

Guide

FOR CONTINGENCY PLANNING FOR KEY POPULATION HIV SERVICES

during COVID-19
and Other Emergencies

2022

for
**NORTH
MACEDONIA**



Author

Irina Lučeska

Coordinator

Nadiya Yanhol

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ICF "ALLIANCE FOR PUBLIC HEALTH"

Address: 24 Bulvarno-Kudriavska street, Kyiv,

Ukraine 01601, Ukraine

Phone: +380444905485

WWW.APH.ORG.UA

E-mail: office@aph.org.ua

facebook.com/AlliancePublicHealth

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Table of Contents

Acknowledgments	3
Abbreviations	5
Contingency Planning for Key Population HIV Services during COVID-19 and Other Emergencies for North Macedonia	6
Annex 1. Action planning for Key Population HIV Services during COVID-19 and Other Emergencies in North Macedonia	13

Abbreviations

ART	Antiretroviral therapy
CSOs	Civil society organizations
CBOs	Community-based organizations
EACS	European AIDS Clinical Society
GP	General practitioner
HIV	Human Immunodeficiency Virus
MoH	Ministry of Health
MSM	Men who have sex with men
OST	Opioid substitution therapy
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PLHIV	People living with HIV
PWID	People who inject drugs
STI	Sexually transmitted infections
SWs	Sex workers
TB	Tuberculosis
WHO	World Health Organization

Contingency Planning for Key Population HIV Services during COVID-19 and Other Emergencies for North Macedonia

Key Populations	Population Size Estimate	Estimated PLHIV	500 at the end of 2020
PWID	~6,800	90-90-90 Progress	66-90-94 at the end of 2020
SW	~2,000		
MSM	~11,000	Overview of Global Fund Eligibility	The country is not eligible for Global Fund funding
Transgender People	Not estimated		

Key Features of Key Population Response and Enabling Environment Prior to COVID-19

The Republic of North Macedonia has a population of 1.84 million citizens and a low-level, concentrated HIV epidemic.

There is an increasing trend of new HIV diagnoses. For the years 2016-2020 there was an average number of 46 new diagnoses annually, ranging from 30 in 2020 to 66 in 2019. The increased number of new diagnoses can be partly attributed to the targeted HIV testing services (HTS) in the key affected populations, through community-based and other civil society organizations. An exemption of this trend is the year 2020, when only 30 new cases of HIV were diagnosed, which could be attributed to the lower number of tests performed, due to the COVID-19 crisis. The number of newly diagnosed cases in 2021 was 44 (42 male and 2 female), i.e. close to the average for the previous five years. Of the new cases, 30% were discovered within the framework of the VCT program implemented by the community-based organizations, approx. 10% were diagnosed abroad, and the rest of the diagnoses were the capacities of the healthcare system. Cumulatively, among the reported HIV cases, sex between men has been the most frequently reported mode of transmission (35 out of 41 cases in 2021 and 76% of all diagnosed cases in the period 2016-2020).

31% (n=13) of the cases in 2021 were diagnosed late, with CD4 cell counts less than 350 cells/μl, while 8 of those were diagnosed during an advanced stage of the infection, when AIDS symptoms were present. Moreover, in 2020 and 2021 the number of registered deaths as a result of AIDS (HIV-related deaths) increased, which can be attributed to the decreased intensity of testing in this period due to the COVID-19 pandemic.*

Prevalence is rising among men who have sex with men (MSM), and in 2018 it was estimated at 5.4%, with a two-fold increase compared to 2014. Several categories of evidence suggest that the epidemic is under control among people who inject drugs and female sex workers.**

The ECDC HIV modelling tool estimated that approximately 500 people were living with HIV at the end of 2020. The continuum of HIV care analysis at the same time point revealed that only 66% (n=332) were aware of their HIV-positive status, which is significantly lower compared to the global average (84%). On the other hand, at least 90% of the diagnosed were receiving ART, out of whom 94% had viral suppression. The data show that there is a need to intensify the HIV testing activities in particular among MSM, increase the awareness raising efforts and introduce new approaches in prevention.

