HIV/AIDS treatment and care in Georgia

Evaluation report

September 2014

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WHO Collaborating Centre on HIV and Viral Hepatitis

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List of abbreviations

3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral treatment
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
CCM	Country Coordinating Mechanism
DRV/r	Darunavir/ritonavir
EFV	Efavirenz
FSW	Female sex workers
FTC	Emtricitabine
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HTC	HIV Testing and Counselling
IDACIRC	Infectious Diseases, AIDS and Clinical Immunology Research Center
LPR/r	Lopinavir/ritonavir
MDR	Multi Drug Resistant
MSM	Men who have sex with men
NGO	Non-governmental organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NSPA	National HIV/AIDS Strategic Plan
OST	Opioid substitution therapy
PI	Protease inhibitor
PLHIV	People living with HIV
PWID	People who inject drugs
RAL	Raltegravir
RNA	Ribonucleic acid
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
TGF	The Global Fund
VL	Viral Load
WHO	World Health Organization
ZDV	Zidovudine

1. Executive summary

This WHO country mission was performed in June 2014 to assess the achievements, strengths and shortcomings in the implementation of the Georgian National HIV/AIDS Strategic Plan (NSPA) across the cascade of care, and to generate strategic recommendations for improving key outcomes and impacts. The mission had specific focus on providing recommendations on standardizing treatment regimens, how to reduce the number of different ARV regimens, and how to optimize the HIV/AIDS investment from a public health perspective.

Care of people who inject drugs (PWID) presents a substantial challenge as they are the most affected risk group and traditionally the most difficult to retain in care. Diagnosed people living with HIV (PLHIV) in Georgia are referred to and followed at the Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC) in Tbilisi or one of its three affiliated regional centres. In 2012 the new HIV/AIDS nationwide surveillance system was introduced within the framework of the Global Fund (TGF), with a comprehensive electronic database collecting data on all PLHIV in care.

The major challenge in the HIV epidemic in Georgia is a high proportion of undiagnosed PLHIV (estimated 48%) as well as a very high proportion of late presentation for care, with 73% presenting for HIV care with a CD4 count <350 and 50% with AIDS. The high proportion of undiagnosed infections makes it difficult to estimate the overall HIV prevalence accurately and to determine whether the HIV incidence has remained stable or not in Georgia.

The above analysis of the epidemic is well articulated among stakeholders in the country as a consequence of a very low HIV testing coverage in Georgia, which does not adequately cover the groups most at risk of infection. More than 70% of people tested annually represent low-risk populations such as pregnant women and blood donors. As the epidemic is still largely driven by PWIDs and an increase in prevalence is observed among MSM in the country, testing among these risk groups needs to be intensified considerably coupled with a comprehensive strategy of linkage to and retention in care, as this will be more challenging for key population groups.

Scaling up testing activities is crucial in order to tackle the HIV epidemic in the country. The actions should include: to scale-up community based testing to reach the most-at-risk groups and to use rapid tests and; to reassess provider initiated testing recommendations and support the implementation of indicator condition guided HIV testing; to increase HIV testing rates among patients presenting with TB from the current 60% to above 95%.

It is important to underline that the care system needs to be prepared to handle the influx of PLHIV as they are diagnosed as this will put an additional burden on the health care system. For example, many more PLHIV will be (or are already) in need of ARV treatment. Importantly, by diagnosing persons earlier in the course of their HIV infection, burden at health care facilities to treat newly diagnosed AIDS patients will decrease.

A specific objective of the mission was to discuss a TGF request to rationalize drug regimens in order to reduce costs. During the mission rationalization and simplification of drug regimens were discussed with the national AIDS Center of Georgia and ministerial representatives. The suggestions for simplification agreed upon during the mission are based on the 2013 WHO

guidelines and represent a shift from an individualized patient approach to a more cost-effective public health approach.
The first stage of implementation will be applied to patients initiating ART. Beginning in June 2014, all newly enrolled patients will be started on one of the four regimens recommended by the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV infection *(1)*. Starting from 2015, patients on an ABC-based regimen will be gradually switched to preferably TDF or ZDV-based regimens. With regard to second and third line regimens, the number of possible regimens will gradually be reduced to seven.

The state programme will gradually take over the procurement of drugs. The mission team found it reassuring that several government stakeholders emphasized the commitment of the Georgian government to finance 50% of ARV procurement, including testing kits, from 2015.

The specific recommendations of the country mission are summarized in chapter 6.

2. Introduction

Georgia has a population of approximately 4.3 million people. It is situated east of the Black Sea, bordering Turkey, Armenia and Azerbaijan to the south, and the Russian Federation to the north. The capital, Tbilisi, has 1.2 million inhabitants. In 2010 the Georgian national income per capita was USD 5,790 according to the World Bank.

2.1. Country epidemic

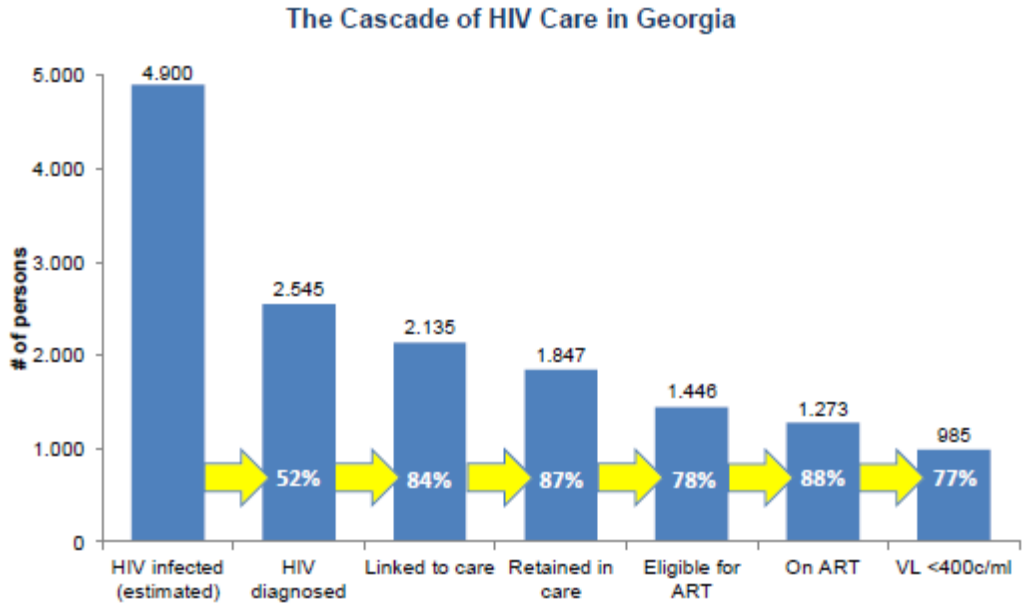
Since the first case of HIV was detected in Georgia the number of annually detected cases has risen steadily. There was an almost fivefold increase in the rates of newly diagnosed HIV infections from 2.3 per 100 000 in 2002 to 10.9 per 100 000 in 2013 *(2,3)*. By June 2014 a total of 4,360 HIV cases were registered at the Infectious Diseases, AIDS and Clinical Immunology Research Center (IDACIRC), with an estimated total number of people infected with HIV around 6,400 (Spectrum EPP) *(2)*.

