



Sustaining effective coverage with Opioid Substitution Therapy (OST) in Georgia in the context of transition from external assistance

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ABBREVIATIONS

CBO - Community Based Organization

CCM - Country Coordinating Mechanism

CIF - Curatio International Foundation

CSO - Civil Society Organization

DCFTA - Deep and Comprehensive Free Trade Agreement

EMCDDA - European Monitoring Centre for Drugs and Drug Addiction

ESPAD - European School Survey Project on Alcohol and Other Drugs

EU - European Union

EUAA - European Union Association Agreement

GNDP - Georgian National Drug Policy Platform

GoG - Government of Georgia

GPIC - Global Projects Implementation Center

GPS - General Population Survey

HIV - Human Immunodeficiency Virus

HMIS - Health Management Information Systems

ICC - Inter-Agency Coordination Council

IDACIRC - Infectious Disease, AIDS and Clinical Immunology Research Center

IDI - In-Depth Interview

INL - U.S. State Department's Bureau of International Narcotics and Law Enforcement Affairs

KP - Key Populations

M&E - Monitoring and Evaluation

MHPA - Center for Mental Health and Prevention of Addiction

MoH - Ministry of Health

MoJ - Ministry of Justice

NCDC - National Center for Disease Control and Public Health

NDO - National Drug Observatory

NFM - New Funding Model

NGO - Non-Governmental Organization

NHA - National Health Agency

NSP - National Strategic Plan

OST - Opioid Substitution Therapy

PAAC - Policy and Advocacy Advisory Council

PIU - The Global Fund Programme Implementation Unit

PLWH - People Living With HIV

PR - Principal Recipient

PTF - HIV and STIs Prevention Task Force

PUD - People who Use Drugs

LMIC- Low and Middle-Income Country

GFATM - The Global Fund to Fight AIDS, TB and Malaria

PWID - People Who Inject Drugs

TDI - Treatment Demand Indicator

TSP - Transition and Sustainability Plan

UNICEF - United Nations Children's Fund

UNODC - United Nations Office on Drugs and Crime

USAID - The United State Agency for International Development

INTRODUCTION

Opioid substitution therapy/treatment (OST) is one of the most effective approaches to significantly reduce illegal drug use and the HIV-related high-risk behaviours, overdose-related deaths, criminal activities, financial burden, and other kinds of stresses faced by people who use drugs (PUD) and their families. At the same time, it is also highly controversial politically and, in some countries, on a societal level. OST is commonly introduced and implemented in low- and middle-income countries (LMIC) by external donors. However, the need for adequate domestic support once external funding ends poses constant risks and challenges to its financial sustainability.

The purpose of this case study is to understand the transition of the Opioid Substitution Therapy (OST) from The Global Fund to Fight AIDS, TB and Malaria (GFATM) assistance, how OST coverage was sustained post-transition including health system adaptations and changes and identify interaction of the policy context and content factors, actors and processes that influenced the transition.

In this section we first present the overall country context that created ground for the transition process, followed by Health Sector and OST related context description.

Country Context

Since regaining its independence in 1991, European aspirations have been a central part of Georgia's political agenda and identity (Mitchell, L. 2020). Georgia clearly looked Westward and became a member of the Council of Europe in 1999. Furthermore, Georgia's Euro-Atlantic aspirations determined by threats emerging from Russia, became most important political priority for the nation and shaped foreign policy agenda for the years to come. This westward drive featured more prominently after the Rose Revolution of 2003 and led to closer engagement with Western partners on numerous fronts. Eventually Georgia signed an Association Agreement with the EU in 2014 (Lejava N, 2021). A transparent and external accountability mechanism, set in motion by the EU, allowed the Georgian public to actively engage and monitor the government's compliance with the agreement promises.

The EU association agreement, and not only, set in motion many structural, policy, legal and institutional changes which occurred in the country thereafter. Just to note a few.

With support from the EU and other donors, the public finance management (PFM) system has gradually evolved. Since 2007 the medium-term budgeting framework was first introduced, followed by new budget code approved by the Parliament in 2009, which established basic rules and responsibilities for budget planning, execution and

monitoring and evaluation. PFM was further enhanced with several electronic management systems such as a fully integrated e-Budget, e-Treasury, e-Customs, etc. As a result of these reforms, in the open budget survey ranking, Georgia moved from 34th place in 2010 to 5th in 2019 with a high budget transparency score of 81 (out of 100) albeit scoring low on public participation 28 (out of 100), especially in budget formulation and execution parts.¹ Such developments proved conducive for financial transition of the programs.

Along with economic developments, Georgia demonstrated significant progress in all six dimensions of the Worldwide Governance Indicators, especially in fighting corruption. Albeit the pace of the country's development has slowed down since 2014 as Georgia has been unable to keep up with the high standards shown in 2014.² Nonetheless, the 2021 Worldwide Governance Indicators still ranked Georgia among the top 20 European countries regarding the rule of law, control of corruption, government effectiveness and regulatory quality.

Finally, Georgia capacitated its state entities and organizations within and outside the health sector over the course of these years. Increased budget revenues on the back of improved economic performance allowed the government to prioritize human capital development in the national policy priority agenda and invest more in health, education, and improved social protection. Thus, the political commitments for these investments were also important for the transition process.

Health Sector Context

After the economic shock caused by independence from the Soviet Union Georgia saw a slow recovery. The Government's comprehensive reforms after the Rose revolution in 2003 focusing on the liberalization strategy and sustainable economic growth through private sector development rendered double-digit GDP growth during 2004-2007, expanding the economy by 35%.³ However, the 2008 war with Russia, the global financial crisis and external regional shocks negatively affected Georgia's economic performance and annual GDP growth averaged around 5% during the past decade.

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¹ Open Budget Index https://www.internationalbudget.org/open-budget-survey/country-results/2019/georgia Accessed April 28, 2022

² IDFI 2021: World Governance Indicators - Georgia in the World Bank Ranking 2021 https://idfi.ge/en/world_governance_indicators%E2%80%93georgia_in_the_world_bank_ranking_2021 Accessed April 28, 2022

³ National Statistics Office of Georgia https://www.geostat.ge Last Accessed January 6, 2022

Georgia's healthcare system underwent significant reforms aiming to expand access to healthcare services for the entire population. In 2013 the Universal Healthcare Program (UHCP) was launched, which significantly increased the number of people able to benefit from state-funded health services. The introduction of UHCP and the removal of financial access barriers led to increased service utilization for both outpatient and inpatient service and drew current health expenditure (CHE) from 1.1 billion US in 2010 to 1.5 billion in 2018,⁴ or 7.2% of GDP, which in per capita terms translates to an increase from 634 \$PPP in 2010 to 970 \$PPP in 2019.⁵

The Government spending levels grew faster than private, which gradually increased the share of government spending in CHE from 22.3% in 2010 to 39% in 2019. Out-of-pocket payments (OOP) places a significant financial burden on the population 47% (2019). Along with these developments, the share of voluntary pre-paid financial resources pulled by private insurance companies also grew, though the percentage in CHE has not exceeded 7% (2019).⁶

Along with these reforms Georgia strengthened purchasing arrangements and established single national purchaser – the National Health Agency (NHA) which pays for all services under UHCP, along with the National Center for Disease Control and Public Health (NCDC) which funds public health and infection control programs through uniform purchasing arrangements with public and private providers alike. All contracted providers (private or public) are reimbursed with case-based, fee-for-service or capitation payments, depending on the program and service type.

OST Context

The OST programme in Georgia was introduced in late 2005 with the support of the Global Fund. The programme was initiated as a pilot intervention, within the national HIV response, with the primary goal of contributing to HIV prevention among People Who Inject Drugs (PWIDs). However, since Georgia has one of the highest prevalence of people who inject drugs in the world (UNODC, 2021), demand for OST exceeded the pilot programme's limited capacity, highlighting the need for state budgetary funding rapidly. State financing of the OST programme was first allocated at the beginning of 2008, and over subsequent years, the programme developed its capacity and coverage in a stable

https://apps.who.int/nha/database/ViewData/Indicators/en Accessed August 2, 2022

https://apps.who.int/nha/database/ViewData/Indicators/en Accessed May 23, 2022

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⁴ WHO Global Health Expenditure database

⁵ WHO Global Health Expenditure database

⁶ Ibid

manner. The complete transition of OST programme funding to the state took place in July 2017.

Contrary to developments in other post-Soviet states, which often featured abusive drug policies and limited political commitment to drug abuse responses, Georgia proved to be a successful country in which OST services, which had initially been introduced and fully supported by the GFATM, were not only fully transitioned to the Government but even scaled-up.

Therefore, in light of this context, this study aimed to better understand how and why Georgia was able to sustain and increase adequate coverage with OST intervention and identify the critical enablers.

STUDY AIM & OBJECTIVES

The overall aim of the study was to better understand how and why Georgia was able to sustain and increase adequate coverage with Opioid Substation Therapy (OST) previously funded by the Global Fund and identify the critical enablers.

Specific objectives:

To achieve the overall study aim, the following key research questions (objectives) were set:

- 1. How did the cessation of external financing affect the coverage of OST services previously supported by donor funding?
- 2. What political and health system factors influenced whether coverage with OST was sustained, once donor funding was no longer available?

In answering these questions, it is critical to understand a) WHAT did (or did not) change in the OST programme as it transitioned out of external assistance; b) WHY this change (or no-change) happened; and c) WHETHER and HOW we can link these to changes (or the lack of them) to the observed coverage achieved after the donor transition.

Further, study meant to generate learning on a) key transition processes in Georgia in relation to the Global Fund transition, and b) what enables sustained coverage post-transition and how health systems can be configured to enable such a sustained coverage.