Government adopts an annual Program for the Protection of the Population from HIV Infection (National HIV Program), which has been in place since the mid-eighties, but was substantially upgraded with the Global Fund financial support starting from 2005 to the end of 2017. The National HIV Program includes both the treatment and the prevention and support components, including peer and psychosocial support for people living with HIV, men who have sex with men and people who inject drugs. Starting from 2018 the Government took over the complete financing of the National HIV Program to sustain HIV prevention services targeting key affected populations, which are implemented by civil society organizations.

ARVs are funded by the state budget from the annually approved HIV programme. Its budgeting is not based on the number of patients and had not increased for four years in row until 2021, even though the number of patients had increased by approximately 50% during that time period. Some of the medicines procured are not recommended by WHO and EACS, but are used to fit the allocated budget for treatment. Optimization of treatment regimens is needed.***

* *Government of RNM. 2022. Program on protection of the population of the HIV infection in the Republic of North Macedonia for 2022. Official Gazette of RNM, No. 33 of 15.02.2022.*

** *Mikikj, V. Stevanovik, M. Senih, A. 2020. The continuum of HIV care in North Macedonia in 2018: assessment report with a special focus on men who have sex with men. – Skopje: Association for Support of People Living with HIV Stronger Together, 2020.*

*** *Report of the Regional meeting on the access and prices of the ARV drugs in SEE countries, December 15, 2020*

Overview of Burden of and Trends in COVID-19 in North Macedonia

North Macedonia faces heavy burden of the COVID-19 pandemic, and is one of the countries with highest population toll. There have been 311,936 confirmed cases of COVID-19 since the beginning of the pandemic (as of 31.05.2022, first case 26.02.2020), or 17,300 in 100,000 population (taking into account the result of the Census 2021).* There are 9,303 COVID related deaths in the country, or ~516 in 100,000 population, which places the country at the 3rd place with highest death toll in the world.**

Currently there is a declining trend in the COVID pandemic, in line with the global trends.

At the same time point ~869,000 were vaccinated, which accounts for ~47% of the population.**

* <http://iph.mk/wp-content/uploads/2022/02/%D0%9D%D0%B5%D0%B4%D0%B5%D0%BB%D0%BD%D0%B0-%D0%B8%D0%BD%D1%84%D0%BE%D1%80%D0%BC%D0%B0%D1%86%D0%B8%D1%98%D0%B0-%D0%BE%D0%B4-14-21.02.2022.pdf>

** Adjusted from <https://www.worldometers.info/coronavirus/#countries> and the new census data available at <https://popis2021.stat.gov.mk/>

*** <https://kovid19vakcinacija.mk/>

Major Impacts of COVID on Services for Key Populations

General health care seeking behavior

As COVID-19 spread in 2020, outpatient consultations at health facilities declined considerably compared to 2019. All health facilities experienced changes in attendance. The main reason patients were no longer coming to health facilities was due to the fact that many of the services were either halted, or transformed into COVID centers. In addition, the fear of contracting COVID-19 was notable among patients, but also among primary care providers. Patients were also no longer able to reach health facilities because of disruption to public transportation services, as well as the lockdown and stay-at-home orders. Some patients delayed seeking care, while others no longer visited clinics due to changes in recommendations for mild illness and elective care.

Specific services for key population

Although the funding of the prevention services for KP was sustained during 2020/2021, the major impact was felt in 2022, when in the middle of the fiscal period (in April 2022), without any consultation with the beneficiaries and partners in the Program, **the funds were cut by 41%** (from an approved total of 46.5 million MKD to 27.5 million MKD). This COVID-related economic aftershock, as well as the general high inflation rate threaten the sustainability of the programs run by CSOs. There is a great risk for disruption in all services, including the procurement of ART and assays for HIV infection management (CD4 cell count and viral load assays) as a result thereof. An additional factor leading to increasing of the risks is the weak administrative capacity of the Ministry of Health to mitigate the economic effects of the COVID crises. As an example: awarding funds for activities to CSOs for 2022 was performed with a 3-month delay.

Major impact of the COVID-19 crisis was felt in the **outreach services**, due to the restricted freedom of movement and transportation (condoms and lubricants distribution, needle/syringe programs, HIV community testing etc.).

The **HIV testing** in 2020 was performed with decreased intensity, which resulted in a lower-than-average detection rate.

