The Global Fund
To Fight AIDS, Tuberculosis and Malaria

STANDARD CONCEPT NOTE

Investing for impact against HIV, tuberculosis or malaria

A concept note outlines the reasons for Global Fund investment. Each concept note should describe a strategy, supported by technical data that shows why this approach will be effective. Guided by a national health strategy and a national disease strategic plan, it prioritizes a country's needs within a broader context. Further, it describes how implementation of the resulting grants can maximize the impact of the investment, by reaching the greatest number of people and by achieving the greatest possible effect on their health.

A concept note is divided into the following sections:

Section 1: A description of the country's epidemiological situation, including health systems and barriers to access, as well as the national response.

Section 2: Information on the national funding landscape and sustainability.

Section 3: A funding request to the Global Fund, including a programmatic gap analysis, rationale and description, and modular template.

Section 4: Implementation arrangements and risk assessment.

IMPORTANT NOTE: **Applicants should refer to the Standard Concept Note Instructions to complete this template.**

SUMMARY INFORMATION			
Applicant Information			
Country	**Armenia**	**Component**	**HIV**
Funding Request Start Date	**01.01.2016**	**Funding Request End Date**	**31.12.2018**
Principal Recipient(s)	**Ministry of Health {GOV PR} and Mission East Armenia {NGO PR}**		

Funding Request Summary Table

A funding request summary table will be automatically generated in the online grant management platform based on the information presented in the programmatic gap table and modular templates.

SECTION 1: COUNTRY CONTEXT

This section requests information on the country context, including the disease epidemiology, the health systems and community systems setting, and the human rights situation. This description is critical for justifying the choice of appropriate interventions.

1.1 Country Disease, Health and Community Systems Context

With reference to the latest available epidemiological information, in addition to the portfolio analysis provided by the Global Fund, highlight:

a. The current and evolving epidemiology of the disease(s)and any significant geographic variations in disease risk or prevalence.

b. Key populations that may have disproportionately low access to prevention and treatment services (and for HIV and TB, the availability of care and support services), and the contributing factors to this inequality.

c. Key human rights barriers and gender inequalities that may impede access to health services.

d. The health systems and community systems context in the country, including any constraints.

a) *The current and evolving epidemiology of the disease(s) and any significant geographic variations in disease risk or prevalence*

Background and Geographical Context

Armenia is located in the South Caucasus region of Eurasia. The country is bordered by Azerbaijan, Nagorno-Karabakh, Iran, Turkey and Georgia. Armenia is the smallest of the former Soviet Republics, with a total population of 3.017million in 2013. Population decline due to migration reaches up to 30-40 thousand people annually.

Armenia is divided into 10 provinces (marzes) with 49 cities and towns. The largest city is Yerevan, the capital, with total population of over 1million. More than 80% of the population reside within the area located 120-130 km from the capital[1]in Yerevan, Shira and Lori marzes.

The largest number of HIV cases was reported in Yerevan, the capital: 667 cases, which constitute around 1/3 of all the registered cases. Shirak marz follows with 222 cases, which constitute 11.4% of all the registered cases. The estimated total number of HIV registered cases per 100 000 population shows the highest rate in Shirak marz 88.4, followed by Lori marz, Yerevan, Gegharkunikmarz with the rates of 79.3, 62.6 and 61.1 respectively.

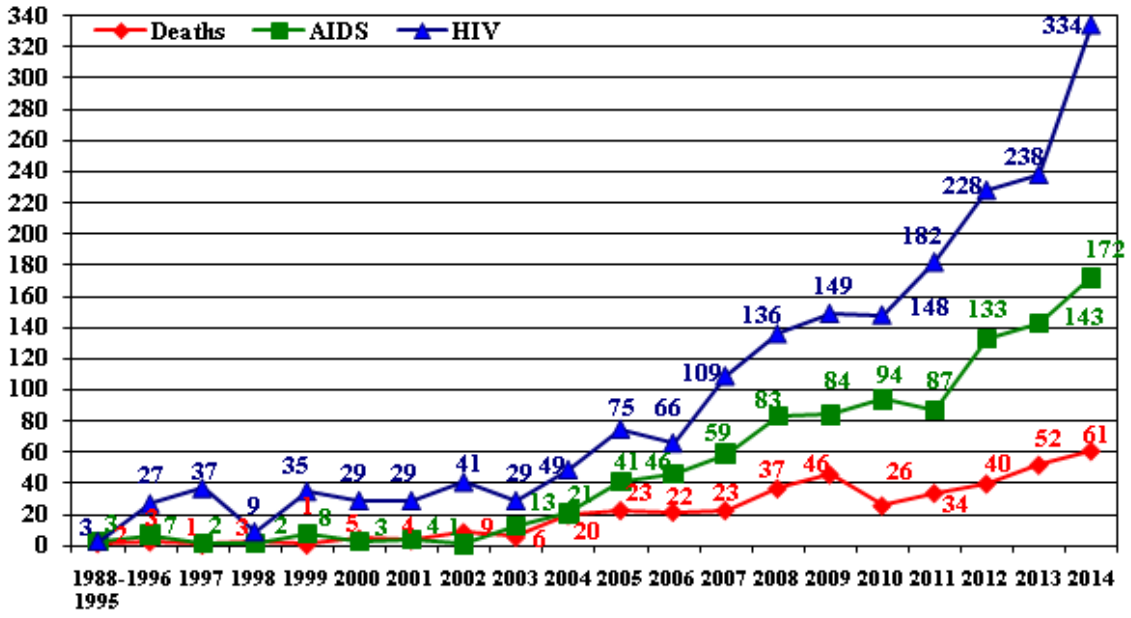
[1]Routine HIV Epidemiological surveillance in the Republic of Armenia. Annual report, 2014 (Annex 2), P.5

Total number of registered HIV cases per 100 000 population	
Shirak	88.4
Lori	79.3
Yerevan	62.6
Gegharkunik	61.1
Syunik	60.7
Armavir	60.3
Ararat	57.0
Kotayk	53.3
Aragatsotn	48.1
Vayots dzor	47.8
Tavush	41.3
Total	62.9

The marz of VayotsDzor is the least populated in Armenia (51.7 thousand people), of whom 64.8% are villagers. The proportion of the Armenian population living in towns and cities is 63.4%, however in six marzes (Armavir, Ararat, Gegharkunik, Aragatsotn, Tavush, VayotsDzor) the proportion of villagers is higher.

Epidemiological Overview

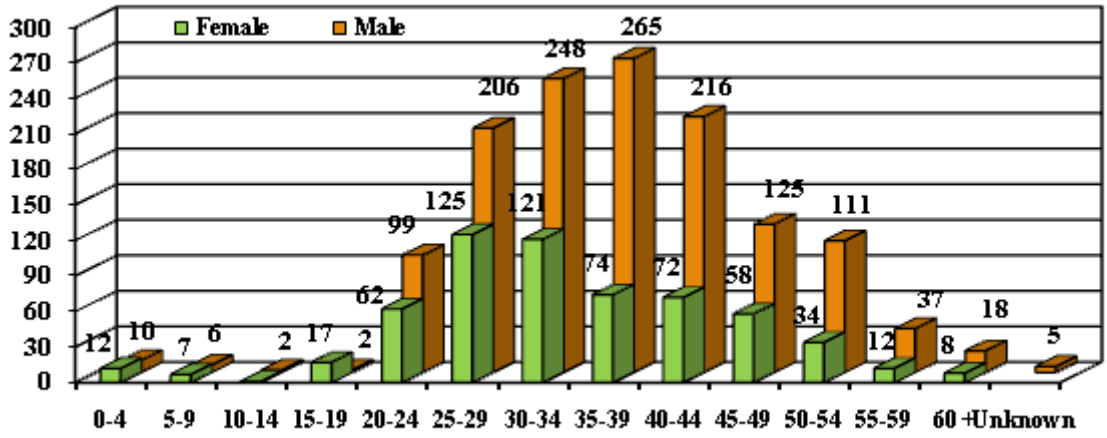
Registration of HIV cases in Armenian started in 1988. By the end of December 2014, 1953 HIV cases were registered in the country among the citizens of Armenia, including 38 cases of HIV infection among children. AIDS diagnosis was made of 1006 patients with HIV, of whom 22 are children; and 417 death cases have been registered among HIV/AIDS patients, including 7 children.The HIV/AIDS situation assessment shows that the estimated number of people living with HIV in the country at the end of 2014is about 4000[2].



[2]Ibid., P.5

The number of registered cases has been increasing each year: the 334 HIV cases registered in 2014 exceeds by 96 the number of HIV cases registered in the previous year. On the whole, more than half of all registered HIV and AIDS cases have been diagnosed within the last 4 years[3].

Allocation of HIV cases by age groups and gender shows that more than half of the all the registered HIV cases (53%) are aged 25-39, and that males constitute a major part in the total number of HIV cases - 69%, females make up 31%.

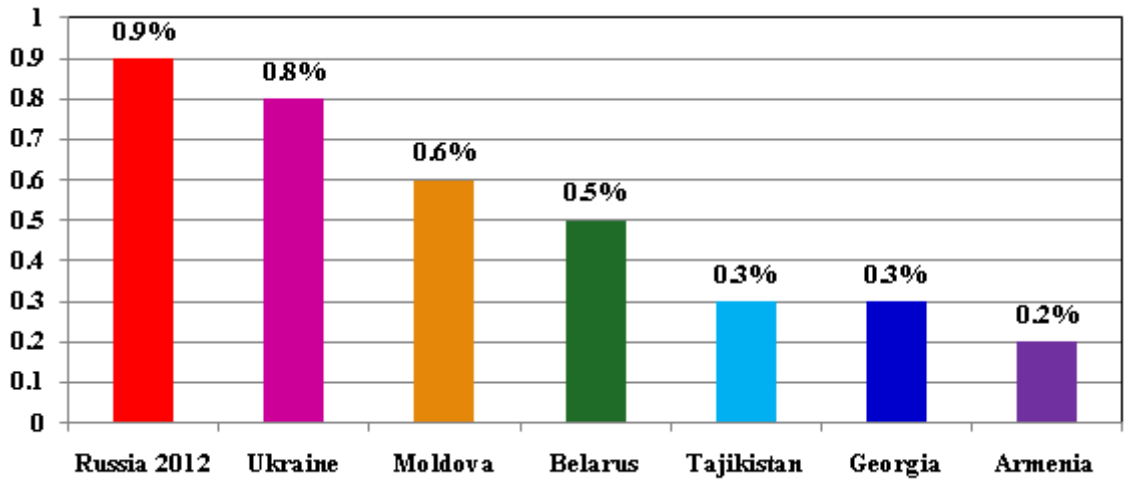


The analysis of the HIV cases registered in Armenia according to modes of transmission shows that the main modes of HIV transmission are through heterosexual practices (63%) and injecting drug use (28%). Additionally, there are also registered cases through homosexual practices (2.4%), as well as mother-to-child HIV transmission (1.8%) and transmission through blood (0.2%)[4].
The analysis of modes of HIV transmission according to gender shows that about half of all the males (49.7%) were infected through heterosexual practices, and through injecting drug use - 40.7%. Almost all the women (97.0%) were infected through heterosexual contacts[5]

While these ratios are unusual, they are explained by the very high levels of HIV infection acquired abroad (see below).

This is a comparison of HIV prevalence among adult population in Armenia with that one in other countries in the region. If HIV prevalence among adult population aged 15-49 in the Russian Federation is 0.9%, in Ukraine - 0.8%, in Moldova - 0.6%, in Belarus - 0.5%, in Tajikistan and Georgia - 0.3%, in Armenia this indicator is comparatively low and makes up 0.2%, that is in three times lower than the average HIV prevalence in the region. However, the fact that the main labour migration flows from Armenia are to the countries with higher HIV prevalence, in particular to the Russian Federation, makes Armenia more vulnerable to HIV[6].

[3]Ibid.P.5
[4]Ibid, P.7
[5]Ibid, P.7
[6]HIV infection. Information newsletter N39,Moscow, 2014; http://data.worldbank.org/indicator/SH.DYN.AIDS.ZS



Key populations

The proportion of key populations of people who inject drugs (PWID), sex workers(SWs) and men who have sex with men (MSM) in the number of registered HIV cases has been reducing year by year to the point where only 16% of HIV cases registered in Armenia in 2014 were among these populations[7].

The results of biological surveillance conducted in 2010, 2012 and 2014 among the key populations at higher risk show that the HIV prevalence was reduced in all these populations. The highest prevalence among PWID was in 2010 (10.7%), falling to 4% in 2014. The highest HIV prevalence among MSM was in 2012 (2.6%), falling to 0.4% in 2014. HIV prevalence among SWs in 2010 and 2012 was 1.2% and 1.3% respectively, whereas no HIV case was detected among SWs as a result of HIV biological surveillance conducted in 2014[8].

Despite these impressive results, significant challenges remain to controlling HIV in Armenia. In particular. As noted by the January 2015 WHO Mission to review the National Strategic Plan, testing remains highly centralized and inaccessible to key populations with low agency to access health care services. The low rates of HIV testing among key populations (in 2014: 26% for PWID, 27% for MSM and 45% for SW) brings into question the ability to generalize IBBS results across all key populations nationally.

Notably, other diagnoses that often serve as proxies for HIV transmission have remained stable.

Hepatitis C prevalence amongst PWID was relatively stable between 2012 and 2014 (52.1% in 2014) and syphilis prevalence was 3.7% in 2014. Hepatitis B prevalence fell from 4.1% among MSM in 2010 to 1.1% in 2014; and syphilis prevalence among MSM was relatively stable between 2012 and 2014 (1.8% in 2014). Gonorrhoea prevalence among SWs fell from 11% in 2010 to 3.8% in 2014; syphilis prevalence fell from 3.1% in 2010 to 0.8% in 2014; and trichomoniasis prevalence remained stable among SW (20.8% in 2014)[9].

Although few PWID are reached with HIV interventions (6.3% in 2014), use of sterile needles and syringes among those reached continues to rise from under 90% in 2010 to 96.9% in 2014). Condom use at last sex has remained stable during 2010 and 2014 at about 44%. As of the end of

[7]Routine HIV Epidemiological surveillance in the Republic of Armenia. Annual report, 2014. P.8
[8]Routine HIV Epidemiological surveillance in the Republic of Armenia. Annual report, 2014, P.14
[9]Ibid, P.14-15

2014 the total number of those receiving methadone substitution treatment was 430 (26 HIV+), of whom 131 are prisoners (6 HIV +)[10].

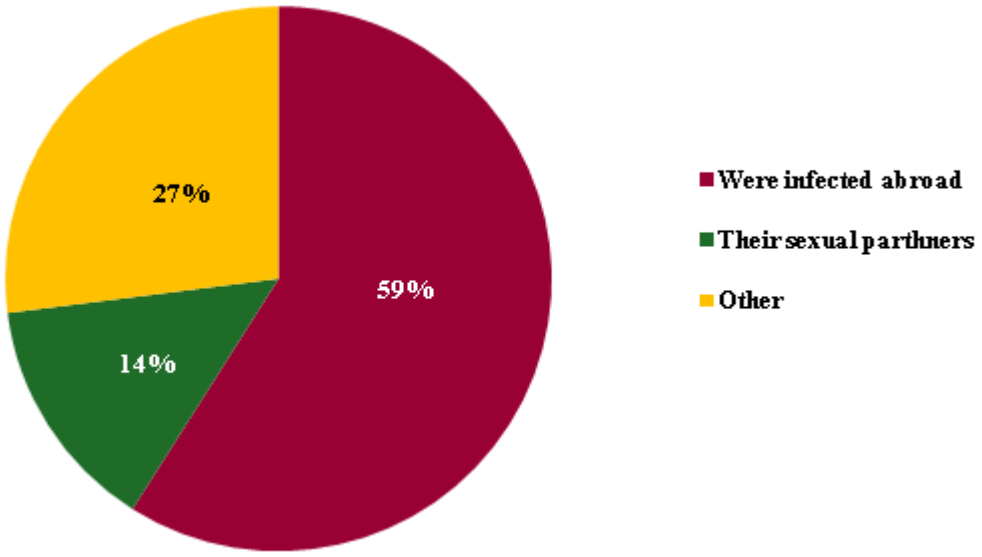
Reach of MSM through HIV interventions was slightly decreased (53.5% in 2014), and 79% met the indicator for knowledge about HIV prevention, with condom use at last anal sex table at about 65% from 2010-2014. Reach of SW with HIV interventions has almost trebled from 22.4% in 2010 to 65.8% in 2014, and condom use at last sex with a client was persistently high (93.9% in 2014)[11].

