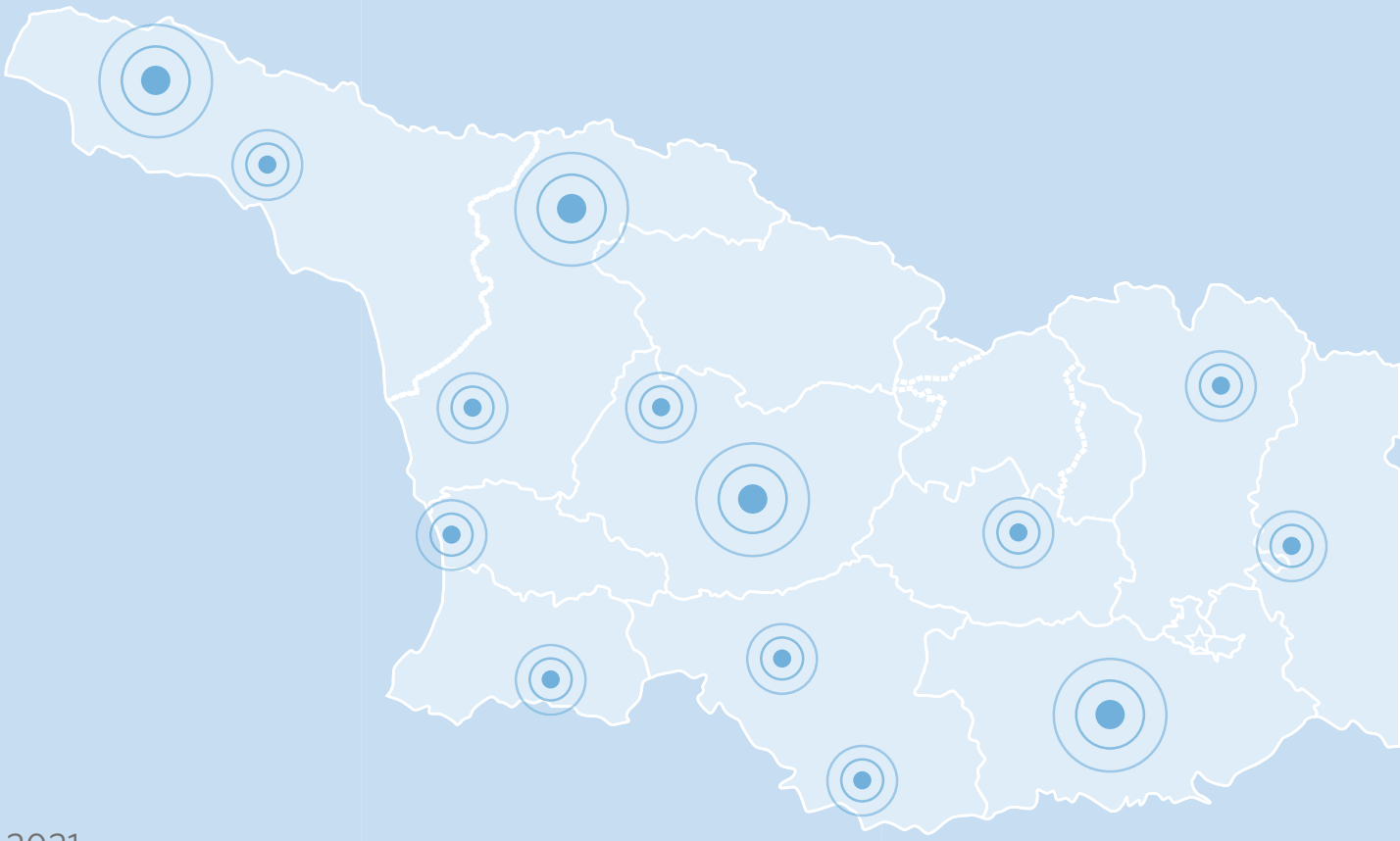
RESEARCH

Changes in Harm Reduction Packages and Unit Costs during Transition from International to Domestic Funding in Georgia



2021

This analytical report is a publication of the Eurasian Harm Reduction Association (EHRA). EHRA is a non-profit public organization that unites and supports 324 activists and organizations in the Central and Eastern Europe and Central Asia (CEECA) region to ensure the rights and freedoms, health and well-being of people who use psychoactive substances.

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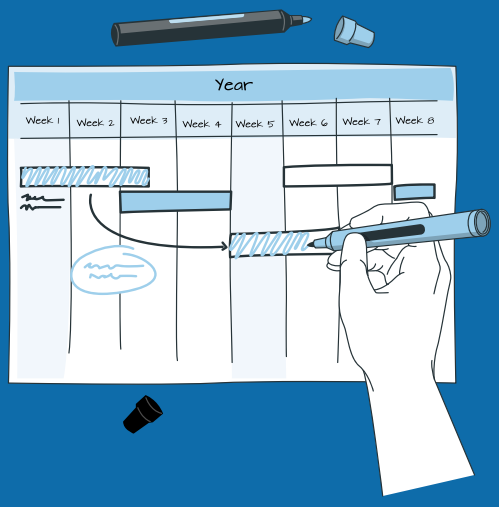
Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
BDD	Basic Data and Directions
CCM	Country Coordinating Mechanism
CSO	Civil Society Organisation
EECA	Eastern Europe and Central Asia
FSW	Female Sex Workers
GAM	Global AIDS Monitoring
GHRN	Georgian Harm Reduction Network
GoG	Government of Georgia
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IBBSS	Integrated Biological and Behavioural Surveillance Survey
MoH	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
MSM	Men-who-have-Sex-with-Men
NCDC	National Centre of Disease Control and Public Health
NGO	Non-Governmental Organization
NSP	Needle and Syringes Program
OST	Opioid Substitution Therapy
PBF	Performance-Based Financing
PDI	Peer-Driven Intervention
PIU	Programme Implementation Unit

Acronyms and Abbreviations

PLHIV	People Living with HIV
PR	Principal Recipient
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RBF	Results-Based Framework
STI	Sexually Transmitted Infection
SVM	Syringe Vending Machine
TB	Tuberculosis
TSP	Transition and Sustainability Plan
VAT	Value Added Tax
VCT	Voluntary Counselling and Testing

Executive Summary



Georgia was one of the first countries in the region to develop the Transition and Sustainability Plan in 2017 and, with the involvement of stakeholders, prepared the basis for successful transition.

Scaling-up and enduring sustainability of the HIV response, and taking into account ambitious goals set out in the global Sustainable Development Goals to end HIV/AIDS by 2030, is a challenging task for many countries, including Georgia. In this regard, although Georgia has made advancements, the first pillar for HIV detection is still underachieved at 76%. With the new Global AIDS Strategy, it is important to focus on key populations, such as people who inject drugs (PWID), in order to control the HIV epidemic and eliminate inequalities which increases their risk of exposure and worsens the outcomes and quality of life.

Achieving those ambitious goals depends on stable and predictable sources of funding of the HIV response, especially when donors are retracting and the government needs to increase its financial commitment, including for HIV prevention interventions for key populations. Georgia was one of the first countries in the region to develop the Transition and Sustainability Plan in 2017 and, with the involvement of stakeholders, prepared the basis for successful transition. In 2019, the plan was integrated into the National Strategic Plan and was endorsed by the Country Coordinating Mechanism (CCM). The initial plan reflected full transition of harm reduction services by 2022.

This report looks at the changes in harm reduction service packages and unit costs in the context of transition from the donor funding to public financing and has made the following observations:

1. The transition context differs from the National Strategic Plan defined processes in Georgia as the country is still eligible for Global Fund support for the next allocation period. This opportunity should be used to further investigate innovative approaches to harm reduction preventive services to enable improvements in reaching targets and in enhancing accessibility to quality services and increased client satisfaction leading to better health outcomes.
2. Georgia has shown progress with regards to taking over the funding of HIV preventive services for key populations and, from 2020, has been financing the harm reduction voluntary counselling and testing (VCT) service for PWID through the non-governmental organisation (NGO), Georgian Harm Reduction Network (GHRN), and NGO/ civil society organisations (CSOs) under the network umbrella. Lessons learned during the transition and programme implementation has informed both sides, the government and the harm reduction network, for further improvements of the transition process.
3. Opioid substitution therapy (OST) services have been fully transitioned to the State since mid-2017, with ensured funding and increased enrollment in the programme. With the increased number of beneficiaries, the need for additional capacity and alternative service delivery modes should be brought to attention. More client-tailored services are needed to increase retention rates in the programme.
4. Despite the strong will of the Government to fulfill its transitional commitments, funds currently reflected in the Basic Data Directions 2022-2025 do not support the need to fully cover HIV prevention services for key populations by 2022 at 50% for PWID services and 45% for female sex workers (FSWs), even though the new method of unit cost calculation has reduced overall funding needed. Advocacy for the allocation of sufficient funds should be considered with the involvement of stakeholders to allow a smooth transition process and the fulfilment of co-financing commitments.
5. The funding mechanism (Fee for Service) used for State funding of NGOs has resulted in a number of challenges to service providers and the introduction of an alternative payment mechanism with strong monitoring tools has significant importance for the further scaling-up of funding from the State. The process was initiated with the support of the Global Fund through an international consultancy and the involvement of key stakeholders who helped the country to develop a set of performance indicators, recommendations for qualitative indicators and relevant implementation timelines were suggested for a Performance-Based Financing (PBF) mechanism for implementation. In the context of primary healthcare reform, where the PBF payment mechanism is planned to also be introduced, it can be aligned with the Results-Based Framework (RBF) introduction to the HIV programme and translated into the overall national policies to enable smooth transition.