STUDY DESIGN

The study applied an analytical case study design and used a framework-based, mixmethod approach to answer the research questions above. Because the transition from donor support occurred over several years, we intended to study health policy change and health system adaptations over a ten-year period, 2010-2020, making our study longitudinal using retrospective analysis of past events and experiences. This approach helped to demonstrate how a range of different decisions and/or interventions, taken at other times and sometimes with unexpected consequences, accumulated over time and shaped the current state and performance of health systems for the selected intervention. Therefore, using the adapted Walt & Gilson policy triangle framework, we first interrogated WHAT has changed in program design during the pre and post-transition periods. We then moved on to exploring WHY and HOW these changes occurred.

METHODOLOGY

The framework application required a **mixed-method approach** using desk review, secondary quantitative data analysis, and in-depth interviews.

The desk review of documents helped the research team to understand WHAT has changed in the program design and implementation during the pre and post-transition periods. Based on a preliminary evaluation of the available documents, it was possible to produce a description of the changes.

Quantitative data covered the programmatic expenditure for OST, intervention coverage and/or service utilization data. Quantitative methods primarily using trend analysis over the 2010-2020 period helped to uncover changes in coverage, access to services, and the financial resources allocated to OST. Triangulated with the qualitative data, quantitative analysis allowed us to arrive at conclusive statements about the changes in intervention coverage during the pre and post-transition periods as well as establishing robust evidence when speaking about the donor dependence of the program as of 2020.

In-depth Interviews (IDI) were carried out with individuals who were most knowledgeable about transition issues and were able to share historical knowledge about the decisions made, programmatic changes and policy amendments introduced. Using a snowball approach, the research team identified a preliminary list of respondents. IDIs served three distinct purposes: (a) to validate findings arising from desk review, where necessary; (b) to interrogate WHY the changes were made to the programs and/or policies; and (c) HOW these changes occurred.

The study used Framework-Based Coding to simplify and standardize the analysis of the qualitative data. The conceptual framework used in the study protocol formed the bases

for the coding. Each QUOTE was characterized with five qualifiers, i.e., CODE that included the following:

- Health System Code reflecting the codes for Health Systems Functions, including Health Financing, Service Delivery, Health Workforce, Medical products, vaccines, and technologies, Information Systems, Governance and Leadership.
- II. **Policy Triangle Codes** reflecting the content of changes, the context in which the changes occurred, or the actors who played a role in the process used for the change.
- III. **Process Related Codes** were proposed to define the explanatory power of the Quote. Namely, was it about WHAT happened, WHY it happened or HOW it happened?
- IV. Outcome/Output Codes denoted the access/coverage arising from the changes that occurred in the program.
- V. **Barrier or enabler code** a qualifier reflecting whether the quote reveals any barriers or enablers inhibiting or facilitating the change in the program and transition.

FINDINGS

A total of 36 documents were reviewed, covering the period from 2003 to 2021. As a result, 226 quotes were identified, with the following distribution:

Health System Codes				
Health Financing		46 codes		
Health workforce		2 codes		
Medical prod	12 codes			
vaccines,				
technologies				
Information Systems 18 codes				
Governance	30 codes			

Policy Triangle Codes			
Actors	22 codes		
Content	161 codes		
Context	21 codes		
Comon	2, 000,00		
Process	20 codes		

Process Related Codes			
How	6 codes		
What	43 codes		
Why	4 codes		

Barrier of Enabler Codes			
Barrier	13 codes		
Enabler	36 codes		

Following the desk review, we still faced insufficient information about the following:

Regarding Health Systems Functions:

- Inputs (Human Resources, Medicines)
 - The development and capacities of human resources/medical personnel,
 considering scale-up of the intervention and number of sites/providers.
 - The procurement and supply chain management systems of medications, and their evolution over the years, pre- and post-transition.

Regarding Policy Triangle:

- Contextual and Process factors
 - Contributing factors leading to decisions regarding allocation and further increases to domestic funding
 - What were the primary triggers affecting the decisions to invest in the intervention, considering the non-conducive political and legal environment regarding drug use-related issues?
 - o How was timing decided, and why?

We therefore planned to retrieve this missing information through IDIs.

In addition to the gaps in information on health system functions and the policy triangle components, IDIs specifically explored the following issues:

- a) What have been the main contributing factors leading to government decision to allocate state funding for OST long before the transition and sustainability agenda and TGF co-financing requirements.
- b) Transition planning process, including key actors and decision-makers involved.
- c) Level of political commitment to transition, including motivational factors and key change agents mainstreaming the role of the state.
- d) What were the biggest stakeholder concerns and if and how those concerns materialized during transition.
- e) Evolution of the capacities of human resources and approaches to their development in transition period.
- f) Improvements in health information systems and data collection for OST, including utilization of information systems and informing decision making post-transition.

In total, 10 in-depth interviews were conducted before reaching saturation, covering the following key informants:

- OST service providers, including state and private clinics
- State authorities
- Current and former programme management representatives
- Civil society stakeholders

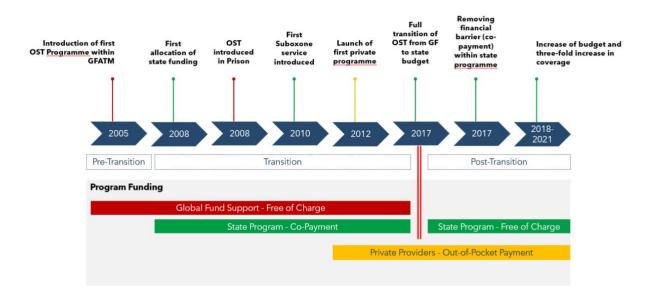
PUDs, community representatives and OST patients

Summary judgement on the success of the Transition

Opioid Substitution Therapy (OST) in Georgia was introduced in late 2005 with the support of the Global Fund to Fight AIDS, TB and Malaria (*Javakhishvili et al., 2006*) and gradually evolved. The transition process of the OST started in 2008 with the allocation of state funding (*Order of the Minister of Labour, Health and Social Affairs of Georgia №111/n May 6, 2008*), leading to a complete transition to state support in 2017.

The transition of OST in Georgia was driven by a gradual and consistent evolution over the years, including the continuous development of the major health system functions.

Figure 1 General Evolution of OST in Georgia 2005-2021



The transition process and the full handover of OST to state funding largely benefited from external accountability measures imposed by the GFATM and other development partners, influencing the government's decision to allocate the budget.

Table 1. Co-Financing Conditionalities and State Investments in OST

	Co-Financing Requirements					
	GFATM Conditionality	Total GFATM Allocation for HIV Programme	Georgia overall domestic co- financing commitments	Total Government Allocation for OST	% of OST out of total government allocation for HIV	
2014-2016	Minimum threshold government contribution to disease programs supported by the Global Fund - 40 %	33,886,454 USD	11.03 million USD	5,299,475 USD	48.04%	
2017-2019	The 2017-2019 allocation amount is dependent on meeting cofinancing requirements, and 25% of Georgia's allocation will be made available upon additional co-financing commitments.	8,412,986 USD	15.9 million USD	7,960,758 USD	50.07%	
2020-2022	Additional co- financing investments in disease programs - 15%	12,076,771 USD	22.6 million USD	9,205,595 USD	40.73%	

The country's accountability to international partners was supported by continuous technical assistance that contributed to the evolution of health systems, including service delivery, financing, information systems, and governance and coordination.

The OST pilot project introduced with the help of GFATM played a catalytic role in influencing the government to allocate and further increase investment in OST. Implementation of the pilot generated increased public health demand, supported by consolidated advocacy efforts by key stakeholders.

The participatory nature of transition planning, implementation, and monitoring, securing the meaningful engagement of key stakeholders, including civil society organizations and communities, established national-level accountability mechanisms, holding government accountable for fulfilling its obligations, in line with the ground-level needs of target beneficiaries.

In response to national and international accountability, the government of Georgia and affiliated structures demonstrated political commitment and leadership, reflected in the continuous programmatic and financial support of OST.

Despite specific challenges, the transition of OST from GFATM to state funding is consensually evaluated as a successful case, as demonstrated by the primary public health outcome of expanded and improved access to OST services and the increased coverage achieved post-transition.

The findings presented below explain how this outcome was achieved and are based on the triangulation of data from the document review and key informant interviews. The findings are analysed using the lens of the health policy triangle structured around the health systems' building blocks. For each building block, we unpack the context, content, process, actors, outcomes, and enabling factors.

Structure of the Findings

Presented findings are structured through five main health system functions: 1. Service Delivery 2. Financing 3. Health Management Information Systems (HMIS) 4. Inputs 5. Governance and Leadership.

Findings for each health system function are presented in respect to the conceptual framework of the study, unpacking the following: a) Policy triangle factors, including context, process and content of health system function pre and post transition, b) main actors engaged in the transition process, c) outcomes and outputs, denoting changes occurred for the health system functions, and d) barriers and enablers, that inhibited or facilitated the change in the function and its effect on transition and outcomes.

Service Delivery

Discussions and preparations for OST service introduction in Georgia started in 1999, within the framework of the harm reduction programme implemented by the Open Society Georgia Foundation's (OSGF) Public Health Programme (Gamkrelidze et al., 2003). Among others, the main component of this programme was preparatory work for the initiation of the first pilot Methadone programme, implemented in cooperation with the Georgian Research Institute on Addiction. Previously, treatment services for people

who use drugs had been limited and in urgent need of development. The country had poor traditions of addiction treatment and lacked adequate institutional capacity, including a limited number of service providers and the diversity of services offered. The main treatment option offered to the PUD was detoxification therapy followed by short-term outpatient rehabilitation measures (*Gamkrelidze et al., 2003*). Thus, preparatory works implemented by OSGF, and Georgian Research Institute on Addiction played an important role in initiating a public dialogue and convincing decision-makers of the necessity of introducing OST in Georgia.

