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POLICY ADVOCACY TOOLKIT FOR MEDICATION-ASSISTED TREATMENT (MAT) FOR DRUG DEPENDENCE

SEPTEMBER 2010
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EXECUTIVE SUMMARY

The human, economic, and social costs of opioid dependence have increased exponentially with the advent of HIV and AIDS. In several regions of the world, most notably Eastern Europe and Eurasia, the unsterile sharing of needles, works, and drugs related to injecting drug use is the principal driver of HIV transmission and puts drug users, their partners, and sexual networks at risk. Medication-assisted treatment (MAT) programs are evidence-based drug treatment programs that result in drug users stopping drug use, changing risk behaviors, and reducing the risk of contracting or transmitting HIV. Most experts agree that the HIV epidemic in these countries cannot be contained without sustainable, widespread access to MAT and removal of barriers to MAT use.

Many countries of Eastern Europe and Eurasia have started pilot MAT programs, instigated and funded by international donors. These countries have developed standards of care, trained providers, and procured commodities to provide limited numbers of injecting drug users (IDU) with reasonably high-quality MAT services. Nevertheless, the success of these pilot programs has not dispelled political and popular opposition to treating drug use. Not only are the pilot programs too small to reach the majority of drug users who might wish to use MAT, but without a legal basis, even these limited programs will not be sustainable once donor funding ends.

The MAT Policy Advocacy Toolkit is designed to assist advocates and policymakers to build and strengthen an enabling public policy environment for successful MAT program implementation and scale-up. The tools in the Toolkit collect and analyze current laws and policies which may enable or restrict implementation of MAT; measure the opinions of key stakeholders regarding drug use and MAT in their country; assess quality of care at MAT program outlets, from both client and provider perspectives; and provide guidance to advocates in navigating the policy change process.

The Toolkit's organizing principles were derived from the most up-to-date (as of mid-2010) international best practices for MAT, including guidance from the World Health Organization, the United Nations Office on Drugs and Crime, and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The developers assembled an International Advisory Group and consulted extensively with group members throughout the process, as well as with various bureaus and field missions of the U.S. Agency for International Development (USAID), the Office of the Global AIDS Coordinator, and the Substance Abuse & Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services (HHS). The European Harm Reduction Network identified national consultants to field test the instruments.

The Toolkit consists of three sets of tools, with extensive descriptions as to why they are important for MAT and how they should be applied. It deliberately avoids technical language so that the tools can be used by a wide range of national stakeholders with different levels of knowledge and policy expertise. The tool sets include (1) instruments and procedures to compile and classify a reference library of country documents, and an analytic framework to compare current policies against international best practices and to assess the extent to which they enable or restrict implementation of MAT (*Inventory of Legislation, Policies, Regulations, Guidelines/ Protocols*); (2) survey instruments to collect opinions and experiences of key informants, MAT service providers, and MAT clients regarding coverage and quality of MAT services; civil society participation in MAT policy dialogue; and stigma, harassment, and other human rights violations faced by people who use drugs in accessing MAT services (*Policy Assessment Index-PAI*); and (3) guidance for advocates to identify and prioritize policy issues, engage stakeholders, and conduct advocacy campaigns (*Policy Advocacy Planning Worksheets*).

The **Inventory** was tested in Albania, Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Tajikistan, and Uzbekistan. Reference libraries of original policy documents were assembled for each

country.[1] Scoring and presentation procedures were tested and revised with the Kazakhstan and Kyrgyzstan documents and the final versions independently tested by the Georgian national consultant. The **Policy Assessment Index** was tested in Georgia and Kazakhstan; responses were translated into English and statistical analyses conducted in the United States. Round table discussions were held with stakeholders in Georgia and Kyrgyzstan to share the pilot results, gather local reactions to the findings, and make recommendations for the final version of the Toolkit. The **Policy Advocacy Planning Worksheets** were not field-tested.[2]

The initial field test experience provides several actionable findings and recommendations.

- There is no substitute for collecting and examining original policy documents. Assembling and fielding a multidisciplinary team to apply the **Inventory** requires some external assistance to select and train consultants and supervise the process. Document collection takes time because there are no national repositories of MAT documents and original documents are difficult to find, but it is manageable. It may take 2–3 months or less, depending on team size. External assistance is also recommended for scoring the collected documents; local experts may be needed to consult on the details.
- The activity of creating the reference library of MAT-related policy documents, in and of itself, may be a catalyst for increased policy dialogue.
- The **Policy Assessment Index** can be readily applied and analyzed by experienced survey researchers. The questionnaires are minimally intrusive. The client intercept does not interfere with clinic functioning and client flow. The challenge for the key informant interviews is to obtain a broad spectrum of respondents from all key stakeholder groups, especially civil society. Also, findings of the facility survey may not be very informative for pilot programs, which generally are well funded and optimally staffed, operate only a few facilities, and serve a small clientele. Problems with quality of care are more likely to arise as countries scale up their programs, decrease staff-to-client ratios, and establish services in more remote areas.
- Lack of access to information is a universal barrier to policy dialogue and reform across Eastern Europe and Eurasia. Three kinds of information sources are sorely needed.
    - National policy documents relevant to MAT. The **Inventory** addresses this need.
    - Scientific information about MAT in Russian and other national languages (Georgian, Armenian, etc.). For example, there are 12 Cochrane Reviews[3] synthesizing primary research on pharmacological maintenance interventions for opioid dependence; none of this information is available in Russian. United Nations documents often are available in Russian but not the other languages of the region. Policymakers, practitioners, and advocates need translations of key documents into local languages.
    - Estimates of numbers of IDU who would seek treatment. What few estimates exist usually have been prepared by outside analysts, have been used primarily for grant applications, are not published or debated nationally, and may contain internally conflicting information or data of dubious quality. The situation is reminiscent of the early days of the HIV epidemic before the advent of routine surveillance, national surveys, and agreement on analytic and projection procedures. Countries and programs need to pay more attention to the numbers.

