HIV Programme Review in Belarus

November 2014





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Evaluation report November 2014

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Abbreviations

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
ARV	antiretroviral
CD4	T-lymphocyte cell bearing CD4 receptor
CN	Concept Note on HIV
EECA	Eastern Europe and Central Asia
FSW	female sex workers
HIV	human immunodeficiency virus
HTC	HIV testing and counselling
KAP	key affected populations
LTFU	lost to follow up
MARP	most at risk population
MoH	Ministry of Health
MoF	Ministry of Finance
MSM	men who have sex with men
MTCT	mother-to-child transmission
NGO	Nongovernmental Organization
NSP	National Strategic Plan
OST	opioid substitution therapy
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
SW	sex worker
TGF	The Global Fund
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
STI	sexually transmitted infections
WHO	World Health Organization

Executive Summary

As of 1 January 2014, 15 711 cases of HIV-infection were registered in Belarus. The estimated overall HIV prevalence is 0.4%. According to the draft National Strategic Plan (NSP), the prevalence among people who inject drugs (PWIDs) is 14.3% (from 13.3% in the 2012 sentinel survey), among female sex workers (FSWs), 5.8% (from 2.4% in 2012); and among men having sex with men (MSM), 4.5% (2.8% in 2012); showing a disturbing increase among MARPs. HIV confirmed cases are registered in all regions (oblasts) of the country, but around 48% are registered in the Gomel region.

The evaluation builds on a desk review and a country mission which took place from the 18-21 November 2014. The preparation phase included a desk review and analysis of available documents (WHO guidelines, national policy/strategy/plans, clinical guidelines, publications, reports, etc.), as well as a review of the draft National Strategic Plan on HIV (NSP) and Concept Note (CN) to the Global Fund.

The progress made during the implementation of the NSP 2011-2015 is acknowledged, in particular the increase in the number of people on ARV treatment and subsequent decrease in mortality, as well as the readiness of the government to take over funding of the HIV programme in the future. Overall the evaluation team agrees on the key priority modules as defined in the Concept Note (CN), which takes into account many of the recommendations presented in the evaluation from 2013.

The following key priorities were identified:

Priority area 1. Strengthen the epidemiological analysis of the epidemic

Priority area 2. Increase coverage of testing in MARPs and enrolment into care

Priority area 3. Increase ARV coverage and retention in care

Priority area 4. Scale up harm reduction and OST

Priority area 5. Optimize service delivery models and use of multidisciplinary teams

Priority area 6. Review legislation related to testing, harm reduction, OST and drug use for an enabling environment

Key recommendations are formulated to each priority area and summarised in chapter 6 along with specific recommendations for indicators and targets to be reformulated or added to the draft NSP and CN for greater impact.

The main recommendations from the review are the following:

Strengthen the epidemiological analysis of the epidemic:

- Collect CD4 at diagnosis. Late presentation is a good indicator of how the epidemic evolves.
- Collect and present data on regional differences. This should drive the planning of activities and coverage indicators.

Increase coverage of testing in MARPs and enrolment into care:

- Scale up community based rapid testing and ensure linkage into care.
- Provide systematic follow-up on those tested positive for HIV and are not enrolled in care.
- Ensure that people are not lost between the first and second HIV test by:
 - changing the instructions for testing:
 - include rapid testing
 - perform ELISA and confirmatory test (blot) on the first sample
 - simplify the counselling algorithm to ensure that patients are not lost

Increase ARV coverage and retention in care:

- Implement mechanisms to ensure follow-up with patients that are lost, through collaboration with NGOs and other stakeholders.
- Start ART without delay in patients with clinical symptoms.
- Simplify drug regimens as a cost-effective public health approach. This includes that all newly enrolled patients should be started on TDF/FTC/EFV as preferable regimen as recommended by the 2013 WHO guidelines.

Scale up harm reduction and OST:

Harm reduction.

- Adopt a legal act by the MOH that defines the package of minimal harm reduction services.
- Involve governmental health institutions in the provision of harm reduction services through allocating funding from the state budget and TGF.
- Develop legal acts that can allow NGOs to provide extensive HIV testing with rapid tests of PWID and other key populations.
- Adopt legal mechanisms which will allow the Government to fund harm reduction services provided by NGOs from the state budget.
- Adopt legal acts defining integrated care through psychosocial support/case-management in government health care facilities and NGOs.

OST

- Work with the Ministry of Internal Affairs in order to remove the excessive requirements for security of OST sites, medication storage and transportation in order to reduce overall OST costs.
- Establish integrated care delivery for PWID with HIV and TB by increasing links between drug addiction, HIV and TB inpatient and outpatient services.
- Open new OST sites in TB and infectious disease centers.
- Remove the existing barriers for PWID to enter OST as the continuation of OST in the hospitals by reviewing and changing accordingly the Clinical protocol of OST (2010) and other relevant legal acts.

Optimize service delivery models and use of multidisciplinary teams:

- Strengthen collaboration between TB/HIV/OST services and build on best practice evidence from Gomel in other affected regions.
- Consider defining specific indicators for the most affected regions and prioritizing interventions in those regions.

Review legislation related to testing, harm reduction, OST and drug use for an enabling environment:

- Consider the review and repeal of the legislation on mandatory testing and treatment (the National Law N° 345-3 'Prevention Socially Dangerous Diseases, HIV'). The law has been in practice since July 2012.
- Remove the existing barriers for PWID to enter OST in health care settings, by reviewing and changing accordingly the Clinical Protocol of OST (2010) and other relevant legal acts.

In addition, the NSP and CN need a detailed cost and budgetary framework specifying funding priorities among the NSP components and interventions, as well as an operational plan clarifying the roles and responsibilities of all implementing partners.

1. Introduction

As of 1 January 2014, 15 711 cases of HIV infection were registered in Belarus. The age group of 30-39 years is most affected by HIV infection, with an estimated HIV prevalence of 0.4%. According to official statistics, close to 60% of registered PLHIV are men (9341 persons), and around 40% are women (6370 persons). Figures on cases diagnosed in the past years however show an increase in the percentage of women infected (1,2). Overall, the rate of newly diagnosed HIV infections in 2012 was 13.1 per 100 000 population and continues to increase each year.

According to the draft National Strategic Plan, the prevalence among people who inject drugs (PWIDs) is 14.3% (from 13.3% in 2012 sentinel survey), among female sex workers (FSWs), 5.8% (from 2.4% in 2012), and among men having sex with men (MSM), 4.5% (2.8% in 2012). The HIV prevalence among these populations has increased over the last two years (1).

Gathered cumulative data by 1 January 2014 show that 41.8% of all HIV-infected persons were infected by route of injection (parenteral), whereas 55.8% were infected by sexual transmission (2). These numbers could imply, that sexual transmission has become the main route of transmission, however injecting drug use continue to play a significant role in HIV transmission.

HIV confirmed cases are registered in all regions (oblasts) of the country, but around 48% are registered in the Gomel region, according to data from the Department for Prevention of HIV/AIDS (2).

The NSP and CN refer to the current National HIV/AIDS Programme 2011-2015. The current programme is associated with expanded ARV coverage to 5 181 people (1.6 fold increase in 2013 compared to 2011), a decrease in mortality and sizeable progress in PMTCT (1,3).

2. Methods

The evaluation builds upon a desk review and a country mission which took place from the 18-21 November 2014. The preparation phase included a desk review and an analysis of available documents (WHO guidelines, national policy/strategy/plans, clinical guidelines, publications, reports, etc.), as well as a review of the draft National Strategic Plan on HIV.

During the country mission, WHO experts visited relevant institutions and facilities and liaised with key informants: policy makers, health care providers and beneficiaries, NGOs, other national partners where appropriate. The experts participated in a national meeting to discuss the draft NSP and provide recommendations, as well as a CCM meeting together with Global Fund representatives.

As a country review was performed in 2013, the assessment followed up on the implementation of the WHO mission recommendations developed during the country mission in November 2013, in order to identify barriers and constraints hindering implementation, and to determine the need for WHO technical assistance.