Labour migrants

However, an increasing proportion of registered cases are occurring among labour migrants to Russian Federation and other countries, and their sexual partners[12].

Of those Armenians infected abroad in 2014, HIV transmission through heterosexual intercourse made up 78%, and through injecting drug use less than 18%.In total, more than half of the HIV patients registered within the last 5 years have probably been infected outside Armenia, (90.4% in Russia, 5.5% - in Ukraine, 1.0 - in Poland, 0.7% - in Kazakhstan, 2.4% - in other countries)[13].

Overall, 59% of registered adult HIV cases in 2012-2014 were infected abroad, together with 14% among their sexual partners, meaning that 73% of cases registered in 2012-2014 are associated with migration. This effect of migration is also being seen in the HIV test results among pregnant women: 56% of the partners of the 26 pregnant HIV positive women discovered in 2014 were former labour migrants; in 2013, 87% of the partners of the 15 HIV positive pregnant women registered were former labour migrants.



Biological surveillance among migrants for the first time was conducted in 2014. The obtained results of the study among 550 migrants showed that HIV prevalence was 0.4%, more than double the background prevalence among the adult population in the Republic of Armenia. The prevalence of Hepatitis C and hepatitis B was 0.5% and 0.4% respectively.

The indicator of knowledge about HIV prevention among migrants was in the range of 25-30%. Condom use at last sex with casual partner was in the range of 62-68%.

[10]Ibid, 2014, P.16,21
[11]Ibid, 2014, P.16-17
[12]Ibid, 2014,P.11
[13]Ibid, P.9, 10

Other populations

According to the results of IBBS among prisoners the condom use at last sex with casual partner and condom use at last sex increased in 2014 to 91% and 72.8% respectively. However, the knowledge about HIV among prisoners dropped from 67.8% in 2012 to 38.4% in 2014, despite that under the current HIV grant they are provided with information/education services. The mentioned drop may be explained by the fact that the prison's population is not stable, and there is significant level of turnover. The IBBS was conducted also among those prisoners who just entered the criminal-executive institutions and thus have not received any Information/education services at the time of survey.

Knowledge about HIV prevention among young people remains low, varying from 20% to 22% during 2010, 2012 and 2014. Condom use at last sex with a casual partner was in the range of 78-85%, and condom use at last sex made up about 68% in 2014.

PLHIV

As of the end of 2014, 1328 PLHIV were linked to HIV care of whom 29 were children (more than 80% of these PLHIV reside 120-130 km from Yerevan), and 1114 PLHIV {84%} were retained in HIV care of whom 25 were children; 741 patients receive ART, of whom 20 are children. Of those on ART, 84.4% remained on treatment for more than 12 months. A total of 214 people were lost to follow-up due to various reasons (left the country, changed the place of residence or died without leaving any contact, etc.). However, the National AIDS Center remains in contact with most of these through intermediaries.

Overall, 41 pregnant women received PMTCT in 2014, of whom 27 completed the whole course during 2014. Out of these 27, 11 pregnant women already had a confirmed HIV diagnosis from the previous years. A further 26 pregnant women received a HIV diagnosis in 2014 and started receiving PMTCT, but only 16 of them completed the course during 2014.

Post-exposure prophylaxis (PEP) was provided according to the National Protocol on Post-exposure Prophylaxis for HIV Infection (2009) to those who had occupational and non-occupational exposure to HIV infected fluids.

This table shows data on CD4 count level at time of HIV diagnosis. More than half (55%) of all HIV patients were diagnosed at the late stages of HIV infection and had CD4 count <350 cells/mm^3.

CD4 Level	**Total % for 2010-14**
<200	37
200-349	18
350-499	16
>500	29

In addition, 86 TB/HIV co-infection cases were registered in 2014, and 43 HCV/HIV and 7 HBV/HIV co-infection cases were registered in 2014.

The prevalence of HIV among notified TB cases is 4.7% (67 cases in 2013).

In recent years the number of recorded TB/HIV co-infected cases in Armenia increased sharply, however, this might be associated with the increased coverage of HIV testing among TB patients. In general, there has been major progress in implementing TB/HIV interventions, such as testing TB patients for HIV and providing co-trimoxazole preventive therapy (CPT) and antiretroviral therapy

(ART) to HIV-positive TB patients. Coverage of HIV testing is high: during the last three year over 95% of TB patients have documented HIV results. Proportion of HIV positive people among notified TB patients in 2011, 2012 and 2013 (when coverage was reasonably high) was 3.3%, 5.2% and 4.7% respectively.

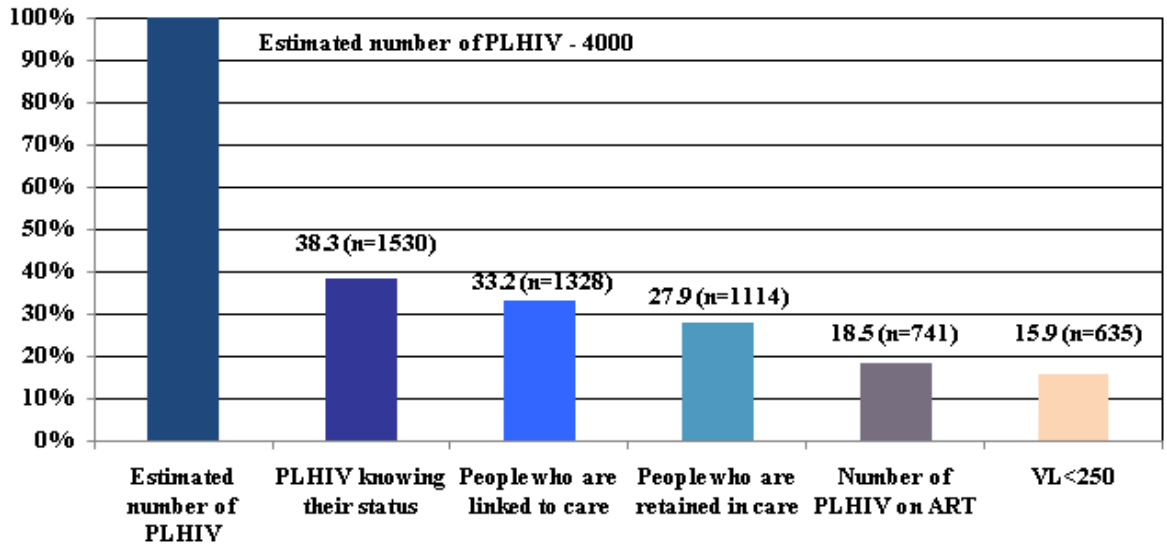
Of 86 HIV-positive TB patients notified in 2014, 73 patients (85%) were enrolled on CPT and the same number of patients started on ART. However, before 2010 both ART and CPT coverage were quite limited

During the past three years the CPT coverage did not exceed 80% (80% in 2011, 70% in 2012, 72% in 2013 and), but it was 85% in 2014

In 2013 only 72% (48 out of 79) of TB/HIV co-infected patients received ART, while in 2014 their proportion reached 81% (70 out of 86).

HIV testing and counselling

As of the end of 2014 the estimated number of PLHIV was 4000[14], of whom only 38.3% know about their status, 33.2% were linked to HIV care, 27.9% were retained in HIV care, 18.5% were on ART, and 15.9% had undetectable viral load. As can be seen from the below HIV Treatment Cascade, the gap between the estimated number of PLHIV and those PLHIV who know their HIV positive status is the largest one.

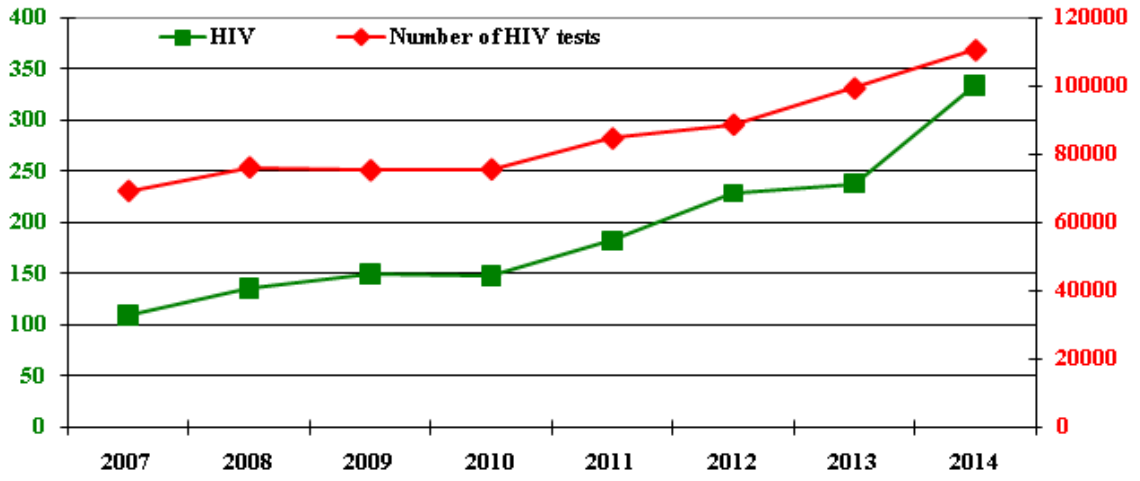


Types of HIV testing and counseling and indication of uses:

1) Provider-initiated (PITC)
   - Clinical indications (OIs, TB, Hepatitis, STIs, etc)
   - Key Populations (PWID, SWs, MSM)
   - Other vulnerable populations (prisoners, migrants and their partners)
   - Pregnant women
2) Client-initiated
3) Mandatory
   - donors of blood, biological fluids, tissue, and organs
   - children born to HIV-positive mothers

[14]Spectrum 2014.

Health care provider-initiated HIV testing and counselling has been scaled up in recent years, and overall the HIV testing system in Armenia has become more efficient at finding HIV-positive people.



While HIV tests among key populations have risen, they have not yet reached the target percentages set by UNAIDS and WHO (>90%):

Key population	Population size	Tested 2010	Tested 2014	%tested 2014
PWID	12700	856	3270	26%
MSM	6600	716	1776	27%
SW	6200	1028	2766	45%

To encourage people to get HIV tested and to popularize HIV testing a number of events were conducted in Yerevan public places in World AIDS Day and under the European HIV Testing Week, when 415 people were HIV tested by rapid tests during 5 days.

However, more regular access to rapid testing in specialized care facilities, through mobile units as well as community based testing is needed in order to approach UNAIDS and WHO targets.

b) Key populations that may have disproportionately low access to prevention and treatment services (and for HIV and TB, the availability of care and support services), and the contributing factors to this inequality

Armenia accepts that key populations for HIV are those designated in the recently released WHO Consolidated Guidelines on HIV Diagnosis, Prevention, Treatment and Care for Key Populations[15]: (1) men who have sex with men (MSM), (2) people who inject drugs (PWID), (3) people in prisons and other closed settings, and (4) sex workers (SW), as well as people living with HIV (PLHIV) who are also present in each of these key populations. An important additional key population is labor migrants, defined here as Armenians who have worked abroad for at least 3 uninterrupted months in the past 3 years.

There are several factors that undermine the ability of key populations to openly discuss, advocate for, plan and implement activities that prevent and treat HIV in Armenia These include:

- HIV-related stigma and discrimination (see next section)
- Mistrust and fear towards street police and other governmental authorities by key populations engaged in criminalized activities such as illicit drug use, commercial sex or sex between men, who have often experienced arrest, detention, harassment and violence on

[15] WHO (2014) *Consolidated Guidelines on HIV Diagnosis, Prevention, Treatment and Care for Key Populations* Geneva P.8

behalf of the authorities.

- Registration issues: Armenians need to register with a health facility related to their place of residence or enroll with certain family doctor working at certain polyclinic to access free of charge services under state benefit package: for key populations who are often highly mobile, this can place barriers in the way of access to health services.

People Who Inject Drugs (PWID)

In Armenia, there are an estimated 12,700 people who inject drugs (PWID). This population has low access to HIV prevention, testing and treatment services. The WHO Mission on HIV/AIDS treatment and care in Armenia found that the main HIV services for PWID included outreach, needle-syringe programs, opioid substitution treatment (OST) programs, HIV testing and ART. Of these, the WHO team noted that current coverage by needle-syringe programs (23%) is rather low (as the global mid-level target is 20-60%); OST coverage is very low; and HIV testing is low.

Factors contributing to low reach of PWID for NSP include lack of legal status, institutionalization and government funding of needle-syringe programs; lack of systematic geographic coverage of programs (provided only by NGOs, and not by government services); and quality of services issues, including lack of facility-based services and inadequate training for outreach workers. Low testing levels are likely a symptom of weak and inconsistent outreach efforts. There is no community-based testing available, and outreach coverage is inadequate to facilitate linkage to testing at the levels recommended by UNAIDS and WHO (90%).

In addition, the WHO team found that barriers to accessing OST include the issue of possible disclosure of the patient data to police causing the fear of further pursue by police of PWID and the current inclusion guideline complicating initiation of OST; and there is a low level of integration with HIV and TB treatment services (patients not referred for HIV testing/TB screening, in case of hospitalization the methadone is to patient transported every day). Needle syringe programs are not protected by legislation and receive no government funding.

Men who have Sex with Men (MSM)

Armenia's official estimate of the MSM population is 6600 (0.22% of the general population). In 2014, 27% of this estimated population of MSM was tested. MSM are stigmatized in Armenia, as elsewhere in former Soviet Union countries. MSM do not wish to disclose their sexuality when accessing health services and it has been difficult to find and reach this population.

Sex Workers (SW)

There are an estimated 6200 sex workers in Armenia, 45% of whom received HIV testing in 2014. As noted above, Armenia has been much more successful in providing regular HIV tests to sex workers than to other key populations. This is a substantial achievement in light of the ongoing campaigns against prostitution in the country that force many sex workers to avoid outreach workers and health services.

Labor Migrants

Labor migrants are also regarded as key population at greater risk for HIV infection in Armenia. There are various estimates of the numbers of labor migrants, but the most accepted figure is that at least 70,000 Armenians (2.3% of the general population, mostly men) leave Armenia each year to work for at least three months in another country (Russian Federation is the most popular destination), and a similar number return to the country each year; up to 500,000 Armenians are living and working in other countries, a part of them for many years.

The largest study on HIV among labour migrants in Armenia was carried out by the Caucasus Research Resource Centre of Eurasia Partnership Foundation in Armenia (CRRC Armenia), with financial support from Mission East - Armenia and technical assistance from the National Centre for AIDS Prevention and Medical Scientific Centre of Dermatology and STIs, between November 2012

and March 2013[16]. The study consisted of a desk study; nationally representative standardized survey of migrants and non-migrant households; in-depth interviews with selected migrants and their partners; free, confidential, and anonymous HIV and STI testing for the study participants; and expert interviews with policymakers and health professionals.

This study found mixed results when comparing migrant to non-migrant households. The study quotes a 2010 research paper[17] which found that the proportion of women diagnosed with at least one sexually transmitted infection (STI) in the previous three years was nearly 2.5 times higher among women married to migrants than among women married to non-migrants. However, the study also found that:

- "always" used condoms was substantially higher among migrant men (55%) than non-migrant men (39.4%) when having extramarital sex; similar results for "refused to have sex without a condom", "consistently used condoms";
- Less of illicit drug use among migrant men (3.3%) than non-migrant men (8.7%);
- Migrant men "often" visited sex workers almost 4 times as much as non-migrant men (7.9% vs. 2.1%);
- 30.7% of migrant men were HIV tested (lifetime), vs. 4.9% of non-migrants[18].

