Review of the HIV Programme in the former Yugoslav Republic of Macedonia

October 2015





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Prepared by:

Dorthe Raben, Stine Finne Jakobsen, WHO Collaborating Centre for HIV and Viral Hepatitis, Anders Sönnerborg, Karolinska Institute, Stockholm, and Emilis Subata, WHO Collaborating Centre for Harm Reduction Keywords AIDS – prevention & control EVALUATION HARM REDUCTION HEALTH SYSTEMS HIV INFECTIONS – prevention & control

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List of Abbreviations

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CCM	Country coordinating mechanism
CD4	T-lymphocyte cell bearing CD4 receptor
CID	Centre for Infectious Diseases
CN	Concept Note on HIV
ECDC	European Centre for Disease Control
EECA	Eastern Europe and Central Asia
	Efavirenz
EFV	
EGAL	Equality for Gays and Lesbians
EHRN	Eurasian Harm Reduction Network
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
FSW	Female sex workers
FTC	Emtricitabine
GO	Government organization
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HERA	Health Education and Research Association
HIV	Human immunodeficiency virus
HOPS	Health Options Project Skopje
HTC	HIV testing and counselling
IDU	Intravenous Drug User
KAP	Key affected populations
LTFU	Lost to follow up
	1
MLSP	Ministry of Labour and Social Policy
МоН	Ministry of Health
MoF	Ministry of Finance
MSM	Men who have sex with men
MTCT	Mother-to-child transmission
NGO	Non-governmental organization
NIDA	National Institute of Drug Abuse
NNRTI	Non-nucleoside analogue reverse transcriptase inhibitors
NRTI	Nucleoside analogue reverse transcriptase inhibitors
NSP	Needle and syringe exchange programme
NVP	Nevirapine
OST	Opioid substitution therapy
PCR	Polymerase chain reaction
PI	Protease inhibitors
PLHIV	People living with HIV
PWID	People who inject drugs
PMTCT	Prevention of mother-to-child transmission
POC	Point of care
PSM	
	Procurement and supply management
PUD	People who use drugs
PWID	People who inject drugs

Ribonucleic acid
Rilpivirine
Sexually transmitted infections
Sex worker
Tuberculosis
Tenofovir
Joint United Nations Programme on HIV/AIDS
United Nations Development Programme
United Nations Office on Drugs and Crime
Voluntary counselling and testing
World Health Organization
Zidovudine

Contents

1. Executive Summary	1
2. Introduction	3
2.1 The HIV epidemic in the former Yugoslav Republic of Macedonia: latest trends and figures	
2.2 Phase out of Global Fund support	5
3. Purpose and objectives	5
4. Methods	6
5. Findings	6
5.1 Strengths and achievements	6
5.2 Weaknesses and challenges	12
Priority area 1: Strengthening and harmonization of the reporting system	12
Priority area 2: Optimize testing coverage among key populations	13
Priority area 3: Adapt service delivery	14
5.3 Cross-cutting issues	19
Priority area 4: Ensure sustainability and rights-based support for key populations	19
6. Recommendations	22
6.1 Main recommendations	22
6.2 Specific recommendations	22
Priority area 1: Strengthening and harmonization of the reporting system	22
Priority area 2: Optimize testing coverage among key populations	22
Priority area 3: Adapt service delivery	23
Priority area 4: Ensure sustainability and rights-based support for key populations	24
7. References	25
Appendix 1	27
Terms of References	27
Appendix 2	31
List of informants	

1. Executive Summary

The former Yugoslav Republic of Macedonia is an HIV/AIDS low prevalence country. The total number of registered PLHIV was 236 for the period between 1987 and 2014, of whom 75 died from AIDS. Currently 151 PLHIV are diagnosed and registered and 112 are on ART. A high number of cases (39%) are concentrated among MSM.

The country has received support from the Global Fund since November 2004, but as it is classified as a middle income country, it is no longer eligible for funding according to the Global Fund Funding Model. With around 95% of TB and HIV prevention activities still depending on the Global Fund (in 2014) the country urgently needs to ensure a continuation of essential services once the Global Fund phases out after 2016. The main focus of the WHO country mission was therefore to provide input into a sustainability plan to be developed for the government to take over activities which until now have been supported by the Global Fund, through an analysis of the current epidemic in the country, the continuum of care, and service delivery models for key populations.

It has been possible to maintain a low level of HIV in the country, and many informants ascribed this to be due to the early initiation of harm reduction services and active NGOs. Over the years very few cases of HIV have been observed among PWID as well as very few cases of MTCT – both factors which also contribute to containing the epidemic. However an increasing number of cases have been reported in the last two years among MSM.

The mission observed some weaknesses in the reporting system and a discrepancy between data in various institutions. Data are available, but not systematically reported or analysed. Data availability and analysis is critically important in order to be able to follow trends in the epidemic and for strategic planning of key interventions. HIV and AIDS should be recorded together as HIV cases (AIDS included). At the moment, HIV and AIDS cases are reported separately. There seems to be underreporting of STIs and data on late presentation and STIs should be available and monitored. Reporting of late presentation (CD4 <350) is an important tool to evaluate the epidemic and effect of testing programmes.

Testing coverage is still low among key populations. The estimations made based on behavioural surveys conducted among the most at risk groups find that only 19% of the MSM population, 33% of PWID, and 44% of SW have had an HIV test done in the last 12 months (for prisoners it is only 4.5%). It also seems as though many tests are performed on people not at risk of HIV, such as blood donors, pregnant women and other people who are required to present an HIV test result.

ART has been rapidly scaled up and linkage to and retention in care for PLHIV in the country is reported to be high and well-functioning. No up to date national clinical protocol however, exist in the country. The CID reports that international guidelines are followed, including both the 2013 consolidated guidelines from the WHO and those from the European AIDS Clinical Society as a basis for the treatment choices. In addition, the CID is in personal contact with consultants in Europe and the USA who can be considered key opinion leaders in the field of ART. The intention of the CID is now to switch to the 2015 updated WHO guidelines for when to start ART which will result in an increase of the presently diagnosed patients on ART from 112 to 151. In addition, increased testing of persons at risk for HIV is likely to identify a larger number of individuals

because of the prediction of a high number of undiagnosed HIV infected patients. The estimated country need will therefore increase substantially in the coming years.

The overall coverage of OST is mid-level at roughly 23% of the current estimated 10 300-10 900 injecting heroin users (ref: IPH and HOPS 2010 study). An EMCDDA survey showed that 96.4% used sterile equipment during the last injection. These figures indicate a high proportion of PWID being in contact, at least episodically, with NSP. The Global Fund funded almost all NSP services, which NGOs provided. Municipalities provided only a very small amount of funding. Thus, the sustainability of NSP programmes after the Global Fund phases out in 2016 is at great risk.

OST has a rather negative image as a medical service among medical professionals and institutions. Key informants at the OST centre and NGOs indicated that hospitals usually establish OST sites in remote areas, apart from their main venues. Medical staff (psychiatrists and nurses) is not willing to work there, as they consider the work with PWID to be difficult, dangerous and unrewarding.

Also, it has been concluded that existing legal mechanisms are inefficient in regards to protecting the rights of people living with HIV and that state institutions involved in this lack mutual coordination. MSM is reported by many informants to be the most stigmatized group in the country, which is problematic in reaching MSM with HIV and to the implementation of the national HIV/AIDS programme.

Although collaboration between organizations could be strengthened, there seems to be good collaboration among NGOs and between NGOs and the CID. This collaboration is important to continue to support in the future to ensure continued high linkage to care as more PLHIV are diagnosed by civil society organizations.

With the financial support of the Global Fund canalised through the MoH as the principal recipient of funds, it has been possible to strengthen preventive activities among high risk groups and initiate capacity building of organizations, which are activities considered extremely important for continued containment of the epidemic.

In order to sustain the low level of HIV in the country and urgently increase access to prevention, testing, care, and treatment, it is crucial to improve social support and case management, integration of services, and education of health care providers.

The main recommendations from the mission are as follows:

- Clarify roles, responsibilities and information flow between stakeholders and strengthen the collaborative structure of the national HIV response, including strong leadership.
- Include the continuation of outreach activities and services targeting key populations in the new strategy on HIV, in particular HIV rapid testing, with allocated funds.
- Ensure that support functions for key populations, in particular PLHIV, MSM and PWIDs, are available and further developed.
- Prepare for a substantial increase in the demand for antiretroviral therapy.
- Ensure monitoring and evaluation of the national strategy occurs.
- Strengthen surveillance indicators of the HIV epidemic and conduct proper analysis to inform policy decisions on priorities within the national HIV programme.