The terms of reference for the mission and a full list of the informants met during the mission can be found in Annex 2.

3. Major strengths and achievements

3.1. Treatment protocol and procedures

The treatment protocol is in line with international standards and recommendations (4,5). Most patients in the first line therapy are treated with drugs recommended by WHO although the total number of treatment regimens used in the HIV care is high (22 regimens), and certain drugs are still being used which are not recommended by WHO. The diagnostic facilities are reported to be well developed including widely available access to HIV RNA viral load and CD4+ T cell count monitoring as well as access to drug resistance methodology, although the extent of the use of the latter has not been communicated. Key medical professionals in Minsk are knowledgeable of antiretroviral therapy (ART). An impressive effort by medical professionals in their work with HIV infected patients, with or without coinfection with tuberculosis, is acknowledged.

According to the official information, access to ART has expanded; a total of 5181 people (including 173 children) have been enrolled in the programme as reported in January 2014, as compared to 4248 in 2012 and 3223 people (including 143 children) in 2011.

It is reported that the implementation of the State HIV Prevention Programme for 2011-2015 in 2011-2013 achieved the expected targets, which included that 96.8% of the registered people out of the total number of people in need of ART were covered (1). However, the number reported to be treated in 2014 is lower than stated in the agreement between Belarus and TGF.

Pregnant women and children have been provided with access to antiretroviral drugs to reduce the risk of vertical HIV transmission. Coverage of pregnant women has increased from 91.3% in 2011 to 95.9% in 2013 and coverage of newborns has increased from 91.5% to 95.9%. Despite this, newborns are still infected (1).

3.2. Opioid Substitution Therapy (OST)

Since 2007, the Ministry of Health (MOH) has opened 19 OST sites in all oblasts, with the funding from TGF, covering a total of around 1000 patients. Current coverage is around 5% of the 18 450 estimated opioid injecting population (the estimated total number of PWID is 75 000).

In 2010, the MoH passed the executive legal act endorsing the Clinical Protocol of OST (6) and another legal act approving OST as part of the Clinical Standards of Treatment of Mental and Behavior Disorders (7).

OST is provided by governmental health care institutions at the city and oblast level: drug treatment dispensaries and one TB dispensary in the city of Gomel. By the end of 2014, OST services were partly covered by governmental funds, for example the salary for OST staff. Medication was purchased and distributed by the GFT.

According to the 2013 evaluation report Evaluation of the Socio-Economic Effectiveness of OST Programs (8), OST is comparatively inexpensive with the total price 1.3 USD per patient per day. The figure includes services (0.3 USD), medication (0.6 USD) and security (0.4 USD) (8). The same report indicates that introduction of OST in the Gomel oblast, contributed to the reduced number of PWID not in treatment, reduction of crime and mortality, reduced cases of HIV and HCV, as well as improved access to ARV. The cost-benefit analysis presented in the report shows that 1 USD invested into OST reduces public costs of 10-11 USD. The report indicates that if OST covers 3000 PWID, the 'black' market of illegal heroin and other opioids will decline by one third (8).

There are signs of growing support from the national and local law enforcement institutions towards OST as an intervention, which will potentially disrupt the illegal market of heroin and reduce petty crimes.

Positions for social workers are available now within drug treatment facilities. Two drug treatment facilities (Minsk and Gomel oblasts) provide psychosocial services and case management in cooperation with the NGO "Positive Movement".

3.3. Harm Reduction

Services have so far been provided exclusively by the NGO Positive Movement. This NGO has extensive experience in the provision of a variety of services: needle syringe programs, HIV testing and counseling (HTC), running mobile units, referring to infectious disease and social services, counselling on adherence to ART, and coordinating multi-disciplinary teams (nurses, infectious disease specialists, drug treatment specialists, social workers). Harm reduction services were provided in 26 drop-in and 6 mobile centers across the country (personal communication with Positive movement).

Positive Movement reached around 21 000 PWID during the first six months of 2014 through different harm reduction services. HIV testing and counselling (HTC) was performed to more than 7000 PWID in 9 months of 2014, including rapid testing. The prevalence of HIV among this group was found to be around 8.5% (the BSS data nationally is 13.5%). Positive Movement through professional and peer support were positioned well to work with those confirmed to have a positive HIV test result and refer PWID to further services.

Harm reduction programs include screening of pulmonary TB among PWID with a 4 item questionnaire. If needed, clients are referred to fluorography in a policlinic (personal communication with Positive Movement).

Positive Movement has developed a structured 6 month programme, which includes the assessment of PWID's needs, referrals and coordination of services, as well as a module to improve a client's adherence to ART. The NGO has qualified and experienced staff assigned to monitorthe activities of the organization.

The progress made during the implementation of the NSP 2011-2015 is acknowledged, in particular the increase in the number of people on ARV treatment and subsequent decrease in mortality, as well as the readiness of the government to take over funding of the HIV programme in the future. Overall the evaluation team agrees on the key priority modules as defined in the Concept Note, which take into account many of the recommendations presented in the evaluation from 2013.

4. Key Priority Areas

4.1 Priority area 1:Strengthen the epidemiological analysis of the epidemic

The WHO 2013 evaluation report identified that surveillance of the HIV epidemic in the country lacks important indicators and has not been adequately analyzed to inform policy decisions on priorities within the national HIV programme. The recommendation was to identify key indicators and ensure centralized mechanisms for analysis (9).

Several challenges and weaknesses can be identified which are clearly illustrated by the estimated continuum of care (Fig. 1). It has not been possible to obtain official figures for several parameters and therefore the assessment of the treatment continuum is based on estimates and personal communications with the Infectious Disease Hospital in Minsk. The issue with suboptimal centralized collection and analysis of key data was pointed out at the WHO mission in 2013. The lack of official figures is a major weakness, which results in difficulties in the basic 'know your epidemic' concept.



Fig. 1. Estimated treatment cascade in Belarus 2014 (10)

* The number of people in care has not been confirmed

The epidemiological analysis presented in the NSP and CN shows data on prevalence in different age groups, and risk groups, as well as some data on incidence rates and mortality. Attempts are made to follow the epidemic through the different steps of the continuum of care, as presented in Fig. 1. This is highly supported and should be a key priority in the future. The different steps in the continuum from the undiagnosed estimated number of people living with HIV to the number of patients on ARV with suppressed viral load should be carefully monitored.

Recommendations:

- Implement alternative methods to estimate the size of the undiagnosed population than only Spectrum, like 'the London method 1' (11), which is more adapted to concentrated epidemics. These methods however require good data on risk group estimates and CD4 count at diagnosis.
- Collect CD4 count at diagnosis. Late presentation is a good indicator of how the epidemic evolves.
- Collect and present data on regional differences. This should drive the planning of activities and coverage indicators.
- Present data on coinfections (hepatitis C and tuberculosis), and trends over time.
- Properly analyse MTCT, for instance, how many pregnant women are tested positive at the second test performed during pregnancy? Why is the prevalence of children born with HIV still high?
- Include the number of rapid tests performed in the overview of yearly total number of tests by risk groups.

Recommendations – indicators and targets:

• Develop a coverage indicator on enrolment and retention throughout the continuum of care (in the current CN draft the indicator only includes the number of people on ARV) (see below on defining targets).

4.2 Priority area 2: Increase coverage of testing in MARPs and enrolment into care

Approximately 1 million HIV tests are performed each year in Belarus. However the majority of these are performed in pregnant women, blood donors and military people, and as a consequence are not targeting key populations with high HIV prevalence (9). For instance, it has been calculated that only 6% of the estimated 75 000 PWIDs have been tested. According to WHO recommendations, all key populations are to have access to VCT (12). A concerning key issue is that people are tested positive but are lost to follow-up before confirming HIV infection, between the first screening test and confirmatory test, with examples of up to 75% lost after the first positive screening test. The target for testing coverage for FSW of 15% and MSM 14% (3), without any planned scale up, is considered a very low target. Likewise, the target for sex partners of PWIDs of 23%, is low. Contact tracing is an important tool and an efficient way to influence the epidemic.

