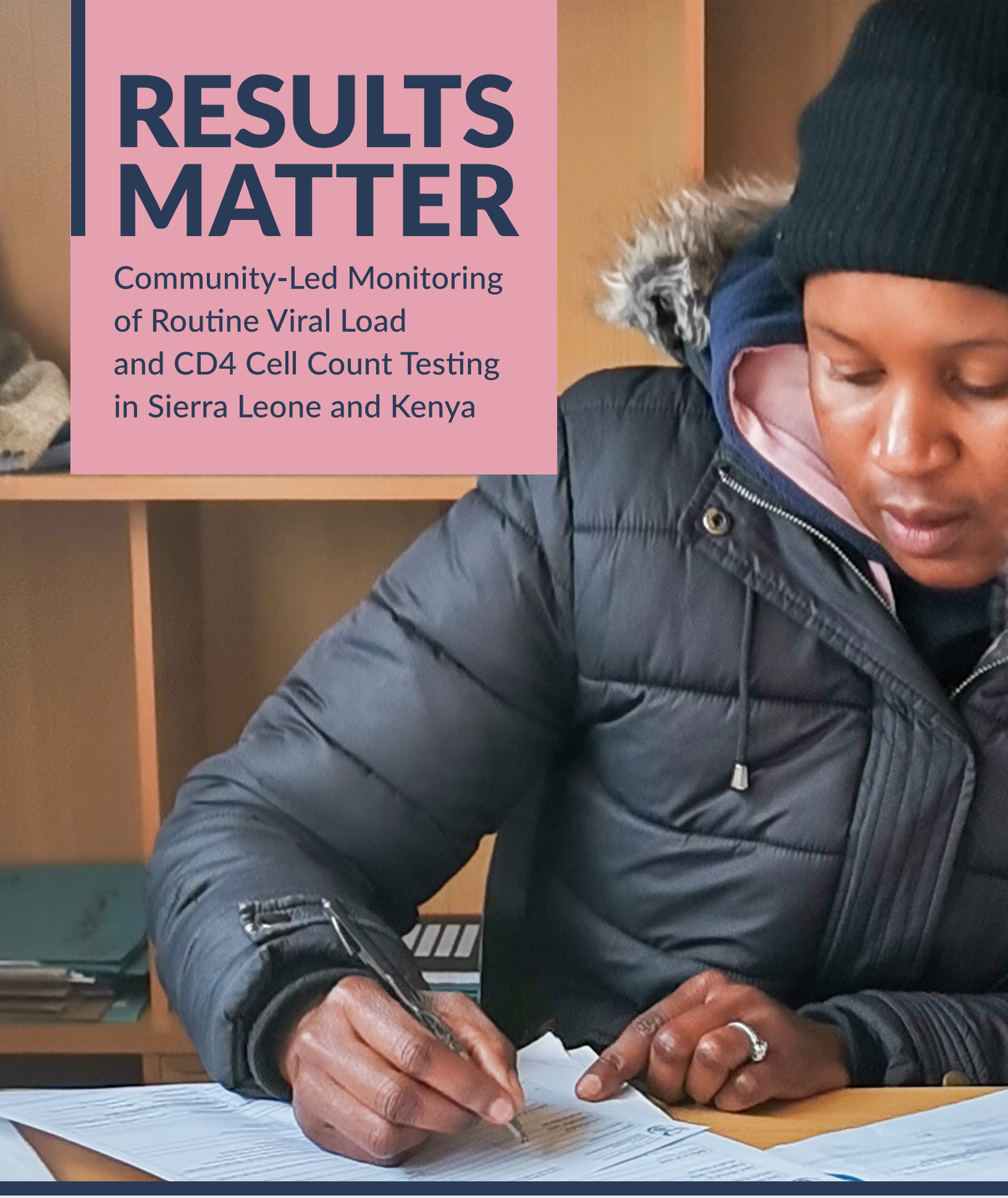
RESULTS MATTER

Community-Led Monitoring of Routine Viral Load and CD4 Cell Count Testing in Sierra Leone and Kenya



DECEMBER 2022

ITPC
INTERNATIONAL TREATMENT PREPAREDNESS COALITION

NETHIPS
Network of HIV Positives in Sierra Leone

NEPHAK say yes to life

ABOUT ITPC

The International Treatment Preparedness Coalition (ITPC) is a global network of people living with HIV and community activists working to achieve universal access to optimal HIV treatment for those in need. Formed in 2003, ITPC actively advocates for treatment access across the globe through the focus of three strategic pillars:

- Make Medicines Affordable
- Watch What Matters
- Build Resilient Communities

To learn more about ITPC, visit itpcglobal.org

ABOUT WATCH WHAT MATTERS

Watch What Matters is a community monitoring and research initiative that gathers data on access to and quality of HIV treatment globally. It fulfils one of ITPC's core strategic objectives: to ensure that those in power remain accountable to the communities they serve. Watch What Matters aims to streamline and standardize treatment access data collected by communities—helping ensure that data is no longer collected in a fragmented way and that it reflects the issues and questions that are most important to people living with and affected by HIV. It relies on a unique model that empowers communities to systematically, routinely collect and analyze qualitative and quantitative data on access barriers and use it to guide advocacy efforts and promote accountability.

To learn more about Watch What Matters and ITPC's community-led monitoring work, visit WatchWhatMatters.org.

ABOUT NEPHAK

Registered in 2003, the National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK) works to unite people living with HIV and people affected by TB, HIV and AIDS through post-test clubs, support groups, community-based organizations, non-governmental organizations, and networks. NEPHAK emerged out of a need, dating to the mid-1990s, to unite the existing support groups and networks of people living with HIV in Kenya.

ABOUT NETHIPS

The Network of HIV Positives (NETHIPS) is a strategic partner in the HIV response in Sierra Leone. It is an umbrella organization for people living with and affected by HIV with over 70 support groups nationwide. Over the past six years, NETHIPS has partnered with ITPC through its Community Treatment Observatory to understand challenges faced by recipients of care along the HIV treatment cascade and secure changes that improve outcomes.

ABOUT THIS REPORT

This report was prepared by NEPHAK and NETHIPS, with contributions from the support team listed below.

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To download this report from the ITPC website, click here.

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EXECUTIVE SUMMARY

This pilot of community-led monitoring (CLM) of routine viral load testing (RVLT) and CD4 cell count testing, carried out in Kenya and Sierra Leone, confirms that the presence of guidelines and policies cannot be used as a proxy for coverage and access to these tests. Stockouts and breakdowns at the facility level, staff shortages, and other factors mean that the services are often not available. When they are available, the results are not always returned to recipients of care and they may be returned without appropriate actions, such as initiation of care for advanced HIV disease or counseling about a viral load result. Both viral load and CD4 cell count results can be motivating and empowering to people living with HIV as they make treatment decisions and experience their outcomes. Indeed, tracking and improving the rate of return of results of RVLT is likely to be crucial in reaching the UNAIDS "95" target for virologic suppression. Simply or solely tracking guidelines and rates of virologic suppression leaves out crucial information about service availability and quality. This pilot strongly supports the case for CLM focused on laboratory services, with an expanded and refined set of indicators that provides information on whether people living with HIV are receiving the tests indicated by guidelines and/or their clinical status. This CLM should be aligned to and matched with monitoring, reporting, and accountability frameworks supported by national and subnational health systems to ensure that policies translate into practice and that the lab conveying results is a central part of person-centered care.

Photo: NETHIPS

Community monitors conduct data quality audit at King Harman Road, Freetown, Sierra Leone

INTRODUCTION

Laboratory Test Results Matter—for Individuals and Epidemiologic Progress in Responding to HIV

It's been nearly a decade since the World Health Organization (WHO) declared routine viral load testing (RVLT) as part of the "gold standard" of treatment for people living with HIV. This declaration coincided with related guidance and the launch of the UNAIDS "Fast-Track" targets: that 90% of people living with HIV know their status, 90% of those individuals are on ART, and 90% of those on ART are virologically suppressed. Achievement of 90-90-90 was promoted as a key part of achieving epidemic control. These targets, updated to 95-95-95 in 2020, are part of the current global push to end the AIDS epidemic by 2030.

There are many benefits to virologic suppression. People whose virus is suppressed have better clinical outcomes and negligible low risk of passing it on to sexual partners or during pregnancy, labor, and delivery. These benefits accrue when a person has their viral load test result. But many other benefits depend on people living with HIV receiving and understanding their viral load test results. An undetectable test result can deliver a sense of wellbeing and confidence in making sexual health and family planning choices, and strengthen a sense of commitment to taking antiretrovirals. Therefore, the push to achieve 95% virologic suppression among people living with HIV is inextricably linked with quality health services that provide timely usable lab results and other information back to individuals. The full value of viral load testing to measure virologic suppression depends on people living with HIV knowing their results and what they mean.