It is evident that labour migrants to countries with much higher background HIV prevalence are at risk for HIV infection, and prevention efforts are hampered by their physical location in countries such as Russian Federation where few prevention services are available. Of greater importance, when a labour migrant is found to be HIV-positive, he or she cannot receive ART or other HIV treatment, care and support in most of the host countries. Migrants then have to make the decision either to come home to Armenia where they can be treated, losing their work and economic opportunities; or remain abroad, either completely untreated or relying on informal mechanisms to import their treatment medications to the host country.

c) Key human rights barriers and gender inequalities that may impede access to health services

There are several significant human rights-related obstacles to effective prevention, testing, treatment and care related to HIV-infection in Armenia, especially among key populations:

- Criminalization of HIV transmission decreases the motivation of people practicing risky behavior to get regular HIV testing,
- The ongoing criminalization of risk behaviors such as participation in sex work and use of psychoactive substances leads to PWID and SW avoiding HIV prevention and testing.
- The practice of discrimination by police officers and medical practitioners towards men having sex with men[19], people using drugs, PLHIV and sex workers prevents those populations from demanding services they need to protect themselves and their sexual partners. Along with gay-, drug- and HIV- related stigma, it drives these populations to marginalization and out of coverage of the national HIV/AIDS program that makes the national epidemiological data inadequate and can affect allocative efficiency of the National AIDS Strategy. Also it decreases or even negates completely the key populations' meaningful involvement into the response to the epidemic.

A number of studies have shown that cases of intentional HIV transmission are rare, since people

[16]Ibid

[17]Sevoyan&Agadjanian V. (2010) Male Migration, Women Left Behind, and Sexually Transmitted Diseases in Armenia. *International Migration Review*, *44*, 354-375

[18]Agadjanian V and Markosyan K (2013). *Labor migration and STI/HIV risks in Armenia: assessing prevention needs and designing effective interventions*. CRRCArmenia. Yerevan. P.37-41

[19] «Ситуация в сфере защиты прав ЛГБТ людей. Годовой отчет. Армения. 2013», PINK, 2014.

living with HIV, who know about their status, are taking reasonable measures to reduce the corresponding risk[20,21]. Nevertheless, the article 123 of the Criminal Code of the Republic of Armenia stipulates liability for infecting with the HIV pathogen. According to the Law, exposing a person to the obvious danger of infection with HIV or infecting a person with the HIV, willfully or negligently, by a person who knows that he/she is infected with this disease is punished with a fine or arrest.

Safety of information about one's health status is also an issue due to weak confidentiality protection that includes unjustifiable sharing of information on clients' HIV status from medical professionals to third parties and, for example, participation of police representatives in the process of enrolment to opioid substitution therapy (OST).

Another issue is the weak awareness among the government officials and some community activists regarding importance of the human rights protection as the critical enabler for efficient and sustainable HIV prevention, treatment and care services.

d) The health systems and community systems context in the country, including any constraints

Armenia's health system is still working to redefine itself from its Soviet legacy, and in some respects faces typical post-Soviet challenges of decentralization, strengthening of primary care and outpatient services, and building successful partnerships between government health systems and private and non-governmental partners. Progress specific to the HIV response are addressed below, utilizing the WHO health systems building blocks as a framework.

Leadership and Governance

Since the end of 1990s, the country's economy has begun to recover, which has allowed potential and conditions for rebuilding the health system. Recognizing the importance of a strong primary health care (PHC) system, the Government, with technical and financial support of international organizations and funding agencies initiated the health system reforms to improve the accessibility and quality of essential services at the PHC level and introduction of family Medicine, while delegating specialized care to hospitals. These reforms are critical in forming the basis for the expansion of HIV testing and other services to more accessible locations outside of NCAP.

Health Care Financing

During recent decades, the Government allocations to the health sector, especially PHC, have been increasing progressively. The free benefit basic package of services provided in outpatient settings has been substantially expanded since 2006, and includes all ambulatory services, including tuberculosis (TB) outpatient diagnostic and treatment services.

However, despite the positive changes, the Armenian healthcare system continues to face serious challenges due to underfunding (public health expenditures make about 1.9% of GDP and 7.9% of the total government expenditure), lack of adequate pooling and equitable allocation of financial resources to health services, which lead to insufficient access to high quality health care.

[20]Marks G et al (2005) "Meta-analysis of high-risk sexual behavior in persons aware and unaware they are infected with HIV in the United States: implications for HIV prevention programs" Journal of Acquired Immune Deficiency Syndromes 39:446-53.

[21]Jacek Skarbinski, MD; Eli Rosenberg, PhD; Gabriela Paz-Bailey, "Human Immunodeficiency Virus Transmission at Each Step of the Care Continuum in the United States", 2014,http://archinte.jamanetwork.com/article.aspx?articleid=2130723

There is no mandatory medical insurance system with some degree of voluntary private medical insurance operation. Under these circumstances, health care services are therefore predominantly paid directly by patients. While the key diagnostic and treatment services for HIV are provided to patients free of charge at the point of delivery (including provision of ART at National Centre of AIDS prevention), the potential out-of-pocket expenses may prevent people from seeking care, especially the poor and unemployed.

A National Health Strategy 2015-2020 (NHS: see Annex 9), currently being finalized, seeks to address these issues. The NHS provides strategies to :

- Increase the state budget allocations to health, maintaining it within the range of 10% of the total state budget, as well as continuing to attract financial resources from different sources, including establishment of mandatory public health insurance and development of alternative funding sources (such as targeted health funds from tobacco and alcohol excise tax, use of mobile phones, fast food, and high sugar beverages).

- In addition, the NHS aims to improved program budgeting through implementation of outcome-based financing system and better management of financial flows, development of health insurance schemes, continuing development of co-payments, and regulation of out-of-pocket payments, assessment of cost-effectiveness of state health policy programs in order to review or modify them to ensure effective use of scarce resources.

Health Workforce

Since 1991, the overall Armenian health workforce has contracted. The number of specialist doctors and dentists has increased (from 59 and 25 respectively per 100,000 in 1999 to about 72 and 42 in 2012), but the number of nurses per capita has fallen substantially(from around 1000 per 100,000 in 1990 to about 500/ 100,000 in 2012)[22]. However, while the supply of physicians in the health system has remained relatively stable in per capita terms, the balance of specialists has not shifted away from hospital services. The specialist health manpower is also geographically mal-distributed with perceived shortage of physicians in rural areas and surplus in the capital city of Yerevan.

The NHS seeks to address these issues by developing and implementing clinical guidelines and patient management protocols; and improving human resources planning. Strengthened human resources management will include implementation of qualification (registration) system and credit system of ongoing educational development of medical staff. In concert, the plans continue to develop implementation of targeted training programs aiming at improvement of medical staff qualifications in the regional health facilities (targeted clinical residency and targeted diploma training programs); strengthen mechanisms for provision of required health specialists in rural areas; and introduce the implementation of a social package for medical personnel in border and remote regions. All of these measures have the potential to aid in strengthening the competence of the health workforce to provide competent HIV care, including risk assessment and HIV testing and counseling and linkage to specialty care where needed.

Medical Products and Technologies

[22]Rechel B, Richardson E and McKee M (Eds) (2014) *Trends in Health Systems in The Former Soviet Countries*European Observatory on Health Systems and Policies. CopenhagenPp 79 and 81; Richardson E (2013) "Armenia Health System Review". Health Systems in Transition, Vol 15 (4). P.54

The NHS sets out to improve control of drug quality and regulation of prices – a critical systems improvement to assure that access to high-quality ART continues to expand. In addition, the strategy calls for the development and implementation of a national strategic plan specifically for the formation of universal laboratory network and institute of reference laboratories. This will assure that accurate, high-quality HIV clinical monitoring and laboratory-based testing (i.e. to confirm rapid testing preliminary positives) is reliably available.

Information and Research

Currently, there are several electronic data collection systems, sometimes overlapping, to gather routine information and surveillance data. Nevertheless, there are serious data limitations and data gaps which impede the use of health information in planning and policy development, and the Ministry of Health is implementing e-health reforms in order to establish a universal electronic data management system. This universal system will support HIV data collection.

Service Delivery

HIV testing and counseling is provided in health care settings according to the HIV testing and counseling procedure, approved by the appropriate Order of the Minister of Health of the Republic of Armenia. Health care settings providing HIV testing and counseling organize HIV testing or storage of collected blood samples and their transportation to HIV testing laboratories located in Yerevan and marzes. Methodological management of HIV testing and counseling activities is carried out by the National Center for AIDS Prevention

State guaranteed free of charge medical care services provided at the "National Center for AIDS Prevention" SNO includes the following:

1) Detecting HIV 1/2 by ELISA, Rapid Tests and Reference methods, HIV counseling, epidemiological surveillance,
2) HIV/AIDS patients follow-up (continuous), including ARV treatment, treatment monitoring, diagnostics of opportunistic infections and co-infections, STIs, TB, prevention and out-patient treatment of opportunistic diseases, provision of medical, psychosocial and legal counseling, organization and referral for narrow profiled medical care related to diseases associated with HIV infection,
3) Prevention of mother-to-child HIV transmission,
4) Post-exposure prophylaxis.

At independence, Armenia inherited an oversized health care system with a focus on specialized care. Since then, there has been a rapid contraction in the number of hospital beds (from 909 beds per 100 000 population in 1990 to 395 in 2011) as financing incentives shifted from input to output measures. While the health system in Armenia strives to provide full and equal access to essential HIV services, a number of barriers in service delivery remain that need to be addressed in order to ensure appropriate HIV prevention, treatment, care and support.

The NHS seeks to address some of the largest barriers to accessible services by introducing implementation of tender-based procurement of health services (to assure that services are responsive to unique population needs); more clearly define criteria for health sector privatization (to allow the private sector to fill gaps not successfully filled by the government); and continue the development of the incentive system introduced at the PHC level to assure that quality of care

continues to rise.

In addition, the NHS continues the restructuring that is underway by introducing definitions of levels for entities delivering healthcare services, and exploring the possibility of accreditation for medical facilities. Alongside these facility-level improvements, the NHS will ensure continuity of quality assurance of medical services, including definition of medical standards and norms of activities of quality commissions and medical second opinion in facilities providing medical aid and services; and defining clinical procedures and clarify standards for hospital treatment referral.

There is a national OST program established since 2009. By December 2014, 430 people were enrolled. Among them, 258 were enrolled in the Republican narcological center in Yerevan, 131 were enrolled in prisons and 41 in Shirak and Lori marz narcology facilities.

Community systems

The community systems in place in Armenia are relatively strong, compared to other countries of the former Soviet Union. A substantial number of non-government organizations (NGOs) works provide HIV activities, especially among key populations.

In the current HIV GF grant the activities among communities are implemented by 11 SRs. 3 SRs implement HIV prevention activities among MSM, 3 - among SWs, 2 - among IDUs, 1 – among migrants and 2 provide care and support to PLHIV.

A 2012 evaluation[23] found that "the current NGO response to support the National HIV Prevention Program is active and effective in doing what it set out to do". Community consultations for the development of this Concept Note similarly found a high degree of trust and request for ongoing services from KP NGOs. The WHO Country Review of HIV/AIDS services in Armenia in January 2015[24] also found that monitoring of NGO services was generally thorough and well carried out.

These evaluations found that there were some challenges for NGOs to provide services beyond the major population centers in Armenia, and that greater linkage between outreach by NGOs and HIV testing of KPs would improve the HIV treatment cascade.

1.2 National Disease Strategic Plans

With clear references to the current **national disease strategic plan(s)**and supporting documentation (include the name of the document and specific page reference), briefly summarize:

a. The key goals, objectives and priority program areas.
b. Implementation to date, including the main outcomes and impact achieved.
c. Limitations to implementation and any lessons learned that will inform future implementation. In particular, highlight how the inequalities and key constraints described in question1.1are being addressed.
d. The main areas of linkage to the national health strategy, including how

[23]Cunningham C (2012). *Independent External Evaluation of the Global Fund RCC Grant on Support to the National Program: NGO response to HIV epidemic in the Republic of Armenia*. Mission East. Yerevan P.41

[24] Presentation from WHO Mission on HIV/AIDS treatment and care in Armenia. 30 January 2015. Slide 11 (Annex 5)

implementation of this strategy impacts relevant disease outcomes.

e. For standard HIV or TB funding requests[25], describe existing TB/HIV collaborative activities, including linkages between the respective national TB and HIV programs in areas such as: diagnostics, service delivery, information systems and monitoring and evaluation, capacity building, policy development and coordination processes.

f. Country processes for reviewing and revising the national disease strategic plan(s) and results of these assessments. Explain the process and timeline for the development of a new plan(if current one is valid for 18 months or less from funding request start date), including how key populations will be meaningfully engaged.

- *The key goals, objectives and priority program areas.*

The National Program on the Response to the HIV Epidemic 2013-2016 in the Republic of Armenia[26] (Annex 3) has as its overall goal: to form an effective response to the HIV epidemic for the period of 2013-2016[27]. The key sections of the program are:

1. An enabling environment for an effective multi-sector response;
2. HIV prevention;
3. Treatment, care and support;
4. Monitoring and evaluation;
5. Management, coordination and partnerships;
6. Financing and finance resource mobilisation.

The National Program is accompanied by an Operational Plan which specifies targets for all priority activities for each year from 2013 to 2016. (The results up to 2014 are provided as Annex 4[28]).

- *Implementation to date, including the main outcomes and impact achieved.*

Results have been entered into the Operational Plan for the years 2013-2014. The WHO review of January 2015 (Annex 5) also assessed outcomes and challenges of the Armenia HIV National Program.

1. An enabling environment for an effective multi-sector response

Strategy 1. Reduce stigma and discrimination towards key affected populations and people living with HIV

Targets were met in 2014 for media campaigns (2) on HIV and AIDS; number of articles in print and electronic media related to HIV and AIDS (50) and TV and radio programmes/clips (100) supplied by Ministry of Health (MoH); and community-based public events aimed at raising HIV/AIDS awareness (2); and number of members of key populations (2) attending HIV/AIDS meetings held locally, nationally and regionally. The first phase of a program of technical assistance for activities on HIV prevention at workplaces has been carried out till the end of 2013. Currently there are not any funds envisaged for this purpose.

Strategy 2. Promote human rights and gender equity pertaining to risk and social issues related to HIV

[25]Countries with high co-infection rates of HIV and TB must submit a TB and HIV concept note. Countries with high burden of TB/HIV are considered to have a high estimated TB/HIV incidence (in numbers) as well as high HIV positivity rate among people infected with TB.

[26] Government of the Republic of Armenia (2013). *Decree N-232-N of 07 March 2013 on Ratification of the National Program on the Response to the HIV Epidemic 2013-2016, List of the Priorities for the National Program, Budget, Monitoring and Evaluation Plan*. Yerevan

[27]Ibid. P. 11

[28]All result statements in this section are from this Annex (apart from WHO statements, referenced separately).

Targets were met in 2014 for campaign (1) to advocate and address human rights and gender-based violence issues related to HIV; and number of peer support groups established to help women who encountered violence (3).

2. HIV prevention

Strategy 1: Reduction in HIV infection through injecting drug use

Targets were almost met for PWID reached by HIV prevention programs, and those PWID who received a HIV test:

	2014 Target	2014 Result
PWID reached	4000	3965
PWID tested	50%	48.1%[29]

Distribution of prevention materials through needle-syringe programs has not reached 2014 targets:

	2014 target	2014 result
Needles & syringes distributed	800,000	682,167
Condoms distributed	200,000	173,919
Educational materials distributed	8,000	6,954

Eight individuals were trained in implementing preventive activities among PWID (target was 20).

The number of PWID on opioid substitution therapy (430 at end 2014) exceeded the 2014 target (330) at 10 clinics (7 of them in penitentiary institutions). The WHO Mission to assess the HIV program in January 2015[30]found that there is continuity in OST provision between penitentiary institutions and community healthcare institutions and the reverse; and that OST is positively valued by administrations of penitentiary institutions and medical staff (due to the reduction of criminality/drug use/drug overdose and integration with ART). An evaluation of the OST program was carried out in 2013.

