



# ESTABLISHING AND DELIVERING EVIDENCE-BASED, HIGH-QUALITY OPIOID AGONIST THERAPY SERVICES



An operational tool for low- and middle-income countries

# Establishing and delivering evidence-based, high-quality opioid agonist therapy services

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## ABBREVIATIONS AND ACRONYMS

ART	Antiretroviral therapy
CDC	United States Centers for Disease Control and Prevention
COVID-19	Novel coronavirus pandemic
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HRI	Harm Reduction International
ICD-11	International Classification of Diseases eleventh Revision
INCB	International Narcotics Control Board
INPUD	International Network of People who Use Drugs
OAT	Opioid agonist therapy
PEPFAR	United States President's Plan for AIDS Relief
SDG	Sustainable Development Goals
STI	Sexually transmitted infection
ТВ	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
USAID	United States Agency for International Development
WHO	World Health Organization

### DEFINITIONS OF KEY TERMS

Advocacy is the process of communication for change, with specific goals directed at individuals and groups that can bring about reforms in policy, law, structures, services and social or cultural environments.

Benchmarks are standards set to standardize performance in relation to best practices.

Community-led interventions are interventions that are designed, delivered and monitored by organizations or networks of people who use drugs [1].

Differentiated service delivery is an approach that simplifies and adapts HIV services to better serve the needs of people living with HIV and to optimize the available resources in health systems [2].

Harm reduction: For the purposes of this operational tool, harm reduction is defined as a comprehensive package of evidence-based interventions, based on public health and human rights, including needle and syringe programmes (NSPs), OAT and naloxone for overdose management.<sup>1</sup> (WHO, 2022)

Low-threshold services aim to minimize the barriers a patient may face in relation to starting, continuing and re-engaging in opioid agonist therapy [3].

Opioid use disorders are characterized in the International Classification of Diseases eleventh Revision (ICD-11) by the pattern and consequences of opioid use [4]. This group of disorders includes harmful use of opioids and opioid dependence.<sup>2</sup>

Opioid dependence is defined in the ICD-11 as a "disorder of regulation of opioid use arising from repeated or continuous use of opioids. The characteristic feature is a strong internal drive to use opioids, which is manifested by impaired ability to control use, increasing priority given to use over other activities and persistence of use despite harm or negative consequences. These experiences are often accompanied by a subjective sensation of urge or craving to use opioids. Physiological features of dependence may also be present, including tolerance to the effects of opioids, with-drawal symptoms following cessation or reduction in use of opioids, or repeated use of opioids or pharmacologically similar substances to prevent or alleviate withdrawal symptoms. The features of dependence are usually evident over a period of at least 12 months but the diagnosis may be made if opioid use is continuous (daily or almost daily) for at least 3 months" [4].

**Opioid agonist therapy (OAT)** refers to the prescription of opioid agonist medications at an appropriate dose to people with opioid dependence. It is provided under medical supervision and supported by access to evidence-based psychosocial interventions [5]. OAT is most effective as a maintenance therapy (sometimes referred to as opioid agonist maintenance therapy or OAMT) and should be provided for as long as a person requires it. OAT is the term used for this intervention in this document [6, 7].<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> Consolidated Guidelines on HIV, Viral Hepatitis and STI Prevention, Diagnosis, Treatment and Care for Key Populations, WHO 2022 <sup>2</sup> The American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (2013) has diagnostic criteria for opioid use disorder and its severity, which are commonly used.

<sup>&</sup>lt;sup>3</sup> The term "OAT" is used in this tool because it reflects the use of an agonist medication, and to indicate that effective treatment involves more than "replacing" or "substituting" an illicit opioid with medication. Much of the existing literature supporting the effectiveness of long-term agonists was defined as opioid substitution therapy. Opioid maintenance and methadone/buprenorphine maintenance treatments are other terminologies. Medication-assisted treatment is a more general term that includes all pharmacotherapies approved for the treatment of opioid use disorder.

Opioid agonist medications are medications that bind to and activate opioid receptors. The World Health Organization (WHO) has listed methadone (full agonist) and buprenorphine (partial agonist) as essential medicines since 2005. Other medications used for OAT include (slow-release) morphine, opium tincture and diamorphine (heroin) [5]. Methadone and buprenorphine are the most-studied agonist medications [5] and are the focus of this tool.

People with opioid dependence in this tool refers to people who meet the ICD-11 criteria for opioid dependence.

People who inject drugs: refers to people who inject psychoactive substances for non-medical purposes. These drugs include, but are not limited to, opioids, amphetamine-type stimulants, cocaine and hypno-sedatives, including new psychoactive substances.<sup>4</sup> Injection may be through intravenous, intramuscular, subcutaneous or other injectable routes.

People who use drugs: include people who use psychoactive substances through any route of administration, including injection, oral, inhalation, transmucosal (sublingual, rectal, intranasal) or transdermal. Often this definition does not include the use of widely used substances such as alcoholic and caffeine-containing beverages and foods.

Sustainable financing includes revenue-raising, pooling of funds and purchasing of health-care services using a country's domestic resources [8].

Universal health coverage means that all people and communities receive the health services they need. These services are received without experiencing financial hardship. It includes the full spectrum of essential, high-quality health services, from health promotion to prevention, treatment, rehabilitation and palliative care across the life course [9].

<sup>&</sup>lt;sup>4</sup>UNODC uses the term "new psychoactive substances (NPS)" which are defined as "substances of abuse, either in a pure form or a preparation, that are not controlled by the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, but which may pose a public health threat" United Nations Office on Drugs and Crime. UNODC Early Warning Advisory on New Psychoactive Substances 2022. Available from: www.unodc.org/LSS/Page/NPS.

### PREFACE

This document is an operational tool for professionals to establish and deliver evidence-based opioid agonist therapy (OAT) services in low- and middle-income countries.<sup>5</sup> It offers practical guidance on the processes to start, roll out and improve the quality of OAT programmes.

This tool is intended for health policymakers, administrators of health-care institutions and managers. It focuses on OAT services in the context of drug-related HIV and hepatitis B and C service delivery in community settings. Details of OAT provision in prisons and other closed settings are not included.

This document is not a clinical guideline. *WHO Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence* (2009) provide clinical guidance [5]. WHO and United Nations Office on Drugs and Crime (UNODC) *International standards for the treatment of drug use disorders* (2020) provides other details of OAT implementation [10]. Other tools that provide operational details are referenced throughout the tool. The process of developing this document is outlined in annex 1: Methodology.

The tool is organized into the following chapters:

Chapter 1: Introduction Chapter 2: A framework for establishing and delivering high-quality services Chapter 3: Laying the groundwork for OAT services Chapter 4: Planning OAT services Chapter 5: Starting OAT services Chapter 6: Rolling out OAT services Chapter 7: Increasing the sustainability of OAT programming Chapter 8: OAT services for specific populations

Chapter 2 describes the various components of an OAT programme along with benchmarks for quality, and the typical phases of a programme. Chapters 3–7 each cover a different phase of OAT programming. These chapters include "How to" sections that focus on the most important interventions during each phase. Chapter 8 provides additional information on services for women and other specific populations. Case studies from selected low- and middle-income countries are included as practical examples of OAT implementation.

<sup>&</sup>lt;sup>5</sup>World Bank classification of countries by income status is available here: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

### KEY MESSAGES



#### OAT IS ESSENTIAL!

Opioid agonist therapy (OAT) is critical for the treatment of opioid dependence and reduces overdose death and transmission of communicable diseases. Countries reporting opioid dependence should implement and roll out evidence-based OAT without delay.

#### OAT IS EFFECTIVE!

Among people with opioid dependence, OAT halves all-cause and drug-related mortality, and halves the HIV and hepatitis C infection risk. It improves overall physical and mental health and well-being, reduces crime and enhances social integration.



#### OAT REQUIRES CONSISTENCY!

OAT is most effective when provided at appropriate dosages for long/ maintenance periods.

4

#### OAT BENEFITS HEALTH MORE WIDELY!

In addition to treating opioid dependence, OAT provides an opportunity to address a range of health issues including HIV, hepatitis B and C, tuberculosis, overdose, sexual and reproductive health, mental health and psychosocial well-being.



## OAT REQUIRES COMMUNITY ENGAGEMENT!

OAT programmes are most effective when they are designed, implemented, monitored and evaluated with the meaningful engagement of organizations and networks led by people who use drugs, and other civil society organizations.



#### OAT MUST BE ACCESSIBLE, VOLUNTARY AND CONFIDENTIAL!

OAT services should be low-threshold, integrated into primary care where possible. Treatment should be voluntary, confidential and agreed between health-care provider and patient.



## OAT REQUIRES DIFFERENTIATED SERVICES!

OAT services need to be tailored to the needs of people with opioid dependence, including people with comorbidities, women, young people, people experiencing homelessness and people in prisons and other closed settings.



## OAT REQUIRES COORDINATION, TRAINING AND RESOURCES!

A multidisciplinary structure is needed to coordinate and oversee OAT programming, with capacitated human resources for health. Managing procurement, the supply chain and the potential risks of diversion of medications is important, with a robust health information system to monitor services and outcomes while ensuring privacy and confidentiality. For sustainability, domestic financing must be assured, with the goal of inclusion in universal health coverage.

# CHAPTER 1. INTRODUCTION

#### 1.1 Why are evidence-based responses for opioid dependence needed?

Opioid dependence contributes to significant morbidity and mortality [11]. In 2019, 62 million people used opioids worldwide [11]. Opioids accounted for 80 per cent of drug use disorder-related disability adjusted life years in 2017 [12]. Most of the deaths and disability were due to overdose and the consequences of chronic hepatitis C virus (HCV) infection and HIV infection [12].

Globally, opioids are the most widely injected drugs [13]. Heroin is the most commonly injected opioid. Since the early 2000s, increased heroin use and injecting has been noted in sub-Saharan Africa, the Middle East and North Africa, central and eastern Europe and the Asia-Pacific regions. The injection of synthetic opioids (e.g. fentanyl and its derivatives) has increased over the past decade, mostly in high-income settings. In 2019, there were an estimated 11.2 million people who inject drugs worldwide, with most living in East and South-East Asia (27 per cent), North America (16 per cent) and eastern Europe (15 per cent) [11].

The use and sharing of contaminated drug-injecting equipment has become the predominant mode of HIV and HCV transmission among people who inject drugs [14]. Repressive laws and practices regarding drug use, and stigma, discrimination and marginalization, increase the risks of infection among people who inject drugs [15]. These factors add to the transmission of HIV, HCV and hepatitis B virus (HBV) among people who use drugs, their sexual partners and the broader community [16]. People who inject drugs have a 35-times higher risk of acquiring HIV than the rest of the population [17]. In 2020, 9 per cent of all HIV infections were among people who inject drugs [17]. Globally, one in two people who inject drugs has been infected with HCV, and every eighth person who injects drugs is living with HIV [11].

Many people who use drugs are in prisons and closed settings [18, 19]. Repressive laws and practices regarding drug use are the main reasons for the incarceration of people who use drugs [20]. Limited access to treatment of drug dependence in the community is a common barrier to the implementation of community-based alternatives to conviction or punishment. Only one in eight people with a drug use disorder has access to appropriate treatment [11].

Women, young people and people experiencing homelessness who have opioid dependence face additional challenges [21]. Women who use drugs experience high levels of violence, additional stigma and notable barriers to service access [22]. Many policies prevent young people who use drugs from accessing services [20]. Furthermore, education and health systems often reject young people who use drugs. Young people who use drugs are seldom able to access the services they require to keep themselves safe [20]. People experiencing homelessness are marginalized, and in some countries criminalized [23]. Stable housing is often a requirement to access health and social services, and abstinence from drug use is commonly required in order to access housing support [24].

COVID-19 has highlighted the inequalities faced by people who use drugs. In many contexts, treatment of drug dependence and harm reduction services (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) were not considered essential services during COVID-19 responses. As a result, many services were erroneously restricted or closed as COVID-19 mitigation measures. Encouragingly, several countries adopted take-home doses for OAT patients, with positive patient experiences recorded and no significant increases in overdoses or diversion reported [25–27]. Conflicts and humanitarian situations expose people who use drugs to additional risks to their health and well-being. Abrupt changes in government or the collapse of governments during wartime or political disturbances can lead to disruptions in essential health and harm reduction services (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) for people who use drugs, either inadvertently or because such services are not prioritized as essential. The same can happen in the humanitarian crises caused by natural disasters or conflicts, where health services collapse or people become refugees and the needs of people who use drugs may not be prioritized by those providing aid.

#### 1.2 OAT as an essential public health intervention

High-quality OAT involves the prescription of opioid agonist medications at appropriate doses for long or maintenance periods, with access to evidence-based psychosocial interventions [5]. Opioid agonist medications, usually methadone or buprenorphine, are the core of OAT services.

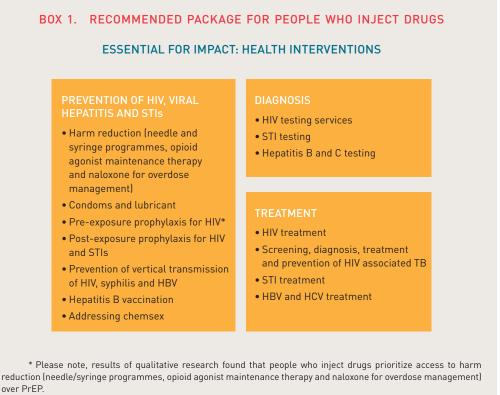
OAT is the most effective treatment for opioid dependence and improves other health and social outcomes [5]. High-quality OAT has marked impacts on health and well-being:

- Halves all-cause and drug-related mortality among people with opioid dependence [5, 28]
- Halves HIV infection risks by reducing injecting frequency and needle-sharing [29, 30]
- Increases linkage to, and retention on HIV antiretroviral therapy (ART) and enhances viral suppression [29]
- Halves the risk of HCV infection [31]
- Improves overall physical and mental health [31] and well-being [5]
- Reduces crime and enhances social integration and functioning [5]

OAT is an economically favourable health intervention [32]. The relative cost-effectiveness of OAT increases when health and social benefits beyond HIV are considered. Cost-efficiency is also improved when the costs of medications and staffing are reduced [32].

OAT should be voluntary. Countries should ban compulsory treatment for drug dependence, as there is no evidence of effectiveness and it infringes on principles of human rights and medical ethics [33].