The restricted movement had a great impact on the **OST programs** through the fixed-site model, due to the fact that the specific healthcare capacities are centralized. Treatment with buprenorphine* was planned for 12 towns in N. Macedonia, but has remained centralized within the Skopje region. Barriers arise due to reduced public transportation even within the capital, considering that only two OST centres are functioning: one in the Municipality of Kisela Voda and one in the General City Hospital "8 September", which has a limited capacity. There is lack of staff not only to disperse the OST centres, but even for the current ones. Since mid-2021 doctors in OST centers have been receiving oral instructions to switch patients from buprenorphine to methadone due to the high price of buprenorphine (some patients purchase it out of pocket). Relapse has been observed among patients that were unable to buy it. Treatment for use at home is dispensed only in exceptional cases, i.e. when a person had a requirement for self-isolation or a quarantine. Loss of jobs during the pandemic has been observed as a result of the generally reduced economy, but also as a result of relapse due to switches to methadone (mental health consequences).

PrEP and PEP – In 2021 national guidelines on PEP and PrEP were adopted and a PrEP program was piloted. Access to PrEP was enabled at the University Clinic for Infectious Diseases, but outreach PrEP services were also piloted in Bitola through a partner CSO. Recruiting community health care workers in other towns to be trained for PrEP delivery was a challenge.

Behavioral assessment and adherence assessment (incl. pill count) has been performed by lay providers from a CSO – within the HIV Center at the Clinic for Infectious Diseases, in accordance with a signed memorandum of understanding. Around 70 persons in Skopje and only 5 in Bitola were taking PrEP at the end of the pilot, while there were discussions for potential promotion in the towns of Ohrid and Strumica. 3-month supply for PrEP is being dispensed to clients after the third month visit. The National HIV Program for 2022 was expected to include PrEP services, but due to the reduction of the initially approved funds, this will be accomplished only in a reduced scope. As a result of a crisis in the provision of ARVs in the first half of 2022, in this period PrEP has been offered only to individuals who had joined the pilot in 2021, while PEP in situations of sexual exposure is still not offered in practice. It is planned that by the end of June the PrEP Program will again be opened for recruiting new clients and PEP for sexual exposure will be finally introduced.

ART – Funding for ART during 2020/2021 was not increased in accordance with the increased number of new patients initiated on ART – the difference between the annual budgets for 2019 and 2020 was ~3% and for 2020 and 2021 it was 0%, while the number of patients increased by ~20% within this timeframe. This complicated the already present situation, where the budget for ART had not been increased for 4 consecutive years – from 2017 to 2021, while the number of patients increased by 50%. As a result, significant proportion of treatment regimens are not in line with the WHO recommendations. For 2022 a significant increase of funding for provision of ARVs was initially approved, in accordance with an estimated increase of the number of patients by 10-15%. However, in April the budget line was reduced by 7.4% and, moreover, this was done after the procurement procedure had already started and without any consultations with the relevant parties – in particular the Clinic for Infectious Diseases – which caused a delay in the procurement process and a high risk of stock-outs. Dispensing of treatment is centralized. Although the period that ARVs are dispensed for has increased from monthly to quarterly dispensing, there are still risks related to situations where there may be restrictions of mobility and movement of the population between municipalities and regions. Delivery of ARVs through a courier service, with the logistic support of the patient organization has certain risks from the point of view of safety of the delivered goods and it is also not clearly regulated from a legal point of view.

* <https://okno.mk/node/92091?fbclid=IwAR2oLcYiavGD1gkVocWgl3nhE8ElfkU21kC5qlxIV7G3g4hr1DUtnChJwA>

Positive Practices for Maintaining Services

The HIV service providers, including the community based and civil society organizations during 2020 and 2021 adapted the mode of service provision, to ensure continuity as best as possible. The health system and health administration supported these efforts by adopting certain general measures.

- The funding of the **prevention and early detection** services for 2020 and 2021 was sustained.
- Good collaboration between the Clinic for Infectious Diseases and the **patient association**.^{*} This collaboration, which during the last 7 years has resulted in greater strategizing of the formulations of tenders and more reliable, predictable procurement processes, as well as improved treatment options, continued in the same manner during the pandemic.
- The HIV center in the **Clinic for Infectious Diseases** quickly adapted the working procedures to **distance consultations** with PLHIV.
- The services for **psychosocial support** consultations for PLHIV were virtualized, which improved attendance.
- The protocol for **ART dispensing** was optimized – multi-month dispensing of ARVs was implemented and medicines were delivered through a courier service with the logistic support from the patient organization.
- The crisis situation has prompted the civil society organizations (CSOs) to partner in the daily provision and **delivery of necessary preventive materials**.