Overall, the country has a low HIV prevalence with 0.07% in 2013 in the general population *(2)*. However, HIV prevalence is higher in the capital city and the port city Batumi *(4)*, and most-at-risk populations such as MSM and PWID show higher HIV prevalence – bio-behavioral surveillance surveys from 2012 found respectively 13% and 3% *(2)*. As in other countries in the Region the epidemic in Georgia has been driven largely by injecting drug use as the transmission mode *(3)*; however, by 2011 heterosexual transmission had become the dominant mode *(2)*. Many of these infections are likely linked to the PWID community. Due to HIV prevalence indicators for most-at-risk populations, Georgia is considered to have a high risk for HIV epidemic expansion into the general public *(2,5)*.

2.2 Key numbers and trends

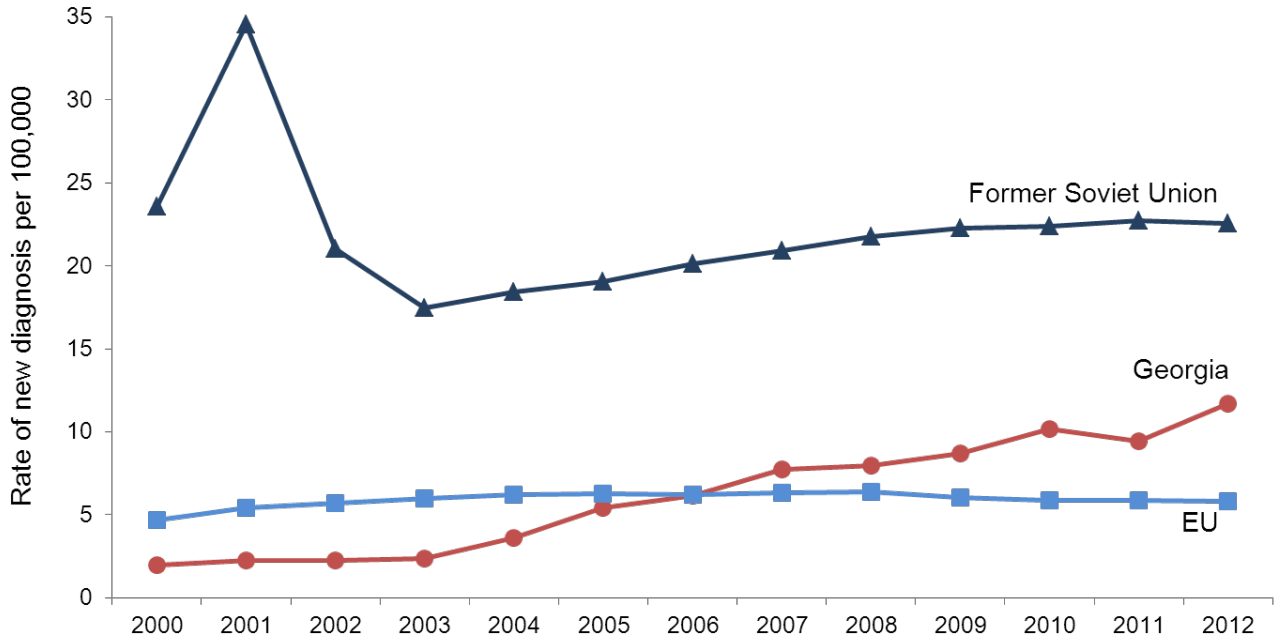
The estimated treatment continuum below shows some of the challenges of the HIV/AIDS treatment and care in Georgia. It should be noted that this is 2012 numbers and that the number of people undiagnosed for 2014 are estimated to be around 6,400 as mentioned above.

Fig. 1: Estimated treatment cascade in Georgia, 2012 *(6,7,8)*



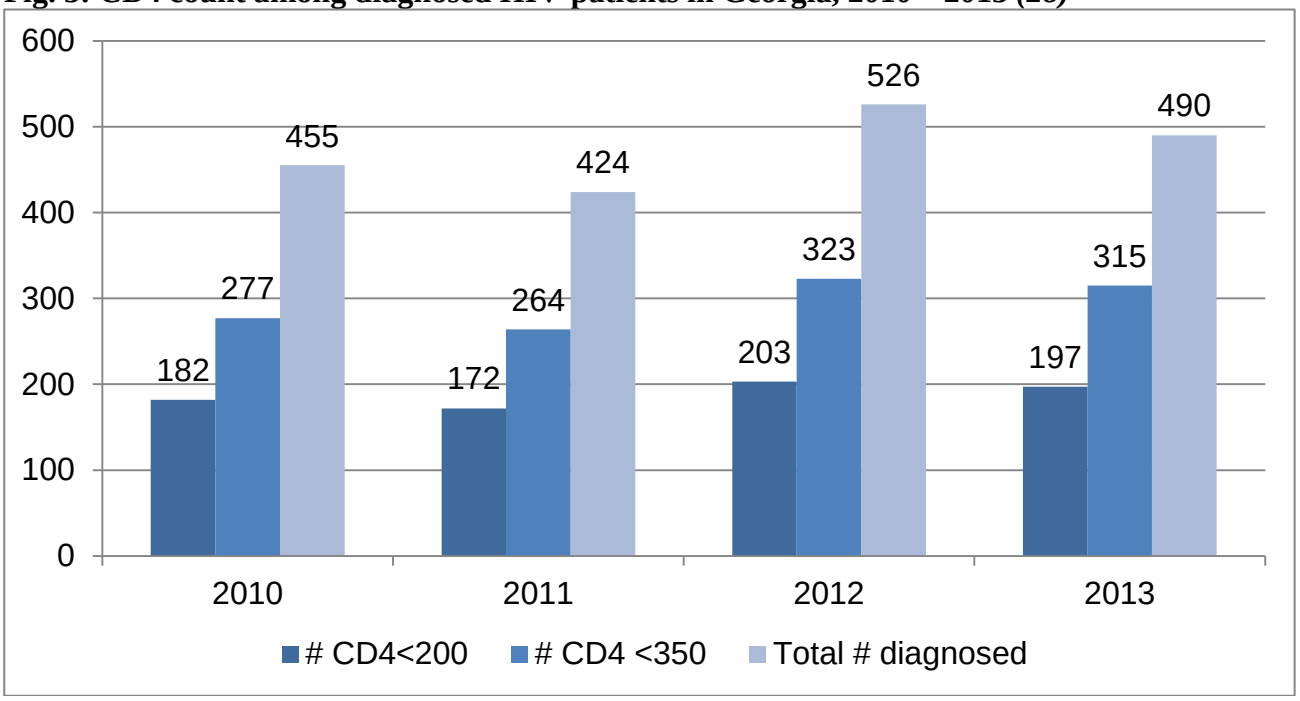
The cascade of care in Georgia is based on the estimation that 48% of PLHIV in Georgia are undiagnosed *(3)*. Of those diagnosed, the majority is linked to care (84%), and this tendency seems to be improving over time. However, the large number of undiagnosed HIV cases is a major challenge for achieving the individual and public health benefits of ART, and currently viral suppression is only achieved in 20% of all PLHIV in Georgia. It should be noted that the components on the "right side" of the treatment cascade look reasonable (although they can be further improved), but detailed analyses in reference *(3)* document that they look less favorable for PWID's who are relatively poorly represented. As more PWIDs enter care, it will be critical to ensure that each of the components of the treatment cascade is maintained at the indicated levels.

