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THEMATIC SEGMENT BACKGROUND NOTE

Testing and HIV

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Summary

1. HIV testing services are the gateway to HIV prevention, treatment, care and other support services. This background note for the 53rd meeting of the Programme Coordinating Board discusses HIV testing and diagnosis in relation to monitoring treatment and identifying comorbidities (e.g., tuberculosis and cryptococcal meningitis), sexually transmitted infections, viral hepatitis and noncommunicable diseases.

2. The note identifies current gaps in reaching the first of the 95–95–95 targets of the treatment cascade,[1] as well as gaps in accessing viral load, CD4 count and other tests that are recommended for people living with, at risk of or affected by HIV. Those people include key populations,[i] pregnant and breastfeeding women and persons,[ii] infants and children, adolescents and young people, men, and other populations, such as Indigenous and migrant populations, orphans, street children, older adults, migrant and other mobile populations, and populations in emergency and humanitarian contexts.

3. Challenges that pose barriers to the delivery of testing and monitoring services are discussed. They include:
   - legal and policy environments (such as laws criminalizing HIV transmission or nondisclosure, and policies and laws regarding age of consent for HIV testing and mandatory testing);
   - social norms (such as stigma and discrimination); and
   - health system constraints and shortcomings (such as not allowing trained lay-providers to perform rapid diagnostic testing, high-demand countries' dependency on importation of testing commodities, and procurement and supply chain management challenges).

4. The important role of community-led organizations in advocating for and implementing HIV testing and monitoring services is noted, as are the challenges that limit their contributions to the HIV response. Those challenges include a lack of legal status, a failure to recognize the value of community-led service provision, an absence of mechanisms to finance these organizations, a lack of standardized methods for measuring their contributions to HIV testing and monitoring, and funding shortages.

5. Informed by country experiences, the background note highlights models and approaches for filling the gaps and improving HIV testing and monitoring. Those approaches include the decentralization of HIV testing services; differentiated, multipronged approaches (including community- and facility-based, integrated and people-centered services); HIV self-testing (either in facilities or in the community);

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[i] "Key populations, or key populations at higher risk, are groups of people who are more likely to be exposed to HIV or to transmit it, and whose engagement is critical to a successful HIV response. In all countries, key populations include people living with HIV. In most settings, gay men and other men who have sex with men, transgender people, people who inject drugs, and sex workers and their clients are at higher risk of exposure to HIV than other populations. However, each country should define the specific populations that are key to their epidemic and response based on its epidemiological and social context. […] The term 'key populations' is also used by some agencies to refer to populations other than the four listed above. For example, prisoners and other incarcerated people also are particularly vulnerable to HIV; they frequently lack adequate access to services, and some agencies may refer to them as a key population." See: Global AIDS Strategy 2021–2026.

[ii] Throughout this guidance, the term "pregnant women and persons" is used to refer to pregnant women and trans and gender-diverse people who can get pregnant. While the majority of persons who are or can get pregnant are cisgender women (who were born and identify as female), this guidance is also inclusive of the experiences of transgender men and other gender-diverse people who may have the reproductive capacity to get pregnant.

greater investment in community-led AIDS responses; social network approaches; allowing trained lay-providers to perform rapid diagnostic testing; and awareness-raising and peer-led outreach to increase demand for testing for HIV diagnosis and to monitor disease progression. The importance of quality assurance for HIV testing and the role of public laboratory systems to improve financing and sustainability of HIV testing are also emphasized.

6. All stakeholders in the HIV response are encouraged to contribute to creating and maintaining an enabling environment and to optimize the reach of sustained, quality HIV testing services. This can be done through a range of activities:
   - Implementation of the latest World Health Organization technical guidance pertaining to testing to prevent misdiagnosis including by using the global testing strategy standard of three serial HIV tests, retesting before initiating antiretroviral therapy, using HIV tests that have been prequalified by the World Health Organization, and instituting quality management systems.
   - Advocacy for and implementation and enforcement of antidiscrimination laws, and making age-of-consent laws and policies work in the best interest of adolescents who need HIV testing services.
   - Creating an enabling policy and regulatory framework that allows for the formation, operation, funding and engagement of civil society organizations in the provision of HIV testing, including HIV self-testing.
   - Mobilizing resources to support capacity building and engagement of community organizations in service provision.
   - Scaling up point-of-care early infant diagnosis as part of ending paediatric AIDS.
   - Supporting continued scale up of viral load testing and continued scientific research and messaging on "undetectable = untransmittable", in accordance with the World Health Organization guidelines[iii], for incentivizing people living with HIV for regular testing and uninterrupted treatment including the latest scientific evidence showing that a person with an undetectable viral load has zero risk of transmitting HIV sexually to others.
   - Expanding access to CD4 count testing as the gateway for identifying persons with advanced HIV disease, and supporting a comprehensive service delivery package for advanced HIV disease, including testing and treatment for common coinfections such as TB and cryptococcal meningitis.
   - Considering Trade-Related Aspects of Intellectual Property Rights[iv] options to improve access to affordable testing commodities, and to improve system efficiencies and sustainability of HIV services, including HIV testing.
   - Improving the quality of testing services including through programmes such as "Strengthening Laboratory Management Toward Accreditation", and "Strengthening Laboratory Quality Improvement Process Towards Accreditation".
   - Encouraging diagnostic integration efforts, when appropriate, to streamline testing across multiple infections, such as HIV, hepatitis, tuberculosis, sexually transmitted infections and COVID-19.

[iii] https://www.who.int/publications/i/item/9789240055179

[iv] The Trade-Related Aspects of Intellectual Property Rights includes several “flexibilities” which signatories can use to protect public health, as outlined in the 2001 Doha Declaration. See: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

- Encouraging research and innovation to make more low-maintenance and affordable point-of-care technologies available.
- Providing HIV testing services in line with the World Health Organization's essential "5 Cs": consent, confidentiality, counselling, correct test results, and connection/linkage to prevention, care and treatment.

7. Recommendations for further improvement are outlined, including recommendations for the Joint Programme, Member States, civil society and community organizations, donors, multilateral partners and the private sector.

Background

8. The Programme Coordinating Board (PCB), at its 51st meeting in December 2022, agreed that the thematic segment at the 53rd meeting would focus on testing and HIV. This note provides the background information for this thematic discussion, which will address priority issues pertaining to testing for HIV diagnosis and testing for people living with HIV as needed, including monitoring treatment.

9. The 2021 Political Declaration on HIV and AIDS: Ending inequalities and getting on track to end AIDS by 2030,[2] and the Global AIDS Strategy 2021–2026: End inequalities, end AIDS,[1] require that, in all countries, by 2025, 95% of all people living with HIV should know their HIV status; 95% of people living with HIV who know their HIV status should have initiated treatment; and 95% of people on treatment should be virally suppressed. These are referred to as the "95–95–95 targets".

The global situation

10. HIV testing services are the gateway to HIV prevention, treatment, care and other support services. Some countries are close to reaching or have met the first 95% target,[3] but many still have challenges and gaps for specific populations, and there is a dearth of HIV testing data particularly for key populations.[4] There are also missed opportunities to link people to appropriate and effective prevention, treatment, care and other support services.

