THE CONTINUUM OF HIV CARE IN THE REPUBLIC OF MACEDONIA

Assessment report for 2017 with a special focus on men who have sex with men

STUDY TEAM:
Dr Vladimir Mikikj¹
Dr Milena Stevanovic²
Andrej Senih³
Rumena Gjerdovska Kojcheski²
Zoran Jordanov⁴

- 1. Institute of Public Health, Republic of Macedonia
- 2. University Clinic for Infectious Diseases and Febrile Conditions, Republic of Macedonia
- 3. Stronger Together, Association for Support of People Living with HIV, Skopje, Republic of Macedonia
- 4. Association EGAL Equality for gays and lesbians, Skopje, Republic of Macedonia

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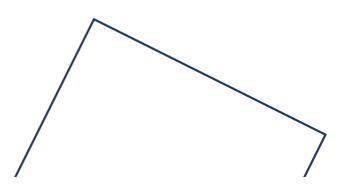
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1. Mikikj, Vladimir [автор] 2. Stevanovikj, Milena [автор] 3. Andrej, Senih [автор] 4. Gjerdovska Kojcheski, Rumena [автор] 5. Jordanov, Zoran [автор]

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CONTENTS

List of abbreviations	4
Introduction	5
Methodology	8
Results	10
National Continuum of HIV Care	10
Stage 1. The estimated total number of people living with HIV	10
Stage 2. Number diagnosed	10
Stage 3. Number on ART	11
Stage 4. Number with supressed virus	11
Continuum of HIV care with focus on men who have sex with men	11
Stage 1. The estimated total number of MSM living with HIV	11
Stage 2. Number of MSM diagnosed	12
Stage 3. Number of MSM on ART	12
Stage 4. Number of MSM with supressed virus	12
The HIV continuum for MSM based on the data from the bio-behavioural survey	13
Discussion	15
Recommendations	17
References	18

LIST OF ABBREVIATIONS

AIDS acquired immunodeficiency syndrome

ART antiretroviral therapy

HIV human immunodeficiency virus
IBBS integrated bio-behavioral survey
MSM men who have sex with men

PLHIV people living with HIV

UNAIDS The Joint United Nations Programme on HIV/AIDS

INTRODUCTION

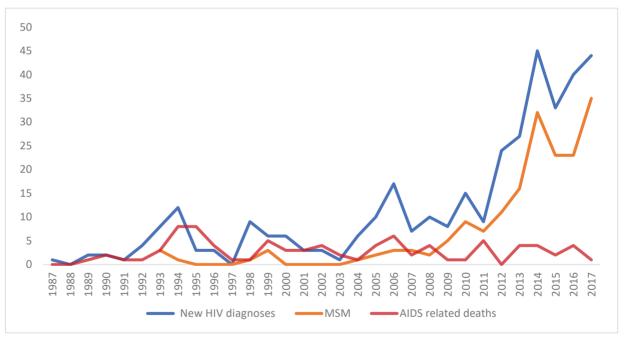
The HIV epidemic in Macedonia

The Republic of Macedonia, a country with approximately 2.1 million citizens¹, has a low-level, concentrated HIV epidemic [1]. Overall, it has one of the lowest absolute numbers of reported HIV cases in the region of Southeast Europe, with only 358 reported cases until 31 December 2017 and 86 reported HIV related deaths.

There is an increasing trend of new HIV diagnoses with 52% of all HIV cases registered in the last five years. For the last 4 years, there is an average number of 40 new diagnoses annually, ranging from 33 in 2015 to 44 in 2017 [2].

Several categories of evidence suggest that the epidemic is under control among people who inject drugs and female sex workers, but prevalence is rising among men who have sex with men (MSM) [3]. Sex between men was the reported mode of transmission in more than half of the total number of HIV diagnoses (51%), with heterosexual contact reported in 42% and injecting drug use in 2% of the cases, while other routes of transmission are sporadic. However, surveillance data show an increasing proportion of MSM among newly diagnosed HIV cases: for the period between 2012 and 2016 this proportion ranges between 58% to 74% on an annual basis (Figure 1). On the other hand, 85% of the total cumulative number of HIV infections by the end of 2017 were diagnosed among men and 95% of the 185 new cases diagnosed within the last 5 years (only 9 women with HIV infection were diagnosed during this period). Annually, the percentage of men for the same 5-year period (2013 to 2017) ranged from 91% in 2015 to 100% in 2017. Sex between men was the reported transmission mode in 81% of the registered cases in 2017, the highest proportion ever recorded.

Figure 1. Number of newly registered HIV cases, number of newly diagnosed HIV among MSM and number of AIDS-related deaths in Macedonia, 1987-2017 (n=358)



The average rate of late diagnoses (CD4 count below 350 cells/mm³) for the past 5 years has been 48%, ranging from 34.6% in 2013 to 73.3% in 2015 [4].

