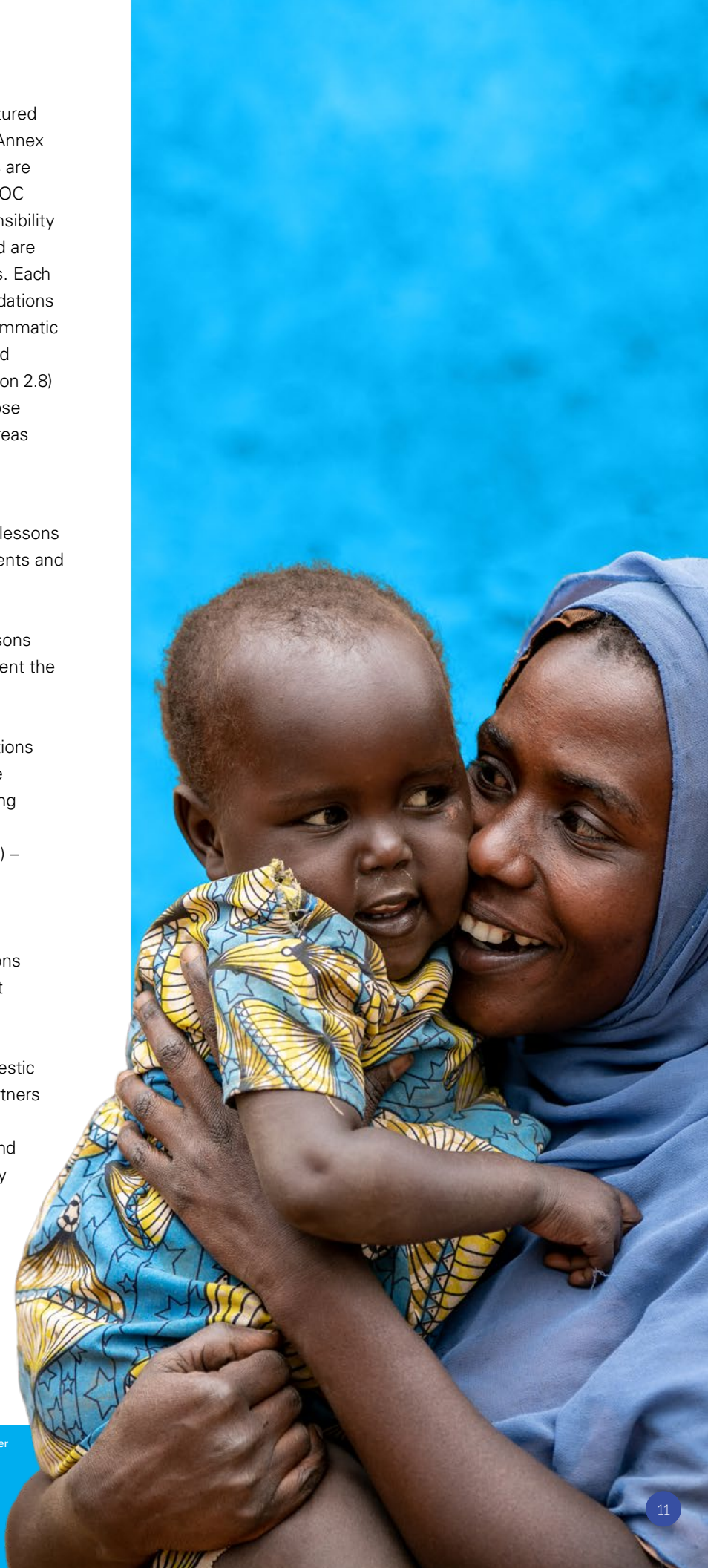© UNICEF/Uganda/2017/Schermbrucker © UNICEF/Uganda/2017/Schermbrucker © UNICEF/Uganda/2017/Schermbrucker

The input-gathering process consisted of semi-structured interviews with a total of 19 UNICEF professionals (Annex 1 lists the names of all who participated). The results are organized under seven key areas of work in the UCPOC Project in which UNICEF had varying levels of responsibility and oversight. A total of 24 individual lessons learned are presented in this document, within these work areas. Each lesson learned includes suggestions and recommendations grouped in two areas: observations regarding programmatic considerations, and additional 'tips' for individuals and organizations involved. The final part of the input (Section 2.8) includes quotes that provide personal insights by those directly involved in implementation. The seven key areas of work (Sections 2.1 through 2.7) are the following:

2.1 Leadership commitment and support – lessons about what was needed from governments and high-level management

2.2 Laboratories and the supply chain – lessons about key elements required to implement the UCPOC Project

2.3 Engagement with civil society organizations (CSOs) – lessons about how to increase awareness and create demand for testing

2.4 Diagnostics network optimization (DNO) – lessons about the DNO process

2.5 Innovation – lessons about novel solutions when implementing the UCPOC Project

2.6 Transition to national governments (domestic funding) and other long-term funding partners (e.g., the Global Fund to Fight AIDS, Tuberculosis and Malaria [Global Fund] and the United States President's Emergency Plan for AIDS Relief [PEPFAR]) – lessons about what worked when trying to sustain momentum for investment

2.7 Grant design and management – lessons about the UCPOC Project design and management

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2. Lessons Learned

"Focus on teamwork – UNICEF can only successfully implement a POC diagnostics project with strong relationships and efficient partnership with the MoH, other implementers, and the civil society."

■ *Hafsa Khalfani (United Republic of Tanzania)*

2.1 Leadership commitment and support

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LESSON

Integration of diagnostics with other disease programmes – support from government leadership is essential for scaling up POC diagnostics, sustaining services (especially when funding priorities change), and supporting market shaping

Programmatic considerations

- Analyse the cost-benefit of diagnostics integration of different diseases (in multiplex devices) as early as possible.

- Report on the effect of the inclusion of several tests, which should not overwhelm equipment capacity.

- Enable coordination discussions at the MoH level to establish roles for the different programmes and to collaborate in the creation of an integrated roll out plan together, considering, at minimum: human resources, supply chain, biosafety issues, waste management, staff training, the mode of cost-sharing, and the ownership of the equipment so that servicing and repairs are not affected.

Observations/analysis

- Importantly, by gathering stakeholders of different disease programmes, the voice of the government when discussing terms and conditions with manufacturers (response time, service maintenance networks and surcharges, warranties and replacements) is strengthened.

- Diagnostics integration can also facilitate the path for countries to reach volume guarantees, which are helpful tools to guide market development and price-point negotiations.

Additional tips and comments

- The idea is to create a POC diagnostics team, and not just restrict efforts to one disease or another. Initial friction among different disease programmes at the MoH can be expected, and therefore communication will be key. Make sure to start the conversation by showing the obvious and potential cost savings that diagnostics integration can cause as well as efficiency and effectiveness gains (e.g., it will eventually allow even more tests to be done for each disease, which will mean more rapid reach of national targets for more programmes). Moreover, diagnostics integration is a patient-centred approach, which is a relevant aspect to be highlighted.

- Plan pilot projects of diagnostics integration among programmes that are already open for the collaboration first and leave programmes that need more convincing for later. Keep leadership informed of the results at all stages, to facilitate their lending of support to a broader POC diagnostics agenda, when needed.

- During pilot projects, somewhat informal but quick ways of connecting (e.g., WhatsApp groups with members of the MoH, of technical working groups [TWGs], and focal points) were found to be helpful to address most issues (e.g., support with devices, supply, storage, etc.) in a timely manner.

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LESSON

With support from high-level management of laboratories and clinics, the involvement of all staff (laboratory technicians, medical staff, nurses, and counsellors) must be guaranteed during supervision meetings, inspections, and POC Diagnostics Annual Reviews

Programmatic considerations

- Enable ongoing coordination discussions at the higher management level of laboratories and clinics aimed at establishing clear roles for the staff, agreeing on a calendar of supervision meetings and inspections, and highlighting what is expected from the staff during these visits (quality assurance, sample referral, waste management, report on availability of tests and breaks of service, patient-centred care, and demand creation).

- To ensure that problems and solutions are discussed yearly, advocate for the organization of annual POC diagnostics review workshops, led by the government, where all staff is invited and not only high-level management from regional and district coordinators of laboratories and clinics.

Additional tips and comments

- Tension can be expected between the end users of the devices (they know the technology) and the clinic staff, but for project success, all professionals should work together. Make sure to start the conversation addressing their biggest pain points, from both sides (e.g., by clarifying reasons for sample rejection and defining mechanisms to inform clinics when devices are broken, or when supplies are running low).

