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NATIONAL OPTIMIZATION STRATEGY FOR TREATMENT AND TESTING OF HIV INFECTION IN THE REPUBLIC OF ARMENIA IN ACCORDANCE WITH THE RECOMMENDATIONS OF THE WORLD HEALTH ORGANIZATION

2023

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Contents

List of abbreviations

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
EFV	Efavirenz
HCV	hepatitis C virus
HIV	human immunodeficiency virus
IFA	immunofluorescence assay
INF	interferon
LPV/r	Lopinavir/Ritonavir
NCID	National Centre for Infectious Diseases
NGOs	Non-Governmental Organizations
PLHIV	People living with HIV
PrEP	pre-exposure prophylaxis
RA	Republic of Armenia
STIs	sexually transmitted infections
TB	tuberculosis
WHO	World Health Organization

Executive Summary

This National Optimization Strategy aligns the Republic of Armenia's approach to HIV treatment and testing with the World Health Organization's 2021 recommendations (1). The strategy aims to enhance the effectiveness of HIV/AIDS interventions, improve public health outcomes, and align national protocols with international standards. At the same time, changes in national protocols that occurred in 2023 were also considered.

However, the WHO guidelines provide a comprehensive and intricately detailed interpretation of the principles. At the same time, the WHO guideline highlights HIV testing services the importance of delivering HIV testing services with a public health and human rights-based approach, which is not emphasized in detail in terms of content in the Armenian guideline. In particular, the principles of informed consent and confidentiality are not described in detail, as well as the procedures for maintaining confidentiality during the provision of HIV services. Although the WHO guidelines state that HIV testing for diagnosis must always be voluntary and consent for testing must be informed by pre-test information, the Armenian guideline defines mandatory testing cases which has objective grounds in some cases.

Addressing priority areas, including universal health coverage, gender equality, and health-related human rights HIV testing services, the WHO guidelines focus on accessibility, availability, acceptability, and quality of services. However, the Armenian guideline does not address or address these issues in a general way, and not specifically. The approach of decentralization of ARV treatment services is not indicated so much in the Armenian guidelines. In addition, the Armenian Guide does not refer to the needs of transgender people and gender issues, nor does it consider the characteristics of vulnerable groups.

To achieve this, the strategy includes the following key harmonization areas: HIV testing and diagnosis, prevention strategies, antiretroviral therapy (ART), and healthcare service provision.

I. HIV testing and diagnosis

1. Pre-Test Counseling Services

Current Practice: Armenian Clinical Guidelines for Counseling Testing and Laboratory Diagnosis of HIV Infection, 2017 provide basic pre-test counseling but lack comprehensive strategies with key considerations for mobilizing demand and implementing effective pre-test services, information, and messaging (2, Page 19, Chapter 9).

WHO Recommendation: Instead of pre-test counseling, programs should provide concise pre-test information for individuals receiving HTS, their families, and their partners in a process that provides general information, answers clients' questions, and offers an opportunity to refuse to test (1, Pages 12-13).

Proposed Change: Move from pre-test counseling to providing pre-test information. Expand pre-test services to include WHO's comprehensive strategies, utilizing digital tools and community participation. In particular, the integration process for expanding the scope of pre-test counseling among the population, programs to expand rights and opportunities for communities, and the use of various media tools and educational programs are missing.

2. Diagnostic Algorithms

Current Practice:

Armenia uses rapid and serological screening tests, including immunoblotting (Western blot) for definitive confirmation. In particular, a positive sample (B1+) should be tested with a second-line test (B2). The second-line test (B2) should be an IV generation test of a different antibody structure or a different manufacturer (use a more specific test if possible), and in its absence, another serological test (rapid test, III generation IFA test); Page 46.

1) In the case of the "B1+, B2+" result, a confirmatory examination is performed. Western blot or immunoblot is used as a confirmatory test.

When choosing tests for algorithms, the following performance characteristics should be considered: Page 52.

1) The highest level of clinical, analytical, and seroconversion sensitivity for first-line tests, regardless of the type of test,

2) The highest level of specificity for second- and third-line tests, regardless of the type of test;

3) The minimum number of invalid results, regardless of the type of test,

4) Minimal difference in the analysis of the results obtained by different specialists with tests based on visual assessment (for example, a quick test, a simple analytical test) (2, Page 46).

WHO Recommendation:

Western blotting and line immunoassays should not be used in national HIV testing strategies and algorithms (strong recommendation, low-certainty evidence).

HIV testing strategy and algorithm WHO recommends that all HIV testing algorithms achieve at least 99% positive predictive value and use a combination of tests with ≥ 99% sensitivity and ≥98% specificity. The first test in an HIV testing strategy and algorithm should have the highest sensitivity, followed by a second and third test of the highest specificity. Countries should consider moving to a three-test strategy as HIV positivity within national HIV testing service programs falls below 5% – meaning all people presenting for HIV testing services should have three consecutive reactive test results to receive an HIV-positive diagnosis. WHO suggests using a testing strategy for HIV diagnosis that is suitable for HIV diagnosis during surveillance and routinely returning HIV test results to participants (1, Page 31).