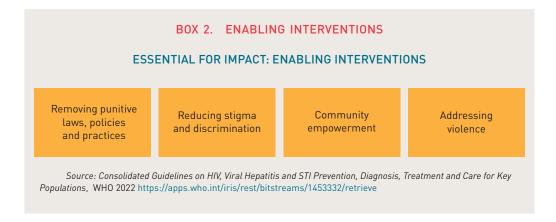
OAT is an essential health service that should be part of a comprehensive package to improve the health and well-being of people with opioid dependence [1][34]. OAT acts synergistically with harm reduction and other health interventions to improve public health impact (see box 1).



### Source: Consolidated Guidelines on HIV, Viral Hepatitis and STI Prevention, Diagnosis, Treatment and Care for Key Populations, WHO 2022.

The protection of people who use drugs from criminal sanctions for drug use and related exclusion is recommended<sup>1</sup> [35]. Alternatives to conviction or punishment should be considered for other offences committed by people who use drugs in contact with the criminal justice system. Involuntary treatment is not recommended as an alternative to conviction or punishment [36]. Implementation of WHO-recommended enabling interventions (see box 2) increases the effectiveness of OAT.

<sup>&</sup>lt;sup>1</sup>United Nations system common position supporting the implementation of the international drug control policy through effective inter-agency collaboration: "To promote alternatives to conviction and punishment in appropriate cases, including the decriminalization of drug possession for personal use, and to promote the principle of proportionality, to address prison overcrowding and overincarceration by people accused of drug crimes, to support implementation of effective criminal justice responses that ensure legal guarantees and due process safeguards pertaining to criminal justice proceedings and ensure timely access to legal aid and the right to a fair trial, and to support practical measures to prohibit arbitrary arrest and detention and torture;" (https://unsceb.org/ sites/default/files/2021-01/2018%20Nov%20-%20UN%20system%20common%20position%20on%20drug%20policy.pdf)



Leave no one behind and end inequalities. Attainment of Sustainable Development Goal (SDG) target 3.3, specifically eliminating HIV and viral hepatitis as public health threats, requires increased coverage and access to OAT, needle and syringe programmes and related HIV, viral hepatitis services for people who inject drugs [37]. Increasing access to OAT is a core component of SDG target 3.5, which relates to strengthening the prevention and treatment of substance use disorders [38]. Addressing inequalities, and reaching 50 per cent OAT coverage for people with opioid dependence by 2025, is a target of the Global AIDS Strategy 2021–2026 [17].

#### 1.3 OAT for impact

High-quality and high-coverage OAT services are required for maximal public health impact [10]. Poor-quality OAT contributes to discontinuation of OAT and missed opportunities for patients and communities to realize the benefits of this intervention [39]. Selected characteristics of high-quality OAT include [1, 10, 40]:

- Services are designed with the meaningful involvement of communities of people who use drugs
- Alignment with evidence-based clinical guidelines (particularly in relation to dosing, treatment duration and take-home dosing) and minimum standards
- Services are based on principles of medical ethics (patient autonomy, confidentiality, informed consent and voluntary involvement in health services)
- Unrestricted access (i.e. low-threshold)
- Service provision by trained health professionals
- Delivery of patient-centred, non-stigmatizing services
- Gender-responsiveness and inclusion of interventions around gender-based violence
- Access to psychosocial and other comprehensive services
- Employment of differentiated service delivery
- Access to emergency management of opioid overdose

# CHAPTER 2.

# A FRAMEWORK FOR ESTABLISHING AND DELIVERING HIGH-QUALITY OAT SERVICES

COMPONENT	INTERVENTIONS
ENGAGING PEOPLE WHO USE OPIOIDS	*
LEADERSHIP AND POLICY SUPPORT	*
FINANCING	
MEDICATIONS	
WORKFORCE	
STRATEGIC INFORMATION	*
SERVICE DELIVERY	

Establishing and delivering high-quality OAT services involves strengthening OAT programme components over time. Table 1 outlines activities that can take place.

	COMPONENT			
PHASE	Engaging people with opioid dependence	Leadership and policy support	Financing, medica- tions, workforce and strategic information	Service delivery
Groundwork	<ul> <li>Assess priority needs</li> </ul>	<ul> <li>Advocate for OAT support</li> </ul>	<ul> <li>Conduct a situation assessment</li> </ul>	
Planning	<ul> <li>Plan OAT service(s)</li> <li>Conduct advocacy around OAT</li> </ul>	<ul> <li>Conduct study tours</li> <li>Conduct knowledge exchange</li> <li>Establish coordinating and oversight structure</li> </ul>	<ul> <li>Register, import and procure medications</li> <li>Develop training, monitoring and evaluation framework and tools</li> </ul>	<ul> <li>Plan initial OAT service(s): protocols and systems</li> </ul>
Start-Up	<ul> <li>Implement community-led advocacy strategies</li> </ul>	<ul> <li>Engage with stakeholders</li> <li>Work with police to support OAT</li> <li>Engage with prison services</li> </ul>	<ul> <li>Monitor implementation</li> <li>Address challenges</li> <li>Map relevant services</li> <li>Ensure medications are available on-site and supply chain is in place</li> </ul>	<ul> <li>Provide OAT from initial site(s)</li> <li>Expand scope of services</li> </ul>
Roll-Out	<ul> <li>Community-led development of community empowerment plan</li> <li>Engagement in mapping activities</li> <li>Enhance people who use drugs' literacy around OAT</li> <li>Establish peer-facilitated mutual aid groups for OAT patients</li> <li>Establish peer-led support and linking to OAT services</li> </ul>	<ul> <li>Establish/adapt HIV and drug policy to support OAT roll-out</li> <li>Develop national policy, implementation strategy and guidelines</li> <li>Strengthen capacities in advocacy and working with the media</li> </ul>	<ul> <li>Develop training materials and system</li> <li>Develop logic model, monitoring and evaluation framework, information system, tools and reporting plan</li> <li>Strengthen system for expanding access to agonists and maximizing safety</li> <li>Forecast and procure medications</li> <li>Collect/synthesize data, adjust implementation</li> </ul>	<ul> <li>Establish coverage areas and infrastructure</li> <li>Identify and establish OAT sites</li> <li>Establish referral pathway</li> <li>Differentiate OAT services</li> </ul>
Sustainability	<ul> <li>Establish community monitoring system</li> <li>Increase advocacy led by people who use drugs</li> <li>Facilitate participation of community-led organizations in coordinating structures and policy processes</li> </ul>	<ul> <li>Ensure sustained funding</li> <li>Social norm change: retention in services; regular update of other services</li> <li>Enhance links and partnerships with stakeholders</li> </ul>	<ul> <li>Institutionalize OAT int</li> <li>Enhance OAT services and closed settings</li> <li>Enhance access for gro</li> <li>Enhance use of efficier</li> <li>Conduct monitoring, ev and programme adjust</li> <li>Integrate into primary</li> <li>Add other health and s</li> <li>Fund OAT services thro</li> <li>Enhance quality assured</li> </ul>	in community, prison pups with special needs nt models of service valuations, data review tment health-care system locial services pugh domestic financing

#### TABLE 1. OAT PROGRAMME ACTIVITIES BY COMPONENT AND PHASE

Source: Adapted from the IDUIT [35]

Note: Refer to table 6 for a definition of the phases.

#### 2.1 Components of an OAT programme and benchmarks

#### 2.1.1 Meaningful engagement with people with opioid dependence

High-quality services require the input of experts with experience [35, 41, 42]. Meaningful engagement with people with opioid dependence in OAT programmes includes their involvement in programme design, implementation, monitoring and evaluation. This process builds trust, mitigates challenges (e.g. retention and diversion), informs differentiated service delivery (e.g. for women, young people or people in prison) and informs stakeholder engagement (e.g. family members).

Community empowerment allows people with opioid dependence to reduce the healthrelated risks they face. It can also improve their access to and retention on OAT and related services [43]. Governmental or non-governmental services must work with and empower communities of people who use opioids, people with previous opioid use, OAT patients, family members and other allies to provide OAT and related services [35]. Repressive laws, policies and practices may prevent community empowerment of people who use drugs [35]. Working towards law reforms to ensure that people will not face punitive or coercive sanctions for personal use reduces incarceration and related public health problems. Furthermore, law and policy reform are important steps towards mitigating stigma and discrimination towards people who use drugs [1]. Laws and policies that are supportive of access to harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) and OAT increase access and retention in OAT services [35].

#### BOX 3. BENCHMARKS FOR ENGAGING PEOPLE WITH OPIOID DEPENDENCE

These include:

- People who use drugs are included in national policies and programmes
- Funding is allocated for organizations and networks led by people who use drugs
- Organizations and networks led by people who use drugs are recognized nationally
- Community resources to support OAT programming are explored
- Linkages with other community services are established and formalized as needed
- Safe spaces are available and supported for people with opioid dependence to engage
- People with opioid dependence are trained and supported around OAT, overdose and related services
- Community empowerment takes place with people who use drugs and people with opioid dependence
- Civil society, including OAT patients and people with lived experience of opioid use, are consulted on OAT governance, procurement and coordination at national and local levels

Sources: [35, 40]

#### 2.1.2 Leadership and policy support

Obtaining political and key stakeholder support for OAT is critical. Political leaders, communities of people who use drugs and people with lived experience, ministries of health, health-care professionals, social service providers as well as law enforcement and justice officials are some of the actors that need to work together to create an enabling environment for OAT service delivery.

Key stakeholders need to be made aware of the cost-effectiveness of OAT as a public health intervention for people with opioid dependence [31]. Stakeholders need to be aware of OAT's positive impact on the well-being of people with opioid dependence and on local and national HIV and hepatitis B and C epidemics [33].

The acceptability of OAT among law enforcement and police is key to effective OAT programming [44]. Punitive laws and policies and a failure to address basic human needs make people who use drugs vulnerable and fearful of police. OAT and broader harm reduction interventions can be important components of public health and public safety [45]. For example, OAT is associated with crime reduction [46–48] and reduced illicit opioid use [5]. Effective collaboration and harmonious policy frameworks are needed between the health and social service ministries and the police, the judiciary and prisons to increase access to and retention in OAT and for continuity of OAT care [1].

Evidence-based national OAT clinical guidelines and OAT operational and governance structures are needed to provide the framework for high-quality services.

#### BOX 4. BENCHMARKS FOR LEADERSHIP AND POLICY SUPPORT FOR OAT

These include:

- Inclusion of OAT in national drug treatment standards and protocols, drug control, HIV and hepatitis strategies and action plans, with commitment to achieving WHO-recommended targets
- Legislation providing explicit support for OAT
- National reporting of OAT-related indicators to regional and United Nations agencies and donors
- Evidence-based OAT as a core component of the national response to manage opioid dependence
- Effective governance and coordination mechanisms for the development and implementation of OAT
- National clinical guidelines for the provision of high-quality OAT
- Inclusion of OAT within law enforcement and police training
- Police standard operating procedures to support the diversion of people with opioid dependence to OAT services, and mechanisms to ensure continuity of OAT if arrested
- Provision of OAT within prison settings and continuation upon release
- Overdose prevention programmes upon prison release

Sources: [1, 14]

#### 2.1.3 Financing

Effective OAT services require adequate, sustainable financing. Affordable OAT services are key to success [49]. Out-of-pocket payments create barriers to OAT access and retention. In many contexts, initial services are funded through international donor or non-governmental sources, often through HIV programmes [14]. Sustainability of OAT programmes requires domestic funding that enables OAT to be scaled up in line with the level required for HIV and HCV epidemic control among people who are opioid-dependent, and to ensure that OAT is accessible to all in need [40].

#### BOX 5. BENCHMARKS FOR FINANCING OAT PROGRAMMES

These include:

- Where donor funding supports OAT services, multi-year financial plans outline processes towards co-financing and transition towards sustainability
- Opioid agonists are included in the state-reimbursed medicine list and are funded from public sources
- OAT services are included in the universal health coverage or state-supported minimum package of health-care services
- Comprehensive OAT services are paid for through sustainable public financing

Source: [40]

#### 2.1.4 Medications

Systems for opioid agonist medication supply management and reporting need to be established in accordance with relevant conventions and local laws and policies. The role of the International Narcotics Control Board is summarized in box 6.

#### BOX 6. THE INTERNATIONAL NARCOTICS CONTROL BOARD

The International Narcotics Control Board (INCB) is an independent, quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions. INCB is also intended to enable countries to have the controlled medications they require for public health interventions.

Methadone and buprenorphine are scheduled under the international Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971, respectively. The drug control conventions do not prescribe what comprises medical use. WHO provides global guidance on the evidence-based use of medications. It is up to national authorities to decide on the medical use of narcotic drugs (e.g. methadone) and psychotropic substances (e.g. buprenorphine) and to support other harm reduction interventions (e.g. needle and syringe programmes, and naloxone for overdose management). The drug control conventions do not prohibit such interventions.

The international trade of methadone and buprenorphine is regulated and is conducted in relation to national annual estimates. There is no limit to the volumes of agonists that a country can estimate, provided it is based on their need. The INCB does not operate on a quota system.

Countries are required to [5]:

- Estimate the annual volumes of methadone and buprenorphine required following INCB guidance [50]
- Submit annual estimates of methadone and buprenorphine required, communicating the method of estimation, to INCB, following predefined timelines
- Report quarterly statistics to INCB on the amount of agonist medication imported and exported
- Report annual statistics on methadone and buprenorphine production, manufacture, consumption and stocks, as well as seizures of narcotic drugs
- Regulate importation and local manufacture of agonist medications as well as licensing, record-keeping, storage and quality control
- Ensure that agonist medications remain in the hands of licensed parties and are dispensed against a valid medical prescription by a licensed and trained individual
- Maintain a system of inspections from importation/manufacture to distribution
- Prevent the diversion and non-prescribed use of agonist medications

Ideally, OAT patients should be able to choose together with the health-care provider the agonist medication that best suits their treatment needs. OAT patients should also have access to a package of essential medicines to prevent and treat other priority health issues (see table 2). Medications need to be locally registered, listed on national essential medicines lists, affordable and available for use in OAT programmes.