The OST pilot project was introduced in 2005, with the support of the Global Fund (Javakhishvili et al., 2006). It started with the establishment of one OST service delivery site in Tbilisi with the capacity to serve up to 60 patients. In the following two years (2006–2007) the Global Fund-supported OST expanded to four service sites, including two in Tbilisi and two in the regions of Georgia (Javakhishvili et al., 2008). In addition, two sites were opened in the penitentiary system in 2008 in Tbilisi (penitentiary institution #8) and in 2011 in Kutaisi (penitentiary institution #2) (Javakhishvili et al., 2012). However, services in the penitentiary system were limited to detoxification for up to six months and have continued with the same approach to date. In the period 2005–2008, the program covered a total of 552 patients (Javakhishvili et al., 2008).

However, considering the high prevalence of opioid use in Georgia (UNODC, 2021), the demand for OST was much higher than the Global Fund programme was able to meet. Patients in need of OST and their families proactively approached service providers and health authorities to ensure their access to OST. As a result, service providers started operating a waiting list of patients. By the end of 2008, there were approximately 330 patients on the waiting list (Javakhishvili et al., 2008).

Advocacy carried out by the patient community and supported by various civil society organizations, the medical community, research institutions and international partners influenced decision-makers and helped expand access to OST.

"Very powerful, multi-component advocacy was very important in influencing the government. It was collective effort by community, service providers and their administrations, human rights groups, international organizations; everyone was pushing for the same goal and it paid off" (IDI Respondent)

This advocacy was implemented on different levels and owes its success to the participatory nature of decision-making platforms (as described in the Governance and Leadership section). The participation of community and civil society stakeholders in these platforms ensured that their voices were heard and provided them with practical instruments to influence and hold the government accountable through oversight and

monitoring of the implementation of commitments. In response to the increased public demand, the Government of Georgia (GoG) expressed its political commitment and launched state-funded OST in 2008 (Order of the Minister of Labour, Health and Social Affairs of Georgia №111/n May 6, 2008).

The political commitment of the government led to the introduction of state investment for OST and its further development, with increased budgetary allocations, an expanded service network and greater coverage.

Analyses of the information retrieved from the IDIs indicate that the GFATM-supported OST played a catalytic role for the government and influenced its decision to support OST. Specifically, the state-supported programme benefited from the experience generated within GFATM-funded OST to a significant extent, including through the terms of establishing the service providers, service delivery, and monitoring systems.

After its introduction, the state-funded OST programme rapidly expanded, and by 2009, 11 sites were operating (Javakhishvili et al., 2009), while by 2021 there were 22 sites (Georgia HIV/AIDS National Strategic Plan 2023-2025), with nearly all major cities of the country covered.

Despite the introduction and rapid geographical expansion of the state-supported OST, which led to improved access, significant barriers persisted for service users, due to the co-payment requirement, which demanded out-of-pocket payments from patients on a monthly basis. However, the financial barriers to access were gradually reduced and after a full transition to state funding, co-payments were fully eliminated since mid-2017.

On this note, the study revealed the importance of continuous advocacy, as its continuous nature was vital in holding the government accountable, stimulating the development, introduction, and expansion of the OST programme and eventually the reduction of financial barriers. After the introduction of the state support for OST, the advocacy carried by the patient community and other stakeholders did not end, but rather refocused on monitoring and oversight of the quality, level of access and affordability of the services.

The successful transition of OST to state funding profited from the creation of a state programme at an early stage of OST development in the country. On the one hand, this secured sufficient time to develop and institutionalize the respective systems necessary for service delivery. On the other hand, it ensured that, by the time of full transition in 2017, the share of the Global Fund programme was already so small that it was not a big burden for the state budget to completely take over the funding.

By 2017, a total of 4800 patients were included in OST (Beselia et al., 2018), while after the full transition to state funding, access to the service increased, and with the complete

removal of co-payment requirements, which eliminated the financial access barrier, access to care and geographical coverage improved. At the end of 2021, 12,500 patients were engaged in OST (*Georgia HIV/AIDS National Strategic Plan 2023-2025*), which constituted a three-fold increase in the number of programme beneficiaries over a four-year period.

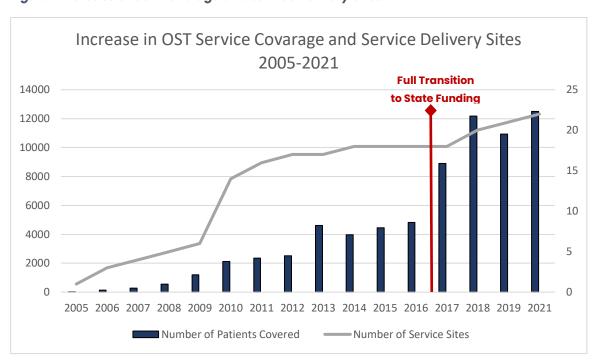


Figure 2 Increase of OST Coverage and Service Delivery Sites 2005-2021

The Global Fund also played a crucial role in influencing the government's financial support to OST. Since the OST services within the Global Fund programme were provided free of charge, the GFATM asked the government to use the same approach post-transition. The National Centre for Disease Control and Public Health (NCDC), a Principal Recipient (PR) of the Global Fund grant, led the advocacy process of advocacy to convince the government to maintain the service free of charge for those patients who were part of the GFATM programme. This process influenced the government to remove the co-payment requirement for beneficiaries in the state-supported programme. The position of the Ministry of Health (MoH) was also vital, demanding equal treatment of all patients on ethical grounds, which also played an important role in the removal of the co-payment and the provision of OST free of charge to everyone.

"... The Global Fund pushed to maintain the service free of charge for its patients (after transition) ... The portfolio manager led the communication with the Ministry of Health, even meeting with the minister. This communication was successful, and the ministry recognized that the service could not be free for some patients and paid for by others, so they decided to fully remove co-funding" (IDI Respondent)

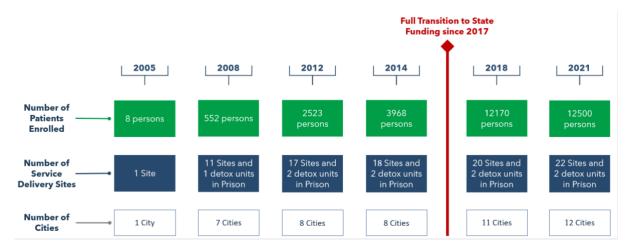
The next important aspect for service provision was its standardization during the transition, which ensured standard clinical management for all program beneficiaries. Specifically, the package/composition of OST services and approaches to their delivery were clearly defined and used to calculate the costs of service provision. This helped the government to plan for the required budget and finance service delivery out of public resources. Clinical protocols of methadone-based opioid substation therapy (Order of Minister of Labour, Health and Social Affairs of Georgia Note 1137/0) and suboxone-based substitution therapy (Order of Minister of Labour, Health and Social Affairs of Georgia Note 1139/0) were approved by decrees of the minister of health in 2016 and served as the legal basis for service costing-pricing. Consequently, state-funded OST includes methadone substitution; buprenorphine/naloxone substitution; psychosocial support; and detoxification in prison, with up to six months of OST.

Since the beginning, the Centre for Mental Health and Prevention of Addiction (MHPA) has been defined as an umbrella implementing partner by the government. The MHPA has been the only provider of OST within the state programme, while the GFATM programme engaged private clinics. However, after the full transition to state funding, the provider network was centralized and fully subordinated to the MHPA.

The service delivery model is defined by a Ministerial Order approved on 3 July 2014 (Order of Minister of Labour, Health and Social Affairs of Georgia N_2 01–41/n) and is implemented at the facility level under medical observation, with daily visits to receive treatment. There are limited exceptions to the rule due to the health and travel conditions of the beneficiary. Up to five days of take-home OST were introduced during the COVID-19 pandemic, although currently there are significant discussions over whether to continue this approach.

The evolution of OST service delivery, coverage and geographical expansion led to improved geographical access to these services in the regions. However, stakeholders continue to have major concerns regarding geographical access: because OST sites are primarily concentrated in the regional centres/cities, the needs of rural patients who have to travel daily to receive treatment are not fully considered.

Figure 3 Evolution of Service Delivery Sites and Coverage during 2005-2021



The overall dynamic of evolution of OST service delivery during transition and the post-transition period shows the positive outcomes of expanded and improved access to OST service, including financial accessibility and increased coverage. Our analysis reveals that several factors contributed to this achievement, including: (a) public demand on the back of increased needs and interest among patients, which generated political commitment and assured the readiness of the government to support the programme (it should be noted that public demand had been increasing throughout the transition period aimed at removing geographical and financial barriers for improved access); (b) the early start of state funding; and (c) the gradual evolution of OST, which ensured the development and gradual expansion of the service provider infrastructure and eased the full transition process later on.

Financing

As mentioned above, the Georgia government started investing in OST long before the GFATM transition, while the sustainability agenda was in place under the New Funding Model (NFM). Nevertheless, other factors also contributed to the stable funding of OST during the transition and post-transition periods, as described below.

First, the Global Fund imposed requirements and conditionalities for counterpart (county) financing in 2015 (Allocation Letter, 2014) as part of the New Funding Model (NFM) and Eligibility and Counterpart Financing Policy (ECFP), which allowed GFATM to focus on the countries with the highest disease burden and least ability to pay. In order to ensure the sustainability of GFATM supported interventions, the Fund requested the country to focus most of the investments on key and vulnerable populations, including PUD. In response to these requirements, several things occurred. Based on the allocation letter for the period of 2014–2016, total allocation for HIV program was 33,886,454 million USD, with 40% as a minimum threshold of the government contribution. Ever since, the

Global Fund financing is gradually decreasing, while state budgetary allocations increasing. Based on the 2019 allocation letter for the allocation period of 2022-2025, the total TGF allocation for HIV programme is 12,076,771 million USD, while government commitment for 2022 equals to 22.6 million USD.