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[1] Original documents and English-language translations of the collection/classification tool are available from the Health Policy Initiative website: http://www.healthpolicyinitiative.com/index.cfm?id=index.

[2] The procedures described are based on *The Policy Circle: A Framework for Analyzing the Components of Family Planning, Reproductive Health, Maternal Health and HIV/AIDS Policies.* Available at http://www.policyproject.com/policycd/ and http://www.policyproject.com/pubs/workingpapers/wps-11.pdf, which has been extensively used in the field.

[3] See: http://www.cochrane.org/.

- The complexity of the MAT policy environment and the sheer number of policy issues may dissuade donors and advocates from taking any action at all. Attempting to solve all policy issues at one time will not work. Advocates need to prioritize problems and opportunities to take incremental steps and build confidence and consensus before moving on to more fundamental policy change. The following examples identify policy issues that might be addressed to improve the legal environment for MAT while possibly avoiding some of the significant political barriers to advocating for immediate full-scale implementation:
    - **Regulatory issues**—Inclusion of methadone on the national list of essential drugs; registration of buprenorphine as a regulated drug. Kazakhstan does not include methadone as an essential drug; it has to be approved for importation every year. Buprenorphine is allowed only for research and not for treatment.
    - **Alignment of existing laws**—The Georgian law on drug relief services recognizes drug dependence as a disease and drug-dependent people as in need of medical aid, but the Criminal Code considers drug use a crime. Decriminalization of drug use would remove a barrier to seeking treatment and bring the Criminal Code into line with the drug laws.
    - **Civil society participation**—In Azerbaijan, the President's Decree # 2271 *On Approval of the Program for Combating Illegal Circulation of Drugs, Psychotropic Substances and Precursors, and the Fight against the Proliferation of Drugs* states that nongovernmental organizations (NGOs) can participate in policy discussions (it does not say that their input is desired); the decree does not specify what kinds of NGOs can or cannot participate. This might be an opening for policy champions to further civil society participation.
    - **Clarification of human rights and legal protections**—In Tajikistan, law enforcement agencies are believed to request and receive client information directly from drug treatment facilities without a court order. This discourages drug-dependent people from seeking treatment. It is not clear if this is permitted by law or is an informal practice; more information would be needed to develop an appropriate policy response.

In summary, Toolkit modules can be applied independently to a specific issue or across the MAT policy spectrum. Policy document review complemented with subjective perceptions and experiences allows advocates and policymakers to pinpoint more precisely where in the policy-to-practice continuum problems occur and assists them to take steps to improve the policy environment for successful MAT program implementation and scale-up. While the tools were designed specifically for Eastern Europe/Eurasia, they easily can be adapted and applied to other countries and regions.

ABBREVIATIONS

AFSC	American Friends Service Committee
ARV	Antiretroviral
DFID	Department for International Development
E&E	Eastern Europe and Eurasia
EHRN	Eurasian Harm Reduction Network
FDA	Food and Drug Administration
HHS	U.S. Department of Health and Human Services
IAS	International Aids Society
IDU	Injecting drug user
IHRD	International Harm Reduction Development Program
IRB	Institutional Review Board
MAT	Medication-assisted treatment/therapy
NGO	Nongovernmental organization
OGAC	Office of the U.S. Global AIDS Coordinator
OSI	Open Society Institute
OST	Opioid substitution therapy
PAI	Policy Assessment Index
PEPFAR	President's Emergency Plan for AIDS Relief
SAMHSA	Substance Abuse & Mental Health Services Administration
TA	Technical assistance
TAC	Treatment Action Campaign
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Twenty-sixth Special Session
UNODC	United Nations Office on Drugs and Crime
USAID	U. S. Agency for International Development
WHO	World Health Organization

INTRODUCTION

Purpose and Target Audiences

This Toolkit is intended to assist advocates, policymakers and decisionmakers, national committees and advisory boards, program developers, service providers, clients, NGOs, and other stakeholders to build a public policy foundation that supports the implementation and scale-up of evidence-informed drug dependence treatment services, specifically medication-assisted treatment (MAT).

The Toolkit was designed for the Eastern Europe and Eurasia (E&E) region but easily could be adapted and applied in other countries or regions. Possible uses of the Toolkit include

- To compare the current policy environment in a particular country against international best practices and identify the extent to which current laws and policies enable or restrict implementation of drug dependence treatment services, specifically MAT. This could also serve as a baseline for program design;
- To identify policy barriers and the strategies and opportunities that could be effective in mitigating these barriers. This could form the basis of planning to design a MAT policy program of action;
- To provide summary best-practices guidance for MAT programmers and decisionmakers in determining the content of MAT programs and planning interventions; and
- To monitor the impact of policy advocacy and implementation. Change in the country's policy/program environment could be measured by re-applying selected modules at a later date and comparing findings against the baseline.

Background

Political and economic upheavals in Eastern Europe and Eurasia in the 1990s following the break-up of the Soviet Union led to budget shortfalls and partial collapse of public health infrastructure, leaving the region ill-prepared to deal either with old public health scourges, such as tuberculosis and diphtheria, or the new and rapidly growing threat of HIV and AIDS. Helping to fuel the HIV epidemic were the equally rapidly growing epicenters of injecting drug use, with their associated primary risk behaviors, such as needle sharing and secondary risk behaviors, such as unprotected sex.