- Reduce stigma related to HIV and key populations in all health care settings through targeted campaigns and education.
- Develop a transition plan for HIV financing.

2. Introduction

2.1 The HIV epidemic in the former Yugoslav Republic of Macedonia: latest trends and figures

The former Yugoslav Republic of Macedonia is located at the Balkan Peninsula in south-eastern Europe. It is landlocked and borders Serbia to the north, Greece to the south, Bulgaria to the east and Albania to the west. The country has approximately 2 million inhabitants. It is a middle income country and has been candidate country for EU membership since 2005.

With a 27% unemployment rate, a considerable part of the population is left without health insurance and experience challenges in accessing health services (1). The economic crisis has resulted in a reduction in national spending on health care, especially the provision of prevention services by the Ministry of Health (MoH).

The country is an HIV/AIDS low prevalence country, but the regional trends in south-eastern Europe as well as the estimated number of undiagnosed PLHIV in the country suggest a risk of an increased epidemic. A high number of cases are concentrated among MSM.

The total number of registered PLHIV was 236 for the period between 1987 and 2014, of which 75 people died from AIDS (2). Of the 236 PLHIV cases, 189 are males and 47 females. The reported modes of transmission are:

114 heterosexual contact (48%) 93 MSM (39%) 12 IDU (5%) 6 Hemophiliacs (2.5%) 6 MTCT (2.5%) 5 No information



Fig. 1. Number of new HIV cases per year in the former Yugoslav Republic of Macedonia

The ratio of almost 4:1 male to female cases might suggest that some MSM transmissions are incorrectly reported as heterosexual transmissions. Of all registered cases in the country, 75% were from the six municipalities: Skopje (>108 people), Tetovo (23 people), Kumanovo (14 people), Prilep (10 people), Ohrid (9 people) and Kicevo (8 people), plus a total of 10 registered cases from abroad (2).

The large majority of HIV-1 infected patients are male; as of October 2015, of the 151 living diagnosed cases 139 were male. Among the newly registered HIV cases, men who have sex with men constitute an increasing proportion: 43.5% (10/23) in 2012 and 59.3% (16/27) in 2013 (Fig 2; 20). By the end of 2014, only 12 PWID had been diagnosed with HIV. Vertical transmission from mother to child is very rare and presently only six cases of HIV-infected children are known; in one of the cases the mode of transmission has not been confirmed (2).

Antiretroviral therapy (ART) was initiated in 2005/2006 with first line ARV drugs, and was extended with second line drugs the same year. The number of people receiving ART increased from two in 2002 to 45 by the end of 2011, and to 112 by the end of 2014 (*3*).

Due to the relatively small number of patients at present, ART is provided centrally in the capital city at the Clinic for Infectious Diseases (CID). Its capacities have been improved by the establishment of a new AIDS inpatient department, and provision of equipment for monitoring HIV infections and ARV treatment. Care and support to PLHIV is provided through the special outpatient counselling centre at the CID as well as through home visits organized by civil society organizations.

Around 20 NGOs work with HIV prevention activities, mainly with sex workers and PWID, only one works with MSM (4).

2.2 Phase out of Global Fund support

The former Yugoslav Republic of Macedonia has received support from the Global Fund since November 2004, but as the country is classified as a middle income country according to the Global Fund's New Funding Model, it is no longer eligible for funding. With approximately 95% of TB and HIV prevention activities still depending on the Global Fund (in 2014) the country urgently needs to ensure a continuation of essential services once the Global Fund phases out after 2016. The main focus of the mission was therefore to provide input into a sustainability plan to be developed for the government to take over activities which until now were supported by the Global Fund.

Withdrawal of the Global Fund support in the EECA region has led to challenges for the governments in the region who are now left with the challenge of raising domestic resources to fill the void left by the donors in the fight against HIV/AIDS. The donor withdrawal can potentially have major consequences for the programmes they have funded in this region as these programmes are mainly targeted towards vulnerable and marginalized groups such as injecting drug users, sex workers, and prisoners, who are often overlooked by domestic governments leaving potentially large gaps in financing of basic HIV services (5).

3. Purpose and objectives

The Global Fund approached the WHO Regional Office for Europe with a request to evaluate the national HIV programme in the former Yugoslav Republic of Macedonia and provide recommendations to inform the development of a sustainability plan for the country after the Global Fund stops its financial support in 2017.

The country mission took place from 5-8 October 2015.

The mission report with main findings and recommendations for increasing effectiveness of the national HIV response to treatment will be posted on the WHO Regional Office for Europe website.

The programme review includes 4 key components:

- A. Epidemiological analysis,
- B. Review of HIV treatment and care along the cascade of services,
- C. HIV services for key populations, and
- D. Analysis of service delivery models for populations affected by the HIV epidemic from the perspective of the health care system.

4. Methods

Readily available information has been drawn from secondary sources (publications, reports, etc.) during the preparation stage for desk review and analysis. During the country mission, WHO experts visited relevant institutions and facilities and interviewed key informants: policy makers, health care providers and beneficiaries, NGOs, and other national and international partners (see mission programme in Appendix).

5. Findings

5.1 Strengths and achievements

The first national HIV/AIDS programme was developed by MoH in 1985, and since then steps have been made to strengthen these efforts. In 2003 a Global Fund proposal was submitted for the first time and the country received Global Fund aid: two HIV Grants (2003-06, 2007-11), a TB Grant, and the latest HIV Grant in Round 10, running from 2012-16 (three HIV grants total).

As a prerequisite for Global Fund grants, the National multisectoral HIV/AIDS Commission was formed in 2003. It consists of NGOs, GOs and UN organizations and is the body accountable for the development and oversight of the National HIV/AIDS Strategy. There is also a Country Coordinating Mechanism (CCM) which is active.

The strategic documents which define targets and budget for ARV are:

1) the National HIV/AIDS Strategy (8), which focuses on:

- Prevention services for the most at risk populations,
- Early testing and admission to health care,
- ART for all in need,
- Closing the link between HIV and TB services, and
- Strengthening surveillance and community systems.

and

2) the National Program for Protection of the Population from HIV/AIDS (9).

A substantial number of demographic and clinical parameters are introduced into a data system at the CID in order to manage the patients receiving care. The system is updated regularly and is reported to be well functioning (29). The system is used mainly in house but is also used to report national statistics on the HIV epidemic to the Institute of Public Health.

By the end of 2011, 12 centres for the prevention and treatment of drug abuse were established. These centres were opened as a result of a joint collaboration among the Ministry of Health (MoH), Ministry of Labour and Social Policy (MLSP), NGOs, and mayors, as well as Faith Based Organizations. These services are also available in the largest prisons, "Idrizovo" and "Skopje". There are 13 needle exchange programmes that have been functioning since the end of 2011. MSM is represented by the NGO Equality for Gays and Lesbians (EGAL), which is working in three cities in the former Yugoslav Republic of Macedonia on HIV prevention for MSM. They work with the NGO HERA that coordinates two youth friendly centres in Skopje named "I Want to Know". The outreach activities are tailored to the needs, including confidentiality, of the specific population by employing representatives from the targeted group as "gatekeepers".

A network of voluntary counselling and testing (VCT) centres and methadone centres have been formed, which also work in prevention activities, including outreach VCT. NGOs and outreach activities are currently funded by the Global Fund and therefore depend on the MoH taking over the funding responsibility when the Global Fund grant ends.

Due to the activities described above, and in particular the early initiation of harm reduction services, it has been possible to maintain a low level of HIV in the country. However an increasing number of cases have been reported in the last two years among MSM, which will be discussed further below. With the support of the Global Fund it has been possible to strengthen preventive activities among high risk groups and initiate capacity building of organizations, activities which are considered extremely important for continued containment of the epidemic in the future.

Over the years, very few cases of HIV have been observed among PWID as well as very few cases of MTCT – both factors which also contribute to containing the epidemic.

Review of HIV treatment and care along the cascade of services

Cases of HIV infected people in the former Yugoslav Republic of Macedonia newly detected by NGOs are efficiently linked to care at the Clinic for Infectious Diseases (CID). ART has been rapidly scaled up and linkage to and retention of HIV-positive patients in the former Yugoslav Republic of Macedonia is reported to be high and well-functioning, although no official statistics were presented during the mission.