The process of transition planning commenced, ensuring meaningful engagement of all stakeholders. The NCDC, as a principal recipient of the Global Fund, led the process, while technical assistance was secured for the elaboration of the strategic documents. The process consisted of consultations with affected communities and civil society stakeholders, while the Country Coordinating Mechanism (CCM) platform was also used for facilitation of national dialogue, and the Policy and Advocacy Advisory Council (PAAC) was established specifically to plan the transition and elaborate the *Transition and Sustainability Plan* (TSP). Consequently, the government's commitment to completely taking over funding of OST was reflected in the GFATM funding request for 2016–2018, in the National HIV/AIDS Strategic Plan (2016–2019) and in the Transition and Sustainability Plan 2016–2020. In our view, this process and the resulting documents played an important role in the country preparations.

Secondly, the Government used its investments in OST as its sole financial contribution to meet GFATM requirements to invest in interventions directly targeting key and vulnerable populations. Thus, through national investments in OST, the country ensured that it complied with the eligibility and co-financing requirements. Moreover, the Transition and Sustainability Plan 2016 clearly outlined that in 2016–2019, the government planned to allocate US\$ 9,263,428 to the prevention of HIV transmission, the detection of HIV, and to ensuring timely progression to care and treatment among the key affected populations. 99% of this sum was allocated to OST services, i.e. interventions targeting KAPs (Georgia Transition Plan, 2016–2020).

Thirdly, the further growth of state funding over the years is explained by long-term, extensive advocacy by community activists, civil society, and other stakeholders. This process was implemented by the Georgian National Drug Policy Platform (GNDP), which united 40 organizations behind the demand to reform national drug response measures and introduce a comprehensive, four-pillar drug policy, including treatment, rehabilitation, and harm reduction interventions. The Health and Social Issues Committee of the Parliament of Georgia led the negotiations process and advocated for the reform. IDI respondents indicate that the GoG wasn't ready to implement comprehensive drug reforms, but a high level of pressure from the public pushed the state to respond. Respondents mention that widespread support for OST was selected as a compromise by the state to fulfil the public's demand, at least in part. In addition,

there was already an OST system in place, thanks to the GFATM and earlier state funded programmes.

"There was very serious pressure from the stakeholders and political actors, including the political opposition ... we were demanding expanded support and widespread reform ... this process encouraged the government to compromise and led to the scale-up of OST" (IDI Respondent)

Fourthly, according to respondents Georgia was praised as a "champion" and a "leader" in ensuring access to OST services in the Central and Eastern Europe and Central Asia (CEECA) region. This made decision makers proud, giving them the opportunity to capitalize on this experience and continuously support the programme.

"Georgia turned out to be a pioneer and a leading country in the wider geographical region in terms of OST, having even better coverage than some western European countries. This represented the government positively and created their image as successful reformers, which was an important factor in their decisions" (IDI Respondent)

"Foreign delegations, including parliamentary delegations who came on official visits to Georgia, were amazed with our achievements in OST. This made policymakers very proud, which was a very important factor for them. During Global Fund and WHO meetings, they shared these stories" (IDI Respondent)

Fifthly, during the transition both GFATM and state programmes existed alongside each other, using different financing and provider reimbursement modalities. However, they were aligned before the transition through the introduction of uniform financing and provider rules. Specifically, the Global Fund programme was initially managed by the Georgia Health and Social Projects' Implementation Center (GHSPIC) and its successor, the Global Projects Implementation Center (GPIC), which used direct provider contracting, using grant funding and covering the full cost of service provision without co-payments. But in 2014 the NCDC was selected as a PR of the GFATM, which highlighted the importance of institutionalizing OST management and financing structures in a state body. The NCDC started contracting service providers through a competitive procurement mechanism using an electronic tender. Monthly reporting was carried out by a contracted institution, and reimbursement was carried out based on a programmatic and financial data review by NCDC's programme implementation unit. The MHPA was a sub-recipient within the Global Fund programme and further contracted regional narcological centres and private clinics as service delivery sites or sub-sub recipients.

At the same time, after its establishment in 2008, the state-funded OST programme became an integral part of the state's health programme, subject to public financing rules as defined by government decree. This decree defines the volume of the service, financing methodology and provider reimbursement procedures, programme implementation mechanisms, and specific regulations on service delivery conditions for all state supported programs. The integration of OST into state health programmes created legal and regulatory space for further absorption of Global Fund supported services by the national budget.

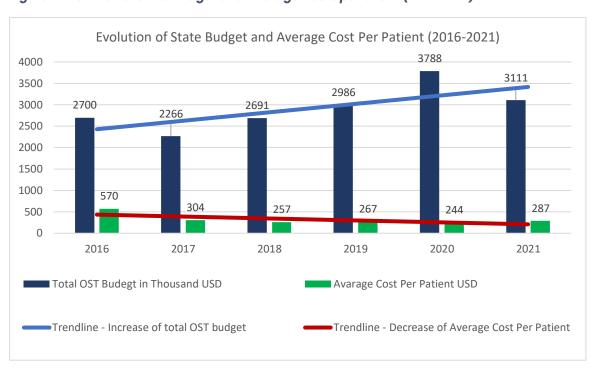


Figure 4 Evolution of State Budget and Average Costs per Client (2016-2021)

Furthermore, the state programme was implemented with the help of the MHPA, a single provider that managed the network of providers involved in OST service provision. From the start, the programme reimbursed the MHPA using a monthly voucher valued at 290 GEL per beneficiary, which was subject to an additional co-payment of 150 Gel by the user on an out-of-pocket basis, creating financial access barriers (as described earlier). In subsequent years, the value of the state-funded voucher was revised, and the co-payment was reduced to 119 GEL per month. In 2014, the voucher-based funding mechanism was replaced with the global budget, with the state paying the MHPA 1/12th of the total program budget on a monthly basis for a set number of target beneficiaries (Decree of Government of Georgia №650). This funding modality is maintained up to date. Having the MHPA as a lead recipient of state funding, with clearly defined rules for OST service payment and a streamlined OST management and service provision structure, facilitated the absorption of GFATM supported beneficiaries into the state program without major challenges and eased the process of transition. The only

challenges that were noted by respondents relate to the increased workload of OST staff members, the number of whom did not increase in proportion to the number of beneficiaries, which potentially could negatively affect the quality of delivered services.

On a final note, since the stable increase of state funding during and after the transition resulted in an increased number of beneficiaries, the average cost per enrolled patient declined, either due to gains in economy of scale, or due to declining quality. While these developments did not play a major role in the financial transition, it would be necessary to closely investigate this issue.

To summarize, several enabling factors have been instrumental in securing state investments in the OST programme, including external/GFATM eligibility and cofinancing requirements; a growing public demand, which translated into effective advocacy for state funding; and the long-term sustainability of the program and integration of funding from within the national system of healthcare financing. Finally, national pride arising from international recognition, which largely operated on an individual level, also seems to have been important in sustaining the political will of key decision-makers to support OST.

Health Management Information Systems (HMIS)

The development of HMIS played an important role in the successful transition. However, the process was multi-faceted, evolutionary, and not only dependant on GFATM support but also determined by contextual developments that occurred alongside GFATM grant implementation. It took almost 15 years, many steps and involved several important players (See Figure 5), as described below.

Due to limited financing and a poorly developed epidemiological surveillance system for drug use in the country, the health management information system needed to facilitate HIV programme planning for key populations was not in place when the GFATM programme was introduced. Therefore, the Global Fund played a crucial role in providing technical and financial resources to improve epi-surveillance, specifically among PWIDs. With the support of the GFATM, bio-behavioural surveillance (IBBS) and population size estimation (PSE) surveys have been implemented in Georgia on a routine basis since 2009. These studies provide essential data and analyses of the behavioural patterns of PWIDs, HIV, HCV and STI prevalence data, as well as population size estimations. The IBBS and PSE generate strategic evidence for programmatic and strategic planning of national HIV and drug use interventions.

Initially, the IBBS and PSE were funded by the GFATM national programme and implemented through outsourcing to research institutions. The biomarker component

within the IBBS survey was also outsourced and implemented by the National Infectious Disease, AIDS and Clinical Immunology Research Centre (IDACIRC). The obligation to assume funding and implementation of the IBBS and PSE surveys by the state was included in the TSP in 2016. Based on the TSP, the Government should have ensured the full public financial commitment to HIV related research (including IBBS and PSE) by the year 2019 (Georgia Transition Plan, 2016–2020). Measures to integrate IBBS and PSE implementation capacities into the NCDC have been considered. Specifically, during the last phase of IBBS and PSE implementation in 2017, NCDC staff were trained on survey methodologies and engaged in data analysis. The biomarker laboratory component was integrated into the NCDC, specifically into the Richard Lugar Center for Public Health Research. Despite these attempts, however, funding still relies on the GFATM, and implementation is still outsourced, with the next phase planned in 2022.

Furthermore, since the introduction of GFATM support in 2003, strategic planning of HIV response has been carried out on a routine basis. National HIV/AIDS strategic plans (NSP) have been elaborated in parallel with the preparation of GFATM funding requests. As part of the strategic plans, a national monitoring and evaluation (M&E) framework of the HIV response was also elaborated on a regular basis. Over the years, national indicators defined within the M&E framework have been gradually refined and aligned with international ones. Specifically, national indicators have been refined in line with the Global AIDS Monitoring (GAM) and WHO consolidated guidelines on HIV strategic information. Technical assistance funded by the Global Fund and provided by WHO and UNAIDS has been instrumental in supporting Georgia in refining and updating national indicators for HIV, including those for OST. Technical assistance was consistently provided at the elaboration stage of the NSP updates and the elaboration of GFATM funding request, in order to ensure that strategic planning and actions are based on refined indicators and targets.