International consensus is that drug dependence and injecting drug use are best addressed as chronic health disorders and not as criminal activities. An effective response should include respect for patient rights and dignity; involvement and coordination among patients, communities, and criminal justice systems; and evidence-based drug dependence treatment that includes medication-assisted treatment with methadone or buprenorphine.[4]

Medication-assisted treatment is a proven HIV intervention. Failure to treat drug dependence drives transmission and hinders access to HIV treatment. Heroin injectors who do not enter drug dependence treatment programs are up to six times more likely to become infected with HIV than injectors who enter and remain in treatment (Sorensen and Copeland, 2000; Metzger, et al., 1998).Drug users living with HIV who receive drug dependence treatment and other healthcare services are more likely to comply with antiretroviral (ARV) treatment regimens and reduce high-risk drug-related and sexual behavior.

Countries in Eastern Europe and Eurasia have begun to mobilize against HIV and AIDS in general but response to injecting drug use has tended to lag behind. Two decades into the epidemic, the vast majority

[4] For example, see the UNODC Treatment Initiative: http://www.unodc.org/docs/treatment/Brochures/10-50007_E_ebook.pdf.

have yet to develop a strong public policy foundation to support MAT programs. Effective access to MAT depends not only on positive policies that enable programs to provide methadone and/or buprenorphine, but also on the absence or elimination of negative policies and practices that act as barriers to keep otherwise motivated people from seeking therapy—such as the fear of being arrested or losing one's job if seen at a drug treatment facility or identified as a person who uses drugs.

This Toolkit is the culmination of an initiative conducted by USAID | Health Policy Initiative, Task Order 1 in the E&E region. The project worked with the USAID E&E Bureau, the Office of HIV and AIDS, and the President's Emergency Plan for AIDS Relief (PEPFAR) Technical Working Group to identify policy barriers that impede the implementation of drug dependence treatment services. More than 300 items were collected and reviewed from journals (e.g., *International Journal of Drug Policy* and *International Digest of Health Legislation*), news sources, and NGO and government resource collections (e.g., United Nations Office on Drugs and Crime (UNODC) drug legislation). Other sources of information included the Beckley Foundation, Open Society, Harm Reduction Networks, and the World Health Organization (WHO).

Collaboration with other U.S. agencies and international partners was essential throughout the project. To align with the priorities of USAID and the Office of the U.S. Global AIDS Coordinator (OGAC) and avoid duplication of similar projects implemented by Department for International Development (DFID) and WHO, project staff periodically met with U.S. government representatives and kept open lines of communication with other projects.[5] Finally, the project assembled an international advisory group representing organizations working with and on behalf of IDU in E&E to ensure that the Toolkit would complement and build on the many existing efforts in the region.[6] The advisory group reviewed and provided feedback on the design and content of project materials, especially at the initial stages.

The Toolkit is useful in addressing fundamental questions for the development and implementation of a national strategy for MAT. These include

1. What is the legal basis for the use of MAT as a component of the national strategy to reduce drug use and prevent HIV infection?
2. How do national MAT policies conform with International Conventions and Guidelines developed by WHO and UNODC?
3. Are there national policies and guidance to allow for the establishment of MAT programs in areas of need and access to MAT services?
4. Is there a national policy on quality of care for MAT, such as program accreditation?
5. What is the quality of the MAT pilot program ongoing in the country?
6. What is the community response to the MAT programs?
7. Who are the in-country advocates for MAT scale-up, and how can a scale-up strategy be developed?

Organization of the Toolkit

The Toolkit consists of three sets of tools:

1. Instruments and procedures to compile and classify a reference library of country documents, and an analytic framework to compare current policies against international best practices and assess the extent to which they enable or restrict implementation of MAT (*Inventory of Legislation, Policies, Regulations, Guidelines/ Protocols*);

[5] These included the joint Temple University and DFID project, Access to Medicines Project for Palliative Care and Medication-Assisted Therapy, the International AIDS Society, and WHO's new global project, Partnership for Action on Comprehensive Treatment: Treating Drug Dependence and its Health Consequences, launched in 2008.

[6] See Acknowledgments section for a listing of the Advisory Group members.

2. Survey instruments to collect opinions and experiences of key informants, MAT service providers, and MAT clients regarding coverage and quality of MAT services; civil society participation in MAT policy dialogue; and stigma, harassment, and other human rights violations faced by people who use drugs in accessing MAT services (*Policy Assessment Index-PAI*); and
3. Guidance for advocates to identify and prioritize policy issues, engage stakeholders, and conduct advocacy campaigns (*Policy Advocacy Planning Worksheets*).

Chapter 1 provides an overview of each of the tools and explains why they are important and how they can be used. Chapter 2 includes the actual instruments and instructions for their use.

Limitations

While the Toolkit provides extensive explanations and documentation for each module, new users should keep the following limitations in mind:

- There are no national repositories of MAT policy documents. Time will be needed to identify and collect policy documents and some information may be totally lacking or inaccessible (e.g., local estimates of treatment needs, as many countries rely on international sources).
- Application of the Toolkit will probably require external assistance, at least to train the data collectors and perhaps to provide assistance in the analysis stage. The Inventory is best collected by individuals already familiar with policy documents.
- It is unlikely that a single person will have the policy and content area expertise to apply the entire Toolkit; thus it is recommended that countries assemble a team of knowledgeable individuals who *collectively* encompass the policy content areas.
- Written policy documents set the stage for program implementation but cannot guarantee program success by themselves. The policy assessment is only the first step of a longer planning and implementation process; stakeholders will need additional resources to disseminate findings, train advocates and develop advocacy plans, support needed policy reform, train service providers, fund expanded treatment programs, and monitor progress.