Proposed Change: Update diagnostic algorithms to exclude immunoblotting (Western blot) and incorporate WHO-recommended diagnostic accuracy characteristics of rapid tests. Consider the including recommendations in the national protocol, during the nearest revision: According to the HIV/AIDS Prevention Program 2022-2026 (7, Page 40).

II. Prevention

3. Community-Based Testing

Current Practice: The Armenian protocol does not include community-based testing (HIV testing in non-medical institutions and for non-medical personnel to conduct HIV testing), as this contradicts the legislation of RA.

However, the concept of "HIV self-testing" has been introduced, which, in addition to the person himself, can be carried out by "people providing other services", and in fact, testing is carried out in different NGOs for their various HIV transmission prevention programs (2, Page 33).

WHO Recommendation: In low-HIV-burden settings, community-based HIV testing services are recommended for key populations, with linkage to prevention, treatment, and care services, in addition to routine facility-based testing (strong recommendation, low-certainty evidence) (1, Pages 17-18).

Proposed Change: Consider the possibility of including recommendations on community-based HIV testing in the national protocol, without contradicting the legislation of the Republic of Armenia or making changes in appropriate legislation.

4. PrEP

Current Practice: The updated National recommendations regulate the implementation of PrEP, the groups of people for whom PrEP is indicated are clearly defined and there is a recommendation for intermittent PrEP "on demand", as well as for the use of vaginal rings with dapivirine (3).

III. Antiretroviral therapy

5. Treatment regimens and approaches

Current Practice: In the current and updated 2023 protocols for the treatment of HIV (4) and HIV/TB (5), in terms of treatment regimens and approaches, the main part is synchronized with the WHO treatment protocol.

According to a study provided in 2017-2019 "Prevalence of HIV-1 drug resistance in Eastern European and Central Asian countries"(9), the prevalence of PDR to any drug class (according to WHO definitions) was 9.2% (95% CI, 4.6%-16.4%) in Armenia. More importantly, the prevalence of PDR to NNRTIs (EFV, NVP) was 6.7% (95% CI, 2.9%-13.1%) in Armenia.

According to the NCID specialists, more than 95% of HIV patients on ARV treatment receive DTG-based ART.

WHO Recommendation: Alternatively, HIV drug resistance testing should be considered where feasible to guide first-line ART regimen selection in settings with no access to DTG-based ART and in which the national prevalence of pretreatment HIV drug resistance to NNRTIs is equal to or greater than 10%.

WHO recommends that countries include the following priority activities in their national HIV strategic plan for planning and budgeting and inclusion in their funding requests (1, Page 483):

- Developing a national action plan on HIV drug resistance, which should be integrated into the national HIV strategic plan and should be by the five strategic objectives of the global action plan on HIV drug resistance (14);
- Annually monitor quality-of-care indicators (early warning indicators) of HIV drug resistance with accompanied appropriately locally tailored response to gaps in service delivery identified by this process;
- Periodic surveys of acquired HIV drug resistance in populations receiving ART (adults and children).

Proposed Change: As new recommendations become available, take into account the inclusion of recommendations in the national protocol during the next revision: The next update of HIV treatment protocols in 2024 according to the HIV/AIDS Prevention Program for 2022-2026 (7, Page 44), as well for the next HIV/AIDS Prevention Program develop a national action plan on HIV drug resistance, which should be integrated into the national HIV strategic plan.

IV. Management of Co-infections and Co-morbidities in PLWH

6. HIV/TB treatment regimens and approaches

Current Practice: In the current and updated protocol for the treatment of HIV/TB (5), regarding treatment regimens and approaches, complete synchronization with the WHO treatment protocol has been carried out. Specifically: Prophylactic TB treatment options are six or nine months of daily isoniazid, a three-month regimen of once-weekly rifapentine and isoniazid, or a three-month regimen of isoniazid and rifampicin

daily (strong recommendation, above average quality of evidence). In infants and children younger than 15 years, the benefits of a three-month regimen of daily isoniazid and rifampicin outweigh the harms given its safety profile, rapid completion compared with isoniazid monotherapy, and the availability of child-friendly fixed-dose combination tablets of rifampicin and isoniazid. Alternatively, a one-month regimen of daily rifapentine and isoniazid or daily rifampicin alone for four months can be recommended (conditional recommendation, low to moderate quality of evidence) (5, Page 32).

WHO Recommendation: The following options are recommended for the treatment of latent TB infection regardless of HIV status: six or nine months of daily isoniazid, or a three-month regimen of weekly rifapentine plus isoniazid, or a three-month regimen of daily isoniazid plus rifampicin (strong recommendation, moderate- to high-certainty evidence in the estimates of effect). A one-month regimen of daily rifapentine plus isoniazid or four months of daily rifampicin alone may also be offered as alternatives (conditional recommendation, low- to moderate-certainty evidence) (1, Page 258).

