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Review of the HIV Programme in Kosovo (in accordance with United Nations Security Council Resolution 1244 (1999))

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List of abbreviations

AIDS	Acquired immunodeficiency syndrome
APMG	APM Global Health
ART	Antiretroviral therapy
ARV	Antiretroviral (drugs)
CCM	Country Coordinating Mechanism
CD4	Cluster of differentiation 4
CDF	Community Development Fund
CSGD	Centre for Social Group Development
DOTS	Directly observed treatment strategy
EU	European Union
FSW	Female sex workers
GARPR	Global AIDS Response Progress Report
GDP	Gross domestic product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCCA	Health Care Commissioning Agency
HIV	Human immunodeficiency virus
ICJ	International Commission of Jurists
IEC	Information, education and communication
KAC	Kosovo AIDS Committee
KAPB	2008 Knowledge, Attitudes, Practices and Behaviour Study on HIV/AIDS with Young People
KAPHA	Kosovo Association for people living with HIV/AIDS
Kosovo	Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999])
KDRA	Kosovo Drug Regulatory Agency
KFSA	Kosovo Food Safety Agency
KOPF	Kosovo Population Fund
MCYS	Ministry of Culture, Youth and Sports
MEST	Ministry of Education, Science and Technology
MMT	Methadone maintenance treatment
MoH	Ministry of Health
MSM	Men who have sex with men
NASA	National AIDS Spending Assessment
NGO	Nongovernmental Organization
NIPH	Institute of Public Health

OI	Opportunistic infections
OST	Opioid substitution therapy
PEN	Peer Education Network
PEP	Post-exposure prophylaxis
PICT	Provider Initiated Counselling and Testing
PLHIV	People living with HIV
PSM	Procurement & Supply Management
PUH	Pristina University Hospital
PWID	People who inject drugs
QC	Quality control
SRH	Sexual and Reproductive Health
STI	Sexually transmitted infection
TB	Tuberculosis
UCCK	University Clinical Centre Kosovo
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNODC	The United Nations Office on Drug
UNSCR	UN Security Council Resolution
VCCT	Voluntary, confidential, counselling and testing
WHO	World Health Organization

1. Executive Summary

This World Health Organization (WHO) mission was performed in September-October 2014 to assess the achievements, strengths and shortcomings in the implementation of the Kosovan programme on HIV/AIDS treatment and care, and to generate strategic recommendations for improving key outcomes and impacts. The mission focused specifically on providing recommendations HIV/AIDS epidemiological analysis, HIV services for key populations, HIV treatment and care along cascade of services, and procurement and supply management of antiretroviral medications (ARVs).

The mission found no evidence of a large-scale HIV epidemic among any key population or the general public. However, there is substantial potential for growth, particularly among men who have sex with men and people who inject drugs; and HIV testing among key populations is lower than optimal, so that no statements can be made with certainty about the size of the Kosovan HIV epidemic. Data on HIV testing (and more generally) is kept partially and in separate institutions: this makes it difficult to gain an overview of the epidemiological situation.

A worrying observation is that, despite only having 14 people on ART, the supply of ARVs to these individuals is so disrupted that severe problems were discovered in their immune response systems (through regular CD4 tests). Also, 60% of those who have tested HIV-positive have been lost to follow-up. Immediate action is required to ensure that adequate stocks of all necessary ARVs are available to the Infectious Diseases Clinic and are provided in line with WHO and (to-be-developed) protocols for Kosovo. The problem of linkage and retention in care needs urgent attention.

Main findings

The HIV epidemic in Kosovo¹ is most likely very small. There appears to be a nascent epidemic among men who have sex with men (MSM), but there have been no recent infections among people who inject drugs (PWID) or female sex workers (FSW). Apart from MSM, most infections have been acquired heterosexually, according to the data that is available. Attempts to estimate the size of the infected population using back-calculation-based methods would currently be impossible given the lack of data on immunological status at HIV diagnosis.

In 2013, a total of 2,857 HIV tests were carried out on people based on clinical indication or risk group, of which 1,125 tests were carried out in the Infection Disease Clinic; 1,452 tests were provided by NGOs to key affected populations (KAPs); and 280 were in prison. However, there is no detailed registry with information on the reasons for testing, nor is there any place (institution, entity or computer) in which data is collated on testing, risk groups etc. Data on CD4 count at diagnosis is not collected systematically, so that estimation of late presenters is currently

¹For the purposes of this publication, all reference to “Kosovo” should be understood/read as “Kosovo (in accordance with UN Security Council Resolution 1244 (1999))”

impossible. Better targeting of HIV testing towards most-at-risk groups as well as more frequent use of rapid tests is highly recommended.

Substantial progress has been made to meet the strategic objectives and sub-objectives of Kosovo HIV/AIDS strategy for 2009-2013 while the new HIV/AIDS strategy for the period 2015-2020 is expected to be developed by the end of 2014 (within the overall Health Sector Strategy). In order to improve the response to HIV, the mission found that future interventions need to focus on key populations and should be based on WHO recommendations concerning key populations (1).

Most-at-risk populations face multiple challenges in accessing health services. In Kosovo the largest most-at-risk group are people who inject drugs; part of this population is being reached through needle and syringe programmes and opioid substitution therapy (OST) sites, and offered HIV testing and counselling. This is successfully reaching a majority of Kosovan PWID, but for methadone maintenance therapy (MMT) in particular, there is a worryingly high dropout rate. The rate of enrolment to private, Nongovernmental Organizations (NGO) and government MMT sites is also very low. Services for MSM appear to be both appropriate and growing in reach, but services for FSW are inadequate and require a complete redesign.

Kosovo's ARV procurement system, forecasting and supply management is inadequate, with reports of stock outs each year for the past six years. The system requires a complete overhaul and requires close monitoring to ensure there are no further stock outs in future. The selection of ARVs is based on the individual clinician's decision rather than on protocols. It is recommended that protocols be developed for Kosovo, based closely on WHO recommendations regarding first- and second-line regimens.

The mission found a negative attitude among many health care providers as well as among clients to the MMT programme. Acknowledging the evidence of the effectiveness of OST programmes to increase adherence to ARV, it is surprising to see this attitude. There is an urgent need to consider how to tackle this situation; and leadership from both clinical society as well as political leadership is needed to change the situation.

The mission identified six priority areas where improvements can be made and provided relevant strategic and technical recommendations in order to improve overall outcomes and impacts of HIV response. These six areas include: leadership, governance and management; HIV services for key populations; optimizing HIV testing; optimizing HIV treatment and care; improving procurement and supply management; and strategic information.

Recommendations

- Protocols and standards for Kosovo for HIV treatment and treatment of co-infection, including paediatric treatment, need to be developed.
- Nongovernmental Organizations working with people living with HIV (PLHIV) need to be strengthened and provided with a clear role in the HIV response (e.g. as "expert patients"), to reduce currently observed loss to follow-up, to provide community-based services, as well as testing services ensuring linkages to HIV treatment and care.

- The Ministry of Health (MoH) Procurement Department needs to coordinate and lead the PSM process for ARVs and test-kits at all stages, and develop a calendar for ARV and test-kits procurement and supply, to eliminate ARV stock outs.
 - MoH needs to monitor the implementation of all HIV activities, ensure that all data from all sources is collated and reported on in a timely manner, and that these reports are widely disseminated for use in planning and implementing HIV services.
 - The decision of MoH to establish a HIV reference Laboratory at the National Institute of Public Health (NIPH), adopted on 16.01.2014, should be implemented immediately.
 - Scaled-up HIV prevention activities and testing among KAPs need to be the priority for Kosovo's HIV response. Approaches to be used should include utilizing salaried outreach workers and incentive based activities carried out by peer educators. Peer educators should be recruited from most-at-risk subpopulations such as MSM who also inject; FSW who also inject; pregnant PWID etc.
 - The Comprehensive Package of Services for PWID and MSM need to be provided nationally, at least in all areas of high concentration of these populations. FSW prevention needs to be reconceptualized, based on research and discussions with FSW throughout Kosovo.
 - Attractiveness of enrolment to and retention in MMT programmes need to be increased, including ensuring that procurement and supply management (PSM) procedures are operating effectively to ensure access to methadone as needed during the scale-up. Further research is needed to understand the reasons for high MMT dropout and for low rates of MMT enrolment in health institutions and prison settings and other issues.
 - A HIV testing and counselling strategy needs to be developed to promote much higher testing among key populations and among pregnant women: this will allow identification of people living with HIV (PLHIV) as early as possible after infection. Those found to be HIV-positive need to be linked appropriately and in a timely manner to care and treatment services. The linkage between the testing and treatment services needs to be strengthened through enhanced collaboration between Nongovernmental Organizations (NGOs) and government health services.
- The testing strategy should also introduce provider initiated HIV testing and counselling (PITC) to the health care system, as well as expanding and improving community-based HIV testing and counselling for key populations. PITC will be recommended in all health facilities for:
- pregnant women;
 - adults, adolescents or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB;
 - adults, adolescents or children who present with symptoms of viral hepatitis or have laboratory markers of viral hepatitis B or C; and
 - HIV-exposed children, children born to women living with HIV and symptomatic infants and children.

2. Epidemiological analysis

According to the 2014 report from the Agency for Statistics (2), Kosovo has a population of approximately 1.8 million people, of whom the majority are Albanians (92%), followed by Serbs (4%), Bosnians and Gorans (2%), Turks (1%), and Roma, Ashkali and Egyptians (1%). About 96% of the population are Muslim, while the Christian population is estimated at 3.69% (Catholic 2.2% and Orthodox 1.48%). The capital city is Pristina with population of 200,000 (3). Kosovo has a very young population - in 2013, 60% of citizens were below 25 years of age.

2.1 Epidemic in Kosovo: latest trends

Total number of registered HIV infections in Kosovo from the first registered case in 1986 up to 2013 is 90, of whom 61 (67.8%) are male and 29 (32.2%) are female. HIV incidence appears to be relatively stable – with 3 new infections discovered in 2012, 3 in 2013 and 2 so far in 2014 (4). All donated blood units are screened for HIV, HBV and HCV and a total of 114,974 blood units have been tested from 2009 to 2013. The HIV epidemic is the smallest, in terms of registered cases, in the European Region, and one of the smallest in the world.