The figure below of the continuum of care for the former Yugoslav Republic of Macedonia was constructed by the mission team with numbers given by informants and discussed at the debriefing as an important tool to monitor the epidemic and its challenges in the country. The different steps of the continuum will be discussed throughout the report.



Fig. 2. The former Yugoslav Republic of Macedonia continuum of care 2015

The CID reports that over the last few years less than 10 HIV-positive patients have not been linked to and retained care. Among the 151 living diagnosed patients, 112 (74.2%) had been given ART as of October 2015. Of these, 109 (97.3%) have reached undetectable HIV-1 RNA in blood plasma according to a cross-sectional evaluation from October 2015, using Taq-man PCR from Roche diagnostics with a sensitivity of 20 copies/ml.

As a result of the predominance of MSM transmission, the patient population includes a low proportion of "difficult-to-treat" patients, and the rate of undetectable viral load (109/112; 97.3%) is very good. However, it should be noted that most of the HIV-infected people are most likely undiagnosed, and whether the undiagnosed population has similar demographic characteristics as the diagnosed population remains to be seen.

HIV/Viral hepatitis and HIV/TB services

No acute hepatitis C virus (HCV) infection has been reported among MSM; only two HIV patients are reported to be co-infected with HCV and nine patients with hepatitis B virus. All HIV patients are screened for hepatitis C and B. The anti-HCV drugs presently available in the former Yugoslav Republic of Macedonia are peg-interferon and ribavirin and will be funded by the Global Fund until 2016 when the government intends to take over funding for HCV treatment.

Few patients with TB-infection have been diagnosed with HIV in the past and no HIV patients are presently being treated for TB. It is mandatory for all TB patients at the hospital to be tested for HIV. The testing rate at the dispensaries was reported to be very low; however, no official data was presented for the mission.

Testing

There has been an increase in testing each year, with 27 340 HIV tests reported in 2014, compared to 18 721 in 2010. However, the report later discusses whether these tests are targeting the populations most at risk. Community testing is increasing, and this may reach a higher number of key populations not reached by other services.

Table 1 outlines an overview of the number of tests reported by the Institute of Public Health, presented as the number of tests performed by each of the health system facilities. It has not been possible to get information on number of positive test results by facility.

Table 1. Number of tests performed in the former Yugoslav Republic of Macedonia 2014 (Source: Institute of Public Health)

HIV Testing in 2014 at health institutions (national level)	Total
Center for Public Health Bilola	1253
Center for Public Health Kumanovo	394
Center for Public Health Skopje	100
Center for Public Health Tetovo	28
Center for Public Health Shtip	438
Center for Public Health Ohrid	100
Center for Public Health Kocheni	101
Center for Public Health Prilep	65
Center for Public Health Strunica	86
Center for Public Health Veles	100
Institute for Public Health Skopje	2717
Clinic for Infectious Diseases, Clinical Center Skopje	3630
City Hospital "8 th September", Skopje	2823
Private Clinic AGI Badem Sistina	7020
Institute for Clinical Biochmy at the University for Medicine – Skopje	1350
Farmahem - Skopje	34
Neuromedica – Skopje	139
Diagnostic Center – Skopje	21
Adria LAB – Skopje	1817
Lemedika – Skopje	4443
Special Hospital for Chemediabises – Diamed	260
Special Hospital Plodvost – Bilola	421
Total	27 340

HIV services for key populations

The provision of services by NGOs to key populations supported by the Global Fund is functioning well. There are a variety of services, including outreach and services that are provided both at the centres and mobile clinics as well as out in the streets of the communities for all key populations (MSM, PWIDs, SWs, and prisoners), and good collaboration among organizations. The community support in the MSM community is considered particularly important because of the high prevalence of HIV among MSM.

"Stronger Together", an NGO for PLHIV, is also dependent on Global Fund support and plays an important role in supporting PLHIV through peer counselling, legal support and in some cases support for travel costs for visits to the CID.

An important process has started to develop criteria for the accreditation of NGOs as service providers. In 2014, in partnership with 16 NGOs, the Platform on Sustainability of Services for HIV Prevention and Support was established with the mission to advocate for providing financial sustainability of HIV services beyond the Global Fund and their integration into the national and local self-government programmes. As a result of the activities of the Platform, the 2015 HIV/AIDS Government programme recognized the need for the accreditation of NGOs (developing criteria for subcontracting NGOs as service providers and setting up a registry of civil associations), including budgeting a modest amount of funds for 14 NGOs to carry out HIV prevention activities among key populations. According to informants, a small amount to support NGOs was set aside in 2015 to test the system of NGOs as recipients by MoH. However, to our knowledge no NGOs have received funding from this source yet because the process of developing the criteria has been delayed and is unlikely to be implemented in 2015. On a positive note, in 2015 a representative from the platform was, for the first time, invited to a meeting at the MoH to discuss the new national HIV/AIDS Programme.

OST

In 2010 various methods were used to estimate the prevalence of injecting drug use in five cities, including Skopje. Extrapolation of the results from the IDU population in Skopje (representing approximately 25% of the total IDU population) to the country as a whole suggested that there were 10 200 intravenous drug users in the country (10). The National Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has estimated the number to be around 8000 heroin injectors in the former Yugoslav Republic of Macedonia.

Substitution treatment has been available in the former Yugoslav Republic of Macedonia since the late 1970s and early 1980s the as main treatment of heroin dependence. The MoH in the former Yugoslav Republic of Macedonia started early OST with methadone in 1992 in Skopje in the psychiatric hospital unit. Since 2006 and with the funding from the Global Fund, the MoH increased the number of OST sites to 10 sites in nine cities, including three in prisons. Key informants indicated that as of 2015 there were 1400 PWID in OST (methadone) programmes, and since 2009 around 200 PWID at the University Toxicology Clinic, Mother Theresa Clinical Center, and Skopje (tertiary level of health care services). There were also a number of patients who paid for buprenorphine or methadone services at private clinics (*11*).

The overall coverage of OST is mid-level, at roughly 23% of the current estimated 8000 injecting heroin users¹ (the mid-level quality indicator is 20-40% of estimated number of PWID as set by WHO/UNDOC/UNAIDS) (12). This is a relatively high indicator in the context of the region. Previous reports from the EMCDDA indicate that the former Yugoslav Republic of Macedonia has the highest coverage with OST compared with neighbouring countries in the region (13).

¹ 10 300-10 900 PWID in 2010

Nevertheless, both OST providers and PWID at interviews indicated that there were currently no waiting lists to access OST with methadone. Treatment was free of charge and funded by the Ministry of Health.

HIV testing and counselling (HTC) with rapid tests was available at the OST unit at the psychiatric hospital in Skopje, funded by the Global Fund. Overall, in 2015 when HTC was allowed to be provided by NGOs, many OST sites started to refer patients to NGOs.

Since 2009, the MoH has taken over the funding of OST with methadone and a limited number of patients (200) with buprenorphine. The OST unit at the psychiatric hospital in Skopje was in charge of coordinating training and supporting the rest of the 10 OST sites, including those in prisons, using limited funding from the Global Fund.

NGOs provided psychosocial assistance for PWID in treatment through employed professional staff (medical, social workers). Other NGOs emphasized self-support groups, developing skills and rehabilitation. These activities from NGOs were fully dependent on funding from the Global Fund.

OST was available in three prisons in the former Yugoslav Republic of Macedonia, including a remand prison in Skopje. In the country's largest prison, "Idrizovo" in Skopje, there were around 1900 inmates, including approximately 100 women. This prison accounts for roughly two thirds of the country's prison population and houses prisoners with the longest conviction terms (three years and longer). The penitentiary department established OST in 2006 with the support of the Global Fund. By 2015, there were 228 PWID in this prison, with the number of patients constantly increasing. The policy of the OST programme in the penitentiary department was to enrol all PWID who would like to continue or initiate OST in prison. The Ministry of Justice funded staff for the OST programme (one physician and one nurse). The MoH supplied the methadone, as the Ministry of Justice was included in the National HIV Prevention Strategy.

The transfer of OST patients from civil sector sites to prison based OST sites and back seems to be well established. OST, both in civil sector and prisons, was coordinated from the OST unit at the psychiatric hospital in Skopje.