Strategy 2: Reduction in HIV infection through sex work

Distribution of prevention materials and other activities have not reached 2014 targets:

	2014 target	2014 result
SW reached	4,000	2,765
Condoms distributed	1,600,000	974,932
Educational materials distributed	8,000	5,491
Trained individuals in preventive activities	20	15

Strategy 3: Reduction in HIV infection through MSM contact

Distribution of prevention materials and other activities have not reached 2014 targets:

	2014 target	2014 result
MSM reached	2,800	2,117
Condoms distributed	392,000	172,210
Lubricants distributed	392,000	71,060
Educational materials distributed	5,600	4,056
Trained individuals in preventive activities	20	2

Strategy 4: Reduction in HIV infection among migrants

Targets met include conducting research aimed at developing the most effective HIV prevention programmes among migrants (completed in 2013); and proportion of migrants among new HIV

[29]This indicator and testing indicators for the other key populations relates to the percentage of clients tested, not the percentage of the total estimated population. This is the way the indicator is constructed for the National Strategic Plan: for the Modular Template, baseline and targets have been converted to percentage of the estimated population.

[30] Presentation from WHO Mission on HIV/AIDS treatment and care in Armenia. 30 January 2015. Slide 23

infections was 57.2% against a target of 60%.

The issue of continuation of the Russian Government-supported Regional Cooperation Program was addressed at the meeting held on 9 April in Minsk, Belarus, attended by the Russian side, UNAIDS and representatives of the regional countries to discuss the new UNAIDS Strategy for 2016-2021 in Eastern Europe and Central Asia. UNAIDS had collected the requested information from the countries involved in the program on their future needs for continuation of the UNAIDS-managed program and submitted it to the Russian Government. Also, AIDS Infoshare NGO, after discussing with Rospotrebnadzor, will submit to the Government the proposal on the activities continuation, including those targeted to the migrants. After submission of program continuation proposals, the Russian Government will review them and make relevant decision expected to happen before the end of 2015.

Currently HIV prevention/testing activities are being conducted in 60 communities under the Russian Government-supported programme. Additionally, HIV prevention/testing activities are being carried out in 40 communities with the support of GF RCC Grant. Therefore, those activities are being carried out totally in 100 of 1800 (i.e. in 5.6%) communities countrywide.

Distribution of prevention materials and other activities were as follows:

	2014 target	2014 result
Migrants covered by prevention programs	40,000	10,948
Trained individuals in preventive activities	20	251

HIV preventive activities under the program supported by the Russian Government and Global Fund have been carried out in 100 town and rural communities among migrants and their family members: this includes HIV counseling as well as testing for HIV, Hepatitis B and C, syphilis and, if necessary, referral to testing for other STIs. Also, under GF-supported projects, TB screening was carried out. These services are provided on the basis of mobile medical and diagnostic clinic, as well as by NCAP mobile medical teams in ambulatories[31].

The package contains HIV counseling, which is given in broader format, covering the issues of reproductive health and family planning. In addition, the package includes testing for HIV, Hepatitis B, C and screening for TB through specially developed questionnaires. Besides, the migrants were provided with referrals to the National AIDS Center for undergoing PCR testing for Chlamydia trachomatis, Trichomonas vaginalis, Ureaplasma urealyticum, Mycoplasma hominis, Gardnerella vaginalis. Testing for HIV, Hepatitis B, C (on blood samples) was performed on sites, and testing for STIs (swab samples) - at the National AIDS Center. The TB suspects (identified through screening with questionnaire), were referred to TB facilities for further diagnosis.

Due to limitations of financing under the NFM, a scale-up of the activities is not envisioned.

HIV testing at community level is carried out by visiting mobile medical groups. Local population readily undergo testing, as being not familiar with the medical groups members there is no fear of disclosure and secondly because HIV testing is provided in complex with other medical services - testing for Hepatitis B, C, syphilis, medical counseling and referral for further medical services.

Strategy 5: HIV prevention among other vulnerable populations (including prisoners, refugees and especially vulnerable young people)

[31]Routine HIV Epidemiological surveillance in the Republic of Armenia. Annual report, 2014.

Distribution of prevention materials and other activities were as follows:

	2014 target	2014 result
Educational materials distributed to prisoners	4,000	5,958
Prisoners covered by preventive activities	2,900	3,068
Trained individuals in preventive activities among prisoners	20	12

HIV prevalence among young people aged 15-24 has remained well below the target of 0.1% (2014 result: 0.01%). Condom use at last sex target (target: 85%) and percentage of young people aged 15-24 who have knowledge on HIV prevention (target: 37%)have not been measured, and no work has been done on training individuals in preventive activities among youth, distribution of educational materials to youth, and retraining of teachers for provision of "Healthy Life Style" training course at schools.

Strategy 6: Reduction of heterosexual transmission of HIV

Targets have been met or exceeded for most indicators under this strategy:

	2014 target	2014 result
HIV counseling & testing in general community	32,000	43,844
HIV counseling & testing at NCAP	15,000	15,699
% of regular partners of PLHIV tested for HIV	75%	66.2%
% of discordant couples counseled	100%	100%
% of pregnant women received HIV testing	95%	99.9%
% of pregnant PLHIV receiving PMTCT	100%	100%
% of donated blood samples tested for HIV	100%	100%

3. Treatment, care and support

Strategy 1. Ensure access to ART for people living with HIV

Targets were met or exceeded for many of the activities in HIV treatment, care and support by end of 2014.

	2014 target	2014 result
Number of health care workers trained in HIV diagnosis & treatment	200	221
PLHIV under follow-up	1270	1328
% of patients under follow-up	85%	92.5%
Adults and children on ART	810	741
% on ART 12 months after initiation	85%	86.3%
% on ART with undetectable viral load	>85%	84%
% of PLHIV who need ART at time of diagnosis	<45%	52.4%
% of patients receiving regular clinical monitoring	100%	100%
Number of patients on 1st-line ART	760	661
Number of patients on 2nd-line ART	50	80
Number of those provided with	200	367

OI treatment		
Number of patients provided with care and support	1000	921
Number of those provided with post-exposure prophylaxis	35	36
Number of those provided with inpatient OI treatment	50	178

In addition, targets were met for regular reviews of National HIV/AIDS Treatment and Care Protocols; and uninterrupted supply of ARV drugs, test kits, and other medical commodities. The WHO review[32] found a high rate of treatment success and a moderate loss to follow-up (11%: the Mission noted that France has a 7% rate).

4. Monitoring and evaluation

Strategy 1: Ensure a robust and comprehensive HIV surveillance system
Targets met for carrying out monitoring and evaluation activities; carrying out IBBS (1), surveys on HIV transmission among partners of PWID, MSM, SWs and clients of SWs (2), drug resistance study (on-going); and production of annual surveillance and monitoring reports.

The WHO Mission found that, overall, a good national surveillance program exists in Armenia for HIV. It noted that there is effective central reporting, with the ability to capture all diagnosed cases and persons attending for HIV care[33].

5. Management, coordination and partnerships

Strategy 1: To increase the leadership capacity of CCM and local authorities
No activities were achieved indicators for this strategy in 2014. Reasons are provided in the next sub-section.

Strategy 2: Leverage partnership between stakeholders and programmes for better performance-based results
Targets were met or exceeded for the following activities under this strategy: an annual workshop was held to strengthen partnerships between HIV/AIDS stakeholders and other allied organizations at national and international levels; two international conferences were held in Armenia on HIV related topics (target was 1); two participants were sent to international HIV conferences; a workshop was carried out to strengthen partnerships between community-based organizations and programmes in marzes; a separate workshop was carried out to build the capacity of community-based organizations to be able to take up HIV intervention programmes; and a workshop was held to keep interested organizations and programmes informed of the most up-to-date information and best practice regarding HIV and AIDS.

6. Financing and finance resource mobilisation

Strategy 1: Increase efficiency and effectiveness of funding
Targets achieved under this strategy include carrying out a National AIDS Spending Assessment study; conducting a review of monitoring and evaluation data with financial allocations;

Strategy 2: Increase new funding resources and sustain the existing funding
The targeted increase of the share of State Budget financing of the HIV/ AIDS program (to 40%) was partially achieved. The target to submit a proposal to GF for funding was not achieved in 2014, but is achieved with this Concept Note.

- *Limitations to implementation and any lessons learned that will inform future implementation. In particular, highlight how the inequalities and key constraints described*

[32]Presentation from WHO Mission on HIV/AIDS treatment and care in Armenia. 30 January 2015. Slide 15
[33]Ibid. Slide 5

in question 1.1 are being addressed.

1. An enabling environment for an effective multi-sector response

Strategy 1. Reduce stigma and discrimination towards key affected populations and people living with HIV

The review of the legislation is planned to be conducted in 2015. Training to mass media representatives on media coverage associated with HIV and AIDS has not yet been carried out due to a lack of financing. People Living with HIV Stigma Index survey has not yet been carried out.

Strategy 2. Promote human rights and gender equity pertaining to risk and social issues related to HIV

A study to determine attitudes towards PLHIV among the general population will be carried out in the framework of the DHS 2015.

2. HIV prevention

Strategy 1: Reduction in HIV infection through injecting drug use

The reasons for not reaching targets were that PWID increasingly purchase injecting equipment and condoms at pharmacies and kiosks and needing fewer free supplies from programs. Education materials are not updated on a regular basis. Training activities were suspended during the previous grant period, leading to fewer individuals trained in preventive activities. Changes to the numbers of needles, syringes, condoms and educational materials have been taken into account for this Concept Note.

The WHO Mission[34] found that:

- HIV testing rates in key populations are low indicating a need to increase uptake at relevant health settings (e.g. STI clinics and NSP) and in the community
- Current coverage with OST is less than 4% of PWID, and OST should be expanded
- Quality of needle-syringe program services is questionable as all services are provided on outreach basis and some outreach workers apparently lack skills in client's needs assessment, counseling on drug treatment availability, etc.

The Mission recommended:

- develop and adopt legal acts of NSP to involve governmental institutions/ provide partial funding from government budget
- establish stationary/mobile NSP sites which will also serve as settings for rapid community HIV testing and counseling
- improve quality of NSP services, including better selection of outreach workers, their training and regular supervision of their work
- integrate better NSP services with drug treatment/HIV and TB care facilities.

Strategy 2: Reduction in HIV infection through sex work

Reasons for not reaching targets include:

- Difficulties in reaching SW caused by police crackdown on sex work
- SWs increasingly purchase condoms at pharmacies and kiosks thus need fewer free supplies from programs as described in Annex 1 of Country Dialogue Report.
- Education materials are not updated on a regular basis.
- Training activities were suspended during the previous grant period, leading to fewer individuals trained in preventive activities.

Changes to the numbers of condoms and educational materials have been taken into account for

[34] Ibid. Slides 22-30

this Concept Note.

The WHO Mission[35] found that:

- Sexually transmitted infection (STI) rates among SW are high, which indicates poor condom use (not using condoms, or using them incorrectly irrespective to the number of condoms distributed to each client): better outreach education is required.

Strategy 3: Reduction in HIV infection through MSM contact
Reasons for not reaching targets include:

- Difficulties in reaching MSM caused by societal stigma towards MSM
- MSM increasingly purchase condoms and lubricant at pharmacies and kiosks and needing fewer free supplies from programs (Annex 1 of the Country Dialogue Report).
- Education materials are not updated on a regular basis.
- Training activities were suspended during the previous grant period, leading to fewer individuals trained in preventive activities.

Changes to the numbers of condoms, lubricant and educational materials have been taken into account for this Concept Note.

The WHO Mission[36] found that:

- STI rates among MSM are high, which indicates poor condom use (not using condoms, or using them incorrectly irrespective to the number of condoms distributed to each client): better outreach education is required.
- Drug use among MSM is not monitored closely: MSM friendly services should be considered

Strategy 4: Reduction in HIV infection among migrants
A study of the existing laws and regulatory acts related to migration and recommendations for amendments has not yet been carried out. The reason the target for migrants was not reached was that there was some confusion between whether migrants programming should be largely focused on testing and treatment or on HIV prevention. While the HIV prevention target was not reached, a large number of migrants were tested for HIV. In this Concept Note, the target for work with migrants is confined to testing and treatment.

Strategy 5: HIV prevention among other vulnerable populations (including prisoners, refugees and especially vulnerable young people)

Planned work on HIV awareness raising activities among refugees has not yet been carried out due to shifting priorities caused by the influx of refugees from the war in Syria. Work with young people could not be carried out due to a lack of financing of these activities.

On HIV testing generally, the GF Portfolio Analysis stated that the HIV testing protocol must be optimized to make testing patient-centred, widely available and rapid. The WHO Mission[37] found that:

- Early diagnosis and treatment is imperative for improved public health outcomes and reducing HIV transmission
- Testing remains largely centralised with most tests on MARPs conducted at NCAP – not easily accessible
- Testing needs to be expanded to a wider range of healthcare settings and health professionals (e.g. universal offer of HIV test at all STI clinics); increased outreach work

[35]Ibid. Slide 11
[36]Ibid. Slide 11
[37]Ibid. Slide 8

using mobile teams in remote communities working with peer outreach workers; targeted testing of key populations through community testing using friendly non-judging mobile teams and peer outreach workers

- Reduce length of pre-test counselling to 5-10 minutes to increase the number of tests performed

3. Treatment, care and support

Strategy 1. Ensure access to ART for people living with HIV

One of the few planned activities not yet completed is the development of a long-term funding plan to ensure sustainability of ART programmes, but the recent agreement of the Government of Armenia to pay for first-line ART medications starting from 2017 has been a welcome step towards this plan.

The GF Portfolio Analysis and WHO Mission[38] stated the number of treatment regimens is excessive (total 1st +2nd line: 22 regimens)and recommended a shift from an individualized patient approach to a more cost-effective public health approach by optimization of national treatment and treatment monitoring guidelines and practices in order to bring them in line with current WHO recommendations.

WHO noted that the high rate of undiagnosed cases results in an estimated rate of only 15.9% of undetectable viral load among all PLHIV in Armenia.

The preferred treatment regimen for first line new patients is TDF/FTC (or 3TC) + EFV. As for shifting from some of the current regimens to the recommended ones, the rationality of switching from the well adhered, well tolerated, viral load suppressing and good-working regiments to TDF-based regimen should be considered. Currently for ART 19 first line regimens are being used, and in new ARV order for 2016, 13 ART regimens are envisaged. Thus, gradual optimization of ART regimens will be implemented by taking into account the ordered ARV quantities, buffer stocks and treatment outcomes.

4. Monitoring and evaluation

Strategy 1: Ensure a robust and comprehensive HIV surveillance system

The WHO Mission recommended that Armenia consider creating a national HIV database and cohort to track persons from diagnosis through to treatment and care; and stated there was a need to improve the tracking of persons tested by setting and risk group; and tracking of new versus repeat testers annually. This information would provide a better understanding of who and where to test and allow for the monitoring of testing programmes. A standardized, national unique identification code for key populations would reduce the possibility of double-counting clients reached and tested.

5. Management, coordination and partnerships

Strategy 1: To increase the leadership capacity of CCM and local authorities

On the advice of the Global Fund, changes are being made to the way that members are appointed / elected to the CCM, after which the activities under this strategy (needs assessment survey on technical support required for increasing leadership capacity of CCM and local authorities, andtraining workshops to meet these needs) will be carried out.

Strategy 2:Leverage partnership between stakeholders and programmes for better performance-

[38]Ibid. Slides 18-20

based results
The only activity under this strategy which did not meet its target was the building of a database of national consultants amongst public authorities, service providers, community-based, faith-based and other allied civil society and community organisations for providing technical support. Work on this is under way.

6. Financing and finance resource mobilisation

Strategy 1: Increase efficiency and effectiveness of funding

Activities not yet carried out, due to funding restrictions were a normative costing of HIV/AIDS, TB/HIV, HBV/HIV, and HCV/HIV management protocols; development of TB/HIV/AIDS subaccounts within the National Health Accounts framework; and strengthening the capacity of procurement specialists.