#### TABLE 2. MEDICATIONS AS PART OF COMPREHENSIVE OAT

MEDICATION	COMMENT
Opioid agonist medicatio	ns
Methadone	Commonly a first-line agent. Wider availability and lower cost
Buprenorphine	Better safety profile. Fewer drug-drug interactions. More expensive
Other medications	
Naloxone	A short-acting opioid antagonist used for the emergency management of opioid overdose
HIV services	HIV treatment, pre- and post-exposure prophylaxis, medications for opportunistic infections, including TB, and STI prevention and treatment
HBV and HCV services	Hepatitis B vaccine, HBV and HCV testing and treatment
Other primary care medications	Contraceptives, medications for common mental health, oral and skin disorders and wound and non-communicable disease management

\* Comments and comparisons are between methadone and buprenorphine. Other agonist medications used for OAT include extended-release morphine, diamorphine, opium tincture and long-acting depot buprenorphine.

High coverage of high-quality OAT is the best method to avoid diversion of agonist medications. Diversion of agonist medications can take place along the supply and value chain. The most significant levels of trafficking and diversion take place at the retail level and higher [51].

At the local clinic level, use of non-prescribed OAT is often linked to poor quality of the prescribed medication, self-medication, or because the non-prescribed medication is the preferred drug, and rarely for euphoric purposes [52] (see table 3). Interventions to minimize diversion are included in table 8.

#### TABLE 3. FACTORS CONTRIBUTING TO DIVERSION OF AGONIST MEDICATION AND USE OUTSIDE OF OAT PROGRAMMES

#### SYSTEM AND SERVICE FACTORS

- Insufficient OAT coverage
- High cost of OAT
- Underdosing of agonists
- Short duration of OAT instead of maintenance therapy
- Access barriers (distance, opening times, attitude of staff, police intimidation of patients)
- Suboptimal coordination between OAT services in community, prisons and closed settings, and law enforcement

#### PATIENT FACTORS

- Reluctance to seek treatment due to fear of stigma and confidentiality concerns
- Concerns about disciplinary action for previous or concurrent illicit opioid use
- Limited person-centred care
- Concerns about limitation of rights and negative impact on family relationships, child custody and employment linked to being a (registered) OAT patient
- Challenges in adhering to treatment and daily attendance
- Challenges to continue care if moving from correctional to community settings
- Low level of information on OAT among potential patients
- Preference for short-term treatment and reluctance to enrol in a longer-term programme
- Sharing of medications with peers who have challenges accessing OAT
- Demand for OAT medication on the black market (potential financial benefits)

#### **BOX 7. BENCHMARKS FOR MEDICATIONS FOR OAT PROGRAMMES**

These include:

- OAT-related medication procurement is integrated into the domestic procurement and supply management system
- Domestic procurement and supply-management capacity is established to avoid interruptions in OAT medication supply
- Methadone, buprenorphine and naloxone are continuously registered with the domestic health products regulatory authority
- Domestic health products regulatory authority's quality assurance system is operational
- Methadone, buprenorphine and naloxone are secured at affordable prices

Sources: [10, 40]

#### 2.1.5 Workforce

OAT services require an authorized medical prescriber (e.g. doctor or nurse practitioner), access to psychosocial service providers, peers, administrative and managerial support and people who are authorized to dispense medications (e.g. pharmacist, doctor or nurse practitioner). Additional team members may include an occupational therapist and people to provide spiritual guidance and support. There is no need for prescription to be limited to addiction specialists, specialist physicians or psychiatrists. Trained general practitioners (and potentially professional nurses and clinical associates with adequate training and support) could prescribe OAT medications. Task-sharing can enhance operational and cost efficiencies [1]. Support from multi-professional and multidisciplinary teams can improve the quality of support provided to OAT patients navigating complex and intersecting health and psychosocial issues.

OAT service quality is influenced by the knowledge, skills, attitudes and demeanour of service providers [39, 49, 55–58]. Stigma and prejudice of OAT service providers towards people who use drugs limits access and retention on OAT. In contrast, engaging and motivating staff can improve patients' health outcomes [58].

#### BOX 8. BENCHMARKS FOR THE WORKFORCE IMPLEMENTING OAT PROGRAMMES

These include:

- OAT is included in the job descriptions of the main health staff and core functions of the state system for drug dependence treatment and care, with relevant predictive capacity and the ability to dispense OAT at scale
- Capacity-building system is adequate for sustainable OAT implementation
- Evidence-based treatment of drug use disorders is included in education for medical doctors, nurses, psychologists, social workers and other relevant health and related professionals

Source: [40]

#### 2.1.6 Strategic information

This includes information that is used as a tool for assessing the need for OAT and tracking service delivery, effectiveness and costs. Initial OAT services should be monitored and evaluated to inform local adaptation and roll-out. As the OAT programme expands and becomes established, ongoing monitoring, evaluation and surveillance should continue to inform policy and practice.

A selection of core OAT indicators is included in table 4. Other indicators, including those relating to structural interventions, are described elsewhere [59]. Population size estimations are important to estimate demand, and routine programme data can be used for ongoing monitoring. The results from periodic biobehavioural surveys, evaluations, cost analysis and surveillance can complement programme data and be used for decision-making, quality assurance, resource allocation and advocacy [59, 60].

#### TABLE 4. PRIORITY OAT SERVICE INDICATORS, FREQUENCY AND METHOD OF COLLECTION AND USE

POPULATION SIZE ESTIMATION			
Indicator	Source and use		
<ul><li>Number of people with opioid dependence*</li><li>Number of people who inject opioids</li></ul>	• Collected periodically through population size estimation activities. Data used to estimate OAT demand. Used as denominator for coverage indicators.		
AVAILABILITY OF OAT			
Indicator	Source and use		
Number and location of OAT maintenance sites	• Routine programmatic data. Used to monitor OAT availability.		
OAT CO	VERAGE		
Indicator	Source and use		
<ul> <li>Individuals receiving maintenance OAT</li> </ul>	• Routine programmatic data to monitor performance. Periodic biobehavioural surveillance and special surveys used to assess coverage (at one time and to assess trends)		
QUA	ALITY		
Indicator	Source and use		
<ul> <li>National policy and OAT service delivery quality [59]</li> <li>Individuals receiving OAT continuously for at least 6 months</li> <li>People receiving OAT maintenance at, or above, the recommended minimum dose</li> <li>Individuals on OAT receiving psychosocial support</li> <li>Number of people with special clinical needs receiving OAT, e.g. pregnant women, people in prison settings</li> </ul>	<ul> <li>Routine programme data and periodic special surveys. Also includes data from community monitoring activities. Data used to assess OAT quality and for quality improvement.</li> </ul>		
	AND IMPACT		
Indicator	Source and use		

\* The population size estimate of people who inject drugs is often used as a proxy for the number of people dependent on opioids.

Sources: [59, 60]

#### BOX 9. BENCHMARKS RELATING TO STRATEGIC INFORMATION FOR OAT PROGRAMMES

These include:

- OAT monitoring systems are in place and are used to manage the OAT programme, including programme need, coverage and quality assurance
- Evidence base for OAT effectiveness and efficiency is generated regularly and informs policy and programme planning
- OAT patient data are stored confidentially in a secure database, and only shared outside the health system with a patient's consent

Source: [40]

#### 2.1.7 Service delivery

The clinical management of opioid dependence with opioid agonists forms the core of OAT programming. Access to and retention on OAT are improved when services are low-threshold, person-centred and community-based [35, 61]. OAT does not routinely require inpatient induction [5]. A person's journey through OAT is outlined in figure I.



Supervised dosing affects a person's ability to function and their family, educational, employment and social responsibilities [62–63]. As a result, restrictive take-home policies negatively affect patients' uptake and retention in OAT [64]. Take-home doses should be considered when the benefits of reduced frequency of attending outweigh medication risks. Consumption of opioid agonist medication by a medication-naïve person can be fatal, and mitigation efforts to avoid this should be put in place (e.g. the provision of safe/child-proof containers).

During the COVID-19 pandemic, several OAT programmes in low- and middle-income countries allowed take-home doses, enhancing efficiency and improving the patient experience without major safety concerns [27, 63, 64]. For example, in Ukraine, roll-out of take-home doses (around a 45 per cent net increase between the first and second quarters of 2020) enabled continued access and reduced clinical contact time without significant increases in mortality [65].

The Global AIDS Strategy target for people who inject drugs is for 50 per cent of those who are opioid dependent to access OAT [17]. Once OAT is started at an initial site, further sites can be added with a tailored (site-specific) approach, and the experience and results can be used to support ongoing advocacy for further OAT roll-out.

Initiation and continuation of OAT in prison and other closed settings is important [1]. OAT in these settings supports people with opioid dependence to access treatment and avoid withdrawal. Linkage between prison and OAT services in community settings can improve continuity of OAT and reduce recidivism [66]. The processes for setting up, implementing, scaling up, monitoring and improving the quality of services in these settings have unique elements and are beyond the scope of this tool.

Quality is further improved through integration of other priority health and social services, and differentiated service delivery [10]. OAT patients should have access to a comprehensive package of services, including for HIV, viral hepatitis, TB, overdose, mental health, drug dependence treatment, sexual and reproductive health, primary health care, and social and legal services. Ideally, services should be provided at a single location (one-stop-shop). Where this is not possible, strong referral systems should be developed and used to support access to comprehensive care [10].

#### TABLE 5. BENCHMARKS FOR OAT SERVICE DELIVERY

AVAILABILITY AND COVERAGE	<ul> <li>OAT is available in all tiers of the health system</li> <li>OAT is available in the public, private and/or non-governmental sectors</li> <li>OAT is available in prisons and closed settings (including for initiation) and during pretrial detention, with systems to support continuity of OAT care upon release</li> <li>Geographic coverage is adequate</li> <li>Coverage of the estimated number of opioid-dependent people with OAT is high (&gt; 50 per cent) [17]</li> </ul>
ACCOMMODATION	<ul> <li>There is a non-judgmental therapeutic culture</li> <li>Mechanisms are in place to report and act on discrimination</li> <li>Drug use during treatment is not a basis for discontinuing treatment</li> <li>OAT programmes are based on the maintenance approach, with no limitation on the length of treatment</li> <li>More than one OAT medication option is available</li> </ul>

ACCESSIBILITY	<ul> <li>Opening hours and days accommodate key needs</li> <li>There are no people on a waiting list to enter the service</li> <li>OAT take-home doses are part of standard practice</li> <li>Treatment is individualized and management plans are produced and offered with the patient's involvement</li> <li>Adequate dosage of methadone/buprenorphine is included in national guidelines and practice, in line with WHO guidance</li> <li>OAT is available and accessible to specific populations with special needs</li> </ul>
ACCEPTABILITY	<ul> <li>OAT services are gender-responsive</li> <li>OAT services are provided in safe, welcoming and supportive environments</li> </ul>
AFFORDABILITY	• There are no user fees or barriers for people without insurance
COMPREHENSIVENESS	<ul> <li>There is access to evidence-based psychosocial services and support</li> <li>Interventions around gender-based violence are integrated</li> <li>A high proportion of OAT sites (&gt;80 per cent) are integrated and/or cooperate with other services and support continuity of care for HIV, viral hepatitis, TB and drug dependence treatment</li> <li>OAT services are integrated with and/or provide access to needle and syringe services</li> <li>OAT services provide take-away naloxone</li> <li>OAT services integrate information on safer sex and include condom and lubricant programming</li> <li>Support is offered to access housing, employment, income generation</li> </ul>
QUALITY	<ul> <li>Possible targets [60]:         <ul> <li>&gt;60 per cent of OAT patients receive OAT continuously for at least six months</li> <li>&gt;60 per cent of OAT patients receive maintenance OAT dose &gt; to the recommended minimum dose</li> <li>&gt;50 per cent of OAT patients on maintenance OAT receive psychological support</li> <li>100 per cent of suggested standards and programme features included in national legislation, policy and guidance</li> <li>100 per cent of OAT service sites meet suggested standards outlined in OAT-related policy and service delivery checklists</li> <li>Community monitoring of OAT services takes place and informs quality improvement</li> </ul> </li> </ul>

Sources: [3, 39, 40, 60]

#### 2.2 Phases of an OAT programme

An OAT programme typically evolves through several phases, from laying the groundwork to increasing sustainability. Several activities take place during each phase. Activities establish and later strengthen a process or system. Different activities take place across the various OAT programme components. A broad description of the phases of an OAT programme is provided in table 6. Additional detail is provided in chapters 3–7.

PHASE	DESCRIPTION
GROUNDWORK	The period before OAT services have started. Activities intended to provide baseline information to guide programming and obtain initial stakeholder support.
PLANNING	Planning for medications, strategic information, training and service delivery at initial OAT site(s). Advocacy continues to garner additional support for OAT.
START-UP	OAT provided from initial site(s). The service is closely monitored and improved. Ongoing advocacy and engagement with communities and other stakeholders.
ROLL-OUT	Efforts are focused on establishing the policy framework and coordination structures for increasing access to and coverage of OAT. New sites are added for OAT services. Additional efforts to provide differentiated service delivery. Community-led organizations and networks continue to be empowered around OAT. Monitoring and evaluation of OAT services, including community monitoring, inform refinement of services and efficiencies. Ongoing strengthening of required components of OAT programme.
SUSTAINABILITY	Community-led organizations and networks assume a greater role in service delivery, support and advocacy. OAT medications are affordable, with secure supply, and where possible, manufactured locally. OAT becomes institutional- ized within undergraduate training of health, social services, law enforce- ment and related service providers. OAT services available across the various health-care systems and tiers, particularly within the primary health-care system. OAT is part of universal health coverage. OAT financing from domestic health budgets. Ongoing monitoring, evaluation and surveillance of OAT programme and quality improvement.

#### TABLE 6. OAT PROGRAMME PHASES

# CHAPTER 3.

# LAYING THE GROUNDWORK FOR OAT SERVICES

COMPONENT	INTERVENTIONS	
ENGAGING PEOPLE WHO USE OPIOIDS	*	
LEADERSHIP AND POLICY SUPPORT	*	
FINANCING		
MEDICATIONS		
WORKFORCE		
STRATEGIC INFORMATION	*	
SERVICE DELIVERY		

Planning OAT services involves obtaining insights into opioid dependence, opioid injecting and the HIV and HCV epidemics among people with opioid dependence in a country. This can be done through a situation assessment or similar activity [35]. Strategic advocacy around OAT with policymakers and other key stakeholders to gain their support is another important initial step towards commencing OAT services.