Recommendations:

- Scale up community based rapid testing and ensure linkage into care.
- Provide systematic follow-up on those tested positive for HIV and not enrolled in care.
- Revisit pre- and post-test counselling procedures with the aim of ensuring that people are not lost.
- Ensure that people are not lost between the first and second HIV test by:
 - changing the instructions for testing:
 - include rapid testing
 - perform ELISA and confirmatory test (blot) on the first sample
 - simplify the counselling algorithm to ensure that patients are not lost
- Collect data and follow trends in:
 - o no test per risk group
 - o no reactive tests
 - o no blood samples submitted for confirmatory test
 - o no true positive
 - o no linkage to care

Recommendations – indicators and targets:

- To reach the target of 44% testing coverage for PWIDs, the involvement of civil society is key. The indicator should include the need to ensure that positive tests are confirmed.
- Scale-up testing coverage for PWIDs to 40%-60% during the NSP period.
- Increase the target for testing coverage for FSW and MSM (now 15% and 14%) to the same level as PWIDs (40-60%) and plan for a scale up over time.
- Increase the target for testing of sex partners of PWIDs from 23% to 40-60%. Contact tracing is a very important tool and an efficient way of influencing the epidemic.

4.3 Priority area 3: Increase ARV coverage and retention in care

The number of patients receiving ART in 2014 was reported to be 5 181 cases. This should be compared with the number of PLHIV, 6 300, who should receive ART according to the agreement between Belarus and TGF. Data on the Spectrum ART estimated need is not available for 2014 but it is estimated that about 50% less than the estimated ART need are treated. No progress has been made compared with 2013. Also it is obvious that there is a high rate of patients lost to follow up in care, both untreated and treated. For instance, it was reported by the Infectious Disease Hospital, Minsk, that 120-130 new patients were started on ART each month and that 50 patients were lost to follow up each month (*10*) (corresponding to a lost to follow up rate of 10%), but no confirmed official data on this parameter were given. Therefore, it is likely that the number of patients with ongoing ART is lower than that presented in the figure of the treatment continuum.

Although it is acknowledged that the HIV infected population in Belarus is difficult to treat and retain in care, it is possible to increase the treatment success rate with adequate support, according to scientific studies and experience from other countries. Thus, the proportion of reported patients to have undetectable viral load while being on ART is only 61%.

A high rate of HIV infection is found among patients with tuberculosis. The process that an epidemiologist communicates the HIV test result and the infectious disease doctor initiates the patient on ART, contributes however to a substantial delay in initiating ART and also to the rate of those lost to follow up. It was also identified that of patients coinfected with TB and HIV, approximately 30% are not started on ARVs (10).

Pregnant women and children have been provided with access to ARVs to reduce the risk of vertical HIV transmission. Coverage of pregnant women has increased from 91.3% in 2011 to 95.9% in 2013, and coverage of newborns has increased from 91.5% to 95.9%. Despite this, newborns are still infected (1).

The number of treatment regimens is relatively high (total: 22 regimens; first line: 9). According to the information given to the WHO mission in 2013, the country was planning to gradually switching to the new WHO guidelines for ART (9), but this was yet to be fully implemented in 2014. The regimen which dominated in the first line treatment in 2013 was ZDV+3TC+ EFV (62%) while TDF+FTC+EFV was used in only 12% of the subjects. Didanosine, abacavir, and lopinavir/r, which are drugs not recommended by WHO as first line drugs, are also used in the first line regimen. Altogether ZDV was used in 80% of patients with first line ART in 2013 compared to TDF which was used in 13%.

The high rate of ZDV-use compared to TDF-use has disadvantages. It is somewhat more costly. According to information obtained, the cost of ZDV+3TC+ EFV is 11.28 USD per patient and more expensive than TDF+FTC+EFV. Also, if TDF+FTC+NVP, which was the cheapest regimen in 2013, had been used instead of ZDV+3TC+EFV, a cost saving of 3 857 USD for the total population would have been obtained in 2013. Importantly, ZDV is associated with a high rate of lipoatrophy which TDF does not cause. It is well established that facial lipoatrophy is stigmatizing. A decrease in ZDV use and a substantial increase in the use of TDF-containing ART is therefore important.

Thirteen second line regimens were used in 2013. Among them EFV and NVP regimens were used which should be avoided if the patient has confirmed treatment failure on a first-line NNRTI-containing regimen due to the full cross-resistance pattern between the first generation NNRTI. It is also noted that the integrase inhibitor raltegravir was given to 13 patients in 2013 but not in 2012. The use of raltegravir in second line regimen (and first line) should be avoided due to the high risk of resistance development and treatment failure, the high costs and the need for simplification of the treatment regimens. Three different protease inhibitors (lopinavir/r, darunavir/r, atazanavir/r) were used in the second line regimens. The darunavir/r-containing regimens were more than 10-times more expensive than the 3TC+TDF+LPV regimen. Darunavir/r should not be used due to the need of simplification and the high costs.

The concept note proposes ART is required for patients with CD4+ T cell counts of less than 500/ml (*3*), which is in line with the WHO general recommendation. However WHO guidelines also state that priority should be given to those with severe or advanced HIV disease, allowing increased coverage for patients with CD4+ T cell counts of less than 350/ml (*5*). Although it is acknowledged that a high coverage rate of ART in all patients with CD4+ T cell counts of less than 500/ml would be beneficial, a priority should be to treat all patients with severe diseases and/or CD4+ T cell counts of less than 200/ml. However, the absolute number requiring treatment among persons in care is not possible to confirm since no data of CD4+ T cell counts at diagnosis could be

obtained. The lack of statistics on CD4+ T cell counts at diagnosis was pointed out in the WHO mission 2013.

WHO guidelines: Initiate ART if CD4 cell count is \leq 500 cells/mm³. As a priority, initiate ART in all individuals with severe/advanced HIV disease (WHO clinical stage 3 or 4) or CD4 count is \leq 350 cells/mm³(5)

The country target in the CN for people on ARVs is 57%. The target is considered low according to international standards and goals.

Recommendations:

- Implement mechanisms to ensure follow-up with patients that are lost through collaboration with NGOs and other stakeholders.
- Start ART without delay in patients with clinical symptoms.
- Increase the coverage of ART to minimize the gap between the estimated number of PLHIV who need ART and those who receive it, especially in patients with low CD4.
- Simplification of drug regimens is a cost-effective public health approach. This includes:
 - that all newly enrolled patients should be started on TDF/FTC/EFV as the preferable regimen as recommended by the 2013 WHO guidelines;
 - that the cheapest PI/r should preferably be used in the second, and any further line, regimens;
 - that ddI, abacavir and raltegravir should preferably not be used in the first and second line regimens.

Recommendations – indicators and targets:

- Develop a specific indicator and target regarding retention in care and on treatment success.
 - Identified and enrolled 75% by 2018 (goal should be 90%)
 - Retained in care -75% by 2018 (goal should be 90%)
 - Virally supressed 75% by 2018 (goal should be 90%)
- Develop specific indicators for each CD4 level in the treatment coverage.

Table 1. Treatment – indicators and targets

Indicator for treatment	Target
CD4 <200 and/or AIDS	Up to 100%
CD4 200-350	>80% (WHO target)
CD4 350-500	>0%*
TB/HIV, Hep B/HIV, pregnant women and children	Up to 100%

*The target is not possible to define due to the lack of data regarding the number of patients in the different CD4 strata at diagnosis. As a priority, initiate ART in all individuals with severe/advanced HIV disease (WHO clinical stage 3 or 4) or where CD4 count is \leq 350 cells/mm³

4.4 Priority area 4: Scale up harm reduction and OST

Harm Reduction

Harm reduction services so far are not defined by the MOH in any legal act. Only one NGO in the country, Positive Movement, provides services with the marginal support from the governmental health care sector. The NGO reached 21 000 PWID from the estimated 75 000. This implies 28% coverage of the PWID (20-60% mid-level coverage indicator as defined by WHO, UNODC and UNAIDS (*8*).