Proposed Change: In the case of new WHO recommendations, the next update of HIV/TB treatment protocols according to the HIV/AIDS Prevention Program 2022-2026 (7, Page 44).

7. HIV/HCV treatment regimens and approaches

Current Practice: Regarding the treatment of hepatitis C in patients with HIV/HCV co-infection, these issues, including modern approaches and treatment regimens (SOF/DCV, SOF/VEL, and G/P), features of the treatment of children and adolescents, on the transition of HIV-co-infected patients /HCV using DTG-containing regimens are included in the national protocol for the treatment of HCV (6), which guides medical specialists. The Clinical Practice Guidelines on Hepatitis C Management, 2020 was updated based on the WHO 2018 recommendations, which refers also to WHO 2021 recommendations.

WHO Recommendation: The global response and opportunities for eliminating HCV infection have been transformed by the introduction of curative, short-course direct-acting antiviral therapy, the widespread availability of rapid diagnostic testing for HCV antibodies, the availability of NAT for HCV viremia and the 2018 updated WHO recommendation of a "treat-all" approach regardless of the stage of disease using three pan-genotypic regimens (1, Page 263-264). For adults without cirrhosis, the following pan-genotypic regimens can be used:

- sofosbuvir + velpatasvir for 12 weeks
- sofosbuvir + daclatasvir for 12 weeks
- glecaprevir + pibrentasvir for 8 weeks.

For adults with compensated cirrhosis, the following pan-genotypic regimens can be used:

- sofosbuvir + velpatasvir for 12 weeks
- glecaprevir + pibrentasvir for 12 weeks
- sofosbuvir + daclatasvir for 24 weeks
- sofosbuvir + daclatasvir for 12 weeks.

Proposed Change: In the case of new WHO recommendations, the next update of HIV/HCV treatment protocols.

8. **Other coinfections treatment regimens and approaches**

Current Practice: According to the WHO 2021 recommendations, treatment approaches for other co-infections have also been updated, particularly in patients with cryptococcal meningitis, ARV treatment should be started 4-6 weeks after initiation of antifungal treatment, as early initiation of ARV treatment increases the risk of mortality (strong recommendation, low quality of evidence in adults for and very low quality of evidence for children and adolescents) (4, Page 29):

WHO Recommendation: Immediate ART initiation is not recommended for adults, adolescents, and children living with HIV who have cryptococcal meningitis because of the risk of increased mortality and ART initiation should be deferred 4–6 weeks from the initiation of antifungal treatment (1, Page 212).

Proposed Change: Consider including recommendations in the national protocol, during the nearest revision: the next update of HIV treatment protocols in 2024, according to the HIV/AIDS Prevention Program 2022-2026 (7, Page 44).

9. **Common noncommunicable disease treatment approaches**

Current Practice: National recommendations talk about the decentralization and integration of the processes of prevention and treatment of non-communicable diseases, as well as when undergoing follow-up about conducting tests or consultations (endocrinologist: for signs of diabetes mellitus, thyroid diseases, cardiologist: for signs of coronary heart disease, neurologist, psychiatrist, etc.) as necessary (8, Page 185), monitoring of adverse reactions of ARV drugs and features of addiction treatment during pregnancy (8, page 185). Patients under follow-up, if necessary, can contact an infectionist at their place of residence or another clinic, who conducts a general clinical examination, and, if necessary, also laboratory and instrumental studies; if concomitant diseases are detected, he prescribes appropriate treatment, and if ARV drugs side effects are identified - appropriate regulatory measures. (8, Page 39).

Opioid substitution therapy with methadone conducted in Armenia, which is carried out by the National Center for Addiction Prevention.

Efavirenz, nevirapine, and lopinavir/ritonavir require increased methadone dosage to prevent withdrawal syndrome. Potential methadone overdose should be considered when reviewing ARV treatment regimens and withdrawing specified ARV drugs (4, Page 53). During undergoing follow-up, patients with HIV infection are provided with several sub-services, including social-psychological counseling(8, Pages 38-39).

Depression often develops and preventive symptomatic treatment is necessary. If there is a history of neurotic disorders or depression, antidepressants (serotonin reuptake inhibitors (eg, citalopram, paroxetine) or tricyclic antidepressants, doxepin) are prescribed before starting treatment with PEGylated interferon (PEG-IFN). Antidepressants are also prescribed when clinical signs of depression appear. When choosing a treatment regimen, consultation with a psychiatrist is necessary. If there

is a history of severe depressive or neurotic disorders, special treatment is necessary to mitigate the destabilizing effect of IFN. If the patient has previously been treated for depression or psychosis, IFN treatment is contraindicated. Benzodiazepines should be avoided if the patient has a history of injection drug use, as they may be addictive (8, Page 337).

WHO Recommendation: Diabetes and hypertension care may be integrated with HIV services (conditional recommendation, very low-certainty evidence) (4, Page 386).