#### 3.1 How to conduct a situation assessment

Data collected to inform OAT planning should be rights-based and follow principles of medical ethics. Strategic information should not be collected and used in a way that could negatively affect the rights, health and well-being of people who use drugs [67].

The Rapid Assessment and Response method can be adapted and used to inform local assessments of drug use, risks and responses [68, 69]. Assessments should be planned and conducted with the engagement of the community of people who use drugs. They should include rural and remote areas [4] as well as prisons. Steps in a situation assessment include:

- Defining the scope of the response (population size estimation and mapping)<sup>2</sup>
- Identify locations in the country where significant numbers of people with opioid dependence are located
- Include collection of data relating to specific populations of people with opioid dependence (e.g. women, young people, people experiencing homelessness)
- Estimate the number of people in a municipality/area and their location, and define risks, service needs and preferences
- Map locations of existing HIV- and drug-related health and social services for people with opioid dependence
- Define processes to reach and engage with different people with opioid dependence for OAT access (or available/existing needle and syringe programmes/drug treatment services) to expand services
- Understand the needs of certain groups with special clinical needs among the group of people using opioids for non-medical reasons
- > Developing a plan for local responses (needs assessment)
- Perform a gap analysis [35]
- Identify priorities
- Identify problems and opportunities
- Identify possible solutions and planning
- Understanding the environment
- Assess factors influencing OAT services (structural, social, behavioural factors)
- Geographical prioritization (size, reachable populations, resources and need)

<sup>&</sup>lt;sup>2</sup>The situation assessment could take a broader approach and assess prevalence and needs around a range of drugs, and inform responses.



#### FURTHER READING

Monitoring guide and toolkit for HIV prevention, diagnosis, treatment, and care programs with key populations (FHI360, 2020).

www.fhi360.org/sites/default/files/media/documents/resource-linkagesmonitoring-tools.pdf

Priorities for Local AIDS Control Efforts (PLACE) tool kit. (MEASURE Evaluation, 2019). www.measureevaluation.org/place.html

Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions (IDUIT) (UNODC, 2017). http://bit.ly/2oghaxx

*Biobehavioural survey guidelines for populations at risk for HIV* (WHO, 2017). www.who.int/publications-detail-redirect/978-92-4-151301-2

Nine steps for developing a scaling-up strategy (WHO, 2010). https://apps.who.int/iris/handle/10665/44432

The Rapid Assessment and Response guide on injecting drug use (WHO, 1998). www.unodc.org/documents/hiv-aids/IDU rapid ass. and resp. guide.pdf

#### 3.2 How to tailor advocacy efforts to increase political support for OAT

A targeted advocacy strategy tailored to the local context and addressing local needs and identified barriers can be useful to gain political support for OAT.

Important aims of OAT advocacy are recognition and acceptance of OAT as a pragmatic, evidence-based, long-term public health intervention that layers onto other core harm reduction interventions, (needle and syringe programmes and naloxone for overdose management). OAT advocacy should also highlight that OAT is an integral part of evidence-based treatment of opioid dependence [5, 10].

The steps in this process are outlined in table 7.

#### TABLE 7. STEPS IN OAT ADVOCACY

STEP	ACTIVITIES
PLANNING	<ul> <li>Identify core advocacy issues based on an assessment of current policy, legal, institutional and social barriers to OAT</li> <li>Use political commitments (e.g. SDGs) and United Nations documents (e.g. WHO evidence-based guidelines [5], UNODC/WHO Standards for the Treatment of Drug Use Disorders [10] or the UNGASS 2016 Outcome Document [71]) that align to a health-centred approach in advocacy strategies and messaging</li> <li>Identify individuals or organizations with legitimacy to engage with government (health, law enforcement and other sectors) and the community to be part of advocacy efforts [41]</li> <li>Identify barriers that prevent actors from embracing change and those that may motivate them to change</li> </ul>
DEVELOP MESSAGING	<ul> <li>Strategic issues in relation to OAT to cover include:</li> <li>The value in national HIV and HCV responses</li> <li>The link with attaining the SDGs</li> </ul>
	<ul> <li>Human rights</li> <li>Improving the health, rights and social well-being of people dependent on opioids</li> <li>The cost-effectiveness of OAT as a public health intervention</li> <li>Addressing misconceptions</li> </ul>
DEVELOP STRATEGY AND WORKPLAN	<ul> <li>Identify appropriate forms and channels of communication to persuade actors to act</li> <li>Identify advocacy opportunities (e.g. processes to develop national</li> </ul>
	<ul> <li>strategies around HIV and viral hepatitis, or around relevant commemoration days)</li> <li>Create advocacy opportunities through special events or activities that focus on a priority issue</li> </ul>
	<ul> <li>Define the steps needed to organize those involved in advocacy activities and define their responsibilities</li> <li>Define resource requirements</li> </ul>
	<ul> <li>Develop a workplan that includes advocacy activities at various levels (local communities and structures), with milestones and reviews</li> </ul>
TRAIN	<ul> <li>Provide training to leading health experts advising policymakers</li> <li>Ensure training for policymakers on a regular basis, taking into account changes in decision-making through elections and political changes</li> </ul>
IMPLEMENT	Implement the plan, reviewing progress and adapting as needed

Sources: [35, 58, 70]

#### BOX 10. COMMUNICATION AROUND OAT

Effective communication includes creative content segmented and appropriate for specific target audiences. Information should be presented in a way that is culturally appropriate, and in local language/s. Content should be developed for use in print media and social media and should be tested through focus groups. The use of personal stories can be powerful. Ensure the information is accurate and covers the benefits, effectiveness and relative risks of OAT and agonist medications.

#### CASE STUDY:

#### POLITICAL AND STAKEHOLDER SUPPORT FOR OAT IN MOROCCO

In Morocco there is high-level political support harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) are supported by national policy and guidelines. Over the past decade the Moroccan OAT and harm reduction programme has reduced HIV prevalence and injecting risk practices among people who inject drugs in the country [72]. OAT is provided through government health centres in community and closed settings [66]. Additional health and harm reduction services are provided in collaboration with civil society organizations. Drug possession and use is illegal in the country; however, law enforcement agencies are supportive of harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management). Advocacy has contributed to the expansion of the OAT programme.



#### FURTHER READING

Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions (IDUIT) (UNODC, 2017). http://bit.ly/2oghaxx

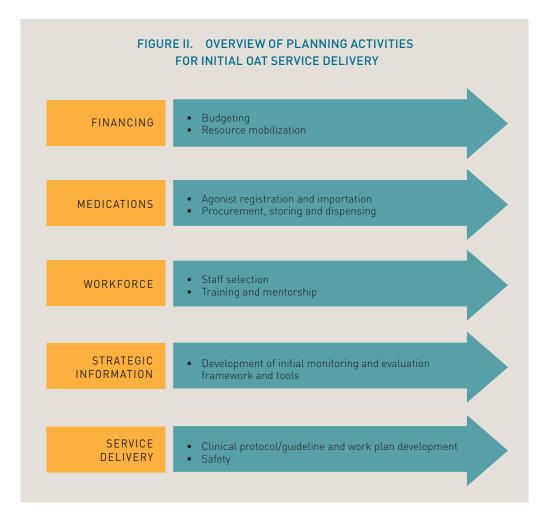
*Policy advocacy toolkit for medication-assisted treatment (MAT) for drug dependence* (USAID, 2010).

www.healthpolicyplus.com/archive/ns/pubs/hpi/Documents/1267\_1\_MAT\_ Toolkit\_FINAL\_09\_21\_acc.pdf

# CHAPTER 4. PLANNING OAT SERVICES

COMPONENT	INTERVENTIONS
ENGAGING PEOPLE WHO USE OPIOIDS	*
LEADERSHIP AND POLICY SUPPORT	*
FINANCING	*
MEDICATIONS	*
WORKFORCE	*
STRATEGIC INFORMATION	*
SERVICE DELIVERY	*

The effectiveness of OAT is well documented [5]. However, countries may require a demonstration project to assess the feasibility of OAT in their setting and inform local planning. Starting services in a limited number of sites initially is a way to focus on getting things right and demonstrating the feasibility and impact of OAT programmes, before rolling out to expand geographical reach. An operational structure (e.g. technical working group) is useful to plan, oversee, coordinate and manage initial OAT service delivery. Planning for initial OAT service delivery involves several activities (see figure II).



Co-location and collaborative provision of services that people with opioid dependence require in a single location in a community setting has many benefits [1]. The "one-stop-shop" approach reduces access barriers and can provide required drug use-related, health and social services in an acceptable manner within a supportive environment [10].

Where one-stop-shops are not possible, efforts are needed to maximize coordination and integration with substance use treatment and other services. Core services include HIV, viral hepatitis, primary health care and mental health services.

# 4.1 How to engage with people with opioid dependence in OAT service design

People with opioid dependence and people with previous opioid use should be involved in planning and working groups that design and oversee OAT services [35, 73, 74]

- Engage with representatives of different specific populations of people who use drugs, including women, young people and people in prison settings
- Assess priority needs of the community of people with opioid dependence in the geographic area where an OAT service is needed [35]

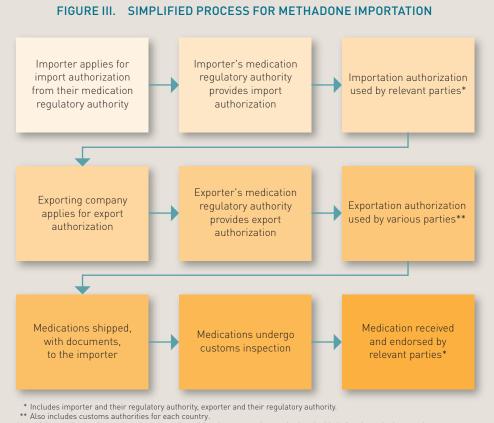
#### 4.2 How to finance initial OAT services

- Cost of OAT could be covered through domestic funds from the beginning
- Where this is not possible, partnership with donors and technical agencies could be explored to support financing of initial OAT services
- Reliance on self-funding for OAT imposes a significant barrier to people with opioid dependence and is not recommended

#### 4.3 How to import opioid agonist medication

The processes for importing methadone or buprenorphine are similar.

- The entity planning to import the methadone (e.g. Ministry of Health, civil society organization) engages with the local medications regulatory authority to obtain support for the process
- The national opioid agonist estimate should be submitted to the INCB six months in advance of when the medication is needed
- > The importation process may start once confirmation of the submitted estimate has been received from the INCB. The general process is shown in figure III [4].



Note: If the medication is not already registered, additional steps may be required to do this before it can be imported.

#### 4.4 How to document OAT service provision

Information should not be shared with police or law enforcement, unless with patients' approval or unless required by law [5].

Core components of documentation include [5]:

- A clinical governance document outlining processes for care
- OAT clinical guidelines should be available to clinical staff
- A record of health-care professional qualifications
- Record of patient's informed consent to treatment
- Up-to-date medical records for all patients, which are confidential and not to be shared
- Up-to-date pharmacy records, covering procurement, storage, dispensing and dosing
- A system for monitoring safety of the treatment service and medication diversion
- A system for collating de-identified summary statistics of OAT services and patients and data flow for national/donor reporting
- Documentation of human-rights violations of OAT patients by any employee, and measures taken in response [10]

#### 4.5 How to start an OAT service in a community setting

- Establish a centre with the requisite staff, including people with lived experience, to provide the range of services that meet the needs of OAT patients [75]
- Train staff on relevant aspects of OAT services in relation to their scope of work
- OAT prescribers can benefit from practical training and peer-to-peer mentorship from experienced providers
- Virtual support and mentorship can be explored, based on the context and available expertise and resources
- Ensure internal processes for collaboration and information-sharing to optimize care

#### 4.6 How to ensure safety of OAT services

The OAT programme should ensure the safety of patients, staff, infrastructure and medication.

- OAT service delivery staff and people with opioid dependence and community [35] representatives should be engaged to develop a code of conduct, or rules, for the centre
- Collaborative development of a code of conduct could cover issues relating to safety, respect and well-being of all, and actions/responses when these are violated
- Services could consider setting up a safety or peace committee to use restorative justice approaches to safety issues that arise [77]
- Rules could be included and discussed as part of the informed consent process when starting OAT

#### 4.7 How to continue advocacy for OAT

- Conduct training and advocacy with local stakeholders to obtain their support for the OAT service (local political and religious leaders, law enforcement, health and social services, civil society organizations, communities of people who use drugs)
- Develop and implement actions to address stigma and discrimination towards people who use drugs that highlight the need to respect the human rights of all people
- Create opportunities to learn from the experience of other OAT programmes through knowledge exchanges, study tours and by hosting technical experts and supportive political leaders
- Highlight the positive impact on public safety of offering accessible OAT. Highlight return of investment, using international data in the absence of local information

Sources for this section: [35, 58, 70]



#### FURTHER READING

International standards for the treatment of drug use disorders (WHO and UNODC, 2020). www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions (IDUIT) (UNODC, 2017). http://bit.ly/2oghaxx

Medicines supply: WHO work on supply systems (WHO, 2017). www.who.int/teams/health-product-policy-and-standards/ medicines-selection-ip-and-affordability/medicines-supply

Guide on estimating requirements for substances under international control (INCB, 2012)

www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating\_requirements/ NAR\_Guide\_on\_Estimating\_EN\_Ebook.pdf

Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO, 2009). www.who.int/publications/i/item/9789241547543

Toolkit for competent national authorities (INCB, 2005). www.incb.org/incb/en/narcotic-drugs/toolkit.html

# CHAPTER 5. **STARTING OAT SERVICES**

COMPONENT	INTERVENTIONS
ENGAGING PEOPLE WHO USE OPIOIDS	*
LEADERSHIP AND POLICY SUPPORT	*
FINANCING	*
MEDICATIONS	*
WORKFORCE	*
STRATEGIC INFORMATION	*
SERVICE DELIVERY	*

Initial OAT services can develop in an iterative manner. OAT service delivery should start without delay once the core elements are in place. Ongoing engagement with people with opioid dependence and other stakeholders (e.g. health-care providers, law enforcement and prison services) remain important in the early stages of OAT service delivery. Referral networks with other partners (health, social services etc.) can increase service offerings and support OAT continuity of care. Additional training and technical support for staff can help to increase the range of services provided at OAT service sites and to address challenges. From the outset, quality and retention within OAT services can be enhanced through inclusion of take-home doses for stable patients as part of standard practice.