Fig. 2: Rates of Reported HIV Infections in Georgia, Former Soviet Union & EU 2000 - 2012 ***(9)***



Looking at the available data on CD4 count at the time of HIV diagnosis from 2000-2012, they are indicating a serious problem with late presentation for treatment and care services in Georgia (see also Fig. 3 below). In 2012, 70.4% of newly identified HIV infected people had a CD4 count of <350cells/mm^3, and 43.9% of these had a CD4 count of <200 cells/mm$^{3.}$.

Fig. 3: CD4 count among diagnosed HIV-patients in Georgia, 2010 – 2013 ***(28)***



ART service delivery is governed by the National HIV/AIDS Treatment and Care guidelines which are primarily based on the 2012 revision of the 'Clinical Protocols for WHO European Region; Protocol 1: Patient evaluation and antiretroviral treatment for adults and adolescents'. The

guidelines also incorporate some recommendations from the 2013 WHO Consolidated Guidelines on the use of antiretroviral drugs for treating and preventing HIV infection and the European AIDS Clinical Society's guidelines version 7.0.

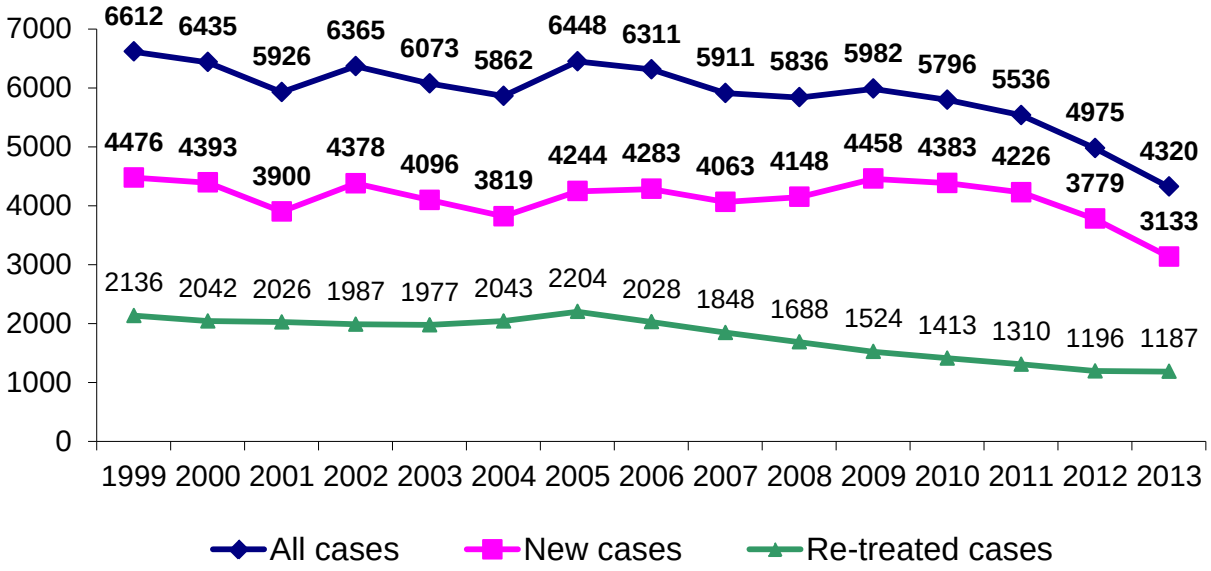
All PLHIV in Georgia are referred to and followed at the IDACIRC in Tbilisi or one of its three affiliated regional centres in Kutaisi, Batumi and Zugdidi (5). In 2013, 2092 HIV positive adults and children were on ART *(7)*. PLHIV on ART have to show up once a month to pick up ART drugs *(10)*.

Coinfections

Scaling up management of opportunistic infections and other comorbidities is a strategic focal point in the Georgian National HIV/AIDS Strategic Plan for 2011-2016. There are already linkages between specialized HIV treatment services and the general health services. This particularly applies to tuberculosis (TB) and all HIV/TB co-infected patients have free access to treatment for both diseases. Co-infections are widespread and almost every second HIV infected individual in Georgia is co-infected with TB (active or latent) and 48% have hepatitis C *(11)*.

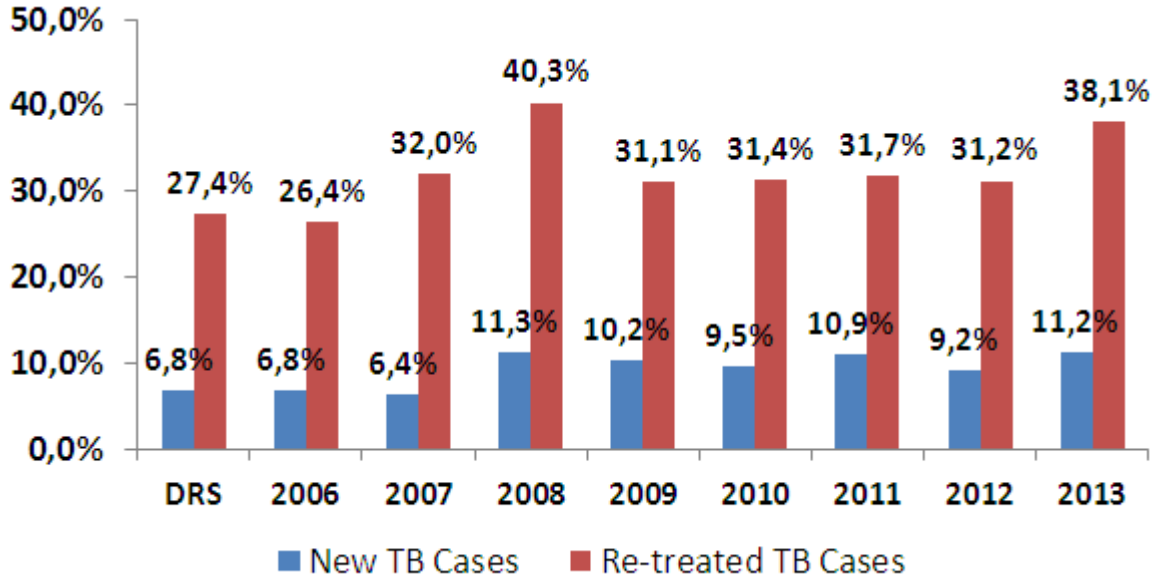
With regards to TB, a fall in the number of notified TB cases has been registered from 6 448 in 2005 to 4 320 in 2013 (see Fig. 4 below).

Fig. 4: Notified TB cases in Georgia (absolute numbers, 1999 – 2013 *(12)*



Among the registered TB infections in Georgia there is a high percentage of multi resistant TB, with a slight increase between 2012 and 2013 and without evidence of improvement during the last 10 years (see Fig. 5 below).

Fig. 5: MDR-TB prevalence, pulmonary cases, 2006 - 2013 ***(12)***



Most-at-risk populations

IDACIRC's data on HIV transmission routes is shown in the table below.