ART should be initiated and maintained in people living with HIV in care settings where opioid substitution therapy is provided (strong recommendation, very-low-certainty evidence). As well, WHO recommends opioid substitution therapy (with methadone or buprenorphine) for treating opioid dependence combined with psychosocial support (4, Page 388).

Co-administering EFV decreases methadone and buprenorphine concentrations. This could subsequently cause withdrawal symptoms and increase the risk of relapse to opioid use. People taking methadone and EFV should be monitored closely, and those experiencing opioid withdrawal may need to adjust their methadone dose. LPV/r may also reduce concentrations of methadone, and both drugs are associated with QT prolongation. (1, Page 184).

Proposed Change: Given the country's efforts to decentralize treatment and care services, a working group should be formed to develop a comprehensive plan to integrate the above services into the overall care and treatment system most appropriate for the country.

V. Healthcare service provision

10. Retesting Before Enrollment in Care and Treatment Programs

Current Practice: In Armenia, there is no recommendation for retesting before enrollment in care and treatment programs. However, Armenia has long used a three-test strategy (2, Page 46), meaning that all people seeking HIV testing services already have three consecutive reactive test results when receiving a positive HIV diagnosis. In addition, according to the latest updated HIV treatment protocol 2023, rapid initiation of ARV therapy is recommended within 7 days after HIV diagnosis, and if the patient is ready, ARV therapy should be offered on the day of diagnosis (4, Page 28). Thus, mandating repeat testing for all patients diagnosed with HIV before starting ART would mean moving to a “four-test” strategy. Based on the above, in the case of Armenia, it is advisable to conduct retesting in the case of those people who know their HIV status but did not start or interrupted treatment. In this case, according to the same WHO recommendations (1, Page 33), repeat testing is an important opportunity to initiate or renew care, as well as to build trust and familiarity with healthcare providers and the care-seeking process.

WHO Recommendation: WHO recommends retesting to confirm HIV status before starting Antiretroviral Therapy (ART) using the same strategy and testing algorithm as for the initial diagnosis. At the same time, retesting among people living with HIV who

already know their status and are on treatment is not recommended because it may give false results if the person with HIV is on ART (1, Page 31).

For some people who know their HIV status but have not initiated or discontinued treatment, retesting is an important opportunity to initiate or re-engage in care build trust and gain familiarity with healthcare workers and the process of linking to care (1, Page 33).

Proposed Change: Incorporate retesting before starting ART in the case of those people who know their HIV status, but did not start or interrupted treatment.

11. Continuity of care

Current Practice: Even though the main directions of complex medical care of patients are support for adherence to the treatment regimen and dispensary control to ensure lifelong ARV treatment (8, Page 42).

Ensuring uninterrupted treatment and care implies actions aimed at (8, Page 43):

1) Ensuring the sequence of involvement in HIV testing and treatment,

2) Dispensary control, patient follow-up,

3) Adherence to the treatment regimen by the patient,

4) Defining the optimal frequency of dispensary visits and receiving medicines.

However, despite the principles voiced in the national recommendations, and the viral load monitoring is provided regularly, the NCID has not implemented a comprehensive support service for PLHIV, aimed at monitoring and ensuring adherence to dispensary observation and treatment.

WHO Recommendation: WHO strongly recommends that adherence support interventions be provided to people receiving ART. Viral load monitoring is the gold standard for monitoring adherence and confirming treatment response. Other approaches to monitoring adherence should be considered as a way to provide additional information about the risk of failure to suppress viral loads or to support daily tablet-taking behavior in settings in which viral load testing is not available. Knowledge of adherence can support decisions about whether a recipient of care is eligible for simplified models of service delivery and whether to switch treatment regimens when viral load is unsuppressed (1, Page 364).

Further research is needed to determine (1, Page 365):

Optimal ways to proactively monitor adherence and identify through simple triage the people in greatest need of adherence support;

The most accurate measures of adherence to ART that are feasible in settings with limited resources to complement viral load testing;

Interventions to support adherence in populations at heightened risk of suboptimal adherence (children and adolescents, pregnant women, men who have sex with men and people who inject drugs);

Potential synergistic effects of combining two or more interventions that could affect individual, social support, and health system factors; and

The effectiveness of long-acting ART in improving adherence and suppression of viral loads.

Proposed Change: There is a need to study, using innovative methods and approaches, the existing strategies and needs of PLHIV in the formation of consistency and commitment to dispensary control and treatment of HIV infection, based on them, the introduction of specialized psychosocial services aimed at changing the behavior of patients with ARV treatment.

12. Decentralization and Integration of Services

Current Practice: In Armenia, HIV testing services are available in medical institutions at all levels, and testing at the community level is also possible (called self-testing conducted with the assistance of a consultant) (7).

Pregnant women are tested simultaneously for HIV, syphilis, and hepatitis.

Patients with HIV receive treatment for general somatic pathology at services that provide HIV treatment.