Introduction

The HIV Situation in Georgia

Georgia is situated in the Eastern Europe and Central Asia (EECA) region with a population of

3.7 million

In 2020, it had a low HIV prevalence

0.3%

in adult population

and the estimated number of People Living with HIV (PLHIV) was

8,400

As of 2020, it was estimated that

76% of PLHIV were aware of their status

86% of those were on antiretroviral (ARV) treatment[1]

HIV/AIDS is largely concentrated among key affected populations, including men-who-have-sex-with-men (MSM), people who inject drugs (PWID) and female sex workers (FSW).

1 UNAIDS data, 2020; https://aidsinfo.unaids.org/

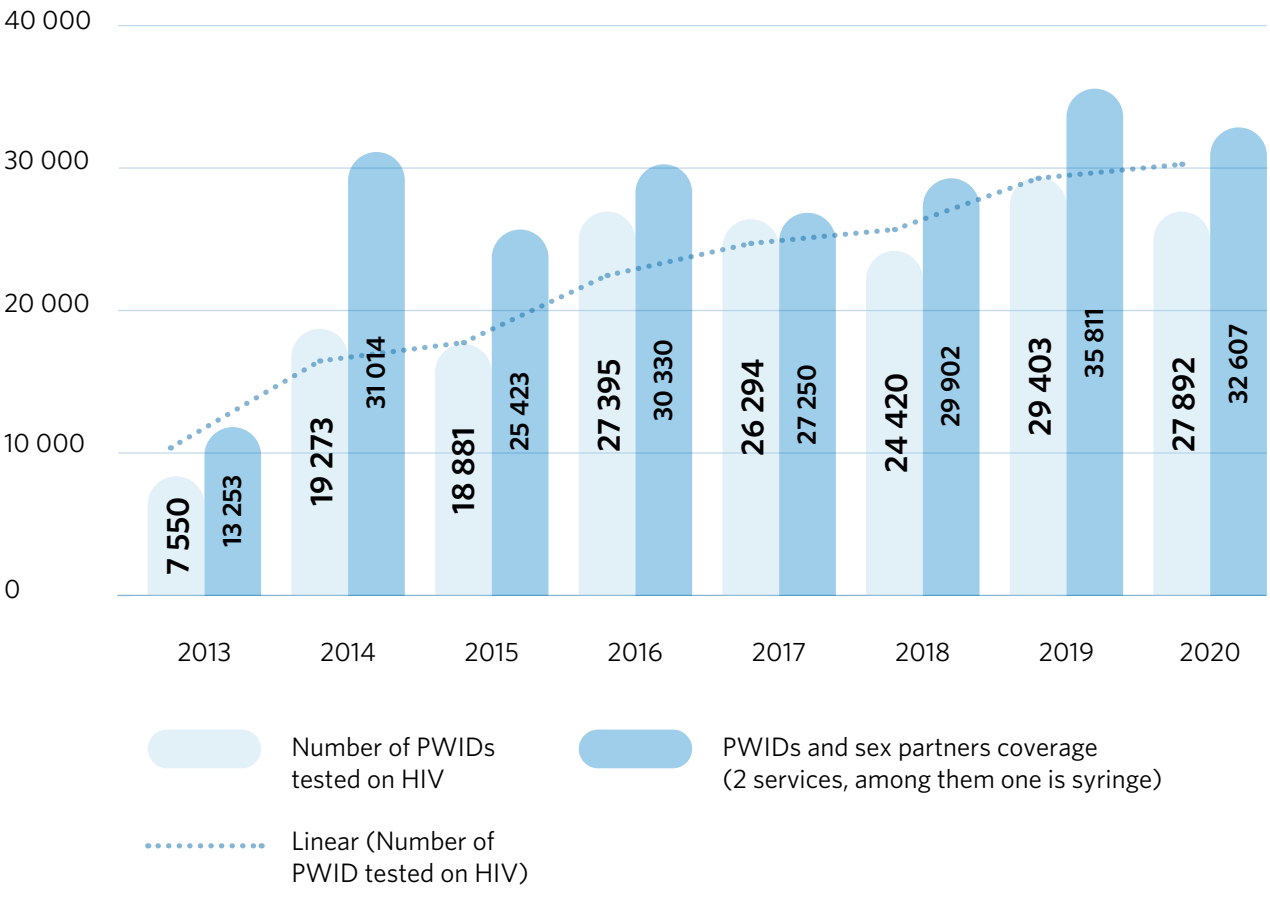
HIV and Harm Reduction Services for People Who Inject Drugs

Georgia has one of the highest prevalence of problem drug use in the EECA region. The number of PWID is estimated at 52,500 and HIV prevalence among PWID is estimated at 2.3% (2017)[2].

According to the National Strategic Plan for HIV (2019-2022), PWID are one of the priority groups for HIV control in the country. The plan defines the provision of a comprehensive harm reduction package to PWID as one of the priorities through domestic and international funding.

Coverage of PWID with a needle and syringe programme (NSP) in 2020 was 86% (32,607 users) and coverage with HIV testing was 79% (27,982 users). Distribution of needles and syringes on country level per person per year has increased from 22 units in 2011 to 70 units in 2020[3].

Figure 1. PWID coverage with needles/syringes and VCT[4]



2 Curatio International Foundation, Bemoni Public Union. Population Size Estimation of PWID in Georgia; 2017; http://curatiofoundation.org/pse2017/

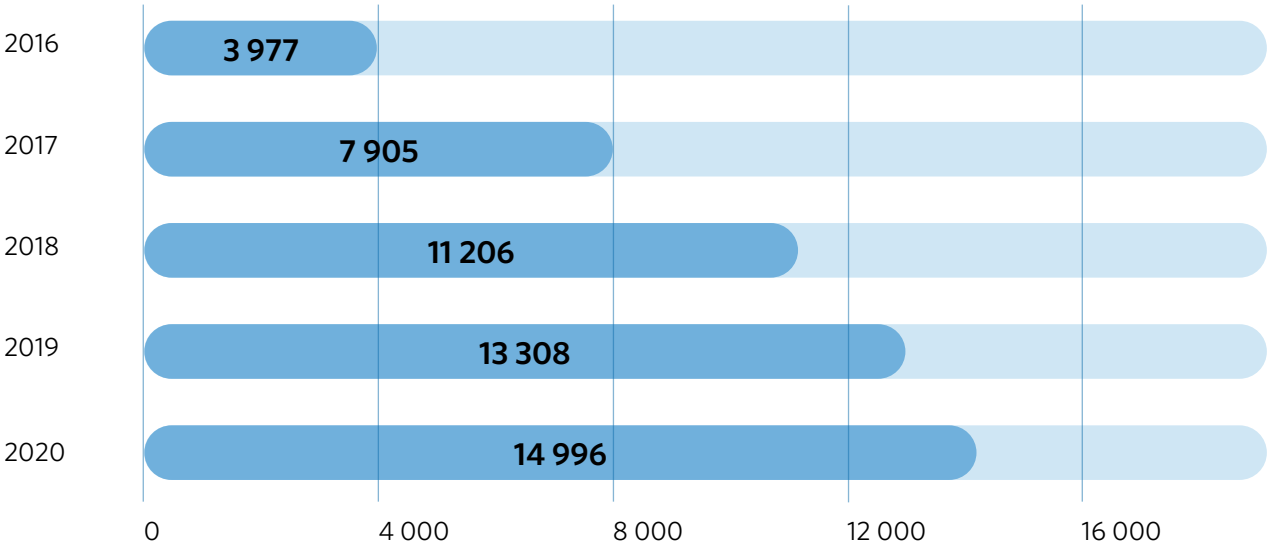
3 National Center for Disease Control and Public Health, HIV Prevention Program (Programmatic data, 2011-2020)

4 National Center for Disease Control and Public Health, HIV Prevention Program (Programmatic data, 2013-2020)

According to the Integrated Biological and Behavioural Surveillance Survey (IBBSS)[5], safe injecting practices increased from 48.1% to 90.4% from 2011 to 2017 and condom use from 22.4% to 36.5% during the same period.

Opioid substitution therapy (OST) coverage, including prisons, in 2020 was over 14,900 clients, which is a substantial overachievement compared to the target of 11,000 clients defined in the National Strategic Plan, 2019-2022.

Figure 2. OST service coverage[6]



The above graph shows that the number of clients on treatment has increased dramatically in recent years.

Since 2003, harm reduction has been developing rapidly in Georgia and, with the efforts of international donor organisations, services have expanded geographically and the variety of services provided has broadened. The number of sites providing the NSP has increased from 6 in 2006 to 15 sites in 2020, delivering harm reduction services in 11 cities, including in Abkhazia. State organisations are also involved in providing harm reduction services. Namely, the OST programme is implemented by the "Centre for Mental Health and Prevention of Dependence", which has 20 sites around the country.

