

‘Nairobi Declaration’ on Access to CD4 Testing to Identify People in Need of the AHD Package of Care and Reduce AIDS-related Deaths

May 21, 2024

Introduction

We are people living with HIV (PLHIV), representatives of ministries of health and national HIV programmes from 12 African countries, clinicians, programme implementers and implementing partners, researchers, academics, non-governmental organizations (NGOs), community and civil society groups who participated in a meeting in Nairobi, Kenya, 20-21 May, 2024 on scaling up access to advanced HIV disease (AHD)¹ services and tools.

We must address unrelenting AIDS deaths and suffering now.

Despite more than two decades of progress scaling up access to HIV testing and care, including antiretroviral therapy (ART), AIDS-related deaths have persisted at more than 600,000 per year over the last four years, including 630,000 in 2022 alone. People with AHD are at the highest risk of death and the most common causes of death among this group are tuberculosis (TB), cryptococcal meningitis (CM), and severe bacterial infections (SBIs). There are an estimated 4 million people with AHD.

AHD develops due to poor access to ART, treatment interruption, and treatment failure. The World Health Organization (WHO)-recommended AHD package of care includes tools to better screen, diagnose, treat, and prevent AHD, including TB, CM, and SBI prophylaxis and treatment. Early pre-symptomatic screening relies on CD4 count testing to identify those in need of the AHD package of care. CD4 testing – as an essential gateway into life-saving care – therefore needs to be scaled-up, available, and fully funded.

There are numerous other urgent AHD priorities, which have been identified during the meeting in Nairobi, many of which need to be acted upon immediately, including enablers for successful AHD testing, prevention, and treatment. These include improved clinical and laboratory referral systems, robust monitoring and evaluation, strengthened procurement and supply management, adequate external and national funding, community engagement and supported leadership, and improved inpatient, paediatric, and follow-up care.

But the CD4 crisis requires immediate and concerted attention and action now.

The CD4 crisis

For many years, ART was only given to people with CD4 counts below 200 cells/mm³ (and later, 350 and then 500 cells/mm³), as these were understood to be the individuals at highest risk of death. As such, CD4 testing was a mainstay of national HIV programmes for ART initiation and monitoring. However, since the treatment paradigm shifted from ‘rationing’ ART to those with the weakest immune systems to ‘test-and-treat’ for all people with HIV irrespective of CD4 count, CD4 testing has been de-prioritised – in terms of attention, support, and usage.

¹ Defined by WHO as CD4 cell count <200 cells/mm³ or WHO stage 3 or 4 (adults and children over five years); children with HIV below five years of age are also considered to have AHD, except those who have been receiving antiretroviral therapy for more than one year, and who are clinically stable.

As Ford et al write in a recent *New England Journal of Medicine* Perspective, “This change led to the perception that CD4 testing was no longer essential. To help pay for increased treatment coverage and assessment of its impact on virologic outcomes, donors and countries reduced their support for CD4 testing, and testing rates within ART programs declined rapidly [often in favor of viral load testing].”² Viral load (VL) testing is essential, but must not come at the expense of CD4 testing, which is equally critical for clinical management as well as identification of those at highest risk of death.

In response to reduced demand for CD4 testing following the switch from CD4 to VL for treatment monitoring, Abbott announced the discontinuation of the production of PIMA instruments; however, CD4 testing cartridges would continue to be available (for an unspecified time). In November 2022, BD Biosciences also announced the discontinuation of the production of BD FACSPresto CD4 instruments, and reagent cartridge orders will be terminated at the end of 2024. A significant number of high HIV burden countries have a large footprint of these POC CD4 devices in sub-Saharan Africa. Two years later, CD4 supply issues have persisted with no resolution of the problems in sight, as have their demand corollaries: the need for communities, clinicians, and governments to go back to basics and (re-)learn the importance of CD4 testing for clinical care.

These point-of-care (POC) CD4 devices, which are the only WHO-prequalified POC systems for CD4 counting, enabled rapid CD4 result delivery and clinical decision-making. With virtually no POC CD4 instrument options in the market, national programmes now have to make difficult but quick decisions to divert CD4 testing from these preferred POC instruments.

Alternatives include centralized/conventional tests that provide quantitative CD4 counts, which are beneficial for clinical management, but require prompt CD4 sample transport to testing laboratories within 48 hours from collection and a longer turnaround time than POC. Another option is Visitect, a disposable POC lateral flow CD4 test, that could be used at decentralized health facilities. It offers a semi-quantitative CD4 result at a threshold of 200 cells/mm³ within 40 minutes, but requires multiple steps and needs to be simplified.

Without CD4 cell count testing, programmes will not have the ability to identify people with AHD, particularly those who are asymptomatic, and provide further screening for opportunistic infections, as well as subsequent therapeutic interventions. Without widely available CD4 cell count testing, ending AIDS as a public health threat by 2030 will be impossible.