Table 1. Rates of late diagnosis per year, 2013-2017

2013	2014	2015	2016	2017
34.6%	47.5%	73.3%	46.7%	37.5%

As part of the active surveillance of HIV prevalence, knowledge, attitudes and practices in this period, several cross-sectional studies were conducted among men who have sex with men, sex workers and people who inject drugs between 2010 and 2018. The data from these studies also suggest an elevated risk of HIV infection among MSM in Macedonia. According to results from the last published bio-behavioural survey done with a respondent driven

¹ Projections from State Statistical Office available at http://www.stat.gov.mk/KlucniIndikatori_en.aspx

sampling method [5], sexual risk behaviours are present among MSM in Macedonia, while HIV prevalence increased from estimated 0% in 2010 to estimated 1,9% in 2014. Furthermore, unpublished data from the survey among MSM in 2017/2018 show an increase in prevalence to estimated 5.4%, revealing a concentrated epidemic among MSM. On the other hand, studies conducted among people who inject drugs and female sex workers in 2010, 2014 and 2017/2018 did not discover any cases of HIV infection.

The last population size estimation was performed in 2017/2018 along with the integrated bio-behavioural survey among MSM in the capital city of Skopje based on respondent-driven sampling. The size estimation was performed using the multiplier method [6] and the study population was defined as all males who have lived in Skopje for at least 3 months, aged 18 to 55 years, and who have had anal sex with a male person within the last 12 months. The population size in the capital city was estimated at 5,094 or 3.15% of the male population at that age (95% CI 4,286-6,557) and 5,556 (95%CI 4,675-7,152) at ages 18 to 59. Extrapolating this proportion to the whole country for the ages between 18 to 59 years gave an estimation of 11,054 (95% CI 9,301-14,229) [7] MSM in Macedonia. An estimation of the total number of people living with HIV was done for 2017 by UNAIDS using the Spectrum modeling tool and official surveillance data as input. The total number of PLHIV in 2017 was estimated at 384 (95%CI = 338-449) [8]. However, no official efforts have been done in the country to perform this estimation nor to construct the cascade of the HIV care continuum. Furthermore, there are no official estimates on the total number of MSM living with HIV.

Policy context related to HIV and sexual health

The national response to HIV in the Republic of Macedonia is structured in the National HIV Strategy as the principle policy document, which is developed by the Ministry of Health and formally adopted by the Government of the Republic of Macedonia. The strategic planning process – normally for a 5-year period – relies on an established practice of a multisectoral approach, including the participation of civil society and people living with HIV. Based on the National Strategy, the 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.

Already since 2009 there has been a gradual transition from Global Fund support to national funding of different components: in 2009 the Ministry of Health took over the funding for opioid substitution therapy, which became part of another program of the Ministry – the one on treatment of dependence – while funding for ART transitioned in 2011. Starting from 2018 the Government took over the complete financing of the National HIV Program, acting upon its preceding decision from September, 2017 to sustain HIV prevention services targeting key affected populations, which are implemented by civil society organizations [9].

Since the 2003 first National Strategy, the national response to HIV has been increasingly focused on key affected populations, with formal recognition of people who inject drugs, sex workers, men who have sex with men, as well as people living with HIV, along with some attention given to people in detention facilities, the general young population and the Roma population.

Prevention and testing services for men who have sex with men

Prevention services for men who have sex with men were first introduced in the country through the National HIV Program in 2005 in partnership with NGO HERA – Health Education and Research Association and a community-based LGBT organization EGAL, whose very establishment was supported by the National HIV Program and the Global Fund grant. Since then, the basic prevention and support services specifically targeting men who have sex with men have been delivered by NGO EGAL. The HIV testing services for MSM are provided within the national voluntary counselling and testing (VCT) program by both NGO EGAL and NGO HERA – Health Education and Research Association and, for the last three years also by community-based organization of people living with HIV, Stronger Together, albeit to a much lower degree. The national VCT program, managed by NGO HERA engages as implementers a number of public health centres and service-delivery CSOs across the country. Although not specifically targeting MSM, these services are also sensitized to deliver testing services to members of this population, in particular the VCT Centre at the University Clinic for Infectious Diseases and Febrile Conditions in Skopje.

NGO EGAL provides a basic package for prevention defined as two condoms, lubricant and an information material. In addition to the basic package, it offers peer education and peer counselling, as well as counselling from a psychologist/psychotherapist. In 2016 EGAL reached 4,643 unique MSM clients with the basic package and 3,597 unique clients in 2017 [10]. The lower number in 2017 can be explained with the interruption of funding during the summer of that year as a result of a challenging transition from Global Fund to national financing of HIV services. In 2017, 1,052 men who have sex with men received HIV testing and counselling through NGO services [11]. Within the National HIV Program there are two youth-friendly centres offering sexual and reproductive health services also to members of the KAPs, free of charge and on an anonymous/confidential basis. Both centres are located in Skopje and they are open to and used by men who have sex with men, as well as by members of other key populations. The SRH centres are providing: STI screening (for syphilis, HCV, gonorrhoea and urinary bacterial infections), support from a social worker, counselling and education, counselling by a psychologist and services for prevention of drug use. In 2017, 206 men who have sex with men received a total of 603 services for STI screening [12].