5 Curatio International Foundation, Bemoni Public Union. Population Size Estimation of PWID in Georgia; 2017; http://curatiofoundation.org/pse2017/

6 UNAIDS GAM report - 2016-2018 data; Ministry of Finance of Georgia, State Budget Execution Report - 2019-2020 data.

Overall, the following harm reduction services are available for PWID in Georgia:

Voluntary counselling and testing (VCT) for HIV

Distribution of injecting equipment

Distribution of condoms to PWID and their sex partners

Diagnosis of the Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), Syphilis and referral to treatment

Naloxone distribution in the community

Raising awareness of HIV and safe injection among PWID

Diagnosis of Tuberculosis (TB) and referral to treatment

Opioid Substitution Therapy (OST)

In addition to the above basic package, **the following are provided as add-on services within the NSP to PWID through community organisations and NGOs:**

- Peer driven interventions
- Case management
- Medical and legal consultations
- Incentive packages for PWID and their partners

The current service package for the NSP includes the following limits per client, per year: VCT service twice a year, including HIV, HCV, HBV, Syphilis and TB Screening (second testing is based on medical indication or risky behaviour); 130 syringes distributed; consultation with a specialist, including doctors and psychologists, case management and incentive packages (mainly includes hygiene items, the number is defined based on available funding); monthly meetings with peers and patient school; and a HIV self-testing intervention, with tests provided at a centre or online through a self-testing platform.

With the involvement of the national stakeholders and donor organisations, in January 2020 Decree 01-16/O[7] was issued by the Ministry of Health (MoH) and guidelines for prevention services for key populations were approved. Amongst them are the guidelines and protocol for the harm reduction services for PWID. The guidelines reflect compliance with international guidelines/recommendations and the service package outlined above. In addition, the guideline emphasises the importance of advocacy activities for legislative changes and policy reforms for facilitating the provision of harm reduction services.

OST implementation is regulated by Ministerial Decree No. 01-41/n[8] "Special Program for Opioid Substitution Treatment " approved by the MoH on 3 July 2014 that outlines client selection criteria, treatment and a list of opioids for treatment. New special rules are introduced

7 HIV Prevention in High Risk Groups – National Guidelines in Public health, Decree #01-16/O; MoH, 24 January 2020.

8 "Special Program for Opioid Substitution Treatment " , Decree 01-41/n , 3 July 2014, MoH https://matsne.gov.ge/ka/document/view/2374811?publication=0

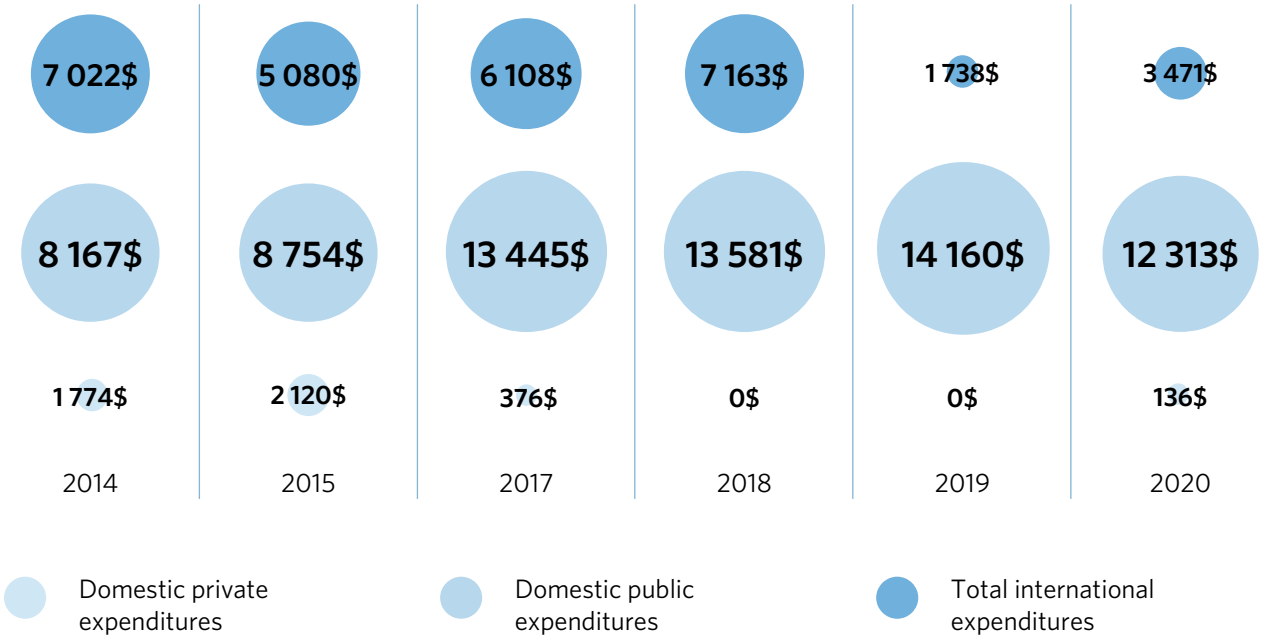
through amendments to the regulation reflecting the changing environment and programme needs. Two medicines are available for OST in the country: a) Methadone substitution programme from 2008; and, b) Buprenorphine/naloxone programme from 2010. In this regard, clinical guidelines were approved by the MoH on 20 June 2016 through the following Decrees: #01-139/O related to 'Suboxone Substitution Therapy' and #01-137/O concerning 'Methadone Maintenance Treatment'[9].

The current OST service package includes a doctor consultation, blood/urine tests and screening for HIV/HBV/HCV upon enrolment; treatment monitoring and observation; drug supply, including storage and transportation; and psycho-social support.

Transition Context in Georgia

The process of transitioning of the harm reduction programme funding from the Global Fund to domestic financing has already started. The overall funding for the national HIV response is increasing annually and the structure of the flow of funds is changing. More public funds are directed to financing HIV prevention and case detection activities. The primary source of funding for the HIV response is the State budget, comprising 77% of total expenditure in 2020. Increasing State funding is also related to adjacent programmes, such as the national Hepatitis C elimination programme for the general population.

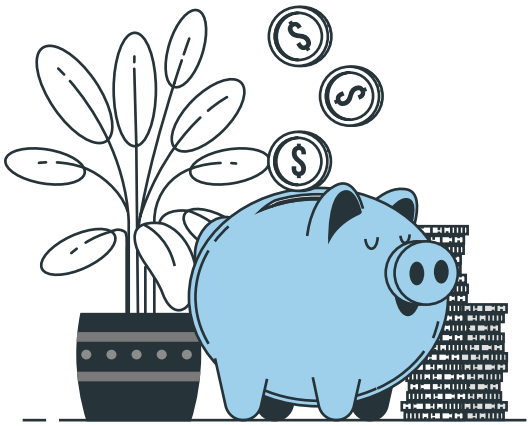
Figure 3. HIV expenditures from all funding sources (in thousand USD) 2014-2020[10]



9 Clinical Guidelines: Suboxone Substitution Therapy, Decree #01-139/O and Methadone Maintenance Treatment, Decree #01-137/O, MoH; https://www.moh.gov.ge/ka/guidelines/

10 UNAIDS financial data - 2014-2020; https://hivfinancial.unaids.org/hivfinancialdashboards.html#

National fiscal policy priorities of the country are reflected in the Basic Data and Directions document (BDD) developed annually by the Ministry of Finance. The current national BDD document covers the 2022-2025 period. Investing in health is still one of the priorities of the national fiscal policy. Based on BDD data and the State budget law, State programmes on health are developed that reflect the programme's descriptions, implementation arrangements and budget. The latter is approved by a special Government decree every year and allows for tracking of central Government allocations for public programmes, including the State HIV programme. It has sub-accounts and a descriptive part that has information on the distribution of funding among interventions. From 2020, interventions directed to key populations have been introduced as separate line, among them is a pilot programme of preventive services for PWID.



According to the BDD, domestic funding for HIV Response in 2021 has increased

by 12%

compared to year 2020 comprising

USD 13,805 K

According to the BDD, domestic funding for the HIV response in 2021 has increased by 12% compared to 2020, comprising USD13,805,000. A further increase in funding is envisaged in following years.

The Transition and Sustainability Plan (TSP), which was developed for the period 2017-2021, emphasises the importance of achieving the medium and long-term targets for tackling the disease and to ensure a smooth transition from Global Fund support to domestic funding by 2022[11]. The plan was developed based on the assumption that full transition will become effective by 2022. However, the funding possibilities have changed and Georgia is still eligible for Global Fund support for the 2020-2022 allocation cycle. Eligibility of additional funding

11 Georgia Transition Plan, "Curatio International", 2016

is still dependent on the Government's funding commitment to increase overall health spending and take-over financing of interventions directed to key populations.

As part of the take-over plan during recent years, the following interventions were fully transitioned to State funding:

- ARV treatment and laboratory and clinical monitoring component;
- Opioid substitution programme: full service package, including service in penitentiary sites and psycho-social support;
- Sexually Transmitted Infection (STI) diagnostics and treatment among key populations; and,
- Pre-exposure prophylaxis (PrEP) clinical monitoring component.

A pilot programme was introduced to fund harm reduction services for PWID from 1st July 2020. As a part of this pilot, HIV testing implemented by the GHRN was financed by the State. Based on the National HIV Programme, and approved by the GoG, a contract was signed with GHRN and the latter — as the primary recipient — has subcontracted, 11 service providers based on the number of the services that they provide.

It is important to note that despite the political will of the Government of Georgia (GoG) to increase its investment and to create a sustainable environment for the national HIV response, many external and internal factors might impact the process. One of the biggest challenges in 2020 was the COVID-19 epidemic, resulting in changes in funding priorities and resource allocations. However, this did not have a direct impact on the financing of HIV interventions but might increase the risk for future allocations.

Eligibility of additional funding is still dependent on the Government's funding commitment to increase overall health spending and take-over financing of interventions directed to key populations

One of the biggest challenges in 2020 was the COVID-19 epidemic, resulting in changes in funding priorities and resource allocations.