Guidelines for OST, adopted in 2012, include information about pharmacological treatment and psychological and social interventions. The guidelines provide a broad overview of the basic principles of OST, which are mainly oriented along the NIDA principles of treatment and WHO guidelines for provision of OST. The key elements are: concrete suggestions for medical examinations; criteria for inclusion in the methadone programmes; therapeutic plan and purpose; and other practical issues, including dosages and treatment schemes of how OST should be carried out (10).

Pharmaceutical industries in the former Yugoslav Republic of Macedonia produce methadone and buprenorphine medicines, ensuring local supply and possibly reduced costs.

Needle and Syringe Programmes

The NGO HOPS (at the time the NGO MASK) had established the first needle exchange programme with external funding early in 1996. The NGO opened two NSPs by 1999. With the financial support of the Global Fund since 2004, the number of NSP has increased to 16 programmes in 13 cities.

The main injecting substance in the former Yugoslav Republic of Macedonia is methadone, which patients divert to the black market from OST programmes. PWID often inject methadone with benzodiazepines and this may account for 90% of injected substances (14).

The NGO HOPS is coordinating NSP activities in the country. In 2012, it reached 2792 PWID; in 2013 it reached 3282 (32%) of the estimated 10 200 PWID, which is a mid-level quality indicator for NSP coverage (20-60% of estimated PWID). Drop-in centres provide comprehensive services for PWID, including needle/syringe programmes, condom provision, social support, outreach, medical services and referrals (*15*). Since 2015, when the MoH allowed HIV testing in drop-in centres, testing has become increasingly available. Six drop-in centres also provide free legal services.

A bio-behavioural survey of a 407 PWID sample in Skopje showed that 76.5% of PWID have received free injecting equipment during the last 12 months (estimated 65.0% of PWID nationally) (14). The survey showed that 77% of the PWID sample in Skopje (estimated 71.1% nationally) received free condoms during the last 12 months. 89.2% of the PWID sample in Skopje (estimated 84.9% nationally) know the results of their HIV test, and 72.8% of the sample size (estimated 65.6% nationally) know where anonymous HIV testing is available. The survey showed that 96.8% (estimated 96.4% nationally) used sterile equipment during their last injection. These figures indicate a high proportion of PWID being in contact, at least episodically, with NSP. Moreover, the study did not find any new positive HIV cases.

Although collaboration between organizations could be strengthened in a number of ways that are addressed elsewhere in this report, it should be noted that there seems to be good collaboration among NGOs and between NGOs and the CID (17). It is important to continue to support collaboration between all key participants in the future to ensure continued high linkage to care as more PLHIV are diagnosed by civil society organizations.

5.2 Weaknesses and challenges

Priority area 1: Strengthening and harmonization of the reporting system

The mission observed some weaknesses in the reporting system and a discrepancy between data in different institutions. Data is available, but not systematically reported or analysed. Data availability and analysis is critically important in order to be able to follow trends of the epidemic and for strategic planning of key interventions.

HIV and AIDS should be recorded together as HIV cases (AIDS included). At the moment HIV and AIDS cases are reported separately. Registered cases are kept in a database and presented as a HIV/AIDS cases, and this is one of the ways of reporting to country officials and internationally (TESSy). Only death cases are registered as deaths due to AIDS (ICD10 - B20).

There seems to be no efficient central monitoring system for STIs, at least this was not presented to the team. Data on late presentation should be available (as presented in Table 2) and monitored. Reporting of late presentation (CD4 <350) is an important tool to evaluate the epidemic and effect of testing programmes.

As a consequence it is, for instance, difficult to conclude whether the increase among MSM is a consequence of increased testing or a true rise in the epidemic as incidence among risk groups is not available and testing data scarce. The decrease in late presentation observed in the last two years is possibly explained by an increase of testing among MSM by NGOs, but cannot exclude a true increase of cases among MSM.

The left side of the continuum of care (Fig. 1) shows a major problem in the former Yugoslav Republic of Macedonia: the potentially high number of undiagnosed HIV infected patients. However, the estimation of 500-1200 PLHIV, with the official number being 900, which is based on Spectrum (UNAIDS), is unconfirmed and performed by bodies outside the former Yugoslav Republic of Macedonia. The consensus in the National HIV Strategy 2012-2016 was 900 PLHIV, but many informants considered it to be too high an estimate. It is recommended to build capacity in the country to evaluate number of undiagnosed PLHIV. It is important to apply different methods to estimate this number and a new ECDC method is available online for countries to use (18). This ECDC method, as well as the 'London method 1' (19), is more suited for concentrated epidemic as seen in the former Yugoslav Republic of Macedonia.

It is important to ensure systematic collection, reporting and analysis of data is official and easily accessed by all involved stakeholders in order to base interventions planned on evidence and continued analysis of the epidemic.

Priority area 2: Optimize testing coverage among key populations

The existing testing guidelines/recommendations in the country outline technical procedures for testing and testing algorithms. It does not outline recommendations for pre-test information or who to offer an HIV test to, such as key population groups and people presenting to the health care system with indicator conditions. According to many informants, no such testing protocol has ever been adopted and testing is far from normalized in the health care system. Other comments received mention that the first National protocol for VCT was developed in 2005, and it was in force until 2011. In 2011 this protocol was revised with amendments and law regulations. The process for revision was open and included members of various institutions and NGOs.

Coverage is still low among key populations. The estimations made based on behavioural surveys conducted among the most at risk groups found that only 19% of the MSM population, 33% of PWID, and 44% of SW have had an HIV test done in the last 12 months (for prisoners it is only 4.5%); and out of those who have had an HIV test, almost all of the MSM knew their results (99.3%), while for both PWID and SW this is slightly lower (85%), (*14 20-23*). It seems that many tests are performed in people not at risk of HIV (blood donors, pregnant women and other people who are required to present an HIV test result), although it has not been possible to get an overview of how many tests are performed in each risk group. The only information regarding risk groups is available within Outreach VCT clinics that are implemented by HERA in partnership with 14 NGOS and 11 Health Institutions. Both Outreach VCT clinics operate in more than 11 cities

throughout the country. This programme is created and designed according the needs of representatives of key populations. In 2014 there were 1590 clients covered with testing and counselling (240 MSM, 270 SW, 815 PHID, and 163 Prisoners. An additional 163 representatives from youth populations have been tested via this service). Information on the number of positive tests is not available.

There is presently no problem with concomitant HIV/TB infections since no patients with both TB and HIV are presently diagnosed and the number of such patients in the past has been very low. However, the number of TB patients being tested for HIV at the dispensaries is reported to be very low. It is important to increase the coverage of testing among people presenting with TB.

Testing for STIs is not offered in connection with rapid HIV testing, not even at the VCT centres. Also, the official statistics on STIs, such as syphilis, most likely underreport the number of cases. Since STIs are strong indicators of undiagnosed HIV infection, it is necessary to strengthen the possibility to test for both HIV and STIs during the same visit.

The 10 VCT centres coordinated by the Institute of Public Health each perform around 100 tests a year but these are of the general population, not the most at risk groups. Four counsellors and 2-4 lab technicians are attached to the VCT centre in Skopje, which is considered to be a lot of resources for a small number of tests which are not reaching the key affected populations, although only part of their time is allocated to the VCT. Further, the VCT centres can only perform HIV testing, so clients in need of STI or hepatitis testing will have to receive this elsewhere. Positive results are sent for confirmation to the IPH. The testing algorithm is in line with WHO recommendations. Collaboration among the VCT centres and the NGOs seems very fragmented.

Testing can only be performed by medical personnel, which can be a challenge for the NGOs doing outreach testing, who need to contract medical staff to be on site. The newly released WHO testing guidelines recommend that testing by trained laypersons should be allowed (24). It is therefore recommended that the former Yugoslav Republic of Macedonia considers initiating a process to facilitate the performance of testing without medical personnel on site, which will mean cost savings and increased flexibility to reach those most at need for HIV testing.

Rapid tests are currently procured through the Global Fund. It is crucial that the government continues to procure rapid tests to support the outreach work of NGOs in particular. In order to ensure the quality of the tests and to keep prices low, it would be essential to look at the possibility of central procurement.

Priority area 3: Adapt service delivery

HIV clinical care and treatment

As previously mentioned, the left side of the continuum of care (Fig. 1) shows a major problem in the former Yugoslav Republic of Macedonia: the potentially high number of undiagnosed HIV infected persons. Although estimations vary, it seems very likely that there are a high number of undiagnosed cases as indicated by the high level of late presentation observed in the country.