11. In 2022, there were approximately 39.0 million people worldwide living with HIV, of whom 1.5 million [1.2 million – 2.1 million] were children (0–14 years old).[5] In 2022, 86% [73–98%] of all people living with HIV knew their status.[5] Only 63% of children living with HIV (or their parent/caregiver) knew their (or their child's) status.[6]

A brief history of HIV testing technologies

- Since 1985, when the first commercial blood test for HIV was approved by the United States Food and Drug Administration, there has been a continuous push to make testing quicker and more accessible and accurate. The first HIV tests were laboratory based. Blood samples were sent to laboratories and the results were returned to individuals, often several weeks later.
- Rapid diagnostic testing has brought major changes. **Rapid tests** have been available for over a decade and are now the most commonly used method for HIV testing. These tests can be performed outside laboratories and the results can be provided rapidly to individuals, often in under 30 minutes, making them ideal for testing in primary health-care sites and community settings. Community health workers and lay providers can perform rapid assays (with a minimum set of competencies as defined by the national programme) using finger-prick-blood or oral fluid samples. The World Health Organization (WHO) has prequalified six HIV rapid tests for people to test themselves, five of which are blood-based and one of which uses oral fluid. Other self-tests are in the pipeline.
- **HIV self-tests**, which many people find empowering and convenient, are becoming increasingly available and widely used. Nearly 100 countries have national policies supportive of HIV self-testing and at least 92 of those countries have products registered. Another 30 countries are in the process of developing policies. In 2022, a total of 17 million self-tests were used, a number that is expected to rise.
- HIV infection in infants and young children younger than 18 months of age can only be detected using nucleic acid testing because maternal HIV antibodies are transmitted across the placenta in utero and remain detectable in infants for up to 18 months. Maternal HIV antibodies are also transmitted to infants via breastfeeding.
- All HIV testing services must be provided in accordance with WHO's essential "five Cs": consent, confidentiality, counselling, correct test results and connection or linkage to prevention, care and treatment.

12. An estimated 76% [65–89%] of people living with HIV in 2022 were accessing antiretroviral therapy (ART), and 71% [60–83%] had a suppressed viral load.[5] Progress for children has been slower: only 57% [44–78%] of all children living with HIV were receiving ART in 2022, and only 46% [36–63%] had a suppressed viral load.[6]

13. To reach the second 95–95–95 target, which focuses on ART access, about 3.5 million additional people living with HIV need to know their HIV status and start treatment.[6] It is essential to focus on increasing HIV testing among people who are at risk of HIV infection, particularly people who are left behind.

14. An HIV status-neutral approach[v] to HIV testing should be used to focus on people at risk of HIV infection. For people who know their HIV status, the approach should include timely post-test counseling with linkage to prevention, care and treatment interventions, including combination prevention programmes. The latter include condoms, pre-exposure prophylaxis against HIV (PrEP), post-exposure prophylaxis (PEP), voluntary medical male circumcision (VMMC), harm reduction for people who inject drugs, ART, tuberculosis (TB) screening and treatment, sexually transmitted infection (STI) services, mental health, and other supportive services. It also has to be recognized that some people presenting for HIV testing will have previously tested HIV-positive, but may not have been linked to ART or may have disengaged from care. Those are opportunities to incorporate them back into HIV services.

15. Achieving targets for HIV testing, case finding, ART coverage and viral suppression will require multisectoral, multifaceted and integrated approaches. Governments, communities and the private sector all have roles to play in maximizing the reach and uptake of HIV testing and in ensuring sustained linkage to HIV and other services.

Gaps and challenges

Gaps in testing for HIV diagnosis

Key populations

16. Members of key populations (i.e., gay men and other men who have sex with men, sex workers, transgender people, people who inject drugs, as per the Global AIDS Strategy 2021–2026 definition) are disproportionately affected by HIV, viral hepatitis and STIs.[7-11] Substantial gaps exist in the diagnosis and treatment of viral hepatitis and STIs, especially for populations who are most vulnerable to HIV.[12] These gaps highlight missed opportunities to integrate services that can be especially beneficial for key populations. Sustainable strategies for improving linkages between HIV and other services are needed to maximize the use and impact of resources.

17. Awareness of HIV status is below the 95% target (across all population groups, genders and ages) among key populations in many countries where these data are available.[3] The median proportion of key population communities who have recently tested for HIV and received their testing results is insufficient for these populations to benefit fully from combination prevention and treatment services. Global data on HIV testing and awareness are not always available for key populations and are especially limited for transgender people and people who use or inject drugs. There are gaps in service uptake across the full continuum of HIV services among key populations.[3] Data for other

[v] A status neutral approach is a person-centred approach to HIV prevention and care that emphasizes high-quality care to engage and retain people in services regardless of whether the services are for HIV treatment or prevention. A status-neutral approach continually addresses the health-care and social service needs of all people affected by HIV so that they can achieve and maintain optimal health and wellbeing.

priority population groups such as migrants, Indigenous peoples, and people living in humanitarian settings are often not collected or reported as official data within specific contexts.

Pregnant and breastfeeding women and persons

18. An estimated 1.2 million [940 000 – 1.5 million] women and girls living with HIV became pregnant in 2022.[13] Without effective interventions, the rate of vertical transmission of HIV to children during the perinatal and breastfeeding period ranges from 14% to 48%.[14]

19. In 2022, an estimated 130 000 new HIV infections occurred among children globally.[5] Approximately 65 000 of those infections were attributable to a failure to diagnose women living with HIV during pregnancy and start them on HIV treatment. Over 27 000 additional child infections were attributable to mothers acquiring HIV during pregnancy or breastfeeding without being diagnosed. In addition, about 29 000 infections in children were attributable to mothers discontinuing treatment during pregnancy or breastfeeding and not being virally suppressed. Vertical transmission of HIV can be prevented by conducting HIV testing during pregnancy and after delivery until cessation of breastfeeding, by initiating and sustaining treatment initiation, and by providing additional prevention choices in high-burden settings for women who are HIV-negative.

20. HIV testing during pregnancy is key for preventing vertical transmission, including identifying women with HIV late in pregnancy, postpartum or during breastfeeding. Timely HIV diagnosis is necessary to initiate ART for pregnant women living with HIV and reduce maternal viral load, thereby decreasing the risk of HIV transmission from the mother to the infant. In high-incidence settings, PrEP can also be offered to HIV-negative pregnant and breastfeeding women and persons to prevent both maternal and infant HIV acquisition.

Infants and children

21. In 2022, approximately 1.5 million [1.2 million – 2.1 million] children [0–14 years old] were living with HIV, only 57% [44–78%] of whom were on treatment.[5] Although children comprise only about 4% of people living with HIV, they account for 13% of deaths due to AIDS. In 2022, approximately 40% of infants who were HIV-exposed globally had not received testing by the second month of age,[6] as per WHO recommendations,[15] thus precluding the opportunity to link infants diagnosed with HIV to treatment as early as possible. Early diagnosis and rapid treatment of HIV infection in infants are essential due to the high morbidity and mortality among untreated infants in their first year of life.

22. The ongoing risk of acquiring HIV during breastfeeding can delay the final determination of HIV status beyond 18 months. However, HIV testing coverage among children over 12 months is generally low. Diagnosis of HIV infection in infants and children throughout the exposure period is needed to identify all infants and children living with HIV who need treatment. In 2016, the World Health Organization (WHO) recommended that, in settings with a high burden of HIV infection, infants and children with unknown HIV status who are admitted for inpatient care, attend services such as malnutrition clinics or have indicator conditions, should be routinely tested for HIV.[16] In addition, as good practice, the biological children of a parent living with HIV or who may have died from HIV should, in all settings, be routinely offered HIV testing services and linked to treatment, as necessary.[16]

23. There is considerable variability in HIV testing coverage regionally. In 2022, infant diagnosis coverage was approximately 83% [69–98%] in eastern and southern Africa,

but only 23% [19–29%] in western and central Africa. It is vital that all HIV-exposed children are tested for HIV infection as early as possible and that those living with HIV are linked to treatment services within the context of comprehensive, child-centred care.

Adolescents and young people

24. In some settings, adolescents (10–19 years) are at high risk of HIV but have low rates of testing.[17-20] For example, in 2015–2020 in the Asia and Pacific region, less than half of young people (under 25 years) from key populations had taken an HIV test in the previous 12 months and knew the result of their test.[21] Critical testing gaps have been identified also among pregnant adolescents.[22-25]

Men

25. In 2022, more than 640 000 men (15 years and older) acquired HIV. Of them, 83% [70–98%] knew their HIV status.[5] However, in most regions, men living with HIV are less likely to know their status than women, and treatment coverage and viral suppression rates are often lower among men than women.[3]

26. Outside of sub-Saharan Africa, the HIV epidemics are concentrated largely in key populations. There, men account for two-thirds of all adults with HIV and they are more than twice as likely as women to have acquired HIV recently.[26]

27. Existing HIV testing practices and provisioning are not well-suited to the needs of men.[27] A combination of individual- and system-level factors present barriers to accessing and using HIV testing services. They include inconvenient clinic hours or locations (especially for employed men); transport and out-of-pocket expenses; and the opportunity costs of obtaining services (e.g., lost work earnings).[27] As a result, many men do not access HIV testing and many of those who do test HIV-positive are not promptly linked to treatment and care. Men generally are also less likely to adhere to treatment. In many settings, HIV mortality rates among men therefore are higher than among women.