Table 1: HIV transmission routes, 1989 – June 2014 ***(13)***

Percentage	Number	Transmission mode
50.5%	2 215	Infected through injecting drug use
40.6%	1 771	Infected through heterosexual contact
5.3%	231	Infected through homosexual contact
1.9%	84	Mother to child transmission
0.5%	22	Bl. recipient
0.9%	37	Unknown

MSM

It is estimated that around 13% of MSM are living with HIV (2, 3, 14, 15). However, outcome indicators on awareness of transmission routes show that a minority of MSM has knowledge of transmission routes *(11).* Bio-behavioral surveillance surveys have found that 34% of MSM received an HIV-test in the past 12 months and know their status, and 73.2% reported using of condom the last time they had anal sex *(2,15).*

PWIDs

The HIV prevalence rate among PWIDs in Georgia is estimated to be around 3% - but ranging from 0.4% to 9.1% from the lowest to the highest prevalence areas *(2,14,15).* A study of PWIDs carried out in 2013 show that just 34% of PWIDs reported the use of a condom the last time they had sexual intercourse *(15).* Among the same group of PWIDs 83% used sterile injecting equipment the last time they injected - whereas only 15% had received an HIV test in the past 12 months and knew their status.

Georgia is considered to be at high risk for an expanding epidemic due to alarming trends including very high number of PWIDs (estimated to be between 39 152 and 41 062 *(14)* and the high prevalence of Hepatitis C in this group *(2,5)*. Only 4 613 receive OST *(15).*

Mobile populations
There is an important population movement between Georgia and the neighboring country, the Russian Federation, as well as between Georgia and Ukraine, which have a higher HIV prevalence *(2,16,14)*. Data suggest that more than half of PLHIV have been infected outside Georgia *(17)*.There is a need to make counseling, testing and treatment more accessible to migrants. Specific efforts should be directed to particular places of transit (border areas, conflict zones, tourist areas, port cities, truck parking etc.) *(16).*

2.3 Investments in the national HIV/AIDS response

Georgia's National HIV/AIDS Strategic Plan (NSPA) for 2011-2016 is the third for the country. The first NSPA covered 2003-07 and the second 2006-10 *(11)*. In 2002 a Country Coordinating Mechanism (CCM) was established to coordinate the national response to HIV/AIDS *(2)*.

Georgia's HIV/AIDS epidemic prevention and control is highly reliant on external technical support and financial assistance, mainly from TGF. Since 2003 TGF has supported Georgia's response to HIV/AIDS, tuberculosis and malaria, with a total of USD 83.5 million. TGF grants contributed about 2.8% of the country's total health expenditure *(18).* As TGF supports access to ART, patients benefit from free HIV-related services while their access to general health services remains limited. *(18,19)*. In 2012 the new HIV/AIDS nationwide surveillance system was introduced within the framework of TGF with an electronic database collecting data on all tested individuals *(2)*. Further, within the TGF programme, the development of a unified HIV prevention database is envisaged that will be part of the National Health Information System.

2.4 General healthcare

Georgia's health system has traditionally been highly dependent on patients' out-of-pocket payments (in 2007 public funds accounted for 18% of total expenditure, and nearly 72% from out-of-pocket payments) *(18)*. It is characterized by a scarcity of qualified providers in the rural areas and shows a very low service utilization rate *(18)*. In recent years the Georgian government has focused on strengthening public health. Based on a considerable budget increase from February 2013 the government has launched a universal health insurance programme with the aim of providing health care services to the more than 2 million uninsured people living in Georgia *(15)*.

3. Purpose and objectives

The purpose of this evaluation of HIV/AIDS treatment and care was to assess the achievements, strengths and shortcomings in the implementation of Georgia's National HIV/AIDS Strategic Plan across the cascade of care, and to generate strategic recommendations for improving key outcomes and impacts.

Georgia's response to the HIV epidemic is supported by the Global Fund (TGF) grant and the country is fully reliant on TGF in covering costs of HIV treatment *(20,21)*. Georgia has prepared an application for Phase 2 of the HIV grant which requires review and alignment with the 2013 WHO

Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Therefore the specific objectives of the evaluation mission were to provide recommendations on: standardization of treatment regimens including use of fixed dose combinations; reducing the number of different regimens/ARVs; standardizing diagnostic and treatment algorithms; optimization of the HIV grant from the public health perspective so to ensure alignment of the proposal with the WHO recommendations and high coverage with services for those who need them.

4. Methods

The evaluation builds on a desk review of readily available information on the country epidemic and HIV/AIDS treatment and care including journal articles, national publications, WHO reports and the like, and a country mission which took place from 4-10 June 2014 in Tbilisi, Georgia.

Annex 4 provides a list of the people met during the country mission.

Logistic support was provided by the IDACIRC (National AIDS Center) in Tbilisi, Georgia.

5. Findings

5.1 Strengths and achievements

The treatment programme stands out positively in the region and is staffed with a professional team with a good understanding of the issues and challenges. Diagnostic facilities are well developed including widely available access to HIV-RNA viral load and CD4+ count monitoring, as well as diagnosis of the various types of opportunistic infections AIDS patients suffer from. The data system that oversees persons in care is well functioning and is critically important. Relevant guidelines are in place. The care component is highly prioritized to the benefit of the patients which results in higher retention rates than in other countries in the Region.

Careful planning is necessary to ensure that the high quality of the treatment programme is maintained as the government takes over from TGF. As mentioned, as future up-scaling of testing activities will lead to a marked increase in HIV diagnosed people in need of care, resources for the various components of the treatment programme will have to be up-scaled to ensure that quality of care is not compromised. The mission acknowledges the indication from stakeholders that the government is planning to cover 50% of the ARV budget as well as test systems from 2015.

5.2 Weaknesses and challenges

As described above, late HIV diagnosis is an important public health problem in Georgia, as well as constituting high morbidity and mortality among those diagnosed and in care (21,22). Current methods used estimate that half of those infected remain undiagnosed. However, the size of the undiagnosed population may be even greater. As pointed out by all stakeholders the mission team met in Georgia, low testing coverage of people at risk is the core of the problem and will be discussed in greater detail below. The mission however also identified a number of questions to be addressed in relation to how surveillance data is being analyzed and presented.

Priority area: Surveillance

In order to properly understand the HIV epidemic in Georgia a number of observations have been made:

Studying the trends in the epidemic, concerns are raised that the number of undiagnosed PLHIV could be even higher than the current estimates. The level of late presentation (73%) indicates that the number of undiagnosed is even higher as it is evident that late presenters who do enter care have been infected for an average of 7-10 years.

Further, the HIV epidemic in Georgia is mainly concentrated among specific at-risk sub-populations, mainly PWIDs, sexual partners of PWIDs, commercial sex workers and men who have sex with men. Such risk groups are generally hard to reach under usual circumstances, and given the levels of social inequality and stigma which seem to be present, gathering data on these sub-populations in order to understand the extent of the size and characteristics of the epidemic remains very challenging.

A recent publication, "Estimating HIV incidence in eastern European country of Georgia: 2010-2012" *(3)* argues that HIV incidence has been stable over 2010-2012. However, as identification of new infections within the surveillance system depends on HIV testing patterns and thus misses people with no access to testing, it is plausible that the true incidence may be considerably higher. If the proportion of undiagnosed cases remained the same or increased during the study period, it is not possible to affirm that the epidemic has remained stable.