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CHAPTER 1: MAT PUBLIC POLICY ENVIRONMENT AND REQUIREMENTS

1.1 Policy Framework for Effective MAT Programming

1.1.1 Components of an overall public policy environment required for effective MAT

Review of the scientific literature and direct analysis of policy documents identified 10 components of an overall public policy environment required for effective MAT. These components can be found throughout country level-legislation, policies, regulations, guidelines, protocols, and operational plans. (See Chapter 2 for full text of the Inventory.)

Authorization

Making treatment for opioid-dependent persons available, accessible, affordable, and appropriate to their medical, social, cultural, and gender needs requires authorization. This usually comes in the form of legislation that authorizes an organization (administrative agency) and delegates to it the power to make decisions and create rules and/or regulations for implementing MAT. While authorization does not ensure quality of implementation, well-crafted legislation can identify standards against which program implementation can be measured.

The integration of treatment services for drug dependence with community health and social services, in a primary care setting, is optimal for effective, long-term treatment and good clinical outcomes. Advocates pursuing such integration should recognize that legislation, policies, regulations, and operational programs may administratively authorize different ministries to provide social, health, and educational services. Consequently, the advocacy team should include persons well-versed in the legislative, policy, and administrative systems of these related ministries.

Budget

Establishing public drug and opioid treatment programs requires budgetary policy and continuing fiscal support. A budget allocates funds for opioid treatment based on national estimates of the number of opioid users who will seek treatment and the amount of controlled medications (methadone and/or buprenorphine) that will be needed for opioid treatment settings. Budgets are set annually or based on other regular cycles to provide the funds necessary for continued operations and activities of the opioid treatment programs.

Registration, scheduling, and procurement

Registration is the process through which a medicinal product, such as methadone or buprenorphine, is licensed or officially listed for trade, subsequent distribution, and dispensing to individuals.

Scheduling identifies levels of control and the use of prescription drugs based on the balance of therapeutic usefulness and abuse potential.

Procurement authorizes acquisition, import, and/or local manufacture of medications such as methadone and buprenorphine.

Participation

Participation identifies the strategic and deliberate involvement of individuals with professional and personal experience with drug dependence and treatment in the planning, provision, and evaluation and monitoring of drug treatment services. Ideally, drug-dependent persons (particularly those who inject drugs), as well as community organizations and NGOs, are active participants in the provision of peer support services, as well as advocates for the development and implementation of treatment, care, and psychosocial support for drug- or opioid-dependent individuals.

Storage, distribution, and dispensing of controlled medications

Methadone and buprenorphine are controlled medications that must be stored in appropriate conditions by qualified personnel. Inventory and storage systems and personnel must ensure that medications do not expire, that stockouts do not occur, and that appropriate measures are in place to prevent theft or diversion into illicit use.

Control of the distribution chain of prescription medications ensures a supply of high-quality medications to the consumer and patient. Wholesale and retail distribution systems require adequate storage facilities and training on the storage, handling, dispensing, and distribution of controlled medications.

Clinical treatment and continuum of care

Use of effective pharmacotherapies for opioid dependence requires individualized treatment plans using MAT with established short- and long-term goals. Medications utilized in the treatment plan are to be supplied at appropriate dosing levels in combination with other services needs for recovery from opioid dependence as part of the continuum of care. MAT is to be offered/accessed in a variety of settings, including through out-patient care, in-patient care, and in prisons and/or other closed facilities.

People in treatment for drug dependence often need a variety of other services for rehabilitation, social reintegration, and aftercare to ensure restoration of their physical, psychological, and social functioning.

Standards of care

Standards of care identify requirements for ethical and effective treatment to achieve MAT therapeutic goals. They also identify critical areas to facilitate training and monitoring of treatment personnel.

Coverage and client eligibility to begin treatment

Eligibility guidelines identify medical requirements that clients must satisfy to receive MAT. For example, the client is to be diagnosed as opiate dependent and give informed consent for treatment. Some programs may give priority to clients with specific medical conditions, such as drug users living with HIV and requiring ARV medications, pregnant women, and those with tuberculosis (TB) requiring a directly observed treatment strategy (DOTS). International best practices and guidelines stipulate that any opioid-dependent injecting drug user who seeks MAT should be admitted for treatment and have not identified any standard or fixed inclusion criteria for eligibility, such as previous detoxification failures.

Women who inject drugs

Women who use drugs often face higher risks of morbidity and mortality and are more quickly addicted to drug dependence at lower drug doses. Women also face a higher physiological vulnerability to HIV infection from unsafe sexual practices, cultural vulnerabilities related to unsafe drug injecting practices, economic vulnerabilities, discrimination, and stigmatization. Effective policies and programs explicitly recognize these special needs and provide interventions as part of the individual treatment plan.

Civil, economic, social, and cultural rights of people who are drug dependent

International best practice identifies that it is important that drug-dependent persons enjoy the same rights under law as all other persons. These rights include the right to work, just and favorable conditions of work, social security, an adequate standard of living, health and education, and participation in cultural life (*International Covenant on Economic, Social and Cultural Rights, General Comment 14, Committee on Economic, Social and Cultural Rights*).

1.1.2 Description of policy document categories

There are many kinds of written policy documents that guide and/or affect the overall public policy environment for effective MAT programs. They differ in terms of the body or agency that issues them. The MAT Toolkit encompasses five categories of policy documents: legislation; policies; regulations; guidelines and protocols; and operational plans.