- Keep leadership informed of the results of supervision meetings and inspections to facilitate early action if problems arise and to avoid them escalating unnecessarily.

LESSON

Engagement with high-level leadership, partners and representatives of other sectors strengthens a multi-disciplinary approach to POC diagnostics

Programmatic considerations

• Organize a national-level conference/workshop to bring awareness, present results, and unite multiple senior level leaders, partners, and representatives of other sectors around POC diagnostics. The theme could be, for example, 'Paediatric treatment and care', and a variety of stakeholders can be invited:

from health programmes (HIV/PMTCT, diagnostics departments of other diseases), health workers, and the laboratory community to directly present the plan and results of the implementation and scale-up of POC diagnostics in the country;

from civil society and community-based organizations, which are critical to create and sustain demand;

from other key government agencies such as the education and welfare ministries, to open space to discussions on combating stigma and improving access to other health services, which are vital components of efforts to support the work led by communities;

from researchers and academia, who can share their latest work and technological advancement in the POC diagnostics space; and,

from regional and global offices and partners who can share experiences in other regions and at global level.

Additional tips and comments

• Engage with headquarters and the regional office for their support and participation, and to invite the participation of other partners when relevant – they can all present experience from other countries in the region and global perspective of POC diagnostics. Importantly, make sure to invite representatives from supply divisions as well, to enrich the discussions with market shaping points of view as well, and not just a programmatic lens.Keep leadership informed of the results of supervision meetings and inspections to facilitate early action if problems arise and to avoid them escalating unnecessarily.

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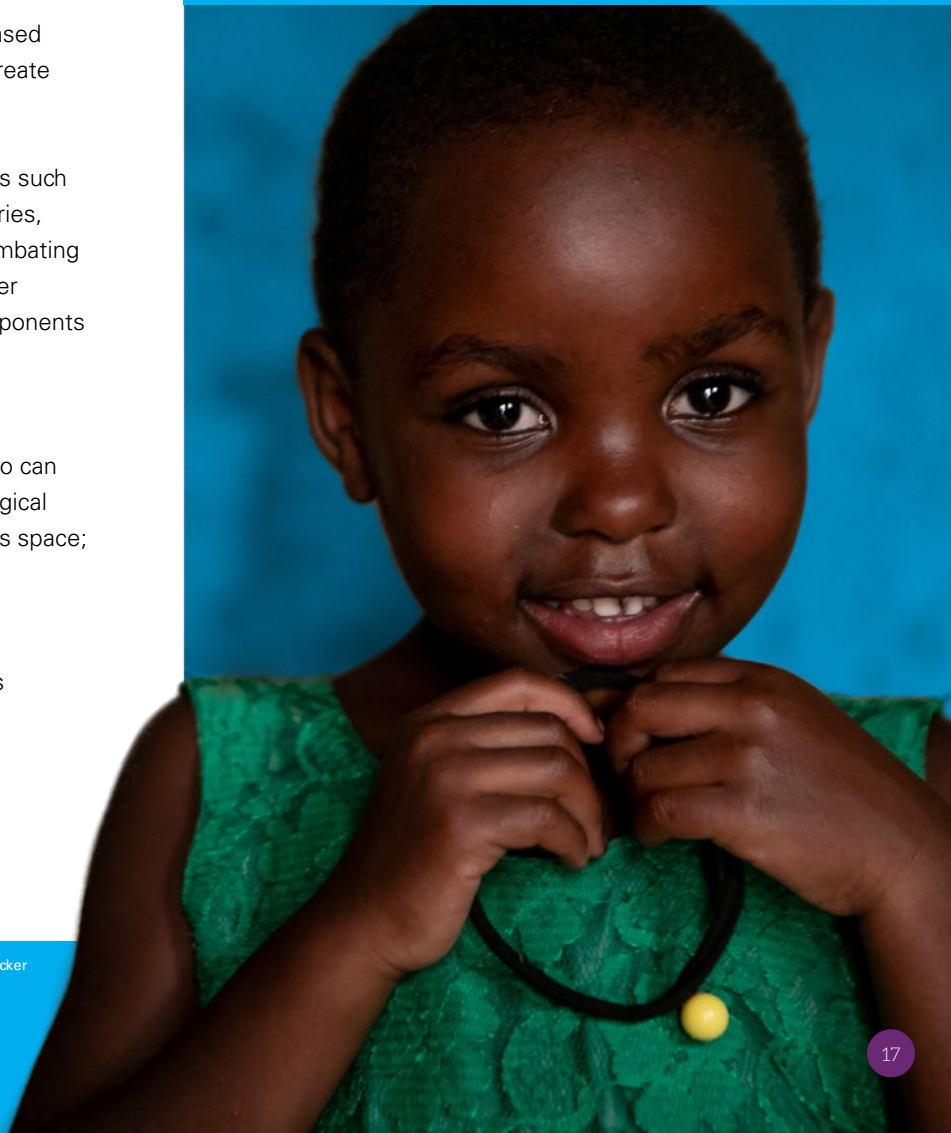
LESSON

Policy advocates/political sponsors involvement is useful to improve service in areas/counties/sites that do not present high burdens of HIV but are being left behind

Observation/analysis

- Improved services in all places and contexts is a useful strategy to contribute to and strengthen the national response to HIV/AIDS. It also brings political clout to the entire POC diagnostics project because new subnational stakeholders are involved, and they become allies. They then can support the project with additional funding as well as other kinds of support that can help facilitate more rapid achievement of national goals and targets.

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Additional tips and comments

- Identify policy advocates/political sponsors who will champion the cause and become active partners in reminding stakeholders of the urgency of and need for HIV EID (and, by comparison, the flattened performance for conventional systems). These 'champions' can help sustain momentum for investment and bring issues related to POC diagnostics to the attention of higher-level leadership. These sponsors (e.g., first ladies, religious leaders, media celebrities) can be crucial for effective lobbying for the creation and expansion of POC diagnostics projects with full government support. However, note that this type of sponsorship can work in some cases but not in all, as it may become 'too political'. So, if that is the situation, trust that there is enough scientific evidence to convince public health officials to adopt innovative POC diagnostics policy without the need for recourse to political support outside the health sector. In these cases, focus on evidence-based policy development to not only introduce POC diagnostics in high burden areas, but also to scale up in remote areas where clients will benefit from a stronger health system

"Work closely with the MoH and learn as much as you can about laboratory issues, use your public health experience to guide you while you dive in a new area of work – it will be challenging, but worth it!"

■ *Tonderayi Clive Murimwa (Zimbabwe)*

2.2 Laboratories and the supply chain

LESSON

When analysing potential bottlenecks, it is vital to understand all pre-requirements of regulatory approvals for medical devices and the introduction of new technologies to the country

Programmatic considerations

- Plan for the time needed to review the country's relevant regulatory policies and expectations and to address their demands and requirements. This period should not be underestimated, and milestones of the approval process should be followed-up diligently.

- Pre-emptively discuss and explore options in case evaluations take too long, considering the urgency to implement POC diagnostics technologies and increase access to tests.

Additional tips and comments

- One possible argument that can be presented early on to the authorities is that POC diagnostics evidence is well published and reviewed in many different countries. It can be argued not only that ample scientific data exists, but also that POC diagnostic technology is recommended and pre-qualified by the WHO[6].

- The letter of agreement between UNICEF, other partners and the MoH can be useful in facilitating a project aiming to implement a new technology. The recognition of UNICEF's expertise by the government helps the authorities accept new implementing partners.

- Keep updated about the country's regulations on introducing technological innovations because the field is a dynamic space and standard operating procedures (SOPs) can change from one year to the next.

LESSON

Sample referral networks of conventional systems can be leveraged to also support and transport samples to be used in POC diagnostics devices at no additional cost

Observation/analysis

- Once POC diagnostics is implemented, certain hub-and-spoke distribution models currently set up to an existing sample referral network for the conventional system can also support POC diagnostics services. Whether as a result of a strategical decision or an as-needed basis, conventional sites can collect samples to be processed in facilities/laboratories with POC diagnostics devices, and vice versa.

- A simple training of transporters about a new mode of transportation of samples (for whole blood and not just DBS) can be added to the sample referral network to optimize distribution of samples among facilities/ laboratories of both systems.

Additional tips and comments

- The use of the existing sample referral network allows for a no-cost solution when conventional systems are overwhelmed and/or when devices break or need maintenance or when supply of commodities fail.