Recommendations

- Apply other methods than UNAIDS methods to estimate the number of people undiagnosed with HIV.
- Build capacity of responsible surveillance experts to ensure proper interpretation of available data as well as including missing variables to describe trends in the epidemic in the country.
- Improve estimation of risk groups' size for better estimations of the undiagnosed population in order to target interventions most cost-effectively.

Priority area: Optimizing HIV testing

As described above, the HIV testing coverage remains low and does not adequately cover the groups most at risk of infection. More than 70% of people tested annually represent low-risk populations such as pregnant women and blood donors. Of particular concern is the low testing rate of the large risk group of PWIDs.

Current HIV testing activities include universal screening of pregnant women and mandatory screening of donated blood, as well as community-based testing aimed at reaching key most-at-risk populations and facility-based HIV indicator disease guided testing *(7)*. The 2013 numbers for HIV-testing are shown in the table below. It should be noted that a total of 5,000 PWIDs were tested, but the size of the PWID population in Georgia is estimated to be more than 10 times higher and the coverage rate is estimated to be a mere 14,68% *(23)*.

Table 2: HIV testing in Georgia 2013 ***(24)***

Population	Numbers tested	Number positive	Prevalence (%)
Pregnant Women	51 180	17	0,03
Blood Donors	52 210	15	0,03
PWIDs	5 394	23	0,43
FSWs	879	2	0,23
MSM	928	9	0,97
TB patients	2 758	21	0,76
Prisoners	5 667	7	0,12
Patients with symptoms of HIV, hepatitis & other	11 769	396	3,36
Total	130 785	490	0.37

Testing coverage for most-at-risk groups has been assessed through various bio-behavioral surveys over the years. For instance, a 2013 bio-behavioral study of PWIDs found that 15% have had an HIV test during the past 12 months and know the result *(15)*.

It is obvious from the above table that the large percentage of annual tests is performed in groups not at risk (pregnant woman and blood donors) where the prevalence is fairly low (0.03%). Although this is not a questionable intervention, neither is it a very cost-effective one. Risks groups are not tested enough and show a high prevalence, making it a very cost-effective and necessary intervention.

A number of actions are necessary in order to decrease the number of undiagnosed people living with HIV and who are presenting very late for HIV care. The testing strategies need to be part of a collaborative effort among community-based organizations and the health care system to ensure access to testing the most at-risk populations and appropriate linkage to care in case of a positive test result *(25)*.

In **tuberculosis** (TB), the test rate is still only 60% (personal communication), and it is evident that those tested for HIV when presenting with TB are diagnosing a large percentage of the yearly HIV diagnosis. It became clear during the mission that coverage of HIV testing in TB patients is low in the regions outside Tbilisi. In particular private clinics treating TB patients do not see it as their responsibility to offer HIV testing. It seems that a Ministry decree/regulation is needed in order to ensure that all clinics in the country caring for TB patients routinely offer an HIV test.

Community-based testing is crucial to reach at-risk populations: PWIDs, FSWs and MSM. It is highly recommended to reconsider the introduction of anonymous testing, as some people disappear when asked for an ID number. Also, there is a need to scale-up information on the benefits of knowing one's status and risk behavior to these groups. The coverage of testing of PWIDs should reach at least 35% estimated number of PWID (between 39,152 and 41,062) annually (and preferably 50-70%), opposed to the current rate of 14.68% *(23)*. Community-based testing has the advantage of operating in the milieu of the risk groups who do not necessarily come to the AIDS centres for testing. Collaboration with the AIDS centres on linkage to care is crucial to ensure that

those testing positive are transferred into the care system and social support provided when needed. The use of rapid tests is important in community-based settings and should be supported by the state programme.

Provider initiated testing is an important component of a comprehensive HIV testing policy. Shifting political systems has meant a change in how testing has been prioritized in the health care system. For instance, a shift in policy in 2011 has meant that the state funded programme no longer includes testing of risk groups in the hospital testing facilities, which means that when reporting justification for a performed test, it can only be because of pregnancy or an indicator condition.

The testing guidance on indicator condition-guided HIV testing *(26)* needs broad implementation by specialists outside AIDS centres and general practitioners, who are key to the health care system after the new health reform and not yet an integrated part of HIV testing in the country. This requires political support by the Health Ministry to adopt the guidance by decree. In addition, experience shows that in order for indicator condition-guided HIV testing to work, an implementation strategy needs to be implemented (and funded) including training, support materials, etc. Because of the high stigma in society and the health care system, it is recommended to also address the stigma /misconceptions around the offer of an HIV test in medical school training.

A number of **barriers to HIV testing** exist and addressing them should be prioritized. On a structural level, the criminalization of drug use is hampering access of PWIDs to HIV testing *(27,28)* as does the unavailability of anonymous testing, which is possible in most countries. Numerous examples of non-protection of for example MSM groups were mentioned during the mission and documented *(29)*. Addressing the structural barriers to the stigmatized groups of PWIDs and MSM is a pre-condition for scaling up health associated services *(30,31)*.

Also within the health care system, information and de-stigmatization education is needed to ensure the proper care of PLHIV. PLHIV do not wish to disclose to primary care doctors and dentists for instance, and it is commonly more accepted to say that one has hepatitis C rather than HIV. This seems to be a particular problem in the regions outside Tbilisi and examples were given of patients being transferred to Tbilisi because doctors refused to treat them for other conditions because of their HIV status. Self-stigmatization is also high and PLHIV tend not to disclose their status to family members etc. The NGOs working with PLHIV explained that even gathering among peers of PLHIV is not evident, in particular among groups of MSM.

The scale-up of harm reduction and OST programmes with the implementation of voluntary testing and counseling within the programmes should likewise be considered. OST and harm reduction are key to stopping the epidemic from spreading to the general population, and one of the most evidence-based interventions *(32)*.

Finally, financial support for HIV tests and for implementation of testing strategies requires inclusion in the state programme.

Procurement of testing kits via the state system has been chosen based on price. WHO recommends that countries undertake a small scale validation study of available products in their country to help decide which would best suit their own testing situation, and to use cost as a secondary variable for product selection.

HIV rapid tests listed as eligible for WHO procurement should be followed, and the current list of diagnostics eligible for WHO procurement includes both WHO prequalified diagnostics and products that are eligible as a transition measure (these are all currently in prequalification) http://www.who.int/diagnostics_laboratory/procurement/purchase/en/

Recommendations

- Testing strategies need to be part of a collaborative effort among both community-based organizations and the health care system to ensure access to testing of the most at-risk populations and appropriate linkage to care in case of a positive test result.
- HIV testing rates in patients presenting with TB should increase from 60% to >95%. Ministry of Health regulation is crucial to ensure that this is introduced routinely in all clinics across the country.
- Barriers at both structural, provider and client level are many in Georgia and it is a precondition for scaling up HIV testing that these are addressed.
- It is recommended to scale-up community based testing to reach PWIDs, MSM, migrants and SWs and to use rapid tests. Care pathways should be carefully organized to ensure linkage to care for these populations groups when tested in community settings.
- Provider initiated testing recommendations need revisiting and support to the implementation of indicator condition guided HIV testing is crucial. The guidance on indicator condition-guided HIV testing should be adopted – with primary care facilities as an important player - and resources secured for its implementation.
- Strengthen collection of data on reasons for testing to evaluate coverage of most-at-risk groups and changes over time.
- Technical and financial support to testing in health care facilities (general practitioners, hospital departments, emergency departments). Training, support materials and financial resources to cover the cost of the test are needed.
- Ensure prequalification of testing kits in procurement.