No up-to-date national clinical treatment protocol exists in the country.² The first protocol was developed in 2005 by an expert work group nominated by the Minister of Health and with support of Dr. Marty Vall Mayans. The protocol was called the National Protocol for treatment and care of patients with HIV/AIDS in the former Yugoslav Republic of Macedonia. The CID reports that international guidelines are followed today, including both the 2013 consolidated guidelines from the WHO (*25*) and those from the European AIDS Clinical Society (*26*) as a basis for treatment choices. In addition, the CID is in personal contact with consultants in Europe and the USA who can be considered key opinion leaders in the field of ART. The intention of the CID is now to switch to the updated 2015 WHO guidelines for when to start ART (*27*).

Some patients living outside Skopje have difficulties affording the frequent travel to Skopje and some of them have received economical support for the travel from the NGO Stronger Together (28).

The patients on ART visit the CID in most cases once a month in order to get antiretroviral drugs and to get adherence support as well as social support. The mean number of patient visits to the clinic is thus very high, but the HIV RNA viral load and CD4 cell count monitoring are conducted less often, in general every 3-6 months. The care component received high priority, to the benefit of the patients. The emphasis on adherence support is high. A minority of the patients are seen less frequently according to an individualized schedule.

Care and support for PLHIV is provided through a special outpatient counselling centre. However, only one doctor is seeing all patients with HIV in the country, and it should be determined if this is sustainable.

According to a list obtained from the CID (for October and November 2015), the antiretrovirals used in 112 patients include a broad spectrum of 17 different treatment regimens (*30*). Altogether 11 different drugs are used: *nucleoside analogue reverse transcriptase inhibitors (NRTI)* - 3TC: n= 64, zidovudine (ZDV): n= 57, tenofovir (TDF): n= 54, FTC: n= 52, abacavir: n= 2; *non-nucleoside analogue RTI (NNRTI)* - efavirenz (EFV): n= 73, nevirapine (NVP): n= 23, rilpivirine (RPV): n= 1; *protease inhibitors (PI)* - lopinavir/r: n= 21, darunavir/r: n= 2; and *integrase inhibitors* – raltegravir: n= 2. Sixty-eight patients are given first line therapy, 47 patients are given second line therapy and in three patients the treatment was initiated in another country. Sixty-five of the 68 patients given first line ART received a combination of 2NRTI and 1NNRTI, of which EFV/3TC/ZDV was the most common (n= 33) followed by NVP/3TC/ZDV (n= 17) and EFV/FTC/TDF (n= 15). Three patients received a LPV/r containing regimen. Among the 47 patients receiving second line ART, 25 were given EFV/FTC/TDF and nine were given LPVr/FTC/TDF. An additional nine different combinations were used.

Patients who are on a stable regimen of ZDV+3TC have not been systematically switched to non-ZDV containing regimens. Thus, 57/118 (49.1%) are treated with a ZDV-containing regimen. A systematic switch from the individualized approach to the public health approach has not been done, as recommended by the WHO.

² There is a clinical guideline developed by a team of experts from the MoH addressing laboratory quality HIV testing and HIV testing algorithms from 2006 which is still in use (National Institute for Health Care, 2006)

Diagnostic facilities at the CID are well developed including access to HIV RNA quantification and CD4 cell count monitoring, as well as diagnostics of viral hepatitis (*31*). Equipment for genotypic resistance testing and sub-genotyping has recently become available but has not yet been put into use.

Most patients have a low CD4 cell count at diagnosis and late diagnosis occurs at a high rate in the former Yugoslav Republic of Macedonia (Table 1). Most of the patients thus need ART at time of diagnosis. The ambition to treat all diagnosed HIV patients will result in an increase of the presently diagnosed patients on ART from 112 to 151³. In addition, increasing testing of persons at risk for HIV is likely to identify a larger number of individuals due to the prediction of a high number of undiagnosed HIV-infected persons. The need for ART in the country is therefore estimated to increase substantially over the coming years.

Table 2 shows the CD4 cell count at diagnosis of patients diagnosed between 2008 and 2014, with late diagnosis (<350) accounting for more than 50%, until 2013.

	New diagnosed	<350 CD4 on		>350 CD4 on	Unknown on time
	HIV cases	time of		time of	of diagnoses
		diagnoses		diagnoses	
2008	10	6	60%	2	2
2009	8	4	50%	4	/
2010	14	10	71%	3	1
2011	10	7	70%	3	/
2012	23	13	57%	6	4
2013	28	10	36%	16	2 (7%)
2014	45	18	40%	18	9 (20%)
Total	138	68		52	18

Table 2. CD4 at diagnosis 2008-2014

Few ARVs are registered in the former Yugoslav Republic of Macedonia as brand name products: TDF (as Viread), TDF+FTC (as Truvada), TDF+FTC+EFV (as Atripla), TDF+FTC+RIL (as Eviplera), lopinavir/r (as Aluvia) and ritonavir (as Norvir). However, most of these have never been purchased at a public procurement as the status of being a registered product is not considered as an advantage in this process. Instead, the lower price automatically leads to the procurement of cheaper non-registered generic products. The procurement of the drugs is done through tenders. This situation makes it difficult to predict the number and categories of ARVs which will be procured, thus strengthening the capacity to predict need and to perform tenders is of great importance. The WHO has been continuously advocating and encouraging the Government to create opportunities for registration of antiretroviral agents and other drugs needed to treat the complications of HIV, encouraged, for example, through free registration.

³ According to the public lists 118 patients are treated with ARV, but verbal communication during the mission stated that only 112 patients are currently receiving ART.

Key Populations

MSM

The Ministry of Health has conducted bio-behavioural studies among MSM in the former Yugoslav Republic of Macedonia that have pointed to the stigma that the MSM population is subjected to, and described how this impacts regular preventive programmes and possibly the number of undiagnosed HIV infected individuals. The bio-behavioural study from 2013/2014 found a prevalence of 2.4% HIV in the sample of 426 participating MSM (estimated to be 1.9% of the entire MSM population) (20).

As mentioned, currently only one NGO (Equality for Gay and Lesbians - EGAL) works with outreach programmes specifically with and for the MSM population. There is thus an urgent need to intensify preventive programmes specifically targeting MSM, including easily accessible HIV testing services, educational activities, free condoms and lubricants. The organization has three facilities in Skopje and two in the provinces. They have recently gained permission from the MoH to perform HIV testing. Previously, they would refer clients to the Clinic of Infectious Diseases for testing. The staff accompanies people who test positive through the outreach programmes for confirmatory testing and linkage to care.

In light of the Global Fund phase-out it is particularly important to address how preventive services, HCT and information targeting MSM, can be scaled up and improved.

PWID and OST

As previously mentioned, overall coverage of OST is mid-level reaching roughly 23% of the current estimated 10 300-10 900 problematic drug users, mainly people who inject drugs. Key informants indicated that there is a lack of medical staff, including physicians and nurses, willing to work at OST sites. According to the legal act, an OST site should minimally include one general practitioner, one psychiatrist and one nurse. Key stakeholders indicated that some OST sites have a serious shortage of physicians, psychiatrists and/or nurses. Therefore, medical services at these sites are limited and of low quality. At the Kisela Voda OST site at the psychiatric hospital in Skopje, there are 450 patients which are cared for by six psychiatrists, nine nurses, two psychologists and one social worker. Most of the patients have multiple health and social needs. Clearly, the site is too understaffed to implement comprehensive psychosocial needs assessment and individualized treatment plans for patients.

In particular, the specific needs of women on OST are unmet. Drug-using partners of female PWID often pushed them into sex work and physically abused them. OST staff could not always guarantee the safety of female patients. Many of the female OST patients were reported to have personality disorders, and 7-10% has a medical history of sexual abuse. Due to the lack of multi-disciplinary staff and its capacity, the OST sites neglected the specific needs of female patients. It is relevant to note that only 10% of all patients on OST are female (*32*).

Due to the lack of capacity, medical staff refer some of their patients to NGOs (e.g. HOPS and others) for psychosocial services, but in a rather unsystematic way. The availability of these services remains limited.

The linkage to HIV, viral hepatitis C and TB services is available at OST sites, although it is limited due to the sites' lack of capacity and an underdeveloped multidisciplinary approach.

In spite of the fact that there are no waiting lists, local experts consider that opportunities for access to drug dependence treatment programmes are limited, especially because the opening hours of the programmes are often incompatible with the habits and needs of potential patients. Treatment venues can also be a long way from patients' homes, which creates additional costs for transport. Also, pharmacological therapy is often carried out in locations that do not allow for sufficient confidentiality, which creates the potential for the identity of the patients to be revealed to the wider community (*32*).