Treatment, care and support for people living with HIV

The treatment and care for people living with HIV in the Republic of Macedonia are centralized and provided only at the University Clinic for Infectious Diseases and Febrile Conditions (Clinic for Infectious Diseases). Since 2015 all people diagnosed with HIV infection are offered antiretroviral treatment upon diagnosis. The Clinic features a small Department on HIV, including a hospital ward and a day centre offering medical appointments, dispensing antiretroviral treatment and support services from a social worker and a psychologist. The HIV Day Centre also offers linkage with community-based support services. These are provided by the community-based organization of people living with HIV – Stronger Together, Association for Support of People Living with HIV, and they include: peer counselling, peer support in adherence, self-help groups, psychosocial (including modest financial support for people with HIV living in particularly difficult social circumstances) and legal support.

Objective of the research

The objective of this study is to assess the overall effectiveness of the national response to HIV by evaluating key stages of the continuum of HIV care, with a particular focus on men who have sex with men. The findings of the assessment are expected to inform the national strategic planning and the necessary programmatic interventions in response to the HIV epidemic in the Republic of Macedonia, especially with a view towards improving the prevention, linkage and treatment outcomes for men who have sex with men as the key population that is predominantly affected in the country.

The assessment was conducted through a collaboration between relevant community-based organizations providing different types of HIV services to men who have sex with men and state institutions responsible for treatment and care and for surveillance. These include: University Clinic for Infectious Diseases and Febrile Conditions; Institute of Public Health; Stronger Together, Association for Support of People Living with HIV; NGO EGAL – Equality for Gays and Lesbians; and NGO STAR STAR – Association for Support of Sex Workers. The assessment is an intervention within the "Right to Health" Program of the Eurasian Coalition on Male Health, with the financial support from the Global Fund to Fight AIDS, Tuberculosis and Malaria and it is the first in-depth assessment of the national continuum of HIV care with a focus on men who have sex with men in the Republic of Macedonia.



METHODOLOGY

For the evaluation of the national continuum of HIV care, we focused on four priority stages in accordance with the global 90-90-90 targets and as recommended by the European Centre for Disease Control and Prevention for monitoring of the progress towards achieving those targets:

- 1) Stage 1: The estimated total number of people living with HIV in the country ('number living with HIV')
- 2) Stage 2: The number/proportion of all people living with HIV who have been diagnosed ('number diagnosed')
- 3) Stage 3: The number/proportion of all diagnosed people living with HIV who are on ART ('number on ART')
- 4) Stage 4: The number/proportion of all people living with HIV taking ART who had suppressed virus (VL <200 copies/ml) at their last visit ('number with suppressed virus')

In addition, as an intermediary stage, we also analysed the number of people living with HIV who are enrolled in care. The four main stages, as well as the intermediary stage, were analysed for people living with HIV overall and in particular for men who have sex with men. The same methods were used for evaluating the stages of the general continuum of HIV care and of the one referring only to men who have sex with men, unless it is otherwise stated.

For determining each of the stages of the HIV continuum, the following definitions and methods were used, in line with those proposed by A. J. Gourlay et al. [13]:

Stage 1, 'number living with HIV': an estimation of all HIV-positive individuals living in the Republic of Macedonia at the end of 2017. To obtain the total number we used the HIV modelling tool developed by ECDC [14] based on the official surveillance data, disaggregated by stage of diagnosis (either CD4 cell count or non-AIDS/AIDS). We used the incidence method with parameters for the model set according to the ECDC HIV modelling tool manual v. 1.3.0 [15] and with time series adjusted to the time when CD4 cell counts at diagnosis were available in the country.

Stage 2, 'number/proportion diagnosed': the number of people living with HIV that were diagnosed (knew their HIV status) by the end of 2017, expressed as a number and as a proportion of the total estimated number of people living with HIV (stage 1). This number was determined based on the total number of cases diagnosed by the end of 2017 including those who in-migrated and excluding those who out-migrated or died by the end of the same year.

Stage 3, 'number/proportion on ART': the number of people living with HIV who were taking ART at the end of 2017, expressed as a number, as a proportion of those diagnosed (stage 2) and as a proportion of the estimated number of all people living with HIV (stage 1). The number on ART was defined as the number of people with at least one record of dispensed ART in 2017 including those who in-migrated and excluding those who out-migrated or died by the end of 2017. This number was determined based on the clinical records at the University Clinic for Infectious Diseases and Febrile Conditions in Skopie.

We also assessed the number of people that were enrolled in care at the end of 2017 as an intermediary stage before stage 3. As enrolled in care we defined those who were diagnosed, excluding out-migrations and those who died, were recorded in the patient registry of the Clinic for Infectious Diseases, and had shown for regular check-ups at least once in the last 12 months.

Stage 4, 'number/proportion with suppressed virus': the number of people living with HIV whose most recent HIV viral load (HIV RNA in blood) result in 2017 was <200 copies/ml or below the level of detection of the assay, expressed as a number, as a proportion of those on ART (stage 3), and as a proportion of the estimated number of all people living with HIV (stage 1). This number includes those who in-migrated and excludes those who outmigrated or died by the end of the same year and was determined based on the clinical records at the Clinic for Infectious Diseases.

