

Standardized protocol for
clinical management and
medical data-sharing for
people living with HIV among
refugees from Ukraine

Abstract

This brief publication sets out recommend principles of clinical management and describes how medical data related to care can be shared among health professionals engaged in providing medical care for refugees from Ukraine who are living with HIV and who are seeking care in other European countries.

Keywords

human immunodeficiency virus
AIDS
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people living with HIV
Refugees
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Standardized protocol for clinical management and medical data-sharing for people living with HIV among refugees from Ukraine

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- the WHO Collaborating Centre on HIV and Viral Hepatitis, Centre of Excellence for Health, Immunity and Infections (CHIP) Rigshospitalet, University of Copenhagen, Denmark;
- the European AIDS Clinical Society (EACS);
- the Euroguidelines in Central and Eastern Europe Network Group (ECEE); and
- the Public Health Centre of the Ministry of Health of Ukraine (PHC).

The protocol was reviewed by the European Centre for Disease Prevention and Control (ECDC).

Background

HIV prevalence among adults in Ukraine is estimated to be 1%. Prior to the war, there were approximately 250 000 people living with HIV (PLHIV) in Ukraine, of whom 98% were adults (1). Antiretroviral treatment was provided to approximately 130 000 PLHIV, including 2700 children.

Initially, the HIV epidemic in Ukraine mainly affected persons injecting drugs, but in the last decade, sexual transmission has been the main reported route of transmission. It is estimated that a comparable number of women and men are infected.

HIV remains a condition associated with stigmatization in Ukraine and elsewhere. According to WHO guidelines, antiretroviral therapy should be provided to all people living with HIV. The approach to care in Ukraine follows WHO guidelines, with the aim of using a standardized regimen of tenofovir, lamivudine (or emtricitabine) and dolutegravir unless there are medical contraindications. Currently, 80% of adult antiretroviral treatment in Ukraine follows this recommendation. The aim is to increase this closer to 100% as patients are transitioned from earlier, now obsolete, regimens.

It is estimated that refugees will be fairly representative of the Ukrainian population of women, children and men over 60. Based on this assumption, a considerable number of adult refugees will be PLHIV (projected to be 10 000 per million adult refugees).

The emergency is significantly affecting neighbouring countries that are first-entry points for many displaced people from Ukraine. The United Nations High Commissioner for Refugees, however, estimates that a large number of people have already moved onwards to other countries. Consequently, there is a need to establish a protocol for the clinical management and medical information required for HIV clinics outside Ukraine to provide antiretroviral therapy to Ukrainian refugees living with HIV.

Criteria required for HIV clinics to continue antiretroviral treatment for adults and children upon arrival outside of Ukraine

A patient care pathway, including necessary investigations during the first appointment outside of Ukraine, is set out in Annex 1.

Documentation that the person is HIV-positive is desirable. If the refugee does not possess this documentation but claims to be HIV-positive, the clinic should perform a rapid HIV test. Where such testing is not possible/available or the result is considered by a clinician to be a false negative, a written declaration from the patient should be considered sufficient to provide an emergency supply of antiretrovirals.

It is recommended that routine HIV serology testing should be performed if proper documentation does not exist; this will enable clinics to provide refugees with the correct documentation should they subsequently move to another country.

Wherever possible, information regarding documentation of HIV status and previous therapy should be sought from the Public Health Centre of the Ministry of Health of Ukraine using the cover letter and instructions for European clinicians and Ukrainian patients (Annex 2) and patient consent form (Annex 3). Information will be provided by the Public Health Centre through a standard template for medical information (Annex 4). Provision of immediate therapy should not be withheld while awaiting this information. When available, the information should be incorporated into documentation provided to the displaced person in case of onward relocation.

It is projected that there will be a relatively large number of undiagnosed persons among the refugees (around 40% of PLHIV do not know their status), so HIV testing, in addition to testing for other blood-borne viruses (such as viral

hepatitis), is encouraged. If discretion is not possible due to the field environment or emergency conditions, self-testing should be considered a viable approach.

For all refugees (adults and children of HIV-positive adults) who are hospitalized, it is strongly recommended that HIV testing is offered to maximize opportunities for testing.