Positive practices for maintaining **general services**, which influenced the lives of key populations:

- The inpatient treatment of COVID patients was completely **free of charge**, regardless of their insurance status.
- Early in the pandemic, the Health Insurance Fund introduced an **e-prescription** for chronic conditions. Starting on 1 May 2020, people with chronic conditions were able to obtain or extend their prescriptions through a phone call, and primary care doctors were enabled to prescribe electronically. The e-prescription was one of the interventions under the primary health care reform, and COVID-19 has accelerated its implementation in the efforts to reduce the contact between the patients and the health-care providers in a health setting and to reduce the risk for transmission of COVID-19.
- In addition, **telephone consultations** and pilot videoconferencing — built within the health information system Moj Termin, the national digital health system — were rolled out.
- An **online platform** for registering people for COVID-19 vaccination was developed. It also enabled the interest for and the uptake of vaccination to be monitored and potentially to develop interventions in geographical areas or among certain age groups where vaccination was lagging.^{**}

^{*} *Report of the Regional meeting on the access and prices of the ARV drugs in SEE countries, December 15, 2020*

^{**} *Atanasova S, Tawilah J. 2021. North Macedonia. Transforming primary health care during the pandemic. WHO. 2021.*

Key Factors That Supported Positive Practices

There are certain factors which can be identified as key in the efforts to safeguard service continuity despite the emergency.

There was political will and support by the (then) minister of health for sustaining the HIV services for key populations during the COVID-19 pandemic.

The health facility mostly involved in HIV treatment and counseling – the Clinic for Infectious Diseases – was the most affected by the pandemic, but at the same time the most resilient, which contributed to timely adaptation to the circumstances.

The communication and the support between the Clinic and the community-based organizations was intensified.

The counseling services provided within the community-based organizations network rapidly adapted to functioning at a distance, especially applying virtual consultations.

Continuing Challenges to be Addressed

Although during 2020-2021 the country overcame many of the direct threats through cooperation, a degree of flexibility and adaptation to the situation, still, the unfavorable conditions that followed in 2022 indicate that the applied measures and mechanisms are **not sustainable**.

In terms of service **funding** – the reduction of the budget for HIV prevention activities for 2022 shows their vulnerability depending on the current political will and economic situation. There is no national HIV strategy, nor adequate strategy for human resources for health, which would cover, among other things, the problem of the shortage of health workforce in emergencies. The Law on Public Health, as well as the Program for Public Health, which cover the segment of public health emergency preparedness, are not comprehensive enough to cover the specific elements of the HIV services.

With regards to the HIV prevention activities, specifically the **harm reduction programs**, the main problem lies in the centralization of the Centers for drug dependence and the shortage of specific health workforce needed to decentralize these services. Also, there is a reluctance of medical staff for take-home medication, as it is considered too risky. So, when mobility and transportation services are disrupted, the beneficiaries of these centers are facing problems, sometimes their condition and advancement is reversed.

The centralization might also occur as a problem related to the HIV treatment as well, since the primary health care is not involved in any stage of the treatment. The **antiretroviral therapy is being dispensed** only by the HIV center at the Infectious Diseases Clinic in the capital. The Clinic does not cooperate with other infectious departments in the country, in order to reduce the logistical burden on patients. ART is not dispensed in pharmacies, although the regulation allows it. This way, the primary level of health care, including pharmacies, as the most readily accessible level of healthcare, is not prepared to respond quickly in providing an alternative to the continuity of health care in the event of emergencies affecting the communicable diseases treatment capacities.

The National HIV Clinical Guidelines have not been updated for more than a decade, and they do not contain adapted monitoring protocols in the events of emergencies of this kind.

In the events of **ART procurement and supply chain disruption**, there are no protective mechanisms for reimbursement of the money patients would have to spend, if they bought the therapy out-of-pocket. The same would be valid for the OST, as well as the therapy for hepatitis.