To evaluate the continuum of HIV care specifically for men who have sex with men we obtained estimates on the total number of MSM living with HIV using the ECDC HIV modelling tool with surveillance data only for male HIV cases where sex between men had been reported. In addition, we compared those estimates to calculations based on the population size estimation for MSM and the estimated proportion of MSM living with HIV obtained through the latest bio-behavioural survey among MSM (unpublished data). The other 3 stages of the continuum were determined according to the same definitions and methods as for the general HIV continuum.

Data matching was performed between the patient registry at the Clinic for Infectious Diseases and the database at the Institute of Public Health in order to determine the actual number of deaths and the number of in-migrations and out-migrations. HIV cases known to have died from non-HIV related conditions were accounted as dead, including in a few instances where an official death certificate had not been sent to the Institute of Public Health.

HIV cases reported until the end of 2004 that were not retained in care beyond that time point and for which there was no information of death or out-migration were counted as deaths for the purpose of constructing stages 2, 3 and 4 of the HIV continuum. The reason for taking the end of 2004 as a cut-off point was the fact that until this time combination antiretroviral therapy was not regularly available in the Republic of Macedonia and there was no psychosocial support system established yet. Beyond this cut-off point, i.e. from the beginning of 2005 until the end of 2017, all diagnosed cases that had not shown up for a regular check-up at least once in the last 12 months were accounted as "lost to follow-up". Out-migrations were determined based on the patient records and information of the social worker at the Clinic's HIV Day Centre. As out-migrated we only counted those patients for whom there was a reliable information that they had moved out of Macedonia AND that they were receiving treatment and care through the health system in another country.

Data on the total number of diagnosed HIV cases and the number of people living with HIV enrolled in care and those receiving ART were manually extracted from patient records of the University Clinic for Infectious Diseases and Febrile Conditions in Skopje, where all diagnosed HIV cases are treated.

We assumed that we had complete data set for the diagnosed people with HIV and number on ART, since the surveillance and ART in Macedonia are centralized. All diagnosed HIV patients on ART are treated at the Clinic for Infectious Diseases and all diagnosed cases are reported to the Institute of Public Health.

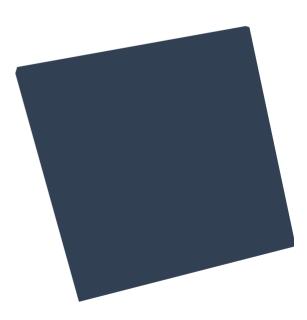
During this research we used anonymized data sets with unique identifiers to match the cases between the Institute of Public Health and Clinic for Infectious Diseases. In no case personal data was used nor was the patient identity revealed.

Biases and concerns in the methodology

Having a reliable estimate of a hidden population where data from different sources is scarce is very hard to obtain. Our estimates of the population size directly influence the estimated number of MSM living with HIV, which can be either under- or overestimated.

On the other hand, data from patient records from the Clinic for Infectious Diseases and the Institute of Public Health is reliable, but probably prone to possible inconsistencies in the entered data due to time period analysed and lack of software for patient management system.

In constructing the continuum of HIV care specifically for men who have sex with men we relied on the officially reported surveillance data on the mode of transmission. However, it can be assumed that a certain number of men diagnosed with HIV never disclosed having same-sex sexual relations, especially in the early years when no adequate system for psychosocial support existed in the country.



RESULTS

National Continuum of HIV Care

Stage 1. The estimated total number of people living with HIV

The estimated number of people living with HIV is the most important denominator [13] for all subsequent estimates of the continuum of HIV care, yet it is the hardest to obtain. The HIV modelling tool developed by ECDC [16] relies on surveillance data, disaggregated by stage of diagnosis (either HIV/AIDS or CD4 cell count). Our team ran the model with data officially reported to ECDC by 2017 which gave an estimated total number of 443 PLHIV (95%CI 375-486). If we account for those who have out-migrated (n=41), then the estimated total number of people living with HIV by the end of 2017 would be 402 (334-445).

Stage 2. Number diagnosed

In Macedonia there are two sources of information available for the number of diagnosed (reported) HIV cases. The first source is the national database of reported HIV cases at the Institute of Public Health and the second one – the patient registry at the University Clinic for Infectious Diseases and Febrile Conditions where all people living with HIV receive treatment and care. We compared data from two data sets using unique identifiers and completed missing information in the national database at the Institute of Public Health, with available data from the patient registry from the Clinic.

According to the National HIV Annual Reports prepared by the Institute of Public and the database of reported cases, from 1987 by the end of 2017 the cumulative number of diagnosed HIV cases was 358. By comparing the data of the Institute of Public Health and the Clinic we identified that of this total number, 41 had out-migrated or were foreign citizens, while the number of deaths was 96 (as opposed to the 86 registered deaths according only to the official surveillance database of the Institute).