The PWID community, including OST patients, indicated that OST is often limited to the dispensing of methadone and the treatment is not able to meet the comprehensive needs of patients. Medical staff at OST sites dispenses methadone to most of the patients for home use, often a week's supply. Illegal benzodiazepine use (possibly though injecting) is quite common among methadone patients and varies from site to site from 53% in Kumanovo to 93% in Ohrid. The diversion of methadone and injecting of diverted methadone is common and indicates deficiency in supervision of methadone intake. Key informants reported known cases of injecting illegal methadone among adolescents.

OST has a rather negative image as a medical service among medical professionals and institutions. Key informants indicated that hospitals usually establish OST sites in remote areas, apart from their main venues. Medical staff (psychiatrists and nurses) is not willing to work there as they consider the work with PWID to be difficult, dangerous and unrewarding.

Some previous studies raised issues of the deficiencies in the quality of OST and called for the "creation of a system for the continuous control of the quality of pharmacotherapy" (11,32). Local experts admit that, although the treatment network for drug addiction is quite developed, there is a perceived need for further capacity building and an increase in the quality of medical care (11).

Needle and Syringe Programme

In 2013, through 16 drop-in centres, NGOs reached 3282 (32%) of the estimated 10 200 PWID in the former Yugoslav Republic of Macedonia. This is a mid-level quality indicator for NSP coverage as it falls into the established range of 20-60% of estimated number of PWID (*15*). In Skopje city, the bio-behavioural survey of a sample of 407 PWID between 18-45 years old indicated that 76.5% have received free injecting equipment, an estimated 65% nationally (*14*). These data show that while two thirds of estimated PWID are in contact at least episodically with NSP, the actual coverage with NSP might be lower according to the indicators recommended by WHO/UNDOC/UNAIDS and there is a high potential for improving the coverage.

NGOs in 2011, through drop-in centres, gave away 636 910 needles and 318 485 syringes, or 94 needles and syringes per estimated PWID per year (11). This is a low-level NSP quality indicator (<100 syringes per estimated PWID per year, the mid-level quality indicator is between 100 and 200 syringes per year) (13), however is good compared to other countries in the region. Nevertheless, it is important to consider that a high percentage (90%) of injected substances is methadone. As methadone's effect to the body lasts much longer than that of heroin, PWID possibly inject methadone only once per day. Therefore, the real need for injecting equipment might be lower than in countries where heroin injection prevails. Nevertheless, with this indicator, the former Yugoslav Republic of Macedonia had the best service provision in 2013 when compared to other countries in the region (12).

The bio-behavioural survey of 407 PWID sampled in Skopje indicated that 37% of PWID have had an HIV test done in the last 12 months, an estimated 33% nationally (the low-level quality indicator is <40% of PWID receiving HIV testing per year, the mid-level quality indicator is 40-75% per year) (14).

The Global Fund is funding almost all NSP services, which NGOs provide. Municipalities provide only very limited funding. Thus, the sustainability of NSP programmes after the Global Fund phases out its support in 2016 is greatly at risk. A process of accreditation of NGOs to provide NSP services has been developed with the participation of the MoH and NGO representatives. The NGO HOPS has produced a study projecting the funding needs from the government budget of the NGOs involved in order to sustain the minimal and optimal models of services (*15*). Nevertheless, the continued functionality of NSP programmes remains at risk in 2017.

The mission was not able to identify a legal act from the Ministry of Health, which regulates the provision of NSP in the country. NSP are seemingly operating according to recommendations, which are partly the Global Fund and NGO agreements.

5.3 Cross-cutting issues

Priority area 4: Ensure sustainability and rights-based support for key populations

Sustainability in allocation of the national resources

The fact that the HIV prevalence in the former Yugoslav Republic of Macedonia is still low should be seen as a very significant opportunity for a cost-effective prevention effort. Conversely, a lack of investment at this time could easily lead to outbreaks and a rapidly expanding epidemic entailing very high future treatment costs for society. Paradoxically, low HIV prevalence may in fact be an obstacle for prevention, as it might be more difficult to convince governments to spend resources on prevention when there does not seem to be a problem right now. However, prevention should be seen as an investment in the future, which will pay itself back through savings on treatment and through the productivity of the population (13).

Presently, dual infection with HCV and/or HBV is rare among the HIV infected patients and increased treatment of HCV mono-infected patients is not necessary from an HIV prevention point of view. On the contrary, it is important that funding for HIV prevention and HIV clinical care are separated from funding for HCV treatment.

ARV treatment is not sustainable as the planning, procurement and administration, which are managed by the government, do not function adequately and needs streamlining. Current public expenditures in the area should be reviewed as to determine financial forecasts for full implementation of the new national HIV/AIDS strategy, as well as the national AIDS spending account for MSM.

Marginalization and discrimination in society make it difficult for gay men and other men who have sex with men to exercise their human rights, including accessing health services. A high level of homophobia among the general population and state officials has been reported (33). The Anti-Discrimination law from 2010 does not include sexual orientation as grounds for nondiscrimination, nor are there any specific provisions on hate crimes in the Criminal Code (33). Government campaigns to reduce public stigma and discrimination towards MSM may be considered, as well as to include this topic in the official curriculums of health workers.

In the former Yugoslav Republic of Macedonia, as in many other European countries, the MSM population is disproportionally affected by HIV. It is the most at-risk group that needs to be addressed due to its role in driving the country's HIV epidemic. There are good experiences with reaching the MSM population through the NGO running outreach VCT and youth-friendly HIV and sexual health services, which may be used as a model for scale-up at national level (*33*).

It is important to ensure separate funding for HIV activities and for financial forecasting, including funding for activities to address the prevailing stigmatization in the country which has consequences for the reach of prevention and testing activities.

PWID

In general the former Yugoslav Republic of Macedonia has shown leadership in developing and sustaining harm reduction interventions among PWID when compared with other countries of the region.

OST, especially, has a strong perspective for sustainability in the former Yugoslav Republic of Macedonia due to following factors:

- There is a long tradition of OST provision in the country;
- Governmental institutions under the Ministry of Health and Ministry of Justice implemented and expanded OST, and integrated it into their regular services;
- The State budget funds OST;
- The Ministry of Health has adopted legal acts on OST and National Clinical Guidelines; and
- There is continuity in OST provision between prisons and community health care institutions and vice versa.

On the other hand, the sustainability of the current provision of NSP is at considerable risk due to the following factors:

- To date, governmental funding is not available for NSP; NSP relies fully on the Global Fund for financial support, except for a small amount from municipalities;
- Governmental institutions are not engaged in NSP;
- So far there are no mechanisms or experience in the provision of NSP by NGOs through provision of the state budget; and
- The Ministry of Health so far has not adopted a legal act for NSP implementation.

Access to services and human rights

Stigmatization of PLHIV and key population groups is dominant in the former Yugoslav Republic of Macedonian society and many examples were mentioned of discrimination and criminalization of people. This seems to be particularly true in the regions outside Skopje.

A person living with HIV was hospitalized in the public health institution Ohrid General Hospital in August 2014 for an appendix removal surgery. After the medical staff learned about the person's HIV status (by performing an HIV test without informing the patient), the patient faced offensive attitude from the staff and was isolated in a separate room marked with a yellow band and a sign denoting 'forbidden entry'. The information about his HIV status spread around to the entire personnel of the hospital and eventually leaked outside of the institution, leading to his psychological agitation, irrevocable damage to his privacy and violation of his personal integrity.

The case and the subsequent steps taken by the person throughout 2014 and 2015 in order to seek protection from several state agencies showed that *the existing legal mechanisms are inefficient in regards to protecting the rights of people living with HIV and that institutions in charge lack mutual coordination*.

Namely, only the Ombudsman's Office concluded that there was actual discrimination on the basis of health status (HIV) and extended recommendations to the hospital in Ohrid. On the contrary, the State Sanitary and Health Inspectorate did not find any discrimination, whereas the Directorate for the Personal Data Protection did not find any infringement of the Law on Personal Data Protection in spite of the fact that the person's HIV status became widely known within his social environment. The Commission for Protection against Discrimination has not yet responded to the submission eight months beyond the deadline as defined by law.