The civil society organizations are still not recognized as healthcare providers, so the possibilities for their involvement as a support of the system in need is limited.

The **weak financial and risk management** of the administration led to serious problems with the procurement of HIV tests for the community, especially in 2021, but the consequences are still felt.

The HIV self-testing is still in its pilot phase and implemented only by one CSO. The health system does not cover the costs for self-testing.

Key Recommendations for COVID-19 and Other Emergency Contingency Planning

It is critical that the Ministry of Health should urgently develop and adopt a new **national HIV strategy**, which would also encompass the response of the health system in the events of public health need and emergencies.

In addition, in compliance with the WHO recommendations given within the International Health Regulations capacities evaluation process, the country should develop a **comprehensive workforce strategy**, which will prioritize the modernization of the workforce towards a multidisciplinary composition that can face new challenges and keep up with developments in surveillance, risk assessment and outbreak detection. In resource limited settings, it is crucial to map how best to leverage existing resources for maximum benefit.*

The Ministry of Health should propose legislative changes to the Law on Health Protection, to recognize **civil society organizations as providers of healthcare services and outreach prevention services provided by the CSOs as health services**. This will enable rapid and agile response and cooperation, where the CSOs can support the existing healthcare capacities. Also, the service providers that work in these CSOs will be free to continue prevention operations as **essential service providers**, including exemptions for staff to travel during lockdown and other emergencies.

The **administrative capacities for budgeting and procurement** in the MoH should be improved, by development/improvement of protocols/standard operating procedures. As the CSOs are the beneficiaries, they need to be involved in the complete budgeting and procurement processes and their monitoring.

The Ministry of Health should develop an action plan for decentralization of the **Centers for treatment of drug dependence**, with special emphasis on incentivizing the medical personnel for performing shifts in more than one center.

The Ministry of Health should provide a **budget for procurement of special vehicles**, dedicated to performing mobile healthcare services in the events of emergencies and transport of drugs and medical supplies. Such vehicles should also be made available to the CSOs as healthcare providers.

The Clinic for Infectious Diseases and the Ministry of Health should develop and adopt new **national HIV clinical guidelines**, in accordance with the WHO and EACS recommendations, which will also encompass adapted monitoring protocols in the events of emergencies of this kind.

The Clinic for Infectious Diseases should develop **cooperation with the regional infectious diseases departments** in the general hospitals throughout the country, so the distribution and dispensing of ART could be rationalized.

To diminish the impact of the potential **disturbances in the processes of procurement and distribution of drugs** (ART, OST, Hep B and C therapy etc.), the following mechanisms should be applied:

- estimation of the needs for buffer stocks, especially for the medications for continuous use, and gradual increase of the fiscal space for these buffer stocks for at least 6 months;
- taking into account that most of the beneficiaries are already covered by the social health insurance scheme, the essential drugs should be transferred to the Positive list of drugs, covered by the social health insurance. Thus, the protective mechanisms for reimbursement of the money patients might have to spend if they need to purchase the drugs out-of-pocket as a result of disturbances in the procurement and distribution, will be active for these drugs as well.

The provision of **HIV self-tests** through the National HIV Program should be implemented and the budget increased. The pharmacies network should be involved as well, and the CSOs will act as a system for support in the segment of consultations and counselling.

* *Joint external evaluation of IHR core capacities of the Republic of North Macedonia. Geneva: World Health Organization; 2019 (WHO/WHE/CPI/2019.59). Licence: CC BY-NC-SA 3.0 IGO.*

Annex 1. Action planning for Key Population HIV Services during COVID-19 and Other Emergencies in North Macedonia

General remark:

The country has one of the lowest levels of public expenditures for health in Europe, which undoubtedly has its impact on the quality of health care, but also contributes to administrative deficiencies. In the events of emergencies, as is the current COVID pandemic, these deficiencies prove to be essential for sustaining the basic right to health. With regards to the HIV protection activities, the country depends predominantly on its own capacities – both financial, as well as administrative. The temporary measures to cope with the pandemic, implemented in 2020 and 2021, proved as unsustainable, thus in 2022 serious threat to the existence of the programs is caused in the first place by the **weak financial and risk management**. As a result, serious cuts in the domestic funding of the programs were imposed, without ensuring appropriate leverage.