Taking the above figures into account, by the end of 2017 there were 221 diagnosed people living with HIV in Macedonia or 54.9% of estimated 402 people living with HIV.

Taking in consideration the 95%CI of the estimated total number of people living with HIV, the number of undiagnosed people living with HIV ranges from 113 to 224.

Table 2. Number and percentage of PLHIV with diagnosed and undiagnosed HIV inection

Estimated total number of PLHIV (range)	Number of PLHIV diagnosed	% of PLHIV diagnosed (range)	% of PLHIV undiagnosed (range)
402 (334–445)	221	54.9%	45.1%

Stage 3. Number on ART

In total, 24 of the diagnosed have been lost to follow-up, while 197 have shown up for regular check-up within the last 12 months and were considered as enrolled in care. According to the clinical records, by the end of 2017 a total of 243 patients had been put on ART, however, if we exclude those who died, those who out-migrated or were lost to follow-up, the number of diagnosed people living with HIV on ART by the end of 2017 was 195, or 88.2% of diagnosed (195/221) (Figure 2). Expressed as a proportion of the estimated total number of people living with HIV the number on ART constitutes 48.5% (43.8–58.2%).

Table 3. Number and percentage of PLHIV diagnosed who are on ART

Number of PLHIV diagnosed	Number of PLHIV diagnosed on ART	% of PLHIV diagnosed on ART	% of PLHIV diagnosed NOT on ART
221	195	88.2%	11.8%

Stage 4. Number with supressed virus

Of those on ART (n=195), according to the data from the Clinic for Infectious Diseases, the last available viral load in 2017 was below 200 copies/ml in 183 patients or 93.8% (Graph 2). Out of those whose virus was not considered suppressed (n=11), 9 had been on ART for less than six months and for 2 data for viral load was missing. The 183 patients on ART represent 45.5% (41.1-54.8%) of the estimated total number of people living with HIV.

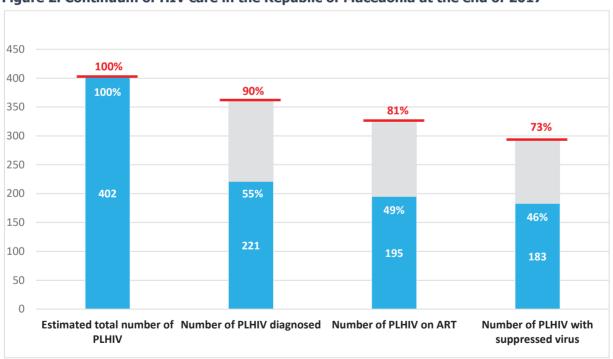
Table 4. Number and percentage of PLHIV on ART with suppressed virus

Number of PLHIV on ART	Number of PLHIV with suppressed virus	% of PLHIV on ART with suppressed virus	% of PLHIV on ART without suppressed virus
195	183	93.8%	6.2%

Table 5. National continuum of HIV care: absolute numbers, percentages out of immediately preceding stage and percentages out of estimated total number of PLHIV (target 90%-81%-73%)

	Estimated total number of PLHIV (range)	PLHIV diagnosed	PLHIV on ART	PLHIV with suppressed virus
Number	402 (334–445)	221	195	183
Proportion of previous stage	100%	55%	88.2%	93.8%
Proportion of estimated total no. of PLHIV	100%	55%	48.5%	45.5%

Figure 2. Continuum of HIV care in the Republic of Macedonia at the end of 2017



Continuum of HIV care with focus on men who have sex with men

Stage 1. The estimated total number of MSM living with HIV

For the estimated number of MSM living with HIV we used the HIV modelling tool developed by ECDC [16] using the data only for those HIV cases where sex between men had been reported as the mode of transmission. The

tool relies, therefore, on surveillance data, disaggregated by the stage of diagnosis and the mode of transmission. We ran the incidence model in the modelling tool, with time series adjusted for the time of introduction of ART and availability of data for CD4 counts at diagnosis. The estimated number of MSM living with HIV by the end of 2017 based on this approach was 245 (95% CI 237-282).

However, according to the unpublished data from the latest population size estimation and the bio-behavioural survey among MSM from 2017 (n=11,054; 95% CI 9,301-14,229) the HIV prevalence among MSM in the country was estimated at 5.4% in 2017. Based on these data on prevalence and on population size, the number of MSM living with HIV would have been 597 at the end 2017 according to the estimation.

Stage 2. Number of MSM diagnosed

Based on the matched data from the patient registry at the Clinic for Infectious Diseases and the database at the Institute of Public Health, by the end of 2017 the cumulative number of diagnosed HIV cases resulting from sex between men as the mode of transmission was 181. In the same period there were records for 17 MSM who died, while additional 18 migrated outside of the country. According to this, the total number of MSM living with HIV who knew their status in Macedonia by the end of 2017 would have been 146 or 59.6% of the estimated number of MSM living with HIV (146/245) if we take as valid the estimation based on the ECDC modelling tool.