- Make it clear that the purpose of any new mode of transportation of samples is to guarantee backup services are available as soon as they are needed and emphasize that training about these modes is a requirement.

[6] https://www.who.int/hiv/pub/vct/hiv-molecular-diagnostic/en/

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LESSON

Participation in all government-led HIV commodities meetings, since the start of a POC diagnostics project, is important to understand the country's supply system in detail and to become an active voice for supporting the development of the POC diagnostics space in the country

Programmatic considerations

- Incorporate POC diagnostics commodities into the National Forecasting Supply Plan as early as possible, making sure there is continued advocacy during HIV commodities meetings held by the government.

- In addition, develop assumptions for the forecasting exercise gradually -- starting small and increasing the proportion of funds for POC diagnostics commodities as the project reaches relevant milestones.

- Regardless of whether electronic systems are in place to centralize and facilitate ordering of supplies from clinics, regularly present the compiled data about commodities usage during the HIV commodities meetings to inform about the assumptions of the forecasting and adjust as needed.

Additional tips and comments

- Discuss and get approval for procurement volumes with headquarters, regional office representatives and the funding agency to avoid any unnecessary changes to the orders, which can cause delays. Moreover, discuss timelines with relevant supply officers in the country to make sure you have the information you need to correctly manage expectations with the government.

- Start participating during HIV commodities meetings held by the government even before a POC diagnostics project starts implementation. This could include having the focal point from the project listen to the current issues and learning how best they can introduce and advocate for POC diagnostics requirements.

- Learn from the POC diagnostics project's results and adjust commodities percentages accordingly: which devices are in higher demand, where the demand is higher, which reagents are used more first, etc. These results will inform a better forecasting and avoid supply becoming a bottleneck for the POC diagnostics services.

- Run the assumptions and forecasting plans with the regional and district coordinators from laboratories and clinics, to get their insights before the government approves the annual plan. This is a useful step to avoid creating a solely vertical system, and instead building a participatory process that will guarantee better service delivery from the POC diagnostics space.

- Advocate for these forecasting meetings to happen at least twice a year in the first five years of a POC diagnostics project led by the MoH. This can help to stabilize the new activities and the inclusion of the new services in the national plans.

POC diagnostics sustainability relies on sufficient dedicated capacity within the MoH to coordinate the supply chain for laboratories as a whole

Programmatic considerations

- Anchor POC diagnostics within the government because the intervention will not work alone in the long term, as it is part of a broader laboratory context.

- Avoid supporting only what is needed for the project's life and/or focusing only on a narrow part of the supply chain.

Observations/analysis

- To guarantee longevity of the new services from POC diagnostics, broad laboratory capacity at the MoH must be created or expanded. A dedicated unit that will guarantee sustainability of these services is ideal.

- In-country focal points can support workshops and training of trainers (ToTs) to include POC diagnostics supply chain training of diagnostics staff within the MoH.

Additional tips and comments

- All aspects of the supply chain should be addressed by a dedicated and independent unit for diagnostics at the MoH, including in terms of distribution mechanisms and schedules, warehousing, stocking, training, and waste management. Usually, the MoH has a supply chain system for medicine/vaccines, but the supply chain needed for POC diagnostics is not the same thing. The tip here is to make sure that specificities of POC diagnostics are addressed properly and because it is a new area, the training of staff who will be involved in the supply chain of POC diagnostics must be emphasized - even when there are teams of experienced staff of conventional diagnostics systems, they should also be trained.

- The Global Fund has experience and can provide help to expand medicine supply chain training to incorporate POC diagnostics needs.

LESSON

Capacity building of health care workers by training and mentorship is a critical component for the implementation and success of a POC diagnostics project, but it is even better when it is done in a targeted fashion

Observations/analysis

- The general objective of training and mentorship of health care workers is to improve the ability of operators to perform high-quality testing, since it is not just about shorter turnaround time but also accurate and consistent results. However, POC diagnostics' training should not be offered as a blanket-type training that is relevant for all health care workers. The quality assurance scheme should also offer targeted training that takes into consideration the specific communities that workers serve (e.g., mothers, adolescents, etc.), their local leadership engagement, and any specific challenge they face in their facility/laboratory to render better results.

Additional tips and comments

- To counteract high rates of equipment errors, contact vendors of the POC diagnostics devices and check the possibility of having yearly end-user training, certification and competency testing to consistently enhance the quality assurance of POC diagnostics services.

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LESSON

POC HIV EID decentralization is a patient-centred approach and can become a true 'one-stop model'

Observations/analysis

- The POC diagnostics project at the MoH level does not only need to be led by a laboratories department; instead it could be operated collaboratively with the PMTCT programme. In this joint model, deployment of the devices is done to clinics instead of laboratories, and nurses become the operators instead of laboratory technicians.

- When selecting which POC diagnostic devices to use, long-term cost and operational efficiencies are important considerations. (For example, certain platforms do not require cold chain or waste incineration.)

- Adjustments in forecasting are needed if POC diagnostics take over testing demands from the conventional system. This could include adjusting conventional volumes, specimen collection, referral mechanisms, processing or return of results, and adjusting dried blood spot (DBS) kit procurement and distribution.

Additional tips and comments

- Perform tactical mapping exercises as early as possible in order to add strategic sites to the national plans to increase specificity for continuous funding, supply forecasting, and for reaching national targets. Subnational governments connected with the sites are relevant stakeholders and should be involved as early as possible.

- This decentralization model is a change in mindset, from the 'laboratory system' mentality to a 'closer to patients' one. In this context, after MoH buy-in is guaranteed, most of the work is focused at subnational leadership level to finalize plans and ensure decentralized operationalization.

- Connection to a previous, related project could be useful in many ways. For the supply chain, if there has been a prior POC CD4 integration into national distribution systems, the experience may pave the way for POC HIV EID and significantly decrease challenges.

"Engage more with all the stakeholders who surround the implementation of POC diagnostics, especially with policy makers, implementers on the ground, and the people who directly benefit from these services, to make sure you leave no one behind!"

■ *Aaron Mdolo (Malawi)*

2.3 Engagement with civil society organizations (CSOs)

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LESSON

Involvement of CSOs in all stages of a POC diagnostics project development and its execution secures community leaders' inputs not only during implementation, but is also important for advocacy with the government, establishing robust monitoring services, and sustaining demand

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Programmatic considerations

- Invite CSOs to local, subnational, and national discussions to receive their inputs on plans and strategies related to the POC diagnostics technologies' implementation and scale-up in the country.

Additional tips and comments

- Begin engaging with and involving civil society representatives at the beginning with a big picture approach. Tools to develop literacy and materials for engagement are available[8] and can be useful when working with CSOs and POC diagnostics advocacy.

- Demand generation is critical to create an economy of scale and leverage market-reshaping discussions, which can cause drops in prices to better, and more competitive levels. Volume guarantees with manufacturers, which are helpful tools to guide market development and price-point negotiations, often result when communities are involved and guarantee demand for these devices and services. However, the work with CSOs must be done carefully, to avoid any hint that project partners are promoting any kind of device. Prioritization of funding and programmatic work to involve CSOs and create mechanisms to sustain the POC diagnostics market must occur with the right device, where there is a gap in diagnostics services, and where the intervention is well-placed to address the real needs from the beneficiaries.

Observations/analysis

CSO's involvement is particularly important for several reasons:

- One is that they are often good at nudging governments to appreciate and go beyond simple and direct cost-effectiveness analysis, including by emphasizing other relevant considerations about clinical impact and turnaround time of POC diagnostics.

- Another reason is that they play a vital role in the sustainability of a POC diagnostics project led by the MoH because they can create and sustain demand. A lack of community engagement is often correlated with an increase in the rate of idle devices.

- A third reason is that although they are not technical, CSOs can provide insights to solve bottlenecks imposed by stigma, communication, and new approaches (frugal innovations[7]) to increase efficiencies of HIV/AIDS and Health programmes in general and help with reaching national targets of the HIV epidemic response, faster. As part of their valuable contribution, CSOs bring beneficiary perspectives from some of the harder-to-reach and more marginalized sub-populations (e.g., adolescents) within the broader target group of pregnant and lactating women.