#### 5.1 How to obtain additional stakeholder support for OAT

Continue the activities listed in section 4.7, and in addition:

- Foster community-led advocacy to address community and government concerns, by dedicated, salaried workers. Examples of activities include: meetings (formal and informal), public information campaigns, and engagement in multisectoral AIDS and drug policy coordination committees.
- Engage and work with civil society organizations participating in health, social and human rights services for people who use drugs
- Highlight the positive impact on public safety of offering accessible OAT. Highlight return of investment, using international data in the absence of local information
- > Enact local laws and by-laws to enable OAT provision

Sources for this section: [35, 58, 70]

#### 5.2 How to support continuity of OAT services

Continuity of OAT care is important for the benefits of OAT to be maximized. The disruptions caused by COVID-19 provided impetus to expand efforts to continue OAT care. In several low- and middle income country settings, this included wider use and longer periods of take-home dosing, and increased use of virtual support and support of people in emergency shelters [77]. These efforts supported retention of people in OAT care [27, 64]. Supporting continuity of care is important when an individual changes their OAT treatment centre (e.g. from a specialist treatment centre to a community-based centre, or from prison to a community setting). Continuity can be enhanced by:

- > Defining and mapping local treatment resources and care networks
- > Engaging and obtaining support from stakeholders for care continuation
- Fostering communication mechanisms between different treatment and care providers (e.g. between prison health services and community-based services)
- > Establishment and strengthening referral mechanisms
- Using referral letters or cards with details of treatment, dosing and contact details of OAT treatment providers [35]
- > Implementing systems for care coordination, case management and navigation [10]

#### CASE STUDY:

#### OAT SERVICE DELIVERY DURING COVID-19 IN MOROCCO

The COVID-19 pandemic led to the closure of the borders of Morocco and increased health service demand for radiological services, disrupting TB services and halting OAT initiations. Civil society organizations responded quickly to COVID-19, collaborating with communities of people who use drugs, medical centres and the Ministry of Health. The Ministry of Health, civil society organizations and health-care workers mobilized and collaborated to avoid potential OAT treatment interruptions. New operating procedures enabled individualized assessment for the provision of take-home dosing of up to a month. Civil society organizations supported implementation and linked with people who use drugs experiencing homelessness to continue nutrition support and enable registration and access to support provided by the government. These organizations also provided access to personal protective equipment. The change in dosing policy enabled the retention of many people on the OAT programme without major safety concerns, and demonstrated the benefits of further lowering thresholds of care.

#### 5.3 How to expand the package of OAT services

- Develop national and local policies that integrate HIV, viral hepatitis and TB prevention, testing and treatment and primary care services in health-care settings
- Implement interventions to address critical enablers, including supportive environments and supportive policy reform
- Develop systems for medical products required for HIV, viral hepatitis, TB, mental health and primary care services (e.g. diabetes, hypertension) to be available at OAT sites
- Enhance the suite of psychosocial services offered (e.g. gender-based violence, crisis intervention, family interventions)
- Explore options to provide access to legal services
- Provide training for OAT clinicians to be able to offer integrated services
- Provide infectious disease, mental health and primary care services from OAT service delivery sites, and routine screening for common infectious disease, mental health and primary care conditions, during initial diagnostic assessment and periodically thereafter
- Layer interventions onto OAT services over time as efficiency, resources and capacity develop
- Establish and support referral pathways, with supported/navigated referral where possible to services that are not available on site

Sources for this section: [10, 35, 49]

### 5.4 How to use community-based network models to increase access to services

In a network model the OAT site forms the central point of a network of service providers. Steps in a network-based approach include [10, 35, 75]:

- Assess priority needs of the community of people with opioid dependence
- Map health and social services (fixed and mobile, government and non-government, community-led) in the geographic region/community [10]
- > Develop a referral network by establishing formal and informal partnerships [78, 79]

- Conduct inter-agency cross-training of staff to enhance capacity to provide highquality services that meet the needs of people with opioid dependence [1]
- Develop and implement a case management (care coordination) system, including processes for individualized assessment, care plan development and confidential information exchange between health and social service providers in the network [75]
- Establish mechanisms for network partners to engage and share lessons and develop solutions to mutual problems [75]



International standards for the treatment of drug use disorders (WHO and UNODC, 2020)

www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

One-stop shop model (Rural Services Integration Toolkit) (Rural Health Information Hub, 2018).

www.ruralhealthinfo.org/toolkits/services-integration/2/one-stop-shop

Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions (IDUIT) (UNODC, 2017). http://bit.ly/2oghaxx

*Comprehensive case management for substance abuse treatment* (US Department of Health and Human Services, 2015).

https://permanent.fdlp.gov/gpo29863/TOC.pdf

Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO, 2009). www.who.int/publications/i/item/9789241547543

#### 5.5 How to safely provide take-home doses

Steps for safe take-home dosing include [5]:

- Ensure staff are appropriately trained on OAT service delivery
- Develop a take-home policy informed by best practice, providing take-home doses for patients on maintenance doses who are clinically stable (patients feel that their mental and physical health is stable). Abstinence from illicit drugs should not be a requirement for take-home dosing
- Requirements of a stable social situation (e.g., housing) may be considered as an additional condition [64]
- Provide additional counselling around the risks of inadvertent overdose and steps to maximize safety, including provision of naloxone [80]
- Patients at high risk of overdose should be identified and provided with additional support and access to other psychosocial services, including telehealth options [64]
- Start with an initial trial of take-home doses, and increase incrementally
- Periods of one to four weeks could be considered

- The period of take-home dosing could move towards the prescribing practices for other chronic conditions, based on local policies
- Access to take-home dosing can be improved through support provided by peer workers and community-based services (e.g. pharmacies)
- Include a system for assessing take-home doses and revert to supervised dosing if needed, based on change in social status or physical or mental health
- Include systems to monitor, report and act on diversion



*Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence* (WHO, 2009).

www.who.int/publications/i/item/9789241547543

#### 5.6 How to manage opioid withdrawal

Medically managed opioid withdrawal aims to stabilize a patient's physical and psychological health while managing the symptoms associated with a reduction or cessation of opioid use [5]. Medically managed opioid withdrawal should be followed by interventions to support patients in maintaining their treatment goals [5].

Return to use after withdrawal management is common. Detoxification decreases tolerance to opioids and increases the risk of opioid overdose. Better health outcomes are associated with long-term maintenance OAT, compared with detoxification [5]. If opioid withdrawal services are provided, they should be part of an integrated approach. The choice of treatment is a collaborative process between the clinician and patient, informed by clinical expertise and the patient's preference and consent [5].

- Make community-based detoxification centres available and accessible
- Detoxification can be done using diminishing daily, supervised doses of opioid agonist medications and symptomatic control, following clinical guidelines [5]
- Psychosocial services should be routinely offered to patients undergoing pharmacological treatment of opioid withdrawal
- Patients who are motivated to abstain from opioid use may benefit from the use of naltrexone (opioid antagonist) as part of relapse-prevention following detoxification [10]



#### FURTHER READING

International standards for the treatment of drug use disorders (WHO and UNODC, 2020).

www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO, 2009).

www.who.int/publications/i/item/9789241547543

#### 5.7 How to prevent and manage opioid overdose within OAT services

The inclusion of overdose prevention and management services, with take-home naloxone, within OAT programmes is essential [35]. The periods of highest risk of overdose among patients on OAT are in the first few weeks of treatment if OAT is interrupted, and at other times when opioid tolerance is reduced, including the first few weeks after stopping OAT. The Stop Overdose Safely initiative has demonstrated the feasibility of take-home naloxone in low- and middle income country contexts [81].

Key steps include:

- > Ensure naloxone is registered, affordable and available
- Consider various naloxone formulations, including nasal formulation for easy administration by non-medical personnel
- Assure access to community distribution of naloxone to patients, family and other first responders [80]
- Provide training on overdose (risks, identification and management) to staff, OAT patients and people in their support network
- Train OAT staff on precautions to take regarding the rate of dose increase among patients being initiated onto methadone
- Counsel patients regarding the elevated risk of overdose due to use of other substances including sedatives, alcohol and benzodiazepines, and about the times and situations of elevated risk of overdose



#### FURTHER READING

Stop Overdose Safely initiative (UNODC and WHO, 2021). www.unodc.org/unodc/en/frontpage/2021/May/stop-overdose-safely\_-howunodc-and-who-save-lives-by-managing-opioid-overdose-in-kazakhstan-kyrgyzstan--tajikistan-and-ukraine.html

Community management of opioid overdose (WHO, 2014). www.who.int/publications/i/item/9789241548816

# 5.8 How to manage concomitant use of opioids, stimulants, alcohol and other drugs

People on OAT may concurrently use opioids, stimulants, alcohol and other drugs. Concurrent use of drugs while receiving OAT medications should not lead to exclusion from OAT. The use of opioids may indicate insufficient dosing. The use of stimulant drugs may be due to agonist-related fatigue, or the desire to experience pleasure or remain connected with the community of people who use drugs [82–85]. Alcohol use disorders are common among people with opioid dependence. Some concurrent stimulant drug use may affect retention on OAT or may increase sexual and drug-related risks for HIV and viral hepatitis infections. Efforts to reduce the potential harms of alcohol, tobacco and drugs and maximize patients' benefits while on OAT could include [35, 85]:

• Using validated screening tools [86] (e.g. the WHO Alcohol Smoking and Substance Involvement Screening Test or ASSIST) [87]<sup>3</sup> as part of Screening Brief Intervention and Referral to Treatment (SBIRT) for alcohol and other drugs

<sup>&</sup>lt;sup>3</sup>ASSIST was developed for use in non-specialized health settings (e.g. primary-care clinics).

- Psychosocial/counselling interventions to reduce alcohol and drug use based on an evidence-based approach, for example motivational interviewing
- Urine drug tests applied as a standard clinical intervention may be considered [10] with the patient's consent, but should not be used for punitive purposes or as a threat to continuation on OAT. If a patient tests positive this should be the basis of a discussion between provider and patient regarding appropriate dosage
- Conduct brief interventions for patients with non-dependent use of other drugs aimed at reducing risks [10]
- Offer patients with high-risk drug use involvement scores, or poly-drug dependence, access to additional support and treatment services
- Assess social, mental-health, physical and OAT-related issues that may be contributing to concomitant drug use
- The Addiction Severity Index is a more detailed assessment which can be used to assess alcohol and drug use and other domains (medical, employment, legal, family and psychiatric) [88] among patients on OAT



mhGap intervention guide: version 2.0 for mental, neurological and substance use disorders in non-specialised health settings (WHO, 2019) www.who.int/publications/i/item/9789241549790

*HIV prevention, treatment, care and support for people who use stimulant drugs* (UNODC, 2019).

www.unodc.org/documents/hiv-aids/publications/People\_who\_use\_drugs/19-04568\_HIV\_Prevention\_Guide\_ebook.pdf

*Treatment of stimulant use disorders: current practices and promising perspectives* (UNODC, 2019).

www.unodc.org/documents/drug-prevention-and-treatment/Treatment\_of\_ PSUD\_for\_website\_24.05.19.pdf

*The Alcohol, Smoking and Substance Involvement Screening Test* (ASSIST) (WHO, 2010). www.who.int/publications/i/item/978924159938-2

# CHAPTER 6. Rolling out services

COMPONENT	INTERVENTIONS
ENGAGING PEOPLE WHO USE OPIOIDS	*
LEADERSHIP AND POLICY SUPPORT	*
FINANCING	*
MEDICATIONS	*
WORKFORCE	*
STRATEGIC INFORMATION	*
SERVICE DELIVERY	*

The roll-out of OAT services should be planned, financed, maintained and adapted towards achieving high coverage (i.e. above 50 per cent) among people with opioid dependence. The capacity and number of authorized prescribers and dispensers of OAT should be enhanced for roll-out. OAT should be provided in community and prison/closed settings [60]. OAT services should be situated in locations where there are people with opioid dependence and these services should be accessible in an equitable manner [5, 49].

As the programme matures, efforts to enhance the literacy of people with opioid dependence around OAT can intensify. Representatives of communities of people who use drugs and OAT patients should be employed within OAT services and capacitated along a pathway of professional development [35].

Physical, mental-health, social and other services provided to patients can be expanded to further support wellness and individual and community empowerment. The roll-out of OAT should ensure access to OAT services tailored for specific populations (including women who use drugs) (see chapter 8).