Methodology

This study was undertaken using the methodology and guidance from EHRA and is part of a multi-country study looking at similar aspects in four countries — Georgia, Ukraine, North Macedonia and Kyrgyzstan.

The study has the following 2 strategies for data collection:

Desk review:

The reviewed documents included national AIDS response strategies and reports on public programme implementation; documents reflecting packages of services; national and Global Fund budgets and their execution; and State procurement tenders and service provider contracts (see Annex 1).

Interviews with the key stakeholders:

Interviews were conducted using the interview guide developed by EHRA with the following respondents: five harm reduction service providers from different cities covering Tbilisi, Rustavi, Zugdidi, Batumi and Ozurgeti; decision-makers regarding the packages of services and unit costs; beneficiaries of OST and needle-syringe programme services introduced by relevant service providers (a list of respondents is at Annex 2).

Georgia does not have an approved unit cost for harm reduction services and, over the past few years, approaches to budgeting and reimbursement have been changing. Therefore, in order to understand changes in the unit cost during transition, we have made estimates for the unit cost of key harm reduction services, i.e. the needle-syringe programme and OST. Approaches used for the estimation are described below:

OST Programme

The unit cost for OST is estimated based on a top-down approach by dividing the reported funding from the State/donor with the number of clients covered. Total funding figures were obtained from the State budget execution reports, the Global Fund expenditures and Global AIDS Monitoring (GAM) reports. Those funding amounts include payment for the service (substitution therapy), medicines and related transportation costs and psycho-social support. The number of clients includes everyone who has received service at least once during the year, including prisoners.

This calculation excludes a private buprenorphine programme due to its small share and limited data availability.

Needle and syringe programme

A top-down approach was again used to estimate unit costs of NSP. In 2019, the Principal Recipient (PR) of Global Fund grants introduced a unit cost calculation methodology based on the following assumptions: for basic services, direct staff cost involved in providing the service was estimated by the time spent on each activity through different service delivery modalities — facility based, mobile ambulatory and outreach. Add-on services provided under the programme (case management, peer-driven interventions, medical consultations, etc.) were costed based on historical cost data; a fixed rate for administration costs was set; the cost of consumables/medical supplies was derived based on programmatic data and average unit cost.

Average unit cots per client, per year, was calculated based on total estimated budget and projected coverage indicators in National Strategic Plan.

For comparability reasons, unit costs before 2019 were also calculated using the same approach: the need for consumables/medical supplies were recalculated in line with the new unit cost calculation methodology and cost categories were grouped in the same cost groups based on the service contracts signed between PR and GHRN.

Note: Actual spending and PWID coverage with the service differs from the above estimates.

The foreign exchange rate to convert GEL to USD is calculated using the average rate during the relevant year (Source: National Bank of Georgia, https://nbg.gov.ge/)

Limitations:

- Calculations do not reflect investment costs in long-term assets; no discounting factor has been applied;
- Needles and syringes: prices for consumables/medical supplies used for estimating budgets are fixed and based on data used by the PR for unit cost calculations; and,
- OST: the number of OST clients reflect beneficiaries who registered for the programme and received service and does not count the retention rate in the programme.

Findings: Changes in Service Package, Funding and Unit Costs

4 in Tbilisi

14 Harm Reduction Centres

9 mobile ambulatories

Needle and Syringe Programme

Service Package

Harm reduction services in Georgia were provided by NGOs under the umbrella of the Georgian Harm Reduction Network (GHRN). GHRN unites and coordinates 11 NGO/CSO organisations to provide the service, with the following service delivery models: 14 Harm Reduction Centres (4 in Tbilisi and the remainder in the cities of Rustavi, Telavi, Gori, Kutaisi, Samtredia, Poti, Zugdidi, Batumi, Ozurgeti; and Sokhumi);

and 9 mobile ambulatories and outreach to PWID. Changes were introduced in the above arrangement from the beginning of 2021: the NGO, "Z. Danelia Union Tanadgoma", provides harm reduction services in Abkhazia through a direct contract issued by the National Centre of Disease Control and Public Health (NCDC) under Global Fund financing; GHRN, previously providing only management and supervisory functions to service provider NGO/CSOs, became one of the harm reduction service providers. The latter were related to changes introduced in tax law regarding value added tax (VAT) of medical services and the launching of a pilot programme through State financing. Since 2021, medical services provided by organisations that are registered as medical service providers are exempt from VAT. Prevention services, including harm reduction, are defined as medical services in the State health programme and NGOs/CBOs, providing those services, are also listed in the document. The latter has allowed those organisations to retain VAT exemption status for those services. In addition, NGOs/CBOs that provide HIV prevention services as part of the State Health Programme were registered with the State Medical Activity Regulation Agency. The registration process and requirements are defined by the GoG in Decree N 359 — "Requirements for High Risk Medical Service Provision"— approved on 22 November 2010[12].

Before the transition, the NSP service package covered the following activities: the Basic Package included distributing needles and syringes, condoms/lubricant, and information materials; VCT testing HIV/HBV/HCV/Syphilis; TB screening with a questionnaire; naloxone distribution in the community; and case management. Add-on services include the provision of minor medical supplies to

Since 2021, medical services provided by organisations that are registered as medical service providers are exempt from VAT.

The registration process and requirements are defined by the GoG in Decree N 359 — "Requirements for High Risk Medical Service Provision"— approved on 22 November 2010

12 "Requirements for High Risk Medical Service Provision", Decree #349 22 November 2010, GoG; https://matsne.gov.ge/ka/document/view/1113752?publication=0

beneficiaries, such as for care of injection sites; peer education meetings and client schools; case management support; incentive packages for sexual partners of PWID (e.g. hygiene packages); medical consultations for PWID and their partners; and art therapy available at 4 sites.

Changes to the composition of the service package has slightly changed in the last five years. The case manager function, arranging social support to clients, was introduced in 2018; in 2017, a new service was offered to clients and their partners through referral to STI diagnostic and treatment facilities with the cost covered by GHRN; currently, STI services targeting key populations is fully transferred to State funding. From 2019, Peer-Driven Interventions (PDI) were removed from the package based on the mutual agreement between the service provider and the NCDC; the position of TB consultant was also removed and the TB screening function based on a questionnaire was integrated into the VCT consultant functions.

Four harm reduction sites are also implementing the national hepatitis C treatment programme through the harm reduction integrated model of hepatitis C treatment that is a motivational factor for PWID to get regular harm reduction and HIV prevention services.

In addition to the above-described model, innovative approaches are used to increase coverage and accessibility. Syringe Vending Machines (SVM) were introduced in mid-2019, providing uninterrupted 24/7 access to sterile injection equipment, condoms, and HIV self-tests for regular HIV prevention service clients and to those who are reluctant to visit such services due to stigma. The operation of SVMs in Tbilisi was implemented by the local NGO "Alternative Georgia" with financial support from the French 5% Initiative and in partnership with the existing Global Fund HIV grant, for which the latter was providing supplies for the machines. Overall, 10 machines were operating. To have access to the products in the vending machine special cards are provided to clients. During the implementation period, the total number of cards distributed to clients was 1,514 and packages dispensed comprised 33,521. Currently, the Global Fund HIV grant has taken over the financing of the project at the same level of funding.

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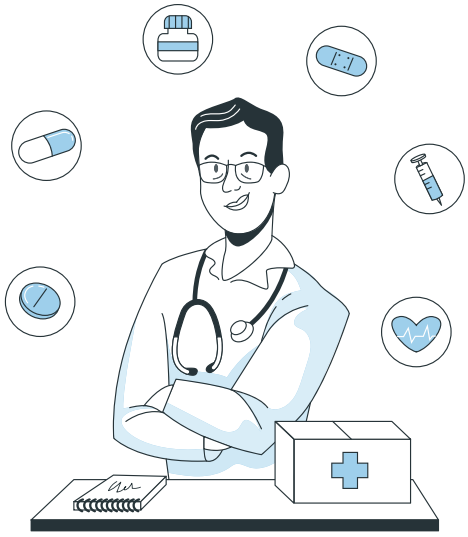


Funding and Unit Costs

Funding: The Global Fund is a main source of funding for the NSP in Georgia. Since 2004, several PR's have changed and, from 2014, the State organisation, NCDC, was selected by CCM to implement the Global Fund grants in Georgia. The NCDC is also in charge of implementation of the State HIV programme related to HIV detection and prevention. Two units are involved in the process: the Global Fund programme implementation unit (PIU) is responsible for donor financing and the State programme department is responsible for the State HIV programme. Different mechanisms are used to procure preventive services for PWID under each source of funding.

The NCDC is a State organisation under the MoH. It follows local regulations applicable to State organisations, including procurement procedures. Strict tendering procedures are defined by law and the process is implemented and monitored through the State procurement web portal (http://procurement.gov.ge). The latter provides for transparency and competitiveness of the procurement process. Tenders are open to every organisation, including NGOs/CSOs. The lowest price is the criteria to start a bid evaluation. The winner of the tender is identified if the proposed documentation is in compliance with the tender requirements.

The above procurement mechanism is used for Global Fund supported activities. A service contract is signed between GHRN and NCDC defining service specifications, payment mechanism, and programmatic and financial reporting. The line-item budget is used for budgeting and payment purposes. Monthly reporting is carried out and reimbursement is proceeded after the inspection of programmatic and financial data.