Moreover, another important instrument for defining OST needs and planning treatment interventions, including OST, is the treatment demand indicator (TDI). The TDI collects information on the number of people entering treatment and provides general trends in drug use, including the number and characteristics of people demanding treatment, the substances used, and the types of treatment offered. By the time the OST programme was introduced in 2005, there was no reliable and valid national-level data on patients treated for substance use disorders. There were also no regulatory mechanisms in place defining and estimating treatment needs. Mostly, the programme was implemented based on routine programmatic data collection, with no surveillance, data analysis systems or instruments in place. The available data was chaotically provided by providers without harmonization, implying a lack of data collection and processing

standards. Subsequently, the country made significant strides in terms of creating institutional mechanisms for the collection of standardized information on treatment demand indicators, which included several steps. In 2013, the NCDC designed a special data collection form, which included aggregated information by gender, age groups, the number of first-time and repeated visits, the administration route, the type of primary and secondary drugs, polydrug use, and HIV testing/results (Javakhishvili et al., 2015). While this was a step forward, the forms required further improvement, with the next development occurring after signing EU Association Agreement (EU ASSOCIATION AGREEMENT, 2014), which helped Georgia to further develop its drug use surveillance system. Specifically, Georgia submitted a formal request for cooperation with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in 2014. This led to a cooperation programme which included steps to enhance the country's monitoring and knowledge base on the drug situation and responses, particularly through harmonising key indicators in areas of supply and demand. As part of this process, in 2015 the NCDC prepared a package of amendments to the Order No. 01-27/n on maintaining and delivering medical statistical information, which was approved by the MoH in 2016 (Order of Minister of Labour, Health and Social Affairs of Georgia N_2 01-2/n). This decree helped to align routine monthly statistical reports from addiction treatment clinics with international standards.

In addition, the EMCDDA defines five key epidemiological indicators and requires country reporting. The indicators include: Prevalence and patterns of drug use; Problem/high risk drug use; Treatment demand indicator (TDI); Drug related death and mortality; and Drug related infectious diseases. Prevalence and patterns of drug use are one of the key indicators used by EMCDDA to assess the drug situation. It helps to understand patterns of use, risk perceptions, social and health correlates, as well as the consequences of the use of illicit drugs. These indicators are sourced through several tools, including data from general and school population drug surveys. Surveys on drug use among youth have been conducted in Georgia on a regular basis (approximately once in a two years) since 1999, mainly within the framework of the "Programme of Assistance for the Prevention of Drug Abuse and Drug Trafficking in the Southern Caucasus (SCAD)", supported by European Union. Although these surveys were based on the European School Survey Project on Alcohol and Other Drugs (ESPAD) questionnaire, they contained major differences, including coverage and sampling methods. However, in 2015 the NCDC joined the ESPAD, which is a collaborative effort of independent research institutions across European countries and the largest cross-national research project in adolescent substance use in the world. Since joining ESPAD, the NCDC has conducted surveys using an international methodology in 2015 (ESPAD Report 2015) and 2019 (ESPAD

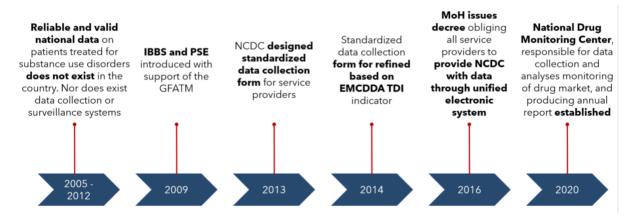
Report 2019). The next ESPAD survey is planned to take place in 2022. ESPAD surveys are an important contributor when monitoring drug use trends among adolescents, defining needs and planning respective strategic interventions.

"The progression of information systems is a large part of the EU association process, in which our systems should be based on and resemble European systems, ... this process was the main trigger for advancing our systems" (IDI Respondent)

Finally, with the support of USAID and the Czech Development Agency, the first National Survey on Substance Use in the General Population in Georgia (GPS) was conducted in 2015 (Kirtadze, Otiashvili and Tabatadze, 2016). The next GPS is planned to take place in 2022 and will be implemented with support of the EMCDDA. This support is provided within technical bilateral cooperation project EMCDDA4Georgia (EMCDDA4GE|www.emcdda.europa.eu, 2021). This project aims to enhance national responses to drug-related health and security threats through enhancing the monitoring and reporting capacity of the Georgian National Drug Observatory (NDO). The NDO was established in 2020, also with technical assistance provided by the EU and the EMCDDA within the obligations under the EUAA and The Deep and Comprehensive Free Trade Agreement (DCFTA 2014). The NDO is chaired by the head of the Department of Public International Law of the Ministry of Justice and is accountable to the Interagency Coordinating Council against Drug Addiction. The NDO's responsibilities includes the collection and analysis of drug use related information and data, observing and monitoring drug markets, and issuing annual reports on the drug situation in Georgia. Previously, these annual reports were developed with the support of different bi- and multilateral donors and development partners, including the EU, USAID, UNDP, and the Czech Development Agency. In 2021, the NDO prepared the first report on the drug situation in Georgia in 2019 (Drug Situation in Georgia 2019, 2021) and, at the time of writing, is in process of developing the second one. This report consolidated essential information in accordance with key indicators. The institutionalization of annual report on drug situation in the NDO ensures the sustainability of this intervention, which is vital in providing strategic information for informed decision making in the field of drug use, including OST.

Since 2021, a pilot electronic data collection project has been implemented with the collaboration of the NDO and NCDC. This pilot is also part of the support provided by the EU.

Figure 5 Evolution of OST Information Systems



As a result of these activities, Georgia has established a unified national electronic data collection system, contributing to informed decision making and improved programme planning around drug use. The elaboration and evolution of information systems has significantly benefited from external assistance, including from the GFATM, and institutionalization in state bodies, including the NCDC and the NDO. External accountability requirements for better information about drug use and treatment most likely drove the need for better quality and internationally comparable information, which placed the demand on national entities and has led to the institutionalization of important data/information collection elements (with the help of data standards, standardized reporting forms and processes reflected in the national regulations) within the health and other sectors. All of this was achieved through continuous technical assistance provided by partners.

Inputs

Medical Products - The Global Fund supported OST programme (2005–2017) only provided treatment with Methadone, while the state programme has provided methadone since 2008, and introduced suboxone (a combination of buprenorphine and naloxone) based substitution therapy in 2010 (*Javakhishvili et al., 2011*).

The procurement of medicines within the state programme was the responsibility of the Social Service Agency, using the state procurement mechanism through an electronic tender. Starting from 2014, after the NCDC became the GFATM principal recipient, the procurement of medicines with GFATM grant funding was also implemented using the state procurement mechanism. Therefore, the use of the same procurement mechanisms for both GFATM and state programmes did not require any adjustments after the full transition. No-major stock-outs have been reported in either the GFATM or state supported programmes.

Human Resources - Prior to the introduction of the OST programme in 2005, the country had a limited number of qualified medical personnel and poorly developed addiction services, including for drug treatment and rehabilitation. However, over the years, their numbers were increased with the help of several initiatives.

External assistance provided by the EU, through the project "Development of Human Resources, Evidence Based and Quality Standards in Addictology in Georgia" (ADDIGE), implemented within the TEMPUS funding mechanism, significantly contributed to the development of necessary human resource capacities in country. The project helped to develop human resources and expert capacity in the field of addictology via university-level and lifelong education in Georgia and helped the country pursue a modern, evidence-based drug policy with contemporary knowledge. The project was implemented with technical assistance provided by academic and research institutions from EU member states, in particular the Czech Republic, Poland, and Germany. Georgian civil society and academic institutions were engaged as partners.

Furthermore, in 2013 the Institute of Addiction Studies and a master's programme in addiction were established with a mission to strengthen the country's capacity for adopting evidence-based approaches for dealing with addiction problems (INSTITUTE OF ADDICTION STUDIES, 2022). The master's programme in addiction studies aims to produce highly qualified professionals capable of handling challenges related to different types of addictions. In addition, graduates are also qualified to work on program planning, undertaking research and monitoring the existing situation to better deliver addiction services to people in need.

Finally, through bilateral cooperation with the EMCDDA (project EMCDDA4GE), the capacity of national authorities was enhanced in the planning and implementation management of drug use policy. The EMCDDA equipped authorities with essential prevention knowledge and the most effective evidence-based prevention interventions and approaches. The EMCDDA also helped to strengthen the national drug treatment system through training and capacity building in evidence-based drug treatment approaches.

These efforts were instrumental in scaling-up OST delivery sites and staffing them, however, according to IDI respondents, the staff to beneficiary ratio in OST clinics has become inadequate relative to demand and may negatively affect the quality of delivered services in the future.

To conclude, external assistance played an essential role in developing the necessary human resources for policymaking, planning and delivery of OST services and, most importantly, HR production capacity has been institutionalized in educational institutions

of Georgia, which should assure the sustainable supply of the necessary human resources in future.

Governance and Leadership

This study revealed the complex intersectionality between separate health system functions and cross-cutting patterns that contributed to better decision making, planning and operation of OST services in the transition period.

Therefore, governance and leadership have been analysed in the context of four main sub-sections, including

- Coordination and decision making, ensuring the meaningful engagement of key stakeholders and establishing the space for multi-sectoral dialogue and coordination in transition planning, implementation, and oversight.
- 2. **The strategic and programmatic framework**, ensuring the alignment of national strategies with in-country context and needs, as well as declaring the strategic obligations of state authorities in transition.
- 3. **Management systems**, ensuring the financial and programmatic management of the intervention, including maintaining these functions during and after the transition.
- 4. **The legal framework**, ensuring the establishment of the legal basis for service implementation and the standardization of these services during and after the transition.

Coordination and Decision-Making

Country Coordinating Mechanism (CCM) - Prior to the GFATM programme, the Sexually Transmitted Infections and HIV Prevention Task Force (PTF) had been operational in Georgia since 2002. The PTF was a professional network uniting leading governmental institutions, NGOs, UN agencies, and international donor organizations engaged in HIV and drug use responses in the country. The PTF played a considerable role in HIV policy and advocacy and acted as the main coordinating platform facilitating national dialogue among the key stakeholders.