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[7] https://www.unicef.org/innovation/stories/frugal-innovation-what-we-have-learned

[8] Strategic Framework "No Time to Wait": http://childrenandaids.org/sites/default/files/2021-03/Strategic-Framework_No_Time_to_Wait.pdf
Advocates FAQ: http://childrenandaids.org/sites/default/files/2021-03/NO%20TIME%20TO%20WAIT%20-%20FAQ%20Fact%20Sheet%20.pdf
Caregivers FAQ: http://childrenandaids.org/sites/default/files/2021-03/Caregivers-FAQ-No-Time-to-Wait.pdf
Job Aid for Peer Supporters: http://childrenandaids.org/sites/default/files/2021-03/Job_Aid_Fact_Sheet_No_Time_To_Wait.pdf
Guidance for Policymakers: http://childrenandaids.org/sites/default/files/2021-03/Policymakers-Fact-No_Time_to_Wait.pdf
Caregivers Poster: http://childrenandaids.org/sites/default/files/2021-03/Poster_Caregivers_No_Time_to_Wait.pdf

LESSON

Building trust with CSOs and strengthening their role in the POC diagnostics space to support monitoring of commodities security and service reliability can greatly improve the effectiveness and uptake of services

Programmatic considerations

- Make sure to have backup services in place when devices break or need maintenance and when supply of commodities fail. Backup plans must be prioritized in hard-to-reach and poorly serviced areas, such as those prone to power outages (or lack electricity at all) and demand greater effort from pregnant women and mothers to reach the facilities (e.g., long distances). These backup plans should be presented to CSOs.

- Clearly and consistently support CSO's having a role in evaluating MoH-led POC diagnostics projects.

Additional tips and comments

- Create a communication 'bridge' between CSOs and the facilities/laboratories that service them. This can help to ensure that CSOs actively and constantly engage with facilities/laboratories and keep communities appraised of the status of services. CSOs can support the management of expectations of the community about POC diagnostics services by tracking service quality and availability in real time, supporting the delivery of results, and triggering backup plans when needed.

LESSON

The involvement of CSOs during the long-term funding transition process away from the POC diagnostics project's implementers by adding their voices to the request for support for POC diagnostics can be a critical factor in successful advocacy with donors

Programmatic considerations

- For Global Fund engagement: work closely with CSOs to raise the issue of POC diagnostics during the country dialogue processes or while the National Strategic Plan (NSP) is being developed; contact community representatives in the Global Fund Country Coordinating Mechanism (CCM) and get information about key dates for the country application to find out how to get involved; and consider reaching out specifically to people living with HIV (PLHIV) representatives on the CCM (usually there is at least one full member and one alternate member). These CCM members are often in the best strategic position to raise grassroots issues and are actively involved in developing country proposals to the Global Fund. In all of these engagements, a strategic approach would be to demand POC diagnostics for all HIV-exposed infants.

- For PEFAR engagement: work closely with CSOs to engage in the Country Operational Plan (COP) discussions in the country/region. If civil society representatives are unable to be involved directly, they can contact their local network or national umbrella organization and call for this issue to be raised during the COP meetings.

Additional tips and comments

- CSOs are likely to be valuable and influential supporters of efforts to transition funding to the government and other long-term funders. PEPFAR and/or the Global Fund can commit funding support for POC HIV EID during proposal development and the COP processes. Actively prepare advocates from CSOs in pre-meetings. A specific advocacy brief[9] has been developed and can be used as supporting material.

"You have to think of a project like this one using a systems approach. Focusing only on specific elements of the system will not be as fruitful as working on it holistically."

■ *Alex Costa (NYHQ)*

2.4 Diagnostics network optimization (DNO) process

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LESSON

The DNO process can be overwhelming but it can be simplified in a stepwise way. Instead of being an afterthought, it can inform or even lead the implementation of a POC diagnostics project and/or guide diagnostics integration

Programmatic considerations

- Assemble a dedicated TWG that will be able to look at the diagnostics services of a country holistically.

- At first, analyse the existing diagnostics landscape in the country pre-DNO and identify the main issues that the DNO process might focus on (e.g., testing coverage by area and by diseases, level of diagnostics integration, turnaround time of results, diagnostics services costs, % of idle devices if they are already available, diagnostics prioritization in the country so far, lack of a national and connected system) and make sure to highlight known challenges for each issue.

- The software for the DNO process should be chosen and consensus achieved on the objective to be reached (e.g., increase testing coverage, integrate tests, improve turnaround time of results, decrease costs, create/improve a national data system) to run adequate scenarios and identify which model outputs are of interest to compare across scenarios.

- Identify if there are enough data available to inform, build and select possible optimization scenarios. If data are needed, devise a process for completing data collection to run the model.

- After running the model and reaching consensus about the optimal network with key stakeholders, consider funding and operational resources available (human resources and infrastructure). At this point, if resources are needed, mobilization to acquire them should be planned and executed. With resources in place, the DNO plan is created according to the chosen scenario.

- Establish a timeline, clearly define stakeholders' roles, and specify how the implementation will be monitored.

- Lastly, analyse the post-DNO diagnostics landscape in the country and plan future rounds of the process.

Additional tips and comments

- DNO discussions can be initiated by bringing stakeholders together to add more than HIV prevalence/high burden areas to the reasoning behind implementation of POC diagnostics in the country. For instance, an area may not present high burden of HIV, but due to its remoteness, the rate of PMTCT identified mothers to the number of HIV EID tests is low.

- In general, device selection and where they should be best placed should be approached as a way to complement conventional diagnostics systems in the country. This means that TWGs should first be able to answer questions such as: how many samples can be processed daily by each system and device; what are the minimum requirements of energy inputs, connectivity and waste management; and what will be the minimum distance from conventional laboratories. The goal is not to have too many devices, but to have them strategically placed and optimized to strengthen the national health]system and improve HIV/AIDS response programmes.

LESSON

Strengthen the area of POC diagnostics data connectivity, monitoring and reporting as early as possible to enable and facilitate DNO in the country

Observations/analysis

- The project should plan for the improvement of network connectivity, and of the M&E framework, as early as possible. This is important to consider because data connectivity, monitoring and reporting are not always emphasized as significantly as they deserve to be. However, this area is crucial in all aspects of a POC diagnostics project – including to maintain political support; to make correct assumptions and supply forecasting; to present a strong case to long-term donors, partners, and civil society; and to optimize the diagnostics network.

- A training module dedicated to address the M&E system should be available and ministered together with the technical elements.

- Moreover, the sustainability of the M&E system after the project is over must also be addressed and incorporated into the MoH's POC diagnostics project.

Additional tips and comments

- Discuss access to the data produced and compiled from a POC diagnostics project early on because it is often a point of contention. Discussing data accessibility and formalizing an agreement among all partners can manage expectations and facilitate planning of activities. The work is strengthened and actions by all different areas expedited when a timeline for the system to be uploaded and data made available to all relevant partners is agreed on. Situations should be avoided in which only one partner or actor has control of all the data and/or does not follow agreed timelines to make them available to all.

- Evidence generation is a key action because sensible decisions come from having good evidence that also has been well analysed. Make sure to add sessions about data access, connectivity, monitoring, and evaluation to annual meetings at the MoH level.

- Request and encourage TWGs to reach out for information from other countries' experiences, including how they are dealing with data management and about the choices they have made so far in their POC diagnostics implementation experience. Stay updated about how they have been expanding their data access, connectivity, monitoring, and evaluation, because their decisions can inform how to improve over time as well (including by indicating which mistakes they may have made when pioneering a POC diagnostics project)[10].

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[10] For reference: UNICEF has POC Diagnostics experience under the UNICEF-CHAI Point-of-Care Project with EGPAF and ASLM in 10 countries (Cameroon, DRC, Ethiopia, Kenya, Malawi, Mozambique, Senegal, Uganda, United Republic of Tanzania, Zimbabwe) and in other 10 countries under the 'Expansion of POC HIV EID in WCA' Project (Burkina Faso, Cabo Verde, CAR, Chad, Congo, Equatorial Guinea, Gabon, Ghana, Mali, Nigeria); besides the first 10 countries listed, CHAI also has experience in South Africa, and EGPAF in five other countries (Côte d'Ivoire, Lesotho, Rwanda, Eswatini, Zambia).

"With innovation, there is disruption, and inevitably resistance from some partners and health authorities – it takes time and persistence to show results."

■ *Mireille Tribie (Mozambique)*

2.5 Innovations when implementing the UNICEF-CHAI Point-of-Care Project

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LESSON

Paving the way for the government to lead innovations in the country can be instrumental in keeping the most important stakeholder involved in the highly dynamic POC diagnostics space

Observations/analysis

- Independent regulatory bodies formed to evaluate innovations in the health sector can play vital roles in assessing things such as ethical considerations, level of risk to the population, and data-ownership issues. The need is especially great regarding POC diagnostics because technologies are rapidly developing, and innovations are constant.