In 2020, a pilot programme was initiated to transfer the obligation for a segment of the harm reduction service package — HIV VCT — from the Global Fund to the State. Prior to this transition, the State programme department already had the payment mechanism for HIV VCT services and fee-for-service payment modality was used.The same mechanism and calculation of fee-for-service was used to pay for HIV VCT for PWID. The design of the pilot programme was reflected in the Health Programme for 2020. The programme defined the medical service providers of the VCT component for key populations — NGO GHRN and the same NGO/CSOs under the umbrella of GHRN that were providing services for the Global Fund programmes. HIV/HBV/HCV/Syphilis tests were provided by the NCDC. The budget allocated to the VCT service in 2020 comprised GEL335,000 (USD108,000). The budget allocated to GHRN for VCT services increased to GEL712,000 (USD218,000) in 2021.

Unit prices for VCT under the State HIV programme are as follows:

- Facility-based: GEL15.53 (USD5.00), including GEL5.68 for pre-test consultation; GEL5.68 for testing and GEL4.20 for post-test consultation.
- Outreach: GEL25 (USD8), including GEL5.68 for pre-test consultation; GEL5.68 for testing; GEL4.20 for post-test consultation; and GEL9.47 for outreach work.

The service contract within the State HIV programme between GHRN and NCDC defines service specifications, payment mechanism and reporting requirements. The split between indicators for outreach and facility-based testing are predefined and the budget ceiling is set. Reporting is through the HIV database controlled by the NCDC.

An important achievement is being able to provide testing without personal identification data through usage of 15 symbol codes. The testing and coding is regulated by Ministerial Decrees #217/O of 23 July 2010 and #01-461/O of 18 September 2020[13]. The service is defined as voluntary testing of PWID for four infections: HIV, HBV, HCV and syphilis together with counseling.

From the start of the pilot programme, several challenges were identified that affected the implementation process, but through negotiations and cooperation between the State programme department and NGOs, amendments were introduced in the State programme on Health and in the service contract. For example, combined testing of four diseases — HIV, HBV, HCV and Syphilis — was mandatory to receive reimbursement, which led to a number of unreimbursed cases if the person did not undergo at testing for all four diseases. With amendments, it was changed and HIV testing remained as the primary component of the service linked to payment and testing of other diseases was tracked only for test kit utilisation records. The HIV database was another challenge named by service providers, which had bugs resulting in time consuming data entry and validation periods. As a result, payments were delayed, resulting in financial challenges for organisations. As mentioned before, currently the issue has been fully addressed.

Through interviews, the payment mechanism was also named as an issue. Organisations were used to a line-item budget reimbursement mechanism which is input-based and covers accrued expenses. Fee-for-service, which is output-based, makes it difficult to forecast cash flow and, due to the lack of experience of cash flow management, the pilot brought a loss for GHRN. On the other hand, this mechanism incentivised providers to focus on the activity and they achieved maximum results. Even though the COVID-19 pandemic had effect on the number of PWID tested at the beginning, during the second half of the year the service was provided at full scale.

Currently, Georgia is undergoing primary healthcare reform and a Performance-Based Financing (PBF) payment mechanism is being considered for introduction, including for the funding of harm reduction services. The introduction of PBF was initiated with the support of the Global Fund through an international consultancy and involvement of key stakeholders who helped the country to develop a set of performance indicators, recommendations for qualitative indicators and relevant implementation timelines. The new mechanism will allow for shifting from input-based financing and link output to funding, aiming to improve results and performance both in quantity and quality. Under the model, to get the best results, a solid verification system is needed both for quantity and quality. The development of a budgeting and monitoring framework is in process. The latter will incentivize performance and the achievement of programmatic results.

13 National Guidelines on HIV/AIDS Epidemiological Surveillance in Georgia: HIV/AIDS Epidemiological Surveillance Recommendations, HIV/AIDS Consultation and testing Protocol; Decree #01-461/O, MoH, 18/09/2020 — https://ncdc.ge/api/api/File/GetFile/1dc4e704-ec47-46cd-a904-0e16078c2f92

The need for a robust monitoring tool has significant importance, especially when personal identification information is not required for providing a service. The current payment method, fee-for-service gives incentive to the service providers reaching predefined targets and receiving available funding. On the other hand purchaser needs strong quality data validation tools in order to verify programmatic data and link to the payment. One of the directions to work is the community monitoring system and use of innovative digital technologies.

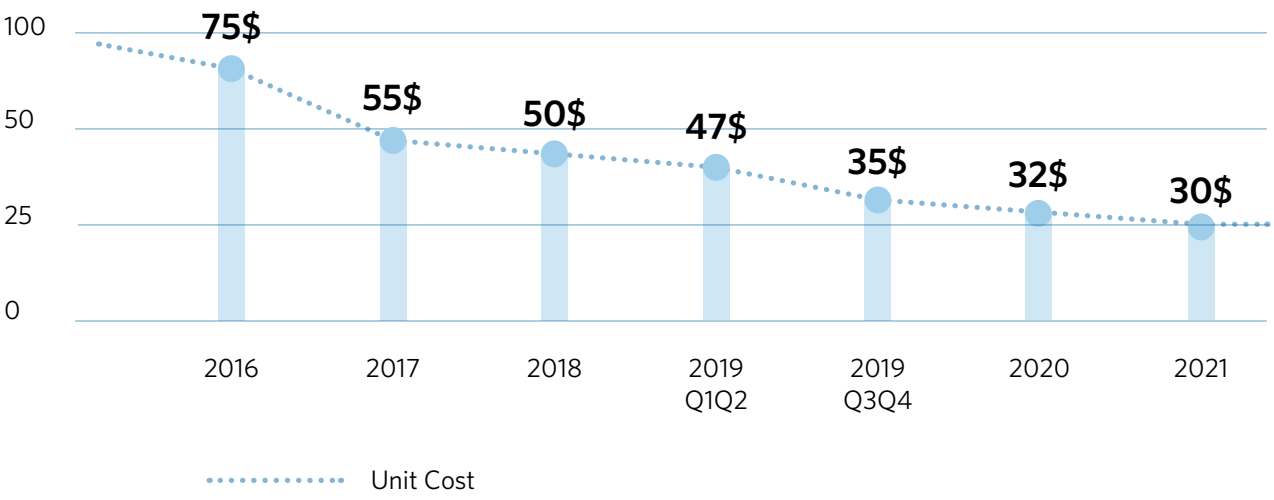
NCDC representative

Introducing the PBF model into the funding of HIV harm reduction services might be a bridge to align to the overall national policies and enable smooth transition. Next year, NCDC plans to expand PBF from VCT to the basic package under State funding and the remaining add-on service under Global Fund support to pilot this model.

Unit Cost: As part of the transition process, to enable smooth and sustainable transition it was important to align donor practices to State funding approaches. During the Global Fund grant negotiations for the 2019-2021 funding cycle, the PR changed the approach to costing of HIV prevention services. Instead of a line-item budget, unit costs per client were calculated and the budget was defined based on coverage targets reflected in the National Strategic Plan. On the one hand, this gave room for the optimisation of resources and, on the other hand, the funding of the service and cost structure was changed considerably. Assumptions were used to define the State co-financing share in preventive services for key populations.

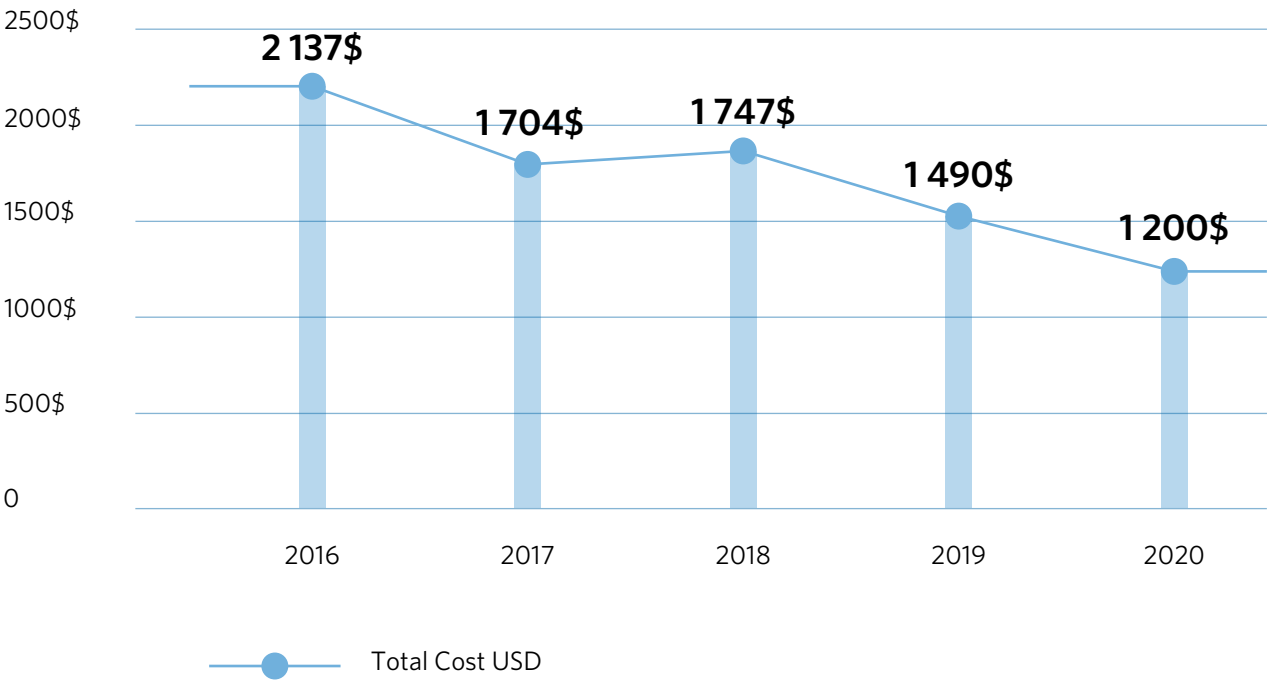
The Figure 4, below, shows the changes in unit costs since 2016 and budget estimates based on the methodology reflected above. Year 2019 is shown in two parts to reflect the cut-off point from line-item budgeting to unit cost budgeting. Other factors affect the decrease of unit costs in addition to the decreased estimated budgets, for example, increased targets.