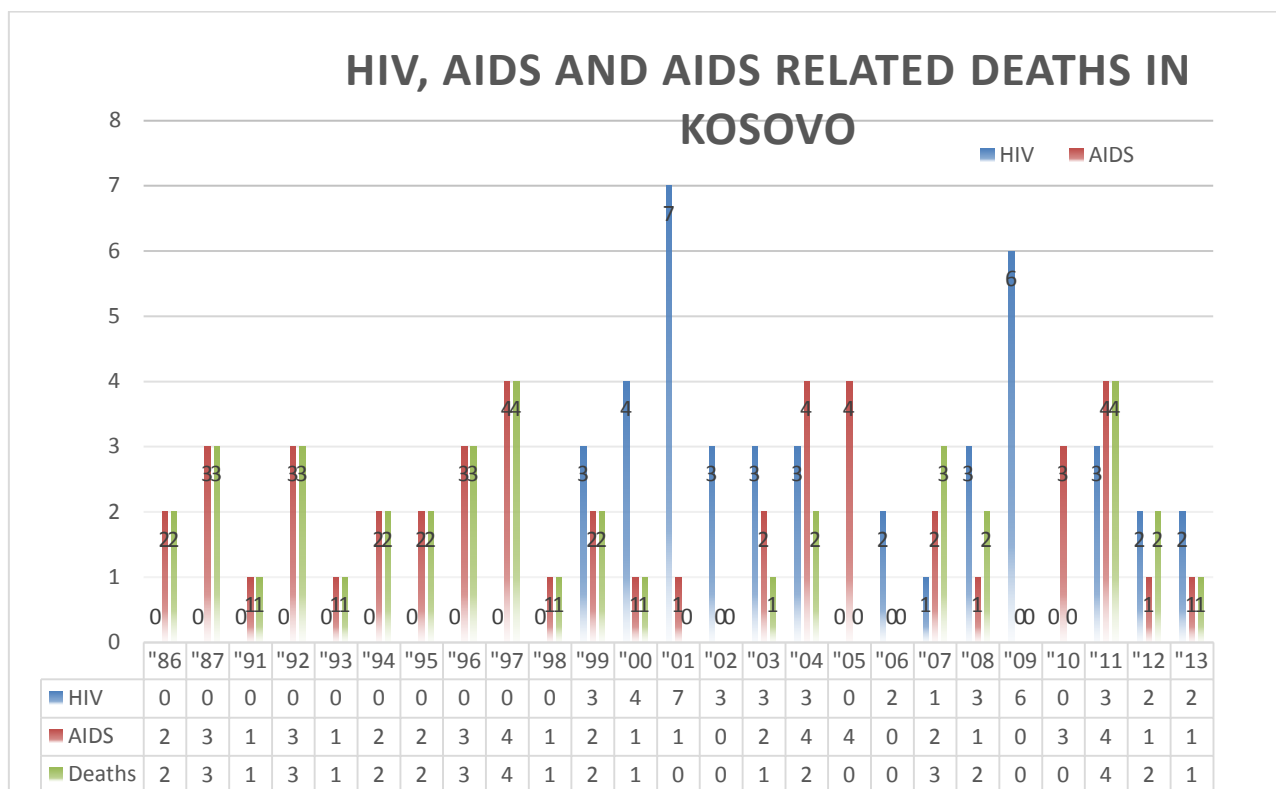


Fig. 1: HIV, AIDS and AIDS related deaths in Kosovo for 1986 – 2013 (4)

Of the 90 registered HIV cases, 48 are registered AIDS cases (4). The number of AIDS related deaths is 40 to date. Of the 50 who are believed to be still alive, only 20 are followed up on treatment in Kosovo, of whom 6 are being monitored and 14 are enrolled in antiretroviral therapy (ART). PLHIV not accounted for in Kosovo surveillance system is relatively high, at 60%. Various sources during the field visit suggested that explanation for this rather large percentage may lie in the fact that Kosovar PLHIV may be receiving HIV services in some of the neighbouring countries. This seems plausible given the highly stigmatized society attitudes towards PLHIV and key affected populations (KAPs) and the ease of registering for provision of ART in neighbouring countries, such as the former Yugoslav Republic of Macedonia, Serbia and Albania (due to proximity and dual citizenship).

The possibility of a high proportion of undiagnosed infections makes it difficult to estimate overall HIV prevalence accurately and to confirm whether HIV incidence has remained stable. No estimation process for PLHIV has been carried out to date and, on current testing figures, it would be difficult to make an estimate with any degree of accuracy. The number of registered HIV cases disaggregated per age group is:

00-14	3 (3%)
15-24	8 (9%)
25-34	32 (36%)
35-44	28 (31%)
45-54	15 (17%)
55+	4 (4%)

Total number of AIDS related deaths is 40 (44.5%) and the number of AIDS related deaths disaggregated per age group are shown below:

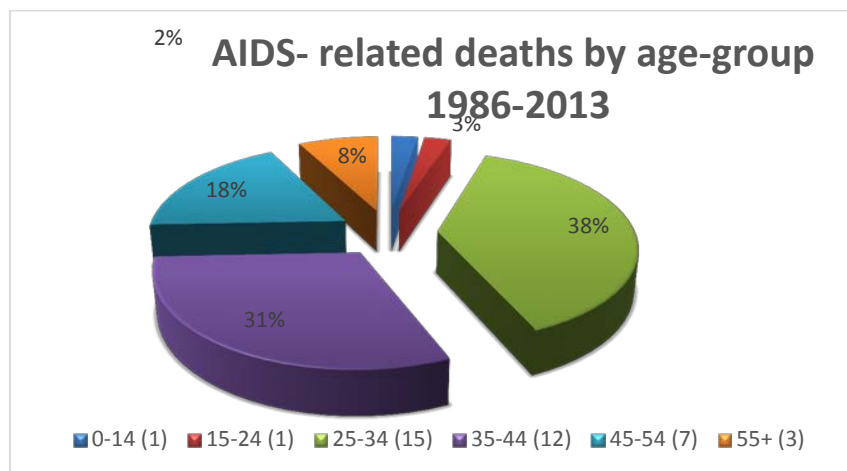


Fig. 2: AIDS related deaths per age group

Although the majority of cases have been registered in Pristina, the figure below shows the data disaggregated for all 20 municipalities.

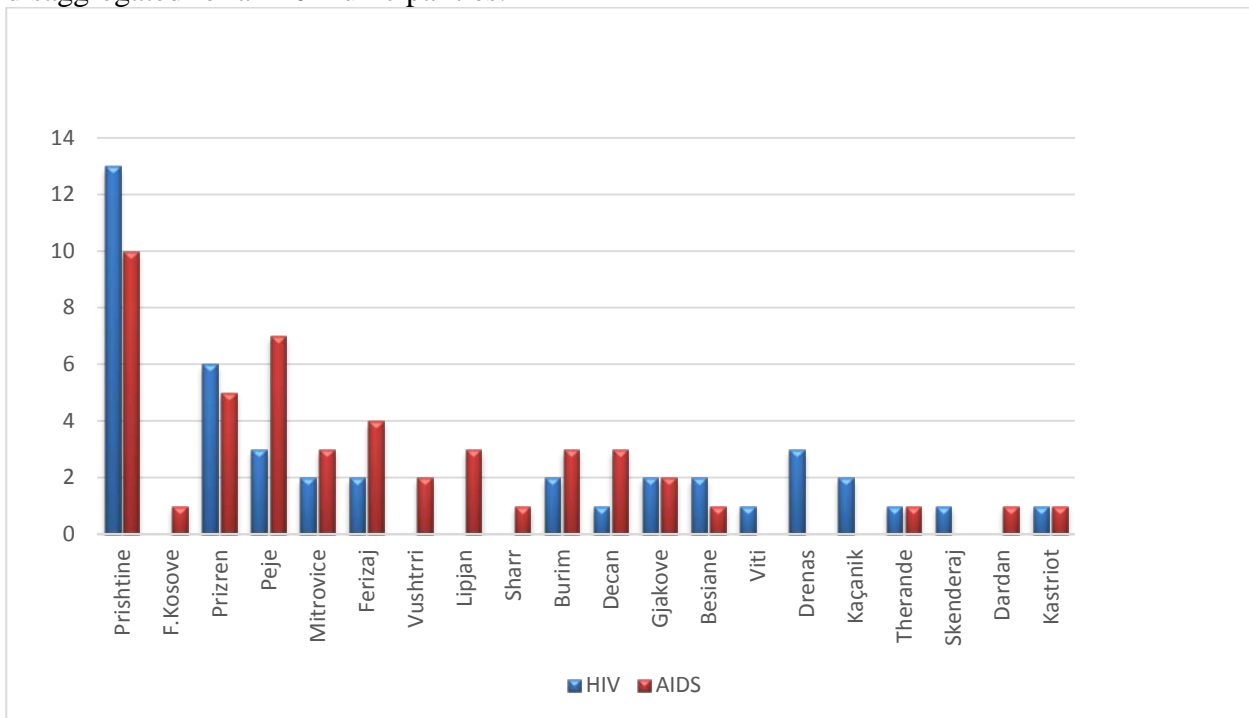


Fig. 3: HIV/ AIDS cases disaggregated by municipality

Mode of transmission, cumulative (1986-2014), for registered cases is as follows: heterosexual – 79 (88%), MSM – 8 (9%), PWID – 1 (1%), and Vertical Transmission – 2 (2%). Given the much higher rates of transmission among MSM in particular in surrounding countries, it should be assumed that some people who have stated “heterosexual” transmission are actually MSM. Lately, more transmission has been reported among men who have sex with men.