Positive Movement reported that they provided HIV testing and counseling (HTC) for up to 7 000 PWID per year. This figure implies coverage of 9% of the estimated number of PWID in the country. The mid-level indicator by WHO, UNODC and UNAIDS is 40-75% [29]. Therefore the current coverage of HTC is too low to identify HIV early.

According to the data provided by Positive Movement, 75 needles/syringes are delivered per PWID annually. The mid-level target indicator by WHO, UNODC and UNAIDS is 100-200 needles/syringes per year (13)At the same time the NGO indicates that stock-out of injection equipment is experienced, and as a result their harm reduction services lose clients.

In recent years, the pattern of drug use in Belarus has changed. Synthetic cannabinoids ('spices') and stimulants (most probably related to amphetamines and mephedrone) are increasingly used. Some of the substances are injected up to 8-10 times daily. The picture is not clear. More systematic research regarding the changing patterns of drug use and the needs of PWID in Belarus would be beneficial (9).

The comprehensive harm reduction package

- 1. Needle and syringe programmes (NSPs)
- 2. Opioid substitution therapy (OST) and other evidence-based drug dependence treatment
- 3. HIV testing and counselling
- 4. Antiretroviral therapy
- 5. Prevention and treatment of STIs
- 6. Condom programmes for people who inject drugs and their sexual partners
- 7. Targeted information, education and communication for people who inject drugs and their sexual partners
- 8. Prevention, vaccination, diagnosis and treatment for viral hepatitis
- 9. Prevention, diagnosis and treatment of TB.

(WHO, UNODC, UNAIDS. Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users, 2012) (13)

The draft National Strategic Programme plans to cover from the government sources, only 3% of 60% of PWID by 2018. The government's provision and financing of harm reduction services remain uncertain.

Recommendations:

- To adopt a legal act by MOH that defines the package of the minimal harm reduction services.
- To involve governmental health institutions in the provision of harm reduction services through allocating funding from the state budget and GF.
- To develop legal acts that can allow NGOs to provide extensive HIV testing with rapid tests of PWID and other key populations.
- To adopt legal mechanisms which will allow the Government to fund harm reduction services provided by NGOs from the state budget.
- To adopt legal acts defining integrated care through psychosocial support/case-management in government health care facilities and NGOs.

Recommendations – indicators and targets:

- Increase the target for the coverage of PWID population with HIV prevention (harm reduction) services by 2018 to 60% (in line with WHO/UNODC/UNAIDS Technical Guide recommendations, 2012) (13)
- Increase the target for the coverage of PWID population with HIV testing and counselling by 2018 to 55% (mid-level target between 40 and 75% as set by WHO/UNODC/UNAIDS, 2012).

OST

The estimated number of injecting opioid users is 18 450. Currently there are 19 OST sites in the country with around 1000 patients. Current coverage of OST is 5% of opioid injecting users. This level is well below the target set by the WHO/UNODC/UNAIDS (20-40% mid-level, >40% high) (13).

Legal requirements for the security at OST sites, as well as storing and transportation needs are excessive and comprise up to 31% of the total OST costs (22). These high costs for security are not justified.

During the seven years of implementing OST there have been no major break-in or assault incidents within OST sites. The MOH alone is not in a position to review and simplify these excessive legal requirements, because they are under the jurisdiction of the Ministry of Interior. This question was raised and relevant international expert's recommendations were suggested in previous reports (14).

Due to excessive security requirements for storing and transporting of methadone, opening new OST sites viewed as an unfeasible option by administrators and staff at TB treatment centers, infectious disease and drug treatment centers, and policlinics.

An executive legal act of the Ministry of Health (2010)(6), which approved the newest clinical protocol on OST, has removed many previous barriers for PWID to OST. Nevertheless, OST as stated in the protocol should be started only after PWID have results for HIV, HCV, syphilis and TB. Both legal acts, which approve clinical protocols (Clinical Protocol for OST and Clinical Protocol for Treatment of Mental and Behavior Disorders) (6,7) do not include infectious disease early detection (HTC, TB screening) and treatment of infectious diseases in cooperation with infectious disease specialists. Neither current legal acts of the MOH define the continuation of OST for patients who are hospitalized with infectious diseases (HIV, TB) or any other disease. In most cases, a single daily methadone dose is transported by a medical personnel and a driver to other hospitals and contributes to the increased costs of the institution, which has an OST site.

Furthermore, according to the current legal acts, OST patients are included within a register after they start treatment (6). They acquire the same status as illegal drug users, who are not in treatment. Inclusion into the register highly stigmatizes OST patients and restricts their chances gaining employment because the common practice for governmental institutions is to require proof that one is not on the drug addict's register.

Among other factors which make OST less attractive to PWID and deters them from approaching for opioid dependence treatment early, is the absence of the legal possibility to receive medications for home use. Even patients, who are successful in treatment and do not use illegal drugs for months and years, who are socially fully integrated and work, cannot have medication for the responsible use at home.

Legalizing medical staff allowing patients to use methadone at home during weekends, or take methadone for 1-2 days to use it at home regularly, especially for those who have jobs and families, could be a very powerful motivational factor for patients investing their efforts to stabilize their life and to stay longer in treatment. In this case, treatment will interfere less with social integration of patients, by reducing their costs and daily travel time to the clinic. Allowing the home use of methadone for stable patients is recommended by the Guidelines for the psychosocially Assisted Pharmacological Treatment of Opioid Dependence (WHO, 2009). At the same time, there should be measures undertaken to minimize the possible diversion of medication by patients to the 'black market'. And if such events should occur, patients should be liable for legal penalties according the existing legislation.

Psychosocial support and case management is available in only 2 OST sites out of 19 (11%). In the other OST sites, only medical care is provided.

Recommendations:

- Work with the Ministry of Internal Affairs to remove the excessive requirements for security of OST sites, medication storage and transportation, in order to reduce the overall OST costs.
- Establish integrated care delivery for PWID with HIV and TB by increasing links between drug addiction, and HIV and TB inpatient and outpatient services.
- Open new OST sites in TB and infectious disease centers.
- Remove the existing barriers for PWID to enter OST as the continuation of OST in the hospitals by reviewing and changing accordingly the Clinical Protocol of OST (6) and other relevant legal acts.
- Develop a reliable new statistical database of people who use drugs (PWUD) in treatment, which should replace the existing regional registry of PWID.
- Expand and further develop best-practice experience of providing psychosocial care, case management, and support for ART adherence alongside the medical care in OST sites.
- Together with relevant ministries, review the possibility of OST pilot projects in prisons, and also adopt the legal acts which will allow continuation of OST in detention centers.
- In widening access of PWID to OST and harm reduction services, retain all necessary measures which will minimize harm to public health by preventing illegal drug use and diversion of controlled medications.
- Together with the Ministry of the Interior, General Prosecutors Office and other relevant institutions, review legal acts in order to allow stable and socially integrated patients to attend OST sites less often than daily, and allow methadone to be used at home, whilst undertaking relevant measures to prevent the diversion of medication.

Recommendations – indicators and targets:

• The target for OST in the National Strategic Programme by 2018 is 4900 PWID in OST, or 27%, and it is recommended to raise this to 40% by 2018 (mid-level target: between 20 and 40% as set by WHO/UNODC/UNAIDS (*13*).

4.5 Priority area 5: Ensuring sustainability and optimizing service delivery models and use of multidisciplinary teams

The integration of OST into the overall health care system is satisfactory: MOH legislation regarding OST exists, OST is implemented in government health care institutions, and the Government covers a significant extent of OST costs. It is planned that in 2016-2018 governmental funding will cover one third of the total funding, leaving two thirds for TGF. The increasing support from the law enforcement sector towards OST on national and local levels improves the sustainability of OST.