Indigenous populations

28. Indigenous populations experience multiple inequalities and are disproportionately affected by HIV, viral hepatitis, STIs and other communicable and noncommunicable diseases.[28-38]

29. There are over 5,000 distinct Indigenous population groups globally.[39] It is generally recognized that Indigenous peoples have poor access to health services due to factors that include geographic isolation, poverty and discrimination. However, data pertaining to HIV testing and engagement in care across the HIV cascade among Indigenous populations are limited. The available data show low rates of HIV testing among Indigenous populations.[31,40]

30. In general, obtaining comprehensive and accurate data on HIV incidence among Indigenous populations is difficult, since very few countries collect Indigenous-specific data at the national level.[41] Gaps in surveillance data present a major challenge to developing appropriate health interventions and monitoring programmes.[42]

Other priority populations

31. Priority populations are groups of people who are important for the HIV response because they are at increased risk of acquiring HIV or are disadvantaged as people living with HIV due to combinations of societal, structural or personal circumstances. In addition to people living with HIV and the defined key populations who are important to HIV responses in all settings, countries may identify other priority populations if there is clear local evidence of increased risk of acquiring HIV, dying from AIDS-related causes or experiencing other negative HIV-related health outcomes. These populations may include adolescent girls and young women and their male partners in locations with high HIV incidence, sexual partners of key populations, people with disabilities, Indigenous peoples, migrants and other mobile populations, and others. Workers in certain industries, such as mining, fishing and long-distance truck drivers, may also face increased vulnerability to HIV.

32. Humanitarian emergencies, such as natural disasters, conflicts and pandemics, disrupt health-care systems and pose unique challenges to public health initiatives, including maintaining and expanding HIV testing services.[43] Humanitarian crises often lead to the destruction or breakdown of health-care facilities that are vital for the providing testing services. Limited access to health-care facilities owing to conflict or destruction of infrastructure hinders both routine and emergency HIV testing, while humanitarian emergencies also strain resources and divert funds and personnel away from HIV testing programmes. This can lead to shortages of testing kits, health-care staff and support for individuals living with HIV. The stigma associated with HIV can intensify during humanitarian crises as social norms and codes of conduct are disrupted, deterring people from seeking testing or treatment due to fear of discrimination or violence.

33. To maximize efficiency and serve people better, priorities for HIV testing services differ between high- and low-burden settings. In high-burden settings, the services should be offered at every point of health contact in facilities, and there should be outreach for key populations, partners of people living with HIV, and in workplaces, as appropriate, as part of broader health and wellbeing screening. As well, all partners of key populations and people living with HIV should be offered testing. In low-burden settings, testing services should be routinely offered in STI and TB clinics and other relevant medical services, and community outreach approaches should be used to reach key populations and partners of people living with HIV. In all settings, all people are encouraged to self-assess their risk of HIV infection and know where to have voluntary counselling and testing services in case of need.

Gaps in testing for people living with HIV

Viral load testing

34. Viral load testing is an important tool to monitor the progress of HIV treatment. Although great progress has been made in scaling up access to viral load monitoring, challenges remain, especially in under-resourced areas. The cost and complexity of nucleic acid testing for viral load monitoring, particularly point-of-care testing, still limits the availability of testing in many places. Scale-up of viral load testing requires national coordination and decision-making around the implementation of centralized laboratory testing and/or point-of-care testing.[44]

35. Plasma samples are a common sample type for viral load testing and can provide the most sensitive results.[45] For plasma-based testing to be effective and useful, samples must typically arrive at the laboratory and be processed within 24 hours. Alternative sample types such as dried blood spot samples are recommended in settings where logistical, infrastructural and operational barriers prevent routine viral load monitoring using plasma specimens. Dried blood spot samples have longer stability than plasma samples and their use can improve testing access, although they do require additional planning and implementation steps in clinic settings and in laboratories.

36. HIV viral load test results can be a motivation for adhering to treatment and achieving the ultimate goal of reducing viral loads to undetectable levels. Current WHO-prequalified tests, including point-of-care and alternative sample types such as dried blood spots, can accurately measure and report viral load results as unsuppressed (>1000 copies/ml), suppressed (detectable but <1000 copies/ml), or undetectable (not detected by the test or sample type used). Emphasizing and strengthening adherence counselling during ART initiation and throughout treatment are essential, including communicating about the prevention benefits of viral load suppression to all people living with HIV.[45]

37. Demand for viral load testing may be low, particularly among key and other priority populations, if there is limited awareness of the importance of viral load testing and the need to return for regular testing. Education and community-led and community-centred strategies, including utilization of peer-based community health workers, help empower individuals to continue treatment and monitoring.[46]

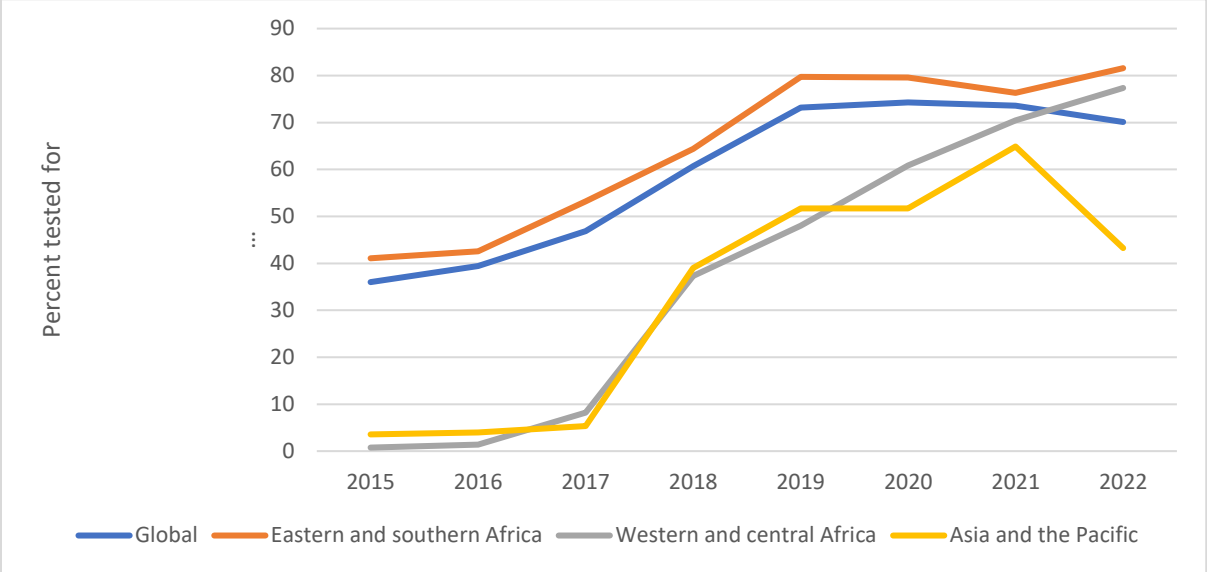
38. Despite the importance of viral load testing for motivating people living with HIV to reach and sustain viral suppression, access to viral load testing is insufficient. Barriers to access and uptake of viral load testing including stockouts of viral load testing consumables, laboratory delays, lack of awareness among providers and patients about the benefits of viral load testing, poor adherence to WHO or national guidelines on viral load testing, and stigma and discrimination in health facilities.

39. In 2022, routine viral load monitoring for adults and adolescents had been implemented countrywide in 74% (98 of 133) of reporting low- and middle-income countries; among the remainder, 51% (18 of 35) reported implementation in many (50–95%) treatment sites.[47]

40. However, viral load test coverage for adults on ART generally has not improved (Figure 1). Since 2015, when data became available from all regions, coverage declined overall from about 76% to 68% in 2022.