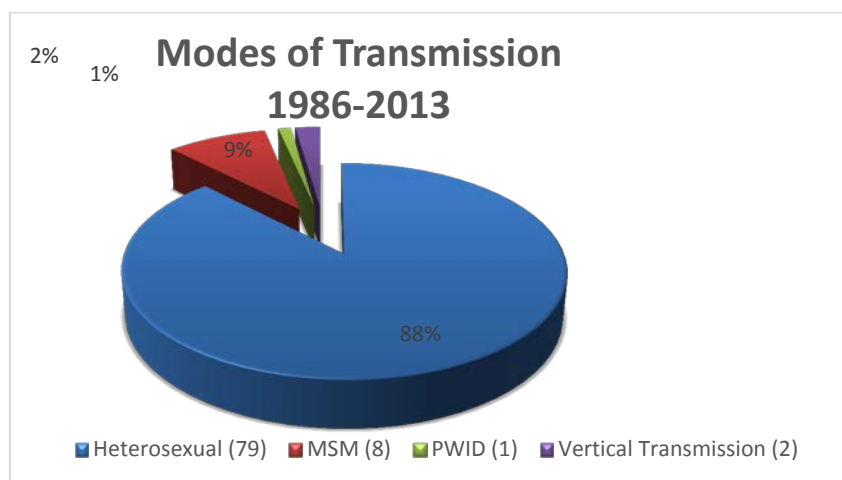


Fig. 4: Cumulative modes of transmission

In the 2014 IBSS, numbers of positive test results for HIV remained low, as did results for other transmissible diseases. The various years are not directly comparable as different populations were surveyed for each IBSS (for example, in 2014, only MSM in Pristina were surveyed; PWID only in Pristina and Prizren; FSW only in Ferizaj) (5,6,7). The hepatitis C rate among PWID, while lower than in 2011, remains a cause for concern both because it reveals a need for hepatitis C treatment, and as a predictor of how widespread HIV infection could become among PWID once it takes hold in this community.

HIV	2006	2011	2014
PWID	0	0	0
MSM	0	0	2.3% (5/217)
FSW	0	0	0
Syphilis			
PWID	0	2%	1.6% (8/499)
MSM	0	2.4%	4.2% (9/217)
FSW	n.a.	3.5%	1.7% (1/59)
Hepatitis B			
PWID	20.1%	6%	4.1% (20/499)
MSM	14.9%	2.2%	5.6% (10/217)
FSW	n.a.	2.5%	0
Hepatitis C			
PWID	12.5%	37.4%	26.7% (133/498)
MSM	0	0.1	n.a.
FSW	n.a.	n.a.	n.a.

In comparison with Kosovo's low number of registered cases, the figure below shows newly diagnosed HIV infections and rates per 100,000 population in the region, by country and year of diagnosis (2006–2012):

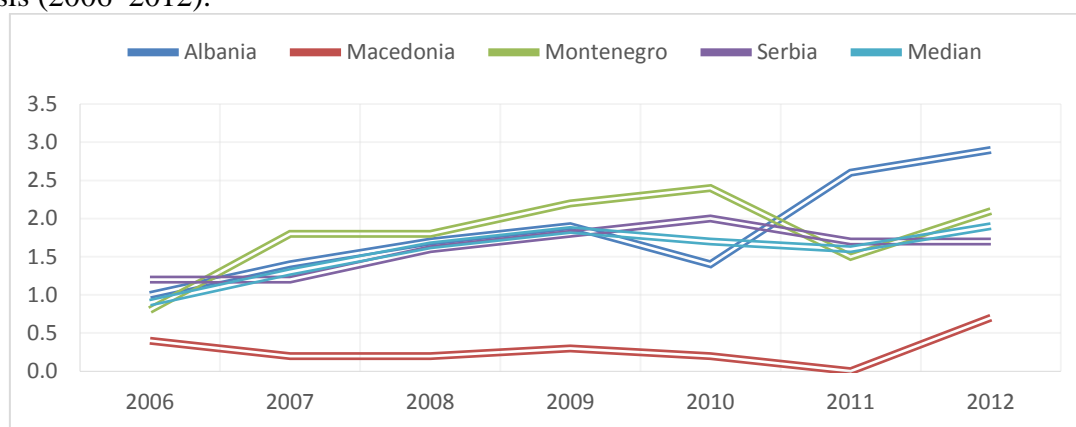


Fig. 5: HIV infections and rates per 100,000 population in the sub-region

Although the TB incidence in Kosovo (47/100,000) is considerably higher compared to its four neighbouring countries: Albania (16/100,000), the former Yugoslav Republic of Macedonia, Montenegro (18/100,000) and Serbia (23/100,000) (8).

In conclusion, the HIV epidemic in Kosovo remains, most likely, a small epidemic with the potential for growth, particularly among men who have sex with men and people who inject drugs. Further work is required to strengthen surveillance and to map and estimate the sizes of key populations. This data will assist in planning and implementing the HIV programme to the scale needed to address both the current epidemic and any new infections that emerge in the years to come.

2.2 Investments in the HIV/AIDS response

As the new HIV Strategic Plan is being developed for the period 2015-2020, the current Strategy for the period of 2009-2013 is still valid and in place. Development of the 2009-2013 Kosovo Strategic Plan on HIV /AIDS was aligned with international standards and supported by UNAIDS/World Bank technical assistance in order to develop a well-prioritized, evidence-based, results-focused and costed AIDS strategy. The process was inclusive and involved main stakeholders in the HIV response. The main goal identified in the 2009-2013 Kosovo Strategic Plan on HIV/AIDS (9) is:

“To maintain the current low HIV prevalence rates among key populations at higher risk in Kosovo below 5% and prevent HIV from spreading into other groups of the general population; and mitigate the impact of HIV and AIDS on persons infected and affected, as well as on society as a whole”.

In 2011, the Ministry of Health (MoH) developed and adopted an Administrative Instruction for HIV-AIDS which includes guidance for the activities, structure and functions of the HIV/AIDS response and related health services. Officially there is no central post-exposure prophylaxis Protocol (PEP) and relevant decisions are made on a case-by-case basis.

A Central AIDS Account was never established, which has made it impossible for Kosovo to participate in National AIDS Spending Assessment (NASA) reporting, which is scheduled biennially through the process of Global AIDS Response Progress Report (GARPR). The international reporting was done through Serbia until 2012 when Kosovo began to participate separately in regular international reporting processes (GARPR, ECDC DD). ARVs are on the essential drug list and the budget for covering the cost of ART comes from the Pharmaceutical Department (MoH); the cost of test services is covered by the MoH.

In 2013 the cost of ARV medicines for ART covered by MoH amounted to EUR 40,000 and approximately EUR 16,000 for cost of testing services. UNICEF has supported MoH in the procurement of ARV therapy for PLHIV, while confirmatory testing with Immunoblot, CD4 cell count, viral load and resistance tests are performed at Pasteur Institute in Paris, France.

Beginning in 2006, WHO supported the development of guidelines for STI surveillance, but the developed guidelines have not yet been officially adopted. WHO guidelines were translated in Albanian and Serbia language, and health staff were trained to implement these guidelines. In addition, in 2012 UNFPA supported the MoH in developing a draft of Guidelines for STI

Syndromic Management but the draft guideline has also not yet been officially adopted. Solidarity/Swiss Fund supported a series of trainings for health workers in cooperation with the Institute for Public Health. The trainings were aimed at increasing HIV, HBV and HCV prevention knowledge and improvement of workplace conditions for health workers: 100 health workers attended the trainings and 200 manuals were distributed.

Kosovo AIDS Committee (KAC), restructured in 2011, is the body in charge of coordination of main institutions and stakeholders in the HIV/AIDS response. The KAC has 20 members representing various relevant institutions and sectors with a mandate to coordinate the appropriate and strategic response.

2.3 General health care

As is the case in the region, the health system in Kosovo is based on Semashko's model of health care delivery, meaning the health system is owned and controlled by the state and health care is free for all citizens (10). The government role is both as the purchaser and the provider of health care services, while municipalities (through health departments) are responsible for public health care. Since 2002, the Kosovo Ministry of Health (MoH) is responsible for policy development, strategic planning, licensing, quality assurance, and budgeting. MoH's primary role is to monitor, supervise and support both the hospitals and primary health care, including the following institutions: Kosovo Medicines Agency, Kosovo Food and Veterinary Agency (KFVA) University Clinical Centre (UCCCK) of Kosovo National Institute of Public Health (NIPH), Kosovo Health Care Commissioning Agency (HCCA). HIV services are regulated by the "Administrative Instruction (Health) No 02/2011 the activity, structure and functions of health services for HIV-AIDS" (11); this instruction clearly mentions harm reduction programmes and the need to make available MMT programmes to drug users.

Today, public health care services in Kosovo include the Central University Clinical Centre in Pristina, seven regional hospitals managed by the Ministry of Health, and a network of family medicine health centres managed by municipal authorities. In 2002, the Kosovo Health Reform process was initiated with the support of international agencies and donors. The Health Sector Strategy 2010-2014 now serves as a guideline for the development of the Kosovo Health System - in line with the government's financial resources and based on the health priorities developed in order to achieve the Millennium Goals. While a legal framework is now in place for the health care system in Kosovo, implementation has been slow and much remains to be done. The Law on Health Insurance was approved in 2014 and is expected to be implemented in the near future (12).

The 2012 USAID / UNDP Kosovo Mosaic Survey: An overview of perceptions on public services and local authorities shows a decrease in satisfaction from 2009 to 2012 with health care services in relation to the quality of staff, equality of treatment and access to medicines and supplies (13), while the report for Public Health Reform conducted in 2010 finds that many Kosovo citizens travel to other countries for health care services, due to distrust and a lack of confidence in the existing health system (14).

3. Purpose and objectives

The purpose of this evaluation of HIV/AIDS treatment and care was to assess the achievements, strengths and shortcomings in the implementation of the Kosovan programme on HIV/AIDS prevention, treatment and care; and to generate strategic recommendations for improving key outcomes and impacts.

Specific objectives were to provide recommendations on how the procurement and provision of ART can be organized, and how prevention work can be improved.

4. Methods

The evaluation builds on a desk review and a mission to Kosovo which took place from 26 September to 3 October 2014 in Pristina, Prizren, and Ferizaj.

Readily available information on the epidemic and HIV/AIDS treatment and care has been drawn from secondary sources including journal articles, publications, WHO reports etc.