- If an independent regulatory body of this sort does not exist or if there is resistance to establishing one, there are other ways to at least create a space for technical discussions to occur. Advocate for the creation of a MoH-led TWG for 'new technologies' to cover not only POC diagnostics, but also rapid testing kits and accurate at-home testing kits, mobile health applications to send test results, and even novelties for the conventional system. The TWG can play an important role not only in expediting decisions, but also in growing capacity, nurturing leadership from the government in the POC diagnostics space, and addressing ethical issues (an evolving term for members of this TWG is 'diagnostics champions'[11]). Such TWGs can support the government to balance the pressure coming from donors as well as other powerful external influences – in particular manufacturers trying to promote and sell their devices and new technologies. (These manufacturers should not have representation on the TWG.)

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Additional tips and comments

- Bring different stakeholders together (including expertise from future long-term donors when possible) and be open to include new ones, but the objective is to make the MoH the technical lead.

- The MoH should chair TWGs on new technologies and lead the technical reviews. To avoid the reality or appearance of decisions being made from a political standpoint, the TWG should at least try to register all verbal or written contributions that were made. Members should rotate to perform secretariat duties and keep detailed records of discussions.

- Whichever partner investigates a new platform or innovation, the TWG is the space where it should be shared, evaluated jointly, and supported offered the MoH to start testing it (or not) by comparing options of competing solutions and evaluating funding requirements/opportunities. Avoid promoting a 'preferred' device or manufacturer. The information should be presented in the most transparent way, which will allow governments to make their own decisions and enable the MoH to technically lead the POC diagnostics space.

- Advocate, when possible, for the countries to diversify their POC diagnostics devices portfolio (from different manufacturers). Considering that countries tend to standardize certain types of services, it is important to offer them counter arguments to this point: to not rely on a single manufacturer and risk the entire health programme of a country on the supply success of only one chain and be at the mercy of a sole manufacturer's pricing decisions.

- When possible, flag innovations with headquarters and regional offices to improve communication and sharing of insights about new technologies and ongoing pilots.

[11] https://aslm.org/

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LESSON

Access to POC diagnostics in difficult-to-reach areas can be solved by using drone technology (unmanned aerial vehicles, or UAVs)

Observations/analysis

- Piloting the use of UAVs technology can be an effective and efficient way to solve challenges with ensuring access to diagnostic services to a country's hardest to reach people. This option may be especially useful in countries with many remote areas or challenging terrain and geography (e.g., mountains, lakes, islands) or obstacles such as conflicts or civil unrest, natural disaster, or normal seasonal events (e.g., rainy seasons). UAVs can be a suitable solution in such contexts because of advantages related to speed, not being affected by most terrain barriers, and more limited reliance on human effort. These aspects are especially beneficial when delivery speed and reliability are important, such as the case of the POC diagnostics supply chain. These kinds of pilots, which couple innovations (POC diagnostics and UAVs technology), require specific funding and increase the complexity of the project, but they also can result in significant gains.To ensure that problems and solutions are discussed yearly, advocate for the organization of annual POC diagnostics review workshops, led by the government, where all staff is invited and not only high-level management from regional and district coordinators of laboratories and clinics.

Suggested Priority Actions

- Consider bringing specific talent to the planning and execution of a pilot and creating a dedicated TWG because this activity has specific challenges that are beyond POC diagnostics.

- Ensure that a supply chain assessment is undertaken. These assessments are necessary to identify and validate the appropriate solution and evaluate the costs in more detail.

- To help improve overall health outcomes for the hardest to reach, consider implementing a multiplex diagnostics device in the remote location or servicing it, enabling integration of different diseases diagnostics and strengthening of the health system beyond the scope of HIV.

Additional tips and comments

- Initially, knowledge of aerial logistics services and network will be needed. Recruit a consultant or company in this area of work to increase the chances of the pilot project being a success. If the results are promising, looking for local start-ups may increase the probability to expand the POC diagnostics services with the use of UAVs technology.

- The USAID Global Health Supply Chain Program – Procurement and Supply Management project (GHSC-PSM) recently conducted projects delivering vital life-saving health services to remote locations in Africa via the use of UAVs[12]. This is one potential source for experience and help in expanding the reach of POC diagnostics services using UAVs.

LESSON

Real-time online supervision of decentralized testing using POC diagnostics devices is crucial to guarantee high-quality of services

Observations/analysis

- A focus on developing and improving connectivity among sites means that a layer of operational support to ensure coverage and technical support to facilities will need to be added to the POC diagnostics project. Real-time online supervision of decentralized testing helps monitor and identify potential problems such as low stock, device malfunctions, unauthorized operators, and abnormally high error rates, etc. – and allows for timely intervention.

Additional tips and comments

- Equip and train stakeholders with a real-time online supervision tool as early as possible. This is necessary to avoid creating any delays in the workplan.

- Try to avoid engaging with new stakeholders (e.g., tool developer, implementer, trainer) during later stages of a POC diagnostics project (when possible), until its first round of completion. New stakeholders at such a late period usually means delays, and it is better to finish a first version and then consider other stakeholders if needed.

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2.6 Transition to national governments (domestic funding) and other long-term funding partners (e.g., the Global Fund, PEPFAR)

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LESSON

The involvement of government (at both national and subnational levels) and future funders must begin with project inception and last through all stages of development and execution of a POC diagnostics project

Programmatic considerations

- To ensure government ownership, support the integration of POC diagnostic technologies into national health sector strategic plans and national plans focused on eliminating mother-to-child transmission of HIV. Two objectives can be added in these plans: (1) to scale-up access to HIV EID and viral load testing, and (2) to scale up POC technologies themselves.

- Encourage and support the MoH to continue strengthening the conventional laboratory system even while it rolls out and uses POC diagnostics.

- Encourage and support the MoH to assess both conventional and POC diagnostic capacity in the country, which will inform the implementation strategy and priorities (e.g., where the gaps are, what needs to be strengthened, what can be shared with other disease programmes).

- Work to ensure that key stakeholders, including from subnational levels and long-term funders, which may ultimately absorb project costs and support project scale-up, are involved in the development of national strategies and plans.

- Work to ensure that the government includes the task of writing a road map as an activity during initial development of the project plan. A road map can help to facilitate a seamless transition from partner organizations to national and subnational authorities.

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Additional tips and comments

- It has been observed that laboratories can easily switch back to using only conventional systems and all the progress achieved through the project implementation can be lost. Therefore, a smooth transition can be critical.

- To facilitate government commitment and avoid a protracted transition process, common objectives and timelines must be agreed by stakeholders and roles and responsibilities must be clarified from the beginning (e.g., partners to catalyse, long-term funders to scale up, and government to lead and take over after an agreed date).

- To ensure sustainability, funding transition should be discussed as early as possible.

- To avoid fragmented implementation of similar POC diagnostics projects, all projects should be integrated into the national health programme.

- Inclusion of POC diagnostics in GF CCMs and NSPs and in PEPFAR COPs can be achieved through advocacy by existing POC Diagnostics TWGs led by the MoH.

- Subnational partnerships can be created to share rollout costs. This can help to facilitate planning and budgeting at subnational level.

LESSON

The interests of different donors and partners supporting the project must be clarified as early as possible and aligned throughout project implementation

Observations/analysis

- TWGs should include representatives of all key stakeholders, even when there are potentially competing agendas (e.g., focus on conventional systems versus POC diagnostic technologies). Discussions should aim at finding an appropriate balance to optimize available diagnostic technologies, highlighting trade-offs and identifying the most suitable systems for each situation/gap. Keeping stakeholders engaged is key to ensure coordination.

Additional tips and comments

- Initial strategy development can take up considerable time when many stakeholders are engaged. Investing in building agreement among all stakeholders on the overall 'big picture' -- the need to find ways to improve access to EID in order to achieve targets and save lives -- can prove helpful and prevent unnecessary burden when trying to balance high level of scrutiny from stakeholders who are new to the POC diagnostics space.

- Review guidance developed by global organizations (e.g., WHO, PEPFAR, the Global Fund) about POC diagnostics. Understanding global priorities will inform the engagement strategy with global donors.