Today, the interconnected benefits of virologic suppression and of knowing one's viral load test results are not equitably distributed among people living with HIV worldwide.

As of July 2022, RVLT for adults and adolescents had been implemented countrywide in 74% of reporting low- and middle-income countries; of the remainder, almost half reported implementation in 50-95% of treatment sites. The majority of countries missing the mark on national routine viral load monitoring (including countries with 50-95% and less than 50% coverage) are in sub-Saharan Africa.[1]

Where the tests are available, the results reveal other inequities. *In Danger*, the 2022 UNAIDS progress update, reported that in roughly half the countries with available data, people from the poorest households also had the lowest levels of virologic suppression. But it is not inevitable that people who live in poverty have unsuppressed viral loads. As the report also noted, "In countries that focus on the most vulnerable—such as Eswatini, Lesotho, Namibia and Botswana—the poorest quintile of people living with HIV have higher levels of viral suppression."

Looking at global progress towards the UNAIDS targets, today, 92% of people on antiretrovirals are estimated to be virologically suppressed.[2] Looking at all people living with HIV, this figure drops: an estimated 68% of all people living with HIV are on antiretrovirals and virologically suppressed. In other words, roughly one-third of all people living with HIV are not virologically suppressed. In many instances, this includes the poorest people in a given country or context; some know their status and some do not.

Closing the gaps in access to RVLT and CD4 cell count tests via systems with the supplies and staff to ensure timely return of results to recipients of care is central to achieving progress in a rights-based, person-centered response to HIV and AIDS. WHO defines viral load testing as "the gold standard

for monitoring adherence and confirming treatment response" and, since 2021, has supplemented this guidance with a good practice statement affirming that viral load for treatment monitoring should be complemented with non-judgmental, tailored approaches to assessing adherence.[3] A detectable viral load result should be the entry point for supportive interventions to remove barriers to adherence; an undetectable result can prompt discussion about what is working and why. Both of these conversations start with a viral load result and require health workers trained in engaging with recipients of care on these results.

While CD4 cell count is no longer a prerequisite for treatment initiation, per WHO, and also is not used as the first choice for measuring adherence,[4] the test remains a crucial tool, particularly for management of advanced HIV disease (AHD). In its 2017 guidelines on advanced HIV disease, WHO estimated that up to half of all people living with HIV who present for care for the first time have AHD; people who initiate ART and stop treatment may also return to care with AHD.[5] In addition, all children under five living with HIV are considered to have AHD, as are adults with CD4 counts <200 cells/mm3. Many key prophylactic and treatment decisions hinge on CD4 cell count results. For example, at low CD4 cell counts (<100 or <200), fluconazole prophylaxis for cryptococcal meningitis is recommended for all adolescents and children, even when cryptococcal antigen screening is not available.[6]

The work to close these gaps must not happen only at a global level or in national capitals and ministries of health. It must take place in clinics, central, and tertiary laboratories and communities—locations where recipients of care and community members are uniquely placed to use community-led monitoring to gather, analyze, and take action on information about vital health services.

ITPC and its partners worldwide have robust expertise in using community-led monitoring to assess access to and quality of health services solutions. In 2022, ITPC and partners in Kenya and Sierra Leone undertook a pilot of CLM of RVLT and CD4 testing. The pilot sought to define and test a CLM model for assessing indicators along the viral load and CD4 cell count cascade, gathering experiences and priorities from recipients of care and health workers.

This work emerged from prior ITPC-supported efforts in six African countries (the Democratic Republic of Congo, Malawi, Kenya, Sierra Leone, South Sudan, and Zimbabwe) to generate demand for RVLT through targeted multimedia communication campaigns. ITPC undertook this work with support from the African Society for Laboratory Medicine (ASLM), a non-profit pan-African society for laboratory professionals that works towards local access to world-class diagnostics in Africa. ITPC and ASLM share a commitment to bridging the gap between science and people. Working with partners, ITPC and ASLM learned that awareness raising is only part of what is needed to expand access to CD4 and RVLT. These campaigns unearthed systemic, supply-side barriers to RVLT, even in countries with supportive policies. This initiative brings the powerful tools of CLM to the task of identifying barriers and solutions to gaps in key RVLT and CD4 tests for people living with HIV.

MEET THE PARTNERS

KENYA: National Empowerment Network of People living with HIV/AIDS in Kenya (NEPHAK)

Registered in 2003, NEPHAK is a national Kenyan network that works to unite people living with HIV and people affected by TB, HIV, and AIDS through post-test clubs, support groups, community-based organizations, non-governmental organizations, and networks. NEPHAK emerged out of a need, dating to the mid-1990s, to unite the existing support groups and networks of people living with HIV in Kenya.

For this project, NEPHAK led the implementation and played a coordinating role with other organizations, including the KP Consortium and Ambassador for Youth and Adolescent Reproductive Health Program (AYARHEP). Among others participating were NEPHAK's member organizations, which identified data collectors. NEPHAK supported and facilitated the data collectors' training, engagement, and contributions to the project, coordinated data analysis, and coordinated the drafting of the final report.

Photo: NEPHAK

Community representatives conduct meeting in Siaya, Kenya

SIERRA LEONE: Network of HIV Positives (NETHIPS)

NETHIPS is a strategic partner in the HIV response in Sierra Leone. It is an umbrella organization for people living with and affected by HIV with over 70 support groups nationwide. The support groups are coordinated by regional offices located in the East (Kenema), South (Bo), and North (Makeni). The community-based approach adopted by NETHIPS through its support groups helps deepen its understanding of the challenges recipients of care face with uptake and quality of HIV services. Over the past six years, NETHIPS has partnered with ITPC through its Community Treatment Observatory to understand challenges faced by recipients of care along the HIV treatment cascade and secure changes that improve outcomes.

For this project, NETHIPS generated evidence from 15 health facilities with geographic coverage in four political regions (South, East, North, and Western Area). These health facilities are staffed by the National AIDS Control Program (NACP), which has collaborated with NETHIPS for over a decade to improve quality of care for recipients of care. The NACP is the technical arm of the Ministry of Health and Sanitation for HIV epidemic control. NETHIPS draws its advocacy strength from Community Consultative Groups, in particular, from the National AIDS Secretariat (the statutory entity that coordinates the HIV response in Sierra Leone), UNAIDS, SOLTHIS, and the AIDS Healthcare Foundation.

Data collection was supervised by the NETHIPS technical team led by Executive Director Idrissa Songo, Programme Manager Martin P. Ellie, M&E Officer Benjamin Flomo, and district supervisors of community monitors.

Photo: NETHIPS

Data collectors at Ola During Children Hospital in Freetown, Sierra Leone

METHODS

This project followed the ITPC Community-Led Monitoring model, which has been used by communities around the world to track a wide range of issues (see Box 1).

At the outset of the project, ITPC and partners gathered for a virtual inception training that included lab-centered "literacy" building about RVLT, CD4, and other aspects of HIV management. From this common foundation, participants discussed the issues present in their communities and local contexts and identified indicators that could be used to evaluate and define strengths and weaknesses in these priority areas.

Following this consultation, ITPC developed a data collection template with indicators that country-based teams were able to adapt to the local context. Derived from the outcomes of the inception meeting, the template was intentionally designed to support partners in gathering clear, usable information about their priority areas. CLM data collection tools are essential for effective work—and ITPC used experience to date to shape these pilot instruments. The indicators aligned with a health quality framework, looking at availability (had people received tests, results, and counseling?); accessibility (costing, transport); and appropriateness and quality (did recipients of care receive their test results, was the information timely and well-understood and did it prompt action, such as switching ART regimens, where warranted?)

To assess access to lab testing for viral load and CD4 cell counts, data was collected for the periods of January-April over the years, 2020, 2021 and 2022.

Once the data collection tools were finalized and reviewed for adaptation by the lead partners, NETHIPS and NEPHAK convened in-person training meetings with data collectors from a range of organizations. These two-day meetings included lab-focused "literacy," a review of the tool, and collaborative decision-making about sampling (that is, determining how many staff and recipients of care to interview per site of a particular size) and how to organize and coordinate data collection teams. In Sierra Leone, district supervisors were identified among the community monitors. These supervisors played a key role in coordination, data quality, and reporting.

In Kenya, the team selected team leads for the different county teams that would support them during the entire process. The team leads were responsible for reaching out to NEPHAK if they required additional support. In addition, a WhatsApp group was created and all the data collectors and NEPHAK staff were members of it; this was used for easy and quick communication among the team.