# 6.1 How to work with community-led organizations and networks to support OAT roll-out

- Work with community-led organizations and networks to raise awareness and share accurate information around OAT [35]
- Empower people with opioid dependence, OAT patients and people with lived experience to refer and navigate patients to access OAT service sites
- Establish mutual aid groups for people on OAT, facilitated by people with experience of opioid dependence/OAT
- Support mechanisms for people with opioid dependence to connect with, support and counsel their peers to persist and (re-)engage in OAT and related services
- Where people with lived experience are employed by OAT service providers, there should be clear, relevant and uniform human resource policies, including equitable, non-discriminatory and supportive policies for people who use drugs [89]

#### 6.2 How to enhance the image of OAT among communities

- Train health-care professionals and social workers on the effectiveness of OAT and identify, explore and dispel OAT-related myths [49]
- Offer accurate information on the risks and benefits of OAT treatment to people with opioid dependence as well as interested family and community members
- Raise awareness of the benefits of OAT among different stakeholders and the wider community where a new service/site is planned
- Provide training for media on the nature, prevention and treatment of opioid dependence, especially OAT and harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management)
- Develop a communications strategy and plan, including a social-media plan with defined target audiences
- Engage with social-media influencers to promote evidence-based campaigns and services
- Enable ongoing dialogue between OAT specialist and patient communities and abstinence-oriented drug-treatment communities to reduce the ideological gap that may exist

- Encourage the formation of support groups for families and broader community members affected by opioid dependence and OAT
- Engage with networks of people who use drugs and people with lived experience of opioid use to share information and support OAT advocacy
- Develop and implement differentiated OAT services and avoid large cohort sizes at OAT sites

#### 6.3 How to foster support for OAT among law enforcement and police

- Develop mutual understanding and trusting relationships
- Provide information and address misconceptions about OAT, and highlight the benefit of OAT from a policing perspective
- Implement cooperation between harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) service providers and police services to encourage referrals from police to harm reduction services as a diversion from arrest
- Engage with courts and probation services to explore alternatives to conviction or punishment for people with opioid dependence charged with offences related to personal consumption, and other minor cases
- Link police to their peers in other countries where OAT and needle and syringe programmes, and naloxone for overdose management is supported, organize knowledge exchange sessions and study tours
- Support shifts in the police organizational culture towards public health and safety, and consult with the police at a high level when planning and expanding OAT and linked services
- Ensure regular consultation between law enforcement, community members, neighbours, OAT service delivery staff and representatives of the community of people who use drugs
- Develop agreements for police to not interfere with OAT services, and to provide information and voluntary referrals to harm reduction services (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) and enable OAT access while in police custody

Sources for this section: [41, 44, 90–91]



#### FURTHER READING

Police & Harm Reduction (Open Society Foundations, 2018). www.opensocietyfoundations.org/sites/default/files/police-harm-reduction-20180720.pdf

Training manual for law enforcement officials on HIV service provision for people who inject drugs (UNODC, 2014).

www.unodc.org/documents/hiv-aids/LE\_MANUAL\_02.10.14.pdf

# 6.4 How to develop operational structures to oversee and coordinate OAT roll-out

Clear oversight and management structures can enhance the efficiency, quality and safety of OAT services as they are rolled out. Steps towards this include [5][35]:

- Integrate OAT into the national strategy for the treatment and reduction of harm relating to drug use disorders.
- Establish a process of clinical governance to ensure safety and effectiveness, outlining the chain of clinical and medication accountability within the health-care system, as well as minimum standards, and roles and responsibilities of actors in OAT service delivery.
- > Set up a national coordinating and technical team that includes experts in health, social services, law enforcement, harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management), and the community of people who use drugs and other sectors to provide oversight, coordination and technical assistance for programme planning, implementation, monitoring and evaluation.

#### 6.5 How to develop national OAT clinical guidelines

Quality standards for OAT service delivery can be set through national OAT clinical guidelines. The guideline development process could involve the following steps [49]:

- Establish a multidisciplinary specialist working group, for example involving the Ministry of Health, a professional association, a university, clinicians and representatives of communities of people who use opioids and who formerly used opioids, as well as other stakeholders (e.g. donors and technical agencies).
- Adapt (and translate) existing WHO and UNODC guidelines (or from another country with similar background) that include an appraisal of available and up-to-date evidence. Guideline appraisal and selection can be informed through the use of validated tools (e.g., the Appraisal of Guidelines for Research and Evaluation (AGREE) has a range of tools to assist in the development, reporting and evaluation of practice guidelines and health system guidance).
- Technical support to adapt and develop clinical guidelines can be obtained from WHO and UNODC.
- > Obtain approval from the national authorities as required.



#### FURTHER READING

International standards for the treatment of drug use disorders (WHO and UNODC, 2020).

www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations, 2016 update (WHO, 2016). www.who.int/publications/i/item/9789241511124

Consolidated Guidelines on HIV, Viral Hepatitis and STI Prevention, Diagnosis, Treatment and Care for Key Populations (WHO, 2022) https://apps.who.int/iris/rest/bitstreams/1453332/retrieve Nine steps for developing a scaling-up strategy (WHO, 2010). https://apps.who.int/iris/handle/10665/44432

*Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence* (WHO, 2009).

www.who.int/publications/i/item/9789241547543

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument (AGREE Enterprise).

www.agreetrust.org/resource-centre/agree-ii/

#### 6.6 How to finance OAT roll-out

Steps towards sustainable financing may involve:

- Develop a costed plan for OAT programme roll-out
- Mobilize resources from multiple sources to implement the roll-out plan, including financing from municipalities
- Where donor funding supports OAT services, multi-year financial plans outline processes towards co-financing and transition towards sustainability

Sources for this section: [14, 40, 49, 56]

### 6.7 How to ensure uninterrupted access to affordable, high-quality opioid agonists and related medications

An uninterrupted supply of affordable, high-quality opioid agonist medication is the cornerstone of OAT services. Important steps include [49]:

- Ensure that OAT procurement is integrated into the national medical procurement and supply management system. WHO has guidance to enhance supply systems, product quantification and forecasting and procurement [92]
- Ensure good capacity without interruptions of supply
- Methadone and buprenorphine should be secured at affordable prices through pooled procurement, with exploration of importation or manufacturing (as appropriate)
- Multiple suppliers of agonist medications should be secured to avoid stock-outs and promote competition
- Prepare for emergency situations: have a stock of medication for emergency situation and a plan to ensure patients' access during periods of restriction on movement restrictions or in conflict situations.

### 6.8 How to strike a balance between safety, diversion and access to agonist medications

A range of interventions targeting procurement and supply management, OAT services, health professionals and OAT patients and the community can be employed to maximize access and minimize diversion (see table 8).

## TABLE 8. INTERVENTIONS TO ADDRESS DIVERSION AND MAXIMIZE SAFETYBY TARGET AREA

#### INTERVENTIONS TO PREVENT DIVERSION

Procurement and supply chain management

- Establish a system to identify instances where access control is compromised
- Develop an integrated pharmacy database
- Maintain a central, confidential health information/data system of OAT patients
- Conduct pharmacovigilance of treatment services and diversion
- Ensure that movement of opioids is only between authorized parties
- Ensure accountability of dispensing facilities for storage and dispensing
- Ensure good record management
- Ensure overall good clinical governance of treatment services in the health system
- Procure and provide a range of OAT medication options
- Have a stock for emergency situations

#### OAT service

- Maximize OAT coverage
- Remove costs related to accessing OAT
- Develop and implement attractive, welcoming, low-threshold services
- Remove requirements for registration as an opioid-dependent person, previous drug treatment attempts, or comorbidity to access OAT
- Encourage users of non-prescribed OAT medications to participate in OAT programmes
- Improve OAT treatment quality and ensure adequate dosing and duration of treatment
- Develop and implement institutional processes on supply management and reporting of controlled medications
- Appoint and designate staff members to be responsible for opioid medication controls
- Follow normative guidance for assessment, induction, maintenance and down-titration

#### Health professionals

- Train health professionals on high-quality OAT service delivery
- Conduct regular training to eliminate stigma and discrimination towards patients
- Develop a system to assess quality, safety and diversion of medications
- Conduct regular clinical audits of OAT practice
- Provide clear guidance on the criteria for take-home medication
- Prescribe safer drug formulations, based on patient preference, and childproof containers for take-home prescriptions

#### OAT patients and family members

- Educate with information on risks and efficacy of longer-term maintenance therapy with opioid agonists, and on safe storage for take-home medication
- Use a treatment agreement, clarifying that the sharing, swapping and selling of medication with others is unacceptable
- Provide supervised dosing in early phase of treatment, with assessment for take-home when requested by patient and when dose, clinical condition and social circumstances are stable
- Implement contingent actions, such as extending periods of take-home dose for improved wellbeing, or reverting to observed dosing if diversion is identified or well-being deteriorates
- Ensure access to social support and social services for all people in need, and where possible support access to housing and income generation



International standards for the treatment of drug use disorders (WHO and UNODC, 2020). www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

*Guide on estimating requirements for substances under international control* (INCB, 2012).

www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating\_requirements/ NAR\_Guide\_on\_Estimating\_EN\_Ebook.pdf

Medicines supply: WHO work on supply systems (WHO, 2017). www.who.int/teams/health-product-policy-and-standards/ medicines-selection-ip-and-affordability/medicines-supply

Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO, 2009).

www.who.int/publications/i/item/9789241547543

Toolkit for competent national authorities (INCB, 2005). www.incb.org/incb/en/narcotic-drugs/toolkit.html

#### 6.9 How to strengthen the workforce to support OAT roll-out

- Train OAT service providers to be empathic, welcoming, non-stigmatizing and to support patient motivation (e.g. through the use of motivational interviewing techniques)
- Implement stigma-elimination and joint-learning initiatives among health, social and related service providers. This could involve dialogues, training activities and awareness campaigns to create mindfulness of the harms of stigma, address irrational fears and challenge moral judgments around drug use and people who use drugs [70]
- Have clear job descriptions outlining roles and responsibilities for OAT team members, including peer counsellors and navigators
- Outline the OAT programme (and site/service), organizational hierarchy and reporting lines and lines of accountability
- Provide technical support to ensure protocols and procedures align with regulations and enable high-quality service delivery
- Conduct formal training of staff where OAT is/could be prescribed, and seek accreditation of training by medical universities
- Disseminate OAT clinical guidelines (print and soft copies), and make these available on relevant websites
- Implement a system of continuous on-site training, including peer-to-peer learning (including mentorship and support for new OAT prescribers)
- Establish criteria and processes for performance review of staff involved in OAT service delivery
- Include mechanisms to provide supervision and psychosocial support for staff to avoid burn-out and staff attrition

- Provide adequate payment, recognition and team building
- Enhance motivation of OAT staff by addressing security and health-service needs and developing a comfortable and welcoming service delivery environment

Sources for this section: [35, 49, 56, 57, 89, 93, 94]



#### FURTHER READING

Treatnet training package (UNODC) www.unodc.org/unodc/en/treatment-and-care/treatnet-training-package.html

#### CASE STUDY:

#### OAT ROLL-OUT IN KENYA

The first OAT clinic in Kenya was set up in Nairobi in 2014. The OAT programme falls under the management of the National AIDS and STI Control Programme. The national OAT programme was established in 2015. The service has scaled up to include a network of seven clinics across several counties. The one-stop-shop model enables the integration of health interventions for people who use drugs and HIV, STI, HBV, HCV and TB testing and treatment services with OAT. The programme has expanded to include people who use heroin through other administration routes. To address resource constraints, the country has adopted task-shifting and developed structured training programmes and supportive guidelines that have enabled clinical officers (health professionals with fewer years of training than medical doctors) to spearhead methadone prescribing, clinical care and OAT clinic management. Strong political leadership and support for harm reduction and the HIV response have resulted in increasing government investment in OAT over time. Multisectoral collaboration through a technical task team and coordinated, ongoing advocacy and sensitization have supported positive shifts in the political and cultural environment for effective implementation. Progress towards the sustainability of the services is on track. Continuity of care among OAT patients who enter the prison system is in place, and the first OAT clinic within a prison was established during the COVID-19 response. The piloting of buprenorphine and plans to enable OAT service decentralization - through mobile services and additional dispensing sites, along with potential take-home doses - will facilitate additional coverage and impact.

#### 6.10 How to handle a stock-out of OAT medications

Interruptions in the supply of opioid agonist medications have significant negative effects. For individuals, the threat of a stock-out is likely to have negative mental health impacts, and loss of confidence in the OAT programme. Many people on OAT will revert to illicit opioid use if there is an interruption in opioid agonist supply. Interruptions can also lead to overdose deaths [95].

Countries should carefully plan (and forecast) their agonist medication requirements to meet their needs and prevent stock-outs. Having access to a reserve stock in case of interruptions in stock may be warranted. INCB estimates can be changed at any time. Written supplementary requests noting the rationale and volumes required will be reviewed within five days of receipt. Currently there is limited guidance on how to manage stock-outs, but important steps include:

- Employ a system to identify and address potential stock-outs
- Assess availability of stock in other OAT centres/locations for use
- Engage with relevant national multisectoral platform(s) to resolve the crisis (e.g. National AIDS Programme, National Drug Authority)
- Engage with United Nations agencies and other donors to mobilize emergency support
- Engage with the local medication regulatory authority to obtain relevant permits for emergency importation/actions
- Contact INCB for emergency support to amend estimated volumes if changes in importation/exportation authorization are required
- Develop a communication plan with community-led organizations and networks on how to manage the process and support people with opioid dependence
- Ensure ongoing access and support to other needle and syringe programmes, naloxone for overdose management and other health services
- Intensify the provision of psychosocial support to OAT patients



#### FURTHER READING

Medicines supply: WHO work on supply systems (WHO, 2017). www.who.int/teams/health-product-policy-and-standards/ medicines-selection-ip-and-affordability/medicines-supply

*Guide on estimating requirements for substances under international control* (INCB, 2012).

www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating\_requirements/ NAR\_Guide\_on\_Estimating\_EN\_Ebook.pdf

Toolkit for competent national authorities (INCB, 2005). www.incb.org/incb/en/narcotic-drugs/toolkit.html

#### 6.11 How to collect and use strategic information to support OAT roll-out

Monitoring and evaluating OAT roll-out is important. This process should be linked into national strategic information processes and structures that relate to HIV, viral hepatitis and drug dependence treatment. Steps could include [35]:

- Develop a monitoring and evaluation framework
- Develop a logic model for the OAT programme
- Define milestones and targets for roll-out
- Define a national set of indicators
- Conduct routine monitoring and data-quality assurance processes
- Plan evaluations to assess progress and outcomes during the roll-out time frame
- Ensure privacy and data protection

- > Ensure regular reporting and collation of data at national level
- Conduct regular reviews and triangulation of data, and develop data-informed quality improvement plans
- Where digital health applications are used, ensure interoperability of platforms for continuity of care and patient tracking



Monitoring guide and toolkit for HIV prevention, diagnosis, treatment, and care programs with key populations (FHI360, 2020).

www.fhi360.org/sites/default/files/media/documents/resource-linkagesmonitoring-tools.pdf

Tool to set and monitor targets for HIV prevention, treatment and care for key populations (WHO, 2015).

https://apps.who.int/iris/handle/10665/177992

WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users (2012 revision) (WHO, 2012).

www.who.int/publications/i/item/978924150437

Nine steps for developing a scaling-up strategy (WHO, 2010). www.who.int/reproductivehealth/publications/strategic\_approach/9789241500319/en/

#### 6.12 How to differentiate OAT service delivery

OAT services can be available across all levels of the health system (primary care to hospitals) and in the public, private and non-governmental sectors. OAT can be initiated and continued in the community and in prison and other closed settings [5, 96]. Table 9 outlines examples of differentiated care with respect to patient population, location and service provider [97].