Strategy 2: Increase new funding resources and sustain the existing funding
The target of more than 2% private sector funding of the total HIV/AIDS spending was not achieved. Targets were not achieved for meetings with private sector representatives or distribution of information materials on the HIV program to the private sector. A planned study on international best practice in innovative financing and appropriateness and possibility of its integration in Armenia was not conducted due to lack of financing.

Overall, the lessons learned from the processes carried out to date are that it is difficult to both reach key populations with prevention messages and equipment and encourage them into HIV testing. This has led to a renewed focus on ensuring that the majority of key populations reached are encouraged into testing, using a range of techniques described in Section 3.2 below. All of the WHO recommendations have been considered and most have been taken up in the new strategies and activities described in 3.2.

In addition to National Strategic Plan activities, a funding optimization study was carried out in Armenia by UNAIDS and the World Bank. The Optima study found that spending on key populations should be carefully monitored and allocated to achieve a balance between the optimal set of activities to prevent HIV infections and the optimal set to prevent AIDS-related deaths. The allocation of funds to various sectors proposed in 3.2 and the Modular Template is based on these Optima recommendations.

- *The main areas of linkage to the national health strategy, including how implementation of this strategy impacts relevant disease outcomes.*

The draft National Health Strategy (NHS: Annex 9
) has HIV morbidity as a key indicator (target 7/100,000 by 2020, compared to 7.5/100,000 in 2012). The new National HIV/AIDS Strategy (see below) will be developed under the NHS. The National Health Strategy is particularly concerned with funding options and ways that these may be applied to all diseases including HIV. Lessons learned from the past 15 years of work on HIV have been taken into account in the design of the National Health Strategy, particularly in relation to financing health care and ensuring that a range of institutions is eventually accredited to work on various diseases.

The decentralization and other issues referred to in this Concept Note are aligned with the draft

NHS.

- *For standard HIV or TB funding requests[39], describe existing TB/HIV collaborative activities, including linkages between the respective national TB and HIV programs in areas such as: diagnostics, service delivery, information systems and monitoring and evaluation, capacity building, policy development and coordination processes*.

Systematic TB/HIV collaborative activities were initiated in 2007 by setting up a joint coordinating body (working group), development of national guidelines and protocols, epidemiological surveillance for HIV among TB cases, training of staff for provision of diagnostic testing and counseling on HIV for TB patients.

A system for active TB screening in people living with HIV has not been implemented yet. TB case detection in PLHIV will be strengthened at the National AIDS Center in line with the latest WHO / UNAIDS recommendations for intensified TB case finding including the application of Xpert MTB/RIF technology. In addition, effective monitoring and evaluation of collaborative TB/HIV activities will be put in place. Given the increasing rates of TB/HIV co-infection, access to diagnostic counseling and testing for HIV (using rapid tests) will be ensured for TB patients at all levels of TB service.

TB/HIV collaborative activities were presented in the TB NFM Concept Note in 2014 where the following measures were envisaged.

Interventions:

3.1. Strengthening capacities for management of HIV-associated TB

3.2. Improving TB and MDR-TB case detection among PLHIV by Xpert MTB/RIF

The new GF TB project will further develop national capacities and improve collaboration between TB services and HIV services, in line with the latest international guidance, e.g. *WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders* (WHO, 2012, http://www.who.int/tb/publications/2012/tb_hiv_policy_9789241503006/en/index.html), and in accordance with the recommendations of the recent WHO NTP Review (July 2014).

External technical assistance will be provided to the NTP and NAP in priority issues of TB/HIV management and aligning the country practices with up-to-date international standards and guidance. Two national consultants (part-time) will be employed to update relevant regulations and service guidelines for strengthening TB/HIV control interventions, improving collaboration between the two services, and overseeing implementation at sites. Targeted training will be provided for TB service staff in modern approaches and practical aspects of management of HIV-associated TB, including provision of diagnostic counseling and testing (DCT) for HIV and use of rapid tests, recording and reporting, etc.

The project will support procurement of rapid HIV tests for all TB service institutions. Annual workshops on TB/HIV collaboration will be organized with participation of NTP and NAP specialists, which will review the progress in implementation of TB/HIV control interventions, identify problems and barriers in collaboration between the two services, and agree on action plans for the following implementation periods.

The key intervention that need to be strengthened in the field of TB/HIV is WHO-recommended measures to intensify TB case-finding in HIV-infected individuals (one of 'the Three I's for reducing the burden of TB among PLHIV), using a clinical algorithm followed by rapid diagnosis with Xpert MTB/RIF in symptomatic persons. According to the recently updated (October 2013) WHO policy guidance on Xpert, the use of this method is strongly recommended in PLHIV suspect for TB (now

[39]Countries with high co-infection rates of HIV and TB must submit a TB and HIV concept note. Countries with high burden of TB/HIV are considered to have a high estimated TB/HIV incidence (in numbers) as well as high HIV positivity rate among people infected with TB.

supported by high-quality evidence); this is particularly relevant for the high MDR-TB setting in Armenia.

An important bottleneck is the insufficient screening for TB among PLHIV; while the majority of registered HIV-infected individuals undergo some screening for TB and other pulmonary disease in HIV/AIDS service; due to stigma and various service barriers not all of them reach TB institutions for bacteriological examination and establishment / confirmation of TB diagnosis. As a result, in many cases appropriate TB treatment is initiated with significant delays, which adds on the risk of advanced TB disease and death among PLHIV.

To comply with the above recommendations, the TB project will support intensified screening for TB and MDR-TB by Xpert MTB/RIF by placing the instruments and initiating testing at the National Center for AIDS Prevention. The NTP and NAP rely on the fact that provision of this 'one-stop' service at the AIDS Center, which is attended by PLHIV on a regular basis, will provide for appropriate use of technology and will lead to improved TB case detection among PLHIV.

A 2-module Xpert instrument will be provided for the AIDS Center in Yerevan in Year 1. It is planned that, after necessary preparations are completed in terms of procurement, installation, training of staff, etc., the testing will start in January 2016, and the full functionality of the machine will be achieved by the beginning of Year 2 (July 2016).

A national consultant (part-time) will be employed to facilitate introduction of Xpert testing among PLHIV, ensure effective information exchange and coordination between the two services, and monitor the machine's use. Training will be organized for the AIDS Center's staff in Xpert MTB/RIF, including initial training on the use of technology and refresher training (in Years 1-2). As for the other Xpert instruments, the project will provide the UPS station and printers for the machines at the AIDS Center, and support maintenance and servicing, including calibration and module replacement costs.

NCAP has the only reference laboratory in the country performing viral load analysis. It is reasonable to have different opportunities for viral load detection for uninterrupted viral load monitoring. Currently NCAP has 2 Real Time PCR devices supplied by GFATM and another one supplied by Russian Government-supported Regional Cooperation Program, which are used for viral load testing. The GeneXpert primarily will be used for TB diagnostic purposes at PLHIV, however the latest guidance on usage of GeneXpert for HIV viral load detection will be considered for implementation, too, and taken into account while making future orders.

- *Country processes for reviewing and revising the national disease strategic plan(s) and results of these assessments. Explain the process and timeline for the development of a new plan (if current one is valid for 18 months or less from funding request start date), including how key populations will be meaningfully engaged.*

A "National Program on the Response to the HIV Epidemic, 2017-2021" will be drafted in 2015-2016 as stipulated by the NHS paper, too. The Ministry of Health will seek support from the UNAIDS for the development of the new strategy. The new HIV Strategy will be based on up-to-date international policies and guidance in line with the guidance provided by the WHO and UNAIDS. The CCM and MOH will ensure a transparent and participatory process with involvement of relevant government stakeholders, non-governmental organizations, representatives of key populations and international partners. Development of the draft of the new strategy for endorsement by a governmental decree by the end of 2016 is envisioned.

A CCM Working Group as proposed in this Concept Note will be established to work on Human Rights, Gender and Community Engagement.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

To achieve lasting impact against the three diseases, financial commitments from domestic sources must play a key role in a national strategy. Global Fund allocates resources which are far from sufficient to address the full cost of a technically sound program. It is therefore critical to assess how the funding requested fits within the overall funding landscape and how the national government plans to commit increased resources to the national disease program and health sector each year.

2.1 Overall Funding Landscape for Upcoming Implementation Period

In order to understand the overall funding landscape of the national program and how this funding request fits within this, briefly describe:

a. The availability of funds for each program area and the source of such funding (government and/or donor). Highlight any program areas that are adequately resourced (and are therefore not included in the request to the Global Fund).

b. How the proposed Global Fund investment has leveraged other donor resources.

c. For program areas that have significant funding gaps, planned actions to address these gaps.

a. The availability of funds for each program area and the source of such funding (government and/or donor).

The predictable sources of funding for the HIV/AIDS National response programs for the period of 2016-2018 are the Government of Armenia and the Global Fund. While there is the likelihood of ongoing funding for some activities from UNAIDS with funds from the Russian Government and elsewhere from other UN agencies and foundations (such as Open Societies Foundation), no prediction of budgets by these organizations have been made at this point.

USD	2016		2017		2018	
Intervention Area	GOV	GF	GOV	GF	GOV	GF
HIV treatment, care and support	635,019	745,568	661,468	958,302	410,674	1,173,586
HIV prevention/ education: general population	471,000	0	471,000	0	471,000	0
HIV prevention/ education: key populations	0	558,420	0	669,858	250,794	425,452
Blood safety	55,000	0	55,000	0	55,000	0
STI services for HIV prevention	824,781	0	915,645	0	915,645	0

b. How the proposed Global Fund investment has leveraged other donor resources.

Throughout the development of this Concept Note, discussions have been held with Government authorities, including the Ministries of Health and Finance and the Cabinet of Prime Minister with the active engagement of the Global Fund Secretariat Representatives on the need of increased co-funding of the National HIV/AIDS program priority direction during the next three years with a possible complete take over after the 2018. The Government of Armenia has agreed to put forth additional resources during the period of 2016-2018 to prepare itself gradually for a possible take-

over after 2018. The Ministries of Health and Finance were tasked to submit budget calculations on the required amount of government contribution to be considered for inclusion in the midterm expenditure framework program of 2016-2018 and also in the annual health care budgets. The following amount of contribution is suggested for inclusion in the mid-term expenditure framework program of 2016-2018 to be submitted to the Ministry of Finance mid May 2015. Based on the mid-term expenditure frameworks adopted yearly by the Government of Armenia the annual health care budgets are further on developed.

- USD 60,000 for HIV tests for the pregnant started from 2016 (for testing 45.000 pregnant annually.
- USD100,000 from GOV to fund PMTCT and first-line ART from 2017 (200 patients)
- USD 150.000 from GOV to fund PMTCT and first-line ART from 2018 (300 patients)
- USD250,794 from GOV to fund methadone costs for MST from 2018(500 patients)

Discussions on possible amounts of funding were also held with the UN agencies, private foundations and multilateral institutions. UNAIDS Armenia representative was involved in the entire process of the Concept Note writing as a member of the CCM Working Group and participated in all National Stakeholders' and CCM meetings in the process along with the on-going process of negotiations between the UNAIDS and Russian Federation (RF) on the follow-on support to Armenia. This will ensure that any forthcoming grant from RF will not duplicate efforts funded by GF. Provision of technical assistance on the development of sustainability plan by UNAIDS was also brought up for consideration.

Open Societies Foundation Armenia, which has traditionally provided some funding for human rights activities among key populations, was closely involved in discussions with GF CRG human rights consultants and OSF has agreed to consider funding requests for human rights interventions which have not been included in this Concept Note due to budget restrictions. Funding will also be leveraged from UN organizations to carry out a Stigma Index study and review of laws and policies affecting HIV.

c. For program areas that have significant funding gaps, planned actions to address these gaps.

Due to the limited amount of the GF allocations for HIV/AIDS to Armenia, and the lack of sufficient funding from other sources, substantial gaps will remain in funding for the following areas:

- ART scale-up to all people with HIV with T cell counts of 500 and below: this issue will be addressed through prioritizing new patients on ART (see Section 3.2) and by seeking ongoing cost reductions for ART medications and increased support from the GOV of Armenia (through the Sustainability Plan: see 3.2). The willingness expressed by the Government of Armenia to take up a proportion of funding for ART first-line medications should be regarded as a very positive step in this regard.
- Funding for HIV prevention and testing among key populations will not be sufficient to approach the global targets set by UNAIDS in the short-term: this will be the major issue addressed through the Sustainability Plan and government funding.
- Additional funding for the blood tests (for treatment monitoring, OI diagnosis, toxicity monitoring) for PLHIV, the amounts of which have been reduced due limitations of the GF budget, will be an important focus of the Sustainability Plan.

2.2Counterpart Financing Requirements

Complete the Financial Gap Analysis and Counterpart Financing Table (Table1). The counterpart financing requirements are set forth in the Global Fund Eligibility and Counterpart Financing Policy.

a. Indicate below whether the counterpart financing requirements have been met. If not, provide a justification that includes actions planned during implementation to reach compliance.

Counterpart Financing Requirements	Compliant?	If not, provide a brief justification and planned actions
i. Availability of reliable data to assess compliance	☒Yes ☐No	
ii. Minimum threshold government contribution to disease program (low income-5%, lower lower-middle income-20%, upper lower-middle income-40%, upper middle income-60%)	☒Yes ☐ No	
iii. Increasing government contribution to disease program	☒Yes ☐ No	

b. Compared to previous years, what additional government investments are committed to the national programs in the next implementation period that counts towards accessing the willingness-to-pay allocation from the Global Fund. Clearly specify the interventions or activities that are expected to be financed by the additional government resources and indicate how realization of these commitments will be tracked and reported.

c. Provide an assessment of the completeness and reliability of financial data reported, including any assumptions and caveats associated with the figures.

The following amount of contribution is suggested for inclusion in the mid-term expenditure framework program of 2016-2018 and corresponding annual public health care budgets.

- USD 60,000 for HIV tests for the pregnant started from 2016
- USD 100,000 from GOV to fund PMTCT and first-line ART from 2017
- USD 150.000 from GOV to fund PMTCT and first-line ART from 2018
- USD 250,794 from GOV to fund methadone costs for MST from 2018

It should be noted Government of Armenia has funding commitments under the NFM TB grant project, too, in the form of take-over of first-line anti-TB medicines purchase starting from 2016 and side effect medication from 2017 formerly paid for by international donors.

Those commitments will be reflected in the mid-term expenditure framework programs and annual health care budgets in particular in the budget lines dedicated to central procurement of medicines by the Ministry of Health. The expenditures will be reported on through annual reports from the Ministry of Health and through UNGASS reports.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

This section details the request for funding and how the investment is strategically targeted to achieve greater impact on the disease and health systems**.** It requests an analysis of the key programmatic gaps, which forms the basis upon which the request is prioritized. The modular template (Table 3) organizes the request to clearly link the selected modules of interventions to the goals and objectives of the program, and associates these with indicators, targets, and costs.

3.1 Programmatic Gap Analysis

A programmatic gap analysis needs to be conducted for the three to six priority modules within the applicant's funding request.

Complete a programmatic gap table (Table2) detailing the quantifiable priority modules within the applicant's funding request. Ensure that the coverage levels for the priority modules selected are consistent with the coverage targets in section D of the modular template (Table3).

For any selected priority modules that are difficult to quantify (i.e. not service delivery modules), explain the gaps, the types of activities in place, the populations or groups involved, and the current funding sources and gaps.

The 2013-2016 National AIDS Program is being supported from the state financial sources, as well as from the financial sources of donor organizations, including GFATM, UN agencies, and multilateral/bilateral organizations. GFATM has been covering the big part of the country response on HIV/AIDS.

Even though the Government of Armenia has committed to increase expenditure on HIV in coming years (see Section 2.2), and will meet many of the staff and clinic costs related to this scale-up, including paying for PMTCT and first-line ART from 2017, methadone cost from 2018, the key prerequisite for successful implementation of the NAP could be ensured mostly through the financial support provided by the GFATM as there is no governmental funding for HIV prevention activities among KPs (MSM, SW, PWID). Governmental institutions do not participate in the HIV prevention measures among KPs except for the provision of MST which is implemented in organizations under the supervision of MoH and MoJ and is supported from the state budget to a very little degree.