Legislation
Laws (civil, criminal) and other documents enacted or originated by the legislative branch of government, such as Parliament or the National Assembly. Also includes customs (importation) codes.

Policies
High-level documents issued by the executive branch of government, such as the President, Prime Minister, and Cabinet of Ministers. Includes edicts, Presidential or Ministerial decrees, resolutions, national plans, and programs.

Regulations
Documents issued by line ministries and departments that specify how laws, decrees, and other high-level policies should be put into practice. Includes orders, provisions, and instructions.

Guidelines, protocols
Published documents prepared by organizations such as WHO, UNODC, and professional associations/societies (e.g., medical, pharmacy, nursing, etc.) that specify the content and delivery of services.

Example of National Legislation
Federal laws can be used to delineate the many characteristics and program scope of a national MAT program including the federal roles of agencies and local agency roles in regulation, coordination and delivery of services as well as defining national treatment standards, clinic accreditation and health care provider certification requirements. In the United States legislation was written and passed into law specifically detailing the rules and regulations for Opioid Treatment Program accreditation and the dispensing of methadone maintenance treatment (*42 CFR part 8*). In addition, later legislation provided the framework and required specific provider training criteria for prescribing buprenorphine treatment in an office based treatment setting with the intent of providing unfettered access and quality treatment of opioid dependence treatment in a primary care setting (*DATA 2000*). This latter legislation included an initial 30 patient cap per health care provider which was later legislatively amended to expand patient access allowing 100 patients per provider. (*Controlled Substance Abuse Act of 2006*)

Operational plans
Published documents prepared by departments and programs (e.g., National Treatment Program), usually on an annual or biennial basis, that specify the type and number of program activities to be conducted, such as training events, supervision schedules, and commodities purchases.

1.1.3 Targeting reform according to policy document types

There are many components involved in effective implementation of MAT programs. The components identified in 1.1.1 must work together to create and sustain an enabling policy environment through coordinated legislative, political, and program involvement and support. Going beyond formal policies, law enforcement and treatment professionals, as well as the public at large, must recognize the value of MAT.

Advocates will want to propose different types of policy reform depending on the specific issues that need to be modified or strengthened. This section provides an orientation on (a) what kinds of policy documents are more likely to contain information on a specific topic, and (b) which type of policy reform may be most appropriate for each content area. In addition, once policies have been created or changed, attention must be paid to policy dissemination, training, monitoring and evaluation, and funding for programs or services.

Legislation
Each country has specific processes to enact new legislative provisions. These processes follow its Constitution, legislative system, culture, economy, and traditions. It is very important that the legislation designate a body or agency to be responsible for the intent of the legislation and clearly and unambiguously empower that designated agency to issue orders or regulations to put procedures into practice (see *Regulations*, below).

A common problem with national *drug treatment* legislation is that the various program components required for effective addiction treatment (e.g., medication supply, distribution, regulation of use, licensing, education) are rarely contained in a single piece of legislation. Usually, references to treatment are scattered across different pieces of legislation and different government sectors, with little attention given to linking goals of each sector to an overarching national strategy. Analysts and advocates need to have broad knowledge of legislation concerning medication procurement and supply chain, clinical practice and standards of care, and law enforcement because relevant legislative provisions seldom have 'drug treatment' or 'Medication-assisted Treatment' in their title. Trade, medication procurement, importation and customs, and criminal laws all affect MAT. However, their titles will refer or correspond to the overarching subject (e.g., trade) and not make explicit reference to 'drug treatment.' Moreover, this lack of linkage among the different sectors that influence MAT is often a major policy constraint at the national level. For this reason, advocates may decide to prioritize measures to establish or strengthen national coordinating bodies so that the legislative goals of different sectors are accommodated in the service of MAT.

Policies / strategic plans

National strategic plans, established by the executive branch of government, are especially important for advocates to analyze. Strategic plans demonstrate the government's understanding of substance abuse problems (e.g., estimates of how many people are drug dependent, where they are located, what other problems they have, etc.) and lay out the government's vision underpinning demand reduction and other prevention and treatment efforts, including MAT.

Example of National Strategy

Australia's national strategy on methadone identifies the following guiding principles:

- Availability—where a need for methadone service exists, there service should be made available.
- Accessibility—methadone service should be accessible to those targeted to use the services.
- Acceptability—the operation of methadone services should be acceptable to major stakeholders.
- Equity—methadone services should be planned and operated to reduce inequities between target groups in terms of access to, and quality of services.
- Accountability—those who manage and operate methadone services should be accountable for the performance of their services to key stakeholders.

Source: National Drug Strategy, National Policy On Methadone Treatment, Commonwealth of Australia 1997.

A comprehensive national strategy would include a range of polices and go beyond MAT to address the supply and/or the demand for illicit drugs; education, treatment, and control; and other programs and policies. Primary goals of national drug policies should focus on drug demand reduction as a public health issue addressing how to use of the criminal code and incarceration in the context of illicit drug possession, as well as social reintegration, rehabilitation, and treatment of drug-dependent persons. Strategies should conform to constitutional provisions and national legislation and be based on respect for basic human rights and the dignity of the individual, showing due regard for the fact that drug dependence is a brain disease and requires medical treatment of the individual drug users.

In many countries, national advisory and coordinating bodies on drug dependence help governments formulate national strategic plans and drug treatment policies. These bodies frequently take the form of drug commissions, narcotic boards, or inter-ministerial committees for drug programs. They are of special interest because they link policy development, program planning, and legislative enactments.