Data collection began after the training meetings. In Sierra Leone, quantitative data on viral load and CD4 testing was collected from health registers and qualitative data was collected from focus group discussions and interviews with lab facility staff and recipients of care attending health facilities. In Kenya, quantitative data was collected via a questionnaire administered to recipients of care and by review of data from facility registers to gain insights into the laboratory functions. The Kenya team also conducted focus group discussions and one-on-one interviews with recipients of care and health workers.

The project started with the identification and training of data collectors on the tools, goals (number of people to be reached by each collector and alignment of collectors and health facilities/sites), and indicators to be used. In Sierra Leone, this training included identifying district supervisors who coordinated data collection in the districts selected. Letters of request to allow data collection at the sites were developed by the coordinating partners and sent to the county/site teams who presented them to the offices of those in charge of the sites.

This step is key to ensuring that the leadership at the site and, often, the district or community level of the health system, is aware of a CLM effort, its purpose, structure, and schedule prior to launch. They also specified the teams' approaches to collecting data, including reviews of records and interviews of staff and recipients of care. Once approval was granted, the data collectors started the collection of data on the selected site. Data collectors used their support groups to reach out to community respondents in addition to those who were approached at the facilities. The questionnaires were coded and analyzed. Both the Kenyan team, led by NEPHAK, and the Sierra Leonean team, led by NETHIPS, used an online software called KOBO-COLLECT; data collectors used the software to capture and submit data from the sites.

In both countries, the lead partners held meetings with all the data collectors and coordinating partners to review and provide feedback on the findings and identify advocacy activities to be conducted to address some of the challenges that had been identified during the project. See the last section of the report for information on these activities and their outcomes.

The ITPC CLM Model

CLM covers four key areas: education, evidence, engagement, and advocacy. It is grounded in education and based on human rights, including the right to health, to ensure that all people are aware of the standard of care they are entitled to receive, as per current WHO guidelines for prevention, testing, care, and treatment for HIV, TB, COVID-19, viral hepatitis, and other relevant conditions. CLM is community-driven and increases accountability for, and improves outcomes of, national and local HIV programs—and the health of community members.

CLM may be used to track a range of issues. Examples are whether and to what extent stigma has made it difficult for people to access HIV services, the proportion of people who have been denied access to HIV prevention and testing, and the number of people who have discontinued ART and the reasons for this. This evidence is fed back to program managers and policy makers, which enables them to increase the "five As" (availability, accessibility, acceptability, affordability, and appropriateness) and the efficiency and effectiveness of HIV services.

The CLM and advocacy approaches of ITPC are designed to put people living with HIV, their communities, networks and/or organizations at the center of decision-making. Learn more at www.clmhub.org.

FINDINGS

This CLM effort gathered information from nearly 1,000 recipients of care via interviews and reviews of service registers and also engaged 133 health workers. The breakdown by country and grouping is summarized in Table 1.

TABLE 1: CLM for Laboratory Indicators Scope and Reach in Kenya and Sierra Leone

	KENYA	SIERRA LEONE
Health facilities	20	15
Districts/provinces/counties	3	4
People living with HIV (quantitative)	558	402 (242 CD4 records from service register, 160 VL records from service register)
People living with HIV (interviews and focus group discussions)	43	165
Health workers	104	19

COVID-19 Impact

The monitoring took place across three data collection periods (January-April 2020, 2021, and 2022). While these periods were selected in early 2020, prior to the start of the COVID-19 pandemic, at an April 2022 meeting with ITPC and partners, the Sierra Leone and Kenya teams decided to classify these periods as corresponding to "pre-," "acute," and "late" phases of the COVID-19 pandemic, based on the timing of government lockdowns (March 2020-late 2021 in Kenya) and/or travel restrictions, availability of vaccines, and rates of known infections and confirmed deaths. The approach to these classifications incorporated the following events and developments:

- **Kenya:** School closures, intermittent curfews, movement restrictions into and out of specific provinces and geographic zones, and curfews all in place (though periodically lifted) through the end of late 2021 (effectively ending the "acute" phase). COVID-19 vaccination began in Kenya in March 2021.
- **Sierra Leone:** Twelve-month state of emergency (March 2020-2021), including bans on public gatherings of over 100 people, a nationwide curfew (23:00-05:00), and restrictions on domestic travel, all of which were lifted in late 2020 (effectively ending the "acute" phase). COVID-19 vaccination began in Sierra Leone in March 2021.
- While these classifications were used in data analysis, it was difficult to make direct linkages between when a person reported having had a VL or CD4 cell count and the period of the pandemic—since each of these tests is indicated at specific periods depending on a person's health, time, and stability on ART, pregnancy status, and other factors.

Data Summary

For the quantitative data, CLM data collectors in Sierra Leone reviewed health records at the facilities identified for the survey. In Kenya, the data were collected from interviews with recipients of care who are members of people living with HIV support groups; a snowballing methodology of contacting additional individuals referred by support group members was used to reach the predetermined sample size. These findings are summarized in Figures 1 to 10. Qualitative data from focus group discussions with people living with HIV (Tables 2 and 3) and interviews with health workers (Tables 4 and 5) added nuanced information about service availability, accessibility, acceptability, and quality.

Quantitative Data

Figures 1 and 1bis show the cascade of RVLT and CD4 access across parameters that map accessibility (the number of people living with HIV who received a given test), acceptability (the number of people who received the result of that test), and quality (the number of people who received information or interventions associated with the test). For CD4, referral for advanced HIV disease care was used as a proxy for quality; for RVLT, an explanation of results was the proxy.

In the Kenyan context, just 7.65% of people who received viral load test results said they had received an explanation of the results. Nearly 50% (48%) of PLHIV who received a CD4 count received their result. There are several possible explanations for the different actions triggered by or associated with the return of the test results. Data collectors did not ask people what their reported results had been, so it is difficult to characterize the percentage of people referred for AHD as high or low, for example. However, this cascade, which tracks the recipient of care's experience from test to result to explanation, can be used to get a more complete view of laboratory services across the AAAQ framework. The first "A", availability, is not represented in Figure 1 as there was not a quantitative indicator centered on service continuity or reliability. However, qualitative interviews with more than 100 laboratory technicians and counselors in Kenya revealed a consistent pattern of stockouts, machinery breakdowns, and challenges with availability.

Figure 2 and 2bis show the cascade across the same parameters in Sierra Leone. In contrast to Kenya, where very few people living with HIV reported receiving explanations of results, 82.5% of people living with HIV in Sierra Leone who received a viral load test result reported that it came with a clear explanation of the results. (The Sierra Leone teams also solicited information on the quality of the result explanation: the remaining 14% said the results were not explained well or hardly at all.) Just 27% of people who received a CD4 cell result reported receiving care for

FIGURE 1: Total PLHIV CD4 results in Kenya

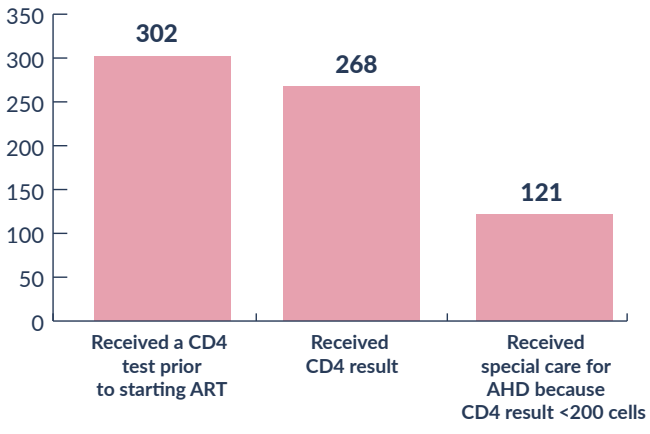
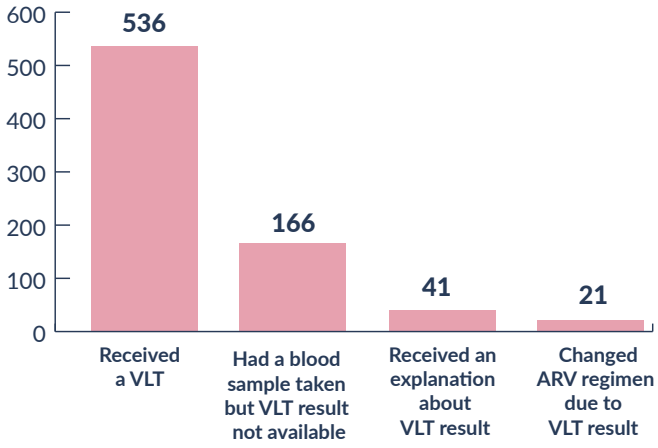


FIGURE 1BIS: Total PLHIV VLT results in Kenya



advanced HIV disease. As in Kenya, availability wasn't measured in an indicator that could be included in the cascade. However, the health staff and recipients of care all flagged significant issues with service availability, including a referral lab that had reportedly been closed for a year. These findings suggest that some components of the RVLT service model, particularly the return of results with comprehensive explanations, are functioning well at the sites surveyed. Additional investigation into the elements of the training and approach could yield insights about replicable best practices.