LESSON

To help ensure the sustainability of POC diagnostics projects, transition to long-term donors and to the government must consider the main issues of service maintenance, warranties and replacements

Programmatic considerations

- Discussions around the sustainability of a POC diagnostics project should consider specific funding for service maintenance contracts with clear inclusion of warranties and replacements. (Often, it is only commodities that are focused on in this area, in terms of funding.)

Additional tips and comments

- Usually, POC diagnostics projects start by bringing funds for the supply of commodities for the pilot efforts. It is important as well to discuss service and maintenance surcharges, warranties and replacements from the start of the implementation of the POC diagnostics project with donors.

- An additional approach could be to request that the terms and conditions with manufacturers include a minimum of two-year warranties for the devices (and not the one-year standard). This can help to mitigate the risk of countries having to use or find extra funding to deal with equipment issues in the first two years of the project.

- Speaking with manufactures with 'one voice' is important. Partners and other donors and funding agencies should have the same approach when discussing these terms with suppliers.
It is important to be vocal about these decisions and align with the different stakeholders.

"What we accomplished by procuring the devices, providing the tests, getting the feedback from the government, health care workers, and the communities… that was one of the highlights of my career."

■ *Pierre Robert (Kenya)*

2.7 The UNICEF-CHAI Point-of-Care Project's grant design and practice

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LESSON

In-country staff and focal points must be involved during the design of the grant for a POC diagnostics project, even if headquarters and/or regional offices are leading its implementation

Programmatic considerations

- It is essential that country-level staff and focal points are involved when the design of the grant is discussed – and that those involved include not only HIV departments and specialists but those with expertise in supply as well, because they will support procurement activities. These country-level colleagues have a better understanding of what is more realistic and feasible to be done in the context of each country and the timeline being proposed.

- Adding country-level perspective to grant design can avoid highly prescriptive budgets that do not account for the level of novelty of a POC diagnostics project, a factor that increases the possibility that country-level offices and staff might face unforeseen situations, delays, and needs.

- Also, as it is expected that supply experts/focal points monitor and support procurement, a percentage of their time should be added to the budget, too. This avoids any perception that their participation in the project is done as a favour.

Additional tips and comments

- If multiple country-level partners are implementing a POC diagnostics project, focal points from all partners should be present during all grant design discussions in order to clarify roles at country level, avoid any ambiguity of understanding, agree on budget management transparency, and avoid duplication of efforts.

- POC diagnostics projects are multi-year endeavours. Stable funding to focal points and other involved staff at country and regional level should therefore be a top priority. Giving contract stability (e.g., yearly contracts, at minimum) avoids high turnover of staff and loss of time due to multiple recruitment processes and onboarding of new staff. Most importantly, stable funding will allow focal points to use their full potential to the project, protect the continuity of the work, and keep robust connections with partners, community leaders, and government officials.

- Establish regular calls, led by headquarters and/or regional offices, bringing all country-level staff together, to facilitate learning across countries for the entire duration of the POC diagnostics project.

- In preparation for the grant design discussions, country-level focal points can be asked to ensure that they understand their country's pre-requirements of regulatory approvals for medical devices and the introduction of new technologies to their countries. These are areas where bottlenecks consistently occur, and therefore preparatory work of this sort can help to ensure compliance with the project's timeline.

- Listen to all country-level staff involved about their perception of how much time is needed for advocacy and lobbying with country leadership about a novel intervention such as a POC diagnostics project. This perspective is another way that they can better inform the timeline of the project.

- Make sure that Supply and Programmes focal points in all offices are in constant communication about the project.

- If multiple country-level partners are implementing a POC diagnostics project, it is highly recommended that they have regular meetings among themselves for alignment purposes. This can help to guarantee that all partners are speaking the same language' even if in contact with the MoH independently.

LESSON

Taking proactive steps to work better with implementation partners improves communication efforts

Observations/analysis

- More transparency among partners is always beneficial, and especially when there is overlap in areas of work (e.g., programmatic work, connecting and communicating with the government, technical expertise).

- Not only should the establishment of roles and responsibilities be clear, agreed upon, and followed, but in addition terms of reference (ToRs), workplans and results of the project should be shared, discussed, and jointly updated on a regular basis. These regular discussions are ways to ensure that all partners implement the project in greater alignment. The project will proceed more effectively when relevant changes, which might affect all implementing partners, are deliberated together in advance and not mentioned or discussed only after they are made.

- Priorities and their criteria should be clear, and consensus reached among all partners before implementation.

- Reporting mechanisms should be independent for each implementing partner, as long as all are contributing to common goals.

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Additional tips and comments

- Promote independence of overall work for each partner, avoid duplication of tasks and redundancies in the workplans, and do not allow any hierarchy among implementation partners (which could result in unnecessary tension among them. These steps can help to prevent multiple changes in plans and late-stage redesigns, which can be frustrating and demotivating for staff and government officials.

- For UNICEF only: UNICEF should not be a subgrantee. The organization is already large and well established, with complex M&E and financial systems. A subgrantee role only multiplies the bureaucracy, causing delays in implementation and making it more difficult to intervene in due time when needed. In such contexts, better options for UNICEF would include MoUs and independent partnership agreements.

LESSON

Initial grant investment in each country should be focused on robust cost-benefit studies and on improving the market, with particular attention to test prices and service maintenance contracts

Programmatic considerations

- Opportunities to engage in the market should be given evenly among key manufacturers. This can help to avoid two things: limitations in the number and scope of actors in the market, and stagnation instead of consistency in reduced pricing.

- Include funding for robust cost-effectiveness/cost-benefit studies in different country settings. These studies are useful when advocating for preferred options with leadership.

Additional tips and comments

- It can take substantial costs, time and effort for market and cost-effectiveness/cost benefit analyses to be done well. Make sure to not underestimate any of them.

- In all cost-benefit analyses and studies, take into account the basic requirements of the devices and their performance in remote locations. Deployment and use in such areas will likely lead to increased funding needs for maintenance and repairs.

2.8
Advice to other professionals involved in or soon to be engaged in similar work

The final part of this effort to gather lessons learned during the UCPOC Project aimed at bringing some subjectivity through personal insights that might be relevant for other professionals who are about to start such work or are already engaged in it.

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In order to accomplish this, UNICEF focal points were asked to imagine going back in time to right before they started the project. Based on their experience with the project since that time, they were then asked to respond to the following two questions: "What would you have liked to know then, that you know now? What is the one piece of advice that you would have really appreciated if someone had told you right in the start of your POC diagnostics journey?".
In an effort to obtain candid and spontaneous input, survey respondents were asked these two questions at the very end of their interviews for this report. Therefore, although their answers were likely influenced by their reflections on the project over the lengthy discussion beforehand, they had no time to come up with carefully scripted answers.

The selection of quotes in this section on personal reflections is followed by an email sent by one of UNICEF's Chiefs of HIV and AIDS, Pierre Robert. He wrote it on the eve of World AIDS Day in 2019, right after the launch by the UCPOC Project of POC diagnostic devices in two counties in Kenya. His message was that through the commitment of professionals from so many organizations, UNICEF and other partners are undeniably responsible for saving lives when they catalyse and scale up POC diagnostics.

This document was written to give valuable insights to professionals working in the POC diagnostics space. It is hoped that words below can also bring more inspiration and determination to all.

"With this project, I have learned a lot, although I am not a 'lab person', I was able to work with different lab stakeholders and this has expanded the scope of my abilities including negotiation skills and have increased my understanding of other operational issues like service level agreements. This is a very interesting project where you learn a lot about laboratory services."

■ *Mary Mmweteni (United Republic of Tanzania)*

"Focus on teamwork – UNICEF can only successfully implement a POC diagnostics project with strong relationships and efficient partnership with the MoH, other implementers, and the civil society. We can and must complement each other with our different strengths and bring all the needed pieces together. It is the only way to move forward! When UNICEF, or your partner, or the MoH start behaving selfishly, it complicates everything. So, teamwork, teamwork, TEAMWORK!"

■ *Hafsa Khalfani (United Republic of Tanzania)*

"The involvement of all stakeholders and taking into account each other's opinions are very important in the development of strategies and the implementation of POC diagnostics services."

■ *Freddy Salumu (Democratic Republic of Congo)*

"Never mind the challenges ahead, dedicate your time, resources and skills to see that no child of your country dies due to late diagnosis and treatment of HIV. So, on your mark, get ready, and go for it!"

■ *Dorcus Abuya (Kenya)*

"What we accomplished by procuring the devices, providing the tests, getting the feedback from the government, health care workers, and the communities... that was one of the highlights of my career. They were all telling us how happy they were that their lives were easier, and better. So, don't despair. The outcome will be far beyond what you expected."