The remaining HIV prevention activities are/were exclusively provided by NGOs in the framework of the current and past GF grants. The coverage by these activities has been expanded, however it remains far from being sufficient.

It is very important to at least continue the activities aimed at forming safe behavior among KPs and achieving universal access to HIV prevention, treatment, care, and support services for them and keep the achievements the country has gained due to implementation of the GF grants.

Access to HTC at the community level remains one of the major gaps in the national HIV program as HIV testing for KPs is not broadly available. By this proposal this gap will be addressed via scaling up Rapid Testing to increase the outreach HTC to the KPs. In this regard the following steps will be undertaken:

1. Revision of the requirements for organizations that provide HTC services for simplification of procedures for obtaining licenses/permits, to introduce the possibility of free licensing for community-based organizations, to reduce the requirements to actually necessary level.
2. Provision of technical support and capacity building to CBOs and NGOs to achieve adequate quality of counseling, reliability of test results and to ensure safety and confidentiality of HTC.

3. Supervision of HTC services provided by community-based organizations.

A programmatic gap analysis is presented in the Programmatic Gap Tables below, as well as separately in the Excel file attachment. These tables present the primary interventions included in the Modular Template, namely:

- *Treatment, care and support* [Indicator: Percentage of adults & children currently receiving ART among all adults & children living with HIV]
- *Prevention programs for people who inject drugs (PWID) and their partners* [Indicator: Percentage of PWID who have received a HIV test and know the result]
- *Prevention programs for sex workers and their clients* [Indicator: Percentage of SW who have received a HIV test and know the result]
- *Prevention programs for MSM and TGs* [Indicator: Percentage of SW who have received a HIV test and know the result]
- *Prevention programs for Labor Migrants* [Indicator: Percentage of labor migrants who have received a HIV test and know the result]
- *Prevention programs for prisoners* [Indicator: *Number of PWID on OST in prisons]*

These interventions are considered high priority based on Armenia's epidemiological context, and represent the major focus of this Concept Note.

Though according to epidemiological analysis the increasing proportion of registered cases occurs among labour migrants to Russian Federation and other countries, and their sexual partners, migrants' component is not reflected in this CN at full volume as currently the HIV prevention activities among migrant population are mainly financed by the Russian Government/UNAIDS and a small part financed through the GF grant. Although there is no official confirmation yet made by theRussian Government/UNAIDS for the continuation of the program after 2015, subject to clarification towards the end of this year, our assumption is that the Global Fund project will continue to serve as complimentary to the main bulk of activities planned under the Russian Aid Project.

The package contains HIV counseling, which is given in broader format, covering the issues of reproductive health and family planning. In addition, the package includes testing for HIV, Hepatitis B, C and screening for TB through specially developed questionnaires. Besides, the migrants were provided with referrals to the National AIDS Center for undergoing PCR testing for Chlamydia trachomatis, Trichomonas vaginalis, Ureaplasma urealyticum, Mycoplasma hominis, Gardnerella vaginalis. Testing for HIV, Hepatitis B, C (blood samples) were performed on sites, and testing for STIs (swab samples) - at the National AIDS Center. The TB suspects (identified through screening with questionnaire), were referred to TB facilities for further diagnosis.

In addition, the Modular Template includes a module for Program Management, Health information systems and M&E, and on Removing legal barriers to access.

The Program Management module has two interventions:

1. Policy, planning, coordination and management

2. Grant management

The *Policy, planning, coordination and management* intervention will give an opportunity to develop the transition plan (above allocation budget). The Operational Outline for the Development of Transition Plan Towards Sustainable HIV Response is presented in Annex 10.

The *grant management* intervention will address management of Sub-Recipients, particularly to assure robust financial management.

Funding for Program Management will come directly from GF funds, as it supports GF program implementation.

A module of Health information systems and M&E will address a current gap in strategic information. This intervention will support integrated bio-behavioral survey (IBBS) in Year 1 to serve as a basis for the development of a new National AIDS Program 2017-2021. A second IBBS is planned in Year 3 under the "above allocation" budget) to measure the impact and outcome indicators for both National AIDS Program and NFM. KP size estimation exercise is included in the Proposal for Russian support program for 2016-2018 to support M&E processes in combination with IBBS.

The module on Removing legal barriers envisages funding above allocation to develop and adopt legislation to protect needle-syringe programs and KP outreach workers.

It includes the following activities as well:

- A CCM Working Group on Human Rights, Gender and Community engagement will be established: funding for this WG will be sought through GF CCM funding for Armenia. In the short-term, the focus of this WG's work will be on addressing confidentiality issues among OST and ART clients, whose medical files are sometimes provided to police. In the longer term, key populations will be resourced to engage meaningfully into the process of developing a national sustainability plan for ongoing funding and resourcing of HIV programs in Armenia beyond 2018.
- *Legal environment assessment and law reform:* Advocacy for legal protection for needle-syringe programs and to KP outreach workers are included under the "above allocation" section of activities.
- *Community-based monitoring*: Groups from key populations will be resourced and trained, using materials developed under the GF-funded EHRN HIV grant, to record access issues for their population, as well as human rights violations, and practical advocacy to overcome key barriers in access to services for KPs. This activity is planned under the "above allocation" budget for each KP (PWID, SWs MSM)
- *Training for officials, police and health workers* to develop human rights protection skills and awareness in dealing with KPs and vulnerable communities: This activity is not covered under the current funding request and will be a subject for possible inclusion in other donors' programs.

Open Societies Foundation Armenia, which has traditionally provided some funding for human rights activities among key populations, was closely involved in discussions with GF CRG human rights consultants and OSF has agreed to consider funding requests for human rights interventions which have not been included in this Concept Note due to budget restrictions. Funding will also be leveraged from UN organizations to carry out a Stigma Index study and review of laws and policies affecting HIV.

3.2 Applicant Funding Request

Provide a strategic overview of the applicant's funding request to the Global Fund, including both the proposed investment of the allocation amount and the request above this amount. Describe how it addresses the gaps and constraints described in questions1, 2 and 3.1. If the Global Fund is supporting existing programs, explain how they will be adapted to maximize impact.

This Funding Request is clearly based on the objectives of the Armenia HIV NSP 2013-2016 (Annex 3), the January 2015 WHO Review of HIV/AIDS Treatment and Care in Armenia (Annex 5), the February 2015 Armenia HIV Portfolio Analysis provided by the GF Secretariat (Annex 6), the February 2015 Optima Investment Case (Annex 7), the 2012 *Strategic information for evidence based planning in the Republic of Armenia* (Annex 8). It is also based on a set of community consultations with Key Affected Populations (KPs) populations (Annex 1).

The Government of Armenia (GoA) has committed to increase expenditure on HIV in coming years (see Section 2.2), but there is a need to urgently scale up outreach programming to reach and encourage HIV testing among KPs, and to ensure that ART and PMTCT programs keep pace with new diagnoses of HIV. GoA will meet many of the staff and clinic costs related to this scale-up, including paying for PMTCT and first-line ART from 2017. This funding request is for those elements of the scale-up and continuation of services not able to be funded from within the GoA's resources.

This funding will support the two key objectives of the HIV NSP 2013- 2016 - to reduce HIV transmission and to reduce HIV morbidity and mortality; and the six key sections of the Program identified in the HIV NSP: Enabling environment; HIV prevention; HIV treatment, care and support; Monitoring and evaluation; Management, coordination and partnerships; and Financing and resource mobilization.

The principles and priorities that underpin this work will be in line with international evidence for effectiveness, set out most recently in the 2014 WHO Consolidated Guidelines on HV Prevention, Diagnosis, Treatment and Care for Key Populations. For Armenia the key populations are people who inject drugs (PWID), sex workers and their clients (SW), men who have sex with men and transgender people (MSM/TG). People living with HIV (who are drawn mainly from the three previous key populations, constitute a fourth focal population.

People in prisons with injecting drug use and/or subjected to other risk behaviors, will be targeted by provision of OST in prisons, and other prevention means.

Because seasonal labor migrant Armenians leaving the country to seek work opportunities outside and returning are an already recognized by technical partners additional group of most-at-risk population this program also includes specific activities of prevention and early detection among labor migrant population, too.

The HIV program in Armenia has been successful in achieving some of the targets set within its HIV Strategic Plan for the years 2013-2014, exceeding targets for ART, PMTCT and enrolment on OST. However, this success has not been extended to HIV testing among key populations, which remains at lower than optimal levels. Knowledge of HIV status is a key first step to effective HIV treatment and care for all KPs and has prevention outcomes as well, as PLHIV access treatment and care, and prevention support that reduce onward HIV transmission.

In addition to low levels of knowledge of HIV status among KPs, the WHO review found high levels of STIs among MSM and SW, which indicates low levels of condom use, and expressed concerns about the quality of needle-syringe programs through PWID outreach. For these reasons, Armenia will re-orient outreach to these populations with substantial changes to structures and practices.
The interventions proposed are also in line with the findings of the recently-conducted Optima Process recommending that the best outcomes on HIV investment would result from:

- Increasing ART funding – to 24% of all HIV funding instead of 17%, as in 2013
- Increased funding to the OST program – to 10% instead of 7%
- Increased funding to the condom and testing program among sex workers and their clients – 9% instead of 7%
- A slight increase in seasonal migrant testing and prevention program – to 5% of allocation instead of 4%

A brief description of the proposed interventions by each objective is set out below.

Objective 1: To reduce HIV transmission through targeted interventions and increased knowledge of HIV status among KPs
Module 1.1 Increased knowledge of HIV status among KPs, with a direct link to treatment and care

for people diagnosed with HIV

The Optima Process identified increased access to ART for PLHIV as a high-priority intervention for an effective response to HIV in Armenia. This can only be achieved if knowledge of HIV status among KPs can be increased. A single NGO will be selected to work with each of the four key populations: MSM, PWID, SW and PLHIV. Each of these organizations will be tasked with providing services in at least the three major population centers: Yerevan, Gyumri and Vanadzor. Services provided by these organizations to MSM, PWID and SW will be based on outreach principles but will involve:

- Redefining the task of outreach workers to ensure they increase their focus on assisting KPs to access HIV testing, understand the result and act on it
- Building skills of outreach workers to participate in rapid HIV testing, and provide support and effective onward referral of newly-diagnosed PLHIV into HIV care and treatment.
- Shifting to new communication technologies, specifically mobile phone-based messaging, except for those poorer and homeless key populations. Sponsorship for training and assisting NGOs to use broadcast SMS and other mobile technologies will be sought from Armenian cellphone companies and mobile network providers.
- Closer collaboration with governmental health services through Coordination Councils to be established in Yerevan, Gyumri and Vanadzor. These Councils, which bring together NGO and government health services to determine local solutions to improving access to health services for key populations – with a particular focus on reducing loss to follow-up for newly-diagnosed PLHIV. These Councils have proven highly effective in Central Asia.

HIV testing approach

Taking into account that the cost of the saliva tests itself is almost 3,5 fold higher than currently budgeted (the cost of the test itself 2,5 fold + extra costs conditioned by small quantities to be transported via air cargo) and with the current positive experience of using rapid capillary blood HIV tests among MARPs in medical facilities in marzes, the preferred approach is to expand the number of testing sites (medical facilities), thus increasing access to testing. Meanwhile, other options for increasing access to testing, such as testing by NGOs after obtaining corresponding license and/or by mobile units using either blood or saliva tests (if appropriate savings are generated to enable procurement) will be exercised within the frames of the project.

Testing will be prioritized through the following activities:

- Support the licensing of NGOs for performing HIV rapid tests, similar to other countries in the region and throughout Europe.
- Ensure the linkage of key populations with rapid HIV positive tests to the Republican AIDS Center through accompanied referral by peers/outreach workers for a confirmation test and enrollment in treatment and care.

HIV testing will be offered to all patients attending TB and STI clinics. Global Fund resources for testing will only be used for HIV tests only among key populations, while testing of other population groups will be subjected to Government and other sources of funding.

The HIV testing algorithm currently in use at NCAP (2 positive ELISA test confirmed by Immunoblot) is fully in line with WHO guidelines "Service Delivery Approaches to HIV Testing and Counseling (HTC): a Strategic HTC Program Framework", 2012 (Figure 7 "HIV testing strategy for diagnosis in low prevalence settings", page 39). Moreover, for newly diagnosed individuals, a positive result should be confirmed on a second specimen to rule out laboratory error.
The guidelines also specify that "In a low prevalence population, the positive predictive value based on two test results remains too low. Therefore, for specimens that are reactive on both the

first and second assays (A1+; A2+), a third assay should be used to confirm HIV-reactive specimens. If the third test result is also reactive (A1+; A2+; A3+), the result can be reported as HIV positive.

In addition, in the WHO information note - 22 October 2014 it is recommended to retest all persons newly diagnosed as HIV positive, with a second specimen before ART initiation, to rule out potential misdiagnosis. Also, WHO recommends standardized testing strategies using at least three serial tests in low prevalence settings.

As a rule, rapid tests results are reported almost immediately. For ELISA tests, the waiting time is as follows:

- NCAP, private and state laboratories: 0-1 days;
- Counseling and testing sites in Yerevan: 5-7 days, depending on the transfer time of blood samples from the collection site to a laboratory, usually to NCAP;
- Counseling and testing sites in marzes of Armenia: 5-30 days, it depends on the transferring time of blood samples from the collection site to a laboratory, usually to Regional laboratories.

The CN envisages quantity of Rapid Tests according to the targets for HIV testing among MARPs. ELISA tests are envisaged for second test for positive results among MARPs, some pregnant women at risk, patients with clinical indications at health care settings (PITC is a main contributor to HIV new cases revealing in Armenia). All HIV positive cases should be confirmed by New LAV BLOT. The period of time passing from the first HIV positive test to link to care in the country is 7 days regardless of the site where this test is performed. This process includes second blood taking for ELISA test, confirmatory test and medical counselling for care.

However, the period of time from the moment of blood taking to performing first HIV test, particularly in the country regions has to be optimized.

The optimization process is envisaged by CN through operation of the existing CT/Lab Support Team supported by the current RCC grant. In the scope of the NFM grant the team will consider the best ways of optimization of this period in each region of the country, taking into account local specificities, problems, barriers, possible ways of solution with providing appropriate recommendation to MoH, and involving local health care authorities when it is needed and applicable. The CT/Lab Support Team will also build capacity and skills of NGO specialists for rapid testing for blood and will support those NGOs which will apply for licensing, support to fill in necessary documents package according to existing regulations.

The team staff consists of a counseling and testing specialist (physician) and laboratory doctor under NCAP management.

Key functions of the team include technical assistance to about 160 health care facilities (antenatal clinics, TB, narcological, and STI clinics, primary health care facilities, hospitals, criminal executive institutions) countrywide per year to provide HIV testing and counseling; technical assistance and methodological support to 42 HIV testing laboratories, HIV testing quality assurance in HIV testing laboratories regardless of their ownership forms, capacity and skills development for laboratory specialists to conduct testing for HIV, Hepatitis, co-infections; capacity building for counselors (health care workers, non-health care workers, NGOs staff, etc.).

All site visits results are analyzed, recorded and reported to NCAP management and the Ministry of Health for decision-making, for services improvement and optimizing and efficiency gaining.

Relevant recommendations are provided also to local health care facilities with implementation monitoring.

A rapid testing system will be implemented by SRs with three key populations: MSM, PWID and SW. Training and test kits will be provided to outreach workers to screen KPs for HIV, and a protocol will be established to ensure confirmatory testing is carried out quickly where KPs screen positive. Outreach workers will be trained in pre- and post-test counseling and the PLHIV SR will assist other SR outreach workers with post-test counseling for those confirmed positive, and assist them into HIV treatment, care and support. Testing for migrants will continue through the NCAP mobile clinic purchased through the current Russian Federation/UNAIDS grant and mobile medical teams in villages and districts where a high percentage of migrants reside.

Module 1.2 Prevention programs for people who inject drugs:

All PWID will be reached with individual or group level counseling on HIV with a certain part receiving HIV testing.

Based on consultations with the beneficiaries, the concept note was designed so that certain services and goods, e.g. condoms, syringes and educational materials are provided not to every single beneficiary, but only to those beneficiaries who request those (please, refer to Annex 1. Country Dialogue). Therefore, the idea of comprehensive minimum package of services to be provided to any beneficiary becomes irrelevant.