Government authorities should collaborate with nongovernmental organizations in the establishment of a nationwide coordinating body to be responsible for guiding the development and maintenance of a comprehensive treatment program for drug dependence. The most effective coordinating bodies share the following characteristics: (a) high-level governmental backing; (b) strong political support; (c) adequate funding; (d) high-level and respected membership from government, nongovernment, and target population; (e) public support; and (f) prominent public visibility and high priority in all areas of government.

Regulations

Once legislation has been adopted, regulations are needed to put the objectives into practice. Other implementation issues, such as the details of day-to-day operations of a treatment service, are also handled best by regulations rather than by the primary legislation. Regulations are more flexible than legislation and can be altered more easily as circumstances change. Relevant regulations may be found in a variety of instruments, including ministerial orders, administrative rules, or departmental or board regulations. These instruments generally are drawn up and promulgated by the agency (e.g., line ministry, department) designated in the legislation.

Example of National Regulation

Poland: National Programme for Counteracting Drug Addiction, 2006–2010

General aim of the national programme: reducing drug use and drug- related social and health problems [which]shall be fulfilled in five areas:

1. Prevention
2. Treatment, rehabilitation, health harm reduction and social reintegration
3. Supply reduction
4. International cooperation
5. Research and monitoring

….

Treatment, rehabilitation, harm reduction, and social reintegration main objective: improvement of health condition and social functioning of drug addicts and persons using drugs in a harmful way.

…...

Course 2: Improving availability of services

Types of actions:

…..

2.4. Increasing number of substitution treatment programs and number of services provided to the extent that will raise the access thereto by at least 20% of opiate addicts.

….

2.5. Increasing number and variety of specialist treatment programs including substitution, rehabilitation and harm reduction addressed to drug addicts at penal institutions and youth detention centers

Source: National Programme for Counteracting Drug Addiction 2006-2010, Regulation of the Council of Ministers of 27 June 2006 Available at: http://www.emcdda.europa.eu/html.cfm/index33623EN.html

Regulations flow from legislation in the following manner:

- Legislation authorizes the administrative agency through delegated authority.
- The delegated authority facilitates the ability of the administrative agency to carry out the legislative mandate.

- The administrative agency has the flexibility, within boundaries of delegated authority, to fulfill legislative goals in the face of changing public health, social, or workplace conditions.

In some legal systems, the drafts of regulations and other subsidiary instruments must be presented to Parliament or a parliamentary committee for approval or review, or must be approved by another public agency, such as the Ministry of Justice. In addition, regulations may be subject to a period of public comment prior to approval.

Guidelines, protocols

These include published documents prepared by organizations such as WHO, UNODC, and professional associations/societies (e.g., medical, pharmacy, nursing, etc.) that specify the content of services and how they should be delivered. Guidelines and protocols can be prepared with the assistance of implementing agencies, such as the Ministry of Health or a specialized drug treatment unit. For example, in the United States, the Center for Substance Abuse Treatment (CSAT) has developed Treatment Improvement Protocols (TIPs). CSAT is part of the Substance Abuse and Mental Health Services Administration (SAMHSA), located within the U.S. Department of Health and Human Services (HHS).

Example of Administrative Order

Kyrgyz Republic, Ministry of Health and Drug Control Agency, Order

1.2 . Objectives:

Substitution maintenance therapy with methadone from opium and opioids is intended for:

- improvement of somatic and mental state of a patient with opiate / opioid addiction, early detection and treatment of opportunistic diseases (tuberculosis, diabetes, mental disorders , etc.) ;
- preventing the spread of HIV, hepatitis B and C among drug users and the complications due to intravenous drug use , and timely treatment of complications caused by intravenous drug use (sepsis, abscesses, hepatitis B and C, trophic ulcer, etc)
- increase the level of social adaptation of drug addicts and their reintegration into society;
- provide medical care for pregnant women who use drugs in pre-and post-natal period
- creation for drug addicts and HIV -infected persons and the conditions to termination of intravenous drug use.

A prerequisite of substitution maintenance therapy is the voluntary consent of the citizen to a course of substitution therapy.

…

Source: Kyrgyz Republic, Ministry of Health and Drug Control Agency, Order "On expansion of the programme of substitution supporting therapy for opioid dependence on the territory of Bishkek and Chuy region", Joint Order No 56/15 (8 February 2007 and 14 February 2007).

Operational plans

Operational plans are prepared by departments and programs, usually on an annual or biennial basis; they specify the type and number of program activities to be conducted, such as training events, supervision schedules, commodities purchases. Operational plans are needed to set out activities across the spectrum of MAT program dimensions. These include establishing activities to meet new requirements that may be imposed by ministerial orders or regulations, keeping up with licensure and accreditation standards, and preparing plans for new advances in treatment and rehabilitation services.

The next section, Section 1.2, provides examples of legislation and other policies that variously enable or restrict access and other operations necessary for effective MAT.

1.1.4 Components and functioning of legislation

Orientation

WHO guidelines (1987) and other authoritative sources (UNODC, 2003) advise that legislation for treatment of drug dependence should include the following components:[7]

1. Statement of purpose—what the law is to accomplish
2. Designation of agency—responsibility for treatment program
3. Coverage and client eligibility—who is eligible for treatment services
4. Budget—how the treatment program is funded
5. Operations—an adequate structure for operation of programs
6. Accountability and evaluation—proper system of accountability and evaluation
7. Delegation of regulatory powers—identification of agency or agencies to carry out day-to-day operations
8. Human rights—fulfillment of civil, economic, social, and cultural rights protects the individual and advances achievement of treatment goals
9. Reconciliation of legislative provisions—new or revised legislation provides for amendments, revision, or repeal of provisions necessary to reconcile them to new treatment law provisions.