It is preferred, but is not an absolute requirement, that refugees have documentation of their most recent HIV-RNA viral load and CD4+ lymphocyte count. Having information on duration of infection and duration of antiretroviral treatment, possible prior treatment-limiting adverse effects and viral failures leading to treatment switches is also preferable, but not required. It may be possible to acquire this documentation retrospectively from Ukraine (see Annexes 2–4).

The initial interview should focus on whether the HIV-positive refugee is aware of any chronic noncommunicable conditions or coinfections (in particular, tuberculosis (TB) and hepatitis B/hepatitis C) in addition to HIV. If comedications are being taken for these conditions, these can also be provided. Where feasible, and in accordance with local practice, screening and management of viral hepatitis, TB and sexually transmitted infections is encouraged. HIV pre-exposure prophylaxis may be provided to people at high risk of HIV acquisition, in accordance with local practice and feasibility.

It is preferred that refugees are able to show clinicians their remaining antiretroviral treatment tablets provided by clinics in Ukraine, but as long as their HIV status is documented as detailed above, immediate provision of antiretroviral treatment is indicated. Therapy should be started as soon as feasible for all HIV-positive refugees not already established on antiretroviral treatment.

It is preferred, if possible, that minimally current lymphocyte count and lymphocyte subsets, hemoglobin, serum creatinine, alanine transaminase and HIV-RNA levels are established by the clinic responsible for HIV care. Baseline viral resistance testing should be undertaken where available. If applicable, co-trimoxazole prophylaxis will need to be provided as part of the WHO package of care for advanced HIV infection (2) and European AIDS Clinical Society (EACS) guidelines (3).

It is recommended that refugees receive enough antiretroviral medication to cover 90 days of treatment. This duration seems reasonable to ensure that refugees have sufficient medication to see them through their initial stay outside of Ukraine, especially for those who may choose to transit onwards into Europe. Refugees should receive documentation from HIV clinics that confirms their HIV status, details the type and amount of antiretrovirals received, lists other medicines provided and presents the results of any laboratory or radiological assessments, in addition to providing the information received, if any, from Ukraine. A hard copy of the documents should be kept at the clinic. Refugees should be encouraged to take a picture of the documentation and provided regimen to retain on their mobile devices.

Type of antiretroviral treatment provided to refugees

After appropriate initial evaluation following the WHO consolidated HIV guidelines (2), therapy should be initiated or continued with the WHO-recommended regimen of tenofovir, lamivudine (or emtricitabine) and dolutegravir. Where this is not feasible or possible, other WHO- or EACS- preferred or recommended first-line antiretroviral treatment should be prescribed, bearing in mind the possible need to switch therapy depending on what may be available in cases of onward migration or return to Ukraine. Alternative antiretroviral therapies or second-/third-line therapies where needed should be discussed with local experts in HIV management.

The costs of treatment, prophylaxis and clinic provision of care for Ukrainian refugees need to be agreed within each country. It is strongly recommended that care, including treatment, is offered at no cost to the refugee. The approach to handling this issue will differ across countries, but it is important that each country makes policy decisions at government level to ensure care is provided in a seamless fashion. The European Council has adopted a Temporary Protection Directive that offers an appropriate response to the present situation by providing immediate protection and rights, including rights to medical assistance (4).

Transfer of medical data and documentation from HIV clinics within Ukraine to HIV clinic outside Ukraine, and between clinics in cases of relocation outside of Ukraine

As medical data and documentation are personal and strictly confidential, transfer can occur only through a secure line of communication established between health professionals responsible for the refugees' care within Ukraine and the current HIV clinic outside Ukraine, or between clinics outside of Ukraine currently responsible for refugees' care. This can only happen, though, with the refugee's signed consent to the transfer of the data and documentation.

For this purpose, the Public Health Centre of the Ministry of Health of Ukraine has developed a "Statement on the provision of information on health and treatment" form that can be used by patients to enable clinics outside Ukraine to receive any medical information needed. Clinicians outside Ukraine can send the form, signed by the patient, to the Public Health Centre in Ukraine, following which the Public Health Centre will provide the medical data in a standard format by email to the clinicians (see instructions for clinicians and patients on how to use the form in Annex 2. The form (in English and Ukrainian language) is presented in Annex 3 and the template for medical information provided by the Public Health Centre in Annex 4.