Priority area: Optimize drug regimens and reduce costs

A specific objective of the mission was to discuss TGF request to save money on the treatment programme, in particular the costs for ARVs. This exercise is not only important for the submission of the TGF application but likewise for the state programme gradually taking over procurement of drugs. It is important to underline that the WHO recommendations insist that quality of care is not compromised in the **simplification of drug regimens** *(33)*. The exercise of rationalizing drug regimens in order to reduce costs is performed in many countries across Europe and not specific to Georgia. The objective of the mission was to discuss ways to address this with the national AIDS centre.

However, there is also a relatively high expense per patient per year. The database system to monitor patients with HIV in the AIDS center is a very important achievement, allowing for proper monitoring and evaluation. Also, the care component is prioritized to the benefit of the patients; patient satisfaction and trust in the system seem very high.

While current treatment combinations follow international standards, efforts to rationalize and simplify the approach should be explored. The suggestions for simplification agreed upon during the mission are based on the 2013 WHO guidelines and recommend a shift from an individualized patient approach to a more cost-effective public health approach.

The following process is recommended and will be put forward by the AIDS Center to the CCM and primary recipient for the upcoming GF application:

1. Switch to the public health approach for selecting ART regimens will be implemented in two stages.

2. The first stage of implementation will be applied to patients initiating ART. Beginning in June 2014 all newly enrolled patients will be started on one of the four regimens recommended by 2013 WHO guidelines. Preference will be given to TDF/FTC (or 3TC) + EFV. This approach will be maintained in the future.

3. Given that antiretroviral drugs for 2014 have already been purchased based on previous quantifications, the programme will retain patients on Abacavir-based regimens, as well as patients on PI-containing and Raltegravir-containing first line regimens, until the end of the year at the same numbers as registered at the end of 2013.

4. Starting from 2015, patients on ABC-based regimen will gradually be switched to preferably TDF or ZDV-based regimens. With regard to patients receiving PI or RAL as part of their first line treatment, 150 of the 250 such patients will be switched to one of the standard first line regimens and 100 patients will be switched to second line regimens, as use of NNRTI-based therapy is contraindicated due to prior use.

5. With regard to second and third line regimens, the number of possible regimens will be limited to 11 by the end of 2014 and further reduced to 8 and 7 by the end of 2015 and 2016 respectively.

6. TDF/FTC (or 3TC) + either ATV/r or LPR/r and ZDV/3TC + either ATV/r or LPR/r will be used for second line treatment and will be selected based on resistance testing and previous treatment history. Third line regimens will contain DRV/r and/or Raltegravir.

The above approach will result in important cost savings without compromising the quality of care. The database should be used as an effective tool to document this as the changes in ARVs outlined above start being implemented. It is also important in light of the need to increase the number of patients (not yet diagnosed) on ARV in the coming years. See the details in Annex 1.

In order to implement this change in drug regimens, it became clear during the mission that a **communication plan** needs to be developed, as reluctance to testing and acknowledgement of the benefits from entering PLHIV in care was observed at the political, provider and patient levels.

Recommendations

- Rationalization of prescribed ART regimens for a more cost effective public health approach without compromising the quality of care.
- Develop a comprehensive plan for ensuring health care capacity and ARVs for the PLHIV that remain undiagnosed.
- Develop a communication plan to ensure the implementation of above.

Priority area: Organization of care – focusing on key populations

It is further recommended to take a look at the organization of care. For instance, the number of visits with an infectious disease clinician could be reduced from once a month to twice a year in persons on fully effective ART known to tolerate the regimen. If additional visits are recommended, these could also include a nurse or case manager rather than a physician.

Viral load measurements could be limited to twice a year, and should only be performed on patients on ARV.

It is important to underline that the care system needs to be prepared to handle a higher number of PLHIV as they are diagnosed. This will put an additional burden on the care system as many more PLHIV will be (or are) in need of ARV treatment. It is recommended to ensure that retention in care is continuously developed and take into consideration the specific patient group of PWIDs and any specific needs for share care models as more PWIDs are tested and enter the health care system. PWIDs can achieve optimal virologic outcomes but require additional adherence support (as they are twice less likely to achieve VL<50. Scaling up OST and harm reduction programmes is key to achieve adherence to ARV treatment for PWIDs.

Further elaborating integrated services is strongly recommended, including collaboration between HIV clinics and NGOs, TB hospitals and drug treatment experts.

Recommendations

- Reassess the organization of care for optimization and cost savings, i.e. number of visits with specialist, number of VL measurements.
- Ensure that retention in care is continuously developed and take into consideration the specific patient group of PWIDs and any specific needs for share care models. As more PWIDs are tested and enter the health care system, strong social support as well as scale up of OST is needed to ensure retention of care in this population group.
- Improve measures to support retention in care and compliance with ARV, e.g. directly observed therapy supplied at OST services.
- Support to immediate counselling and active linkage to services.
- Reduction of stigma in health care settings through targeted campaigns and education.
- Support to shared care and more widespread services with one-stop for methadone and antiretroviral treatment (and Hepatitis or TB treatment for coinfected patients).
- Increase PWIDs' access to voluntary testing and counselling at outreach sites and through community based HTC with the expanded use of rapid tests and active linkage to further HIV care, ensuring social support.
- Promote integration of OST services into the mainstream health care system through developing "best practice" and innovative models of integrated or shared care.

5.3 Cross-cutting issues

Sustainability and access to services

The transition to more co-funding by government and the possible discontinuation of GF support needs to be addressed to ensure the sustainability of programmes. It is reassuring that several government stakeholders expressed that the government has confirmed a plan to take over 50% of ARV procurement for 2015 as well as costs for testing kits.

It is recommended to see the HIV/AIDS prevention and care programme as a unified programme and not one GF and one state programme. As one informant expressed: “it is not only about the money, but about the system in place.”

Focus should be on capacity building of involved institutions that will take over the procurement, planning of testing programmes, etc., which needs to start immediately in order not to compromise the sustainability of the good work done thus far.

Recommendation

- Ensure that systems are in place to tackle the transition to more government co-funding of the HIV/AIDS programme in the country in order to ensure sustainability and quality.

Human rights

As described under the priority area on testing coverage, a number of human rights issues hamper the HIV response in the country.

The criminalization of drug use is one of the main issues. There is a high fine if someone is found in possession of drugs, and the fact that the police often circle around the OST centres to check clients is very counterproductive.

There is not a free environment for PLHIV due to limited knowledge in the population about HIV as well as stigma in the health care system including examples of discrimination, for instance a surgeon who did not want to operate a person with HIV. The patient then had to be transferred to Tbilisi. PLHIV tend to hide that they have HIV, and it is more acceptable to say that you have hepatitis C. Even support organizations have difficulties as people are afraid of meeting someone they know. The MSM population is highly stigmatized and anonymous testing is unavailable which is problematic.

Recommendations

- Consider decriminalizing drug use.
- Consider reintroducing the possibility for anonymous testing.
- Prioritize destigmatization of MSM and HIV in the Georgian society and in the health care system.

6. Recommendations

6.1 Main recommendations

Surveillance of the HIV epidemic in the country lacks interpretation of the trends in the epidemic, risking an underestimation of the number of undiagnosed people with HIV.