During the country mission, the WHO experts met with representatives of World Health Organization, Ministry of Health, Ministry of Culture, Youth and Sports, Country Coordinating Mechanism (CCM), Infectious Diseases Clinic, Blood Transfusion Centre, Institute of Public Health, Pristina University Clinical Centre, United Nations Population Fund (UNFPA), persons living with HIV (PLHIV), civil society organizations - Community Development Fund (CDF), Integra, Labyrinth, Kosovo Population Fund (KOPF), Centre for Social Group Development (CSGD) and other partners (see complete list in Annex 2).

5. Findings – strengths and achievements

5.1 HIV testing

HIV testing is carried out at a low level in Kosovo. While much of the HIV testing is directed towards key populations, there are insufficient numbers of key populations being tested to understand the extent of the epidemic and to ensure that people with HIV are offered treatment.

In 2012, the Kosovo Government developed and adopted a Guideline and Protocol for Voluntary, Confidential, Counselling and Testing (VCCT) (15). Relevant medical staff was trained for provision of VCCT services prior to 2009. One VCCT Centre was established in 2003 and is located at the Pristina Clinic for Infectious Diseases. VCCT services for the general population are available in the Infection Disease Clinic where 1,125 tests were carried out in 2013. VCCT for KAPs is voluntary and total of 1,452 tests were provided by NGOs in 2013. HIV testing for prisoners is voluntary as well and a total of 280 tests were carried out in 2013 in the prison setting. Anonymous HIV testing is available at several private laboratories in Kosovo, but the data on actual number of tests carried out is not reported and therefore is not available.

The number of HIV tests carried out through GF Programme in 2013 was 1,690, out of which:

597 PWID	0 HIV+
463 FSW	0 HIV+
350 MSM	0 HIV+
280 Prisoners	0 HIV+

The number of HIV tests for KAPs carried out through Clinic for Infectious Diseases in 2013 was 232, of whom 92 had no registered risk factors; 23 were PWID and 19 were MSM.

While further research is needed to show strong evidence that an epidemic is quietly growing among MSM, other data clearly shows the potential for rapid spread of HIV, especially among PWID, at any time in the future (37% of PWID had hepatitis C in 2011 IBSS (5), falling to 21% in 2014 IBSS). The high proportion of undiagnosed infections makes it difficult to estimate the overall HIV prevalence accurately and to determine whether the HIV incidence has remained stable or not. The incidence trend over time is thus highly subject to introduction of new testing policies in addition to a possible actual increase of new infections.

Kosovo Centre for Blood Transfusion is the nationally coordinated blood transfusion service guided by the international protocols and is in charge of:

- collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- reduction of unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible

A total of 114,974 blood units were donated in the period from 2009 to 2013 and screened for HBV, HCV and HIV. The number of tested blood units in 2013 was 25,589. No HIV-positive cases were found.

5.2 Services for Key Populations at Risk (PLHIV, PWID, SW, MSM, prisoners and youth)

People who inject drugs

Outreach and other elements of the Comprehensive Package of Services for PWID are operating well, with the exception of opioid substitution treatment. Harm reduction is included in both the previous HIV Strategy and in the Strategy on Narcotics 2012-2017, including peer education for PWID (16) which is funded by the Global Fund Programme.

The most active Nongovernmental Organization working with PWID is Labyrinth, founded in 2002 in Pristina. It has two sets of services: prevention, dealing with prevention of drug abuse and infectious diseases associated with injecting drug use (HIV, hepatitis B and C); and treatment which provides methadone maintenance treatment (MMT) and psycho-social assistance for PWID. Labyrinth has a multidisciplinary centre in Pristina and two drop-in centres in Gjilan and Prizren. The wide range of services provided by Labyrinth to PWID in these cities includes:

- needle and syringe exchange programme, including outreach activities
- voluntary, confidential, counselling and testing for HBV, HCV and HIV
- drop-in centre services
- psychosocial counselling
- primary health care & medical referral
- ambulatory detoxification (outpatient)
- psycho-pharmacotherapy
- rapid drug assessment
- individual, group and family therapy
- counselling for parents and interested parties
- MMT (Pristina only)

The Labyrinth model is to provide needles, syringes, other injecting equipment, condoms, and education and information on drugs and HIV through outreach to “sites” (mostly damaged/ abandoned houses, factories and other buildings) which function as “shooting galleries” where PWID come to inject their drugs. Through provision of injecting equipment and building trust through outreach, PWID are encouraged to come to the drop-in centre. There, several choices can be made. A HIV test is encouraged with pre- and post-test counselling (using a rapid test kit), MMT is offered, as are various forms of counselling and assistance for those trying to control or cease drug use. In addition, a common room is provided where PWID can simply sit and watch TV and can ask questions of passing staff.

Labyrinth drop-in centres visited by the review team in Pristina and Prizren are friendly, inclusive and in spaces well-designed for multiple purposes (including MMT dosing, accessing sterile injecting equipment, counselling, group work etc.). Labyrinth staff training and education level is appropriate which ensures that regular clients are provided with services of high quality. Most notably, and in contrast to trends in the region, very good relationship and cooperation was reported between Labyrinth, law enforcement and health services.

The main problem with this model in most countries is that it develops into a “club” which does not welcome new clients. This does not seem to be the case at Labyrinth, possibly because they have quickly moved to significant numbers of PWID as regular clients (given the estimated size of the PWID population). Labyrinth reached 2,795 PWID in 2013, of the 30,000 estimated PWID in Kosovo (5) and distributed 32,832 sterile injecting sets - which gives a “needles and syringes distributed per PWID per year of 25 per drug user reached or just over 1 per drug user in Kosovo, which is extremely low: the WHO target is usually around 144/PWID/year (17). Using the WHO target, needle-syringe programmes should be distributing (or ensuring access to) 4.32 million needles and syringes per year.

The opioid substitution programme in Kosovo provides methadone maintenance treatment (MMT). MMT in Kosovo was established after the Kosovo Government in 2010 developed "Administrative Instruction No.10/2010 on Methadone Administering and Managing for the Maintenance Programs", followed by the 2012 Working Protocol for Methadone Maintenance Treatment (MMT) in Health Institution. MMT is available at 5 sites (including 1 in prison settings). The number of PWID enrolled in MMT as of October, 2014 is:

- Labyrinth: 47 (from 113 enrolled since 2012)
- University Clinic: 16 (from 44 enrolled)
- Prison: 1 (from 15 enrolled)
- Gjilan regional hospital: 24 (from 50 enrolled)
- Gjakova regional hospital: 10 (from 36 enrolled)

Based on the data available from 2014 IBSS for KAPs, PWID use of sterile needles the last time they injected is 83% in Pristina and 91% in Prizren. Fewer than 20% of PWID received HIV counselling and testing services in the past 12 months but, of those, 96% know their result (5).

Many of the elements are in place in Kosovo to develop and scale up implementation of the Comprehensive Package of Services for PWID.

Men who have sex with men

Outreach and other elements of the Comprehensive Package of Services for MSM are operating well in Kosovo. The Centre for Social Group Development (CSGD) is an NGO working with the lesbian, gay, bisexual and transgender (LGBT) populations of Kosovo. CSGD has reported that because of cultural and traditional attitudes, gays and lesbians have difficulties in revealing their sexual orientation. Similarly, Libertas Kosovo, a local NGO that provides emergency shelter and counselling to LGBT individuals, claims the majority of transgendered LGBT persons did not publicly acknowledge their sexual identity for fear of social ostracism, employment discrimination, or renunciation by their families (18). LGBT people who have experienced stigma or discrimination do not want to come forward and use the anti-discrimination avenues of redress because this would result in publicity. "There were no overt impediments to the centre's operation; however, social pressure and traditional attitudes had the effect of limiting its activities" (18).

CSGD provides the following Services for the MSM population in 6 cities in Kosovo:

- safe sex packages to 1,390 MSM through outreach workers and peer educators
- 350 VCCT services
- group education (workshops)

CSGD premises in Pristina (visited by the review team) were substantial and provided spaces for many simultaneous activities such as testing and counselling, group education, and CSGD office work. Based on the 2014 IBSS among KAPs, 70.3% of the MSM sample reported condom use at last anal sex, a substantial increase over the 2011 figure (52.5%). Percentage of MSM tested for HIV in the past 12 months was 46.5%, and 92.7% of these know their result. Percentage of MSM

who received counselling and testing services and know their result in the past 12 months is 67.9%. Almost 7% of MSM surveyed in Pristina had been paid for anal sex in the past 12 months. This suggests a population of 3,100 male sex workers out of the total estimated MSM population of 45,632 (5).

While the main successes of MSM services include good geographical coverage (6 main cities plus suburbs of each city) and moving towards implementation of the Comprehensive Package of Services, the challenges remain: very high stigma, difficulties reaching young MSM who mostly seek sex partners on the internet, and Serbian-speaking MSM in Mitrovica (north) are very hard to reach. In order to address the latter population, CSGD has established a working partnership with Serbian NGO.

Female sex workers

The main success of work with FSW is the fact that some FSW are reached in spite of very difficult political environment. The main challenges in working with FSW in Kosovo is the decrease in number of persons reached and services not being aligned with Comprehensive Packages of Service for this specific population.

The most active Nongovernmental Organization providing services to FSW population is the Kosovo Population Fund (KOPF). KOPF is using a coupon system to provide free HIV/STI testing and SRH services to FSW. In addition, 59,040 condoms were distributed among FSW in 2012, funded by Global Fund and managed by CDF. A population size estimation for FSW was carried out in 2014 through IBBS but due to reliability issues, a mapping exercise is currently being conducted with GF support.

People living with HIV

Nongovernmental PLHIV support services appear to be working well in Kosovo, to the extent that they are able to reach and work with HIV-positive people. The Kosovo Association for people living with HIV/AIDS (KAPHA) offers a variety care and support services for all PLHIV. Services KAPHA provides to PLHIV include psycho-social and medical counselling (for members of their family and/or partners as well), special PLHIV support packages, promotion and awareness raising among health care and social workers to ensure adequate provision of health services.

Prisoners

The incarceration system in Kosovo comprises six detention centres and two prisons, with a total population of approximately 1,600 detainees, of whom the majority are located in the high security “Dubrava” prison for men. HIV and STI testing services are available for prisoners on a voluntary basis. As observed earlier, the potential for prisons to become sources for rapid HIV spread, if adequate measures are not taken, has not been addressed to date.