Harm reduction services are not in any way legally defined by the Ministry of Health. It is not clear which harm reduction services are regarded as essential. There is no legal definition about which specialists in which health institutions should provide harm reduction services. The documentation and tools (e.g. data collection for needle-syringe programs, tools for psychosocial assistance and the coordination of multidisciplinary team) which are used by the NGO, are not officially approved by the MOH. So far governmental health care and public health institutions have not participated in the provision of these services. Only a few contribute minimally to the provision of harm reduction services by providing the premises for the NGO on a discounted fee basis.

Mechanisms that can allow purchasing services from governmental funds from the NGOs do not exist as yet.

The draft National Strategic Programme plans to cover only 3% of 60% of PWID registered with the government sources by 2018. The government's provision and financing of harm reduction services remain uncertain.

High staff turnover, lack of SOP for forecasting and the procurement of drugs, and inability of the state to fund NGOs, is jeopardizing the sustainability of the programme. In the NSP and CN there is reference to multi-disciplinary team, but it should be specified how this is planned to be implemented, who will be involved, and with clear indicators for evaluation.

Also, it is recommended to take into account the increased burden on the health system and collaboration required with organizations to provide social support through the creation of multidisciplinary teams (whereby the infectious disease doctor initiates and supervises treatment, with recognition that the involvement of other support functions remains crucial).

Recommendations:

- Strengthen the collaboration between TB/HIV/OST services and build on best practice evidence from Gomel in other affected regions.
- Consider defining specific indicators for the most affected regions, and prioritizing interventions in those regions.

Recommendations – indicators and targets:

• Include indicators for integrated services, e.g. each OST center/Infectious Disease department/TB center to have at least one social worker/case manager.

Possible re-allocation of resources:

- Simplify the testing strategy.
- Evaluate the effectiveness of testing women twice during pregnancy.
- Consider simplification of drug regimens.
- Decrease lost-to-follow-up patients, meaning the efficient use of available resources (testing, drug cost, and clinical care costs).
- Testing is proven cost effective when the prevalence is >0.1% (15,16).

4.6 Priority area 6: Review legislation related to testing, harm reduction, OST and drug use for an enabling environment

As pointed out at the WHO mission in 2013, the environment in which PLHIV are received is extremely important in order to secure a diagnosis and retention in care (9, 17). The National Law N° 345-3 'Prevention Socially Dangerous Diseases, HIV' was implemented in July 2012, allowing mandatory HIV testing for a number of professional categories and lists professionals who cannot maintain their duties if they have HIV, e.g. surgeons (18).

The law permits compulsory HIV testing if a person evades or declines mandatory testing, or if there is "a valid reason to suspect a person has HIV". The law states that disclosure of status is allowed upon request by the Ministry of Health or Ministry of Internal Affairs, and compulsory isolation and treatment for socially dangerous diseases (including TB) can be forced upon an individual. This law raises serious concern of the voluntary and confidential nature of the test procedures as the core principles of global and regional testing guidelines and recommendations (19,20).

PWIDs that approach health institutions for services are included into the state register of addicts, on the same terms as PWIDs who are not in treatment. This procedure significantly stigmatizes patients. With respect to employment, governmental institutions in Belarus usually request proof (a certificate), verifying that applicants are not registered in the regional registry of addiction centers. This practice hampers integration of patients into the labor market and discourages PWIDs to seek treatment in their early drug use phase.

Through a current legal act, OST patients are, upon arrest, denied continuation of treatment in detention centers and prisons. Consequently, they face serious symptoms of opioid withdrawal when treatment with methadone is stopped. For a number of years, OST in prisons has been successfully implemented in some post-Soviet Union countries, including Kyrgyzstan (21), Republic of Moldova (22) and Estonia (23). OST in prisons is similarly recommended by WHO (24).

Adoption of the proposed national legislation, which will increase penalties (criminalization) for personal drug use, could significantly undermine access of PWIDs to harm reduction services and OST. In this case, the risk of HIV spread among PWID and non-PWID communities will significantly increase.

Recommendations:

- Consider the review and repeal of the legislation on mandatory testing and treatment (The National Law N° 345-3 'Prevention Socially Dangerous Diseases, HIV'). The law has been in practice since July 2012.
- Remove the existing barriers for PWID to enter OST in health care settings, by reviewing and changing accordingly the Clinical Protocol of OST (6) and other relevant legal acts.
- In consultation with the National Drug Control Agency together with Ministry of Health, other relevant ministries (Ministry of Justice, Ministry of Internal Affairs) and bodies (General Prosecutor's Office), review national legal acts, which define the country's long term national drug policy against the main mission of International Drug Control Conventions, to improve public health. International Drug Control Conventions as an utmost priority call governments to strengthen the public health of a country's population, by maximizing the access of patients in need of opioid medications for opioid dependence and pain treatment, and through HIV, viral hepatitis B and C, TB and STI management among injecting drug users.

5. The National Strategic Plan (NSP) and Concept Note (CN)

5.1 Situation analysis

The strengths and weaknesses of the NSP/CNs situation analysis are listed in the following:

Strengths and weaknesses - the NSP & CN situation analysis	
Strengths	*Epidemiological data with prevalence rate among general population (disaggregated by age groups and sex) and key populations. *Description of uptake in ARV programme *CN breakdown of strengths and weaknesses of the NAP 2011- 2015 *Expressed commitment to a wide country dialogue (CN)
Weaknesses	 *Lack of data on CD4-count at diagnosis and ARV-treatment outcomes. *Within the NSP, testing and treatment numbers are not compared with the number of persons eligible for testing and treatment (but described in CN's programmatic gap table). *KAP figures are marked in percentages (only) and not in numbers. *Little data on KAP/MARPS inclusion in present testing and treatment services *Analysis of past and current health sector responses is absent in the NSP, but touched upon in the Concept Note.
Implications for Successful Implementation	*The current epidemiological data/indicators are preferably expanded in order to: create an overview and; monitor implementation of a number of described goals and service packages.
Suggested Actions	*Expanded analysis of past and current health sector responses. *Utilizations of additional epidemiological data and monitoring indicators.

5.2 The process of developing the NSP

5.2.1 Policy review and plan-coherence

The current document states that the NSP 2016-2020 is in line with the tasks of the Social and Economic Development Programme of the Republic of Belarus, including reducing costs related to HIV/AIDS, and that related regional HIV/AIDS programmes and plans are to be developed (1).

As described under priority area 6, the plan-development-process should include a review of existing national guidelines and the issue of policy-coherence. In this respect, thorough multidisciplinary analysis should highlight how the legal framework and national guidelines have supported previous HIV/AIDS programmes, as well as how the current legal framework supports the current NSP objectives, such as "Universal access" and "Reduction of HIV spread in high

infection risk groups". Various implementing partners (public/non-public) should preferably be invited to take part in the analysis.

Policy review questions could include:

- Has the law on mandatory testing and treatment been in support of the previous State HIV Prevention Programmes?
- Is the regulatory legal act on the registration of PWIDs to receive OST in support of the current NSP objectives?
- What are the expected outcomes of the regulatory legislation on dispensary observation of HIV-positive pregnant women and pregnant women from high HIV risk groups?

5.2.2 The CCM and multi-stakeholder involvement

From the onset, the current NSP draft appears to have been developed by a limited group of people, as the draft has few references to the role of the CCM and involvement of stakeholders. In opposition to this, the draft Concept Note expresses commitment to a wide country dialogue and states that the NSP "*is being developed through wide country dialogue involving key national players, international agencies, PLHIV and representatives of key affected populations*" (3).

As specified in TGFs revised guidelines for Country Coordinating Mechanisms (CCM), it is the role of a CCM to submit one national proposal, "drawing on the strengths of various stakeholders to agree on strategy, identify financing gaps in achieving the strategy based on existing support, prioritize needs, and identify the comparative advantages of each proposed partner" (25).

As stated earlier, it is essential that the ongoing NSP-planning process adhere to principles of multistakeholder involvement, including the involvement of NGOs and civil society. It has the rewards of qualifying the NSP, specifying partnerships under the NSP/NAP 2016-2020, and establishing legitimacy around the analysis, goals and objectives of the plan. Upcoming versions of the NSP document will preferably include an explicit description of the planning process.