FIGURE 2: Total PLHIV CD4 results in Sierra Leone

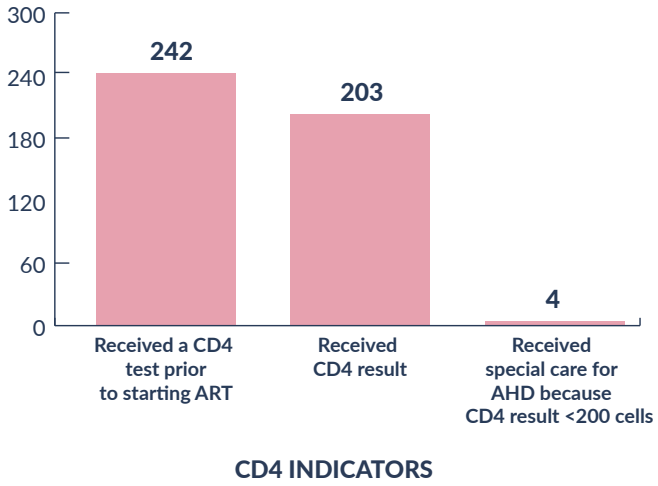
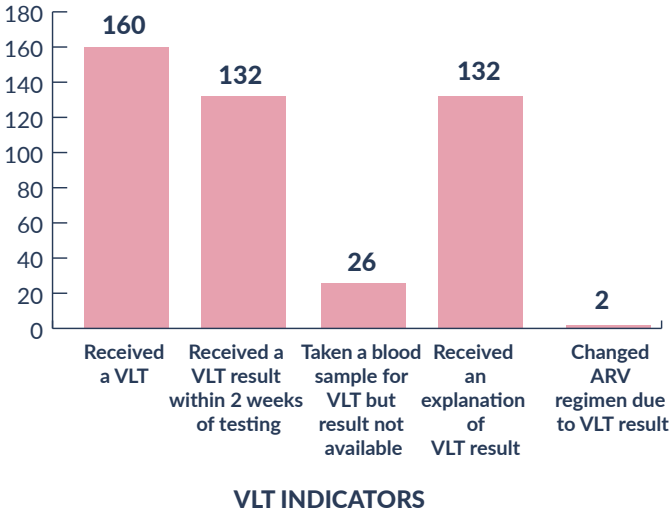


FIGURE 2BIS: Total PLHIV VLT Results in Sierra Leone



Disaggregated Quantitative Indicator Data in Kenya

(Figure 3 to Figure 6) From interviews with recipients of care at clinics

FIGURE 3: PLHIV CD4 results in Kenya, by gender

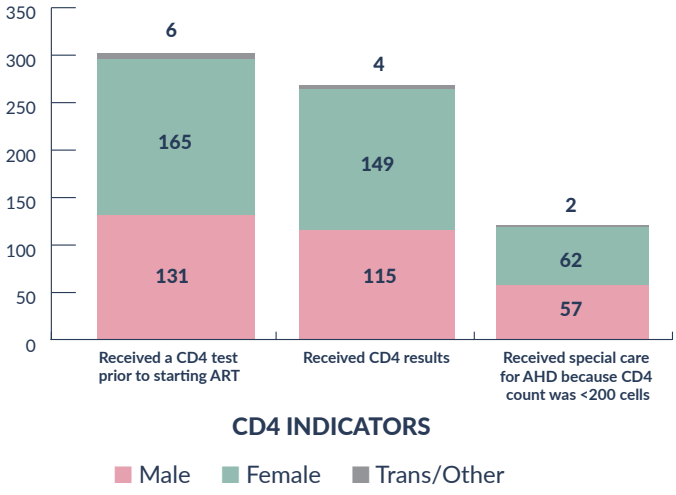


FIGURE 4: PLHIV CD4 results in Kenya, by age

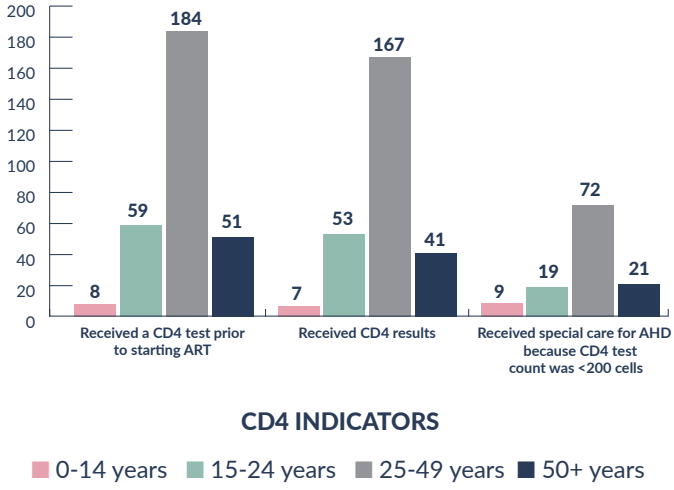


FIGURE 5: PLHIV VLT Results in Kenya, by gender

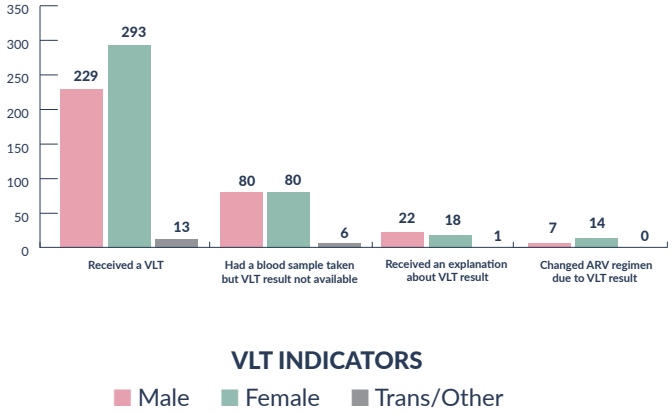
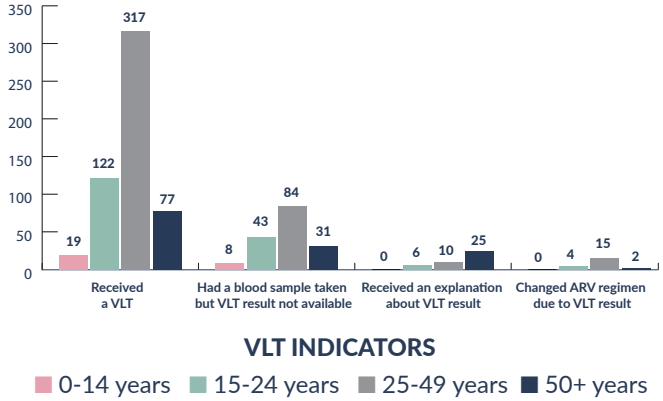