Call to action

We call for a comprehensive roadmap and concerted action to support the development, production, introduction, and scale-up of new effective CD4 technologies, including point of care tools, and a 3-5 year action plan to ensure a ‘bridge’ that will guarantee access to existing tools. Specifically, we call upon all relevant actors – including WHO, donors, global health actors, national programmes, companies/manufacturers, and regional bodies – to take the following actions:

² Ford N, Ehrenkranz P, Jarvis, J, Advanced HIV as a Neglected Disease, *N Engl J Med* 2024;390:487-489
DOI: 10.1056/NEJMp2313777, [VOL. 390 NO. 6](https://doi.org/10.1056/NEJMp2313777)

Immediate term (before end 2024)

- National programmes to conduct diagnostic network optimization (DNO) for CD4 testing instruments so as to map location and functionality of POC or conventional instruments.
- Manufacturers to reverse their decision to stop manufacturing instruments and/or POC CD4 consumables as soon as possible and commit to sustain production until countries have stable alternatives, regardless of product-specific earnings.
- Manufacturers to commit to reasonable and sustainable CD4 test prices.
- If WHO deems it necessary, manufacturers to urgently refurbish the majority (+/-2000) of non-functional POC CD4 instruments (PIMA and/or FACSPresto) and redistribute according to national programmes' plans to address under-served areas.
- Global health actors and governments to collectively secure CD4 production capacity and supplies (POC and consumables) at favorable prices to allow for at least a tripling of CD4 coverage for PLHIV as part of their ART work-up and return to care.
- WHO to provide a tool for countries to forecast CD4 volumes based on epidemiological data.

Medium term (3-5 year 'bridge')

- Governments to secure conventional high through-put CD4 testing instruments and scale up centralized and district level CD4 testing with assurance of prompt and reliable sample and result transport.
- WHO to lead exploration of the implications of semi-quantitative LFA tests with a threshold of 200 cells/mm³ and consequences of requiring all other subsequent screening and prophylactic guidelines to use the cut-off of 200 cells/mm³.
- WHO to provide normative guidance on use of semi-quantitative CD4 lateral flow assay (LFA) in screening for AHD.
- Global health actors and governments to collectively engage industry about lapses and gaps in implementing service and maintenance agreements.
- WHO to coordinate design of national monitoring and evaluation frameworks for reporting on facility coverage (% of outpatient facilities equipped with CD4 and the AHD package), CD4 coverage (% of people starting ART and returning to care who received a CD4 test result), and AHD rates and outcomes, in order to inform forecasting of commodities and national programme management.
- Donors to fund national community and civil society organizations' literacy and accountability work to increase demand for and availability of CD4.
- Global health actors to promote CD4 tests as an essential component in national HIV programmes.
- Civil society to develop and maintain online trackers and 'heat maps' noting where procurement levels dip below 75%, 50%, and 25% of need.

Long term

- Global health actors to model future demand, make business cases, and explore options for regional manufacturing.
- Africa CDC and other relevant actors to explore regional manufacturing and technology transfer for recently discontinued POC CD4 instruments (PIMA and FACSPresto) as well as simplified LFAs.
- Global health actors to support development of simplified and accurate CD4 POC tests: semi-quantitative LFA tests with fewer manipulation steps, longer shelf life, automated test reader and digitisation of results, and not affected by sample type (venous or capillary blood); and

quantitative systems that are accurate, robust, affordable and comes with adequate service and maintenance plans.

- WHO to provide guidance regarding optimal placement of new CD4 technologies (e.g. LFAs at community and primary health care levels and quantitative technologies at hospitals).

To endorse the Declaration, click [here!](#)

Signed

Representatives of ministries of health and national HIV programmes from the following countries:

- Central African Republic
- Democratic Republic of Congo
- Ethiopia
- Guinea
- Kenya
- Malawi
- Mozambique
- Nigeria
- Sierra Leone
- Tanzania
- Uganda
- Zimbabwe

The following community groups, civil society organisations, and NGOs:

- AfroCAB
- The Aurum Institute, South Africa
- Coalition for Health Promotion and Social Development (HEPS), Uganda
- Coalition of Women and Girls Living with HIV (COWLHA), Malawi
- COMPASS Zimbabwe CSO Coalition, Zimbabwe
- The CQUIN Network/ICAP, Kenya
- Dandora Community Aids Support Association (DACASA), Kenya
- Dignity and Wellbeing For Women Living with HIV, Tanzania
- Drugs for Neglected Diseases initiative (DNDi)
- Elizabeth Pediatric AIDS Foundation, Kenya
- End AIDS Action Group
- Fight AIDS Coalition (FAC)
- Global Network of People Living with HIV (GNP+)
- Journalists Against AIDS (JAAIDS), Nigeria
- Médecins Sans Frontières (MSF)
- Mozambique Treatment Access Movement (MATRAM), Mozambique
- Network of People Living with HIV/AIDS in Nigeria (NEPWHAN), Nigeria
- Partners in Hope, Malawi

- Solthis, France

The following academic/research institutions and entities:

- Center for Global Health Policy & Politics, O'Neill Institute for National & Global Health Law, Georgetown University, US
- Department of Clinical Medicine and Therapeutics, University of Nairobi, Kenya
- Department of Paediatrics and Child Health, Stellenbosch University, South Africa
- Infectious Diseases Institute, Makerere University, Uganda
- St. George's, University of London, UK
- Innovation in Global Pediatric Infectious Diseases, Fundación Hospital 12 de Octubre, Complutense University, Spain