5.3 Cost and budgetary framework of the NSP

The current version of the National Strategic Plan for 2016-2020 has no cost and budgetary framework, whereas the Concept Note involves an initial programmatic and financial gap analysis (26).

The National Strategic Plan should be costed, and a detailed cost and budgetary framework should be developed, demonstrating how the proposed plan-components are financially viable, achievable and realistic (27,28,29). The expenditure framework should enlist the major forms of funding, from government, non-governmental and international sources as well as stipulating how the respective sources of funding are utilized to finance respective plan components.

It is currently undefined, whether the Government of Belarus is able to gradually increase its level of funding for the NSP 2016 – 2020, in order to achieve sustainability. The NSP refers to the national budget as follows: "financing of the State Programme is proposed to be done within the funds stipulated in the national budget for the corresponding budget year allocated" (1,p.9).

It is similarly uncertain, to what extent recurrent and investment financing is required to implement the NSP, including the costs of human resources, ARV-medicines, decentralized management, infrastructure and social protection mechanisms.

Whilst developing the cost and budgetary framework, it is advised to consult the toolkit of IHP+ Joint Assessment of National Health Strategies (JANS) Tool & Guidelines (30).

Recommendations

- Include a detailed cost and budgetary framework in the NSP.
- Accompany the cost and budgetary framework with a programmatic and financial gap analysis, spelling out funding priorities among the NSP components and interventions.

Strengths and weaknesses - the cost and budgetary framework of the NSP		
Strengths	*Objectives, components and many service packages for the coming 5 years are scheduled. A cost and budgetary framework can be developed upon these.	
Weaknesses	 *The NSP's cost and budgetary framework is yet to be developed. *Is the national budget able/willing to fund an increased proportion of the State HIV Prevention Programme for 2016 – 2020, in pursuit of sustainability? *New supplementary activities and related costing are to be qualified. *No indication of co-financing of the efforts of non-governmental organizations (e.g. procurement, testing kits, diagnostics) *Further development of the programmatic and financial gap analysisis needed (initiated in relation to the Concept Note) 	
Implications for	*The absence of an expenditure and budget framework undermines	
Successful	the eligibility of the NSP.	
Implementation		
Suggested Actions	*The NSP is supported by a cost and budgetary framework.	

5.4 Implementation and management arrangements

Within the NSP and supporting documents, there is a need to specify and implement a number of plan components and service packages further. One such need for specification relates to prevention programs for key populations. Along with implementing plan components comes the definition of roles and responsibilities.

The current NSP pinpoints that the Ministry of Health will be the state customer and coordinator of the NSP 2016-2020. In all, 14 government institutions will be contracting organizations (9, p. 10). The current document further schedules upcoming partnerships between local executive authorities and NGO's, cross-sectorial HIV/AIDS working groups and promotes social contracting. However, the NSP and supporting documents should specify roles and responsibilities in the implementation of respective plan components and objectives.

Currently:

- the NSP states little about the roles and responsibilities of NGO's, CBO's and international organizations engaged in HIV/AIDS;
- the NSP appear to favor a multi-sector-response to HIV/AIDS, marked by the fact that 14 ministries are to become contracting organizations. Ideally, this approach can boost the political commitment and participation behind the NSP. However, there is need to specify the role & responsibility of every ministerial organization and pinpoint the means of coordination. This is necessary in order to support and empower the Ministry of Health as the state customer of the NSP 2016 2020. The components are similarly necessary to avoid functional overlap, slowness in operational procedures and lack of accountability;
- CCM is not mentioned in any detail although the committee is established as a leading and uniting structure (31,32,33). Hence, the instrument for ongoing coordination and dialogue between implementing partners needs to be made explicit.

It is recommended, that the NSP is made operational through a plan, defining the organization of service delivery attached to every major programme component, and describing the roles and responsibilities of each implementing partner. Multi-stakeholder involvement should help to shape the further development of NSP 2016-2020, including policy dialogue with the non-governmental organizations engaged in HIV/AIDS. Similarly, information on the final NSP should be disseminated to the widest possible group of stakeholders.

Recommendations

- It is recommended, that multi-stakeholder-involvement is used to shape the further development of NSP 2016-2020 and help define the organization of service delivery.
- It is recommended, that an *operational plan* is developed, defining the organization of service delivery and clarifying the roles and responsibilities of all implementing partners, attached to every major component of the NSP.

Strengths and weaknesses - implementation and management arrangements		
Strengths	*The NSP schedules central challenges, and outlines a number of partnerships, e.g. among local executive authorities and NGO's.	
Weaknesses	 *Roles and responsibilities of government stakeholders are irregularly touched upon. *Roles and responsibilities of non-governmental stakeholders are not specified. *The structure attached to the CCM is not mentioned in any detail. *Multi-stakeholder involvement and ongoing country dialogue is not described. *Roles & responsibilities are especially lacking with respect to testing strategies towards high risk groups: CSW, MSM, and PWID. 	
Implications for Successful Implementation	*It is vital to define channels of service delivery and to establish clarity of the roles of different service providers/implementing partners.	
Suggested Actions	*Clarify the organization of service delivery, partly through multi- stakeholder-involvement. *Develop an operational plan.	

5.5 Monitoring, evaluation and review mechanisms

The current draft of the NSP speaks of the need for a single national monitoring system to support the HIV programme. It states that one national system for monitoring and evaluating will be developed, using the following sources of information:

- the republican register of HIV-infected patients
- sociological research to evaluate efficiency of HIV control activities
- research to evaluate efficiency of the HIV/ AIDS information strategy
- sociological research on the levels of stigma surrounding key populations

The scheduled M&E mechanism should reflect the goals and objectives of the NSP; and provide key data able to measure the progress of respective plan components and, to a certain extent, the performance of implementing agents/contracting organizations in charge of respective plan components (as specified in an operational plan).

A number of additional M&E indicators have already been proposed in chapter 5, priority area 1. With respect to key populations, the programmatic gap table describes the coverage indicators: HIV testing, HIV prevention packages and opioid substitution therapy. Since inclusion of key populations is a central objective of the NSP 2016-2020, the monitoring system could preferably be extended to cover the continuum of care for key population, thus enabling the visualisation of how these groups are included in the continuum of care. It is further advised to consult WHO's Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations [12].

Recommendations

• It is recommended, that the continuum of care for key populations is involved as part of a regular M&E mechanism.

Strengths and weaknesses - M&E mechanisms		
Strengths	*A national M&E mechanism will be developed for the HIV	
	programme, according to the NSP.	
Weaknesses	*Certain NSP plan components need to be specified along with	
	M&E-related coverage indicators and sources of information.	
	*The number of scheduled coverage indicators on key populations	
	need to be expanded in order to provide proper possibilities for	
	M&E.	
	*At present. Limited considerations concerning possible data gaps,	
	collection methods, performance reviews and data sharing.	
Implications for	*Organizational and operational clarity needs to be enhanced further,	
Successful	along with the development of a national monitoring and evaluation	
Implementation	mechanism.	
Suggested	*Identify key coverage indicators and possible data gaps.	
Actions		

6. Recommendations

6.1 Main recommendations

Strengthen the epidemiological analysis of the epidemic:

- Implement alternative methods to estimate the size of the undiagnosed population than only Spectrum, like 'the London method 1' (Working Group on Estimating of HIV Prevalence in Europe, 2011 AIDS) (11), which is more adapted to concentrated epidemics. These methods however require good data on risk group estimates and CD4 count at diagnosis.
- Collect CD4 count at diagnosis. Late presentation is a good indicator of how the epidemic evolves.
- Collect and present data on regional differences. This should drive the planning of activities and coverage indicators.
- Present data on coinfections (hepatitis C and tuberculosis), and trends over time.
- Properly analyse MTCT, for instance, how many pregnant women are tested positive at the second test performed during pregnancy? Why is the prevalence of children born with HIV still high?
- Include the number of rapid tests performed in the overview of yearly total number of tests by risk groups.