OST services will be expanded, though this expansion will need to be gradual as funds become available. This issue will be elaborated in the Transition Plan. Funding "above allocation" is sought in this Concept Note to develop and adopt legislation to protect needle-syringe programs and KP outreach workers.
Stronger linkages between needle-syringe programs/ PWID outreach and OST services will be established via close collaboration and information sharing between PWID outreach program and the OST service as well as mutual referral to ensure that PWID have a range of services available to them.
Key activities will include:

- Individual or group level counseling on HIV
- Distribution of condoms
- Distribution of needle and syringe
- Distribution of eeducational materials on HIV testing and counselling
- Increasing the number of OST sites. Currently there are 7 OST sites in prisons and 3 in the civil sector. The MoJ is considering the possibility of providing OST in some additional prisons, while inclusion of the remote Syunik marz narcology clinic under the NFM is under consideration by the Ministry of Health.
- Ensure quality of OST delivery (in line with WHO guidelines) by:
    - Ensuring that the dose of OST is correct, through updating of guidelines, provider training and quality monitoring
    - Standardizing inclusion/exclusion criteria to ensure consistent access
    - Building patient trust and OST adherence by ensuring the confidentiality of patients by keeping medical registers private, including from the police,
    - Complementing existing OST sites with comprehensive psychosocial services by employing more trained social workers, who would be able to assess individual patient needs and promote social integration of patients;
- Initiate a discussion with the Ministry of Justice to advocate the need of gradual increase in governmental budget for OST in prisons.

Module 1.3 Prevention programs for sex workers and their clients

All SWs will be reached with individual or group level counseling on HIV with a certain part receiving HIV testing.

Based on consultations with implementing SRs and beneficiaries, the concept note was designed in a way, that certain services and goods, e.g. condoms and educational materials are provided not to every single SW, but only to those beneficiaries who request those (Annex 1. Country Dialogue). i.e. the idea of comprehensive package of minimum services to be provided to any beneficiary becomes irrelevant. That approach focuses on promotion of behavior change by encouragement of beneficiaries to purchase prevention means, since the further funding in 3 years is unclear.

Key activities will include:

- Individual or group level counseling on HIV
- Distribution of condoms
- Distribution of needle and syringe
- Distribution of educational materials
- HIV testing and counselling
- Training and mobilizing peer outreach workers to sex work sites in Yerevan, Gyumri and Vanadzor
- Behaviour change communication with a focus on assisting sex workers and clients to access STI and HIV testing – accompanied referral
- Psychological support to newly-diagnosed SW with HIV by project staff
- Outreach workers to act as brokers for SW to access full range of sexual and reproductive health services
- Work with local police on a harm reduction approach to sex work – allowing outreach to occur, reducing harassment, violence, stigma and discrimination
- Collaboration with sexual assault services to ensure access for sex workers who have been assaulted

Module 1.4 Prevention programs for MSM and transgender people

All MSM will be reached with individual or group level counseling on HIV with a certain part receiving HIV testing.

Based on consultations with implementing SRs and beneficiaries, the concept note was designed in a way, that certain services and goods, e.g. condoms and educational materials are provided not to every single beneficiary, but only to those beneficiaries who request those (Annex 1. Country Dialogue), i.e. the idea of comprehensive package of minimum services for all beneficiaries became irrelevant. The current approach focuses on promotion of behavior change by encouragement of beneficiaries to purchase prevention means, since further funding in 3 years is unclear.

- Key activities will include: Individual or group level counseling on HIV
- Distribution of condoms
- Distribution of educational materials
- HIV testing and counseling
- training of STI doctors in sexual history taking to include attention to the possibility of anal STIs
- work with policy to reduce harassment, blackmail, violence
- exploration of BCC through mobile phone meeting Apps, websites

Module 1.5 Prevention programs for labor migrants

Key activities will include:

- Testing for HIV, HCV, HBV

- Individual or group counseling on HIV

Module 1.6 Prevention programs for prisoners
Key activities will include

- *OST for prisoners*
- *Needle and syringe program*

Objective 2: Scale-up of ART

Success under this objective relies heavily in the success of increased access to HIV testing and onward referral of newly-diagnosed KPs with HIV under Module 1.2 above.
Module 2.1 Improved access to and quality of treatment

Key activities will include:

- Provision of ART to 1300 PLHIV by 2018
- Provision of treatment monitoring
- Provision of OI prevention and treatment
- Provision of follow-up for PLHIV (VL and CD4 testing for PLHIV not yet on ART)

Module 2.2 Increased support to PLHIV to maximize health and wellbeing and to reduce onward transmission by maintaining the lowest possible viral load
An important issue addressed in this Concept Note is the strengthening of HIV care and support through ongoing funding to a PLHIV SR. As well as the interaction with other KP SRs described above (in post-test counseling of those found to be HIV-positive), this SR will continue its work with PLHIV both within and outside the medical system in assisting PLHIV to stay connected to clinical care services, reinforcing prevention messages, reducing barriers to accessing ART and increasing treatment adherence.

Objective 3: Strengthening the Enabling Environment for HIV programs:

Module 3.1 Removing barriers to services for KPs

The module on Removing legal barriers envisages funding above allocation to develop and adopt legislation to protect needle-syringe programs and KP outreach workers.

It includes the following activities:

- A CCM Working Group on Human Rights, Gender and Community engagement will be established: funding for this WG will be sought through GF CCM funding for Armenia. In the short-term, the focus of this WG's work will be on addressing confidentiality issues among OST and ART clients, whose medical files are sometimes provided to police. In the longer term, key populations will be resourced to engage meaningfully into the process of developing a national sustainability plan for ongoing funding and resourcing of HIV programs in Armenia beyond 2018.
- *Legal environment assessment and law reform:* Advocacy for legal protection for needle-syringe programs and to KP outreach workers are included under the "above allocation" section of activities.
- *Community-based monitoring*: Groups from key populations will be resourced and trained, using materials developed under the GF-funded EHRN HIV grant, to record access issues for their population, as well as human rights violations, and practical advocacy to overcome key barriers in access to services for KPs. This activity is planned under the "above allocation" budget for each KP (PWID, SWs MSM)
- *Training for officials, police and health workers* to develop human rights protection skills and awareness in dealing with KPs and vulnerable communities: This activity is not covered under the current funding request and will be a subject for possible inclusion in other donors' programs.

Open Societies Foundation Armenia, which has traditionally provided some funding for human rights activities among key populations, was closely involved in discussions with GF CRG human rights consultants and OSF has agreed to consider funding requests for human rights interventions which have not been included in this Concept Note due to budget restrictions. Funding will also be leveraged from UN organizations to carry out a Stigma Index study and review of laws and policies affecting HIV.

Module 3.2 Improving Strategic Information available to support program planning and review:
As recommended by WHO, several changes will be made to increase Armenia's strategic information capability related to HIV. The module will be implemented by the M&E unit of the NCAP.

Key activities will include:

- Develop a national HIV database and cohort to track persons from diagnosis through to treatment and care. Such a database would be housed at NCAP.
- Improve the tracking of persons tested by setting and risk group and tracking of new versus repeat testers annually. The current system provides test volumes and mixes risk and setting. This information will provide a better understanding of who and where to test and allow for the monitoring of testing programs.
- Improve accuracy of estimates of undiagnosed populations by revising population size estimates for KPs. Different methodologies will be compared including the soon-to-be-released ECDC method, along with Spectrum.
- Improve the tracking of rate and cause of HIV-related death through the matching of databases/Excel spreadsheets with the National Statistics Service (this is now possible with computerized records).
- Death data will be improved through matching with data from the national surveillance system. Routine reconciliation between databases will provide insights into loss to follow up or not linked to care. Armenia will carry out an operations research to establish a better understanding of causes of loss to follow up.

Module 3.3 Sustainability planning
The Armenian CCM is aware that some countries that have 'graduated' from GF funding have faced major problems including, in the case of countries such as Romania, a very fast-increasing HIV epidemic among PWID after the end of GF funding. The CCM is concerned that the ongoing changes to the ways countries like Armenia can access GF funds means that there will likely need to be a transition to other funding sources within the near future.

As recommended by the WHO Mission on HIV/AIDS treatment and care in Armenia in January 2015, this Concept Note includes an operational outline for a country transition plan towards financial and programmatic sustainability (see Annex 10). The CCM and PR(s) will work with International Technical Assistance to develop a Transition Plan Towards a Sustainable HIV Response for discussion with the Government of Armenia in 2016-17.

The WHO report recommended that an outline of the Transition Plan be included in this Concept Note. The Plan would provide answers to the following questions:

1. Description of the current state of the epidemic and how is that expected to change.
2. Where are we focusing our efforts and resources today? What is the current impact? And where does the money come from?
3. What program elements are required and at what scale for an optimal response? What is the programmatic gap?
4. What would be the impact of this optimal program?
5. What bottlenecks and inefficiencies can be addressed and how?
6. How much money will be needed for HIV in the future to maintain the current level of infection

7. What is the funding gap? Quantify the discrepancy between current funding levels and those required to meet HIV epidemic targets, as identified in Question 6.
8. What financing options are available to close any remaining financing gap once efficiency gains
9. What are the steps towards securing the alternative funding for prioritized activities?

3.3 Modular Template

Complete the modular template (Table3).To accompany the modular template, for both the allocation amount and the request above this amount, briefly:

a. Explain the rationale for the selection and prioritization of modules and interventions.

b. Describe the expected impact and outcomes, referring to evidence of effectiveness of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

The modules selected for this Concept Note are the standard modules appropriate for a low-prevalence country, seeking to balance HIV prevention, care and support among key populations with ensuring that all people living with HIV receive appropriate treatment, care and support.

The module on Treatment, Care and Support takes into consideration the substantial investment by the Government of Armenia (GoA) into medical and nursing staff and facilities, including those specifically addressing HIV, and the many narcological, dermatovenereological, gynecological/ obstetric and other facilities accessed by key populations. In addition, the allocation targets and budget have been adjusted to take into account the Government funding of first-line ART from 2017. The targets for the Allocation amount for this module are established through the National Strategic Plan (for 2016, extrapolated at a similar rate of expansion for 2017 and 2018).

For the key populations work, three of the modules are standard for low-prevalence epidemics. Targets for each of these – PWID, MSM and SW – were set in the same way as above. Seasonal workers (labor migrants) are a large, widely spread out population in Armenia and no method has yet been found to reach and provide HIV testing and counseling to the whole population. While it is acknowledged that only a small minority of migrants will be addressed through GF funds – in those marzes where the proportion of labor migrants is highest – the Government of Armenia will continue to seek other funds and resources to increase reach into this population in the coming years. The Program Management module is also standard.

Given the reduction in funding over previous years, it is not to be expected that a dramatic further reduction in HIV incidence will occur during the three years of this Program. However, the Concept Note interventions and targets should:

- increase the ease with which key populations can access HIV testing and counseling, leading to an increased level of HIV testing among key populations, leading to a larger proportion of those living with HIV knowing their status
- increase the speed with which people diagnosed with HIV can be assessed for ART and enrolled on ART, leading to a greater proportion of those needing ART accessing this treatment
- increase ART adherence, particularly among HIV+ PWID through greater integration of OST and ART, leading to longer retention and greater likelihood of viral load suppression
- increase the identification of TB among PLHIV, and of HIV among people accessing TB services, leading to a reduction in HIV-related deaths.

3.4 Focus on Key Populations and/or Highest-impact Interventions

This question is <u>not</u> applicable for low-income countries.

Describe whether the focus of the funding request meets the Global Fund's Eligibility and Counterpart Financing Policy requirements as listed below:

a. If the applicant is a lower-middle-income country, describe how the funding request focuses at least 50 percent of the budget on underserved and key populations and/or highest-impact interventions.

b. If the applicant is an upper-middle-income country, describe how the funding request focuses 100 percent of the budget on underserved and key populations and/or highest-impact interventions.

This Program meets the GF Eligibility and Counterpart Financing Policy, with more than 50% of budgeted activities being directed specifically towards key populations.

As well as the four modules of interventions aimed only at key populations, it has been calculated by the National AIDS Center that at least 30% of all PLHIV being followed up or on ART are from key populations.

SECTION 4: IMPLEMENTATION ARRANGEMENTSAND RISK ASSESSMENT

4.1 Overview of Implementation Arrangements

Provide an overview of the proposed implementation arrangements for the funding request. In the response, describe:

a. If applicable, the reason why the proposed implementation arrangement does not reflect a dual-track financing arrangement (i.e. both government and non-government sector Principal Recipient(s).

b. If more than one Principal Recipients nominated, how coordination will occur between Principal Recipients.

c. The type of sub-recipient management arrangements likely to be put into place and whether sub-recipients have been identified.

d. How coordination will occur between each nominated Principal Recipient and its respective sub-recipients.

e. How representatives of women's organizations, people living with the three diseases, and other key populations will actively participate in the implementation of this funding request.

Considering that according to CCM April 10, 2015 decision dual- track financing will be preservedwith the same PR organizations—the Ministry of Health and the Mission East Armenia will continue collaboration throughout program implementation. Coordination between PRs is managed by CCM through CCM secretariat. As key program documents, i.e. M&E Plan, PSM Plan, etc. are integrated for the 2 PRs, uninterrupted and effective implementation of the program requires close cooperation between PR Implementation Teams. During last 6 years of RCC grant the PRs managed to establish effective communication, using both formal and informal channels.

The Principal Recipients will execute their functions through the Project Coordination/Implementation Teams, established in the framework of the ongoing TGF programs,

and apply procedures in accordance with the Global Fund requirements and in compliance with the national legislation. The grant funds will be transferred to the special account of the PRs. The PRs will be responsible for all practical issues related to the project implementation including oversight of the Sub-recipients (SRs). The PRs will undertake the functions of procurement of health and non-health products, equipment and services, financial management, project-related monitoring and evaluation and reporting to the Global Fund. All relevant procedures will be carried out in accordance with the Project Operations Manual.

Taking into account that the NFM grant is the continuation of the current HIV grants and the main activities needs to be continued or expanded, the activities administered by the MoH will continue to be implemented by the same SRs, which are the following state health institutions:

1. National Center for AIDS Prevention

2. Republican Narcological Center

3. Lori marzpsychoneurological clinic

4. Gyumri psychological health center

In case of the OST expansion to one more marz (SyunikMarz) additional state health institution can be considered for being an SR for OST project.

For NGO SRs carrying out outreach activities among key populations will be selected through a selection procedure described in Annex 11.

Before signing the SR agreements, the PRs will carry out the assessments of prospective SRs in terms of their correspondence to the Global Fund requirements vis-a-vis the capacities for financial management, procurement, M&E and other aspects. The activities of SRs will be continuously monitored on the basis of verification of programmatic and financial indicators towards project implementation progress, including visits to SR project sites.

NGO and Government PRs communicate program related information to SRs through various communication channels. They regularly share with SRs Management and Implementation Letters from GFATM Portfolio Management Team, hold regular formal meetings with SRs to discuss implementation issues and challenges. Financial and programmatic management is coordinated through regular monitoring visits to SRs, data verification, as well as based on analysis of SR quarterly and semi-annual reports. PRs also discuss and coordinate implementation of recommendations made by Local Fund Agent during monitoring and data verification visits.

Representatives of women's organizations, people living with HIV and NGOs working with key populations are members of CCM. All CCM members have an opportunity to observe program implementation on sites through works of CCM oversight body.

The Country Coordination Mechanism (CCM) will oversee the overall implementation of the project and ensures proper coordination between different sectors as well as different programs implemented by other external partners. The CCM will closely monitor the project progress through its Oversight Committee to ensure that the activities are carried out according to the work-plan, and indicators of programmatic and financial performance are accomplished. It will make the key financial and programmatic decisions and will have the responsibility to address the

main problems and challenges related to the project.

The CCM meetings will be convened quarterly or more frequently as necessary. Technical working groups for each component will work with the stakeholders between the CCM meetings and prepare the documentation to be endorsed by the CCM. The CCM and the Ministry of Health will carry out the role of coordination with other programs and development initiatives. The CCM will ensure practical coordination and collaboration with all local partners involved.