ART is initiated in people living with HIV who are receiving opioid substitution therapy.

Even though in 2023 a pilot project was carried out to provide ARV drugs in certain regions (7, Page 42) of the country, ARV drugs are still provided mainly by the NCID center - this happens centrally.

WHO Recommendation: Consider the feasibility of decentralizing ARV treatment services, weighing the benefits against potential stigma and discrimination risks.

Integration is the co-location and sharing of services and resources across different areas of health care settings, including the provision of HIV testing, prevention, treatment, and care services along with other related health services.

WHO recommends integrating HIV services, including testing services, as well as a range of other relevant clinical services, such as tuberculosis, hepatitis, STIs, maternal and child health, sexual and reproductive health, primary health care, programs for key populations, such as harm reduction programs for people who inject drugs and, in certain countries, voluntary medical male circumcision (1, Page 29).

To reinforce the delivery of ART at scale, WHO promotes a public health approach to ART, using simplified and standardized ART that supports the decentralization of care, task sharing community delivery and, more efficient procurement and supply management(1, Page 340).

Treatment of diabetes and hypertension can be integrated with HIV prevention and testing services (conditional recommendation, very low level of evidence) (Page 386).

ART should be initiated and maintained in people living with HIV receiving opioid substitution therapy (strong recommendation, very low evidence). WHO recommends opioid substitution therapy (methadone or buprenorphine) for the treatment of opioid dependence in combination with psychosocial support (1, Page 388).

Proposed Change: Decentralization of ARV Treatment Services: The Ministry of Health and the NCID should assess the possibilities of decentralizing ARV treatment services to regional healthcare institutions, also taking into account the experience of

the pilot project for the provision of ARV drugs in the regions. Conduct a cost-benefit analysis considering transportation costs, wait times, and potential benefits.

Establish training programs for healthcare providers at regional healthcare facilities to ensure they are capable of providing ARV treatment, including prescription and monitoring.

Develop guidelines and protocols for decentralized ARV treatment services, emphasizing the importance of maintaining confidentiality and reducing stigma and discrimination.

Support for Key Populations: Tailor HIV testing and treatment services to the specific needs of key populations, such as people who inject drugs.

Implement harm reduction programs for key populations, including access to opioid substitution therapy (methadone or buprenorphine) in combination with psychosocial support, as recommended by WHO.

Ensure that key populations have access to confidential and non-discriminatory services.

Engage key stakeholders, including healthcare providers, patients, and community organizations, in the implementation and evaluation process.

VI. Policy and Regulatory Updates

Current Practice: No registration of drugs included in the regimens ARV treatment series 1, 2, 3 (only a short list of registered drugs (Aluvia, Viread, Norvir, Tivicay, Instgra, Epclusa, Softvel). The list of essential drugs with low demand has not been updated since 2013. The drugs included in this list, didanosine, and stavudine, are not included in the updated treatment regimens. At the same time, several drugs used in treatment regimens are not included in this list, in particular, the integrase inhibitor raltegravir, and dolutegravir.

WHO Recommendation: The overarching objective of procurement and supply management systems is to support national policy with the adequate and continuous availability of the most effective, heat-stable, fixed-dose, quality-assured ARV drug formulations, diagnostics, and other consumables at service delivery sites, in the right quantities, at the lowest possible cost, with the right remaining shelf life on delivery and promptly (1, Page 420).

Proposed Change: Even though the lack of registration and the absence of drugs in the list of essential drugs is not a barrier to procurement, it is still recommended to update the List of Essential Medicines with Low Demand (not updated since 2013) to include drugs used in ART regimens - by HIV treatment protocols. It is necessary to reduce the cost of second-line regimens, either through the gradual displacement of lopinavir/ritonavir or through the purchase of a generic version of lopinavir/ritonavir and ritonavir as a separate drug, taking into account the fact that the patent holder has waived intellectual property rights worldwide, including the territory of the Republic of Armenia. It is necessary to optimize the structure of procurement of ARV drugs by the latest WHO data, in particular, it is recommended to increase the share of EFV at a dosage of 400 mg.

VII. Human rights and enabling environment

Informed Consent: Armenian and the WHO guidelines underscore the significance of informed consent for HIV testing and counseling, with the Armenian guideline mentioning the right to withdraw, while the WHO guideline provides more detailed information about the consent process, including the voluntary nature of certain testing approaches. The Armenian guideline emphasizes that consent for HIV testing and counseling is required, and it can be given verbally after receiving relevant information about the process. The focus is on the individual's right to withdraw from the process. However, to start ARV treatment, written informed consent is obtained from the patient. On the other hand, the WHO guideline also stresses the importance of informed consent for HIV testing services. It explicitly mentions that verbal consent is sufficient, and written consent is not required. It further highlights HIV testing services and the need to inform individuals about the testing and counseling process and emphasizes the right to decline testing. Additionally, the WHO guideline specifies that people who request or report self-testing should not be assumed to have provided consent implicitly.