41. Access to viral load testing allows people receiving ART to know whether the treatment is successful and whether their viral loads are undetectable, to be confident that they cannot transmit HIV to sexual partners). A systematic review of the literature showed zero risk of sexual transmission from persons with undetectable viral loads.[48] Undetectable = Untransmittable (U=U) is an important and empowering message that can encourage people to seek testing and ART and continue on ART to have their HIV viral load remain undetectable, but messages on U=U in low- and middle-income countries are often limited and unclear.[49-51]

Figure 1. Estimated percent of people on treatment tested for viral load, global and selected regions, 2015–2022



CD4 testing

42. The CD4 cell count is an indicator of immune function in people living with HIV. If CD4 levels are low, a person with HIV may develop serious infections from viruses, bacteria or fungi that usually do not cause problems when a CD4 cell count is in the normal range. Measuring CD4 levels can inform decisions about clinical management, for example offering opportunistic infection prophylaxis. However, point-of-care CD4 count technologies are limited and the sample for CD4 counting is logistically difficult to manage.

43. Availability of CD4 testing is limited in many low- and middle-income countries. Globally, 26 countries have adopted policies or strategies on CD4 testing at point-of-care. CD4 testing as a screening tool for linking to an advanced HIV disease care package is used in 56 countries. In 110 out of 118 countries with available data, CD4 tests are used for immunological staging, and 69 countries use baseline CD4 tests to diagnose advanced HIV disease.[52] The lack of CD4 testing and the inability to identify people with advanced HIV disease results in higher morbidity and mortality. [53-55]

Other tests

44. Even in settings with routine access to CD4 and viral load testing, there is limited access in many countries to testing for coinfections that are major causes of morbidity and mortality, such as cryptococcus and histoplasmosis.

45. Additional barriers to laboratory testing uptake include testing backlogs, supply chain disruptions, difficulties sourcing and retaining qualified laboratory staff, inappropriate sample collection and transportation (leading to sample rejection), and slow turnaround of results.[56]

Diagnostics integration

46. Diagnostic gaps across several diseases exist and could be supported by optimally using existing resources.[57] Diagnostics integration efforts, such as sharing laboratory technologies and resources across diseases, should be strongly supported.

47. COVID-19 initially disrupted many laboratory services, as resources shifted to address the pandemic. However, its impact and lessons learned presented opportunities to develop integrated national testing policies for multiple diseases and to streamline guidelines, policies and procedures.[58]

48. An integrated package of HIV testing services includes testing for HIV diagnosis, viral load monitoring, CD4 testing, testing for major coinfections, and kidney and liver function monitoring to ensure safe administration of ART. Multiple country programmes have also been successful at integrating HIV services with services for other diseases, such as TB, hepatitis C and COVID-19.[59]

49. A total of 115 countries have adopted WHO recommendations to offer interventions for advanced HIV disease.
    - Sputum Xpert MTB/RIF is offered as a first test for TB diagnosis in symptomatic patients in 27 countries.
    - Urine LF-Lam is offered in four countries for TB diagnosis for people experiencing symptoms, particularly those with a CD4 count of ≤100 cells/mm3 or who are critically ill.
    - Cryptococcal antigen screening is used in 53 countries, as a crucial method for identifying and addressing cryptococcal infections among individuals with advanced HIV.

50. The triple elimination agenda for vertical transmission requires HIV, syphilis and hepatitis B testing to be provided together for pregnant women, followed by prompt and efficacious interventions to treat pregnant women who test positive and to prevent transmission of the infection(s) to their infants. Other necessary services, interventions and factors include counselling for pregnant women and their partners; safe delivery; follow-up of exposed infants, including the hepatitis B vaccine birth dose and completion of the three-dose series of the hepatitis B vaccine; optimal infant feeding; and follow-up treatment and care for mothers, children and families.[60]

Challenges

Legal environment and social norms

Criminalization

51. Laws criminalizing HIV transmission or nondisclosure can deter individuals from getting tested and disclosing their status due to fear of legal consequences. In 2023, of the 190 countries with available data, 143 countries reported having criminalization or prosecutions based on general criminal laws of HIV transmission, nondisclosure or exposure.[61]

52. Criminalization of certain behaviours does not provide an enabling environment for testing. As of 2022, there were 20 countries that criminalized and/or prosecuted transgender people, 70 countries that criminalized same-sex sexual relations, 115 countries that criminalized the possession of limited amounts of drugs for personal use, and 153 countries that criminalized any aspect of sex work. A systematic review reported that knowledge of HIV status among gay men and other men who have sex with men who are living with HIV in Africa was three times higher in countries with the least repressive lesbian, gay, bisexual and transgender people laws, compared with countries with the most repressive laws.[62]

Stigma and discrimination

53. Anticipated HIV stigma (i.e., an HIV-negative individual's expectation that they would experience rejection if they were to acquire HIV) and/or discrimination is associated with the avoidance or delay of accessing HIV testing services among diverse populations globally, including key populations, adolescents and young people, women and migrant populations.[63-69]

54. Age-of-consent laws can be a barrier to adolescents accessing HIV testing.[70] Nearly three quarters (106) of 144 countries with available data report having age-of-consent laws or policies that require parental consent for adolescents to access HIV testing.[71] In some countries, these laws are inconsistent in relation to age-of-consent laws pertaining to sexual activity. This means that adolescents may legally have sex before they can legally access HIV testing and other services and information relating to safer sex practices or contraception, which puts them at greater risk of acquiring HIV and other STIs, and of unintended pregnancy. Adolescents and youth from key populations are especially affected.

55. Minimum age-of-consent policies are not mistaken in principle. However, if the stipulated ages are too high, the policies can block access to HIV testing services for adolescents who are sexually active and mature enough to take their own decisions regarding HIV testing.

Mandatory testing

56. Mandatory HIV testing is a violation of individual's rights to dignity, privacy, work and freedom from discrimination. Fifty-three countries report that they require mandatory HIV testing, for example for marriage certificates, travel or visa requirements, or for certain professions.[72]

Concerns regarding confidentiality

57. Fear of unauthorized disclosure of one's HIV status can serve as a deterrent to HIV testing.[73-75]

Policy and systems

58. Although trained lay providers can be used to independently conduct safe and effective HIV testing using rapid diagnostic tests,[15] several countries limit their use. Data from Global AIDS Monitoring reporting show that less than half of the 166 countries reporting had lay providers performing HIV testing in 2022.

59. The 2021 Political Declaration on HIV and AIDS requires that community-led organizations should deliver 30% of testing and treatment services. Several challenges stand in the way, however.
    - Community-led organizations lack legal status in several countries; many governments do not recognize the value of these organizations in service provision, including HIV testing services; and mechanisms to finance the organizations are rare.
    - Monitoring of the contributions of community-led organizations to HIV testing is challenging, due to a lack of standardized measurement tools for doing so.[29] For example, surveys measuring HIV testing often only document the number of people tested, but do not reflect the efforts related to awareness-raising and peer-led outreach for creating demand and linking people to care.[29]

- Current funding for community-led organizations does not match the commitments made in the Paris Declaration or in the 2021 Political Declaration on HIV and AIDS. Most of the funding for supporting these organizations comes from external donors; reliable domestic funding inadequate, especially for organizations that work with people from key populations and with girls and women.[30] Although social contracting (whereby governments contract civil society organizations to provide certain services) is a proven way of supporting community and civil society organizations to provide services, many countries are not using social contracting at scale due to a lack of political will and limited local evidence and motivation.

60. Most of the funding available for HIV testing in low-income countries comes from external sources. The domestic share of total resources for HIV testing in 2022 was an average 80% across lower-middle-income countries and 91% across upper-middle-income countries.[52] However low-income countries relied on external financing for 95% of their resources for HIV testing in that year.[52] Furthermore, external sources of funding accounted for more than 99% of spending on CD4 and viral load commodities in low-income countries.[52] This is problematic for multiple reasons, including those related to sustainability, avoidance of test stock-outs, and country ownership of HIV responses.