Youth

Substantial HIV prevention activities have been carried out to date with youth in Kosovo. The main prevention activities targeting youth in Kosovo are peer education, training of peer educators, distribution of sexual and reproductive commodities, distribution of IEC materials and awareness raising activities.

The Ministry of Education, Science and Technology (MEST) and Ministry of Culture, Youth and Sports (MCYS) ensured that education on healthy life styles (including information on SRH and HIV/STIs) is offered in the curricula of 398 schools throughout Kosovo, supported by the GF grant. Starting in 2009, a total of 500 teachers received HIV/AIDS training through support provided by the GFATM programme in Kosovo.

United Nations Population Fund (UNFPA) implemented activities for youth in cooperation with Nongovernmental Organizations, namely Peer Education Network (PEN), Artpolis and KOPF. This cooperation included implementation of awareness raising activities, distribution of information, education and communication (IEC) material for HIV/AIDS and STIs, distribution of sexual and reproductive health commodities, theatre performances, training of trainers and training of peer educators.

In 2013, UNFPA in a social marketing collaboration with KOPH provided services for youth and the general population on "Improving Reproductive Health and Behavior Change" including 639,720 condoms distributed through pharmacies: 25,339 through condom vending machines; and free distribution of 30,672 condoms.

Data available from the Knowledge, Attitudes, Practices and Behaviour Study On HIV/AIDS with Young People In Kosovo (KAPB) carried out in 2008 (19) show that 55% of young people aged 15-24 report the use of condom last time they had sexual intercourse with non-regular partners; 17.7% of male and 17.3% of female (age 15-19: 16% and age 20-24: 20%) age 15-24 correctly identify ways of HIV prevention, and reject major misconceptions about HIV transmission. "Research on the market of preservatives in Kosovo" carried out by UNFPA and KOPF in 2010 (20) indicate that that 46.3% of people aged 15-45 report the use of condom during the last sexual intercourse.

6. Findings – weaknesses and challenges

6.1 HIV testing

In spite of plans for opening eight VCCT Centres in total, only one is functioning in the public sector at the moment. There is an urgent need for Kosovo to develop and start the implementation of a HIV testing and counselling strategy, introduce provider initiated HIV testing and counselling (PITC) to the health care system, as well as expand and improve community-based HIV testing and counselling for KAPs. This is highlighted by results from the 2014 IBBS (5) showing that only 41% of PWID in Pristina and 27% in Prizren knew where to get a free and anonymous test for HIV.

PITC should be recommended in all health facilities for:

- adults, adolescents or children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB;
- adults, adolescents or children who present in clinical settings with signs and symptoms of viral hepatitis B or C or have laboratory markers of HBV or HCV;
- HIV-exposed children, children born to women living with HIV and symptomatic infants and children;
- pregnant women;
- key populations (notably men who have sex with men, transgender people, sex workers and people who inject drugs) accessing sexually transmitted infection, hepatitis and TB services, antenatal care settings and services.

HIV testing of pregnant women is voluntary and only two HIV positive cases of MTCT/vertical transmission were registered since 1986. The only exception to the rule of voluntary testing for pregnant women is Caesarean section delivery, in which case pregnant women need to be tested for HIV. The last detected paediatric HIV positive case was diagnosed just before the death of patient which indicates lack of access to HIV testing for pregnant women and missed opportunity to provide PMTCT interventions.

Main recommendations

1. Develop a HIV testing and counselling strategy to allow identification of PLHIV as early as possible after acquiring HIV infection. Those found to be HIV-positive should be linked appropriately and in a timely manner to prevention, care and treatment services. The linkage between the testing and treatment services should be strengthened through development of appropriate policy, normative acts and precise terms of reference for referral.

Specific recommendations

1. As described in detail in the WHO Consolidated guidelines on HIV prevention, diagnosis, treatment and care for Key Populations, rapid HIV diagnostic tests are strongly recommended to be used at point of care or by NGOs and have become an important tool to expand access, provide rapid testing results and enable appropriate linkages and follow-up.
2. As the equipment for performing all testing services is available in Kosovo and health care workers are trained for utilising this equipment, the HIV reference Laboratory should carry out these tasks forthwith.

6.2 Services for Key Populations

People who inject drugs and men who have sex with men

Many of the elements are in place in Kosovo to develop and scale up implementation of the Comprehensive Package of Services for both PWID and MSM. The main challenges in working with PWID and MSM will be scaling up activities to reach and test 80-90% of clients regularly as stipulated by international standards (21), including HIV tests for up to 90% of clients (twice a year).

However, the number of PWID on MMT (98, less than 0.3% of the estimated number of PWID) is extremely low - the usual target is 40% (16) - and the figures provided above highlight a serious issue with retention. A dropout rate of 56% (160 of 258 ever enrolled) is far higher than in most countries (where the average is around 20-30% due to travel, death, attempts/success at stopping drug use). These data suggest serious problems in the MMT system. It should be noted that Kosovo has carried out an assessment of its MMT system, with international technical assistance. This assessment noted the need to scale up MMT services and to investigate the high dropout rate (22).

Additional activities have to be developed in order to reach the population of young female PWID, as well as Serbian-speaking PWID in Mitrovica who were hardest to reach in the past years. While scaling up reach, special attention has to be paid to retaining quality of services for PWID.

Challenges to be faced in scaling up services for PWID include high stigma (including from health care workers towards MMT clients); ways to increase MMT enrolment and retention at government sites (including prisons); increasing family and community understanding of benefits of MMT. At present, the system is not prepared for an increase in HIV-positive cases among PWID and procedures need to be established to provide ART and MMT together if/when they are needed.

FSW

Although previously KOPF provided HIV services to sex workers in five cities, only one location is presently active (in Ferizaj, visited by the review team). Closure of other sites is mainly caused by problems in cooperation with law enforcement and limited access to FSW. The main challenges in working with FSW in Kosovo is the decrease in the number of persons reached and services not being aligned with Comprehensive Packages of Service for this specific population.

Based on the data from the 2014 IBSS among KAPs, only 33% of female sex workers reported using condoms with all clients. Almost 40% of FSW interviewed had been offered more money to have sex without a condom: of these, one third agreed to have sex without using a condom the last time this offer was made. The average number of clients per week was three in Ferizaj: if this figured is found to be true across SW in other cities, with an estimated population of 6,342 FSW (5), this means the annual need for condoms among FSW is at least 989,352.

PLHIV

Nongovernmental Organizations working with PLHIV should be adequately strengthened and provided with a clear role in the HIV response in Kosovo (e.g. as “expert patients”), to reduce currently observed loss to follow-up, to provide community-based services, as well as testing services ensuring linkages to HIV treatment and care.

Prisoners

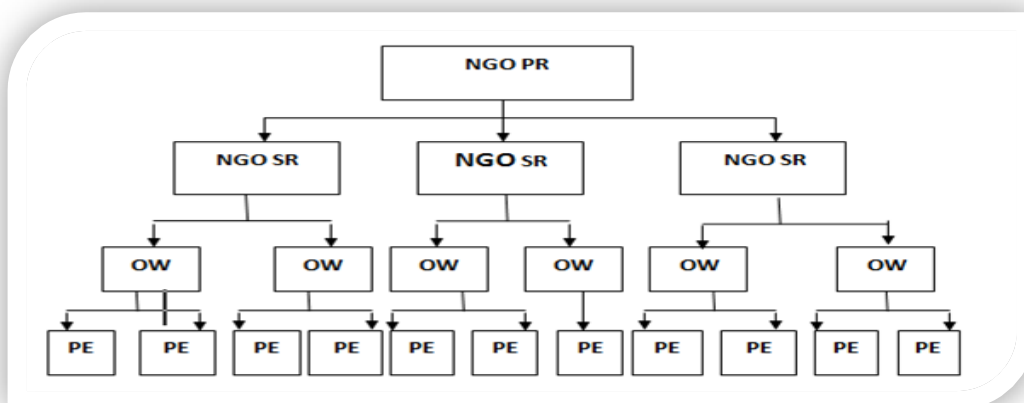
The statement from the 2009-2013 Kosovo Strategic Plan on HIV /AIDS that “...very little is known about prisoners' sexual practices, including same-sex practices, nor about their sexual health-care needs. Unprotected sex among male prisoners, including rape and other forms of sexual violence, may lead to STI or HIV infection...” points the direction that needs to be taken for successful programming activities for this population.

Main recommendation

- Scaled-up HIV prevention activities and testing among KAPs should be the priority for a successful HIV response (including the nascent MSM epidemic and addressing risk factors present for possible explosive epidemic among PWID). There is an urgent need for the introduction of new, attractive and effective programmes which will increase targeted HIV testing in Kosovo among KAPs and pregnant women.

Specific recommendations

1. Services for FSW need to be reconceptualized and developed based on research. Based on the potential for spread among FSW and their clients, these populations should remain a priority for prevention and research activities in the future.
2. A scaled-up outreach and peer educator system should be considered for all identified KAPs. Based on recent population size estimates and reach figures provided for 2013, a significant scale-up of services for key populations is required. Possible approaches to be used include utilising salaried outreach workers (OW) and incentive based activities carried out by peer educators (PE). Peer educators should be recruited from most-at-risk subpopulations such as MSM who also inject; FSW who also inject; etc. An example of establishing an efficient outreach system:



2

3. All policies and activities for KAPs should be harmonized with international standards, particularly the WHO Consolidated Guidelines on HIV Prevention, Treatment, Care and Support for Key Populations (1). As the process to bring current services towards Comprehensive Packages is consultative by nature, meetings of KAPs to deal with gaps and barriers can also be used as Community Consultations for the development of future GFATM Concept Notes.
4. Attractiveness of enrolment to and retention in MMT programmes should be increased, including ensuring that administrative procedures in the Memorandum of Understanding between MoH and CDF facilitate access to methadone as needed during the scale-up.
5. Appropriate training should be provided to all health care workers involved in MMT prescription, dosing and monitoring, including the proper health care approach in working with PWID.
6. The draft Guidelines for STI surveillance, and Guidelines for STI Syndromic Management, should be adopted and used as the basis for scaling up STI services for key populations.