FIGURE 6: PLHIV VLT Results in Kenya, by age



Disaggregated Quantitative Indicator Data in Sierra Leone

(Figure 7 to Figure 10) From health records at 15 health facilities

FIGURE 7: PLHIV CD4 results in Sierra Leone, by gender

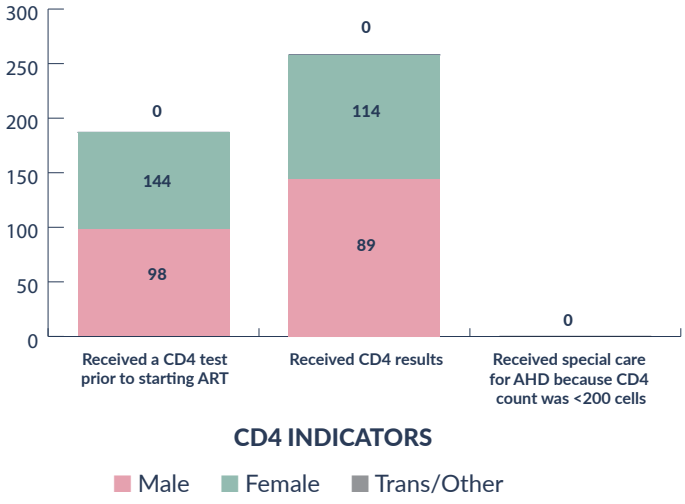


FIGURE 8: PLHIV CD4 results in Sierra Leone, by age

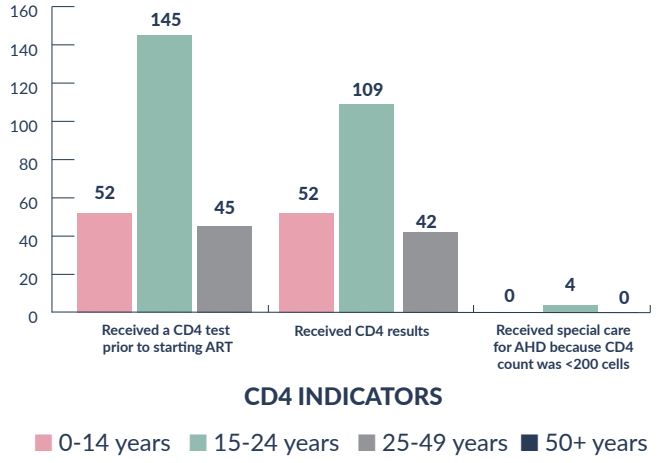


FIGURE 9: PLHIV VLT results in Sierra Leone, by gender

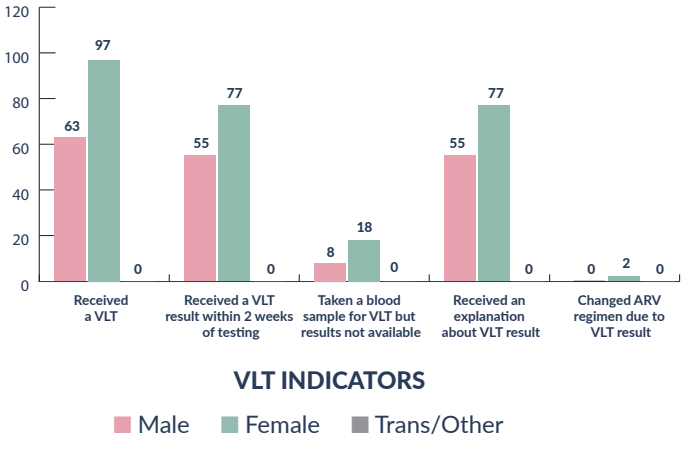


FIGURE 10: PLHIV VLT results in Sierra Leone, by age

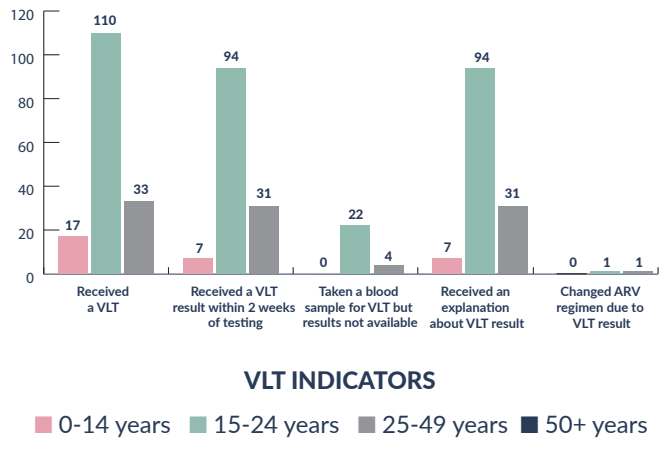


TABLE 2: Qualitative Findings – Viral Load Testing

AAAQ[7] PARAMETER	KENYA	SIERRA LEONE
AVAILABILITY	**Most people living with HIV had ever received a viral load test; however, COVID-19 severely disrupted availability of viral load tests on an annual basis, as per Kenyan guidelines**. A total of 60% of participants in the focus group discussions had not received a test in the current calendar year, with reported delays due to government prioritization of specific groups, including pregnant and breastfeeding women.	**Most people living with HIV had ever received a viral load test; however, service availability was often interrupted, creating challenges for routine monitoring, as per Sierra Leone's guidelines.** A total of 87% of people interviewed had received a viral load test. A viral load machine at a reference laboratory serving government-supported facilities across Sierra Leone was not functional for over a year. Other labs experienced short-term (1-2 month) issues with machine breakdowns and shortage of supplies. These issues were not tied to COVID-19 (repurposing of VL machines, staff, or reagents).
ACCESSIBILITY	System-based barriers to care exist, including caps on the number of tests per day, insufficient staff, and lab hours that do not meet the needs of recipients of care.	**The majority of people living with HIV reached in the qualitative survey (78%) said they did not have difficulty accessing CD4 cell count tests. Those who did cited the cost of transportation as the most common barrier.**
ACCEPTABILITY* *This parameter is defined as ethically and culturally appropriate and respectful of identity-based norms. It is applied here to the indicators related to receipt of results with explanations. The right to know one's viral load status can be defined as an ethical obligation, and that information is relevant across the lifecycle for a diversity of reasons.	**Less than 10% of people who reported receiving a viral load test received their results.** In qualitative interviews, recipients of care explained that only those individuals with detectable VL were called to come to the facility. Those with undetectable VL might receive their results when picking up medications via multi-month dispensing or not receive them at all.	**Two-thirds of people living with HIV received viral load results with explanations about what the result meant.** Two-thirds of people living with HIV who received a viral load test also received their results; of those who did not receive results, three-quarters had been contacted to receive them. The majority of individuals who received results felt they were well-explained and felt comfortable asking questions.
QUALITY	**Challenges in steady access mean that viral load is not being used consistently to guide treatment decisions.** One-third of focus group discussion (FGD) participants had their regimens changed without viral load tests due to lack of reagents.	**The majority (70%) of people who had to change regimens did so after receiving a viral load test; of these, the majority (93%) were switched to DTG-containing regimens.** The use of the test to guide treatment decisions, the general sense that the results were explained and that it was safe to ask questions suggest the service, when available, meets quality standards.

TABLE 3: Qualitative Findings – CD4 Cell Count Testing

AAAQ[8] PARAMETER	KENYA	SIERRA LEONE
AVAILABILITY	**Most people living with HIV have received a CD4 count test but availability may have been compromised by COVID-19.** CD4 cell count is not required prior to treatment initiation. However, more than 50% of individuals reached in the quantitative survey had received a CD4 cell count test. None of the participants in the FGD (N=15) had received a CD4 cell count test since 2020. CD4 is recommended for all individuals at baseline, returning after treatment interruption or for clinical investigation. The FGDs did not ascertain whether this was because of eligibility or other issues, but did report that recipients of care may not be receiving tests due to lack of reagents.	**A total of 65% of people living with HIV (105 out of 160) received CD4 cell count tests; of these, 91% (95 out of 105) got their CD4 cell count tests prior to initiating ART. However, staff reported major issues with supplies and machines.**
ACCESSIBILITY	**Service delivery barriers impede access.** Caps on the number of recipients of care tested per day, restricted morning hours which do not work for many recipients of care, and the need to go to other facilities for the test are all impediments to accessibility noted by FGD participants.	**Roughly 18% of people (19 out of 105) who received CD4 cell count tests reported difficulties.** These included lack of reagents, inconvenient time, having to go to another site for the test, and feeling uncomfortable at the facility.
ACCEPTABILITY* *This parameter is defined as ethically and culturally appropriate and respectful of identity-based norms. It is applied here to the indicators related to receipt of results with explanations. The right to know one's CD4 count and what it means can be defined as an ethical obligation, and that information is relevant across the lifecycle and for a diversity of reasons.	**FGD participants reported limited information about the purpose of a CD4 test and meaning of the results.** Less than half reported receiving a comprehensive explanation. Others were told that the results were for the healthcare providers to decide which treatment to offer them.	**All of the respondents felt that counseling on CD4 results was fair, good, or done very well.**
QUALITY	In both Kenya and Sierra Leone, CD4 cell count is no longer required for treatment initiation or as part of routine monitoring, though it can be used in instances where recipients of care have advanced HIV disease. The nature of the data collected, which does not specify how long a recipient of care has been on treatment or whether those who had been diagnosed with AHD were (or were not) among those who did (or did not) receive CD4 cell counts, make it difficult to assess the quality parameter in this survey and suggest additional refinements for CLM on laboratory tests.	