Later, in 2003 the Country Coordinating Mechanism (CCM) was established with the support of the Global Fund. The CCM ensured the broad representation of stakeholders in the decision-making process and created inclusive spaces for mounting a multisectoral national response. The CCM was established under the auspices of the Ministry of Health and was chaired by the Minister. In 2012, regulations governing CCM operations were approved by the Government of Georgia (GoG) (Resolution of Government of Georgia №220). The resolution defined the CCM's goals and objectives,

as well as its composition. The key purpose of the governmental resolution was to ensure that the coordination of the national HIV and TB response funded with state, GFATM and donor funds was adequately facilitated across governmental, non-governmental and international organizations. The adoption of this normative document by the GoG ensured the institutionalization of inclusive coordination mechanisms and contributed to the sustainability of participatory decision-making during and after the transition.

The membership of the CCM is multi-sectoral and includes representatives of governmental, international, non-governmental and private organizations, as well as other civil society representatives. The greater involvement of civil society has been achieved through effective collaboration with the PTF. Initially, two civil society representatives were nominated by the PTF to the CCM but eventually, through continuous advocacy by the PTF, CSO representation increased to four members in 2013. While people living with HIV and TB patients had been CCM members since its establishment, representatives of affected communities were absent, but eventually, MSM/LGBT and PUD representatives were added to CCM. The engagement of affected communities afforded the space for advocacy and eventually contributed to better alignment of national policies and practices with their needs. These developments were facilitated by the GFATM's eligibility requirements for CCM composition, which helped to ensure the meaningful engagement of diverse stakeholders. The CCM in Georgia is operating in full compliance with the GFATM's rules, and alongside governmental and international organizations, ensures the membership of people living with and affected by HIV and TB, as well as people representing key populations (KP). Currently, the CCM includes 28 members, including 10 state authorities, 5 international bi-and multilateral partners, 1 representative of the private sector, 1 representative of academia, 1 representative of the Georgian Orthodox Church, 6 civil society and 4 community representatives (Members of the CCM, 2022).

Oversight is a core function of the CCM. Its overall purpose is to ensure that national strategies and programmes are implemented as planned and that challenges and bottlenecks are identified and addressed in a timely manner. The CCM oversight committee was established in 2014. Representatives of civil society and the community are members of the oversight committee. This provides them with functional mechanisms for monitoring and oversight of the implementation of the national response, including the implementation of obligations by the state during the transition period. Oversight committee reports are an important instrument of advocacy and influence decisions.

Overall, the CCM's and oversight committee's operations ensure the meaningful engagement of civil society and community participants, which is a result of the PTF's

advocacy efforts. It should be noted that, in response to advocacy efforts, the CCM chair, secretariat and state authorities adequately engaged with CSOs and community members. These developments were catalysed with the help of training, mentorships and technical assistance rendered to CSOs and CBOs that were funded through small grants by the GFATM and other donors. The Global Fund's regional multicounty programs, which have been implemented since 2012, also significantly contributed to these capacity building and community-led advocacy efforts. The Global Fund multi-country programs refers to catalytic investments, addressed at the issues which cannot be adequately addressed by country allocations alone. Multi-country funds target a limited number of critical, pre-defined strategic priorities and are designed to accelerate regional response to HIV and to strengthen health systems by tackling regional bottlenecks and cross-border issues. Multi-country funds for the region of Eastern Europe and Central Asia are focused at sustainability of services for key populations, including HIV prevention, testing and treatment services, as well as addressing structural and systematic barriers to access.

Finally, the Global Fund provides technical assistance to ensure the sustainability of the CCM. As a result, the CCM sustainability plan was elaborated in 2017, which continues to help to sustain the coordination mechanism. The purpose of the plan is to provide the framework for identifying, planning, and caring out activities that will help the Georgian CCM to make the successful transition after the Global Fund support to the country ends. Importantly, it ensures that the CCM functions continue in a way that is understood and agreed upon by all CCM members and stakeholders, including sustaining diversity in representation of stakeholders and meaningful engagement of communities.

The objective of the CCM transition and sustainability plan is to provide a phased process to:

- allow for CCM functions and responsibilities to remain within the same structure as a national body to coordinate, support and oversee development and implementation of national strategic plans and corresponding health programs after the Global Fund support to the country ends.
- enhance the capacity of CCM members to implement functions effectively.
- delineate the CCM's sub-structures, including any sub-committees, technical working groups, and a Secretariat.
- identify staffing and needed funding for the CCM Secretariat and ensure financial sustainability.

Policy and Advocacy Advisory Council (PAAC) - After the GFATM introduced its New Funding Model (NFM) and set the requirements for increasing state financial contributions, the planning process for transition and sustainability took place in 2015-

2016. For these purposes, the CCM established the Policy and Advocacy Advisory Council (PAAC) in 2016 with the mandate of identifying transition-related challenges and developing potential solutions. The transition plan was developed and approved by the CCM in February 2017 (Georgia Transition Plan, 2016-2020). As the PAAC successfully accomplished its role, the CCM decided to use it as a platform for stakeholder consultations and discussions related to TB and HIV national strategies, the CCM Transition Plan, the GF budget split for the new allocation period, and funding request preparation. The PAAC is engaged in advocacy efforts aimed at improvements in legislation, regulations, operational policies, and practice standards related to TB and HIV prevention and service delivery and provides technical assistance and recommendations to the CCM. The PAAC has a technical and advisory role, but not a decision-making one. Decisions on specific topics considered by the PAAC are made by relevant government agencies as per their mandates (Terms of Reference of Policy and Advocacy Advisory Council., 2019). The establishment of the PAAC broadened in-country dialogue with a greater group of stakeholders and constituencies.

Interagency Coordinating Council for Combating Drug Abuse (ICC) - At the beginning of the 2000s, Georgia did not have a national drug strategy or coordination mechanism between state authorities responsible for the implementation of drug abuse-related interventions. In 2007, the Parliament of Georgia approved the key priorities of the national drug strategy. Among others, these priorities included improved interagency coordination. However, due to a lack of political will, it took an additional four years for the Interagency Coordinating Council (ICC) to emerge in 2011, which was subordinated to the Ministry of Justice (MoJ). Initially, the presidential decree "On the approval of the composition and regulations of the interagency coordinating council for combating drug abuse" provided the legislative basis for the ICC, but later in 2014, the ICC's composition and regulations were revised by a GoG resolution (Resolution of Government of Georgia No.342). The ICC is focused on the coordination and elaboration of the national anti-drug strategy and corresponding action plan. The ICC commenced functioning in 2012, chaired by the Minister of Justice. It unites representatives of the Ministry of Justice, the Ministry of Health, the Ministry of Education, the Ministry of Finances, the Ministry of Internal Affairs, the Ministry of Correctional Facilities, the Ministry of Sports and Youth, the Prosecutor's Office, the Parliament of Georgia and the MHPA. In addition to state authorities, ICC members are representatives of international organizations, including EU, UNICEF, USAID, UNODC, INL, as well as one representative of civil society – the Addiction Research Center Alternative Georgia. The establishment of the ICC was an important milestone during the transition period, as it contributed to the coordination and decision-making on OST as part of the national drug use response

measures and not only for HIV prevention. The EU provided technical support in the elaboration of national drug strategies and action plans, thus contributing to the practical functioning of the ICC.

Conclusion on coordination and decision making - In summary, since the introduction of the OST program in Georgia, key coordinating bodies have emerged that have played an important role in the national response. Importantly, inter-agency coordination among state authorities contributed to effective coordination and decision-making across state institutions. Ensuring the participation of a broad group of civil society stakeholders and communities, including PUDs, in the CCM, involving them in monitoring and oversight functions and enabling them to hold the government accountable were crucial steps. Engagement into the oversight committee enables community-led monitoring (CLM) of quality of the services, including assessment of available resources, availability, accessibility and affordability of the services. In addition, CLM focused at monitoring of local conditions and barriers that undermine or hinder the delivery of health services and limit human rights. All above mentioned, creates the systematic approach to governments internal accountability.

Furthermore, external demands on the coordination structure and composition of the CCM, which were imposed by the Global Fund, triggered the emergence of a participatory and transparent decision-making space. In addition, civil society advocacy efforts further contributed to the inclusive functionality of the CCM, giving serious consideration to civil society and community concerns/needs. Technical assistance rendered by donors was an important factor in building the civil society and community capacity necessary for ensuring effective advocacy and oversight and holding the government accountable.

Table 2. Coordination and Decision-Making Bodies in Georgia

Coordinating and Decision- Making Body	Main Functions	Affiliation to the State Structure	Members	Opportunity for CSO and Community engagement
Country Coordinating Mechanism (CCM)	 Strategic Planning of national HIV response. Coordination of the national response. Taking decisions in regard to national response to HIV and ensuring high-level policy dialogue. 	Established under th Ministry o Health	-Ministry of Health;	7 CSOs and 4 community constituents represented in CCM. Represented communities are:

	- Participation in elaboration of respective legislations in HIV and cross-cutting fields Oversight and monitoring of national HIV response.		- National Center for Disease Control and Public Health (NCDC); - Infectious Diseases, AIDS and Clinical Immunology Research Center; - National Center of Tuberculosis and Lung Diseases; - Center for Mental Health and Prevention of Addiction (MHPA); - Patriarchate of Georgia - Academia - Tbilisi State Medical University; - Private Sector - Georgian Employers Association International / Development Partners: USAID, EU, WHO, UNFPA; - Civil Society Organizations - 7 members; - Communities - 4 members.	- People Living with HIV (PLWH) TB Patients People who Inject Drugs (PWID) Men who have Sex with Men (MSM). Thus, CSO and community holds 11 seats and 11 voting voices, that creates a solid base for influencing the decisions.
Policy and Advocacy Advisory Council (PAAC)	The key role of the PAAC is to lead on the development and implementation of CCM Transition Plan, HIV and TB National Strategic Plans and GF applications focusing on a range of essential areas including: To identify strategic fiscal space to engage and influence and identify strategic information gaps required to make a case for more focused investment during the transition and beyond. Ensure alignment of legislative and	Established under the auspices of the CCM	Chaired by Minister of Health. 22 members - Ministry of Health; - Ministry of Finance; - Ministry of Justice; - Administration of Government of Georgia; - Tbilisi City Hall; - National Center for Disease Control and Public Health (NCDC); - Infectious Diseases, AIDS and Clinical Immunology Research Center; - National Center of Tuberculosis and Lung Diseases; - Center for Mental Health and Prevention of Addiction (MHPA); - UNFPA; - WHO;	5 CSOs and 6 community constituents represented in PAAC. Represented communities are: - People Living with HIV (PLWH). - TB Patients. - People who Inject Drugs (PWID). - People who Use Drugs (PUD).