Further research is needed to:

- a) understand the reasons for high MMT dropout and for low rates of MMT enrolment in health institutions and prison settings;
- b) determine the most effective way to reach and involve FSW in HIV prevention activities and testing service, including ways to work effectively in the current law enforcement / political environment;
- c) provide mapping of population sizes in the largest population centres in Kosovo, in order to assist effective programme planning and monitoring;
- d) determine risk factors for Roma, Ashkali and Egyptian youth to develop prevention programmes for these youth, if needed.

²The diagram refers to an NGO Principal Recipient of a Global Fund project; SRs are Sub-Recipients (in this case, also NGOs); OW are outreach workers and PE are peer educators

6.3 HIV treatment and care cascade

Currently, there are no developed and approved standard clinical protocols for HIV clinical case management in Kosovo. In most cases physicians are guided by the European AIDS Clinical Society (EACS) Guidelines for the Clinical Management and Treatment of HIV-infected Adults (23) for considering ART initiation. Assessment of HIV patients at initial and subsequent visits is supposed to be done according to the same guidelines. There is some necessary laboratory equipment for ART monitoring, however the test kits and consumables are not being procured.

Tenofovir/Emtricitabine + Efavirenz is the first choice of ART regimen while initiating ART for PLHIV without prior ART exposure. The necessary immunological and virology tests (CD4 cell count and viral load testing) for PLHIV assessment visits are implemented outside of Kosovo, at the Pasteur Institute in Paris, France. The remaining laboratory assessments are done in Pristina, Kosovo.³

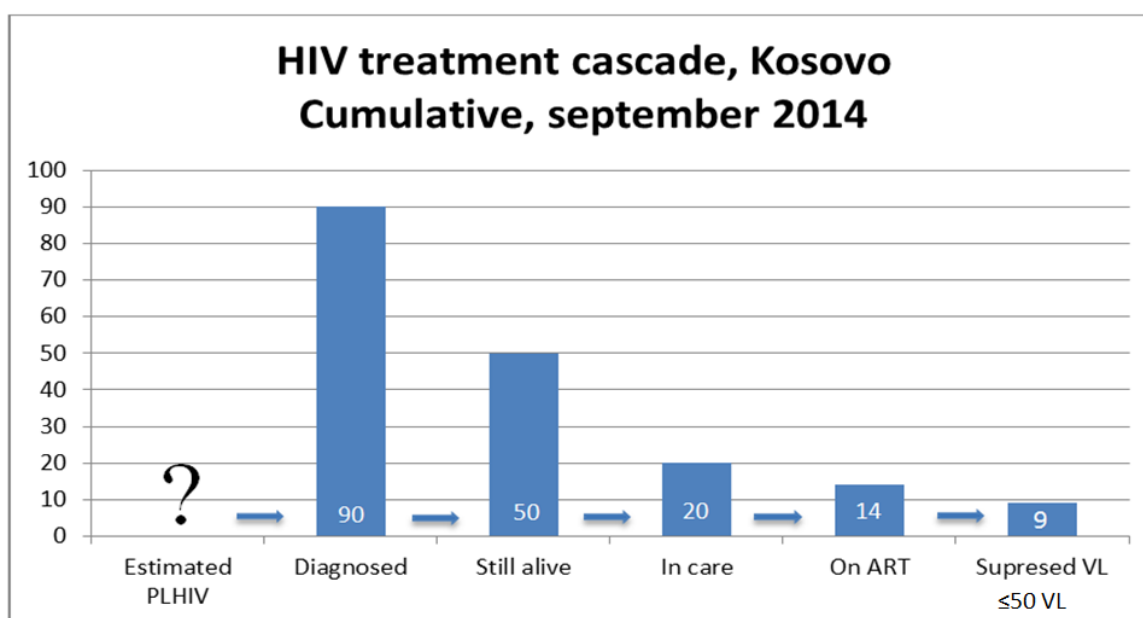


Fig. 6: Cumulative HIV Treatment cascade, as of September, 2014

While 40 people from 90 diagnosed with HIV in Kosovo have died, the cause of death is not tracked within the system. Only 20 people from 50 PLHIV that are alive are attending the infection disease clinic for care and follow up. The reason for loss to follow-up in case of 30 PLHIV in Kosovo is not known. Out of 20 PLHIV included in follow-up, 14 are receiving ART and the remaining 6 have no indications for ART initiation. Only 9 (of 14 PLHIV on ART) have suppressed viral load.

³Coinfections (STIs, hepatitis, Tuberculosis and others); Co-morbidities (Liver disease - ALT/AST, ALP, Bilirubin; Renal disease - eGFR (aMDRD); Lipids - TC, HDL-c, LDL-c, TG; Glucose – blood glucose; Hematology)

From the available viral load data of PLHIV enrolled in ART, it is plausible that treatment interruption is caused by frequent ARV stock outs, inappropriate follow-up procedures and absence of standardized clinical protocols negatively affect the therapy results and the overall health condition of PLHIV.

	1st VL result		VL at subsequent assessments⁴											
Patient 1	290	49	16,57	1,261	<20	<20								
			4											
Patient 2	161	>20	>20	104										
Patient 3	2,113	2,004	>20	>20	>20	<20	<20							
Patient 4	256	<20	<20	<20	23	54	<20	28,34						
								7						
Patient 5	92,075	<40	<20	21	37	52	<20	21,41						
								9						
Patient 6	448,63	<20	24,79	6,360	39,59	67	<20							
	1		7		9									
Patient 7	21,517	<40	<40	<20	<20	1,92	58	<20	<20	31				
						1				292				
Patient 8	<40	<40	<20	<20	<20	<20	<20	<20	<20	<10				
Patient 9	204,00	1,910	17,80	<50	71	159	74	19,51	7,69	2,04	58	48	<20	
	0		0				695	0	2	5				
Patient 10	30,900	90,80	48,70	426	<50	<50	<50	<40	<40	<40	<4	<40	<20	
		0	0								0			
Patient 11	782,96	<40	<40	<40	<20	<20	<20	<20	<20	<20	<2	9,51		
	8										0	6		
Patient 12	50,400	<50	<50	<40	<40	<40	<40	<40	<20	<20	36	<20	<20	
Patient 13	19,600	537	<50	<50	<50	<50	<40							
Patient 14	485,00	7,170	<50	146	51	46								
	0													

Fig. 7: Viral load data

⁴ It is impossible to define the frequency of testing because of inconsistent testing intervals and lack of data provided by the clinic.

Currently, four ART regimens are being implemented in Kosovo for 14 PLHIV on ART.

ART regimens	# of patients
<i>Zidovudine / Lamivudine 300/150mg + Efavirenz 600mg</i>	6
<i>Tenofovir / Emtricitabine 300/200mg + Efavirenz 600mg</i>	6
<i>Tenofovir / Emtricitabine 300/200mg + Lopinair / Ritonavir 200/50mg</i>	1
<i>Didanosine 200mg + Avacavir 300mg + Lopinair / Ritonavir 200/50mg</i>	1

Fig. 8: Current ART regimens

CD4 test results in Kosovo do not exhibit the characteristics of typical patients on ART (Fig. 9). The extreme variations in CD4 results again point to the problems caused by treatment interruption due to stock outs.

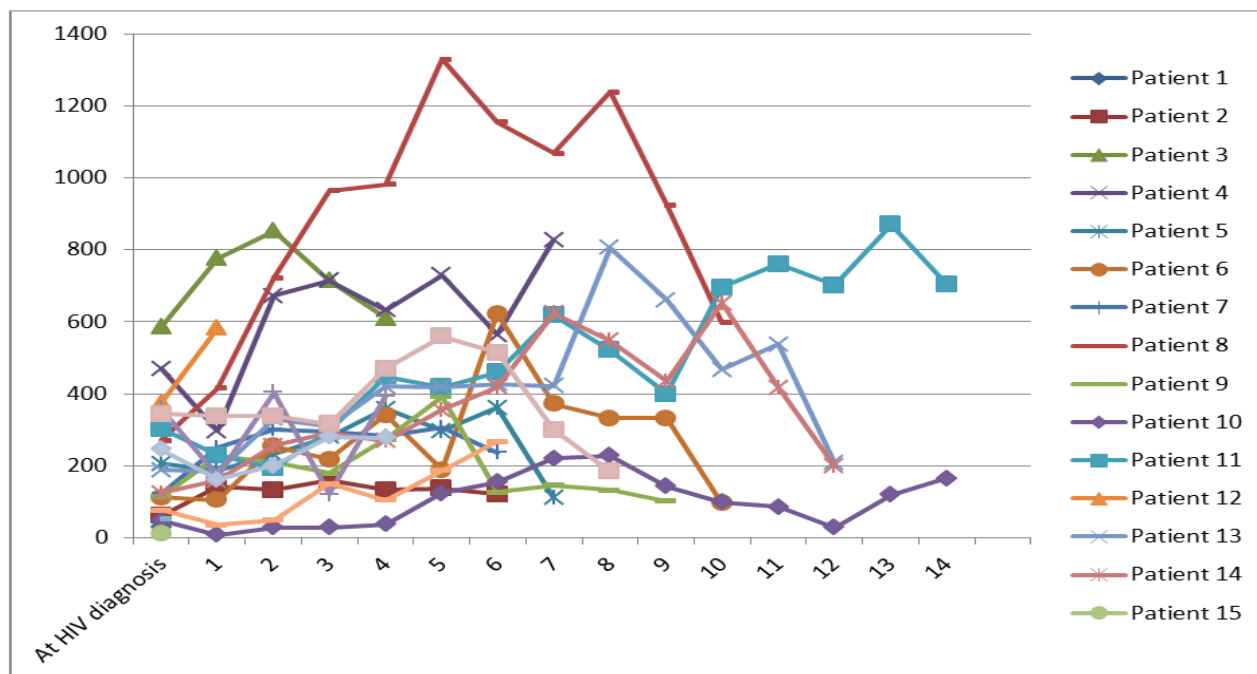


Fig. 9: CD4 count test results in Kosovo (Patient 3 is not receiving ART)⁵

Confirmed HIV-VL > 50 copies/mL six months after therapy initiation (or modification) for PLHIV on ART is considered as a virological failure and physicians responsible for ART follow the recommendations described in European Guidelines for treatment of HIV-infected adults in Europe. There are consistent delays in implementation of necessary immunological and virology tests for assessment of HIV patients at initial and subsequent visits. The required tests are not implemented with the periodicity suggested by any of the existing internationally recognised guidelines. The delays are caused by stock outs of test kits and reagents, and by implementing testing outside of

⁵There is no consistent time interval between the CD4 tests in Kosovo. Tests are performed every 3-4-5-6 months, depending when the clinic is able to collect necessary amount of blood samples for sending to France.