Increase coverage of testing in MARPs and enrolment into care:

- Scale up community based rapid testing and ensure linkage into care.
- Provide systematic follow-up on those tested positive for HIV and not enrolled in care.
- Revisit pre- and post- test counselling procedures with the aim of ensuring that people are not lost.
- Ensure that people are not lost between the first and second HIV test by:
 - o changing the instructions for testing:
 - include rapid testing
 - perform ELISA and a confirmatory test (blot) on the first sample
 - simplify the counselling algorithm to ensure that patients are not lost
- Collect data and follow trends in:
 - No test per risk group
 - No reactive tests
 - No blood samples submitted for confirmatory test
 - No true positive
 - o No linkage to care

Increase ARV coverage and retention in care:

- Implement mechanisms to ensure follow-up with patients that are lost through collaboration with NGOs and other stakeholders.
- Start ART without delay in patients with clinical symptoms.
- Increase the coverage of ART to minimize the gap between the estimated number of PLHIV who need ART and those who receive it, especially in patients with low CD4.
- Simplification of drug regimens is a cost-effective public health approach. This includes:
 - that all newly enrolled patients should be started on TDF/FTC/EFV as the preferable regimen as recommended by the 2013 WHO guidelines.
 - that the cheapest PI/r should preferably be used in the second and any further line regimens.
 - that ddI, abacavir and raltegravir should preferably not be used in the first and second line regimens.

Scale up harm reduction and OST:

Harm reduction

- To adopt a legal act by the MOH that defines the package of the minimal harm reduction services.
- To involve governmental health institutions in the provision of harm reduction services through allocating funding from the state budget and GFT.
- To develop legal acts thatcan allow NGOs to provide extensive HIV testing with rapid tests of PWID and other key populations.
- To adopt legal mechanisms which will allow the Government to fund harm reduction services provided by NGOs from the state budget.
- To adopt legal acts defining integrated care through psychosocial support/case-management in government health care facilities and NGOs.

OST

- Work with the Ministry of Internal Affairs to remove the excessive requirements for security of OST sites, medication storage and transportation, in order to reduce the overall OST costs.
- Establish integrated care delivery for PWID with HIV and TB by increasing links between drug addiction, and HIV and TB inpatient and outpatient services.
- Open new OST sites in TB and infectious disease centers.
- Remove the existing barriers for PWID to enter OST as the continuation of OST in the hospitals by reviewing and changing accordingly the Clinical Protocol of OST (6) and other relevant legal acts.
- Develop a reliable new statistical database of people who use drugs (PWUD) in treatment, which should replace the existing regional registry of PWID.
- Expand and further develop best-practice experience of providing psychosocial care, case management, and support for ART adherence, alongside the medical care in OST sites.
- Together with relevant ministries, review the possibility of OST pilot projects in prisons, and also adopt the legal acts which will allow continuation of OST in detention centers.
- In widening access of PWID to OST and harm reduction services, retain all necessary measures which will minimize harm to public health by preventing illegal drug use and diversion of controlled medications.

• Together with the Ministry of the Interior, General Prosecutors Office and other relevant institutions, review legal acts in order to allow stable and socially integrated patients to attend OST sites less often than daily and allow methadone to be used at home, whilst undertaking relevant measures to prevent the diversion of medication.

Optimize service delivery models and use of multidisciplinary teams:

- Strengthen the collaboration between TB/HIV/OST services and build on best practice evidence from Gomel in other affected regions.
- Consider defining specific indicators for the most affected regions, and prioritizing interventions in those regions.

Review legislation related to testing, harm reduction, OST and drug use for an enabling environment:

- Consider the review and repeal of the legislation on mandatory testing and treatment (The National Law N° 345-3 'Prevention Socially Dangerous Diseases, HIV'). The law has been in practice since July 2012.
- Remove the existing barriers for PWID to enter OST in health care settings, by reviewing and changing accordingly the Clinical protocol of OST (6) and other relevant legal acts.
- In cooperation with the Ministry of Health, other relevant ministries (Ministry of Justice, Ministry of Internal Affairs) and bodies (General Prosecutor's Office), review national legal acts, which define the Republic's long term national drug policy, alongside the main mission of the International Drug Control Conventions to improve public health.

6.2 Specific recommendations – indicators and targets

- Develop a coverage indicator regarding the enrolment and retention throughout the continuum of care (in the current CN draft, the indicator only includes the number of people on ARV) (see below on defining targets).
- To reach the target of 44% testing coverage for PWIDs the involvement of civil society is key. The indicator should include the need to ensure that positive tests are confirmed.
- Scale-up testing coverage for PWIDs to 40%-60% during the NSP period.
- Increase the target for testing coverage for FSW and MSM (now 15% and 14%) to the same level as PWIDs (40-60%) and plan for expansion over time.
- Increase the target for testing of sex partners of PWIDs from 23% to 40-60%. Contact tracing is a very important tool and an efficient way of influencing the epidemic.
- Develop a specific indicator and target on retention in care and on treatment success.
 - Identified and enrolled 75% by 2018 (goal should be 90%)
 - Retained in care 75% by 2018 (goal should be 90%)
 - Virally supressed 75% by 2018 (goal should be 90%)
- Develop specific indicators for each CD4 level in the treatment coverage.

Table 1. Treatment – indicators and targets

Indicator for treatment	Target
CD4 <200 and/or AIDS	Up to 100%
CD4 200-350	>80% (WHO target)
CD4 350-500	>0%*
TB/HIV, Hep B/HIV, pregnant women and children	Up to 100%

*The target is not possible to define due to the lack of data on the number of patients in the different CD4 strata at diagnosis. As a priority, initiate ART in all individuals with severe/advanced HIV disease (WHO clinical stage 3 or 4) or CD4 count \leq 350 cells/mm³

- Increase the target for the coverage of PWID population with HIV prevention (harm reduction) services by 2018 to 60% (in line with WHO/UNODC/UNAIDS Technical Guide recommendations, 2012) (13).
- Increase the target for coverage of PWID population with HIV testing and counselling by 2018 to 55% (mid-level target between 40 and 75% as set by WHO/UNODC/UNAIDS (2012).
- The target for OST in National Strategic programme by 2018 is 4 900 PWID in OST, or 27% and it is recommended to raise this to 40% by 2018 (mid-level target: between 20 and 40% as set by WHO/UNODC/UNAIDS (*13*).
- Include indicators on integrated services, e.g. each OST center/infectious disease department/TB center to have at least one social worker/case manager.

6.3 Specific recommendations - NSP and CN process

- Include a detailed cost and budgetary framework in the NSP.
- Accompany the cost and budgetary framework with a programmatic and financial gap analysis, spelling out funding priorities among the NSP components and interventions.
- It is recommended, that multi-stakeholder-involvement is used to shape the further development of NSP 2016-2020 and help define the organization of service delivery.
- It is recommended, that an *operational plan* is developed, defining the organization of service delivery and clarifying the roles and responsibilities of all implementing partners, attached to every major component of the NSP.
- It is recommended, that the continuum of care for key populations is involved as part of a regular M&E mechanism.

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ANNEX 1 - Terms of reference

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 programme review in Belarus

18-21 November 2014

1. Background

By the end of 2012, Belarus had reported a cumulative total of 13 623 HIV cases, including 3 523 that had progressed to AIDS and 1 259 deaths among AIDS cases, to the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC). In 2012 alone, 1 223 HIV cases, 527 AIDS cases, and 171 deaths among AIDS cases were reported. The rate of newly diagnosed HIV infections in 2012 was 13.1 per 100 000 population and continues to increase each year. Of the newly reported cases with information about transmission mode in 2012 (99%), 76% were infected through heterosexual contact, 20% through injecting drug use, 3% through male-to-male sexual contact and 1% through mother-to-child transmission. Belarus has reported a cumulative total of 214 mother-to-child transmission cases, including 16 (7%) in 2012.