Oversight	regulatory environment with the best practice requirements for effective HIV Prevention and Care. - Development and promotion of specific mechanisms for increased involvement of people living with the diseases and KPs, as well as civil society organizations and networks. - The development and application of procurement and supply regulations related to essential medicines and other health products. PAAC has a technical and advisory but not a decision-making role - Oversight of the	Established	- Civil Society Organizations - 5 members Communities - 6 members. Chaired by Deputy Minister of Health.	- Men who have Sex with Men (MSM). Thus, CSOs and community holds half of the PAAC seats.
Committee	national HIV response, including implementation of the Global Fund supported program.	under the auspices of the CCM	-Ministry of Health; - Ministry of Justice; - WHO; - 1 Civil Society Organization; - 2 Community Members. Chaired by CSO.	community constituents. Represented communities include - People Living with HIV, and TB Patients.
				Thus, CSO and community hold 50% of oversight committee.
Interagency Coordinating Council for Combating Drug Abuse (ICC)	- Coordination and elaboration of the national drug policy, strategy and corresponding action plan.	Established under the Ministry of Justice	Members - Ministry of Justice; - Ministry of Health; - Ministry of Education; - Ministry of Internal Affairs; - Special Penitentiary Service; - Parliamentary Secretary of the Government of Georgia;	1 civil society organization. Represented CSO has right to participate in the meetings of the ICC, but has no right to vote.

	- Chief Prosecutor of Georgia; - Healthcare and Social Committee of the Parliament of Georgia; - Legal Committee of the Parliament of Georgia; - Supreme Court of Georgia; - Center for Crime Prevention and Innovative Programs; - EU Delegation to Georgia; - The Council of Europe; - USAID; - UNICEF; - UNODC; - Center for Mental Health and Prevention of Addiction (MHPA); - US Department of Justice; - Bureau of International Narcotics and Law Enforcement Affairs;	Overall, the meetings of the ICC are public and open, any CSO and community can request participation and will have opportunity to attend the meeting.
	Enforcement Affairs;	

Strategic and Programmatic Framework

National HIV/AIDS Strategic Plan (NSP) – Elaboration of the NSP was an imposed precondition for accessing the GFATM funds because the NSP had to ensure that the requested grant from the Global Fund was in line with national priorities, as determined through an inclusive country dialogue. The first HIV NSP was elaborated in 2003 and was regularly updated thereafter, defining key strategic directions for the national response, setting clear objectives, and determining the required financial resources through detailed implementation plans. All NSPs included monitoring and evaluation frameworks and defined the responsibilities of respective state authorities.

Key interventions and obligations regarding OST, as well as its transition and the takeover responsibilities of the government, became an integral part of the respective NSPs, implementation plans and M&E frameworks. National strategic plans defined the core priorities and set national coverage targets for OST. The elaboration of NSPs entailed national consultations, including the involvement of key stakeholders, communities, and civil society. Technical assistance was usually rendered by the GFATM, the WHO, UNAIDS and other partners. Their inputs played a crucial role in the alignment NSPs with global approaches and priorities while adjusting to national specificities. Elaborated NSPs were approved by the CCM and thereafter by the GoG. The NSPs, as the main strategic document for the HIV response, were the main documents defining the government's actions in ensuring access to, and the sustainability of, essential services, including OST.

Transition and Sustainability Plan (TSP) - As mentioned above, in response to NFM requirements, Georgia started planning for the transition and sustainability of OST and other services under the HIV response. The Transition and Sustainability Plan (TSP) was elaborated in 2016 with financial support from the GFATM. The planning process was facilitated by the NCDC, with technical assistance provided by the Curatio International Foundation (CIF). As noted above, the PAAC was established to ensure the involvement of a broader group of stakeholders in this process. The elaborated TSP defined key government obligations with regards to transition and sustainability. TSP defined obligations included ensuring the sustainability of OST and its complete take-over by the state after 2017. The TSP was approved by the CCM, while later obligations defined in the TSP were integrated into the NSP 2019 (Georgia HIV/AIDS National Strategic Plan 2019-2022). The Global Fund's regional, multi-country projects played an important role in supporting civil society and community monitoring of the transition process and significantly contributed to their respective advocacy and accountability activities.

National Drug Strategy and Action Plan - As mentioned above, in 2007 the Parliament of Georgia approved a list of key priorities for national drug use response measures (Javakhishvili et al., 2011). This list was approved by the Health and Social Issues Committee of the Parliament of Georgia and presented a policy direction for drug treatment and prevention. Among other things, the list mandated inter-agency coordination actions and the elaboration of a national strategy and action plan, which was defined as an obligation of the ICC. Consequently, in 2013 the first National Drug Strategy and Action Plan was elaborated and defined the obligations of the state to ensure access to treatment and rehabilitation services, monitor drug markets and determine the national demand for treatment. While this strategy operated on a crosssectoral level, it clearly reinforced implementation of the HIV NSP and created traction for OST beyond it. The second national strategy and action plan 2021-2022 was elaborated in 2020, and requires sustaining treatment and rehabilitation services, including OST. In addition, this action plan further enhanced demands for information systems, surveillance, and monitoring in line with the EMCDDA's key indicators and practices. EU and EMCDDA assistance was crucial in the elaboration of national drug strategies and action plans and their implementation.

In conclusion, OST introduction, implementation and transition were always part of strategic planning, defining state obligations and responsibilities clearly and assuring conformity with donor and state-funded programs. This has been achieved through several enablers, including the external strategic planning requirements imposed by the GFATM, which required regular updates of the national strategies and thereafter the elaboration of a transition and sustainability plan. Demands from the EU/EMCDDA for the development of a national drug strategy and action plan elevated OST needs beyond the health sector. Technical assistance provided by international donors and partners over the years significantly contributed to the alignment of national approaches with international practices. The transparent and participatory process employed by the government when elaborating strategic documents was also important.

Management

From 2005 to 2014, the Georgia Health and Social Projects Implementation Centre (GHSPIC) and its successor Global Projects Implementation Centre (GPIC) were responsible for the management of the GFATM grant. In 2014, management responsibilities were moved to the NCDC, which established a Programme Implementation Unit (PIU) for the management of GFTAM programmes, including OST. This decision contributed to the institutionalization of the management responsibility within the state institution that applied national rules and management procedures, including service procurement, provider contracting, monitoring, reporting, and service financing. All of this significantly helped the OST transition process from donor support to the government, without significant impediments.

Legal Framework

Some legal and regulatory acts supporting the introduction, delivery and transition of OST in Georgia have been mentioned above. In this section, we will primarily focus on the most important ones that served as critical milestones.

In 2002, the Parliament of Georgia adopted the "Law of Georgia on Narcotic Drugs, Psychotropic Substances and Precursors and Narcological Assistance". The adoption of the law was the result of collaborative efforts between national experts from the Ministries of Justice, Internal Affairs and Health Care. A national working group established under the auspices of an EU-funded SCAD project entitled "Reinforcement and Harmonization of National Legislative and Regulatory Frameworks" made a significant contribution to the elaboration of the law. The law both regulated all aspects of licit circulation of controlled drugs and set mandates for the treatment of drug addicts. Under this law, Georgia began to treat drug addiction as a disease, defined the responsibilities of the state regarding drug users, stipulated that the state would bear

costs for their medical examination, treatment and rehabilitation, and make provision for substitution therapy. In other words, this law created the legal basis for recognition of the state's obligations towards ensuring access of PUD to health services paid by the government, including OST. This law played an important role in eventually allowing the government to develop a budget code and initially allocate financial resources for OST in the state budget. It also allowed the MoH to recognize OST as a method of treatment and develop regulations for OST service provision, whilst enabling the MoJ and other structures, including the MOH, to actively engage in drug use strategy development.

The next important development occurred in 2009, when the MoH issued an order regulating substitution therapy provision for opioid drug users (Order of Minister of Labour, Health and Social Affairs of Georgia N_2 37/n). This order regulated issues related to patient inclusion and exclusion criteria, the prescription of treatment and completion procedures, the rules of use, storage and distribution of substation drugs, and rules for maintaining medical documentation within the programme. In 2014, the MoH released an amendment to this order that provided a special rule for the implementation of OST in specific situations, including the provision of OST for hospitalized patients, allowing the provision of take-home doses, and expanding the list of opioids and medications for OST (Order of Minister of Labour, Health and Social Affairs of Georgia N_2 01-41/n).

On 22 November 2011, the President of Georgia issued special decree no. 751, 'On the approval of the composition and regulations of the interagency coordinating council for combating drug abuse'. The newly established Interagency Coordinating Council started work in 2012, facilitated by the MoJ. This decree not only established the interagency coordinating council but also mandated the government to develop and implement a national drug strategy, including responsibility for the implementation of treatment interventions.

This is not a complete list of that legal and regulatory acts that supported the institutional framework for OST delivery to emerge and clearly defined state mandates for drug abuse treatment, which obviously were fulfilled. Most of these developments occurred over many years without GFATM support, resulting from contextual developments within the country.