TABLE 4: Healthcare Worker – Qualitative Data in Kenya

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM SITE STAFF OFFERING CD4 AND/OR VIRAL LOAD TESTS
What is your role in HIV-related lab services (CD4 count, viral load testing)?	Collecting samples from recipients of care, processing this sample, and preparing the results Giving results back to recipients of care when they are ready
How long have you been working at this site?	On average, the facility staff had been working with that site for five years.
Has this site had any difficulty operating normally during COVID? **What was the impact on the site?** **What was the impact on your ability to carry out your duties?**	Yes. During the COVID-19 period, there were disruptions of services resulting from several factors, including: ■ Reagents of viral load not available, leading to a testing backlog ■ Lack of commodities, such as gloves and other basics, as well as basic support for recipients of care ■ Low turnout of recipients of care and missed appointments due to lockdowns and cessation of movement ■ Most staff remaining at home ■ Machine breakdown ■ Competition for machines that were repurposed for SARS-CoV-2 diagnosis
Are there enough staff at this site to perform CD4 count and viral load testing?	Out of the 104 responses, 58 (55%) reported that there were enough staff at the sites to support CD4 and VL testing; 46 (44%) indicated that there were not enough staff to support the services.
Do you feel sufficiently trained to carry out your duties? **What type of training could help you improve in your duties?**	A total of 78 (75%) of the 104 respondents indicated that they felt that they are sufficiently trained to carry out both VL and CD4 testing, and 26 (25%) felt the need to get additional training for the services they are currently offering. Safety training, including infection prevention, and training in counselling were two highly requested areas of training for the facility staff.
Do you have the necessary equipment, materials and supplies you need to perform your lab-related functions (stockouts, malfunctioning machines)?	On equipment, materials, and supplies, 60 (58%) reported lack of necessities to perform their lab-related functions.
Have any issues with equipment, materials, and supplies been resolved quickly and adequately?	A total of 70 (67%) reported that issues with equipment, materials, and supplies were not resolved timely and adequately; 34 (33%) reported quick and adequate resolution of the issues.
How are test results communicated to recipients of care? • **CD4 count** • **VL test**	Most of the site staff indicated that results from the reference lab were communicated electronically to the laboratory and then to the Community Care Centre (CCC) site health provider or from the reference lab electronically to the CCC site in-charge officer. The in-charge officer then assigned the task of returning results to the nurse or peer mentors.

TABLE 4: Healthcare Worker – Qualitative Data in Kenya (cont'd)

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM SITE STAFF OFFERING CD4 AND/OR VIRAL LOAD TESTS
On average, how many tests of each do you perform each day? • **CD4 count** • **VL test**	The responses for this question differed depending on whether the facility offered the testing on site or sent samples to other labs for testing. Below are some of the responses: ■ "It depends on how the CCC staff books them. But on a daily basis, we harvest 10-20 samples to be taken to the reference lab. At times, it can be 50-100 if dispensaries also bring their samples to be transported to the reference lab." ■ "We do not perform VL tests, but we only collect and send to KEMRI CDC in Kisian. We collect around 100 to 200 daily." ■ "Depends on the number of clients who qualify to take the test on that particular day. Depending on clients' due dates, 2-3 clients."
On average, how many people do you counsel on their results each day? • **CD4 count** • **VL test**	In most high-volume facilities, the lab staff indicated that they did not offer counselling services. This service was provided by psychosocial and adherence counsellors. At low-volume facilities, lab staff reported offering these sessions at an average rate of 10 recipients of care per day.
How can this testing site be improved to provide CD4 count and VL testing?	■ By making sure that the machines are available and personnel are well trained and in good number ■ By providing personal protective equipment (PPE) materials, timely deliverance of equipment, and installation of a waiting bench at the waiting bay ■ By providing an adequate supply of reagents and machines to perform viral load testing ■ By providing point-of-care testing, that is, providing the site with its own equipment to conduct the tests, rather than sending them to the reference laboratory
What works well?	■ Adequate resource allocation ■ Continuous mentorship and sensitization ■ Using community health workers and peer educators ■ Integration of services and the introduction of differentiated care models ■ Efficient networks for shipping samples out and receiving results
What are the challenges?	■ Frequent stockouts ■ Long turnaround time for results ■ Less manpower, insufficient machines, machine breakdowns, reagent stockouts, and limited workspace

TABLE 5: Healthcare Worker – Qualitative Data in Sierra Leone

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM CD4 TESTING SITE STAFF	MAIN RESPONSES FROM VL TESTING SITE STAFF
What is your role in HIV-related lab services (CD4 count, viral load testing)?	**Nurse counselor:** The role includes HIV counseling and testing. The nurse counselor also assesses recipients of care to determine who is eligible for CD4 and viral load testing services. **Lab technician:** The lab technician collects samples for CD4 and viral load testing. At the majority of facilities, the lab technician collects and sends blood samples for viral load testing to the reference lab at Lakka in Freetown. Kenema Government Hospital in Kenema District has its own viral load machine. The lab technician carries out CD4 count tests at the health facility.	**Community health officer:** This person assesses recipients of care and ensures that they receive services based on their diagnosis. **Lab technician:** The lab technician collects and performs tests on samples for CD4 and viral load testing.
How long have you been working at this site?	Average in months: 54.9 months Average in years: 4.6 years **NOTE:** The above is derived by aggregating the total number of years divided by the number of respondents.	Five years and above
Has this site had any difficulty operating normally during COVID? **What was the impact on the site?** **What was the impact on your ability to carry out your duties?**	**YES: 6** **NO: 12** **Impact of COVID-19 on the facility**: During the different waves of COVID-19, some recipients of care did not keep their ART refill appointments due to fear of contracting COVID-19. **Impact of COVID-19 on healthcare workers:** There was fear of contracting COVID-19 among healthcare workers. Measures taken by the government to tackle transmission of COVID-19 included restriction of movement, which affected delivery of care to recipients of care. Even though essential workers were allowed to move or travel to their place of work, there were challenges with public transportation. Sometimes, mobile phones were used to reach out to recipients of care on treatment.	**YES: 1** **NO: 0** **Impact of COVID-19 on the facility**: A reduced number of recipients of care were opting for viral load services out of fear of contracting COVID-19.

TABLE 5: Healthcare Worker – Qualitative Data in Sierra Leone (cont'd)

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM CD4 TESTING SITE STAFF	MAIN RESPONSES FROM VL TESTING SITE STAFF
Are there enough staff at this site to perform CD4 count and viral load testing?	**YES: 15** **NO: 3**	**YES: 0** **NO: 1**
Do you feel sufficiently trained to carry out your duties? What type of training could help you improve in your duties?	**YES: 7** **NO: 1** **YES but not sufficient: 10** **Responses:** Colleagues require additional skills, like sample collection for CD4 counts, viral load testing, and problem-solving skills. Refresher training could equally be helpful.	**YES: 0** **NO: 0** **YES but not sufficient: 1** **Responses:** Among other things, staff look forward to improving their skills in ways to relate to recipients of care and in sample management.
Do you have the necessary equipment, materials, and supplies you need to perform your lab-related functions (stockouts, malfunctioning machines)?	**YES: 7** **NO: 11** **Responses:** ■ Supplies, including reagent, gloves, soap, and test kits, are usually not available or are stocked out. ■ The CD4 count machine is sometimes down due to lack of cartridges required to carry out CD4 counts. ■ Viral load machine at the reference lab at Lakka was reported to be down for over one year. ■ Reagents, sample collection kits, and cartridges are stocked out.	**YES: 1** **NO: 0**
Have any issues with equipment, materials, and supplies been resolved quickly and adequately?	**Responses on issues with equipment, materials, and supplies that were resolved quickly and adequately**: **YES: 1** **NO: 17** There are instances where the CD4 count machine was out of stock of printing paper, cartridges, and ink.	**YES: 0** **NO: 1**

TABLE 5: Healthcare Worker – Qualitative Data in Sierra Leone (cont'd)