Recommendations

- Apply other methods than UNAIDS methods to estimate the number of undiagnosed people with HIV in order to better understand the dynamics of the epidemic and the size of the infected not yet diagnosed group of patients, for instance the 'London method 1' (Working Group on Estimation of HIV Prevalence in Europe, 2011, AIDS).
- Capacity building of surveillance responsible to ensure interpretation of the data available as well as missing variables to describe trends in the epidemic in the country.
- Improve estimation of risk groups for better estimations of the undiagnosed population in order to target interventions most cost-effectively.

HIV testing is low and does not target key most at-risk populations

Recommendations

- HIV testing rates in patients presenting with TB should increase from 60% to >95%. Ministry of Health regulation is crucial to ensure that this is introduced routinely in all clinics across the country.
- Barriers at both structural, provider and client levels are significant in Georgia and it is a precondition for scaling up HIV testing that these are addressed.
- It is recommended to scale-up community- based testing to reach PWIDs, MSM and FSWs and to use rapid tests. Care pathways should be carefully organized to ensure linkage to care for these populations when tested in community settings.
- Provider-initiated testing recommendations need revisiting, and support to the implementation of indicator condition guided HIV testing is crucial. The guidance on indicator condition guided HIV testing should be adopted and resources secured for its implementation.
- Ensure prequalification of testing kits in procurement.

Treatment programmes should provide the best possible treatment to patients while at the same time reducing costs by optimizing drug regimens.

Recommendations

- Rationalization of prescribed ART regimens for a more cost-effective public health approach without compromising the quality of care.
- Develop a communication plan to ensure the implementation of above.
- Reassess the organization of care for optimization and cost savings, i.e., number of visits with specialists, number of VL measurements.

- Ensure that retention in care is continuously developed and take into consideration the specific patient group of PWIDs and any specific needs for share care models as more PWIDs are tested and enter the care system.

The organization of care should have a diversified strategy towards stable patients and PWIDs.

Recommendations

- Reassess the organization of care for optimization and cost savings, i.e. number of visits with specialist, number of VL measurements.
- Ensure that retention in care is continuously developed and take into consideration the specific patient group of PWIDs and any specific needs for share care models. As more PWIDs are tested and enter the health care system, strong social support as well as scale up of OST is needed to ensure retention of care in this population group.
- Improve measures to support retention in care and compliance with ARV, e.g. directly observed therapy supplied at OST services.
- Reduction of stigma in health care settings through targeted campaigns and education.

The transition to more co-funding by government and the possible close down of GF support in future needs to be addressed.

Recommendation

- Ensure that systems are in place to tackle the transition to more government co-funding of the HIV/AIDS programme in the county to ensure sustainability and quality.

The HIV response in the country is hampered by a number of human rights issues.

Recommendations

- Consider decriminalizing drug use.
- Consider reintroducing the possibility for anonymous testing.
- Prioritize de-stigmatization of MSM and HIV in the Georgian society and in the health care system.

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Annexes

Annex 1 – Simplified ARV regimens

1st line adult	31-12-2013	31-12-2014	31-12-2015	31-12-2016
ABC,3TC,EFV	320	320		
ABC,3TC,NVP	13	13		
ABC,3TC,LPV/r	47	47		
ABC,3TC,ATV/r	6	6		
ABC,3TC,RAL	2	2		
TDF/FTC,EFV	575	1.035	1.800	2.170
TDF/FTC,NVP	134	162	200	240
TDF/FTC,LPV/r	103	103		
TDF/FTC,ATV/r	27	27		
TDF/FTC,DRV/r	3	3		
TDF/FTC,RAL	10	10		
ZDV,3TC,EFV	457	520	625	665
ZDV,3TC,NVP	82	105	145	165
ZDV,3TC,LPV/r	49	49		
ZDV,3TC,ATV/r	2	2		
ZDV,3TC,RAL	1	1		
	1.831	**2.405**	**2.770**	**3.240**
2nd/3rd line adult				
ABC,3TC,LPV/r	20	20		
ABC,3TC,ATV/r	1	1		
ABC,3TC,DRV/r	2	2		
ABC,ddi,LPV/r	10			
ABC,TDF,LPV/r	3			
ABC,3TC,FPV/r	3			
TDF/FTC,LPV/r	78	106	170	190
TDF/FTC,ATV/r	37	65	90	100
TDF/FTC,DRV/r	6	10	15	20
TDF/FTC,RAL	8	8	10	12
TDF/FTC,FPV/r	2			
TDF/FTC,RAL,LPV/r	1			
TDF/FTC,RAL,ATV/r	1			
TDF/FTC,RAL,DRV/r	1			
TDF/FTC,ETV	2	6	4	
ZDV,3TC,LPV/r	22	50	107	120
ZDV,3TC,ATV/r	4	15	45	55
ZDV,3TC,DRV/r	2	2	4	5
ZDV,TDF/FTC,LPV/r	3			
ZDV,ddi,LPV/r	3			

ZDV,ABC,FPV/r	1			
ZDV,ATV/r,RAL	1			
ZDV,ddI,ATV/r	1			
ZDV,TDF,DRV/r	1			
LPV/r,RAL,ETV	1			
3TC,LPV/r,RAL	1			
ddi,3TC,LPV/r	1			
	216	**285**	**445**	**502**

Children 1st				
ABC,3TC,EFV	7	8	9	9
ABC,3TC,NVP (syrup)	2	2	2	2
ABC,3TC,LPV/r	4	4	4	4
ABC,3TC,LPV/r (syrup)		1	2	2
ZDV,3TC,EFV	7	7	7	7
ZDV,3TC,NVP	10	10	10	10
ZDV,3TC,NVP (syrup)	1	1	1	1
ZDV,3TC,LPV/r	5	5	5	5
	36	**38**	**40**	**40**
Children 2nd				
ABC,3TC,LPV/r	2	4	5	6
ABC,3TC,LPV/r (syrup)		1	2	3
ZDV,3TC,LPV/r	4	4	5	6
ZDV,3TC,LPV/r (syrup)	3	3	3	3
	9	**12**	**15**	**18**
GRAND TOTAL	**2092**	**2740**	**3270**	**3800**

The process is made in agreement with the National AIDS Center and will be put forward to the CCM and primary recipient for the GF application.

1. Switch to the public health approach for selecting ART regimens will be implemented in two stages.

2. The first stage of implementation will be applied to patients initiating ART. Starting from June 2014 all newly enrolled patients will be started on one the four regimens recommended by 2013 WHO guidelines. Preference will be given to TDF/FTC (or 3TC) + EFV. This approach will be maintained in future years as well.

3. Given that antiretroviral drugs for 2014 have been already purchased based on previous quantifications, the programme will retain patients on Abacavir-based regimens, as well as patients on PI-containing and Raltegravir-containing first line regimens, through the end of the year at the same numbers as registered by the end of 2013.

4. Starting from 2015, patients on ABC-based regimen will be gradually switched to preferably TDF or ZDV-based regimens. With regard to patients receiving PI or RAL as part of their first line treatment, of 250 such patients 150 will be switched to one of the standard first line regimen, and 100 patients will be switched to second line regimens because use of NNRTI based therapy is contraindicated based on prior use.

5. With regard to second and third line regimens, the number of possible regimens will be limited to 11 by the end of 2014, and the number of regimens will be reduced further to 8 and 7 by the end of 2015 and 2016 respectively.