SETTING	COMMUNITY HEALTH SERVICE	HOSPITAL	PRISON/ CLOSED SETTING
FOR WHOM	• Patients with opioid dependence [98] without complicated comorbidities	<ul> <li>Patients with special clinical needs (e.g. pregnant women with gestational hypertension and opioid dependence)</li> <li>Patients admitted to hospital for other health conditions</li> <li>Patients accessing emergency services</li> </ul>	<ul> <li>People who are arrested and incarcerated, on remand or who are sentenced, or placed in closed settings</li> </ul>
WHERE	<ul> <li>Harm reduction (needle and syringe programmes, opioid agonist therapy and naloxone for overdose management) centres</li> <li>Mobile OAT services</li> <li>Primary care clinics</li> <li>Drug treatment centres</li> <li>Doctors' offices and community pharmacies</li> </ul>	<ul> <li>Emergency units</li> <li>Hospital wards</li> <li>Outpatient clinics</li> </ul>	<ul> <li>Police holding cells</li> <li>Detention centres</li> <li>Prisons and correctional facilities</li> </ul>
вү whom	<ul> <li>Trained nurse/ physician's assistant</li> <li>Doctor (generalist and/or specialist)</li> <li>Pharmacist</li> <li>Peers</li> <li>Counsellors</li> </ul>	<ul> <li>Doctor (generalist and/or specialist)</li> <li>Pharmacist</li> <li>Counsellors</li> </ul>	<ul> <li>Nurse/physician's assistant</li> <li>Doctor</li> <li>Pharmacist</li> <li>Counsellors</li> </ul>
HOW	<ul> <li>One-stop-shop approach</li> <li>Community-based network approach [10]</li> </ul>	Specialist treatment services [10]	<ul> <li>Treatment services for people in prison and closed settings [99]</li> </ul>

#### TABLE 9. EXAMPLES OF DIFFERENTIATED OAT SERVICE DELIVERY

Source: Adapted from IAS Differentiated Care Decision Framework (2018) [97]



#### FURTHER READING

International standards for the treatment of drug use disorders (WHO and UNODC, 2020).

www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

Differentiated service delivery for HIV: a decision framework for differentiated antiretroviral therapy delivery for key populations (International AIDS Society, 2018).

www.differentiatedservicedelivery.org/Portals/0/adam/ Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision Framework Key Population Web\_Post\_Conference\_FINAL.pdf

#### 6.13 How to maximize availability and coverage of OAT services

OAT services should be designed to be accessible to those who require them and be based on a clinical assessment [40]. Services should be delivered using a low-threshold approach to maximize access in terms of availability, accommodation, accessibility, acceptability and affordability (see table 10), and as part of a continuum of care.

# TABLE 10. INTERVENTIONS TO MAXIMIZE OAT ACCESS USING A LOW-THRESHOLD APPROACH, BY ACCESS DIMENSION

DIMENSION	LOW-THRESHOLD APPROACH AND INTERVENTIONS TO INCREASE ACCESS
AVAILABILITY	<ul> <li>Plan, implement and roll out OAT so that capacity meets demand</li> <li>Generate demand among people with opioid dependence through outreach, community-led organizations, social networking, peers and service delivery</li> <li>Decentralize and integrate services</li> </ul>
ACCOMMODATION	<ul> <li>Offer OAT to all people with an opioid dependence, irrespective of mode of use, age, sex, gender or engagement in marginalized activities</li> <li>Provide differentiated care for populations with special clinical needs</li> <li>Include sensitization training for staff</li> <li>Provide mechanisms for patients to report discrimination and have systems in place to address complaints</li> </ul>
ACCESSIBILITY	<ul> <li>Avoid waiting lists, make same-day induction available</li> <li>Urine drug testing should not be used in a punitive manner that could limit access to OAT. If the patient tests positive this should be the basis of a discussion between provider and patient regarding appropriate dosage</li> <li>Have flexible admission criteria</li> <li>Provide services during times that suit the needs of patients</li> <li>Locate services where they are easily accessible to diverse patients, including primary-care and community settings</li> <li>Provide outreach and mobile OAT service delivery, and consider online services where appropriate</li> <li>Individualize treatment to the patient's needs</li> <li>Offer flexible access to methadone and buprenorphine</li> <li>Allow patients to remain on OAT as long as needed</li> <li>Anticipate the concurrent use of opioids and other drugs for non-medical purposes, and support patients who non-medically use opioids and other drugs while on OAT</li> <li>Support take-home dosing – make available the option for take-home for all stable patients, including through pharmacy pick up</li> <li>Offer flexibility around discharge and re-entry into OAT</li> <li>Invest in critical enablers to address stigma and discrimination, and training for health-care workers and law enforcement</li> </ul>

DIMENSION	LOW-THRESHOLD APPROACH AND INTERVENTIONS TO INCREASE ACCESS
ACCEPTABILITY	<ul> <li>Assure voluntary and informed consent</li> <li>Ensure confidentiality</li> <li>Provide high-quality services, including responding to patients' requests to increase or decrease their dose</li> <li>Create safe and supportive environments</li> <li>Adapt service protocols and procedures in light of the specific context (hospital versus general practitioner office) and for populations with special clinical needs (e.g. pregnant women with opioid use disorders)</li> <li>Tailor services to meet patient needs, and adapt the service based on community monitoring and patient feedback</li> <li>Provide integrated access to HIV, viral hepatitis, overdose, sexual and reproductive health and other core health services</li> </ul>
	<ul> <li>Offer integrated social service support</li> <li>Train health-care providers on issues relating to people who use drugs and OAT</li> <li>Avoid involuntary discharge from OAT services</li> <li>Community engagement: Ensure acceptability of service site in the community where the OAT service is located (including using mobile services), provide information and maintain communication</li> <li>Ensure service monitoring and evaluation in line with nationally relevant standards to demonstrate the public-health and public-safety impacts of service provision</li> </ul>
AFFORDABILITY	<ul> <li>Ensure sustainable resources</li> <li>Provide services at no or low cost to patient</li> <li>Reduce operational costs through efficient delivery approaches and coordinated approach at (health) systems level</li> </ul>

Sources: [40, 60, 62, 96]

#### 6.14 How to provide OAT in rural areas

The prevalence of opioid dependence in rural and remote areas in many parts of the world has been documented [11]. Access to OAT is often lower in rural areas, partly due to limited treatment facilities and professionals, geographic and transport barriers and challenges with anonymity, stigmatization and criminalization [4]. Steps towards providing OAT in remote areas include [4]:

- Assess opioid use and treatment needs, planning and implementation in remote and rural areas
- Plan OAT service, including the model of service delivery, in light of the context and resources, and plan to appropriately capacitate the workforce
- A community-based system of care can be adopted and used, placing OAT services within existing primary health-care services, with engagement and support from other community services
- Prioritize take-home dosing for stabilized patients
- Explore support from peers and other community-based support services to support retention on OAT
- Use technology to support access to specialist support, using tele-health and mobile phones [100]
- Develop specialist centres at a district/regional level for people with severe conditions or complex comorbidities.



International standards for the treatment of drug use disorders (WHO and UNODC, 2020).

www.unodc.org/documents/drug-prevention-and-treatment/UNODC-WHO\_ International\_Standards\_Treatment\_Drug\_Use\_Disorders\_April\_2020.pdf

One-stop shop model (Rural Services Integration Toolkit) (Rural Health Information Hub, 2018).

www.ruralhealthinfo.org/toolkits/services-integration/2/one-stop-shop

Prevention of drug use and treatment of drug use disorders in rural settings (UNODC, 2017).

www.unodc.org/documents/17-01904\_Rural\_treatment\_ebook.pdf

# CHAPTER 7.

# INCREASING THE SUSTAINABILITY OF OAT PROGRAMMING

COMPONENT	INTERVENTIONS
ENGAGING PEOPLE WHO USE OPIOIDS	*
LEADERSHIP AND POLICY SUPPORT	*
FINANCING	*
MEDICATIONS	*
WORKFORCE	*
STRATEGIC INFORMATION	*
SERVICE DELIVERY	*

Ideally, OAT would be provided in primary health-care settings, with liaison to specialized services to support clinically complex cases. Over time, reliance on donor funding, if appropriate, should reduce (see case study: Towards OAT sustainability in Ukraine) and OAT should become part of universal health coverage. Progress towards integration of OAT into the public health-care system and increasing efficiencies, for example through task-shifting (see case study on OAT roll-out in Kenya), will support sustainability. Ultimately, mature OAT programming will enable ongoing high-quality OAT and provide opportunities and support for networks and organizations of people who use drugs to focus on other community priorities. Routine OAT programme monitoring and quality assessment should take place and inform health systems strengthening needs and service adjustments (see section 7.5).

## 7.1 How to empower community-led organizations and networks to lead sustainability efforts

- Support people with opioid dependence and people with lived experience of opioid use to lead OAT community monitoring (including collection of, and action on, OAT service-related complaints and compliments)
- Provide access to financial resources (including support for core operating and overhead costs) and technical support for community-led organizations and networks [73]
- Include representatives of people who use drugs and people with previous use in national multisectoral HIV, viral hepatitis and drug prevention and treatment coordinating and funding structures
- Support community-led organizations and networks in conducting relevant advocacy [73]
- Support the establishment and capacity development of groups led by people who use drugs and people with lived experience of drug use
- Support links between people who use drugs and regional and international networks of people who use drugs for technical assistance and support

#### CASE STUDY:

#### COMMUNITY MONITORING OF OAT SERVICES IN UKRAINE

Community empowerment has been pivotal in the success of OAT in Ukraine. In 2008, the Association of OAT Clients in Ukraine was established to advocate for the rights of people who use drugs, raise awareness around OAT and support people on OAT, their families and communities. A decade later, the Ukrainian Network of People who use Drugs (VOLNA) was established, in part to monitor government commitment to ensure ongoing access to, and roll-out of OAT after transitioning to domestic financing. In 2019, researchers from the Support, Research and Development Centre worked with VOLNA, Drug-Users Ukraine, the Drop-In Centre and the ENEY to conduct an OAT patient satisfaction survey. The study recruited patients at government-, donor- and privately funded OAT sites in two regions of Ukraine. Between 30-40 per cent of patients in the study had access to take-home agonist medication. The mixed-method assessment identified patient dynamics of satisfaction with treatment and the OAT service environment as well as interactions with service providers and their subjective treatment experiences. It identified a "paradox of satisfaction": although participants were happy to access OAT because it helped them to function in their daily life, more than half noted room for improvement in the overall quality of care, particularly regarding the social and psychological support services provided. The study highlighted areas to improve OAT quality that would likely increase long-term retention. It also identified other issues for future advocacy on the value of measuring quality of life on treatment outcomes, enhanced service integration, and for ongoing human rights protection.

Source: EHRA (2020) [58]



On the a-gender: community monitoring tool for gender-responsive harm reduction services for women who use drugs (INPUD, 2020).

https://inpud.net/on-the-a-gender-community-monitoring-tool-for-genderresponsive-harm-reduction-services-for-women-who-use-drugs/

Community-led monitoring tools (PEPFAR Solutions Platform, 2020). www.pepfarsolutions.org/resourcesandtools-2/2020/3/12/ community-led-monitoring-implementation-tools

Words matter! Language statement & reference guide (INPUD, 2019). www.inpud.net/en/words-matter-language-statement-reference-guide

Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions (IDUIT) (UNODC, 2017). http://bit.ly/2oghaxx

#### CASE STUDY:

#### SUSTAINABLE OAT SERVICES IN THE ISLAMIC REPUBLIC OF IRAN

The Islamic Republic of Iran has one of the world's largest harm reduction programmes. The emergence of the HIV epidemic among people who inject drugs was noted at the turn of the century. OAT is available through a network of private, registered OAT clinics and also through low-threshold government services. Needle and syringe programmes have extensive coverage in community settings, and OAT services are well integrated within the prison system. A network of women-specific centres is also well established. A civil society organization started the first OAT maintenance programme in 1999, using buprenorphine; this was followed by two research studies over the following three years using methadone. OAT was then adopted in light of demonstrated effectiveness, and provided in community and prison settings [101]. Needle and syringe programmes, provided via drop-in centres and outreach programmes, expanded in parallel. Support from political leaders, the media, religious leaders and communities provided the enabling environment needed for an effective response. In 2019, OAT was available at over 5,000 treatment centres (including services provided by civil society organizations), serving over 450,000 patients (± 90 per cent receiving methadone, and 10 per cent buprenorphine), including 50,000 patients within prisons [102]. Of the 90,000 people who inject drugs in the Islamic Republic of Iran, 28 per cent are receiving OAT [103]. The provision of affordable, appropriately dosed agonist medications for as long as people need it, in a low-threshold approach, has significantly reduced HIV incidence among people who use drugs in the Islamic Republic of Iran [103], reduced trends in injecting opioids and averted the associated morbidity and mortality [101].

#### 7.2 How to sustainably finance OAT services

The WHO Universal Health Coverage Compendium includes OAT as an essential service that countries should include as part of the national health-benefit package's primary health-care package, funded through domestic health budget allocation sources (e.g. national health insurance) [104].

- Opioid agonists should be included in the state-reimbursed medicine list/essential medicine list and should be funded from public sources [10].
- Countries should secure appropriate allocation of health, social-services and drugcontrol budgets towards OAT, and ensure resource pooling and central procurement to obtain affordable medications and commodities.
- Countries should implement OAT using well-demonstrated and efficient models.



#### TOWARDS OAT SUSTAINABILITY IN UKRAINE

An estimated 350,000 people inject drugs in Ukraine, and about one in five people of these is living with HIV [105]. Increasing access to OAT over the past 16 years has been an important element of the national HIV response for people who inject drugs. Rollout has taken place through a network of public- and private-sector OAT service providers, alongside expanded access to needle and syringe programmes [106]. The country's commitment to sustainable domestic financing has set an example for other countries [107]. Local production of methadone and buprenorphine has increased access to affordable opioid agonist medication. Strong civil society involvement, including organizations led by people who use drugs, in partnership with state actors and donors has enabled advocacy for harm reduction service delivery. Community-led advocacy and monitoring has contributed to the expansion and changes in legislation and policy to support OAT service delivery [58, 106]. Advocacy has also led to the removal of compulsory registration to access OAT. The OAT programme has increased access to opioid dependence treatment and HIV services, and has improved adherence to ART and TB treatment among patients on OAT [108–110].