61. Affordability of test commodities and supply chain risks are also a concern, as regions with the greatest demand for HIV tests rely entirely on imported products. Those regions currently also have limited capacity to produce diagnostic technologies. Some countries with the highest burden of HIV also experience stockouts of consumables for testing as a result of procurement and supply chain management challenges.

Additional barriers to testing

62. Gender-based violence can impede uptake of HIV testing, care and treatment. The effects may vary across different geographic and epidemic settings and should be carefully considered when promoting and implementing HIV testing.[67]

63. In some cases, low perceived risk of acquiring HIV has been associated with low demand and uptake of HIV testing services across diverse populations globally, including key populations, adolescent and young women, incarcerated populations, and men.[65,76-78] However, when people have easy access to testing, including through self-testing, uptake is high across all populations.

Quality of testing

64. It is important to provide quality HIV testing services to prevent misdiagnosis, which can have serious implications for individuals and for public health generally. People who receive a false positive diagnosis may suffer psychosocial consequences and could potentially take unnecessary antiretroviral treatment. Misdiagnoses can also undermine trust in the health system. False negative diagnoses, meanwhile, mean that people who need ART miss out on life-saving treatment and may transmit HIV to others. A lack of quality-assured testing and laboratory services therefore limits the effectiveness of HIV services and undermines the HIV response.[71]

Limited linkages with other services people need

65. There are often limited linkages between required HIV services and other essential services. Many people living with or at risk of HIV also face challenges related to mental health, sexual and reproductive health (including access to contraception and STI services), substance use and other health conditions, as well as socioeconomic

disparities. The lack of a coordinated approach means that individuals must navigate fragmented systems, which leads to gaps in care, missed opportunities for early interventions, and suboptimal health outcomes.

Solutions

Testing for HIV

What works to reach those left behind?

66. The challenges outlined above require new focus and approaches to reach people with undiagnosed HIV earlier in their infection. Many countries and programmes are looking for innovative approaches to deliver HIV testing services, including increasing access to HIV self-testing, social network testing and virtual interventions. For example, the Alliance for Public Health in Ukraine implemented optimized case finding, an approach that involves active tracing and recruitment of at-risk social networks of HIV-positive people. This approach uses mobile clinics to reach people at risk of HIV, resulting in increased testing of hard-to-reach populations.

Key populations

67. To reach people with undiagnosed HIV sooner after acquiring HIV and to provide them with information about the benefits of testing—including linkage to treatment and prevention, and messaging around U=U while continuing scientific research—a multipronged approach is needed to maximize access to testing. Current strategies include integration of HIV testing with other services, facility-based testing, community-based testing, and HIV self-testing (either in a facility or in the community) and regarding the latter, individuals with a reactive HIV self-test result must receive further testing from a trained tester using the full national testing algorithm. .

68. HIV testing service integration with other services can create and/or expand opportunities to offer HIV testing and increase the numbers of people who are tested and linked to prevention or treatment services and to other health programmes, including mental health services. For example, in Namibia, the UN Population Fund has partnered with civil society organizations to increase access to integrated services for marginalized populations, which has helped advance the HIV response in remote and under-served areas.

69. Opportunities for integration need to be maximized, particularly for testing and screening for STIs, TB and viral hepatitis. Opportunities for integration include hepatitis C testing and treatment services for people who inject drugs, TB services for people in prisons, and syphilis and other STI services for sex workers, gay men and other men who have sex with men, and trans and gender-diverse people.

70. Facility-based HIV testing services may be offered in clinical settings, drop-in centres or “one-stop shop” services. For people who use or inject drugs, the services may be offered at stand-alone sites that offer harm reduction services such as needle and syringe exchange and opioid agonist maintenance therapy.

71. Community-based HIV testing services are recommended for reaching members of key and other priority populations and their partners who may be hesitant or unable to access facility-based services. These services can be made available in many ways and in different settings and venues. Differentiated approaches include providing HIV testing services at fixed locations in the community, including community-based voluntary

counselling and testing sites; via mobile outreach in hotspots and community sites such as parks, bars, clubs, cruising sites and saunas; and at events, places of worship, workplaces and educational establishments, and via mobile vans. It is important that community-based services among key and other priority populations are strategically designed and well-focused, as costs can be high.

72. Community-based HIV testing services can be conducted by trained lay providers and peers using rapid diagnostic tests. The services can be delivered alone; together with testing and screening for other infections such as TB, viral hepatitis and STIs; or as part of maternal, child health and other services.

73. HIV self-testing, which can be offered either at a facility or in the community or home, can be particularly effective for reaching members of key and other priority populations who may not otherwise test or who are at ongoing risk but test less frequently than recommended. There are many ways to implement and distribute self-testing kits among key and other priority populations, including through community and facility settings, online platforms (e.g., Berliner Aids-Hilfe e.V.),[79] pharmacies, and private sector settings (e.g., kiosks or retail outlets), as well as through secondary distribution of test kits by partners or other contacts, and peer distribution via sexual or social networks or networks of people who use drugs.

74. Social network HIV testing approaches that leverage the social, sexual or drug-using of members of key populations can increase testing among sexual partners and social contacts of test promoters. WHO recommends social network-based approaches that can be offered as part of a package of partner services to reach people who would benefit from testing but who have not tested in other settings.

75. Social network approaches can also increase the number of first-time testers, thereby helping to close the gaps in testing coverage and reducing the number of people with HIV who are undiagnosed and/or not linked to ART.

76. People in prisons and other closed settings also need access to a comprehensive package of testing, treatment, care and prevention services. It is essential that the services give accurate information; obtain informed consent; maintain confidentiality; ensure that use of the services is voluntary; and link people with HIV to ART.

Infants and children, including early infant diagnosis

77. Point-of-care molecular testing is essential to reduce the turn-around time for early infant diagnosis, but the pricing of the point-of-care technologies is a barrier. Although point-of-care testing for early infant diagnosis is costlier than laboratory-based testing, it has been shown to be more cost-effective than comparable standard-of-care laboratory testing, particularly given the increased and more rapid rate at which results can be returned and, hence, the increased initiation of treatment in infants.

78. Implementation of point-of-care early infant diagnosis testing in 52 facilities across six countries (Cameroon, Democratic Republic of the Congo, Ethiopia, Kenya, Senegal and Zimbabwe) enabled successful same-day diagnosis and treatment of initiation of infants in public sector health-care facilities.[80,81]

79. Additional strategies are needed to reach children older than 18 months, and community-based and paediatric-focused linkage to care programmes are needed to ensure testing and adherence.

80. In accordance with the Global Alliance to End AIDS in Children,[82] accessible testing, optimized treatment and comprehensive care for infants, children and adolescents living with and exposed to HIV are all vitally important. Implementing robust multimodality testing programmes to find and link all infants, children and adolescents living with HIV is an important approach for such care. The components can include early infant diagnosis; index-testing; population-specific case finding; routine opt-out testing in outpatient clinics for children with unknown status; congregation-based testing; community outreach in geographic areas with high unmet need; community- facility- or family-based testing; and self-testing.

Men

81. Integration of HIV services, including testing, and sexual and reproductive health services, can help avoid missed opportunities and increase the likelihood that men are able and willing to obtain the services they need.[83] Closing men's service gaps requires a holistic approach that improves service delivery while minimizing social barriers to service access and utilization.[84,85] Health systems in settings with high burdens of HIV should use every opportunity to engage men when they visit health facilities.

82. Men access a range of health services in clinical facilities. In HIV high-burden settings, it is important that the services routinely include offers of HIV testing to men. In all settings, men who have HIV-related symptoms, TB, viral hepatitis, STIs or other indicator conditions should be offered HIV testing.

83. Facility-based services should be inclusive, friendly and accessible to men, including those from key and other priority populations. To optimize access, facilities could offer testing during extended hours and over weekends. Men may also access facility-based HIV testing services through partner testing, particularly in HIV high-burden settings and during a female partner's pregnancy.

84. Community-based HIV testing services are important because men often are less likely than women to use health facilities. Community-based approaches may be particularly useful for reaching men who have never tested and for men from or with partners from key populations.[86,87] Across all community-based HIV testing services approaches, programmes need to carefully consider and implement methods to facilitate linkages with prevention and treatment services. Without those linkages, men living with HIV may not benefit from early ART initiation.