Table 6. Number and percentage of MSM living with HIV with diagnosed and undiagnosed HIV infection

Estimated total number of MSM living with HIV (range)	Number of diagnosed	% of MSM living with HIV who are diagnosed	
245 (237-282)	146	59.6%	40.4%

Stage 3. Number of MSM on ART

As enrolled in care we counted those who were diagnosed (excluding out-migrations and those who died), were recorded in the patient registry at the Clinic for Infectious Diseases, and had shown for regular check-up in the past 12 months. Summing up the above, the number of MSM living with HIV that were enrolled in care at the end of 2017 was 134.

According to the patient registry, the total number of diagnosed MSM patients (excluding deaths, out-migrations and lost to follow-up) on ART by the end of 2017 was 133 or 91.1% of those who know their HIV status (133/146) (Figure 3). As a proportion out of the estimated total number of MSM living with HIV according to the ECDC modelling tool, the number on ART constitutes 54.3% (Table 9).

Table 7. Number and percentage of diagnosed MSM living with HIV who are on ART

Number of diagnosed MSM living with HIV		% of diagnosed MSM living with HIV who are on ART	
146	133	91.1%	8.9%

Stage 4. Number of MSM with supressed virus

Of the MSM who are on ART (n=133), according to the data from the Clinic for Infectious Diseases in 122 patients the viral load was under 200 copies/ml during their last measurement in 2017 or 91.7% of those on ART (Table 9). Of those in whom the virus was not suppressed, 9 cases had been on ART for less than 6 months and for 2 patients data on viral load was missing. The number of MSM with suppressed virus constitutes 49.8% of the estimated total number of MSM living with HIV.

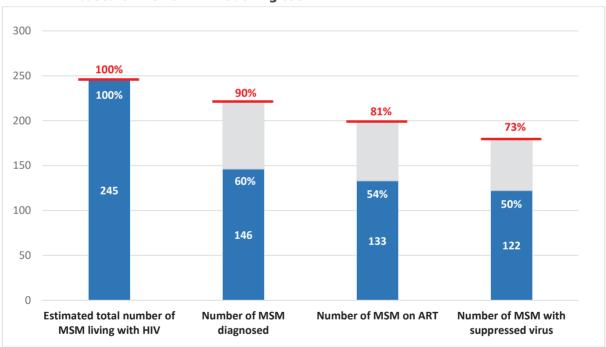
Table 8. Number and percentage of MSM living with HIV on ART with suppressed virus

Number of MSM living with HIV on ART	Number of MSM living with HIV with suppressed virus	% of MSM living with HIV on ART with suppressed virus	% of MSM living with HIV on ART without suppressed virus
133	122	91.7%	8.3%

Table 9. The continuum of HIV care for MSM: absolute numbers, percentages out of immediately preceding stage and percentages out of estimated total number of MSM living with HIV (target 90%-81%-73%)

	Estimated total number of MSM living with HIV (range)	MSM diagnosed	MSM on ART	MSM with suppressed virus
Number	245 (237-282)	146	133	122
Proportion of previous stage	100%	59.6%	91.1%	91.7%
Proportion of estimated total no. of MSM living with HIV	100%	59.6%	54.3%	49.8%

Figure 3. Continuum of HIV care for MSM living with HIV by the end of 2017 with an estimation based on ECDC HIV modelling tool



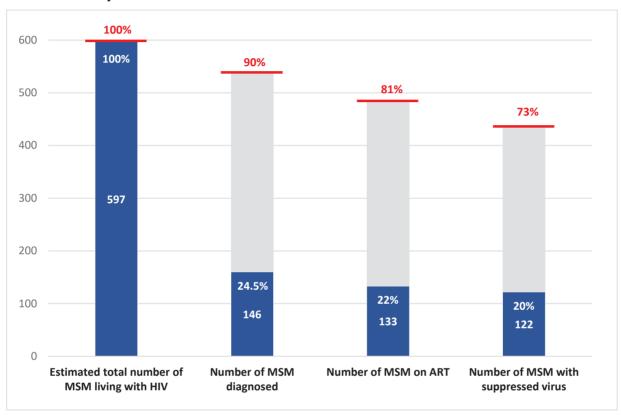
The HIV continuum for MSM based on the data from the bio-behavioural survey

If we consider the data from the biobehavioural survey and population size estimation the total number of MSM living with HIV would be 597, assuming population size of 11,054 and HIV prevalence of 5.4% in 2017 (unpublished data, Institute of Public Health). In this case the cascade would reveal a significantly worse situation, with only 24.5% of MSM living with HIV that would have been diagnosed (Figure 4).

Table 10. The continuum of HIV care for MSM according to prevalence and population size estimations (target 90%-81%-73%)

Estimated total number of MSM living with HIV		Number of MSM on ART	Number of MSM with suppressed virus
597	146	133	122
100%	24.5%	22.3%	20.4%

Figure 4. National HIV cascade, MSM living with HIV by the end of 2017 according bio-behavioural survey results





DISCUSSION

This is the first study done in the Republic of Macedonia to analyse and evaluate the national continuum of HIV care, giving a special focus on men who have sex with men as the predominantly affected population in the country. It provides valuable insights on the successfulness of the national response to the epidemic and identifies its major gaps.