#### FURTHER READING

Measuring the sustainability of opioid agonist therapy (OAT) – a guide for assessment in the context of donor transition (Eurasian Harm Reduction Association, 2020).

https://harmreductioneurasia.org/harm-reduction/ost/ ost-assessment-methodologies/oat-sustain-method/

What does universal health coverage mean for people who use drugs: a technical brief (INPUD, 2019).

https://idpc.net/publications/2019/09/what-does-universal-health-coveragemean-for-people-who-use-drugs-a-technical-brief

#### 7.3 How to develop human resources for OAT in a sustainable way

- Ensure that the national legal framework allows for trained medical doctors and, where possible, physician's assistants/professional nurses to prescribe OAT medication, and for professional nurses to dispense medication
- Align institutional treatment policies and quality assurance procedures and relevant indicators with recommendations and quality indicators set by normative bodies or national guidelines
- Describe the relevant capacities required to prescribe and dispense OAT
- Include training on OAT and clinical guidelines in undergraduate medical, psychology, pharmacy, nursing and social work training, as well as specialist postgraduate training

#### CASE STUDY: OAT ROLL-OUT IN VIET NAM

Political support, enabling policy and the success of a two-site pilot programme have enabled Viet Nam to scale up OAT services since 2008. By the end of 2020, there were 344 OAT clinics serving 53,383 people on methadone and buprenorphine. Investment in OAT reflected a move away from the use of compulsory detention centres as a response to opioid dependence. OAT services were integrated as part of national HIV/AIDS response activities. Technical guidelines (including quality assurance processes and supervision) and training materials were used to build a strong network of OAT service providers and facilities across the country. Many people access OAT through needle and syringe programmes, which have extensive coverage. An impact evaluation 10 years after initiation reflected reduced opioid use, fewer violations of the law, reduced HIV risk practices, reduced HIV incidence, enhanced quality of life and better community integration among people who inject drugs in Viet Nam. Take-home methadone dosing and buprenorphine-based treatments are being piloted. Efforts are being made to include OAT under National Health Insurance. Innovations are being conceptualized to manage the rising prevalence of amphetamine-type substance use in general and among patients on OAT.

Sources: [111, 112]

# 7.4 How to collect and use strategic information in a mature OAT programme

This process should be linked into national responses to HIV and viral hepatitis, and drug dependence treatment. Steps could include [35]:

- Revise the monitoring and evaluation framework as appropriate, with a view to integrating key indicators into broader primary health-care service surveillance
- Conduct routine monitoring and data quality assurance processes
- Conduct regular evaluations (either integrated with or separate from biobehavioural surveys), triangulating data from monitoring, research, community feedback and surveillance to assess impact and for quality improvement
- Where digital health applications are used, ensure interoperability of platforms for continuity of care and patient tracking
- > Data collection should be disaggregated by sex, age group, ethnic group and geographical distribution

#### 7.5 How to sustain high-quality OAT services

- Set up routine quality assurance mechanisms to ensure that institutional/site procedures align with guidelines and best practice
- Include mechanisms for regular external review and support (e.g. peer review or interdisciplinary intervisions)<sup>4</sup>
- Include a system for regular consultation with patients, and provide mechanisms for anonymous feedback/complaints, and evaluations and feedback from community monitoring

<sup>&</sup>lt;sup>4</sup>An intervision is a peer learning method among a group of equals guided by a chairperson, focusing on improving individual staff functioning or on improving services.

- Ensure regular inspections/audits by external authorities, funding bodies and institutional internal quality-control services – of medical records for fidelity to guidelines and to legal requirements, and develop and implement quality improvement plans to address any gaps identified
- Regularly review programmatic monitoring and evaluation data, and special research and surveillance data, to inform areas for quality improvement

Source for this section: [49]



#### FURTHER READING

Monitoring guide and toolkit for HIV prevention, diagnosis, treatment, and care programs with key populations (FHI360, 2020).

www.fhi360.org/sites/default/files/media/documents/resource-linkagesmonitoring-tools.pdf

Intervision guidelines (UNODC Project Office for the Baltic States, 2010). www.unodc.org/documents/balticstates/Library/PharmacologicalTreatment/ IntervisionGuidelines/IntervisionGuidelines.pdf

# CHAPTER 8.

OAT SERVICES FOR SPECIFIC POPULATIONS

#### 8.1 How to provide differentiated OAT services for specific populations

A one-size-fits-all approach to OAT services will not be appropriate for people with various needs. In addition to differentiation by care setting, the unique needs of specific groups of people with opioid dependence should be addressed. Steps towards this include [20, 21, 35]:

- Engage with people who use drugs and their communities to obtain insights into specific groups of people who use drugs and their needs
- Collaboratively develop and adapt OAT service delivery to be gender-responsive and to meet the needs of specific populations following evidence-based guidance, for example women (including pregnant women), young people, trans and genderdiverse people, sex workers, people in prison and closed settings, people with disabilities
- > Tailored OAT services are also needed for people with opioid dependence from ethnic and religious minority groups, migrants, refugees and in emergency settings
- Ensure people with community-connectedness to the specific population of focus are part of OAT service delivery teams
- Differentiated service delivery for people experiencing homelessness could involve: use of mobile OAT services; provision of services from a drop-in centre that provides other services (e.g. nutrition and hygiene services) [24]
- Conduct regular, routine assessments of performance and quality and adjust services accordingly



#### FURTHER READING

Harm reduction: key principles in homelessness services (Correlation - European Harm Reduction Network, 2021).

http://fileserver.idpc.net/library/211019\_HR20Key20Principles20FINAL-compressed\_1.pdf

Adolescent and young key populations (ayKP) toolkit (UNICEF). www.childrenandaids.org/aykpToolkit

Step by step: preparing for work with children and young people who inject drugs (International HIV/AIDS Alliance, 2015).

https://youthrise.org/wp-content/uploads/2021/04/Harm\_Reduction\_Step\_by\_ step\_tool1-1.pdf

Kraft Center for Community Health mobile addiction services toolkit (Massachusetts General Hospital, 2019).

www.kraftcommunityhealth.org/wp-content/uploads/2020/01/Kraft-Center-Mobile-Addiction-Services-Toolkit.pdf

#### 8.2 How to tailor OAT services to the needs of women

Women with opioid dependence have unique needs. Those who are at the intersection of poverty, criminalization and motherhood face a particularly high risk of infectious diseases, affecting them as well as their households [113]. Globally, women who use drugs experience high levels of violence, exploitation, abuse and other forms of trauma [114, 115]. Social, traditional and gender roles and patriarchy contribute to the stigma affecting women who use drugs. The risks and challenges affecting women with opioid dependence who engage in sex work are compounded where these practices are criminalized [114, 116]. Separation of sexual,

reproductive, maternal and child health services from OAT programmes negatively affects access, retention and the health outcomes of women with opioid dependence [113]. The fear and threat of losing custody of children prevents many women with opioid dependence from accessing OAT services [113].

The gender-responsiveness of OAT services can be enhanced through these steps [117, 118]:

- Ensure clinical OAT guidelines and OAT policies reflect the needs of women (not limited to pregnancy, breastfeeding, clinical visits with children)
- Develop OAT policies and operating procedures that prevent trauma from being repeated (see table 11)
- Employ a diverse group of female staff, across all staff cadres
- Provide women-specific services
- Adopt approaches to engage women with opioid dependence in planning, implementing and monitoring OAT services
- Train, mentor and support staff to provide gender-responsive and gender-affirming care
- Integrate, or enable referrals to access, sexual and reproductive health (including STIs and cervical and breast cancer screening) and maternal and child health services
- Provide or refer for parenting and childcare support
- Provide clinical and sociopsychological assessment of women engaged in OAT who
  are caring for children, to assess areas where support or referral is needed
- Provide access to commodities that could support women, including separate washing facilities, nutrition support, pregnancy tests, condoms, child-care products, feminine hygiene products [119]
- Integrate or provide referral to access mental health care services, where available
- Integrate and provide gender-based violence and related services [119]
- Ensure information, education and communication materials include issues relevant to women with opioid dependence
- Provide access to legal support
- Enquire about the desire for including and engaging family, friends and the support system, and provide information and support based on the woman's decision
- Educate broader community stakeholders about opioid dependence and OAT to address stigma and misinformation and to promote support
- Build a community of support for women with opioid dependence, through inclusion of peer role models, woman-to-woman mentorship and safe spaces for women, and develop a resource list and network for women with opioid dependence
- Provide or refer women to income-generating activities
- Provide support for gender-based violence prevention, legal support to report gender-based violence and support and treatment for its victims

UNDERSTANDING THE SIGNS AND IMPACT OF TRAUMA	<ul> <li>At each level of OAT programmes, champions should be identified, trained and supported to ensure that trauma-informed care remains a priority</li> </ul>
	<ul> <li>Establish partnerships and referral networks of organizations providing trauma-informed care</li> </ul>
	<ul> <li>Train staff on trauma (causes, impacts, triggers, de-escalation and support techniques)</li> </ul>
RECOGNIZING AND RESPONDING TO SIGNS OF TRAUMA	<ul> <li>Establish and nurture trusting relationships</li> <li>Provide peer support by women with similar experiences</li> <li>Empower patients and provide choices</li> <li>Engage with women with opioid dependence</li> </ul>
PREVENTING THE REPETITION OF TRAUMA	<ul> <li>Ensure OAT service delivery environments are safe and calm</li> <li>Avoid stereotyping and stigma</li> </ul>

#### TABLE 11. CORE COMPONENTS OF TRAUMA-INFORMED OAT SERVICES

Source: [120]

### 8.3 How to provide OAT services during pregnancy

All women have a right to high-quality perinatal care. However, women who use opioids and who are pregnant or a parent face high levels of stigma, negatively affecting their access to care. OAT service providers should exemplify unconditional positive regard for all patients. OAT using methadone or buprenorphine is safe in pregnancy [121], and pregnant women dependent on opioids should be encouraged and supported to use OAT. Women who use drugs who are pregnant should have access to comprehensive and integrated services for prevention of mother-to-child transmission of HIV, HBV and syphilis [122].

- Support pregnant patients to mobilize relevant support structures and medical and social support as appropriate for their pregnancy and their OAT
- Ensure local guidelines follow evidence-based practice [121]
- Clinicians should ensure doses are adjusted based on the patient's experience while pregnant, including options for split doses
- Apply principles of trauma-informed care to perinatal services [118, 120]
- Counsel and support mothers around the safety of breastfeeding while on OAT
- Counsel patients about increased risk of overdose during pregnancy from use of illicit opioids
- Counsel patients about the risks of detoxification
- In the case of an opioid overdose during pregnancy, the benefits of providing naloxone outweigh the risks
- Ensure evidence-based management of infant withdrawal syndrome

#### 8.4 How to support breastfeeding among mothers on OAT

Breastfeeding enhances attachment between mother and infant and should be encouraged [121]. This is particularly important for women who may have feelings of guilt related to opioid use during pregnancy. The incidence and/or severity of neonatal withdrawal syndrome (also known as neonatal abstinence syndrome) among opioid-exposed infants may be reduced through breastfeeding/breastmilk. Lactation reduces the stress response and can be beneficial for women with opioid dependency post-partum [121].

Pregnant women who are on OAT should be counselled on the benefits of breastfeeding. Women on OAT who wish to stop breastfeeding may wean their children gradually to reduce the risk of development of withdrawal symptoms [121].

#### 8.5 How to support newborns of mothers on OAT

Neonatal withdrawal syndrome is diagnosed when a neonate shows signs of withdrawal from exposure to psychotropic substances in utero [121].

- Skin-to-skin contact is important regardless of feeding choice and should be encouraged for a mother with a substance use disorder who is able to respond to her baby's needs [121].
- Health-care facilities providing obstetric care should have a protocol in place for identifying, assessing, monitoring and intervening with neonates prenatally exposed to opioids, using non-pharmacological and pharmacological methods [121].
- An opioid should be used as initial treatment for an infant with neonatal opioid withdrawal syndrome, if required [121].



#### FURTHER READING

Addressing the specific needs of women who use drugs: prevention of mother-tochild transmission of HIV, hepatitis B and C and syphilis. Technical brief. (UNODC, 2021).

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Addressing the specific needs of women who inject drugs: practical guide for service providers on gender-responsive HIV services (UNODC, 2016).

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# ANNEX 1 Methodology

This tool was developed through an iterative process that included oversight and coordination from a working group; review of existing OAT guidance; country case study development; a targeted literature review; information synthesis; external review and document finalization. The project did not include a systematic review on OAT in low- and middle-income countries.

Working group: A working group was set up in mid-2021 to oversee the development of this tool. Members included experts from UNODC, WHO, UNAIDS, INPUD, HRI and clinicians experienced in OAT roll-out in low- and middle-income countries. The working group provided guidance on areas of focus and selection of countries for case study development. The working group identified key information sources and documents for review.

Review of available resources on OAT implementation: The consultant collated and reviewed guidance, toolkits and reports developed by UNODC, WHO, UNAIDS, INPUD, HRI, Global Fund and other international or national organizations and agencies relating to OAT planning and implementation, relevant to low- and middle-income countries.

Case study development: Case studies were developed for OAT programmes in the Islamic Republic of Iran, Kenya, Morocco, Ukraine and Viet Nam. Data were primarily obtained through semistructured virtual interviews done with representatives experienced in OAT service delivery in each country. The number of interviews was limited by the available resources. UNODC suggested interviewees (UNODC and other experts based or working in the countries of focus) and introduced the consultant to them. The hour-long interviews covered: background and process of establishing OAT services; components of the OAT programme (service delivery, medications, human resources, information); and successes and challenges in roll-out. Interviews were audio-recorded, and the consultant to the focal areas of OAT programming. Interviewees provided supporting information and literature on the OAT programmes and outcomes for each respective country.

Review of supplementary information: The consultant conducted a targeted desk review to address information gaps that emerged. The search was done on Medline, Google Scholar and WorldCat. Searchers were around OAT and programme outcomes (HIV, HBV and HCV prevalence or incidence in case study countries and retention) as well as barriers and facilitators to care, OAT quality improvement and OAT services in the context of COVID-19 in low- and middle-income countries. Additional resources were identified from citation lists of identified documents and OAT implementation resources and guidelines.

Information synthesis: Data and inputs were synthesized in relation to core components of OAT programmes. Information was adapted and presented in relation to common questions on how to implement OAT programmes.

Review and finalization: In late 2021, the tool was revised based on inputs received from the working group, case study interviewees and a broader set of reviewers experienced in OAT service delivery. The tool was finalized and launched in 2022.

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