85. HIV self-testing can be particularly effective for reaching men with high ongoing HIV risk who may not test otherwise, such as those employed in mining companies, transport and logistics, the military and other uniformed services. Reactive HIV self-testing results must receive further testing from a trained tester using full national testing algorithm while negative HIV self-testing do not require additional testing. . Focused community, peer mobilization, activity-centred (e.g., sports) and mobile outreach with self-testing distribution can also facilitate testing for men.

86. Secondary distribution of self-testing kits can be offered by women to their male partners, and by key population members to their sexual partners, since social contacts can also be effective in increasing testing uptake among men. However, such approaches should be adopted with care to limit the risk of intimate partner violence and to ensure that the initiator feels comfortable with this option. WHO does not recommend distribution of self-testing by sex workers to their clients.

87. Workplaces are potential venues for reaching men in settings where HIV prevalence is high. Offering HIV testing services, including HIV self-testing, at formal and informal workplaces is an effective, acceptable and feasible approach for reaching men and identifying previously undiagnosed infections.[88]

88. The collection of disaggregated data is vital to guide and monitor efforts to increase male engagement in HIV services.

Adolescents and young people

89. Sexually active adolescents and young people in high-burden settings may benefit from HIV testing services that are provided as part of broader HIV prevention, STIs and unplanned pregnancy prevention; as part of sexual and reproductive health interventions and messaging, including through comprehensive sexual education; and as part of focused outreach efforts to reach those with undiagnosed HIV infection.

90. It is important to focus testing on adolescents and young people in settings with a high burden of HIV. Routinely offering HIV testing services to all adolescents and young people in low-burden settings would identify very few HIV infections and may not be an effective investment in resource-limited contexts. Instead, testing adolescents and young people in settings where the burden of HIV is low should focus on those with heightened vulnerability to HIV acquisition, such as young people in key populations. Adolescents and young people should have access to information about HIV, risk behaviours and testing options including as part of comprehensive sexuality education as well as education on sexual and reproductive health and HIV prevention so they can make informed choices about testing.

91. Both facility- and community-based testing services can be offered to adolescents as part of sexual and reproductive health and HIV prevention packages. In HIV high-burden settings, such as southern Africa, the services may also be a part of HIV prevention efforts including voluntary medical male circumcision services for adolescent boys and young men and in sexual and reproductive health, contraception and family planning services. High HIV prevalence has been reported among adolescent girls and young women attending contraception services in eastern and southern Africa, but HIV testing is often not routinely offered to them.

92. All HIV testing services for adolescents and young people, whether in health facilities or communities, should be adolescent-friendly and should address people's psychological and physical health needs. Services for adolescents should be designed to improve accessibility and offer HIV testing in a non-judgemental, non-discriminatory and non-stigmatizing manner.

93. HIV self-testing has been shown to be effective and acceptable among adolescents and young people, including those from key and other priority populations. The use of focused, youth-designed and -led community-based outreach and promotion through social media platforms can improve access to self-testing.

94. A lower legal age of consent could increase the uptake of HIV testing and counselling, especially in countries with more restrictive legislation.[70] HIV testing uptake among adolescents, in turn, has been associated with lower incidence of HIV infection over time. The results also indicate a stronger association between lower age-of-consent laws and increased rate of HIV testing among females than males. This suggests that lowering the legal age of consent could have a greater effect on adolescent girls, who are more at risk of HIV than their male peers.

Indigenous populations

95. The establishment of an Indigenous baseline for data on HIV, including data on gender diversity, is needed to tailor programmes and to monitor progress. Indigenous people must be involved in the development, implementation and monitoring of those programmes, and in analysing and disseminating the findings. Models of health care should consider Indigenous concepts of health and preserve and strengthen Indigenous health systems as a strategy to increase access to and coverage of health care.

Pregnant and breastfeeding women and ending AIDS in children

96. Essential triple elimination of mother-to-child transmission services include testing for HIV, syphilis and hepatitis B virus, followed by prompt interventions to treat women who test positive for their own health and to prevent transmission to their children.[60] Including linkage to programmes that can support women's mental and physical health is important to ensure the right to health for women and their infants and to support their retention in the treatment and care continuum.

97. High coverage of HIV testing for pregnant and breastfeeding women and persons is essential for the elimination of vertical HIV transmission and for ensuring the health and wellbeing of pregnant and breastfeeding women and persons. That is best achieved through the integration of HIV services in antenatal care and broader primary health-care systems. HIV, syphilis and hepatitis B testing should be offered together to pregnant women as part of triple elimination.

Other populations and general considerations

98. For women and girls in all their diversity, as described in the Global AIDS Strategy 2021-2026—including cis- and trans-women, sex workers, women who use drugs, and women in prison—testing must be accompanied by appropriate information about HIV and STIs, funding, capacity building and support for their networks, to ensure that anyone testing positive can receive peer support.

99. Ideally, HIV testing services could be integrated with other primary health-care services, including maternal and child health, sexual and reproductive health, and, in priority countries, voluntary medical male circumcision programmes, provided those primary health-care settings can accommodate the integrated services.[15]

100. Service integration can ensure a continuum of both HIV prevention and care—sometimes termed the HIV status-neutral testing approach—which can optimize access to ART or combination prevention as well as to ongoing care that is coordinated with people's other primary care needs.[15]

101. The provision of HIV testing along with other screening services (e.g., body mass index, blood pressure and blood glucose screening) can be successful in formal and informal workplaces in settings where HIV prevalence is high, and may reduce HIV-associated stigma and increase HIV test acceptance. Offering multiple health tests may be appropriate and acceptable, particularly for older people with multiple health problems and priorities.

102. Decentralization of HIV testing services, (e.g., providing HIV testing services at peripheral health facilities such as primary health-care facilities and outside health facilities in the community) is an appropriate strategy to reach under-served and inaccessible populations in both high- and low-prevalence settings.[89,90]

103. Lay health providers who are trained and supervised to use rapid diagnostic tests can independently conduct safe and effective HIV testing services both in communities and in health facilities.

104. In humanitarian crisis contexts, the deployment of mobile clinics and outreach teams to migrant and displaced settlements and transit areas can facilitate convenient access to HIV testing services. Training health-care providers to communicate effectively in multiple languages and adapting testing and counselling approaches to respect cultural sensitivities can improve engagement with migrants. Engaging mobile communities themselves in HIV awareness and testing initiatives can help reduce stigma and improve access to testing.

105. Investment in demand-creation activities should prioritize people with ongoing HIV exposure and who do not know their HIV status. Selection of demand-creation interventions must consider risks and benefits, context-specific factors, feasibility and sustainability, country ownership, and universal health coverage across disease areas. Mobilization, U=U messaging, couple- and motivation-oriented counselling, peer-led interventions, and conditional fixed value incentives, are high-impact demand-creation interventions and should be prioritized for programmatic consideration.[91]

106. Innovation in differentiated service provision includes virtual HIV testing interventions that make the best use of popular social media platforms and digital and mobile technologies (e.g., SMS). Digital technologies can also enhance advocacy efforts. For example, in Thailand, digital campaigns, online forums, and social media mobilization efforts served as catalysts for public engagement and helped create a conducive environment for dialogue among policy-makers, health-care providers and community members.

107. Multipurpose, multidisease tests are also being developed; they may reduce costs by combining tests for infections. Planned multidisease tests include HIV, hepatitis B and syphilis (including for antenatal care), and HCV and syphilis for people who use or inject drugs. Platforms that can also diagnose STIs (e.g., chlamydia and gonorrhoea) would be useful, but they do not yet exist.

Ending AIDS in children and elimination of mother-to-child transmission of HIV, syphilis and hepatitis B

There are an estimated 1.3 million pregnant women living with HIV worldwide, 1 million pregnant women with active syphilis infection and 65 million women of childbearing age are living with chronic hepatitis B infection.