Figure 4. Unit cost of needle and syringe programme 2016-2021 (USD)



The change in volume is shown in Figure 5, below

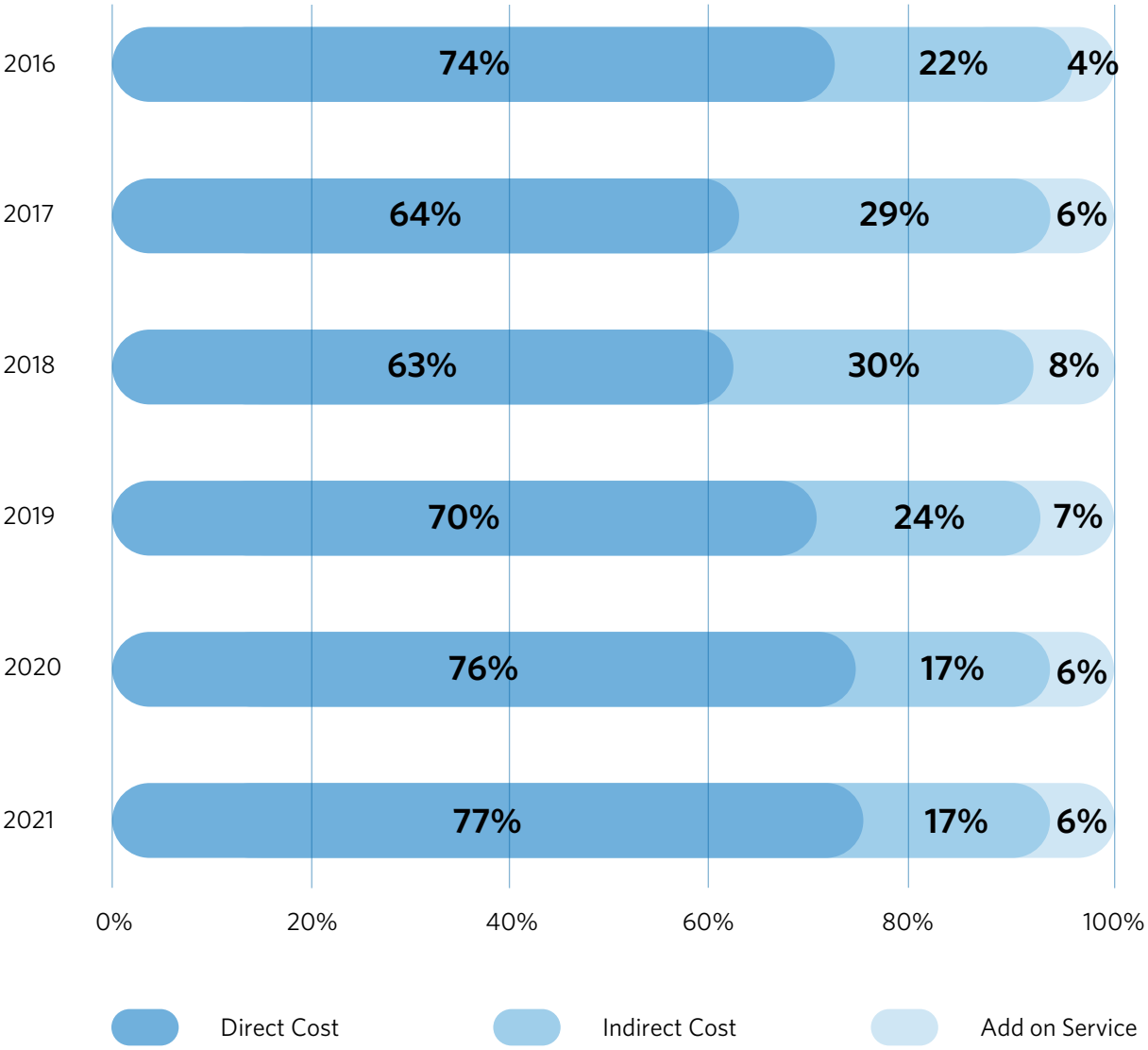
Figure 5. Budget estimates based on unit cost of the needle and syringe programme 2016-2021



The change of the costing method had a big influence on harm reduction budgeting and financing. The decrease in total volume compared to 2016 comprises 23% in local currency and up to 44% in USD. The latter difference in percentage change is related to GEL/USD foreign exchange fluctuations. The estimations led to changes in the cost structure, as shown in Figure 6, below. The value of indirect costs was affected the most. The latter includes

overhead at service delivery level (such as administrative personnel, office rent, utilities and communication, etc.) and the cost of programme administration at the GHRN level; the composition of direct costs, such as personnel involved in providing services, has increased and the proportion of add-on services has slightly decreased.

Figure 6. Cost structure of the needle and syringe programme 2016-2021 (%)



Key Findings

Implementation of the pilot programme has led to significant challenges for the entire network of service providers, including changes in the payment mechanism and the HIV prevention database used as the reporting system.

Change of the financing modality was the greatest challenge. Shifting to the fee-for-service financing modality, where reimbursement was linked to target achievements, was very painful. Organisations were used to the global budget principle, where actual costs were reimbursed in line with the approved budget and payment was not related to performance. Initial impressions are that State funding will significantly reduce income, but through long discussions and analysis anticipations have changed.

Preparation for transition started before the first pilot programme was implemented, but after launching the programme unexpected issues were identified, which challenged programme implementation. For example, indicators linked to mandatory testing of 4 infections; reporting through the HIV prevention database, which had bugs that led to a long data entering and validation period, affecting reimbursement.

It is important to note that successful cooperation with State programme representatives and through joint efforts, the issues were solved.

Representatives of Harm Reduction service centres

The interviews showed the need for capacity building in financial management for programme management staff. In this regard, it is important to engage stakeholders in the process of developing a new funding mechanism — PBF — that will define quality indicators and the payment mechanism with strong monitoring tools. The PBF model should motivate and incentivise service providers to provide higher quality service and increase service utilisation.

The recalculation of unit costs and reduced funding for the needle-syringe service has greatly affected the administrative costs of the programme. Interviews showed that budget reduction had an effect on salaries, monitoring and administrative costs. To cover other costs, add-on services were reduced by the implementer, while pointing out that these services are attractive for new users and impacts on the client retention rate.

During interviews, **the following issues were underlined by clients:**

1. The reduction in add-on services to a basic package included case management, medical consultations and medical supplies, such as ointment for injection site wound treatment, and others.

The staff of the service centre are like family to me; they do their best to support us, but lately the social support package, like case management and providing minor medical supplies, has reduced due to financing issues.

Programme beneficiary

This issue was addressed by the PR and a minimum percentage for add-on services were added to avoid redistributing funds allocated for these services to administrative costs.

2. Some shortages in consumables, such as 1, 10 and 20ml syringes, vein sets; the PR commented that this was a result of the effect of the COVID-19 pandemic on the supply chain and emphasised that, currently, all issues are resolved and beneficiaries now have access to all types of consumables.
3. The need for diversification of the basic preventive package, such as by adding spoons, citric acid and filters. The PR mentioned that these supplies are not available at the local market and also through the pooled procurement mechanism of the Global Fund; this may be the basis for further discussion.
4. The importance of peer-driven interventions and the need to reach new groups, especially young PWID and non-injecting drug users, as well as female PWID and to create safe and friendly environment in service centres for these groups as well.

Great consideration should be given to new groups, such as young injectors, non-injecting drug users and female injectors. Harm reduction service centres should create appropriate and comforting environments for all age and gender groups.

Activists and peer educators have a great impact on successful programme implementation and in creating trust in the services, especially when drug consumption is criminalised. If we want the effective continuation of the programme under State funding, service delivery should be maintained and peer driven interventions should be expanded.

Programme beneficiaries

The PR confirmed that priorities set by the consultants for the new Global Fund grant application will focus on these areas.

The OST Programme

Service Package

The opioid substitution programme, with Global Fund support, has been implemented since 2005, starting with one site in Tbilisi and expanding in the following years up to 4 sites, including two regional sites. Two sites were opened in the penitentiary system in 2008 and 2011 — Tbilisi #8 and Kutaisi #2, respectively, providing only a detoxification programme for up to 6 months. The donor funded programme was catalyst to the Government which launched its own programme with State funding in 2008. In 2009, 11 sites were opened within the OST programme across the country: 6 in Tbilisi, Imereti region; 1 in Samegrelo, Svaneti region; 2 in Kakheti region; 1 in Guria; and is currently being scaled-up to over 20 sites across the country. The implementing entity is the Centre for Mental Health and Drug Prevention.

The OST programme service package covers the following activities: the methadone substitution programme; the buprenorphine/naloxone substitution programme; psycho-social support; and the detoxification programme in prison, with up to 6 months substitution therapy.