Consent to HIV testing is considered important for pre-test service providing. However, while noting this, the Armenian guideline specifically does not mention that even though pre-test counseling can also be done in groups, consent to conduct HIV research must be given separately and confidentially.

The Armenian guideline is tailored to the national legal context, outlining mandatory testing for particular groups such as donors of blood, biological fluids, tissues, and organs, as well as children born to mothers with HIV infection. In contrast, the WHO guidelines offer broader, global recommendations that are adaptable to various local contexts and legal frameworks, not restricted to any single country's laws.

The Armenian guidelines define that HIV testing is conducted upon receiving the visitor's verbal informed consent during the pre-test counseling or if a patient does not explicitly refuse the testing. Without such consent, HIV testing may be conducted when the visitor is critically ill or unconscious, the patient's relatives or caretakers are absent, and knowledge of the visitor's HIV status is necessary for the proper organization of the patient's treatment. In such cases, the decision regarding the testing is made by a medical consultation (consilium), and in case of its impossibility, by a doctor. However, the Armenian guideline does not address the issue of informed consent for persons under the influence of drugs or alcohol or with mental health issues, they should not be forced to be tested for HIV because they are unable to give informed consent.

Confidentiality: The Armenian guidelines state that confidentiality implies that the subject undergoes HIV testing and counseling by the principle of confidentiality, but does not define what that principle is. However, the WHO guideline defines that HIV testing services must be confidential, which means that what the HIV testing services provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Also, the WHO guideline highlights that confidentiality should be respected, at the same time, it should not be allowed to reinforce secrecy, stigma, or shame. Counselors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family members – trusted others – and healthcare

providers is often highly beneficial. However, Amendments and additions were made to the Law of the Republic of Armenia "On Medical Assistance and Services of the Population" (10.), and what medical confidentiality is defined. According to that health-related personal data is the information about the patient's health condition or about applying for or receiving medical care and services, as well as data revealed during the provision of medical care and services. In addition, the requirements for the development of medical confidentiality, including the legal grounds for its transfer, are defined.

In the case of a positive diagnosis of HIV, both the WHO guideline and the Armenian guideline are guided by the same principles, however, there are certain differences between them. In contrast to the Armenian guideline, the WHO guideline emphasizes the features of disclosure of the status of HIV-positive persons and preservation of confidentiality. HIV-positive individuals have serious concerns about the confidentiality of their status and questions about disclosing it.

The WHO recommends that couples and partners should be offered voluntary HIV testing services with support for mutual disclosure. Disclosing one's HIV-positive status to one's sexual partner, family members, and friends can have significant benefits, especially for couples and sexual partners. However, many patients who learn of their HIV-positive status before disclosing it to anyone need to accept and realize it and may need additional counseling. These nuances are not described in the Armenian guideline.

Healthcare workers should inform HIV-positive individuals that other healthcare workers involved in the patient's care need to be aware of the status to receive appropriate medical care and services. However, the patient's fundamental right to privacy must be preserved within the scope of such disclosure. It is considered unethical to disclose information about a patient's status to the police or other law enforcement bodies unless the patient has given consent. In this case, medical workers need the written consent of the patient to provide the mentioned information to law enforcement bodies.

Social network-based approaches: The WHO guideline recommends social network-based approaches that can be offered as an HIV testing approach for key populations - men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, and transgender people as part of a comprehensive package of care and prevention. The WHO guideline emphasized that providing education on human sexuality can enhance awareness and comprehension of sexually diverse communities, particularly individuals who identify as lesbian, gay, bisexual, transgender, queer, or intersex (LGBTQI), as well as adolescents and young people. This education aims to offer accurate information and services related to sexual and reproductive health and rights HIV testing services. The WHO guideline recommends comprehensive HIV response must address key populations, as the HIV burden continues to be very high among them, mentioning that poor coverage and low uptake of HIV testing services among key populations is in part due to a lack of accessible, available, and acceptable services. Legal and social issues related to people from key populations and their behaviors also increase their vulnerability to HIV and impede access to HIV services including prevention, testing, treatment, and care. Such issues include HIV-related stigma and discrimination, criminalization, and punitive laws and practices.

The WHO guideline addresses the voluntary nature of provider-assisted referral and social network-based approaches, underlining that these services are implemented only with the consent of clients and contacts. At the same time, the WHO defines women who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support. Healthcare providers should ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by intimate partner violence, to improve diagnosis/identification and subsequent care. Meanwhile, the Armenian guideline does not address these issues.