The estimation of the total number of people living with HIV (the first stage of the continuum of HIV care) obtained through the ECDC modelling tool (402; 95%CI 334-445) is comparable to the one obtained by UNAIDS using the Spectrum tool and based on the same surveillance data, which is 384 (95%CI 338-449) – however, not accounting for out-migrations. This supports the likelihood that the total number of people living with HIV at the end of 2017 may have been within the range between 334 and 445, as this study showed.

However, a significant discrepancy arises between the two approaches to estimate the total number of MSM living with HIV, i.e. 245 based on the ECDC monitoring tool and 597 using the prevalence and population size data from the last bio-behavioral survey in 2017. These results with regards to MSM also raise a question regarding the estimated total number of people living with HIV and, accordingly, regarding the number and proportion of people living with HIV not aware of their HIV infection. Therefore, these findings, require further exploration both in terms of possible overestimations of prevalence and underestimations of population size as a result of the respondent-driven sampling survey among MSM in Skopje in 2017, or possible underestimations obtained using the ECDC HIV modelling tool. Regarding the projection obtained through the ECDC tool for the total number of MSM living with HIV, it is reasonable to assume that it may be an underestimation, considering that newly diagnosed MSM with HIV do not always disclose having had sex with other men and this was especially true for the earlier years of the Macedonian epidemic, when there was no system for comprehensive treatment, care and support services. Therefore, the input number that was used for performing the estimation is likely lower than the actual number of MSM among the newly diagnosed cases annually and over the years. On the other hand, the total number of MSM as estimated based on prevalence and population size does not take into account any out-migrations.

The results of this study clearly show that the major gap in the continuum of HIV care in Macedonia is in the progress towards reaching the first "90": only 55% of the estimated total number of people living with HIV were aware of their status at the end of 2017. This result is considerably lower compared to the EU/EEA countries where 83% (57-98%) of PLHIV were diagnosed in 2016 [17], and slightly under the non-EU/EEA countries' average of 58%. Assessed only for MSM, the proportion of those aware of their infection among the total estimated number of MSM living with HIV is 59%. Making a significant progress towards reaching a proportion of 90% by 2020 is a serious challenge for the national response to HIV, but at the same time it clearly shows the direction in which national efforts must be focused and strengthened.

The possible explanation for the low proportion of people living with HIV who know their status could be the fear of stigmatization after a positive HIV test and a low up-take of HIV testing. HIV tests in Macedonia are currently performed in medical facilities, civil society organizations with special permit from the Ministry of Health and with a mobile unit. According to programmatic data from 2017, only 1052 or 9.5% of the estimated population of MSM have been tested in 2017, which may support the assumption that HIV testing is not sufficiently accessible for MSM. On this line, the last integrated bio-behavioural survey among MSM showed that 63% of MSM know where they can make confidential HIV testing, but only 29% of MSM have done HIV test in the last 12 months (compared to 20% in the 2014 survey), 97% of whom also knew their results; 24% of MSM did not know where to do an HIV test. The survey also showed a relatively low perception of HIV risk: a significant proportion of MSM (47%) believe they are exposed to a small (44%) or no risk (3%), and only 23% of MSM consider themselves exposed to a high or very high risk of HIV infection.

Another possible explanation can be that the proportion of diagnoses in the recent years among the total diagnosed is higher than in the EU/EEA, pointing to a sharper growth of the epidemic (EU/EEA has older epidemic so PLHIV had longer time to get diagnosed).

Taking into account the low-level epidemic overall and the absolute number of people with undiagnosed HIV infection, which ranges from 113 to 224, as well as the fact that most of undiagnosed people with HIV probably belong to the MSM population, it is possible to assume that the problem can be tackled with an intensified and targeted strategy to increase testing among men who have sex with men.

Another major overall observation of the study is that once people living with HIV know their status, the continuum of care performs significantly better. Regarding the second "90" of the UNAIDS 2020 targets – 90% of PLHIV who know their status are receiving ART – it is important to note the high percentage of 88%, or 91% for MSM. This may be explained with the fact that there is a comprehensive system for care and support involving both the Clinic for Infectious Diseases as the only reference institution for HIV treatment and care, as well as the community based support and the linkage between the Clinic and the services provided by civil society organizations. The proportion of diagnosed who are on ART is higher than the 2016 reported [17] average of 85% in the EU/EEA countries and significantly higher than the average of 53% from the non-EU/EEA countries.