These components are needed whether or not the legislation is broad-reaching or addresses a narrower, specialized, aspect (e.g., MAT) of drug dependence. Obviously, the text will vary according to the purpose of the legislation and the country context. Government lawyers, especially in the Ministry of Health and the Ministry of Justice (attorney general's office), should be consulted to advise on the design, drafting, and interpreting of legislation regarding treatment of drug dependence.

This section presents selected legislative provisions illustrating the various components. Unless otherwise indicated, the source is Poland Law of 29 July 2005 on Counteracting Drug Addiction (UN, 2007).

1.1.5 The legislative components

Component 1: Statement of purpose

The WHO (1987) Guidelines note that a statement of purpose in legislation should include the following: (a) an indication of the problems that the legislation seeks to remedy, and (b) the main purposes of the legislation.

WHO (1987) recommends also that the statement of purpose should be prepared carefully, since it forms the basis of efforts to win support from interested groups and thus ensure that the proposed legislation becomes law. It should also emphasize that the treatment program will assist in the prevention and control of illicit drug use by preventing and repairing the damage done to the community and individuals.

Example:

Article 1. Purpose of this Part

The purpose of this Part is to provide a legal framework for the provision of treatment programs for drug dependence, including opioid agonist treatment, by:

(a) encouraging the widespread availability and accessibility of said treatment;
(b) protecting the human rights of those who receive treatment;
(c) ensuring quality of care in the treatment provided; and
(d) improving the physical and mental health of those people who seek treatment.

Model law provision of the legal framework for the provision of treatment programs for drug dependence, including opioid agonist treatment. (Network, 2010).

[7] Some legislative components, set out in WHO guidance documents, are consolidated in this tool.

Discussion:
It is immediately clear what the law is supposed to accomplish—improve health by means of a human rights-based approach focusing on provision of quality services designed to improve physical and mental health. The words "availability" and "accessibility," in addition to their common-sense usage, carry special legal significance: they are terms used in the International Covenant on Economic Social and Cultural Rights (see Section 1.1). The countries of the Central Asia and Eastern European region are parties to this treaty. One of the fundamental obligations included in this Covenant is the 'right to health.' Using 'availability' and 'accessibility' in the statement of purpose of the new law creates several advantages for advocates and stakeholders. The government of a country can point to this provision in its required periodic reports to the Committee on Economic, Social and Cultural Rights to demonstrate the country's progress in fulfilling its obligations under the treaty. Advocates can point to these provisions when holding to account those obligated to achieve the legislative purpose.

Example:
Establishing principles, rules of conduct, and performance duties for counteracting drug addiction.

Article 1.
This Act shall establish
1) principles and rules of conduct in counteracting drug addiction;
2) tasks and prerogatives of public administration bodies and local governments as well as other entities in the field of counteracting violations of law such as trade, manufacture, processing, conversion and possession of addictive substances;
3) relevant bodies in performance thereof [……]
4) penalties for violating the provisions hereof and the regulations referred to in paragraph

Article 2.
Counteracting drug addiction shall be performed through proper social, economic, educational, upbringing and health policy-making and in particular through
1) upbringing, educational, informative and preventive activities;
2) medical treatment, rehabilitation and reintegration of addicted persons;
3) reduction of health and social harm;
4) control of addictive substances;
5) combating illicit trade, manufacture, processing, conversion and possession of addictive substances;
6) control of cultivation of plants containing addictive substances.

Discussion:
Article 1 makes clear that principles and rules of conduct (to counter drug addiction) are purposes of the law. Article 2 reveals that the legislature intended a broad set of methods of performance ('proper social, economic, educational, upbringing and health policy making'), which includes medical treatment.

Component 2: Designation of agency responsible for treatment program
WHO (1987, 1999) notes that it is essential that the legislation designate the agency or agencies responsible for carrying out the treatment program. The country will select the agency most appropriate to be responsible for the treatment program—e.g., the Ministry of Health or a newly established drug treatment board. The designated agency should be identified in the legislation itself. The agency should be directed in the legislation to coordinate the comprehensive program of treatment, rehabilitation, community and patient education, and epidemiological and other scientific research outlined in the preamble or statement of purpose. WHO guidelines state that, whatever agency is selected, the aim should be to centralize the leadership of the program and ensure effective coordination of treatment services.

Example:
Legislation designates a range of institutions with assigned duties.

Article 6.

1. Counteracting drug addiction shall be performed by the National Bureau for Drug Prevention, hereinafter referred to as "the Bureau".
2. The Bureau shall be a state budget unit subordinate to the Minister competent for health matters.
    a. The Bureau's tasks shall comprise the following: [a list of enumerated tasks, assigned to different sectors]

Legislation in a number of countries establishes national coordinating bodies or boards responsible for advice or policymaking in connection with drug problems. These entities can be effective in bringing together the different stakeholder sectors that have duties of drug control, prevention, and treatment. Thus, law enforcement and public health sectors can find common ground to work out memoranda of understanding (MOU) that reconcile police and treatment goals, to mutual benefit. The legislation serves to establish the duties and powers, both of which should be spelled out clearly (WHO, 1987).

Article 12.

1. The Council for Counteracting Drug Addiction, hereinafter referred to as "the Council", is hereby established.
2. The Council shall operate by the Chairman of the Council of Ministers.
3. The Council shall operate as a coordinating and advisory body in the field of counteracting drug addiction.
4. The Chairman of the Council of Ministers shall prescribe, by way of a Regulation, the Council statutes, considering specific conditions and procedure for the operation thereof, including ways of operation of work teams referred to in Article 17.