General recommendation:

It is critical that 1) community-based and other civil society organizations are legally recognized as providers of health services (article 96 of the Law on Health Protection), 2) prevention services are recognized as health services, 3) new national HIV strategy is developed and 4) appropriate budgeting of HIV prevention and treatment is performed.

Monitoring:

Development of updated Standard Operating Procedure/-s for programs' budgeting and procurement, encompassing the functioning in the events of emergencies.

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
HIV prevention	<p>1. Distribution of condoms and lubricants – funding of this program component was maintained throughout 2020-2021, but it was affected by the budget cut by 40% for prevention activities in 2022. This, in addition to the fact that awarding funds for activities to CSOs for 2022 was delayed, as well as the general high inflation rate threaten the sustainability of the programs run by CSOs; intensity of prevention activities was somewhat reduced in 2020-2021 as a result of the reduced social interaction; there have been problems with the procurement of condoms and lubricants due to increased prices, low interest among distributors and low administrative capacities in the Ministry of Health.</p>	1. Adapt the outreach approach towards clients.	<p>Civil Society Organizations (CSOs)</p> <p>Ministry of Health (MoH)</p>
		2. To improve administrative capacities in MoH and optimize the procurement process, a protocol for procurement should be developed, where the CSOs as final beneficiaries will be involved in the development of procurement specification and monitoring of processes and timeframes.	

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
	<p>2. Harm reduction programs – sustainability threatened by the budget cuts – budget in 2022 is decreased by ~40% compared to the average of the years 2018-2021; treatment has remained centralized so barriers arise due to reduced public transportation; there is lack of staff; since mid-2021 doctors in OST centers have been receiving oral instructions to switch patients from buprenorphine to methadone; relapse has been observed among patients that were unable to buy it; treatment for use at home is dispensed only in exceptional cases, i.e. when a person has a requirement for self-isolation or a quarantine; loss of jobs during the pandemic.</p> <p>Reduced scope of work of administration and counter service – which has caused problems in obtaining documentation.</p>	<ol style="list-style-type: none"> Center for treatment of drug dependence should be opened in more towns throughout the country. The lack of staff should be addressed by financially incentivizing field work of doctors from Skopje. Dispensing treatment for longer periods should be implemented in selected patients. The distribution of clean needles and syringes should be adapted (delivery to clients in quantities sufficient for a few days). The National HIV Program should include funds for purchase/rental of vehicles to be used for OST, as well as ART distribution. 	<p>CSOs</p> <p>Public healthcare providers (Psychiatry clinic, Toxicology clinic, General hospitals)</p> <p>Ministry of Health</p>
	<p>3. PrEP and PEP – in 2021 national guidelines on PEP and PrEP were adopted and a PrEP program was piloted; access to PrEP was enabled at the University Clinic for Infectious Diseases, but outreach PrEP services were also piloted in Bitola through a partner CSO; around 70 persons in Skopje and only 5 in Bitola were taking PrEP at the end of the pilot, while there were discussions for potential promotion in the towns of Ohrid and Strumica. The National HIV Program for 2022 was expected to include PrEP services, but due to the reduction of the initially approved funds (overall budget cuts partly due to the economic COVID aftershock), this will be accomplished only in a reduced scope. Major impact is due to a crisis in the provision of ARVs in the first half of 2022.</p>	<ol style="list-style-type: none"> The process of annual procurement of ARVs, including stocks for PrEP and PEP, should be completed urgently. The process of planning of the annual procurement of ARVs and the coordination between the Ministry of Health and the Clinic for Infectious Diseases should be improved through the adoption of standard operational procedures for all phases of the process. 	<p>University Clinic for Infectious Diseases</p> <p>Ministry of Health</p> <p>CSOs</p>
	<p>Relevant for all prevention interventions:</p>	<ol style="list-style-type: none"> The budget for prevention activities targeting key populations in the National HIV Program should be restored at least to the level of annual funding during the last 4 years. CSOs providing prevention services should be given a license from the Ministry of Interior Affairs and the Ministry of Health for free movement in the event of emergencies. 	