Enabling environment: The WHO guideline pointed out that creating an enabling environment is especially emphasized to support more effective health interventions and better health outcomes. Services should be delivered in safe and acceptable spaces that offer protection from the effects of stigma and discrimination, where individuals and partners can freely express their concerns, and where providers demonstrate patience, understanding, acceptance, and knowledge about the choices and services available. Adolescent-friendly health services should be implemented in HIV services to ensure engagement and improved outcomes. Enabling interventions to address structural barriers to accessing services may increase access to, uptake of, and adherence to prevention as well as testing and treatment services. Such interventions address the critical social, legal, political, and enabling environment that contributes to HIV transmission, including legal and policy reform towards decriminalizing behavior such as drug use and same-sex sex, and sex work to reduce stigma and discrimination, including in the health sector, promoting gender equality and preventing gender-based violence and violence towards key populations, economic and social empowerment, access to schooling and supportive interventions designed to enhance referrals, adherence, retention, and community mobilization.

Decentralization: The WHO guidelines address the issue of decentralization, describing both its positive and negative aspects. The WHO defines decentralization of HIV testing services refers to providing HIV testing services at peripheral health facilities such as primary healthcare facilities as well as outside of health facilities in the community. Providing HIV testing services in places closer to people's homes may reduce transportation and other costs and waiting times experienced in central hospitals, thus improving accessibility and uptake. HIV testing services in community settings may be more attractive for men, young people, and key populations, who are otherwise less likely to test in facilities. Close collaboration between community programs conducting HIV testing and nearby health facilities and healthcare providers is likely to improve rates of early enrolment in care. Linkage for ART and care services should be provided as quickly as possible, ideally in all decentralized sites and programs.

Decentralization of HIV testing services may not always be appropriate or acceptable to potential users. In some settings, centralized HIV services may provide greater anonymity than neighborhood services for key populations or others who fear stigma and discrimination. In some low-prevalence settings, decentralizing HIV testing services may be inefficient and costly. Context, needs, service gaps, and overall costs and benefits should be weighed to determine the extent and manner of decentralizing HIV testing services.

Although the Armenian guideline does not address this issue, in general, in practice, this method is partially applicable in Armenia as well. In practice, HIV testing and counseling are carried out both in Yerevan and in the RA provinces in medical institutions, sometimes even rapid testing is carried out by sectoral NGOs, as well as in the National Center for Infectious Diseases through mobile clinics. However, a final diagnosis and further treatment can only be obtained at the National Infectious Diseases Center of the RA Ministry of Health, which can be a significant obstacle, especially for the population living in remote provinces, who have to spend several hours to reach the Center every time. However, to avoid discrimination, many people prefer to receive HIV testing and treatment at a medical facility as far away from their place of residence as possible.

Recommendations for human rights and enabling environment:

1. **Voluntary Nature of Testing:**
    - Align the guideline more closely with the WHO's emphasis on the voluntary nature of HIV testing services, explicitly stating that testing for diagnosis must always be voluntary.
2. **Consent for ARV Treatment:**
    - Reevaluate the requirement for written informed consent to start ARV treatment. Consider adopting the WHO's approach, emphasizing the sufficiency of verbal consent, and ensuring consistency in the consent process.
3. **Group Counseling and Research Consent:**
    - Clearly state within the guideline that, even in group pre-test counseling, consent for HIV research must be obtained separately and confidentially, aligning with international best practices.
4. **Special Cases and Informed Consent:**
    - Define procedures for obtaining informed consent in specific cases, such as persons under the influence of drugs or alcohol or those with mental health issues, ensuring they are not forced into testing due to inability to provide informed consent.
5. **Clear Definition of Confidentiality:**
    - Define explicitly what confidentiality means in the context of HIV testing services, following the Law on Medical Assistance and the WHO guidelines, and elaborate on how the principle of confidentiality is maintained during service provision.
6. **Disclosure of HIV-Positive Status:**
    - Address the nuances of disclosure of HIV-positive status, as recommended by the WHO. Guide counseling patients who need to accept and realize their status before disclosing it to others.
7. **Shared Confidentiality:**
    - Emphasize the benefits of shared confidentiality with partners, family members, and healthcare providers within the guidelines, promoting open communication while maintaining privacy.

8. **Integration of Social Network-Based Approaches:**
    - Consider integrating social network-based approaches into the guideline, particularly for key populations. Address education on human sexuality to enhance awareness among diverse communities.
9. **Violence Disclosure:**
    - Address the issue of violence disclosure within the guideline. Provide support for individuals facing intimate partner violence, aligning with the WHO's recommendations.
10. **Creating an Enabling Environment:**
    - Emphasize the creation of an enabling environment within the guideline. Encourage services in safe and acceptable spaces, ensuring protection from stigma and discrimination.
11. **Adolescent-Friendly Health Services:**
    - Explicitly mention the implementation of adolescent-friendly health services within the context of HIV services to improve engagement and outcomes for young individuals.
12. **Consideration of Decentralization:**
    - Integrate a phased and context-specific decentralization plan for HIV services in Armenia, emphasizing increased accessibility for remote populations. Prioritize collaboration with local health facilities, community programs, and key stakeholders to ensure seamless service delivery while considering the unique needs of different provinces.
13. **Mitigating Discrimination Concerns:**
    - Address concerns related to discrimination by discussing strategies to mitigate discrimination, ensuring that individuals receive testing and treatment without fear of discrimination based on location.