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM CD4 TESTING SITE STAFF	MAIN RESPONSES FROM VL TESTING SITE STAFF
How are test results communicated to recipients of care? • **CD4 count** • **VL test**	**CD4 and viral load test results were communicated in the following ways:** ■ Results were communicated during visits to health facilities for ART refills. ■ Results were explained to recipients of care during their ART refill. ■ Results were attached to the files of recipients of care and later the doctor explained it to them. ■ Staff called recipients of care to give them the information. ■ Results were communicated on the same day of the test before recipients of care were initiated on treatment. ■ Results were communicated during clinical consultation and counseling at the service provision site.	
On average, how many tests of each do you perform each day? • **CD4 count** • **VL test**	**16** **NOTE:** *The above is derived by aggregating the total number of CD4 counts done by all health facilities divided by the number of health facilities.*	**10** **NOTE:** *The above is derived by aggregating the total number of viral load samples collected by all health facilities for testing divided by the number of health facilities. It is also important to note that only one health facility (Kenema Government Hospital) has a viral load machine. The other health facilities collect samples and send them to the reference lab at Lakka.*
On average, how many people do you counsel on their results each day? • **CD4 count** • **VL test**	**14** **NOTE:** *The above is derived by aggregating the total number of CD4 count results divided by the number of health facilities.*	**9** **NOTE:** *The above is derived by aggregating the total number of results received divided by the number of health facilities.*
How can this testing site be improved to provide CD4 count and VL testing?	■ We need CD4 count machine at our facility. ■ Train more staff on how to carry out CD4 count tests. ■ Provide needed machines/equipment for testing or treatment monitoring. ■ We need more cartridges, ink, and printing paper. ■ Provide all necessary equipment to carry out the work. ■ We need to have the CD4 testing machine. ■ Add to the human resources.	■ We need to get the results early. ■ Make sure the viral load test machine is active or functional. ■ Machines must be available to perform viral load tests. ■ Solve the viral load machine problem permanently. ■ We need additional buildings as testing sites. ■ Provide GeneXpert machines at hospital facilities without viral load testing machines. **NOTE:** *Responses captured views at all 15 health facilities, including Kenema Government Hospital. This hospital has its own viral load machine for viral load tests.*

TABLE 5: Healthcare worker – qualitative data in Sierra Leone (cont'd)

QUESTIONS FOR TESTING SITE STAFF	MAIN RESPONSES FROM CD4 TESTING SITE STAFF	MAIN RESPONSES FROM VL TESTING SITE STAFF
What works well?	■ Recipients of care demonstrate willingness for their samples to be taken. ■ Testing equipment, like for CD4 count, is available at health facilities. ■ Staff are available to support the process.	■ Having a microscope helps. ■ People living with HIV are always willing to have their samples taken for screening. ■ Staff are available to support the process. ■ Viral load blood sample collection works well.
What are the challenges?	■ We need equipment to carry out our service to the people. ■ Both CD4 and viral load machine are not working at the moment. ■ There is not enough space to do the work, and it floods during rains. ■ Our recipients of care are referred to another center for CD4 counts. ■ There are stockouts of printing paper, cartridges, and ink. ■ Machines malfunction and there are sometimes stockouts of test kits. ■ There are stockouts of test kits and breaking down of machine. ■ At the moment, there are no viral load and CD4 count tests taking place at the facility due to malfunctioning machines. ■ When samples are collected for viral load testing, it is sometimes challenging to take them for testing and to return test results within the two-week turnaround time.	■ We need equipment to carry out our service to the people. ■ Both the CD4 and viral load machine are not working at the moment. ■ There is not enough space to do the work, and it floods during rains. ■ Recipients of care are being referred to another center for their CD4 count tests. ■ There are stockouts of printing paper, cartridges, and ink. ■ Machines malfunction and there are sometimes stockouts of test kits. ■ We really need enough test kits. We have a new freezer but we are not using it because we don't have electricity.

Qualitative Data

Tables 2, 3, 4 and 5 provide highlights from the qualitative evidence of the two country teams. Of note, the COVID-19 response in Sierra Leone was not cited as an obstacle to availability of services in terms of reagents, equipment, and staff normally dedicated to HIV being diverted to the emergent pandemic. Government policies and repurposing of equipment did emerge as an issue in Kenya. It is possible that differences in the trajectory of COVID-19 infections, illness, and death played a role—that is, different levels of severity led to different strains on the health system and/or policies—but this study was not designed to rigorously test explanations for inter-country differences. In both countries, health workers reported recipients of care being hesitant or reluctant to come to the clinic for services and laboratory evaluation and raised concerns about defaulting.

Cross-cutting Issues

Even where national policies and guidelines support RVLT and accessible CD4 cell count tests, systemic shortages and stockouts of reagents and supplies and machinery breakdowns prevent implementation. These issues were not tied to repurposing of viral load or CD4 cell count machines during COVID-19. However, in Kenya, interviewees did report that tuberculosis diagnoses and capacity were negatively impacted by the need to diagnose SARS-CoV-2.

Current approaches to the return of viral load results do not fulfil all recipients of care's "right to know" their virologic status and should be re-examined to better align with differentiated service delivery models. In Sierra Leone, a third of recipients of care did not receive their results. While most of these were contacted for follow-up, they did not receive the information. In Kenya, only individuals with detectable viral load received outreach; many with undetectable viral load received no update or received just a simple message: "uko sawa" ("You're alright"). Differentiated service delivery models allow people living with HIV who are stable on their treatment to receive multiple months of ART at a time, often at community dispensing sites: such innovative steps should be taken to deliver information on viral load to all people living with HIV who are recipients of care.

Photo: NETHIPS

Laboratory service at Connaught Hospital in Freetown, Sierra Leone

CD4 cell count availability is impacted by infrastructure and supply challenges; it is underutilized as an advanced HIV disease (AHD) management tool. As CD4 is not part of routine HIV management and is no longer required for initiating or switching treatments, its most powerful use is in the context of AHD. The quantitative assessments, interviews, and focus group discussions did not fully discern the extent to which people with AHD were receiving routine CD4 as part of their management: some people reported receiving treatment for AHD, but there was no sampling of people with AHD who did (or did not) receive CD4 cell counts. However, it is clear from the data that CD4 cell counts are often unavailable. It is clear from the qualitative data that their crucial role in AHD management is poorly understood by recipients of care and, in all likelihood, by staff who indicated they would like additional training.

ADVOCACY ENGAGEMENT WITH KEY FINDINGS

The impact of community-led monitoring comes when communities turn the data into information and action. In Kenya and Sierra Leone, NEPHAK and NETHIPS convened meetings with data collectors and other stakeholders after the data collection and analysis phase, prioritized issues for follow-up, and devised strategies for action.

In Sierra Leone, NETHIPS worked with its Community Consultative Groups (CCGs). NETHIPS carefully selected CCGs to support with prioritization of advocacy issues and for targeting. Based on the target audience, NETHIPS planned all advocacy engagements. Advocacy engagement included report-backs and requests for remediation of key issues identified in the monitoring at health facility level, district health partner level, and national or policy level. In addition, NETHIPS used media and outreach, including radio and television discussions, jingles, letters, and emails to share key messages.

In Kenya, NEPHAK engaged with people living with HIV and recipients of care who were members of key populations and other groups engaged as data collectors, media, and public health officials at the site and subnational and national levels. Since this CLM effort was completed, the government policy on repurposing VL machines for SARS CoV-2 has shifted, and prioritized groups of people living with HIV, such as pregnant women, can now access RVLT while the country works towards ensuring that all recipients of care have full access.

Community-led monitoring of labs at the facility level led to accountability work at multiple points on the supply chain and service delivery continuum.

To tackle stockouts and equipment malfunctions that limit the availability of services, both groups engaged stakeholders at multiple points in the service delivery continuum: national-level medical stores, district pharmacies, and peripheral health units. Lack of reliable transportation between locations, paperwork requirements, and missed reporting emerged as key barriers, as did poor communication. In Sierra Leone, activists determined that the viral load facility at Lakka, which had been down for a year for repairs, had not notified facilities that depended on it for labs when it had reopened.

Commitments to solve problems and address challenges will require follow-up and additional CLM.

Both groups raised issues about breakdowns and supply shortages with relevant stakeholders, including leadership responsible for district health hospitals. In Sierra Leone, the National AIDS Control Program assured NETHIPS that the issue of stockouts would be addressed. However, months after the engagement, the issue persisted. Follow-up and additional CLM will clarify the extent to which requested changes were made and the extent to which improvements were durable or short-lived.

Dissemination of findings to recipients of care built "laboratory literacy" and expanded the community of engaged advocates, linking community-led monitoring to demand generation in a powerful combination.

In both pilot countries, activists presented the results from the lab-focused CLM to recipients of care. These presentations were used as an opportunity to provide information on the rationale and national guidelines for the specific tests—informing people of their rights as health consumers and also providing a snapshot of how those services are actually being provided. Participants built understanding of the importance of VL and the use of CD4, particularly related to advanced HIV disease, and were motivated to share their experiences and priorities with health facilities.

DISCUSSION AND RECOMMENDATIONS

This pilot study confirms that monitoring guidelines and policies on how and what recipients of care should expect and be able to access in terms of RVLT and CD4 cell counts cannot be used as a proxy for coverage and access to these tests. Stockouts and breakdowns at the facility level, staff shortages, and other factors mean that the services are often not available. When they are available, the results are often not returned to recipients of care. Both viral load and CD4 cell count results can be motivating and empowering to people living with HIV as they make treatment decisions and experience their outcomes. Indeed, tracking and improving the rate of return of results of RVLT is likely to be crucial to reaching the UNAIDS "95" target for virologic suppression. Simply or solely tracking guidelines and rates of virologic suppression leaves out crucial information about service availability and quality. This pilot strongly supports the case for CLM focused on laboratory services, with an expanded and refined set of indicators, as described below. This CLM should be aligned to and matched with monitoring, reporting, and accountability frameworks supported by national and subnational health systems to ensure that policies translate into practice and that the lab conveying results is a central part of person-centered care.