CONCLUSIONS

This case study provides a detailed account of the transition process, breaking it down into pre-transition, transition and post-transition periods. The report, where possible, elaborated policy triangle components, describing contextual factors, key actors and the process followed for OST transition. While the description is organized by health system

blocks, in many instances the information presented in each section spans across the set of health system functions/blocks. Furthermore, the narrative draws on a broad range qualitative information about HOW the transition happened and WHY it came to be successful. Finally, it tries to reveal which critical enablers contributed to the observed outcomes.

First and foremost, we would like to note that transition from donor support is a lengthy and multi-dimensional process, involving not only program staff but the whole of society, multiple state sectors and important development partners. Secondly, many factors that determined the successful transition of OST in Georgia arose in a much broader context, which extended far beyond the health sector and evolved over time. Contextual developments required gradual adjustments of transition steps/approaches to these changing circumstances. Therefore, we will first discuss the health system-related factors, which were evolutionary and, we think, determined the successful transition of OST services from donor support, when access to and coverage with OST services was significantly expanded during and even after the transition from GFATM.

This analysis demonstrates that the success of transition was driven by, and significantly benefited from, the gradual and consistent evolution of almost all health system functions/blocks, because enhancing these functions was an integral part of the transition process, contributing to the country's readiness to implement and manage the OST programme in a sustainable manner after the end of Global Fund support.

Developments in service delivery systems were critical in ensuring sufficient and sustained access to OST during and after the transition. The country gradually increased the network of service providers, including the production of the necessary human resources, which helped to expand geographical coverage and increase access to OST. An increase in service coverage was possible due to the allocation and gradual increase of domestic funding and improved service financing modalities when financial access barriers were removed for beneficiaries.

Sustainable OST financing significantly benefited from early state budget contributions, which in turn were enabled by the legal framework (the law "On Drugs, Psychotropic Substances, Precursors and Narcological Aid"), which gave legal permission and a mandate to the Ministry of Finance to allocate resources towards OST services in the state budget. This was important both in smoothly increasing state funding for OST services, in response to public demand, and in seamlessly moving away from GFATM support.

Furthermore, the country primarily relied on the procurement of OST medicines through state procurement mechanisms instead of using GFATM supply channels, which simplified the transition process and helped service expansion without any stock-outs. The supply of necessary human resources was secured with the help of other donors and through the establishment of educational programs, which ensured the supply of qualified medical and management staff.

The development of **health management information systems** had multiple causes, extending beyond the health sector. The collection of strategic information and surveillance was critical in ensuring proper program planning and implementation monitoring. The case study shows the stable and gradual evolution and development of HMIS on different levels and with support from different donors, its eventual standardization and alignment with international requirements, and most importantly its durable institutionalization (at least a large part of it except BBS).

The introduction and development of **governance and leadership** structures, along with their gradual evolution over the years, played a crucial role in the transition of OST from external support in Georgia. The evolution of coordinating bodies and decision-making mechanisms, including the CCM, the PAAC and the ICC, created the space for inclusive national dialogue and meaningful participation by a broad group of stakeholders, including civil society and communities. Participatory decision-making ensured the space for collaborative partnership and systematic reflection of the needs and interests of diverse stakeholders. Decisions and strategic priorities defined within those platforms were reflected in national strategies and action plans. Thus, a stable approach to **strategic planning** was an integral part of the transition process, ensuring the definition of the Government's obligations towards the OST program and its transition. Regular strategic planning, including the HIV strategic plan, the national drug strategy and action plan and transition and sustainability planning, contributed to a successful transition. Management structures (NCDC) and systems were also institutionalized and aligned with national processes through the institutionalization of key management functions within state authorities, including contracting, procurement, monitoring and evaluation, reporting and other functions. Lastly, the country ensured a supportive legal framework for the implementation of the OST programme with the development of normative documents in support of the transition.

These evolutionary developments were facilitated by enabling factors that included the following:

External Accountability – external accountability and conditionalities were instrumental in influencing the government's actions. The Global Fund's co-financing and eligibility requirements contributed to increased government spending on key populations to meet the GFATM's access to funding conditions. Further, the Global Fund's requirements to align funding requests with updated strategic plans triggered the regular

development of national strategies and action plans. Moreover, the Global Fund's transition preparedness requirements prompted the elaboration of the transition and sustainability plan, outlining the state's obligations and setting the timeline for the transition. In addition, the Global Fund's requirements for the CCM ensured the participation of civil society and communities in coordination and decision-making. External demands for an adequate drug policy from international partners, including the EU, led to national strategy development in health care and other sectors. Finally, external demands for accountability concerning drug use and the national HIV response played an important role in information system development within and outside the health sector.

External Technical Assistance – this study revealed that external technical assistance was crucial in the evolutionary development of health system building blocks. Technical assistance provided by the Global Fund, the WHO and UNAIDS contributed to the development of quality HIV NSPs and actions plans, including the transition and sustainability plan. Furthermore, this technical assistance ensured the alignment of the in-country monitoring and evaluation framework and indicators with Global AIDS Monitoring (GAM) and with the WHO's strategic information guideline on HIV indicators. The EU and EMCDDA supported the elaboration and evolution of information systems on different levels, including improving surveillance, data collection and reporting on drug use indicators, including the treatment demand indicator (TDI). Moreover, this technical support ensured alignment with EMCDDA's five key epidemiological indicators. Bilateral cooperation with EMCDDA encouraged the establishment of the National Drug Observatory (NDO). Overall, this technical support ensured the evolution of systems for strategic information that informed the decision-making processes. External support provided by the EU also contributed to the capacity development of human resources in the field of addictology, including strengthening the delivery of evidence-based drug treatment approaches and implementing, maintaining, and improving the quality of interventions. Continuous training provided by the Global Fund and other donorsupported programmes capacitated local civil society and community organizations and enhanced their abilities to advocate and influence decision-makers.

Internal accountability – Internal accountability was mainly achieved through two main factors: (a) public demand; and (b) civil society and community participation in advocacy and oversight. Public demand was triggered by an imbalance between the need/demand for OST and the limited-service delivery capacity, which was unable to accommodate a sufficient number of patients. Consequently, increasing the needs and interest of patients led to waiting lists for OST and continuous demands on the government to ensure access. Patient demand was reinforced by civil society and

community advocacy efforts. The government's accountability was secured through the participation of civil society and the community in decision-making platforms and processes, including the CCM, the PAAC, the ICC and practical instruments to hold the government accountable. The oversight committee in the CCM is a good example of an accountability instrument, providing CSOs and the community with the possibility to formally monitor and evaluate the progress and efficiency of the programs, reveal challenges, and demand solutions. Overall, advocacy implemented on different levels including advocacy concerning financing and access to OST services, the implementation of state commitments and ensuring the sustainability of OST, was crucial in creating public demand and holding the government accountable.

Political commitment – in response to external and internal accountability, the government and respective authorities expressed their political will and ensured proper responses, which were justified through increased investments in and support of OST. Specifically, in response to the community's demand for OST, the state ensured budgetary investments at an early stage of the programme, even though there was no external requirement for this at the time. The government's political commitment was reflected not only in budget allocations but also in contributions toward the expansion of the service delivery network and geographical coverage. Contrary to the overall repressive drug policy in the country, OST has never been subject to significant opposition and, compared to other drug treatment options, has been prioritised and continuously supported.

Institutionalization – major health system functions were institutionalized during the transition process. The selection of NCDC as the Global Fund's principal recipient ensured alignment across the GFTAM and state–supported programme management and implementation. This included medicines service procurement and contracting through state procurement mechanisms, monitoring of service delivery, and reporting. Furthermore, the institutionalization of health management information systems was ensured during the transition period. Specifically, epidemiological surveillance surveys in both HIV and drug use fields, including IBBS, PSE, and GPS and ESPAD surveys, are implemented by the NCDC, assuring trust and the validity of survey findings. An electronic data collection system has also been institutionalized in the NCDC, while monitoring, collecting and analysing information and production of drug situation reports falls under the NDO. Institutionalization played an important role in ensuring the sustainability of coordination and decision–making. Although the CCM, PAAC and ICC have been established in response to external requirements, they have become an integral part of state institutions under the Ministry of Health and Ministry of Justice.

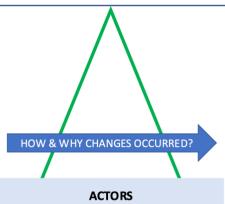
Figure 6. Schematic Summary of Conclusions in Line with the Conceptual Framework of the Study

CONTEXT

- Overall prioritization of health and increased state budget and spendings on health
- The Global Fund Transition, Sustainability and Co -Financing Policy and requirements for increased state investments, with focus on key populations
- EU Association Agreement and requirements to harmonize Georgian drug response policy and system with EU standards
- Advocacy movements towards reform of drug policy and decriminalization

CONTENT

- Public demand and interest from patients' community.
- External/GFATM accountability and co-financing requirements.
- External accountability in evolvement of health system functions, including HMIS, legal framework.
- Development of national electronic data collection system.
- Developing the human resources for policymaking, planning and delivery of OST services.
- Institutionalization of HMIS, HR capacity building.
- Development of Institutional and legal framework for OST.



External Actors: The Global Fund, EU, EMCDDA. In-Country Stakeholders: Civil Society Organizations, Community, Field Experts Governing bodies: CCM, PAAC, ICC National structures: NCDC, MoH, MHPA

PROCESS

- Advocacy implemented by community and supported by civil society
- Wide engagement of community, CSOs and other stakeholders in decision-making (e.g. CCM, etc.)
- Holding government accountable
- Participatory and inclusive strategic and programme planning, including transition planning.
- Early state investments, ensuring gradual evolution of OST systems
- Developments in service delivery systems (expanded network,
- Technical assistance provided by external partners (GF, EU)

OUTCOME

Expanded and improved access to OST services and the increased coverage achieved post-transition.

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