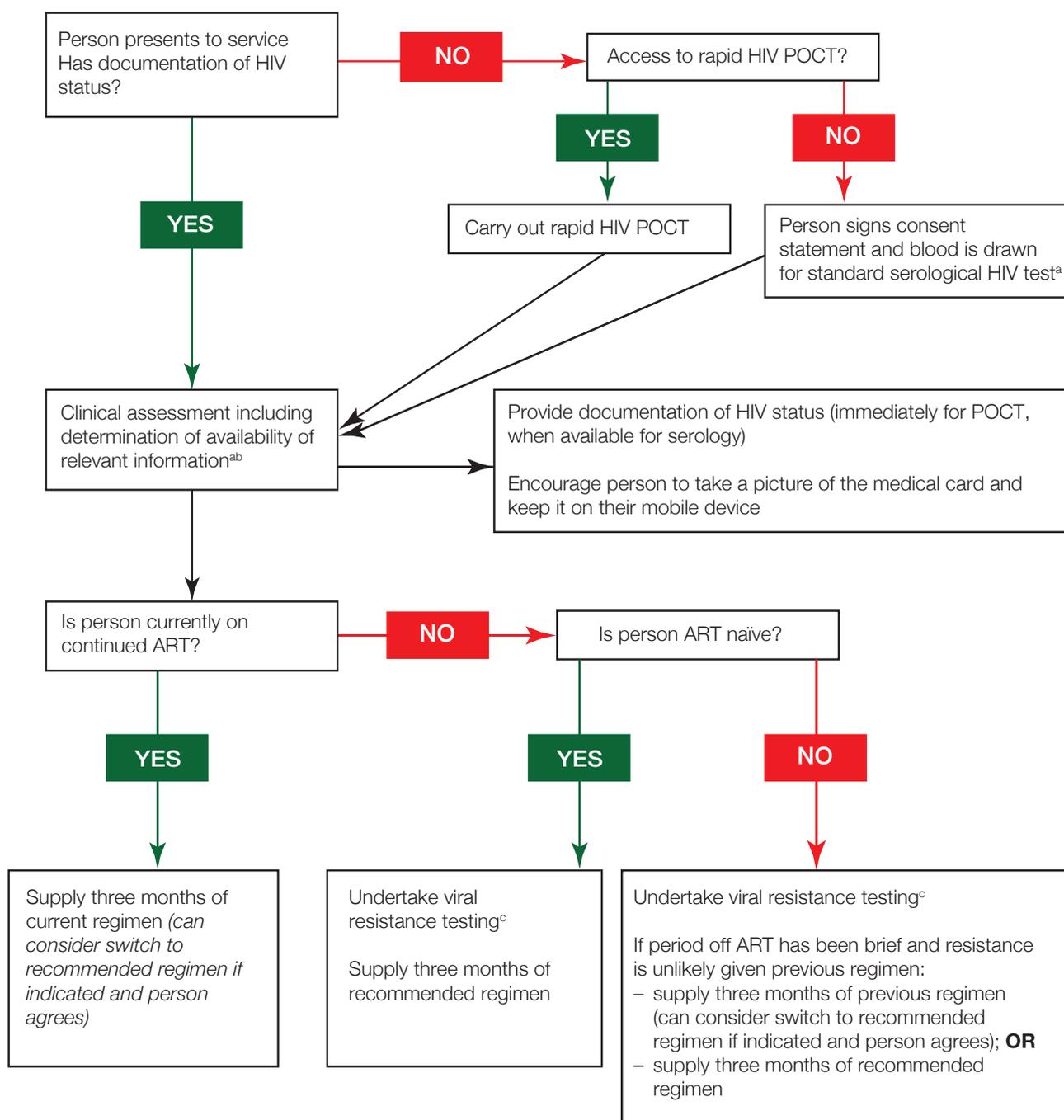
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1. AIDSinfo [website]. Geneva: Joint United Nations Programme on HIV and AIDS; 2020 (<https://aidsinfo.unaids.org/>).
2. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach, 2021 update. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/handle/10665/342899>).
3. Guidelines version 11.0 October 2021. Brussels: European AIDS Clinical Society; 2021 (<https://www.eacsociety.org/guidelines/eacs-guidelines/>).
4. Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof. O. J. E. U. 2021, L 212:12–23 (<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0055&from=LT>).