1

CLM implementers, national governments, and relevant funders must develop and align indicators that monitor key elements of viral load and CD4 test availability.

These could include indicators tracking continuous availability (the months a machine is operating in a given facility) and/or the number of people living with HIV (disaggregated by gender, age, and key population status) who have received the laboratory evaluations recommended in national guidelines. While most people with HIV had one or both tests at some point in their care, this CLM effort suggests that these tests are not routinely and consistently used and that people with undetectable viral loads are not receiving their results, even though this information is, arguably, just as valuable to the recipient of care as the information that there is unsuppressed virus.

2

National governments should, with engagement and input of people living with HIV, develop messages, materials, and, where needed, updated guidelines that simplify, clarify, and set indicators for measuring the use of CD4 cell tests in the context of AHD.

Return on investment for CD4 cell count machines, supplies, and staff time for recipients of care and communities depends on tracking where and how this test is used, the ways that it guides decision-making, and recipients of care's understanding of their treatment choices and decisions. CD4 cell counts are no longer a prerequisite for treatment initiation or monitoring, but remain a key tool for the management of AHD. This study strongly suggests that recipients of care and health facility workers are not seeking or using CD4 cell counts as a key tool for AHD management.

3

CLM for laboratory service availability should be resourced to include monitoring and visits to locations other than health facilities: central laboratories, national medical and laboratory supply centres, and regional pharmacies.

Such monitoring could be built into the follow-up to initial facility-based monitoring and agreed to as part of follow-up actions during dissemination of initial results.

This CLM initiative identified issues at multiple levels of the health quality framework. However, issues with availability must be tackled to ensure that supplies, machines, and staff are available as needed. While the effort was focused on the facility level, these systemic challenges with procurement and supply chain management require intervention at multiple points along the continuum of service delivery. In many instances, follow-up advocacy led to stakeholder commitments to solve problems. However, CLM is needed to ensure that the solutions are implemented and have the desired impact. In some instances, the "fix" may occur at a site or stage in the supply chain that is physically removed from the facility where the problem was identified.

4

National ART programs, in collaboration with civil society and led by people living with HIV, should rapidly assess rates of the return of results, identify best practice approaches, and then test, evaluate, and scale up strategies that work.

Return of results, particularly for RVLT, is a major challenge. Multi-month dispensing and community-based delivery models mean that many recipients of care do not have other reasons to return to facilities after their samples have been collected. In Kenya, many recipients of care with undetectable viral loads appeared to be deprioritized for receiving their results. Recipients of care who were asked to come to the clinic did not always return for their results—with no additional follow-up. Across both countries, there appears to be a misalignment with differentiated service delivery models that ease the burden on recipients of care on the one hand and approaches that ensure that all recipients of care receive their results with a clear explanation in a timely manner. There is a range of approaches, from SMS-based communication and telemedicine to point-of-care diagnostics, that can be explored to improve the rates of return of results without changing service delivery models that are convenient for recipients of care, ease the burden on health workers, and help decongest health systems.

5

Funders and implementers of a CLM framework should share experiences and refine indicators to capture the extent to which people are receiving labs per national guidelines and in alignment with their health status.

In this pilot initiative, most people living with HIV surveyed had received a viral load or CD4 cell count test at some point after their diagnosis. In both countries, more people had received those tests before COVID-19 than in acute and subsequent phases of the pandemic. This suggests, and qualitative interviews corroborate, that the pandemic led to some of these disruptions. However, more information is needed to fully understand the relationship between reported testing experiences and time since treatment initiation and/or disease status. National guidelines call for more than one viral load test in the first year of treatment, and one annually after a recipient of care is undetectable. CD4 cell counts are not indicated as a criterion for treatment initiation or as part of standard monitoring. To better understand whether services are being delivered per guidelines, it will be important to develop tools that, while respecting confidentiality and upholding ethical standards, provide CLM-derived insights into the experience of recipients of care.

6

CLM implementers should refine lab monitoring indicators and ensure robust accountability work.

CLM implementers, including ITPC, learn from each monitoring project. In this pilot project focused on labs, limitations on how the indicators were designed and/or used included an inability to link answers about accessibility, acceptability, and quality to clinical and other information that could further indicate whether tests had been administered on time as indicated. Indicators on the timing of return of results were not always adjusted or tied to national policies or local clinical practice—in the context of multi-month dispensing, a recipient of care will not always return to the site where the laboratory work was done within two weeks for results.

The full cycle of community-led monitoring work includes focused and sustained engagement to secure changes and shifts based on the findings. In this effort, the shifts—which include systemic changes in supply chains, staffing, and service delivery approaches—have, by and large, not yet occurred. Nor will they occur if CLM focuses solely on monitoring and analyzing data. It is essential that groups have resources and technical support to pursue advocacy and accountability actions based on findings, and that the systems for tracking progress and capturing these outcomes be as robust as the data collection phase.

Photo: NETHIPS

Community monitors conduct data collection at Princess Christian Maternity Hospital in Freetown, Sierra Leone

CONCLUSION

This study occurred as the HIV and COVID-19 pandemics collided in countries all over the world. As these findings underscore, COVID-19 exacerbated issues with accessibility of viral load and CD4 cell count tests, but it did not cause root problems. The "new" pandemic shone a harsh light on old and enduring problems with supply chains, procurement, repair, transportation, and staff shortages that hinder availability of RVLT, CD4 cell count tests, and other diagnostics and treatments. These problems pre-date COVID-19 and persist even as attention on the global crisis wanes. In both Kenya and Sierra Leone, guidelines and policies for viral load and CD4 cell count testing exist that reflect WHO-endorsed best practices. Often these policies were adopted as a result of advocacy and demand generation by people living with HIV who understand that person-centered care requires routine lab monitoring along with clear and timely explanation of the results. As this pilot shows, these policies do not translate into practice on the ground.

COVID-19 itself also highlighted the extent to which normative agencies, funders, countries, and communities are ill-prepared for routine testing and provision of results for most pathogens, whether emergent or established. WHO delayed recommending rapid antigen diagnostic tests for low- and lower-middle-income countries, creating bottlenecks for procurement and deployment of these tests and the most effective treatments for acute disease. Today, there are enormous challenges with ensuring that countries and communities have the laboratory systems for testing, the human resources for returning results, and the community support systems for ensuring that these results translate into better health outcomes. If these challenges are not resolved, the UNAIDS "95" target for virologic suppression will not be realized, HIV will persist as a pandemic, and future outbreaks will not be detected and contained. Against this backdrop of urgency, ITPC and its partners are committed to expanding on this pilot to make CLM of laboratories and results a routine part of our collective effort to realize the right to health for all.

Photo: NEPHAK

A data collector interviews a member of staff at a laboratory in Kisumu, Kenya

ENDNOTES

1 World Health Organization Global HIV, Hepatitis and STI Programme. 2022. Latest HIV estimates and updates on HIV policies uptake, July 2022. https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/2022_global_summary_web_v12.pdf

2 World Health Organization. 2022. "Key Facts: HIV." July, 2022. https://cdn.who.int/media/docs/default-source/hq-hiv-hepatitis-and-stis-library/key-facts-hiv-2021-26july2022.pdf?sfvrsn=8f4e7c93_5

3 World Health Organization. 2021. Updated Recommendations on Service Delivery for the Treatment and Care of People Living with HIV. April 2021. https://www.who.int/publications/i/item/9789240023581

4 WHO (ibid above) states that CD4 cell count >200 plus another objective adherence measure, such as weight gain, can be used as an indicator that a person with HIV is stable on ART treatment—and therefore eligible for multi-month dispensing and other differentiated service delivery approaches.

5 World Health Organization. 2017. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. July 2017. https://www.who.int/publications/i/item/9789241550062

6 World Health Organization. 2020. Package of care for children and adolescents with advanced HIV disease: stop AIDS. July 2020. 2020. https://www.who.int/publications/i/item/9789240008045

7 IFHHRO: Medical Human Rights Network. "AAAQ Framework." https://www.ifhhro.org/topics/aaaq-framework/

8 IFHHRO: Medical Human Rights Network. "AAAQ Framework." https://www.ifhhro.org/topics/aaaq-framework/

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