On a semi-annual basis (or more frequently as requested by the CCM), the Principal Recipient will prepare the summaries of project progress for review by the CCM. These summary reports will present the current state of the epidemic, project implementation progress, financial expenditures and implementation challenges and problems. The CCM will use this information to approve the changes in the program setup and resource allocation when necessary. The CCM will negotiate the recommended changes with the Global Fund through the country's Fund Portfolio Manager (FPM) and the Country Team.

4.2 Ensuring Implementation Efficiencies

Complete this question only if the Country Coordinating Mechanism (CCM) is overseeing other Global Fund grants.

Describe how the funding requested links to existing Global Fund grants or other funding requests being submitted by the CCM.

In particular, from a program management perspective, explain how this request complements (and does not duplicate) any human resources, training, monitoring and evaluation, and supervision activities.

The current RCC grant in support of the National Program on the response to HIV/AIDS Epidemic in the Republic of Armenia is implemented by MOH and Mission East. The end-date of those projects is 30 September, 2015. However, an extension has been negotiated with TGF, until December 31, 2015. Therefore, taking into account that the NFM grant will start on 1 January 2016, there is no duplication of funding or activities across the current and new projects.

This Funding Request is clearly based on the objectives of the HIV NSP 2013-2016 (Annex 3), January 2015 WHO Review of HIV/AIDS Treatment and Care in Armenia (Annex 5), February 2015 Armenia HIV Portfolio Analysis provided by the GF Secretariat (Annex 6), February 2015 Optima Investment Case (Annex 7), 2012 Strategic information for evidence based planning in the Republic of Armenia (Annex 8), and for all interventions related to key populations, on community consultations with those populations (Annex 1).

Implementation of the HIV NSP, including the development of external funding applications in support of its implementation, is coordinated by the Country Coordination Mechanism for HIV and TB, an inter-ministerial and inter-sector decision-making body that includes technical working groups and enhances coordination and capitalizes upon the values added by joint efforts of key stakeholders from different sectors. The CCM provides a platform for discussing the key problems and identifying additional interventions in HIV/AIDS and TB control, ensuring effective coordination of efforts and avoiding duplication of activities. The CCM regulations provide clear guidance to all interested parties for contributing to the national HIV and TB responses through

this mechanism.

Interventions proposed under the current application have been designed following a thorough analysis of program needs for the coming three years and their coverage under the existing and planned funding from both governmental and external sources. The process has been carried in a transparent, cooperative and participatory manner, through a country dialogue involving relevant governmental entities, international agencies and civil society, with the aim to avoid overlapping of activities, as well as to ensure that all priority interventions are covered by either domestic or external resources. A number of general CCM meetings and CCM HIV technical working groups took place during the process of development of this NFM application.

4.3 Minimum Standards for Principal Recipients and Program Delivery			
Complete this table for each nominated Principal Recipient. For more information on minimum standards, please refer to the concept note instructions.			
PR 1 Name	Ministry of Health of the Republic of Armenia	**Sector**	Governmental
Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?		☒ **Yes** ☐No	

Minimum Standards	**CCM assessment**
1. The Principal Recipient demonstrates effective management structures and planning	Technical, managerial and financial capacities of the Principal Recipient – Ministry of Health of the Republic of Armenia - to manage and oversee program implementation are strong. The Principal Recipient has built its program management capacities during almost eight years currently managing TGF-financed HIV, TB and HSS grant programs in Armenia. The Program Coordination Team (PCT) was established within the Ministry of Health to implement Global Fund grants with an efficient organizational structure staffed with public health and finance/business administration specialists and creating synergies between the different grants through joint processes of procurement, logistics and finance management. The PCT is engaged with annual planning, budget forecasting of program activities, implementation and monitoring in line with programmatic performance targets. It reports to the Global Fundsecretariat, CCM, Ministry of Health, Ministries of Finance and Economy, Charitable Commission of the Government and other governmental entities. Within MOH, the PCT is supervised by senior management of the Ministry (Minister, Deputy Minister, Head of Staff) through periodic submission of financial, procurement and programmatic reports for enhanced oversight and decisions on grants.
2. The Principal Recipient has the capacity and systems for effective	MOH PR signs annual SR agreements with all of them with obligations of the SRs to the PR, similar to those of the PR to the GF under the Grant Agreement. The contracts contain annexes on workplan, budget, performance indicators and reporting templates for the agreements' duration (one year), whereby SRs are required to submit

management and oversight of sub-recipients (and relevant sub-sub-recipients)	quarterly reports reflecting their financial activity during the quarter in question and cumulatively from the beginning of the project as well as programmatic reports, including description of activities supported by quantitative data on patients served, health products used and progress achieved towards the milestones set forth in the project document. Based on the SR assessment results, the PR has carried out training of the SRs' financial staff to improve their financial management systems. Through the team comprising the program coordinator, financial officer and M&E specialist, the PR carries out routine monitoring over the SRs' performance throughout program implementation, through periodic review visits and spot-checks to review and verify SRs' expenditures and supporting documentation, as well as holds meetings / briefings on various aspects of project implementation.
3. The internal controlsystem of the Principal Recipient is effective to prevent and detect misuse or fraud	Any possible misuse or fraud is prevented by the PR through internal controls, such as verification of contracts and payments by the PCT financial manager, legal advisor and manager, and further approval by the supervising Deputy Minister, Head of Economy Department of MOH and Head of Staff (Chief Financial Officer) of MOH by electronic signatures. Moreover, Client Treasury accounting software ensures verification of contracts and the corresponding payments against annual budgets and procurement plans approved by the Government of Armenia. External audit of the grant programs is conducted on annual basis and the reports are shared with TGF, LFA and MOH officials.
4. The financial management system of the Principal Recipient is effective and accurate	MOH PCT is staffed with finance officers and accountant whose activities are controlled and managed by the Finance Manager. The PCT operates 1C accounting software as well the central Client Treasury software allowing accurate and effective control over all financial transactions.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	All drugs, laboratory consumables and other health products are registered, stored and distributed in the central humanitarian warehouse of the Ministry of Health at the time of quality checks of products at importing and customs clearance process, after which they are distributed to the warehouse of the NCAP. The NCAP warehouse staffed by two pharmacists. Conditions (temperature regimen, humidity, security etc.) in the central warehouse are strictly followed by the NCAP staff and regularly monitored by the PR. Methadone used at OST sites is stored at a central pharmacy of the supplier organization licensed for the import and also storage of narcotic drugs according to the licensing regulations and requirements of the country. The OST sites (narcological institutions) periodically receive supply of methadone (on monthly or quarterly bases—proceeding on the need) and store it in their pharmacies for further daily distribution to beneficiaries.
6. The distributionsystems	All health products, including drugs and laboratory consumables are timely and regularly distributed to HIV marz laboratories, MST sites

and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment/program disruptions	and NCAP throughout the year, without interruptions in the supply chain. Similarly, the PR ensures continuous and regular ordering and procurement of health products and consumables internationally through VPP mechanism, as well as locally. No stock-outs have occurred under the current grant program. At the end of each year PR requests the SRs to provide their need and calculations for drugs (including methadone), lab. Consumables and other supplies for the upcoming year by quarters by taking into account the remainders. Based on that the PR plans its procurement activities, announces tenders and signs contracts according to relevant state procurement procedures. The products are provided to the relevant SRs based on the order of the Minister on product distribution in line with the timeline mentioned in the needs of beneficiary organizations (SRs). For the provided goods SRs provide quarterly reports on goods inflow, outflow and balance to MOH. The SRs use relevant registers for the distribution of the goods to beneficiaries. It includes but not limited to data on beneficiaries who receive the product (ID or name/surname), date, quantities, etc. The OST sites receive supply of methadone on monthly or quarterly bases—proceeding on the need and store it in their pharmacies for further daily distribution to beneficiaries. All OST sites use methadone distribution registers approved by the MOH/daily distribution sheets to be signed by the beneficiaries.
7. Data-collection capacity and tools are in place to monitor program performance	The programmatic monitoring of the program performance is implemented based on Integrated M&E Plan, approved by the GFATM. Throughout program implementation PR shared with SRs reporting forms, facilitating collection, verification, aggregation/disaggregation and analysis of data. SRs submit quarterly reports to PR (both programmatic and financial). Relevant SR staff is regularly trained on data collection and management to improve the quality of reported programmatic data.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Programmatic performance is reported through functional reporting and recording systems, while financial reports are generated through properly functioning accounting software which are timely reported on to the PR with further verification by the PR M&E specialist and finance officer.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Grant funds are used for purchasing pharmaceuticals and diagnostic products that comply with applicable national guidelines and/or are consistent with the WHO guidance. On national level, the Center for Drugs and Medical Technologies Expertise (CDMTE) of the Ministry of Health hosts the national quality control laboratory for pharmaceutical products carrying out quality control testing of medicines and providing expert conclusion to the Drug Policy Department of the Ministry of Health for subsequent registration by the Ministry of Health (Drug Department) and inclusion in the National Register of Pharmaceuticals. The Drug Department of the Ministry of Health jointly with CDMTE performs random check-ups of the quality of drugs in the warehouses and at

	facility level. All pharmaceuticals procured by the Ministry of Health, including those under TGF grant funds (OI medications, methadone) should be authorized/registered for use in the Republic of Armenia. All TB and ARV drugs procured through GDF and TGF's VPP mechanism are supplied by WHO prequalified suppliers. For diagnostic products, the National Institute of Standards (NIS) is the body responsible for quality control of all products imported to the country through issuance of quality certificates. Periodic inspections (measurements) to certify proper work of equipment are also carried out by NIS. At the Principal Recipient level, quality of pharmaceuticals is assured through development of detailed technical specifications (TSs), which in case of drugs describe the active pharmaceutical ingredient (or combination of ingredients), dosage and strength, form and packaging, minimum shelf-live at delivery and, in case of diagnostic products, also include manufacturing standards and other requirements, such as approval by internationally recognized regulatory authorities (ISO 13485:2003, ISO 2009 series, CE-Marked, etc.), offering the advantage of quality assured reagents, test-kits and equipment labeled for use under defined conditions. The TSs are defined by the Sub-Recipients, reviewed by PCT and approved by the evaluation panel (tender committee), based on which a tender is announced to obtain the lowest possible price on products with the defined TS. The goods are accepted by careful checking the correspondence of the supplied items by the PCT staff members (program coordinator, procurement specialist), SR representatives and by signing acceptance acts approved by the MOH Head of Staff. The storage facilities of the central and regional warehouses and distribution systems are sufficient to ensure adequate conditions, integrity and security of health products, and uninterrupted supply to the end users. Capacity building of the staff as a quality assurance component is carried out through on-the-job training, local and international training to comply with international standards, regulations and requirements.

PR2 Name	Mission East Humanitarian Aid Organization, Armenian Branch	**Sector**	NGO

Does this Principal Recipient currently manage a Global Fund grant(s) for this disease component or a cross-cutting health system strengthening grant(s)?	☒ **Yes** ☐No

Minimum Standards	**CCM assessment**
1. The Principal Recipient demonstrates effective management structures and	Mission East HAO, Armenian Branch has developed its capacities throughout last two decades of working in Armenia in health, social and education fields. Since 2009 Mission East is acting as the Principal Recipient for the NGO sector of the HIV Round 2 RCC grant. The program coordination is implemented by the PRIU Team, supervised

planning	by the Country Director. PRIU Team involves highly qualified professional staff with proper education and background. Throughout program implementation PRIU staff participated in a number of professional trainings and conferences aimed at increasing effectiveness of overall program coordination. To ensure uninterrupted implementation, the PRIU in coordination with the GFATM prepares annual PR and SRs work plans and budgets, as well as conducts monitoring in line with programmatic performance targets.
2. The Principal Recipient has the capacity and systems for effective management and oversight of sub-recipients (and relevant sub-sub-recipients)	NGO PRIU has experience of working with more than 10 SRs throughout last 6 years of RCC grant. All SRs underwent thorough SR assessment in line with GFATM requirements. PRIU conducts regular programmatic and financial monitoring of SRs. The programmatic monitoring is implemented based on Integrated M&E Plan, approved by the GFATM. Based on the results of annual PR and SR financial audit, PRIU in consultation with the GFATM shares recommendations with SRs and follows up on steps taken to address those. Also, PRIU has developed financial guidelines and forms for SR reporting. PRIU has created clear financial control mechanism both for PR internal and SR financial reporting.
3. The internal controlsystem of the Principal Recipient is effective to prevent and detect misuse or fraud	Potential misuse or fraud is prevented by the PR through internal rules and mechanisms, such as verification of contracts and payments by PRIU Team Leader, Finance Officer, Finance Director and Country Director.
4. The financial management system of the Principal Recipient is effective and accurate	NGO PR is staffed with finance officer, whose activities are controlled and managed by the Finance Director, Team Leader and Country Director. The PRIU operates accounting software, allowing accurate and effective control over all financial transactions.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	NGO PRIU rents a central warehouse to optimize storage and distribution of health products to SRs. The warehouse has adequate conditions and security for the storage of health products. PRIU Procurement and Logistics Specialist manages the warehouse using special database to follow the stock and turnover of the products.
6. The distributionsystems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid	PRIU Procurement and Logistics Specialist is responsible for procurement of health products according to PSM Plan and further distribution to SRs according to agreed schedule to ensure uninterrupted program implementation.

treatment/program disruptions	
7. Data-collection capacity and tools are in place to monitor program performance	The programmatic monitoring is implemented based on Integrated M&E Plan, approved by the GFATM. Throughout program implementation PRIU shared with SRs a unified database and reporting forms, facilitating collection, aggregation/disaggregation and analysis of data. Relevant SR staff is regularly trained on data collection and management to improve the quality of reported programmatic data.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Semi-annual SR programmatic reports are generated based on information collected in unified SR databases. SR financial quarterly reports are collected using unified reporting form, based on information generated by accounting software.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	At the Principal Recipient level, quality of products is assured through development of detailed technical specifications (TSs), in line with international (WHO, GFATM) recommendations where applicable. The TSs are defined by the Sub-Recipients, reviewed by PRIU, based on which a tender is announced to obtain the lowest possible price on products with the defined TS.The storage facilities of the central warehouse and distribution systems are sufficient to ensure adequate conditions, integrity and security of health products, and uninterrupted supply to the end users. PRIU Procurement and Logistics Specialist has been trained in different aspects of local and international procurement.

4.4 Current or Anticipated Risks to Program Delivery and Principal Recipient(s) Performance

a. With reference to the portfolio analysis, describe any major risks in the country and implementation environment that might negatively affect the performance of the proposed interventions including external risks, Principal Recipientand key implementers' capacity, and past and current performance issues.

b. Describe the proposed risk-mitigation measures(including technical assistance) included in the funding request.

a. Major risks:

The Portfolio Analysis does not refer to any specific risks. As can be seen from Section 1.2, there have been problems in the past in reaching ambitious targets, in particular for testing of key populations. There is a risk that these problems will continue and targets will not be reached.

Another risk is that the Program might be successful in finding many new cases of HIV, requiring a substantial increase in the number of people requiring ART against the numbers planned under the current ART program.

An important risk, identified by GF and WHO, is that, if the country receives no further funding from GF after this grant, the Government of Armenia (GoA) may be unwilling or unable to to

assume much of the funding currently provided by GF.

b. Mitigation strategies

Several interventions have been included into this Program to address the specific issues that hindered reaching the targets in relation to HIV testing among key populations in the past. These include: the introduction of rapid testing by outreach workers; increased emphasis on legal and policy barriers to access; reduction in waiting time for test results.

To address the issue of larger numbers of people needing ART, a buffer stockis planned under the Program. In case of any unmet need of ART in the course of the Program potential savings from any other component would be used to purchase additional quantities of drugs. Measures to increase ART access for PLHIV from a range of clinics other than the NCAP are envisioned.

To mitigate the last risk, a Sustainability Plan has to be developed with a clear step-by-step process for the government to take over funding in 2019 of the remaining HIV activities covered by this Program.