6. TDF/FTC(or 3TC) + either ATV/r or LPR/r and ZDV/3TC + either ATV/r or LPR/r will be used for second line treatment and will be selected based on resistance testing and previous treatment history. Third line regimens will contain DRV/r and/or Raltegravir.

	2014	**2015**	**2016**
	# Pts	# Pts	# Pts
ABC/3TC	427	18	19
ABC (syrup)	4	6	7
TDF/FTC	1.535	2.289	2.732
ZDV/3TC	755	938	1.023
ZDV	15	15	15
ZDV (syrup)	4	4	4
3TC	15	15	15
3TC (syrup)	8	10	11
ddI	5	5	6
EFV	1.860	2.411	2.821
EFV	30	30	30
NVP	290	355	415
NVP (syrup)	3	3	3
LPV/r	392	296	331
LPV/r (syrup)	5	7	8
ATV	116	135	155
DRV	17	19	25
RTV	133	154	180
ETV	6	4	0
RAL	21	10	12

Annex 2 – Terms of References

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

Evaluation of the HIV/AIDS Treatment and Care in Georgia

2-6 June 2014

1. Background

Georgia has a growing HIV epidemic. By the end of 2012, Georgia reported a cumulative total of 3 641 HIV cases to the joint database of the WHO Regional Office for Europe and the European Centre for Disease Prevention and Control (ECDC). The rate of newly diagnosed HIV infections in 2012 was 11.9 per 100 000 population; the rate has steadily increased since 2004 when it was 3.5 per 100 000 population. The majority of new HIV cases in 2012 were male (73.3%). Among the newly diagnosed HIV cases with information about transmission mode 42.6% were infected through injecting drug use, 46% through heterosexual contact, 8.2% through sex between men and 1.7% through mother-to-child transmission. In total, Georgia has reported 77 mother-to child-transmission cases, including 9 cases in 2012. Despite its currently low HIV prevalence, Georgia is considered to be at a high risk for an expanding epidemic due to injecting drug use and risky sexual behaviour.

The number of people receiving antiretroviral therapy (ART) is 2029 in 2013. However, 2012 data on CD4 count by the time of HIV diagnosis indicated late presentation for treatment and care services in Georgia: 70.4% of newly identified HIV infected people had CD4 <350cells/mm^3, of whom 43.9% had CD4<200 cells/mm^3. Georgia has a "successful" HIV treatment programme in that 77% on those on ART achieve viral suppression. However with an estimated 48% of PLHIV in Georgia undiagnosed viral suppression is only achieved in 20% of all PLHIV in Georgia. Undiagnosed HIV is a major issue to achieving the individual and public health benefits of ART.

Country's response to the HIV epidemic is supported by the Global Fund (TGF) grant and the country is fully reliant on TGF in covering cost of HIV treatment. Country has prepared an application for Phase 2 of HIV grant which requires review and alignment with the WHO 2013 consolidated guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV infection Concerns have been expressed about the number of different treatment regimens and range of antiretroviral used in Georgia.

In a framework of the WHO and TGF collaboration and during a discussion with the national counterparts, it has been agreed that WHO Regional Office for Europe through its collaborating centre on HIV and Viral Hepatitis will provide technical assistance to Georgia by evaluating national HIV treatment and care programme and application to TGF.

2. Objectives of the mission

The WHO country mission will evaluate the HIV treatment and care programme in Georgia along the cascade of care and services and will provide recommendations on: standardisation of treatment regimens (including use of fixed dose combinations); reducing the number of different regimens/ARVs; standardising diagnostic and treatment monitoring algorithms; optimization of the HIV grant from the public health perspective so to ensure alignment of the proposal with the WHO recommendations and high coverage with services for those who need them.

The following technical areas will be evaluated:

- HIV testing and counselling, including community-based testing for key populations and linkage to HIV treatment and care services, CD4 count at time of diagnosis
- Enrolment and retention in HIV care, including general HIV care, management of co-infections and co-morbidities, integration of HIV/Viral hepatitis, HIV/TB, HIV/OST services
- Access to and coverage with HIV treatment and care services for key populations: IDUs, MSM, FSW
- ART: estimated need and coverage, criteria for ART initiation, retention and adherence
- ART regimens – ways to optimize and minimize number of regimens for TGF application
- ARV prices
- Monitoring of ART response: Viral load, ARV toxicity, HIVDR, other high technologies – ways to optimize clinical/laboratory management and cost for TGF application

3. Participants

2 experts from the WHO Collaborating Centre on HIV and Viral Hepatitis, Copenhagen, Denmark: Prof Jens Lundgren and Dr Dorthe Raben.

4. Methodology

Readily available information will be withdrawn from the secondary sources (publications, reports, etc.) during preparation stage for desk review and analysis.

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

Logistic support will be provided by the WHO Country Office in Tbilisi and national health authorities.

5. Time and duration of the mission

Mission is planned for June 2-6.

6. Deliverables

Major findings and recommendations will be shared with the national counterparts and TGF principal recipient by the end of the mission.

As a result of the mission a report with findings and recommendations on improving the national HIV treatment and care programme and optimization of Phase 2 HIV grant application will be prepared and submitted no later than end of June 2014.

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

Annex 4 – Review team and informants

Review team members

From WHO Collaborating Centre on HIV and Viral Hepatitis, Copenhagen, Denmark:
Dr Jens Lundgren, MD
Ms Dorthe Raben, MSc

List of informants

Ministry of Labour, Health and Social Affairs of Georgia

Dr Mariam Jashi, Deputy Minister

National Center for Diseases Control and Public Health (NCDC)

Dr Amiran Gamkrelidze, Director General
Dr Irma Khonelidze, Deputy Director General
Dr Ketevan Stvilia, Manager of the Global Fund project

Infectious Diseases, AIDS and Clinical Immunology Research Center (National AIDS Center)

Dr Tengiz Tsertsvadze, Director General
Dr Nikoloz Chkhartishvili, Manager of HIV/AIDS Treatment and Care Program
Dr Lali Sharvadze, Head of HIV Outpatient Department
Dr Pati Gabunia, Head of HIV Inpatient Department
Dr Nino Badridze, Head of Epidemiology Department
Dr Otar Chokoshvili, Manager of National AIDS Health Information System
Dr Akaki Abutidze, Manager of HIV/HCV Co-infection Treatment Program
Dr Nino Gochitashvili, Leading Physician
Dr Mariam Svanidze, ID Physician

WHO Country Office

Dr Rusudan Klimiashvili, Head of the WHO Country Office
Dr Nino Mamulashvili, Program Officer

Other organizations:

Dr Khatuna Todadze, Head of Research Institute on Addiction
Ms Marine Gogia, Program Director at the Georgian Harm Reduction Network
Mr David Ananiashvili, CCM oversight committee chair
Ms Izoleta Bodokia, Director of HIV/AIDS Patients Support Foundation
Dr Nana Kiria, Medical Director at the National Center for TB and Lung Diseases
Dr Ucha Nanava, Database Manager at the National Center for TB and Lung Diseases
Mr Akaki Lochoshvili, Director of Global Projects Implementation Center (former PR of the Global Fund)
Ms Nino Tsereteli, Director of Center for Information and Counseling on Reproductive Health ‘Tanadgoma’