Taking undiagnosed infections into account, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO estimate that 25 000 (24–27 000) people were living with HIV in Belarus at the end of 2013, that 2 700 people became newly infected and that less than 1 000 people died from AIDS-related causes during 2013. HIV prevalence in the adult population was estimated to be 0.5% (0.5–0.5%).

As reported to the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC), 683 125 HIV tests (73.1 per 1000 population) were performed in Belarus in 2012, a 10% increase compared with the number of tests in 2011.

A total of 11 654 people had been enrolled in medical HIV care at the end of 2013, including 5 181 people who were receiving antiretroviral therapy (ART). Among the total estimated number of people living with HIV in the country, an estimated 20% (19%–21%) were receiving ART at the end of the year.

WHO and the Global Fund have Cooperative Agreement regarding the provision of WHO technical assistance to applicants to the Global Fund prior to submission of their concept notes. The contract is effective during the period from 1 January 2014 until 31 December 2015. Technical assistance is organized through two WHO Collaborating Centres: on HIV and Viral Hepatitis and on

Harm Reduction, and based on discussions with the countries and the Global Fund Portfolio Managers and formal country requests.

Belarus is eligible for the Global Fund grant county to support the national programme on HIV/AIDS. The country requested the WHO Regional Office provide technical assistance to conduct an HIV programme review, and review of the National Strategic Plan for development of the Concept Note.

This assessment will follow up on the implementation of the WHO mission recommendations developed during the country mission in November 2013. It will identify barriers and constraints which prevent implementation, and will clarify the need of WHO technical assistance.

2. Programme review

The programme review will include 4 key components:

- A. Epidemiological analysis
- B. Review of HIV treatment and care along cascade of services
- C. HIV services for key populations
- 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:

- Assessing the level of, and trends in, HIV disease burden (incidence, prevalence, mortality), including estimated data on the HIV epidemic
- Assessing whether trends in HIV burden are plausibly related to programmatic efforts or other factors
- Following-up on recommendations given to improve measuring trends in HIV disease burden in future

B. Review of HIV treatment and care programme along cascade of services

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

C. HIV services for key populations (PWID, SW, MSM, prisoners)

• Needle and syringe programme

- Drug dependency treatment
- ART access
- Prison settings

Analysis of HIV services for key populations will focus on the 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

Analysis will be focused on:

- the capacity of the national health system to provide effective human, financial and infrastructural resources to address the health needs of those affected by the HIV epidemic, including key populations which require a proactive approach in service delivery with strong social support and case management
- 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. National Strategic Plan on HIV

The review of NSP should focus on its the components and ensure that:

- NSP defines and determines priorities and strategic directions over a period of time (e.g. five years and aligned with the national health plan)
- NSP provides a clear framework that specifies the appropriate strategic interventions to reach the country's HIV/AIDS care and control goal(s), objectives and targets.
- It guides decision making on allocating resources and on taking action to pursue strategies and set priorities.
- Interventions and objectives are adequately and coherently linked. Moreover, activities and sub-activities inherent to each intervention are clearly specified, highlighting clear target(s) for each intervention and identifying where and when each activity or sub-activity should be implemented and who will implement it.
- NSP specifies the budget needed to implement interventions and activities.
- It also clearly describes how the interventions and activities will be implemented as well as how the implementation will be monitored and their effect will be evaluated
- It provides information on the technical assistance needed to make this implementation effective.

4. Participants

Three external experts:

- ✓ Dorthe Raben, Team leader, Public Health expert, WHO CC on HIV and Viral Hepatitis, Denmark
- ✓ Anders Sonneborg, professor, clinical expert, Karolinska Institute, Sweden
- ✓ Emilis Subata, Harm Reduction expert, WHO CC on Harm reduction, Lithuania

External consultants will be supported by WHO country staff member:

✓ Valentin Rusovich – national professional officer, WHO CO (Minsk)

5. Methodology

The preparation phase will include a desk review and an 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 liaise with key informants: policy makers, health care providers and beneficiaries, NGOs, other national partners where appropriate. Together with local clinical experts they will also have access to the medical records of PLHIV for a review of clinical management.

6. Time, duration and geographical sites of the mission

The mission is planned for November 18-21, 2014. Additional days will be added for a desk review and an analysis of national background documents and report writing.

4 days mission (all)

5 days desk review and reporting (all)

9 days for desk review of HIV NSP and separate report writing (WHO CC on HIV and viral Hepatitis)

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

7. Deliverables

- Key recommendations based on a 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, that is, 'Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection (2013)'¹ and 'Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (2014)'² will be ensured.
- All team members will provide their written contribution using the template (will be delivered) to Dorthe Raben by **28 November 2014.** A draft mission report will be shared with team members for comments. Key recommendations will be agreed and finalised no later than **December3, 2014**, and will be shared with the stakeholders in Belarus and will inform the final Concept Note version.
- The final report with findings and recommendations will be submitted to WHO Regional office for Europe by **December 17, 2014**.
- The report on the HIV National Strategic plan review with recommendations will be submitted to the WHO Regional office for Europe by **December 17, 2014**

¹<u>http://www.who.int/hiv/pub/guidelines/arv2013/download/en/</u>

²<u>http://www.who.int/hiv/pub/guidelines/keypopulations/en/</u>

The reports will be posted on the WHO EURO web site.

ANNEX 2 - Key persons met during the mission

Ministry of health

Dmitry Pinevich	First deputy Minister of Health of the Republic of Belarus
Igor Gaevsky	The Deputy Minister of Health, the chairman of the
	Country Coordination Mechanism (CCM)
Elena Bogdan	The head of the department of the organization of
	medical care of the Ministy of health)
Tatiana Migal	The deputy head of the department of the organization
	of medical care of the Ministry of health, head of the
	department of specialized care

Minsk city infectious diseases hospital

lgor Karpov	The head specialist of the MOH on infectious diseases
Dmitry Paduta	The deputy head of the infectious disease hospital,
Tatiana Pechko	Executive director of the NGO (HIV services) "Positivnoye
	dvizhenie"

Department of prevention of HIV/AIDS at the Republican center for hygiene, epidemiology and public health.

Elena Fisenko	The head of the department of prevention of HIV/AIDS at the Republican center for hygiene, epidemiology and public health.		
Anna Rusanovich	The epidemiologist the department of prevention of HIV/AIDS at the Republican center for hygiene, epidemiology and public health.		
Liudmila Naroichik	The deputy head of the Republican center for hygiene, epidemiology and public health.		
Republican Scientific and Practical Center for Pulmonology and Tuberculosis (RSPCPT)			
Republican Scientific and Pra	ctical Center for Pulmonology and Tuberculosis (RSPCPT)		
Republican Scientific and Pra Henadz Hurevich	ctical Center for Pulmonology and Tuberculosis (RSPCPT) Director of the Republican Scientific and Practical Center for Pulmonology and Tuberculosis, NTP manager		
-	Director of the Republican Scientific and Practical Center		
Henadz Hurevich	Director of the Republican Scientific and Practical Center for Pulmonology and Tuberculosis, NTP manager Deputy director of the Republican Scientific and Practical		

Department of substance substitution therapy at the Minsk regional psychoneurological dispancer.

Ludmila Andreeva	The head of the Department of substance substitution therapy at Minsk regional psychoneurological dispancer.
GLOBAL FUND	
George Sakvarelidze	Fund Portfolio Manager, Eastern Europe and Central Asia
	Team, The Global Fund to Fight AIDS, Tuberculosis
	andMalaria
UNDP/THE GLOBAL FUND PR	OJECT IMPLEMENTING UNIT
Olga Atroshchanka	Program Officer, UNDP, Belarus
Oleg Dubovik	Senior Advisor on HIV, GFATM Grants, UNDP Belarus
Inna Nekrasova	Senior Advisor on TB, GFATM Grants, UNDP Belarus

UNAIDS

Vera Iljenkova

UNAIDS coordinator in Belarus

WHO Country Office in Belarus

Valentin Rusovich Na

National professional officer on communicable diseases (TB), WHO Country office in Belarus



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