It is also a regular practice in several gynaecological clinics that perform deliveries to perform an HIV test just before birth, often without informing the woman prior and certainly without any counselling. A case was reported by several informants where a woman was actually sent off to the Clinic for Infectious Disease after a false positive result on the very day of her appointment for caesarean section in a private clinic. On the other hand, official regulations on antenatal care oblige every gynaecologist to recommend pregnant woman have an HIV test within the first trimester on a voluntary basis. It seems that this is sometimes done, but it is also sometimes being misinterpreted to mean that the woman must bring an official result back to her gynaecologist – thus some of the tests in the VCT centres are pregnant women.

MSM is reported to be the most stigmatized group in the country, which is problematic for reaching MSM with HIV. The former Yugoslav Republic of Macedonia is the only country in the region where sexual orientation is not part of the legal protection act for minority groups. It was recently suggested to change the constitution to only allow a family to be husband and wife. Homophobia and non-protection of sexual orientation is extremely problematic for the adequate implementation of the national HIV/AIDS programme.

6. Recommendations

6.1 Main recommendations

- Clarify roles, responsibilities and information flow between stakeholders and strengthen the collaborative structure of the national HIV response, including strong leadership.
- Include the continuation of outreach activities and services targeting key populations in the new strategy on HIV, in particular HIV rapid testing, with allocated funds.
- Ensure that support functions for key populations, in particular PLHIV, MSM and PWIDs, are available and further developed.
- Prepare for a substantial increase in the demand of antiretroviral therapy.
- Ensure monitoring and evaluation of the national strategy occurs.
- Strengthen surveillance indicators of the HIV epidemic and conduct proper analysis to inform policy decisions on priorities within the national HIV programme.
- Reduce stigma related to HIV and key populations in all health care settings through targeted campaigns and education.
- Develop a transition plan for HIV financing.

6.2 Specific recommendations

Priority area 1: Strengthening and harmonization of the reporting system

Immediate term

- Improve monitoring of HIV tests performed on risk group and positive results.
- Collect yearly data on:
 - CD4 cell count at diagnosis;
 - HCV, STIs and TB tests and diagnosis; and
 - HIV tests by risk group and setting.

Mid-term

• Implement analysis of the Continuum of Care on a regular basis in order to follow the development of the HIV epidemic and patients in clinical care.

Priority area 2: Optimize testing coverage among key populations

Immediate term

- Continue and expand HIV testing in civil society and OST centres (rapid testing).
- Ensure continued central procurement and distribution of rapid tests.

Mid-term

- Develop clinical testing guidelines for health care sector, in line with WHO testing guidelines.
- Testing for HIV and STIs during the same visit should be established, as STIs are one of the strongest indicators for HIV in an HIV epidemic driven by sexual transmission.
- Consider initiating a process to facilitate performance of HIV rapid testing without medical personnel on site (cost savings method and increases flexibility).

Priority area 3: Adapt service delivery

Clinical care

Immediate term

- Phase out ZDV whenever feasible from a clinical point of view.
- Decrease the mean number of clinical visits to the CID, from every month to every fourth or sixth month, in selected cases, when clinically feasible, in line with the current recommendations in this area.
- Develop, by the end of 2015, a comprehensive plan for ensuring health care capacity and ARV drugs for the PLHIV that remain undiagnosed, with special attention paid to key populations and increase the ART levels to treat all who are diagnosed.

Mid-term

- Develop up-to-date national clinical guidelines.
- Optimize the presently used drug combinations with a focus on simplification and costsavings following the public health approach of the WHO.

Key populations

PWID

Immediate term

- Comprehensively assess the present quality of OST services and develop an action plan in order to ensure the quality of OST delivery by aligning with WHO guidelines to:
 - Strengthen the quality assurance system;
 - Attract sufficient medical staff for OST, and include a review of the existing funding mechanism;
 - Complement existing OST sites with comprehensive psychosocial services by employing more trained social workers, who would be able to assess individual patient needs and promote social integration of patients through the application of a multidisciplinary approach and case management; and
 - Review treatment protocols on drug dependence treatment and strengthen linkages with HIV, TB and STI services.
- Continue OST in prisons and ensure the quality of services there.

Mid-term

• To develop a legal act on the quality requirements for the provision of NSP services.

MSM

Immediate term

• Scale up prevention and testing for MSM in the light of the Global Fund phase-out and address how preventive services, HCT and information targeting MSM can be improved and expanded.

Mid/long term

• Work to reduce public stigma and discrimination towards MSM, for example by including this in the official curriculums of health workers.

Priority area 4: Ensure sustainability and rights-based support for key populations

Immediate term

• Support NGOs to continue activities to fight discrimination and criminalization of key populations.

Immediate/mid-term

- Governmental/national (and other) activities should focus on acting against stigmatization/criminalization and promotion/normalization of testing among key populations.
- Continue the process of licensing NGOs and develop sustainable funding mechanisms for their services from the state budget by the end of 2016.
- Support NGOs and the PWID community in advocating for access for PWID to HIV testing and harm reduction services, using all available means, including HIV testing campaigns.

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Appendix 1

Terms of References

WORLD HEALTH ORGANIZATION **REGIONAL OFFICE FOR EUROPE**

WELTGESUNDHEITSORGANISATION REGIONALBÜRO FÜR EUROPA



ORGANISATION MONDIALE DE LA SANTÉ BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Evaluation of the HIV program review in the Former Yugoslav Republic of Macedonia

5-8 October 2015

1. Background

Since the beginning of national reporting and through to the end of 2013, the Former Yugoslav Republic of Macedonia has reported a cumulative total of 71 HIV cases, 133 AIDS cases and 64 deaths among AIDS cases to the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC). In 2013, 15 new HIV cases, 10 new AIDS cases and three deaths were reported. Although the numbers remain low, the HIV increase is above the WHO European Regional average (80%), compared to 2004.

Of the newly diagnosed HIV infections with information about transmission mode in 2013 (100% of cases), 87% were transmitted through sex between men, 13% through heterosexual contact and 0% through injecting drug use. 100% of the new HIV cases were male. The Former Yugoslav Republic of Macedonia has reported a cumulative total of two children infected through mother-to-child transmission, with zero reported cases in 2013.

Taking undiagnosed infections into account, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the WHO estimate that less than 200 people were living with HIV in the Former Yugoslav Republic of Macedonia at the end of 2013, that less than 100 people became newly infected and that less than 100 people died from AIDS-related causes during 2013. HIV prevalence in the adult population was estimated to be less than 0.1%.

Only 8% of people diagnosed with HIV in 2013 (one person) were diagnosed at an advanced stage of infection (CD4 cell count <200 per mm³ blood) which is well below the European Regional average of 49%. The percentage of late presenters has decreased substantially compared to 2009 when 50% of new cases were diagnosed late. Because of the small numbers of cases, some of the observed decrease is likely due to random variation.

As reported to the WHO Regional Office for Europe and ECDC, 24 562 HIV tests (11.9 per 1000 population) were performed in 2013, a 393% increase compared with the number of tests in 2004 (4983 tests). Among key populations, an estimated 97% of PWID, 29% of MSM and 38% of sex workers were reported to have been tested for HIV and received their results in 2012.

The number of people receiving antiretroviral therapy (ART) increased from 11 in 2006, to 36 in 2010, with numbers unavailable for 2013. The number of people enrolled in medical HIV care increased from 33 in 2006, to 36 in 2010, with numbers unavailable for 2013.

The Global Fund supports implementation of the national HIV program of the Former Yugoslav Republic of Macedonia with the grant which will end in 2016. The Global Fund has approached the WHO Regional Office for Europe with a request to evaluate national HIV program in Macedonia and provide recommendations which should inform the development of a sustainability plan for the country after the Global Fund stops its financial support.

2. Program review

Program review will include 4 key components:

- A. Epidemiological analysis,
- B. Review of HIV treatment and care along the cascade of services,
- C. HIV services for key populations, and
- D. Analysis of service delivery models for populations affected by the HIV epidemic from the perspective of the health system.

A. Epidemiological analysis will focus on:

- Assessment of the level of, and trends in, HIV disease burden (incidence, prevalence, and mortality), including estimated data on the HIV epidemic;
- Assessment of whether trends in HIV burden are plausibly related to programmatic efforts or to other factors; and
- Defining the investments needed to directly measure trends in HIV disease burden in the future.