■ *Pierre Robert (Kenya)*

"Ensure you keep long-term vision in mind as these multi-year, multi-stakeholder projects face many challenges, especially early on. With innovation, there is disruption, and inevitably resistance from some partners and health authorities – it takes time and persistence to show results."

■ *Mireille Tribie (Mozambique)*

"Create strong partnership with and buy-in from the government along with consistent advocacy among the leadership, to bring all paediatric HIV actors on board!"

■ *Yayeh Negash (Ethiopia)*

"Engage more with all the stakeholders who surround the implementation of POC diagnostics, especially with policy makers, implementers on the ground, and the people who directly benefit from these services, to make sure you leave no one behind!"

■ *Aaron Mdolo (Malawi)*

"It is important to consider the national foundation for diagnostics that have been laid before implementing POC diagnostics: consider the conventional system already in place and innovate from there. POC diagnostics does not compete with the existing conventional system, it complements it, helping to fill the gaps in diagnostics services for all. In this sense, work hard to find a balance between these two types of diagnostics services in your country."

■ *Muluh Clifford (Cameroon)*

"Having a clear understanding of what a project implementing and scaling up POC diagnostics really does, is key. This is a very technical type of project. Work closely with the MoH and learn as much as you can about laboratory issues, use your public health experience to guide you while you dive in a new area of work – it will be challenging, but worth it!"

■ *Tonderayi Clive Murimwa (Zimbabwe)*

"When an HIV-positive mother delivers her baby, I think that what is in her mind is to know if her baby is HIV-positive or -negative, whether she lives in a rural or in an urban setting. So, as implementers of a POC diagnostics project, make sure you give the opportunity to each HIV-positive mother, no matter where she lives, to access EID services in a time-efficient manner. In this way, you will enable that better care can be provided timely; and more: with the viral load services that these devices also provide, these mothers will also be able to know if the treatment is working."

■ *Basile Keugoung (Cameroon)*

"Improve the sharing of real-time information between headquarters, regional offices, partners and country offices as much as possible, as the project really benefits from better communication among UNICEF staff."

■ *Ndeye Ngom (Senegal)*

"You have to think of a project like this one using a systems approach. Focusing only on specific elements of the system will not be as fruitful as working on it holistically – consider the infrastructure, the human resources capacity, the supply chain, quality management, biosafety, beneficiaries... Look at all these elements as a system (how they connect with each other) and evaluate what you need to build (because it's not there yet) and what you need to strengthen, in order to build a system that works and that can be sustained over time."

■ *Alex Costa (NYHQ)*

"I would like to give you a historical perspective: a few years ago, when I heard about these POC diagnostics devices for the first time, we were trying to understand what this technology could mean to Africa. We were worried about the investment needed to implement this innovation and our expectations were quite reserved, because we did not think it was cost-effective. It seemed like a luxury, especially when compared to how much we required to address all the other needs we had. It's safe to say we thought POC diagnostics devices were meant for high-income countries, and that some international organizations and manufacturers were pushing us to accept it as a valuable solution to our context as well. Then, we guided the first discussions to answer the following question: how many lives can we save in making ART more available, prevention more effective, and have more women in PMTCT, with one device? Between that moment and now, it's been a journey, and it has been worth it. So much so, that it is worth going further and faster, because these devices save lives. Now, I think about the smile of a child who would have been lost to follow-up, only because it takes three to four months in some remote regions in Cameroon to get the results back when we use the conventional system of sending samples to the capital city – after those months, if the baby is still alive, it can be a nightmare to find them. So, the smile of that baby, who had the chance to be tested at the very end of Cameroon, in the South border with Gabon, and be benefitted of same day testing and same day treatment is... priceless."

■ *Abdelkader Bacha (Cameroon)*

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From: Pierre Robert
Sent: Saturday, November 30, 2019
Subject: We did something really good...

Dear Werner, Trish, Maniza, Andrew and Doug,

This is a word of thanks from the HIV Team, the Kisumu Zonal Office, the leaders and the communities of Laikipia and Migori counties and from the thousands of mothers and children who will benefit from their new point-of-care testing devices.

As planned, we simultaneously launched the devices in both counties yesterday as a pre-World AIDS Day activity to the delight of Governor of Laikipia and the CEC in Migori and their respective teams. The reception that UNICEF received, and the gratitude expressed by everyone at the events was in fact very moving. In both counties we had set up the machines two weeks ago and trained laboratory workers, community leaders and spoke health centre staff on its use and its benefits. On the day of the launch, the machines were already up and running and some children had already benefited by the Early Infant Diagnosis (EID) tests UNICEF had also provided.

Point-of-care testing in these counties will greatly assist in reducing the number of complex steps in the blood-testing process, it will reduce the potential for errors, accelerate availability of critical test information to help expedite diagnosis and disposition of patients and help improve overall hospital efficiency. In Laikipia, it took an average of 34 days from sample collection from the infant to receipt of results for clinical decision, with some results taking as long as 77 days to retrieve. With the procurement of this new point-of-care testing device, turnaround time for obtaining the results will now be less than one day. Doctors, nurses and other medical staff who regularly deal with the treatment of HIV-infected infants will now be able to ensure they have the earliest possible access to life-saving antiretroviral therapy.

Life Saving! That's what these machines are going to do, they will save children's lives.

Yesterday was one the best days of my career and I'm sure my awesome colleagues felt the same way. We really did something good here and I wanted to share some of the heartfelt gratitude we all received and personally thank you all for the support you provided throughout the whole process.

Happy World AIDS Day,

Pierre

Pierre Robert
Chief HIV and AIDS

3. Annexes

3.1 List of UNICEF Offices and focal points of the UNICEF-CHAI Point-of-Care Project

LOCATION	OFFICE	NAME	E-MAIL	POSITION
Yaoundé	Cameroon CO	*Abdelkader Bacha	abacha@unicef.org	Chief HIV/AIDS
		*Basile Keugoung	bkeugoung@unicef.org	HIV/AIDS Specialist
		*Muluh Clifford	mclifford@unicef.org	HIV/AIDS Specialist
Kinshasa	DRC CO	Francine Kimanuka	fkimanuka@unicef.org	Senior Health Specialist
		*Freddy Salumu	fsalumu@unicef.org	HIV/AIDS Officer
		Lydia Mulongo Kabamba	lmkabamba@unicef.org	Health Manager
Addis Ababa	Ethiopia CO	Julia Battle	jbattle@unicef.org	Health Specialist
		*Yayeh Negash	ynegash@unicef.org	Health Specialist
Nairobi	Kenya CO	*Dorcus Abuya	dabuya@unicef.org	HIV/AIDS Specialist
		*Pierre Robert	probert@unicef.org	Chief HIV/AIDS
Lilongwe	Malawi CO	*Aaron Mdolo	amdolo@unicef.org	HIV/AIDS Specialist
		Diana Chikuwa	dchikuwa@unicef.org	Procurement Specialist
		Steve Okokwu	sokokwu@unicef.org	Programme Manager
		Tedla Damte	tdamte@unicef.org	Chief Health
Maputo	Mozambique CO	Dezi Cornelia Mahotas	dmahotas@unicef.org	Health Specialist
		*Mireille Tribie	mtribie@unicef.org	HIV/AIDS Specialist
Dakar	Senegal CO	Halima Dao	hdao@unicef.org	Chief Child Survival & Development
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Kampala	Uganda CO	Barbara Asire	basire@unicef.org	HIV/AIDS Specialist
		*Esther Nyamugisa	enyamugisa@unicef.org	HIV/AIDS Specialist
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Dar es Salaam	United Republic of Tanzania CO	*Hafsa Khalfani	hkhalfani@unicef.org	HIV/AIDS PMTCT Specialist
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*Attended the lessons learned interviews/replied to the questions

3.2 Latest trends in the HIV response where UNICEF is involved in the UNICEF-CHAI Point-of-Care Project

For context, relevant HIV response data from the 10 countries where UNICEF is engaged in the UCPOC Project are presented below. The information, from the Global AIDS Monitoring and UNAIDS estimates[13], includes the following: the number (2019) of pregnant women living with HIV receiving effective ARVs for PMTCT, percentage (2016–2019) and number (2019) of infants born to pregnant women living with HIV who received a virological test for HIV within two months of birth, and the percentage (2016–2019) and number (2019) of children living with HIV receiving ART.