Kosovo and in order to alleviate cost, the blood samples are grouped and sent for testing. At the moment, PLHIV needing results of the analysis have to wait for enough blood samples to be grouped and sent abroad for testing.

As of October 2014, no official data is available on the estimated number of PLHIV in Kosovo. ART is always recommended to any HIV positive person with a CD4 count below 350 cells/ μ L. For PLHIV with CD4 counts above this level physicians are making decisions on case-by-case basis and are guided by the EACS protocol recommendations.

At present 14 PLHIV are receiving regular ARV therapy at the UCC Clinic for Infectious Diseases; 5 PLHIV have no indications for ART initiation (CD4 cell count $> 350/\mu$ L and no other indications) and 1 PLHIV has rejected enrolment in ARV therapy. Of these 14 patients, the mission was told that none were from key populations and none have coinfections. We were informed in the infection disease clinic that there are no MSM and PWID on ART. It is difficult to believe that the PLHIV in Kosovo that are under follow up have no coinfections. There appears to be a lack of testing and that there is a lack of standardized protocols and analysis of comorbidities prevalence and incidence.

In terms of adherence, ART interruptions due to stock out of ARVs in Kosovo and absence of a patient tracking system are the big challenges for achieving sustained viral suppression and substantial CD4 gains.

The loss of 60% of known cases to follow-up due to lack of system in place is a serious concern which needs to be addressed in the future Kosovo HIV programming.

Although the Protocol and Guideline for PMTCT was developed and officially adopted in 2011, so far no capacity building activities were undertaken to ensure proper implementation of the protocol by health care workers.

There is an urgent need to establish a HIV patient tracking system in order to have a viable system for HIV patient enrolment and retention. The ART regimens as well as list of ARVs to be procured should be updated before the new quantification and placement of future ARV procurement requests.

Main recommendations

1. Ensure 90% of people diagnosed with HIV are enrolled and retained in HIV treatment and care programme.
2. Ensure 90% of HIV patients receiving ART have suppressed viral load.
3. Kosovo HIV treatment and case management protocols need to be developed and adopted based on the latest WHO recommendations in order to properly provide ART to PLHIV.

4. Development and approval of new protocols takes time, therefore it is suggested to use the following 1st line ARV regimens for ART treatment initiation for adult and adolescent PLHIV: please refer to WHO guidelines for dosages and administration (24).

Preferred option:

- TDF + 3TC (or FTC) + EFV

Alternative options:

- TDF + 3TC (or FTC) + NVP
- AZT + 3TC + EFV
- AZT + 3TC + NVP

5. Establishing standards for 1st and 2nd line ARV regimens based on WHO protocols will allow physicians to strategically plan treatment regimens and avoid extra cost for expensive HIV drug resistance tests which are currently implemented outside Kosovo.
6. Based on WHO recommendation, using boosted PI + two NRTI combinations is the preferred strategy for 2nd line ART for adults: please refer to WHO guidelines for dosages and administration (24).

Preferred option:

- AZT + 3TC + LPV/r
- AZT + 3TC + ATV/r

(DRV/r can be used as an alternative PI and SQV/r in special situations; neither is currently available as a heat stable fixed-dose combination, but a DRV + RTV heat-stable fixed-dose combination is currently in development.)

Alternative options:

- TDF + 3TC (or FTC) + ATV/r
- TDF + 3TC (or FTC) + LPV/r

Specific recommendations

1. Active follow up with patients (scheduled appointments, SMS reminders, social support) is needed in order to ensure retention and adherence. Consider involvement of civil society organizations representing PLHIV for these interventions.
2. Investigation and management of coinfections and co-morbidities including of HIV/Viral hepatitis, HIV/TB should be standardized.
3. Ensure laboratory monitoring of CD4 cell count and VL in Kosovo for all PLHIV enrolled in HIV treatment and care in accordance with WHO guidelines.

4. Protocols should be developed for providing ART and MMT to HIV-positive PWID, if/when required.

6.4 Management and organization of HIV testing, treatment and care services

Clear roles and responsibility should be defined for all stakeholders in the HIV response, including lines of reporting and management between MoH, Institute of Public Health, Infectious Diseases Clinic, Blood Transfusion Service, NGOs, CDF, Kosovo AIDS Committee and CCM.

Main recommendations

1. MoH, through the HIV AIDS coordinator (or other relevant structure), should coordinate all processes, ensure existence and use of approved and standardized normative documents and reporting forms. MoH should monitor the implementation of all processes and timeline and widely disseminate the received reports among all stakeholders to ensure that only up-to-date information is used while planning for HIV services, programming and decision making.

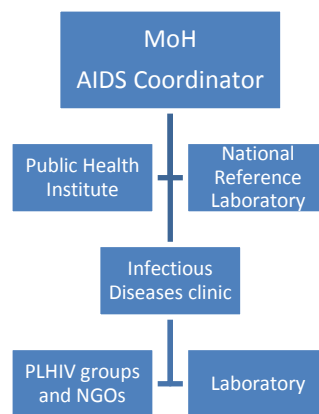


Fig. 10: Organization of antiretroviral treatment - coordination and reporting (Proposed model)

2. The decision of MoH to establish a HIV reference laboratory at the NIPH, adopted on 16.01.2014, should be implemented as soon as possible. The main roles of the reference Laboratory are:
 - a) conducting diagnostics of HIV infection with serological and molecular methods;
 - b) measuring viral load and CD4 count as part of patient monitoring;
 - c) developing Standard Operating Procedures for HIV lab testing;
 - d) overseeing quality of HIV laboratory testing in Kosovo health institutions;
 - e) organizing and coordinating participation of Kosovo institutions in internal and external quality control HIV testing;
 - f) training and educating staff on HIV testing procedures.

Specific recommendations

1. All organizations should refer and follow up HIV seropositive blood samples for confirmatory test to National Reference Laboratory (NRL) for further analysis: it should be mandatory for private laboratories to participate in this process. Organizations working with KAPs should make serious attempts and work with the seropositive clients to bring them for final diagnosis and facilitate their involvement in care.
2. Ministry of Health should approve the referral forms, developed by the Public Health Institute, for referring those with a positive test result to the NRL. Referral forms should contain information related to HIV seropositive person (name or code, sex, age, reason for test etc.) as well as information related to the test (name of HIV test kits, manufacturer, batch number, date of test and optical density) (in case of ELISA test).
3. NRL should develop HIV testing QA protocols and get approval from the Ministry (order) to perform annual HIV testing quality assessment of laboratories in Kosovo, regardless of the type of ownership.
4. The results from all laboratories should be analysed and presented in an annual report to the MoH.
5. As the NRL is located within the NPHI of Kosovo, it should submit a monthly report on HIV tests to the relevant department of the NPHI.
6. National Reference Laboratory (NRL) should inform the “sender” about confirmed HIV positive test, and health care workers from sending the blood sample for HIV organization should be responsible for referral of the HIV-positive person to the University Clinical Centre Kosovo (UCCCK) for the patient’s further assessment, follow up and treatment.
7. Post-test counselling should be provided by trained health care provider in UCCCK.
8. UCCCK is responsible for follow up of HIV patients and ART and OI provision. UCCCK should develop HIV clinical protocols for Kosovo. It is highly recommended to use Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection 2013 (24) and Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations’ 2014 (1) as a basis for developing the protocols. Clinical protocols should be approved by MoH.
9. PLHIV groups and NGOs should be involved at all stages of HIV patients’ clinical management and help the physicians to organize follow up and be a part of adherence control programme.
10. NRL should be used for patients’ laboratory assessment at the time of getting a HIV diagnosis and subsequent assessments: VL and CD4 count equipment is available in Kosovo and test kits should be procured (and not subject to stock outs).
11. Internal and external quality control (QC) procedures should be developed and established in Kosovo as soon as possible in order to minimize false-positive and false-negative results⁶ and to ensure that HIV testing and counselling is always conducted in an effective and acceptable manner. Kosovo HIV laboratory should plan for annual QC procedures for all laboratories providing HIV testing (including private sector). External QC laboratory should be selected for reference laboratory quality control.

⁶ A high number of HIV seropositive false results was mentioned during the visits in Blood Transfusion Centre: these were found to be negative on subsequent testing in the Reference Laboratory which were diagnosed negative during the consequent tests. Further analysis is needed of this issue.

6.5 Procurement and supply management

From the available viral load data of PLHIV enrolled in ART, it is plausible that treatment interruption is caused by frequent ARV stock outs, inappropriate follow up procedures and absence of standardized clinical protocols negatively affect the therapy results and the overall health condition of PLHIV.

Kosovo MoH covers the cost of ARVs and is assisted by Kosovo UNICEF Office in procurement procedures. University Clinical Centre (UCC) Department for Infectious Diseases in Pristina is the only institution in Kosovo responsible for provision of ART. Selection and quantification of ARVs is being done by the UCC physicians who are responsible for provision of ART. UCC submits to MoH Pharmacy Department an official procurement request, which is then forwarded to UNICEF Office in Kosovo for follow up. The Mission found clear evidence that due to poor planning, the current logistic management information system is not adequate and could not prevent ARV stock outs. The stock outs were frequently observed each year since 2009 and, at times, lasted up to eight months. The lack of coordination of overall procurement processes was observed during the field Mission.

The target for NSP 2015-2020 should be 0% stock outs of ARV medications. The current buffer stock of two months is not sufficient for preventing stock outs in Kosovo. Based on current agreements with UNICEF and the “order lead time” a new quantity of buffer stock should be set (preferably calculating six months buffer stock).