B. Review of HIV treatment and care program along the cascade of services will include:

- HIV testing: for the general population and key populations, including community-based testing and linkage to HIV treatment and care services, and CD4 count at time of diagnosis;
- Early HIV infant diagnosis, MTCT and paediatric ART;
- Enrolment and retention in HIV care, including general HIV care, management of coinfections and co-morbidities, and integration of HIV/Viral hepatitis, HIV/TB, HIV/OST services;
- ART: estimated need and coverage, criteria for ART initiation, and adherence;
- ART regimens (1st line, 2nd line and 3rd line);
- Monitoring of ART response and diagnosis of treatment failure: VL, ARV toxicity, and HIVDR;
- Patient tracking system; and
- ART outcome: viral suppression.

Analysis of HIV treatment and care programs will also include a review of treatment and care policies and national clinical protocols.

- C. Review of HIV services for key populations (PWID, MSM, SW, prisoners) will include:
 - Prevention services, including harm reduction services for PWID and OST;

- Community outreach (HIV testing and linkage to HIV treatment and care services, ARV dispensing, case management/social accompanying);
- Access to HIV testing;
- Access to HIV care and ART;
- Prison settings; and
- Recording and reporting data on prevention activities among key populations (PWID, SW, MSM) and PLHIV implemented by NGOs.

Analysis of HIV services for key populations will focus on coverage, quality and integration with other health services within the health system

- **D.** Analysis of service delivery models for populations affected by the HIV epidemic from the perspective of the health system will focus on:
 - Capacity of the national health system to provide effective human, financial and infrastructural resources to address the health needs of populations affected by the HIV epidemic, including key populations which require a proactive approach in service delivery with strong social support and case management; and
 - Health systems barriers and interventions needed to optimize and monitor HIV services along the continuum of care and ensure high coverage with HIV testing, enrolment to HIV treatment and care, adherence to ART, and integration and linkage of services.

3. Participants

Three external consultants:

- ✓ Dorthe Raben, Team leader, Public health expert, WHO CC on HIV and Viral hepatitis, Copenhagen University (Denmark)
- ✓ Anders Sönnerborg, Clinical expert, Karolinska Institutet (Sweden)
- ✓ Emilis Subata, Harm reduction expert, WHO CC on Harm reduction (Lithuania)

External consultants will be supported by the WHO staff member:

Arta Kuli - national professional officer, WHO CO for Macedonia

4. Methodology

The preparation phase will include a desk review and analysis of available documents (WHO guidelines, national policy/strategy/plans, clinical guidelines, publications, reports, etc.)

During the country mission WHO experts will visit relevant institutions and facilities and consult with key informants: policy makers, health care providers and beneficiaries, NGOs, and other national partners where appropriate.

Together with local clinical experts they will also have access to medical records for PLHIV for a review of clinical management.

5. Time, duration and geographical sites of the mission

The mission is planned for 5-8 October 2015. Additional days will be added for desk review and analysis of national background documents and report writing.

5 days mission (all)

5 days desk review and reporting (all)

3 days for compilation of feedback from the team and finalization of report (team leader)

Logistic support will be provided by the WHO and national health authorities.

6. Deliverables

- Key recommendations based on the public health approach will be developed and presented to the national stakeholders by the end of the mission. Compliance of approaches and recommendations with the main WHO recommendations, i.e. 'Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection' 2013⁴ and 'Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations' 2014⁵ will be ensured.
- All team members will provide their written contribution using the template (and will be delivered) to Dorthe Raben by **16 October 2015.** The draft mission report will be shared with team members for comments.
- The final report with findings and recommendations will be submitted to the WHO Regional Office for Europe by <u>26 October 2015</u>.

The reports will be posted on the WHO Regional Office for Europe's website.

⁴ <u>http://www.who.int/hiv/pub/guidelines/arv2013/download/en/</u>

⁵ <u>http://www.who.int/hiv/pub/guidelines/keypopulations/en/</u>

Appendix 2

List of informants

Date	Venue	Meeting Participants
5 October		
		FUNDATM)
		Dr. Zvonko Milenkovic, National Coordinator for
		HIV/AIDS
		Dr. Milena Stevanovic, Clinics of Infectious diseases;
		Nermina Fakovic, Preventive Care Dpt., Ministry of Health
		Hristijan Jankuloski, Executive Director of NGO "Hops",
		Country Coordinative Mechanism Chair (CCM)
		Ana Filipovska, CCM Secretariat
		WHO Mission Team
	Institute for Public	Dr. Zharko Karadzoski, Epidemiologist, Head of HIV
	Health	Dpt.
		Dr. Golubinka Boshevska, Head of Virology Dpt./
		Laboratory
		Dr. Gordana Kuzmanovska, Head of Sector,
		Epidemiology
		WHO Mission Team
	NGO STAR STAR	Borce Bozhinov, Program Coordinator
	(HIV services for SW)	WHO Mission Team
6 October	OST Centre Kisela	Dr. Liljana Ignjatova, Psychiatrist, Coordinator of OST
	Voda	Centers
		WHO Mission Team
	Global Fund Office	Dance Gudeva Nikovska, Project Manager, TB PIU,
	(TB PIU)	Ministry of Health
		WHO Mission Team: Dorthe Raben, Public Health Expert;
		Andres Soneborg, Clinical Expert
	NGO "Doverba"	Slavica Shekutkovska, Program Manager
		WHO Mission Representative: Emilis Subata, Harm
		Reduction Expert
	NGO HOPS	Hristojan Jankuloski, Executive Director
		Silvana Naumova, PM of services Program
		Darko Veleski, Project assist. For Harm Reduction
		Ivana Andreevski, Project Ass. For SW Program
	NGO HODG 1	Davor Smilanov, Medical Staff
	NGO HOPS, drop-in	Daniela Simovska, Social Worker
	Centre, Kapishtec	Zharir Simrin, Needle Exchange Assist
	Municipality	Aleksandra Spasovska, Coordinator
	NCO HODE data '	WHO Mission Team
	NGO HOPS, drop- in	Eleonora Chichevska, Coordinator
	Centre for SW in Gazi	Katerina Todorovska, Social Worker
	Baba Municipality	Afrodita Zaharieva, Assistant at the Centre
		WHO Mission Team

	NGO EGAL	Zoran Jordanov, Programme Coordinator	
		Fana Aleksovska, Team Member	
		WHO Mission Team	
7 October	Clinic for Infectious	Dr. Zvonko Milenkovic, Director of the CID, National	
Diseases (CID),		Coordinator of HIV/ AIDS	
	Skopje	Dr. Katerina Spasovska, Infectologist	
	Бкорје	Dr. Milena Stevanovic, Infectologist	
		WHO Mission Team	
	Preventive Care Dpt.,	Dr. Jovanka Kostovska , Head of Preventive Care Dpt.	
	Ministry of Health	Nermina Fakovic, Preventive Care Dpt.	
	Willistry of ficaltin	WHO Mission Team	
	VCT Centre, Prolet,	Dr. Lilijana Stefanova	
	Skopje	WHO Mission Team	
	NGO Hera	Bojan Jovanovski, Programme Manager	
		Elizabeta Bozhinovska, Programme Coordinator	
		WHO Mission Team	
	NGO Strong Together	Andrej Senih, Program Coordinator	
	ride strong regetier	WHO Mission Team	
8 October	Ministry of Health	Natasha Nikolovska Stankovic, Program Manager PIU	
0 0 0 0 0 0 0 0		Global Fund MON	
		Lidija Kirandziska, Finance Manager, PIU Global Fund	
		ATM MOH	
		Aleksandra R. Eftimova, Cabinet of the Minister of Health	
		Dr. Jovanka Kostovska, Head of Preventive Care Dpt	
		(MOH)	
		Nermina Fakovic, Preventive Care Dpt (MOH)	
		Borce Bozhinov, Program Coordinator, NGO STAR STAR	
		Silvana Naumova, Program Manager, NGO HOPS	
		Slavica Shekutkovska, NGO Doverba	
		WHO Mission Team	
	Prison Idrizovo,	Jasminka Doncevska, Coordinator of the Program at the	
	Skopje	Ministry of Justice	
		Salush Arifi, Deputy Director of the Prison Idrizovo	
		Magdalena Kopcarova Dedic, Sociologist, Program for re-	
		socialisation	
		Biljana Kokolanova, Pedagogue, Program for re-	
		socialisation	
		WHO Mission Team	



World Health Organization Regional Office for Europe

UN City, Marmorvej 51 DK-2100 Copenhagen Ø Denmark Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01 Email: aids@euro.who.int Web site: www.euro.who.int/aids