The service delivery model is defined by Ministerial Decree No. 01-41/n[14] on "Special Programme for Opioid Substitution Treatment" approved on 3 July 2014 and is implemented at the facility level under observation, with daily visits to receive treatment. There are limited exceptions from the rule due to health conditions and travel. Due to the COVID-19 pandemic, an amendment was issued to Ministerial Decree No. 01-41/n allowing a 5 day take-away dosage during the pandemic; but from June 2021, this option was removed from the Decree.

The OST programme uses an electronic, web-based, real-time data collection system where data is entered on a daily basis and captures the basic characteristics of the patient and treatment history. The database is used to evaluate programme effectiveness and the programme implementer has devoted a group consisting of several people to work on this matter.

Regarding the service package, the National Strategic Plan emphasises the need for mental health services for clients of the harm reduction programme and to further the promotion of the OST programme through strengthening psychosocial support for OST clients, accommodating specific needs of women, and introducing long-term OST in penitentiary institutions[15].

To address programme needs, the following two interventions were supposed to be launched: the introduction of a mobile ambulatory service to reach areas that are not covered by OST sites and introducing long-term substitution programmes in prisons. Projects were supported by the Global Fund. It envisaged the procurement of mobile ambulatories with specific design and technical support to develop a model in prison. Implementation of the projects was rescheduled due to the COVID-19 epidemic and inter-sectoral negotiations should continue further.

14 "Special Program for Opioid Substitution Treatment " , Decree 01-41/n , 3 July 2014, MoH https://matsne.gov.ge/ka/document/view/2374811?publication=0

15 Georgia HIV/AIDS National Strategic Plan2019-2022; Approved by CCM Georgia on 20 July 2018. http://www.georgia-ccm.ge/?page_id=23&lang=en

Introducing a new service through mobile ambulatory was an excellent initiative. The inter-sectoral negotiation started positively, but at this stage the process is paused and State financing is not available.

OST service provider representative

Funding and Unit costs

Funding: Since 2005, the OST programme was supported by the Global Fund and in 2008 State funding was introduced. Currently, the service has fully transitioned to State funding. There is also a paid Suboxone programme implemented by private providers, but its share is small. The price of the private service is up to GEL30 (USD9) per day which is a barrier to enrollment for many beneficiaries.

Different procurement modalities have been used for State funding and Global Fund support.

From 2014, when the NCDC became the PR, the service provider was identified through a competitive State procurement tender. A service contract was signed between the NCDC and the Centre for Mental Health and Drug Prevention that defined the service specifications, payment mechanism, and programmatic and financial reporting. The Centre united 8 sites providing the substitution programme, 2 of them in prisons. In addition, psycho-social support was provided to beneficiaries through 3 organisations. The line-item budget approach was used. Monthly reporting

The Centre united 8 sites providing the substitution programme, 2 of them in prisons. In addition, psycho-social support was provided to beneficiaries through 3 organisations.

was carried out and reimbursement proceeded after the inspection of programmatic and financial data.

The State methadone substitution treatment programme is approved annually and programme funding is implemented by the National Health Agency under the MoH. The programme defines the service package, budget and payment mechanism and selection criteria for service providers.

The funding modality of OST services under the State has changed several times. Until 2017, the programme was based on the co-payment principle from the client side. Clients living with HIV and socially vulnerable individuals were exempt from co-payment. The global budget principle was used to finance the programme from the beginning and in 2012 a voucher principle was introduced. The monthly value of the voucher was GEL290 (USD175) and co-payment from the client was GEL150 (USD91). In the following year, the value of voucher was revised and comprised GEL215 (USD55) and the co-payment was GEL110 (USD64). Funding based on a voucher was changed in 2014 when funding was based on a global budget with a monthly ceiling up to 1/12 of the total budget. Since then, the latter modality has been maintained. To control the number of enrolled clients, a quota was introduced which was removed from 2017, in addition to removing co-payment from clients.

From the start of the State programme, the fixed global budget model was used for reimbursement. This allowed service providers to have financial stability and to invest in expansion. At the later stage, in order to increase coverage and allow more competition, the State programme was opened to new providers and the payment model was changed from fixed budget to per a client tariff — a fixed amount to be paid for one month of service, called a 'voucher'. This approach resulted in an increase in the number of providers and beneficiaries; however, retention of co-payment requirements from clients continued to be a barrier to client enrollment. This model has also created risks for the State budget — payment by clients was dependent on the number of clients and, as their number grew, expenditures also grew, and the budget became unstable. Hence, the global budget approach was re-introduced and over the last several years the exclusive provider of the service is the State organisation, Centre for Mental Health and Drug Prevention Ltd.

Overall, the global budget approach in the last few years has delivered positive results — coverage grew and the budget was kept within annual limits. But on the other hand, each year the OST budget allocation of the service also grew.

The OST service was the first harm reduction service to be fully transferred to State funding from July 2017. Long preparatory work preceded this decision. A working group from different stakeholders was created at the MoH to lead the process. One of the challenges identified was that the service under the Global Fund programme was free of charge, but the State-funded programmes were based on the co-financing principle. The decision was made to increase the budget of the programme and remove payment requirements.

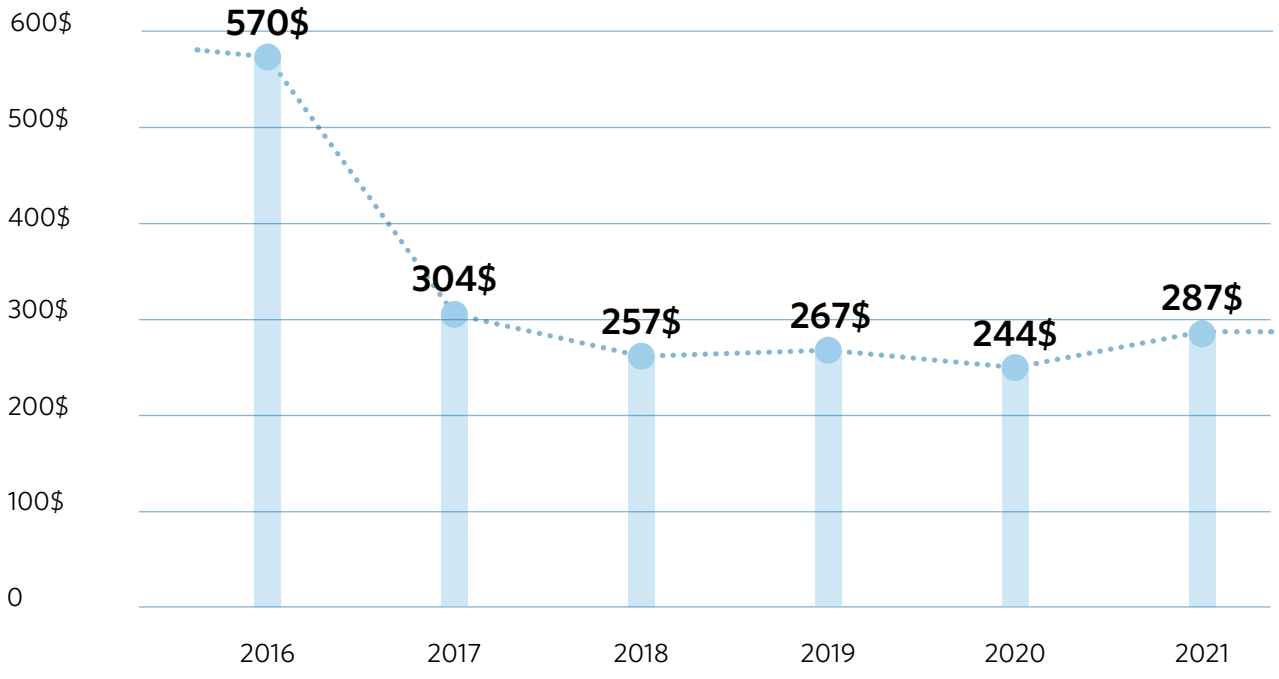
Removing financial barriers and monthly quotas for enrolled clients, in addition to expanding geographic access, increased the number of clients significantly. However, it was mentioned that geographic accessibility is still an issue as is availability of the Suboxone programme (the programme has higher costs compared to the methadone programme) which is limited, with only about 3% out of the total number of OST clients on treatment enrolled in the Suboxone programme. The gap is partially filled by the private sector where treatment is fully covered by the client

> The number of sites is not sufficient. Removal of the co-financing burden on clients resulted in a significant increase in programme clients and there is a need to increase the number of sites, especially in regions where the service is not available. For example, the Kakheti region where only one site is available and clients have to travel every day between one and one-and-a-half hours each way. The current budget is fully used for programme activities, but our plan is to address those issues in the future and expand geographically, as well as increase capacity in existing sites by adding new windows to serve an increased number of clients.
>
> **Respondent from an OST service provider**

Unit Cost: The volume of funding in the local currency is increasing annually, although the trend in unit cost is decreasing, which is mainly led by the increased number of clients and the benefits of economies of scale. The decrease in unit cost in local currency in 2020 comprised more than 50% compared to 2016 and up to 50% in US Dollars; the latter difference in percentage change is related to the GEL/USD foreign currency fluctuations.