¹ All references accessed 12 April 2022.

Annex 1

Care pathway (including investigations) for first appointment



ART: antiretroviral therapy. POCT: point-of-care testing.

^aRequest relevant information from Ukraine, with patient consent (see Annexes 2 and 3), where appropriate and feasible.

^b Undertake investigations where data missing including HIV viral load, CD4 and renal function, and include serological HIV test if required, and viral hepatitis, syphilis and TB testing where appropriate.

^cInclude viral resistance testing if feasible, required and available.

Annex 2

Cover letter and instructions for European clinicians and Ukrainian patients

Dear colleagues

Thank you very much for providing medical care to patients from Ukraine.

We would like to share our data exchange algorithm which is designed to assist you in acquiring medical information about Ukrainian patients who come to your clinic for HIV care without any medical documentation.

When a patient comes to your clinic for HIV care without any medical documentation, please fill out the Patient's Statement [see Annex 3] along with the patient, ensure it is signed by the patient, and send the signed and scanned copy to the email of the Public Health Centre of the Ministry of Health of Ukraine: stop.hiv@phc.org.ua.

The Statement signed by the patient will allow the Public Health Centre to facilitate the transfer of medical information about the patient to you, according to the Patient Information Template [Annex 4].

You will receive the patient's medical information 1–2 days after sending the signed Statement to stop.hiv@phc.org.ua.

Please note the following when filling out the Statement.

- Please make sure the Statement is completed in both languages – Ukrainian and English. You may keep the signed Statement as part of medical documentation of the patient.
- “*Person applying*” in the Statement is the patient.
- In the top left part of the Statement, please indicate your country and clinic in the “*country of temporary stay; name of the clinic where medical care is received now*” section.
- “*Name of the person signing the Statement*” at the bottom of the document is the patient's name, and the signature required is the patient's signature.
- In the section “*please specify an email to which medical information will be sent*”, please indicate your email address.

If the patient is planning to travel to another country or another city, we kindly ask you to print out and provide the patient with the medical information you have received as well as all relevant information about medical care received in your clinic. This will allow the patient to share required medical information that will enable him/her to receive care in another clinic.

Thank you so much for supporting Ukraine!

Annex 3

Statement on the provision of information on health and treatment

English-language version

To: public institution Public Health Centre of the Ministry of Health of Ukraine, HIV Management and Counteraction Department
(email: stop.hiv@phc.org.ua)

From:

(name of the person applying; date, month and year of birth)

(series and number of the Ukrainian national passport, authority which issued the passport, date of issue)

(country of temporary stay; name of the clinic where medical care is received now)

Statement on the provision of information on health and treatment

I, _____,
(last name, first name, patronymic of the person applying)

who was under medical supervision in Ukraine in a medical facility

(indicate the name of the health-care institution in Ukraine where the person received medical care; and if available ambulatory card number; personal number in Medical Information System for HIV)

inform you that because of the military aggression of the Russian Federation against Ukraine and the change of my place of permanent residence, by forced relocation outside the state border of Ukraine, in order to further receive HIV treatment at my temporary residence, I kindly ask the Public Health Centre of the Ministry of Health of Ukraine to facilitate the provision of information to me from my attending physician or health-care institution where I was under medical supervision, regarding:

- confirmatory tests for serological markers of HIV;
- clinical diagnosis of HIV infection and date of its establishment;
- the current antiretroviral therapy (ART) schedule and its prescription date;
- history of ART, dynamics of CD4 count and HIV viral load levels (if available); and
- most recent test results for CD4 count, HIV viral load and antiretroviral resistance testing (if available).

If it is not possible to provide the requested above information, please facilitate the provision of any available information regarding my HIV treatment. Please send information about my health and treatment to:

(please specify an email address to which medical information will be sent)

By signing this Statement, I give unambiguous informed consent to the Public Health Centre of the Ministry of Health of Ukraine, including medical staff from the HIV Management and Counteraction Department, for access, processing, disclosure and transfer of my confidential information, in the sense of Article 39 of the Fundamentals of the Legislation of Ukraine on Health Care and Article 13 of the Law of Ukraine on Counteraction to the Spread of Diseases Caused by the Human Immunodeficiency Virus (HIV) and the Legal and Social Protection of People Living with HIV, which, in particular, is related to my further treatment.