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
<p>HIV Testing and Linkage to Care</p>	<p>1. HIV testing in health care facilities – confirmatory HIV tests are performed only in Skopje, in two institutions – University Clinic for Infectious Diseases and Institute for Public Health; the number of tests in 2021 was reduced, compared to the average in the previous 5 years period.</p>	<p>1. Algorithms for diagnosis should be revised in accordance to WHO recommendations, with the aim of simplification.</p> <p>2. Centers for Public Health across different towns should be involved in some phases of the testing.</p>	<p>University Clinic for Infectious Diseases Institute for Public Health</p>
	<p>2. Community-based HIV testing – sustainability threatened by the budget cuts – budget in 2022 is decreased by ~50% compared to the average of the years 2018-2021; testing is available in 10 towns, but nevertheless the number of tests was reduced. This is to some extent due to problems with the procurement of HIV tests for the community by the Ministry of Health in the period 2020-2022, and the leverage was provided by the civil sector. As a result the proportion of late diagnoses in 2021 was significant.</p>	<p>1. The funds for community-based HIV testing within the HIV Program should be urgently increased (at least to the previous years' levels), to prevent the further trend in late diagnosis.</p> <p>2. To improve administrative capacities in MoH and optimize the procurement process, a protocol for procurement should be developed, where the CSOs as final beneficiaries will be involved in the development of procurement specification and monitoring of processes and timeframes.</p>	<p>Ministry of Health CSOs</p>
	<p>3. HIV Self-testing – in 2020 and 2021 the National HIV Program envisaged the development of a protocol for self-testing and the introduction of the service, but this has not been implemented; since 2021 the self-testing kits are available for free through an on-line order from CSO HERA, provided by donations, and not with the Program's budget; counseling is offered through a special phone line of the same CSO.</p>	<p>1. Budget for the self-testing service should be increased in the National HIV Program, including funding for its promotion – to be led by CSOs.</p> <p>2. Self-testing should additionally be introduced as an option through a network of pharmacies.</p> <p>3. CSOs should be involved in the counseling component of self-testing.</p>	<p>Ministry of Health CSOs</p>
	<p>4. Starting treatment – a high percent (90%) of those who were diagnosed have been started on ART and 94% of those on ART have had a suppressed virus.</p>	<p>1. Recommendations on regular provision of ARVs (noted below) should be applied – as a basic prerequisite for timely treatment initiation.</p> <p>2. New national HIV treatment guidelines should be developed, in order to sustain the good practice.</p>	

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
HIV Care and Treatment	<p>1. ART – funding for ART during 2017-2022 is not increased in accordance with the increased number of new patients initiated on ART: the budget for ART had not been increased from 2017 to 2021, while the number of patients increased by 50%; as a result, significant proportion of treatment regimens are not in line with the WHO recommendations. For 2022 a significant increase of funding for provision of ARVs was initially approved, to compensate the previous situation; however, in April the budget line was reduced and, moreover, this was done after the procurement procedure had already started and without any consultations with the relevant parties – in particular the Clinic for Infectious Diseases – which caused a delay in the procurement process and a high risk of stock-outs. Dispensing of treatment is centralized; although the period that ARVs are dispensed for has increased from monthly to quarterly dispensing, there are still risks related to situations where there may be restrictions of mobility and movement of the population between municipalities and regions. Delivery of ARVs through a courier service, with the logistic support of the patient organization also has certain risks from the point of view of safety of the delivered goods and it is also not clearly regulated from a legal point of view.</p>	<ol style="list-style-type: none"> 1. Longer-term estimation of the needs for ART should be made, taking into account the pricing trends, as well as an estimated need for reserve in case of unforeseen and urgent situations and crises. 2. The treatment guidelines should envisage multi-month dispensing of ARVs for a defined target group and in exceptional circumstances or dispensing/distribution to be organized through a collaboration between the Clinic for Infectious Diseases with regional units for infectious diseases within general hospitals throughout the country. 3. Distribution of medicines by CSOs for the benefit of patients should be regulated, as well as the delivery through courier service or through distributing companies. 4. Costs for distributing ARVs to relevant centers in other towns should be envisaged in the National HIV Program. 5. The process of planning of the annual procurement of ARVs and the coordination between the Ministry of Health and the Clinic for Infectious Diseases should be improved through the adoption of standard operational procedures for all phases of the process. 	<p>University Clinic for Infectious Diseases</p> <p>Ministry of Health</p> <p>CSOs</p>
	<p>2. Monitoring of HIV infection (assays/tests for HIV infection management – CD-4 cell count and viral load assays) for people on ART – funding during 2020/2021 was not increased in accordance with the increased number of new patients initiated on ART – the difference between the annual budgets for 2019 and 2020 was ~3% and for 2020 and 2021 it was 0%, while the number of patients increased by ~20% within this timeframe; testing for viral load and CD4-count among patients stable on ART was being performed once in 12 months – a reduction from twice a year, as a result of the COVID-19 situation; for new patients monitoring is done every 3 months.</p>	<p>A longer-term estimation of the needs for monitoring tests should be made, taking into account the pricing trends, as well as an estimated need for reserve in case of unforeseen and urgent situations and crises.</p>	<p>University Clinic for Infectious Diseases</p>