Elimination of mother-to-child transmission—also referred to as elimination of vertical transmission of HIV, syphilis and hepatitis B—is a global health priority. WHO recommends that pregnant women be tested for HIV, syphilis and hepatitis B surface antigen at least once during pregnancy, preferably in the first trimester.

In some resource-limited settings, programmes may need to use resources strategically for testing and retesting during pregnancy—by focusing on women in geographic areas with high HIV burdens, women from key populations, women who have partners with HIV or from a key population, and women with high HIV risk for any other reason.

In some resource-limited settings, programmes may need to use resources strategically for testing and retesting during pregnancy, focusing on women in geographic areas with high HIV burden, women from key populations, women who have partners with HIV or from a key population and women with high HIV risk for any other reason.

Dual HIV/syphilis rapid testing can be considered as the first test in antenatal care (in combination with a single hepatitis B surface antigen test, where epidemiology warrants), except for women with HIV who are receiving ART and for women who have been diagnosed already with and treated for syphilis during the current pregnancy.

Testing for people living with HIV

108. HIV viral suppression is crucial to improve individual health, prevent sexual transmission and reduce perinatal transmission. Viral load testing is recommended as the preferred monitoring approach to determine people's responses to HIV treatment and to identify and confirm treatment failure. Viral load testing is done using nucleic acid test technologies and require laboratory-based or point-of-care testing platforms and testing kits.

109. Viral load monitoring is also needed to measure progress towards the third “95” in the 95–95–95 targets: the percentage of people on HIV treatment who have a suppressed viral load. People living with HIV who have an undetectable viral load (based on WHO-approved testing methods) have zero risk of transmitting HIV through sex, as long as they continue to take their ART as prescribed, in accordance with the latest World Health Organization Policy Brief[vi]. This has given rise to the U=U campaign.

110. For all people, including breastfeeding or pregnant women and persons, routine viral load monitoring should be done by 6 months of treatment initiation, at 12 months, and then every 12 months thereafter if the person is established on ART and has an undetectable viral load. Having a suppressed viral load is a key milestone for a person on ART, in addition to being on ART for at least 6 months, having no current illnesses other than well-controlled chronic health conditions, and having a good understanding of lifelong treatment adherence.[15]

111. Viral load scale-up has been successful in countries in all regions. Public-private partnerships have addressed barriers and strengthened laboratory systems. For example, the Riders for Health programme created and improved supply chain and sample transportation networks in the Gambia, Kenya, Lesotho, Malawi, Nigeria, Zambia and Zimbabwe, improving access to health care for 14.5 million people.[92]

112. Information about a person's viral load should never be used to undermine their rights. Viral load testing should be complemented with nonjudgmental, tailored approaches to assess treatment adherence, such as reviews of pharmacy refill records, pill counts and self-reported data on pill-taking during the previous week.[93]

113. Testing for HIV and treatment monitoring should be planned in comprehensive ways with fully mobilized public laboratory systems to assure the quality of testing. For example, South Africa’s National Health Laboratory Service has established a national HIV cohort to facilitate HIV testing, monitoring, evaluation, and research.[94] The national laboratory network has provided over 60 million CD4 and viral load tests to over 12 million patients in the last 20 years, enabling treatment initiation, linkage to care and ongoing HIV services. [94]

HIV viral suppression and reducing transmission (U=U)

114. U=U messaging needs to be amplified through continued, collaborative partnerships among people living with HIV, partners of people living with HIV, and health-care providers and other stakeholders. Messaging must be consistent and clear and effectively communicated with diverse populations.[45]

CD4 testing for advanced HIV disease

[vi] https://www.who.int/publications/i/item/9789240055179

115. WHO recommends CD4 cell count testing at HIV diagnosis and ART initiation to identify advanced HIV disease. Both laboratory and point-of-care options for CD4 testing are available. On average, 30% of individuals initiating ART have advanced HIV disease, although that may be an underestimate in many settings.[93,95] Advanced HIV disease is associated with worse hospitalization outcomes and increased morbidity and mortality.[96]

116. All individuals with advanced HIV disease should receive a package of interventions that includes screening, treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation, and intensified treatment adherence support. Testing for other infections, such as TB, cryptococcus and histoplasmosis, is an important part of a comprehensive service delivery package and can help avoid immune reconstitution inflammatory syndrome.

117. In settings where viral load testing is not routinely available, CD4 count and clinical monitoring should be used to diagnose treatment failure. However, this is not as effective as viral load testing for detecting virological failure.

Quality assurance systems

118. All programmes need to establish quality assurance systems and expand them while increasing their delivery of testing services. Scaling up rapid test programmes involves ensuring the quality of test kits, training, supportive supervision, testing procedures, and post-market surveillance.[97] Similarly, CD4 and viral load testing programmes, including point-of-care and laboratory-based testing approaches, also need to be part of established quality assurance systems in order to ensure reliable results and effective care and treatment.[98]

HIV drug resistance testing/surveillance

119. HIV drug resistance can limit the effectiveness of ART in reducing HIV-associated morbidity and mortality and the risk of HIV transmission. Drug resistance testing requires laboratory services that are more complex than those used for HIV diagnosis and viral load tests and therefore are typically performed in national or district-level reference laboratories.

120. WHO recommends that countries routinely implement nationally representative HIV drug resistance surveillance. Understanding drug resistance patterns can help programmes optimize ART regimens for people living with HIV.[99]

121. Four indicators are commonly used to contribute to drug resistance surveillance: viral load testing coverage, viral load suppression rates, drug stock-outs, and rates of switching from first- to second-line ART regimens. Those indicators are part of Global AIDS Monitoring reporting; the data collected can be analysed to identify challenges related to drug resistance. It is important to integrate HIV drug resistance surveillance into national drug resistance programmes, including linking it with broad antimicrobicide resistance programmes.

Enablers

Legal environment and social norms

122. Age-of-consent laws for accessing sexual and reproductive health and rights services, including HIV testing, should work in the best interest of adolescents who need testing. Where appropriate, countries should review age-of-consent policies and revise them where needed, recognizing adolescents' rights to make choices about their own health

and well-being (with consideration for the average age of sexual debut, as well as different levels of maturity and understanding of implications of HIV testing).

123. Countries should work towards implementing and enforcing antidiscrimination policies and laws, including laws that are protective of people in same-sex relationships or with nonconforming gender identities.

124. Attitudes and behaviours of health workers need to be inclusive and non-stigmatizing. Delivery of differentiated approaches should be accomplished in a people-centred and non-judgmental way, allowing people to lead the decision-making about their own care in an informed, supported fashion.

Policy environment and programme considerations

Community engagement in HIV testing services

125. Community engagement can enhance HIV and other health interventions, as seen during the responses to COVID-19 and mpox. It can also help remove social and cultural barriers to testing. In South Africa, for example, UN Women has adapted the "HeForShe" initiative to facilitate transformational change in attitudes and behaviours among men to end violence against women and to facilitate access to HIV testing and treatment among men and women.[67] [100]

126. Countries should consider creating enabling policy and regulatory frameworks, consistent with international human rights norms, to support safe, open and inclusive civic space that allow for the formation, operation, funding and engagement of civil society organizations, including community-led organizations and networks, in the provision of HIV testing (including self-testing) and other services. Lay health providers should be permitted to provide HIV testing services after training. Countries should also support community-led monitoring of testing and other health-care services.

127. Programme managers should identify opportunities for delivering testing services, through mutually trusted civil society organizations, faith-based organizations, humanitarian aid organizations, and members of affected communities.

128. Sustainable funding, capacity building and support is needed for key population and priority population networks and organizations to participate in testing services. Social contracting also needs to be scaled up.

129. Shared definitions, appropriate indicators and standardized tools are needed to measure the contributions of civil society organizations (including community-led organizations) to the delivery of HIV testing services.[100]

Improving the reach of sustained, quality HIV testing services

130. Programme management should be improved to optimize the quality, efficiency and effectiveness, including cost-effectiveness, logistic and commodity management of HIV and other testing services, as needed.

131. HIV testing services programmes need to review who is being reached with their services and implement interventions that are specifically tailored to reach people who might be missed. Reviews should also cover the methods of service provision and whether they meet needs of the service users.