The percentage of people not on ART out of those who know their status (12%) predominantly reflects the number of people considered as lost to follow-up, i.e. 24 out of 26 people not being treated. In other words, out of 197 patients enrolled in care, 195 were on ART at the end of 2017 with only two people refusing treatment, according to the information from the Clinic. This reveals a situation where people are offered treatment upon diagnosis and have access to psychosocial and peer support services, however a relatively significant proportion (nearly 11%) of people living with HIV who know their status have been lost to follow-up. This is important to consider as the number of those lost to follow-up accounts for the period after 2004 and was determined after the data cleaning process in which known out-migrations and known deaths were excluded. Having in mind the relatively good system of psychosocial support in place, the number/proportion of those lost to follow-up may be attributed to the impact of stigma and the fear of being potentially exposed as a person with HIV during the visits to the Clinic. In addition to this, a possible explanation may include unreported out-migration. If the latter is the case, it can be assumed that some of these patients might have sought care abroad.

In regards to the third "90'' - 90% of PLHIV on ART have achieved viral suppression – the target was surpassed with a result of 94% and – among MSM only – 92% at the end of 2017. Such a high result may be explained with high adherence to treatment among patients, the good psychosocial and peer support services, including a relatively individualized approach to the choice of treatment regimens.

The high results for stages 3 and 4, however, must be considered within the limitations set by the insufficient progress towards reaching the first target -90% of all people living with HIV know their status. According to the continuum of HIV care framework, when all three 90-90-90 targets are achieved, at least 73% of all people living with HIV will have viral suppression. With only 55% of PLHIV in Macedonia being aware of their status at the end of 2017, the percentage of those who have achieved viral suppression is actually 46%, as opposed to the 2020 target of 73%. This ratio is slightly better among MSM alone, with 50% of all who are living with HIV having achieved viral suppression. This result is lower than the percentage of those with viral suppression out of the total number of PLHIV in Europe and Central Asia (60%) and the EU/EEA (65%) and significantly higher than the average in Eastern Europe and Central Asia.

It is important to note that if a sharp progress in diagnosing people with HIV is made a priority in the next few years, it would also need to be accompanied by increased provision of treatment and an adequate capacity of the care and support services in order to respond to an increased number of people who will be enrolled in care and to sustain the high results for stage 3 and stage 4 of the continuum.

RECOMMENDATIONS

Considering the results of the analysis of the continuum of HIV care in the Republic of Macedonia, it is obvious that there is an urgent need for scaling up the HIV testing programmes, in particular focusing on men who have sex with men where the burden of HIV is the highest. It can be assumed that a substantial progress towards reaching the target of 90% of people with HIV to know their status is possible with an intensified and targeted strategy to increase testing among men who have sex with men.

In addition to increased funding to scale up the coverage of the existing programs, a progress towards reaching the first '90' is also likely to require the introduction of new and innovative approaches. There is an urgent need for diversifying the availability of HIV testing, by further supporting testing within the community, including through funding for innovative approaches based on internet and mobile applications, introducing lay provider testing, as well as self-testing.

At the same time there is a need for targeted awareness raising and promotion of HIV testing among MSM, since according to the findings from most recent surveys, MSM in Skopje do not consider themselves exposed to a significant risk of HIV.

Planning of activities and budget within the national HIV program must be based on evidence, ensuring the continuation, and scale-up where needed, of existing programs for sex workers and people who inject drugs, while substantially scaling up programs targeting men who have sex with men. Furthermore, the intersections between key populations should be explored and taken into consideration and comprehensive packages of services should be offered.

Community-based and other civil society organization should be proactive in adopting good practises from around the world and should propose innovative strategies to reach out to men who have sex with men considering their diverse needs and the specific subgroups of MSM.

Taking into consideration the discrepancy between estimations on population size, prevalence and number of people living with HIV obtained through different methodologies, it is crucial that new integrated biobehavioural surveys among MSM be planned in the near future. Seeking additional technical support regarding estimations may need to be considered.

Should new strategies to diagnose more people living with HIV prove to be successful in the next 2 to 3 years, the Ministry of Health must be ready to provide treatment and care for an increased number of patients, in order to maintain the high results in stages 3 and 4 of the continuum of care. Strategies to reduce costs for ARVs should be considered in parallel.

In order to improve the surveillance and the flow of information between the Clinic for Infectious Diseases and the Institute of Public Health introducing a unified electronic database should be considered.

Recommended actions of priority

- Increase testing among men who have sex with men with a targeted strategy.
- Diversify HIV testing by strengthening community-based service delivery, introducing lay providers and self-testing and considering other options.
- Targeted awareness raising and promotion of HIV testing among MSM.
- Up-date and scale up prevention programs for men who have sex with men and offer comprehensive package of services considering the intersections of the key affected populations.
- Support innovative strategies to reach out to men who have sex with men considering their diverse needs and the specific subgroups of the population.
- Conduct new integrated bio-behavioural survey and population size estimation within a period of two years in order to reassess trends in the epidemic and in behavior
- Plan for increased need of treatment and care as a result of a strengthened strategy to diagnose more people living with HIV.
- Improve surveillance and flow of information between the Clinic for Infectious Diseases and the Institute of Public Health by introducing a unified electronic database.

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Editor:

Andrej Senih

Authors:

Dr Vladimir Mikikj, Dr Milena Stevanović, Andrej Senih, Rumena Gjerdovska Kojcheski, Zoran Jordanov

Graphic design: Emilija Tashkova