Main recommendations

1. An ARV inventory management system needs to be developed and used to prevent stock outs in the medium- and long-term and negative impact of stock outs on PLHIV enrolled in ART. A warehouse stock out of ARVs and “expiry date end” early warning system should be established and implemented.
2. The Pharmacy Department should lead and supervise the ARV quantification process based on patients forecast and ARV selection made by physicians from the Infectious Diseases Clinic and monitor the remaining stock of ARVs in order to prevent stock outs and ensure that the optimal quantities are quantified and requested for procurement. An emergency procurement mechanism should be developed as well.

Specific recommendations

1. Despite the small number of patients on ART and the quantity of procured ARVs, the physicians involved in product (ARVs) selection should be appropriately trained to do forecast and quantification.

2. The entity responsible for collecting, validating, analysing, and utilizing the information to ensure an uninterrupted supply of ARVs should be defined and provided with necessary capacity building and/or technical assistance.
3. The MoH Procurement Department should coordinate and lead the PSM process for ARVs and test-kits at all stages and develop a central calendar for ARV and test-kits procurement and supply. The calendar should be developed according to agreements with suppliers and lead times quoted (together with contingency). The calendar should be presented and explained to all parties involved in PSM.

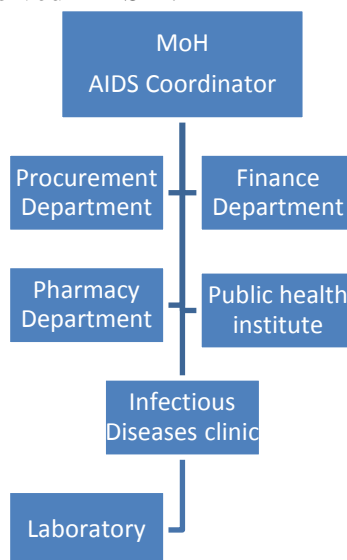


Fig. 11: ARVs and test-kits procurement- coordination and reporting (Proposed model)

4. Forecasting of the number of new patients in need of ART should be carried out by PHI based on annual number of new HIV cases, anticipated increase of PLHIV due recommended expansion of HIV testing and introduction of PITC, CD4 count at time of HIV diagnosis and estimated number of PLHIV who would need ART.
5. Ensure procurement of HIV diagnostic tests (rapid tests, confirmatory Immunoblot tests, CD4 and Viral load tests) in sufficient quantity
6. Forecasting in coordination with all partners and training on quantification and forecasting of ART.

6.6 Strategic information

As information is the key to retaining low-epidemic status, strategic information flow procedures should be refined, approved and introduced for all health institutions in Kosovo. One institution with the appropriate mandate should aggregate and analyse all HIV epidemiological and testing data (from NGOs and all governmental and private institutions), to be used for tracking of the current epidemic and to provide the evidence base for programming and strategic decisions. The option of appointing National Public Health Institute and providing it with material and technical resources for proper operation of this role should be considered by all stakeholders. The new system should ensure that strategic information related to treatment is collected, analysed and used for planning the treatment, forecasting the ARVs for evaluating the effectiveness, etc. It should also ensure that all prevention and testing data is collected and analysed for programme planning purposes.

Main recommendations

1. Strategic information related to treatment and care should be collected, analysed and used by Kosovo Ministry of Health for future planning of treatment regimes, forecasting the adequate supply of ARVs and evaluating the effectiveness, etc.

Specific recommendations

1. It is recommended that the below structural and data flow arrangements be implemented.

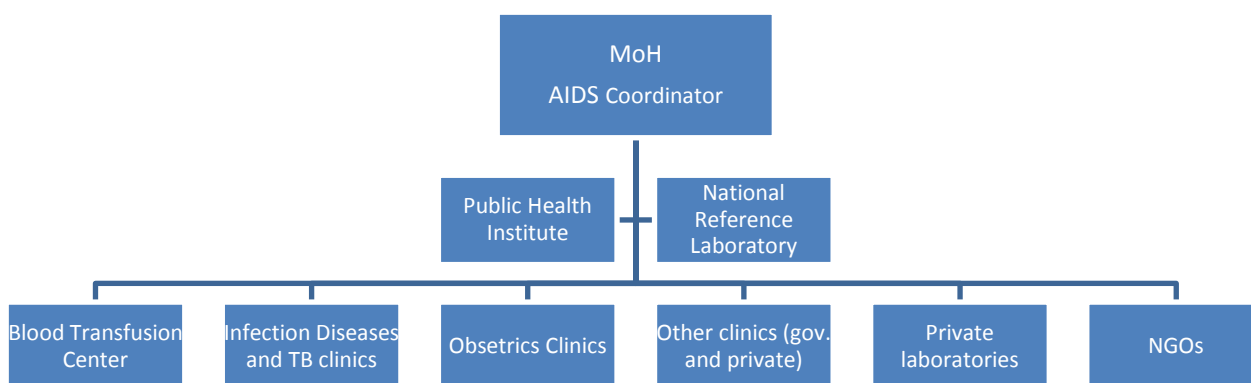


Fig. 12: HIV testing and counselling – coordination and reporting (Proposed model)

2. All organizations, where HIV testing and/or counselling (HTC) is provided or offered should submit HIV counselling and testing monthly data⁷ to the National Public Health Institute (NPHI).

⁷ Number of people tested is disaggregated by sex and reason for testing and number of HIV seropositive cases.

3. HTC reporting forms should be developed by the NPHI. The reporting forms and reporting periodicity should be approved by order of the Ministry of Health. The reporting forms should contain information on number of people who received pre-test counselling, number of people tested, number of people who received post-test counselling and number of HIV seropositive cases revealed. Where possible, breakdown by gender, age and key population should be provided.
4. NPHI should aggregate and analyse all submitted information and prepare an annual report with situation analysis, findings and recommendations to be submitted to the MoH.
5. UCK should collect, aggregate and analyse all information related to HIV patients which are under follow up in the clinic. Information should be available in the premises of the clinic. Information related to patients who do not wish to be under follow up in the clinic and their reasons should be collected through PLHIV groups and NGOs, and analysed in order to eliminate barriers and make services more attractive.
6. UCK should report to the NPHI on the number of patients on follow up, number of patients on ART, number of patients on each ART regimen, number of patients with suppressed VL, number of virologic failure cases. Specialists of UCK should consistently monitor clinical data for all patients.
7. NPHI should verify the quality of provided data and include them in the annual report to be submitted to the MoH.
8. Further sentinel HIV prevalence surveys among key populations are recommended to be carried out every two years. This is the foundation for tracking the current epidemic situation and making best possible programming and strategic decisions.

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Appendices

Annex 1 - Terms of Reference

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE



ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ
ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Evaluation of the HIV programme review in Kosovo

26 September – 3 October, 2014

1. Background

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 period from 1 January 2014 until 31 December 2015. Technical assistance is organized through external consultants and based on discussions with the countries and the Global Fund Portfolio Managers and formal Country Requests.

Kosovo is eligible for the Global Fund grant to support local programme on HIV/AIDS. The Kosovo counterparts requested the WHO Regional Office for Europe to provide technical assistance in evaluating situational analysis and reviewing Kosovo Strategic Plan on HIV.

2. Programme review

Programme review will include 4 key components:

7. Epidemiological analysis
8. HIV services for key populations, including prevention of HIV and access to care
9. Review of HIV treatment and care along cascade of services
10. Procurement and supply management of ARVs

A. Epidemiological analysis will focus on:

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

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

- Needle and syringe programme
- Drug dependency treatment (OST)
- Condoms
- ART access

- Community outreach (HIV testing and linkage to HIV treatment and care services, ARV dispense, case management/social accompanying)

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

C. 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, CD4 count at time of diagnosis
- Early HIV infant diagnosis, MTCT and paediatric ART
- Enrolment and retention in HIV care, including general HIV care, management of co-infections 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

Analysis of HIV treatment and care programme will also include review of treatment and care policy and clinical protocols.

D. Procurement and supply management of ARVs (PSM)

Analysis will be focused on:

- PSM policy/strategy/plans appropriateness and sustainability
- Selection of ARVs (acceptability of generics?) and forecasting
- Planning and coordination of procurement, stock out risk management
- Procurement methods, ARV prices, fixed dose combination of ARVs

3. Kosovo Strategic Plan on HIV

The review of the Strategic Plan should focus on the components of the Plan and ensure that:

- The Plan defines and determines priorities and strategic directions over a period of time (e.g.: five years and is aligned with Kosovo's health plan)
- The Plan provides a clear framework that specifies the appropriate strategic interventions to reach Kosovo'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 operationalized 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 operationalization effective.

4. Participants

External consultants

- Dave Burrows
- Dr. Aram Manukyan
- Mirza Musa

5. Methodology

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

During the country mission WHO experts will visit relevant institutions and facilities and discuss with key informants: policy makers, health care providers and beneficiaries, NGOs, and other partners where appropriate. Together with local clinical experts they will also have access to medical records of PLHIV for a review clinical management.

6. Time, duration and geographical sites of the mission

Programme review includes 6 days mission to Kosovo (September 26-October 3, 2014).

7. Deliverables

As a result the key recommendations (including recommendations on NSP) based on public health approach will be developed and presented to the stakeholders by the end of the mission for informing the Concept Note. Compliance of approaches and recommendations with the main WHO recommendations, e.g. 'Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection' 2013⁸ and 'Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations' 2014⁹ will be ensured.

Final report with findings and recommendations will be prepared by Dave Burrows, director of AIDS Project Management Group and submitted to WHO regional office for Europe by the **end of October 2014**.

⁸<http://www.who.int/hiv/pub/guidelines/arv2013/download/en/>

⁹<http://www.who.int/hiv/pub/guidelines/keypopulations/en/>

Annex 2 –Review team members and list of informants

Review team members

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Dr. Aram Manukyan, Clinician and Epidemiologist, APM Global Health, Armenia

Mirza Musa, Prevention, Policy and Public Health expert, APM Global Health, Bosnia and Herzegovina

List of informants

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Dafina Muqaj	Psychologist	Labyrinth
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Bekim Fusha	Pharmaceutical Department Director	Ministry of Health
Ismet Hyseni	Procurement Department Director	Ministry of Health
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Burbuqe Zatriqi	Donation Department Chief	Ministry of Health
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	Director	
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Arber Nuhiu	Director	CSGD