COUNTRY	Per cent of infants born to pregnant women living with HIV who received a virological test for HIV within 2 months of birth[13]				Per cent of children living with any HIV receiving ART[13]			
	2016	2017	2018	2019	2016	2017	2018	2019
Cameroon	61.5	61.5	69.5	64.4	22.1	27.5	30.9	33.0
DRC	14.7	25.4	16.3	16.0	19.8	24.6	22.8	27.8
Ethiopia	52.9	45.7	60.0	-	39.7	42.7	45.5	48.2
Kenya	57.0	53.2	66.5	68.8	57.5	67.3	62.1	62.9
Malawi	36.4	62.7	>95	76.2	48.5	58.6	63.5	74.1
Mozambique	49.9	57.1	66.4	70.8	43.3	50.8	56.7	63.2
Senegal	13.4	24.3	24.5	-	26.9	28.7	34.1	38.5
United Republic of Tanzania	45.4	42.0	47.7	46.6	51.8	54.4	61.1	66.0
Uganda	33.2	46.4	47.0	56.3	52.1	55.7	61.3	64.7
Zimbabwe	65.6	61.7	61.1	55.7	67.0	72.8	58.9	71.0

Legend: Green cells highlight increase from previous data in the same variable and country; red cells highlight decrease from previous data in the same variable and country

COUNTRY	Number of pregnant women living with HIV receiving effective ARVs for PMTCT in 2019[13]	Number of infants born to pregnant women living with HIV who received a virological test for HIV within 2 months of birth in 2019[13]	Number of children receiving ART in 2019[13]
Cameroon	17,100	15,000	10,400
DRC	13,900	4,900	19,000
Ethiopia	14,100	-	21,300
Kenya	59,300	43,400	70,100
Malawi	43,300	32,600	48,000
Mozambique	112,000	76,300	95,100
Senegal	1,400	-	1,500
United Republic of Tanzania	74,600	37,600	61,200
Uganda	96,000	53,800	66,200
Zimbabwe	57,600	35,400	59,800

3.3 Questionnaire answered by each country office

1. How was the transition process to Government and long-term funding in POC Diagnostics and how was momentum sustained for their investment? (please consider if POC Diagnostics was incorporated in the national strategy and plans, PEPFAR COP/GF, and other)

2. What were the key elements related to laboratories and the supply chain that were required to implement this project in your country?

3. What were the main actions that needed to be undertaken by leaders to increase their commitment and support a successful implementation of a POC Diagnostics in your country?

4. What did you and your team do that didn't work and is worth sharing with other implementation teams in other countries?
   - What was the background of the situation?
   - What was the cause/why do you think it didn't work?
   - Which insight was generated/what should others avoid?
   - Were any objective unmet or were there any strategy or activity unsuccessful?
   - How did you change your action to make it work, eventually?
   - Can your solution be expanded or applied to other situations/settings?

5. Can you cite any innovative practice which is effective and suitable for replication in other countries as well?
   - Who was involved in this innovation?
   - What are the implications of the innovation? (Did it create an unforeseen problem? Did you have to engage with a new stakeholder? Did it create any kind of delay?)

6. Have civil society organizations (CSOs) been involved in the implementation process to increase awareness and demand for POC Diagnostics in your country? How?
   - If yes, which CSOs did you engage with?
   - How did you involve the CSOs?
   - What did you learn from the process?

7. What information technology solutions were implemented in your country to collect, share and analyse data across POC Diagnostics devices?
   - What data did you find most useful to collect and analyse? Why?
   - How might a country prepare in advance to more effectively set up data management solutions to collect, share, and analyse data?
   - What improvements do you recommend for other countries – and areas to avoid - when they prepare to select IT vendors?
   - When they prepare to develop a data management/IT solution?
   - When they prepare to implement the solution(s)?
   - What lessons learned might you pass on regarding setting up a national dashboard? What barriers/challenges should a country anticipate, and what do you recommend to countries to help them better prepare for these challenges?
   - Given the disruption of COVID-19, how do you think the IT solutions in place could have better supported COVID-19 response? Would you recommend doing anything different to better prepare for future disruptions?

8. About the design of the grant and its practice:
   - What would you do differently and what should be avoided?
   - What would you do in the same way?
   - How did these lessons affect the success or the failure of the project?
   - Whose involvement was important and why?

9. What were the most important lessons learned?
   - What would you do differently?
   - What would you do in the same way?
   - How did these lessons affect the success or the failure of actions?
   - Whose involvement was important and why?
   - If you could share one piece of advice to other professionals who are about to start a similar project as the UCPOC, what would you let them know that you think would improve their chances of success?

3.4 Additional questionnaire answered by country offices with specific experience in DNO

1. Which of the following network contexts describes the diagnostic network in your country pre-DNO (mark all that apply):
   - ☐ a. Sub-optimal testing coverage (specify which disease area)
   - ☐ b. Limited MoH visibility to testing coverage achieved within existing network
   - ☐ c. Sub-optimal device utilization, suggesting that capacity for optimal testing coverage is available, but that that the available network is not designed to meet it
   - ☐ d. Limited MoH visibility into device utilization rates across the full network
   - ☐ e. Sub-optimal cost per test
   - ☐ f. Limited MoH visibility to total network cost and cost per test
   - ☐ g. Siloed/non-integrated diagnostic networks
   - ☐ h. Limited collaboration across MoH Disease Programmes
   - ☐ i. Limited visibility into resources available for full dx network
   - ☐ j. Difficulty prioritizing available resources within dx network
   - ☐ k. Other; specify

     _____
     _____

2. For each selected, please briefly describe why the network challenges exists/existed.

   _____
   _____
   _____
   _____

3. Which of the following DNO goals best aligns with the original DNO objective in your country?
   - ☐ a. Increase access to testing and generate public health impact
   - ☐ b. Increase network efficiencies
   - ☐ c. Decrease total cost per test

   - ☐ d. Create greater visibility leading to more effective allocation of funding
   - ☐ e. Unlock MoH capability to generate continuous network improvements
   - ☐ f. Create a more competitive and dynamic marketplace
   - ☐ g. Other; specify

     _____
     _____

4. Please list the stakeholders engaged within the DNO exercise.

   _____
   _____
   _____
   _____

5. For each stakeholder, briefly describe their role or input to the process.

   _____
   _____
   _____
   _____

6. Please indicate where you are within the DNO process:
   - ☐ a. Define scope and reach of stakeholder alignment
   - ☐ b. Data collection and validation
   - ☐ c. Build and select optimization scenario
   - ☐ d. Implement optimized network and monitor impact

7. If you have completed DNO Process '1' (Define scope and reach stakeholder alignment), briefly explain:
   - How was DNO first communicated, and how were the DNO objectives agreed upon by all stakeholders?
   - Challenges in achieving stakeholder agreement
   - Length of stage in days/weeks/months

     _____
     _____
     _____
     _____

8. If you have completed DNO Process '2' (Data collection and validation), briefly explain:
   - Key data inputs required for DNO
   - Initial data availability (25%, 50%, 75%, or 100%)
   - Process for completing data collection
   - Challenges
   - Time required

   _____
   _____
   _____
   _____

9. If you have completed DNO Process '3' (Build and Select Optimization Scenario), briefly explain:
   - What software did you use to model the network?
   - How did you identify scenarios to model?
   - What were the core model outputs that you compared across scenarios?
   - How did you achieve consensus on one optimal network?
   - Challenges
   - Time required

   _____
   _____
   _____
   _____

10. If you have completed DNO Process '4' (Implement and Monitor Impact), briefly explain:
   - How did you identify if network capacity was sufficient for optimization? i.e. HR capacity, data capacity, management, operations, infrastructure, etc.
   - How did you estimate funding need and mobilize resources?
   - How did you develop an implementation plan?
   - How is implementation continuing to be monitored?
   - Challenges
   - Time required

   _____
   _____
   _____

11. Were there other constraints, bottlenecks not mentioned above? If so, what were they and how were/are you able to overcome them, what were/are your solutions/transformations?

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   _____
   _____
   _____

12. Once one full DNO is complete, when do you think the next DNO will need to happen?

   _____
   _____
   _____
   _____

13. Given where you are within the DNO process, is there anything you would do differently next time?

   _____
   _____
   _____
   _____

14. Please inform any DNO considerations in light of the national COVID-19 response.

   _____
   _____
   _____
   _____

Acknowledgements

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Wherever he lives.
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A future.
A fair chance.
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