132. Community participation in monitoring the quality of service provision for HIV testing, treatment, care and prevention have been shown to help improve service planning and provision in many countries.[101] Data from public and private settings, including community-led monitoring data, should be collected, analysed, disseminated and used to inform HIV testing services programming. This information should be available to and used by health workers, community members and other stakeholders to address both clinical and nonclinical aspects of HIV testing. Information gaps should be identified and filled through appropriate research, including community-driven research. The information should be reliable and accurate.

133. Organizations that provide testing services must have sustained access to affordable necessary medical products and supplies, and consistent supplies must be achieved to avoid stock-outs.

Increasing HIV literacy

134. Community members should be informed of their rights and receive practical information about where to obtain HIV testing services. For self-testing, clear guidance and information must be provided with the self-test kit to support proper use and facilitate additional assistance, if needed. The information should include how to interpret the test results and where to seek prevention or diagnostic testing. It should also clearly note that a nonreactive self-test is likely negative, but that a reactive test does not constitute a conclusive diagnosis. People with a reactive self-test result need to follow the national HIV diagnostic algorithm for confirmatory tests as recommended by WHO.[15]

Financing

135. Wider recognition is needed of the critical roles of budgetary allocations and financing strategies in creating an enabling environments for achieving targets for testing coverage and linkage to prevention, care and treatment services, and for overall health outcomes.

136. Sustainable resources need to be mobilized for the HIV response, including for HIV testing, and the investments must meet the needs of key, vulnerable and priority populations. Increased external financing is necessary to ensure sustainability and promote global solidarity in places where financing gaps cannot be fully closed with domestic resources. In all settings, regardless of the share of external resources, strategies are needed to move towards reducing the reliance on those resources.

137. Advocacy and dialogue are needed with key decision-makers to demonstrate the importance of investing in HIV testing and other services to improve the health and wellbeing of people living with, at risk of and affected by HIV, and to enhance the health systems which contribute to equitable access to testing services.

Quality assurance

138. Programmes such as "Strengthening Laboratory Management Toward Accreditation" and "Strengthening Laboratory Quality Improvement Process Towards Accreditation" work with laboratories to improve the quality of testing services.[102] A worldwide network of WHO Collaborating Centres also provides support for HIV diagnostic and laboratory services.

Affordability and procurement supply chain management

139. It is important to understand the availability, gaps and needs through data collection and analysis, market research, challenges analysis and best practice documentation to better address intellectual property-related barriers and the other hindrances that affect the availability, affordability and accessibility of testing and diagnostic commodities for HIV and HIV coinfections and comorbidities in low- and middle-income countries. Better planning, forecasting, procurement, storage, distribution and functional logistic management information systems are also needed to prevent stock-outs of testing and diagnostic commodities and to safeguard HIV testing services.

Role of the private sector

140. The private sector can contribute through research and innovation to make more point-of-care technologies, including multidisease diagnostic tests, more affordable. The private sector should engage the expert knowledge of communities in cocreating interventions for end-users.

141. Pharmacies, where available, should be used for messaging and distribution of HIV self-test kits, as well as condoms, PEP and PrEP, as appropriate (including through total market strategies).

142. Private service providers, including laboratories and clinics, should follow the national guidelines on testing, share information with the public health sector, and actively participate in national reporting, monitoring and HIV rapid detection surveillance systems.

The way forward

Recommendations

143. The recommendations below are based on the evidence reviewed for this background note, the gaps that were identified, the available guidance and evidence of successful approaches and interventions.

<u>Recommendations for the Joint Programme</u>

- Promote the dissemination, popularization and local adoption and implementation of the normative guidance, including differentiated approaches for testing service delivery based on a country's epidemic profile and local situation to overcome testing gaps.
- Focus on quality of services to eliminate misdiagnoses.
- Advocate for sustainable financing, including increased domestic resource allocation to HIV testing services, promoting the inclusion of HIV testing as part of essential health services to be included in national health benefits packages, strengthened capacities for community-led service deliveries and international solidarity in support of low-income countries, while optimizing programme design for efficiency gains.
- Advocate for multisectoral, comprehensive, integrated services and differentiated approaches that meet people's needs.
- Advocate for an enabling environment, including stigma and discrimination-free services and the removal of legal, policy and implementation barriers related to age-of-consent requirements for HIV testing.

- Document and share best practices for advancing testing services for HIV and comorbidities, and for linking HIV combination prevention or treatment and other services to address broader health needs, including through primary health care.

Recommendations for the Member States

- Close the HIV testing gap by using national epidemiology and by focusing on the people who are currently left behind, for example key and other priority populations, as relevant to the national context. Use a people-centred mix of differentiated approaches that include facility-based and community-based testing, self-testing and social network testing, while allowing trained lay-providers to perform triage and rapid diagnostic HIV testing.
- Review policies to allow and support trained lay-providers, especially people living with HIV and members of key and other priority populations, to perform HIV rapid diagnostic testing.
- Plan testing for both HIV and treatment monitoring (viral load testing), as well as for comorbidities (LF-LAM, CrAG testing) and advanced HIV disease (CD4 testing) in a comprehensive way with fully mobilized public laboratory systems to assure the quality of testing and to contribute to responses to other public health emergencies.
- Broaden the aim of testing programmes beyond case finding for HIV (or "yield"). Use an HIV status-neutral approach focus on people at risk of HIV infection and programme testing services as part of a holistic package that includes messaging on U=U while continuing scientific research and that links with prevention, treatment and care services for HIV and other health issues.
- Where appropriate, revisit legal provisions on the age of consent for HIV testing to ensure that they serve the best interests of adolescents in different country contexts.
- Increase domestic resource allocations to HIV testing services, including HIV testing as part of essential health services to be included in the national health benefits packages, and enhance programme design to achieve greater efficiency.
- Make testing-related health technologies more affordable, including by taking full advantage of TRIPS flexibilities and by exploring opportunities for local production of diagnostic technologies, including rapid diagnostic tests.
- Improve procurement and supply chain management for testing commodities as part of health systems strengthening.
- Make continued efforts to remove stigma and discrimination associated with HIV and promote service approaches that are led and monitored by key and other priority populations for greatest access, appropriate linkage and sustainable impact.
- Implement and scale up point-of-care nucleic acid testing for early infant diagnosis to contribute to the elimination of paediatric AIDS.
- Encourage community-led service provision through the participation and meaningful engagement of community and other civil society organizations in HIV testing services. Consider using community-generated data (i.e., from community-led monitoring) as a complement to data that are sourced from monitoring and evaluation systems to inform decision-making around service quality improvement.
- Scale up social contracting to enable communities to fulfill their full potential in providing testing services and contributing to improved programme accountability.

- Promote self-testing as a useful strategy to reach people who are otherwise unlikely to take an HIV test, for individuals with a reactive HIV self-test result, further testing from a trained tester using the full national testing algorithm must be done.
- Promote linkages of HIV testing with treatment, prevention and other services, including management of comorbidities, noncommunicable diseases, STIs, viral hepatitis and social protection, as needed and in integrated ways.
- Focus on the quality of testing and testing services to prevent misdiagnoses.

Recommendations for community and other civil society organizations

- Actively participate in testing services provision, bridging the gap between service providers and recipients and contributing to approaches for testing service delivery.
- Mobilize community and service recipients, improve HIV literacy, increase awareness and demand for testing services, including U=U and HIV prevention messaging while continuing scientific research, and inform people about what services are available and where to obtain them.
- Close feedback loops by co-creating and monitoring solutions in how to improve service quality with service providers and partners.

Recommendations for donors, multilateral partners, and the private sector

- Facilitate the sharing and transfer of knowledge and support capacity building for local partners to have sustained HIV testing services, especially in low- and middle-income countries and resource-poor settings.
- Promote the innovation of health technologies so more affordable, reliable and low-maintenance, multipurpose testing technologies are available and accessible to the primary health care level and in community-based settings.
- Exercise international solidarity in support of low-income countries to capacitate technological know-how and the production of testing and diagnostics through renewed political commitments for sustainable, equitable financing and for supporting communities in playing key roles in the global HIV and testing response.

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