(name of the person signing the Statement)

(signature)

(date, month, year)

Ukrainian-language version

До: Державна установа «Центр громадського здоров'я Міністерства охорони здоров'я України»
відділ управління та протидії ВІЛ-інфекції (email: stop.hiv@phc.org.ua)

Від:

(ПІБ особи, яка звертається; число, місяць та рік народження)

(серія та номер внутрішнього паспорту громадянина України, ким виданий, дата видачі)

(країна тимчасового перебування та назва клініки де зараз отримується медична допомога)

Заява щодо надання інформації про стан здоров'я та лікування

Я, _____, який
(прізвище, ім'я, по батькові особи, яка звертається)

(яка) перебував (-ла) під медичним наглядом в Україні у Закладі охорони здоров'я

(вказати найменування закладу охорони здоров'я в Україні, де особа перебувала під медичним наглядом; та, якщо можливо, номер амбулаторної картки; індивідуальний номер в МІС ВІЛ)

повідомляю, що у зв'язку з військовою агресією Російської Федерації проти України та зміною місця мого постійного проживання, шляхом вимушеного переміщення за межі державного кордону України, з метою подальшої можливості отримання лікування ВІЛ-інфекції за місцем мого тимчасового перебування, прошу сприяти наданню мені інформації від мого лікуючого лікаря або закладу охорони здоров'я, де я перебував (-ла) під медичним наглядом, щодо:

- підтверджувальних досліджень на наявність серологічних маркерів ВІЛ;
- клінічного діагнозу ВІЛ-інфекції та дати його встановлення;
- поточної схеми АРТ та дати її призначення;
- історії АРТ, динаміки кількості CD4 та рівня ВН ВІЛ (за можливості);
- останніх результатів обстеження на CD4, ВН ВІЛ, досліджень антиретровірусної резистентності (за наявності).

У разі неможливості надати запитувану інформацію, прошу сприяти наданню будь-якої наявної інформації, що стосується мого лікування ВІЛ-інфекції. Інформацію щодо стану мого здоров'я та лікування прошу надіслати на:

(будь ласка, вкажіть електронну адресу (email), на яку буде надіслано медичну інформацію)

Підписуючи цю заяву, я надаю однозначну усвідомлену згоду Державній установі «Центр громадського здоров'я Міністерства охорони здоров'я України», включаючи медичних працівників відділу управління та протидії ВІЛ-інфекції, на доступ, обробку, розкриття та передачу конфіденційної інформації про мене, у розумінні статті 39 Основ законодавства України про охорону здоров'я та статті 13 Закону України «Про протидію поширенню хвороб, зумовлених вірусом імунодефіциту людини (ВІЛ), та правовий і соціальний захист людей, які живуть з ВІЛ», що, зокрема, пов'язано з моїм подальшим лікуванням.

(ПІБ особи, що підписала заяву)

((підпис))

(число, місяць, рік)

Annex 4

Template for medical information provided by the Public Health Centre of the Ministry of Health of Ukraine



STATE INSTITUTION PUBLIC HEALTH CENTRE OF THE MINISTRY OF HEALTH OF UKRAINE

Date: _____

Personal information

Name of the patient

Date of birth (DD/MM/YYYY)

Sex (male/female)

National passport number

Name of the health-care institution in Ukraine where patient received medical care

Personal number in Medical Information System for HIV

Date and type of confirmatory tests for serological markers of HIV

Date of HIV diagnosis

Clinical diagnosis

Current ART regimen

Date of current ART regimen start

ART history

	Date (DD/MM/YYYY)	ART regimen	Notes
Initiation of ART			
Switching ART regimen			
Switching ART regimen			
Switching ART regimen			

Dynamics of CD4 count and HIV viral load

Date	CD4, %	CD4, cells/mm ³	VL HIV-1 RNA, copies/mL	Notes

Additional information (concomitant diagnosis, opportunistic infections, tuberculosis treatment now and in history, hepatitis C and hepatitis B diagnosis/treatment, concomitant drugs used to evaluate potential drug interactions, etc.)

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