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
	<p>3. The national HIV guidelines are not updated.</p>	<p>To develop new (updated) national HIV guidelines, which will also encompass circumstances for multi-month dispensing of therapy, as well as reduced frequency of clinical monitoring.</p>	<p>University Clinic for Infectious Diseases</p>
	<p>4. Psychosocial support for people living with HIV – the budget for this segment is constant throughout 2019-20-21 and is not progressively increased in correlation with the increase of number of PLHIV; counseling is performed by telephone and Zoom platform, although no protocol for doing so exists; psychosocial support is performed by members of staff who are not of medical specialty – psychologist and social worker, and peer support interventions are frequent.</p>	<p>Proper evidence of the psychosocial support services given by the professionals at the Clinic for Infectious Diseases and in the community, including phone/e-mail counseling, is necessary, so that proper planning can be performed.</p>	<p>University Clinic for Infectious Diseases CSOs</p>
<p>Coinfection and Co-morbidities (TB, HCV, mental health)</p>	<p>1. Tuberculosis – The Institute for TB was transformed into a COVID center; the resources were reallocated; thus the TB healthcare was directly compromised; HIV-TB co-infection is very rare.</p>	<p>1. The Institute, in collaboration with the CSOs, should prepare an assessment of feasibility of mobile TB screening, alongside other mobile services for key populations. 2. Video DOT protocol should be developed, including the medications delivery mechanisms.</p>	
	<p>2. Hepatitis C co-infection is rare and is treated at the Clinic for Infectious Diseases.</p>	<p>The process of obtaining approval from the Ministry of Health and the Health Insurance Fund for procurement of the Hepatitis C drugs should be planned regularly on an annual basis.</p>	<p>University Clinic for Infectious Diseases</p>
	<p>3. STI – funding of STI prevention services for key populations was maintained throughout 2020-2021, but it was affected by the budget cut by 40% for prevention activities in 2022; CBOs and other CSOs are still not recognized as providers of health services.</p>	<p>Amendments in the Law on Health Protection to recognize CBOs and other CSOs as providers of health services should be initiated by the Ministry of Health.</p>	

Intervention Being Assessed	Assessment of the situation	Action planning (recommendations)	Performers
<p>General Care</p>	<p>1. Primary care visits – during COVID pandemic, especially in 2020 only a portion of the GPs did check-ups in their offices; certain GPs do not examine PWUD and do not perform wound dressing. E-prescription of drugs and devices for the co-morbidities (chronic conditions) has been introduced.</p>	<p>The GPs should be incentivized to perform minor scale medical interventions as well as e-consultations.</p>	<p>Social health insurance (Health Insurance Fund)</p>
	<p>2. The diagnostics and treatment of Covid-19 in public healthcare institutions is free of charge, regardless of the insurance status.</p>	<p>To initiate adaptation of the legislation, so that the testing and treatment for all public health emergencies of international concern should be completely free of charge for all patients.</p>	<p>Ministry of Health</p>
	<p>3. Administrative procedures which are managed by the social health insurance were temporarily facilitated by e-mail communication e.g. the procedures for the longer sick-leaves.</p>	<p>The procedures and the health information system of the social health insurance should be reviewed to enable administratively facilitated processes. They should be implemented for the everyday functioning (not only in cases of emergencies), taking into account the strengths and weaknesses of the adaptations during the pandemic.</p>	<p>Social health insurance (Health Insurance Fund)</p>