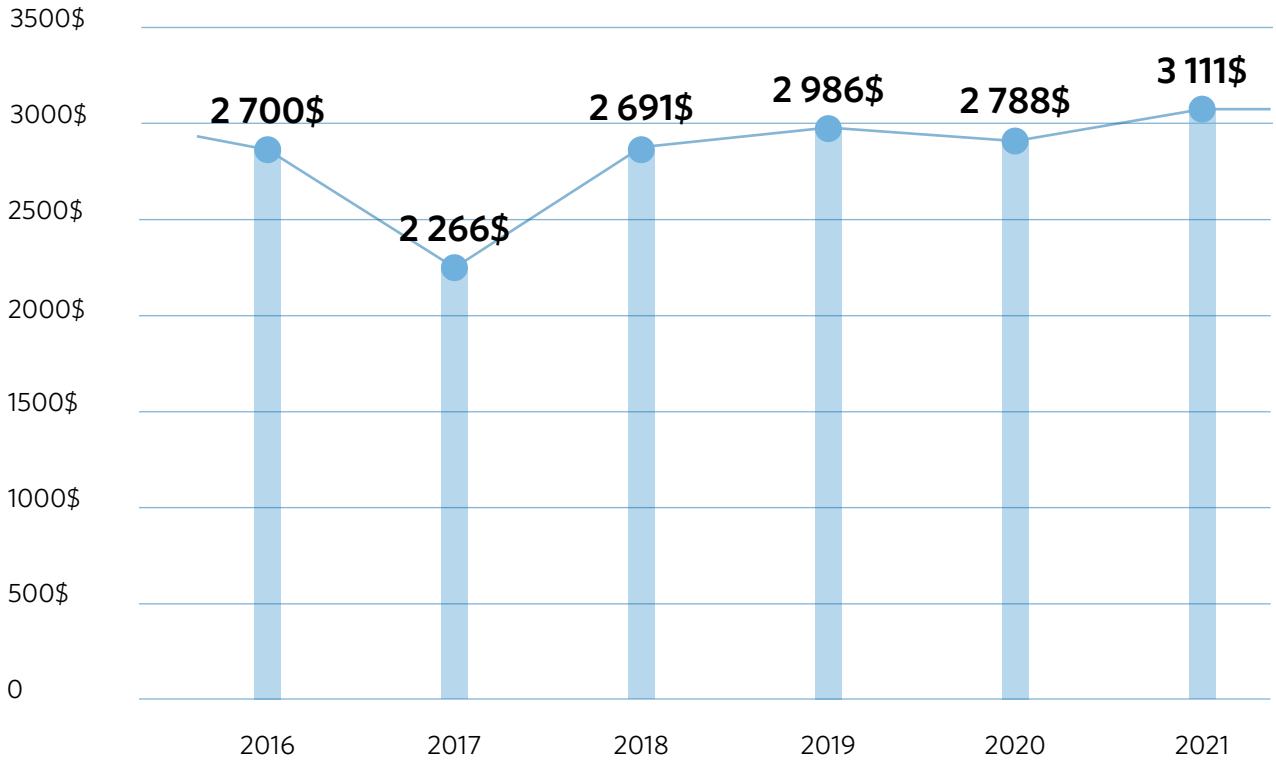
Starting from 2017, the number of beneficiaries increased significantly and State funding follows this trend, but not at the same rate. The global budget approach was made available to optimise expenses and to align the budget of the service provider with available funds. Funding was not named by the service provider as an issue. Despite the annual increase of funding, there is a weakness in the quality of services. Service delivery is unchanged, geographic coverage creates accessibility issues, the number of sites does not accommodate the increased number of beneficiaries and the availability of psycho-social services is limited.

Figure 7. Estimated unit cost per client in the OST programme 2016-2021 (USD)



Total annual expenditure is shown in Figure 8, below.

Figure 8. Total OST programme expenditure 2016-2021 (in thousands of USD)



Key Findings

Coverage of the OST programme has increased significantly during the last few years, but geographic coverage, the number of sites and the quality of service delivery still remain challenges. Interviews with clients confirms this gap. Daily visits and long-distance transportation to sites hinders successful outcomes and results in drop-out from the programme. Sites are operating 9am - 4pm and for reduced hours at weekends. Despite client appointments being distributed throughout the working hours, morning time is always crowded and waiting times grow. All respondents highlighted the importance of the change regarding take-away doses, introduced for a short time period due to COVID-19 restrictions and which have now been cancelled. Service providers confirmed the need for increasing geographic coverage, especially in the Kakheti and Kvemo Kartli regions.

> In the past, I didn't have much interaction with other clients while arriving at the site, but now the site is overcrowded and the waiting time has increased, it is a big concern, especially during the COVID-19 epidemic. The big relief was 5 days take-away doses which is now cancelled.
>
> Long-distance and waiting times is a big constraint; sometimes you need 2 hours to get the medicine and it is an issue when you are working.
>
> **OST programme clients**

In addition, it was mentioned that demand for the Buprenorphine/naloxone programme is high, but due to the relatively high cost compared to methadone, funding constraints do not give the opportunity to increase the number of clients, with many on the waiting list for the programme.

Clients mentioned that the programme is still stigmatised and clients face barriers in their social integration and work environment. For example, clients face obstacles in acquiring a driving license or to work in State organisations. Some improvements in drug policy were underlined, but still the policy is punitive and is a barrier to the effective implementation of harm reduction services. Adaptation and professional skill building programmes for improved job opportunities are also important.

Adaptation and professional skill building programmes for improved job opportunities are also important.

Psycho-social support has an important role in increasing the effectiveness of the programme. The Centre for Mental Health and Drug Prevention provides this service at its sites but with limited volume and, in some cases, OST clients do not have information about the availability of the service. Due to the COVID-19 pandemic, individual online consultations were introduced.

Psycho-social support has an important role in increasing the effectiveness of the programme.

Recommendations

Based on the findings from the analysis of unit costs and service packages in the context of transition, several areas for improvement can be highlighted. This will facilitate the improvement and effectiveness of the programme in achieving its targets while ensuring the service is quality oriented to the individual need of clients.

1. Allocate sufficient funds for the HIV Prevention Component of the State HIV Programme budget directed to key populations to ensure sustainable and smooth transition; furthermore, the GoG has clearly shown a commitment to increase funding for HIV prevention services for key populations but the composition of the NSP service package should be further discussed. To ensure service continuity and quality in the long-term, the service package funded by the State should expand and cover not only the VCT component and the basic package, but add-on services that attract and retain clients.

2. Use more effectively the already existing cooperation between the State and NGOs to further increase the funding of harm reduction services through the NGO platform. Despite the existence of State procurement procedures that allows for the contracting of NGOs/CSOs, a more specific legal environment should be developed for contracting NGOs/CSOs in the health sector. The procurement rules and procedures should be detailed and bid evaluation should be based on the proposed programme, quality indicators and service pricing. Procedures for monitoring volume and quality of the services delivered should be defined. This will lead to better programme implementation, budgeting and evaluation of the effectiveness of interventions.

3. By the end of 2021, the development of innovative funding mechanisms — the Performance-Based Financing (PBF) model — should be completed with the engagement of national stakeholders in order to adequately reflect the new model in the State health programmes for 2022. The model should define a new payment mechanism, quality indicators and a strong monitoring framework that will enhance efficiency and cost-effectiveness of the harm reduction programme through facilitating the uptake of services by PWID, increasing funding utilisation and motivating staff to provide higher quality care. The monitoring capacity at the implementer level should be adequately enhanced. A pilot may be introduced in several sites and scaled-up afterwards.

4. Capacity building in financial management of NGOs and CSOs is important for ensuring strong skills to manage diversified sources of funding and to adjust to new payment mechanisms.

5. The assumptions used in the budget calculation should be reviewed periodically (every 3-5 years) to reflect changes in the macro environment and service provision.

6. Ensure that the NSP service package better reflects the needs of existing clients and is attractive to new clients through the scaling-up of existing services and by introducing new activities in line with the changing drug scene that will allow new groups of drug users, especially younger sub-populations, to be reached.

7. Improving accessibility to harm reduction products to diversify the service packages should be considered.

8. Increase accessibility of OST by expanding geographic coverage through the opening of new service sites and increasing the capacity at existing facilities. Introduce differentiated OST service delivery to improve programme effectiveness, such as mobile OST units.

9. To increase adherence and effectiveness of the OST programme, more client-oriented services should be offered. The criteria for an individually adjusted treatment plan, including takeaway doses and psycho-social support, should be developed and offered to clients.

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Annex 2. List of respondents

Name	Affiliation
Irma Khonelidze	Deputy Director at the NCDC/Director of the Global Fund Programme in Georgia.
Ketevan Stvilia	Programme Manager of the Global Fund HIV Programme.
Alexander Asatiani	M&E Officer of the Global Fund HIV Programme.
Vladimer Getia	Head of the State Health Programme Department NCDC.
Khatuna Todadze	Head of the OST programme, The National Institute of Mental Health and Drug Prevention.
Marine Gogia	NGO, Georgian Harm Reduction Network.
Koka Labartkava	NGO, New Vector, a harm reduction service provider.
Otar Jijeishvili	NGO, Pheonix, a harm reduction service provider.
Nino Janashia	NGO, Qsenoni, a harm reduction service provider.
Miranda Jghenti	NGO, Imedi, a harm reduction service provider.

Annex 2. List of respondents

Name	Affiliation
Temo Khatiashvili	Community member.
Edisher Khalvashi	Community member.
Elguja Vashakmadze	Community member.
Gela Sichinava	Community member.
Kakhaber Baghishvili	Community member.
Levan Murckhvaladze	Community member.
Temuri	Community member.
Mamuka	Community member.