Implementation

To ensure the successful implementation of this strategy, Armenia must develop a detailed plan with a timeline for implementing the updated protocols. The effectiveness of the strategy should be regularly assessed, and changes made as necessary to keep up with emerging evidence and WHO updates.

Table 1. Summary of main proposed changes to national legislation and algorithm for introducing amendments

#	Name of national guidelines	Proposed changes	The mechanism for amending the guidelines (who & how)	Approx. dates of proposed actions
1	Clinical Guidelines for Counseling Testing and Laboratory Diagnosis of HIV Infection	Update diagnostic algorithms to exclude immunoblotting (Western blot) and incorporate WHO-recommended diagnostic accuracy characteristics of rapid tests. Incorporate retesting before starting ART in the case of those people who know their HIV status, but did not start or interrupted treatment. Move from pre-test counseling to providing pre-test information.	MoH and NCID, The National Expert Group	End of 2024 (according to the HIV/AIDS Prevention Program 2022-2026)
		Include recommendations on community-based HIV testing. Expand pre-test services to include WHO's comprehensive strategies, utilizing digital tools and community participation.	The National Expert Working Group of representatives of the MoH, NCID, and the Civil Community	
2	Clinical Guidelines for Anti-Retroviral Treatment of HIV Infection	Decentralize ARV treatment services to regional health care institutions, also taking into account the experience of the pilot project for the provision of ARV drugs in the regions. Conduct a cost-benefit analysis considering transportation costs, wait times, and potential benefits. Develop guidelines and protocols for decentralized ARV treatment services, emphasizing the importance of maintaining	The National Expert Working Group of representatives of the MoH, NCID, and the Civil Community	End of 2024 (according to the HIV/AIDS Prevention Program 2022-2026)

#	Name of national guidelines	Proposed changes	The mechanism for amending the guidelines (who & how)	Approx. dates of proposed actions
		confidentiality and reducing stigma and discrimination.		
		Develop a comprehensive plan to integrate services for common noncommunicable disease management in PLHIV into the overall care and treatment system most appropriate for the country.	MoH and NCID, The National Expert Group	End of 2024
		Study the existing strategies and needs of PLHIV in the formation of consistency and commitment to dispensary control and treatment of HIV infection. Based on them, introduce specialized psychosocial services aimed at changing the behavior of patients with ARV treatment.	MoH, UNAIDS The National Expert(s)	End of 2024
		Implement harm reduction programs for key populations, including access to opioid substitution therapy (methadone or buprenorphine) in combination with psychosocial support.	The National Expert Working Group of representatives of the MoH, NCID, and the Civil Community	End of 2024
3	List of Essential Medicines with Low Demand (not updated since 2013)	Update the List of Essential Medicines with Low Demand to include drugs used in ART regimens - by HIV treatment protocols	MoH and NCID	End of 2024
4	HIV/AIDS Prevention Program (current version is for 2022-2026)	Develop a national action plan on HIV drug resistance, which should be integrated into the national HIV strategic plan.	MoH and NCID, The National Expert Group	End of 2024

Conclusion

This strategy addresses the key discrepancies and aims to optimize the HIV treatment and testing protocol in Armenia, ensuring compliance with WHO standards and improving the overall quality of HIV care in the country. Regular updates to the strategy will be critical to adapt to changing WHO recommendations and the changing health situation in Armenia.

The analysis underscores the alignment of guiding principles in WHO and Armenian HIV testing guidelines. However, the WHO guidelines offer a more nuanced, globally adaptable approach, emphasizing the importance of human rights and public health. The Armenian guidelines, while reflecting national legal considerations, lack detailed provisions on informed consent, confidentiality, and universal health coverage. Recommendations advocate for refining these aspects, integrating WHO's comprehensive approach, and focusing on the needs of vulnerable groups. Furthermore, acknowledging the benefits of decentralization in HIV services could significantly enhance accessibility in Armenia, aligning with the broader global health context.

References

1. Consolidated guidelines on HIV prevention, testing, treatment, service delivery, and monitoring: recommendations for a public health approach, 2021
2. Clinical Guidelines for Counseling Testing and Laboratory Diagnosis of HIV Infection, 2017
3. Clinical Guideline for Human Immunodeficiency Virus Pre-Exposure Prophylaxis, Order No. 5466-L of the RA Minister of Health of November 25, 2022
4. Clinical Guidelines for Anti-Retroviral Treatment of Human Immunodeficiency Virus Infection, 2023
5. Clinical Guidelines for The Management of Patients With HIV/TB Co-Infection, 2023
6. Clinical Practice Guidelines on Hepatitis C Management, 2020
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8. Clinical guidelines for the treatment and prevention of HIV infection using antiretroviral drugs, 2017
9. Prevalence of HIV-1 drug resistance in Eastern European and Central Asian countries, 2022
10. The Law of the RA "On Medical Assistance and Services of the Population"