Discussion:
Legislation that fails to clearly assign responsibility to a particular agency creates a barrier to effective treatment. Effective drug treatment programs require services from different sectors, including social services, data collection and reporting, and education and training. The legislation should direct the designated authority to coordinate all of the services and coordinate activities with law enforcement agencies, as well, consistent with the protection of rights set out in the statement of purpose (WHO, 1987).

Component 3: Coverage and client eligibility
Example:
Coverage means that treatment is permitted and funded under the legislation. Client eligibility to begin treatment refers to minimum requirements necessary to enter treatment for drug dependence. Legislation sets out how medical treatment is to be provided to an addicted person.

Article 26.

1. Medical treatment of an addicted person shall be provided by a health care centre or a medical practitioner performing medical practice, including group medical practice.
2. Rehabilitation of an addicted person may be provided by:
   a. medical practitioner specialised in psychiatry;
   b. person holding a certificate of addiction therapy specialist.
3. Rehabilitation of an addicted person may be provided by a person with certificate of addiction therapy instructor.
4. Reintegration of addicted persons may be provided by social integration centres established pursuant to social employment regulations as well as entities referred to in paragraphs 1 and 2 and Article 5(3).

The services referred to in paragraphs 1-4 provided to an addicted person, regardless of his or her place of residence in the country, shall be free of charge.

Example:
Legislation sets out how an addicted person may be treated according to an opioid treatment program.

Article 28.

1. An addicted person may be treated according to the substitution treatment program.
2. Substitution treatment may be provided by a health care centre upon license from the provincial governor (wojewoda) issued upon positive opinion of the Bureau Head in relation to meeting requirements set forth in regulations issued pursuant to paragraph 7.
3. The substitution treatment program licence in health care centres for persons deprived of liberty shall be issued by the General Director of Prison Service upon opinion of the Bureau Head.
4. The substitution treatment licence may be granted to the health care centre which has:
   a. hospital pharmacy or has entered into an agreement with a pharmacy to distribute a substitute substance;
   b. rooms adapted to:
      i. distributing a substitute substance,
      ii. provide group therapy,
      iii. the work of a medical practitioner, a therapist or a social worker,
      iv. collect samples for analysis,
      v. store and prepare substitute substances in the way that prevents access
      vi. of unauthorized persons thereto;
   c. proper personnel capacity adequate for the provision of outpatient treatment with particular reference to program head as well as program-trained nurses and auxiliary staff.
5. The licenses referred to in paragraphs 2 and 3 shall be issued by way of an administrative decision.
6. The substitution treatment licence shall be revoked in the event that a health care centre ceases to meet criteria for issuing the licence.
7. The Minister competent for health matters shall prescribe by way of a Regulation specific rules of conduct in substitution treatment as well as specific conditions which the health care centre providing substitution treatment must meet, considering the welfare of addicted Persons.

Component 4: Budget

The legislation should set out a budgetary policy and provision of continuing fiscal support for the mandate.

Example:
Legislation provides for funding of the entities performing the tasks.

> **Chapter 1. General Provisions**
> **Article 2. and 3.**
> 2. The tasks referred to in paragraph 1 (1-3) shall be financed through statutory funds of the entities performing tasks in counteracting drug addiction, funds allocated to the implementation of health programmes co financed by the state budget to be disbursed by the Minister competent for health matters and the National Health Fund.
> 3. The tasks referred to in [section y] shall be financed through the state budget from the resources to be disposed of by relevant ministers.

Discussion:
One of the identified barriers (see Section 1.3) for drug treatment is a failure of the legislation (and other policy documents) to provide sufficient funds from government sources on a sustained basis. Financing provided by Global Fund or other international donors does not provide the financial stability for the range of services needed for a successful MAT program. One strength of the above provisions is that they specify that 'statutory funds' shall be used for prevention, treatment, and harm reduction activities. This suggests that public funds will be made available. However, advocates need to understand how health funds are raised and allocated in a country to be sure that appropriate financing is designated for treatment services (see WHO, 2009 at Section 1.5), which may mean examining other legislation or policies that direct allocation and disbursement of funds.

Component 5: Operations

Legislation should set out a structure for program operations that administrators can follow and implement. Operational details should *not* be specified in the primary legislation but rather in regulations or other subsidiary legislation (see *delegation of regulatory powers*, below).

Other operational aspects of drug treatment should be covered in legislation, including the following:

- **Research, training, and education**. Legislation should provide for central planning (and financing to the extent determined) for research on the treatment of drug dependence and for the education and training of qualified personnel.
- **Minimum standards for staffing and resources.** Provision should be made for the establishment of a policy that sets out minimum standards (in such detail as may be deemed necessary and desirable) for treatment program staffing and resources, including regulation of professional competence and adequacy of treatment facilities.
- **Regulation of methods and procedures**. Provision should be made for the establishment of a policy for regulating the methods and procedures used in the treatment program, including clear legislative definitions of persons eligible for treatment, grounds (eligibility), and release.

Legislation and national policies often are out of date and lag well behind health and technical scientific advances and guidance developed by researchers, investigators, and others working on drug treatment. Community advocates seeking to strengthen MAT and other drug treatment legislation, national policies/strategies, regulations, guidelines, protocols, and operational programs should ensure that they take into consideration the latest science-based guidance on drug treatment, such as that reported through WHO expert advisory committees on drug dependence.

Through its Technical Report Series, WHO makes available the findings of various international groups of experts that provide the latest scientific and technical advice on a broad range of medical and public

health subjects. The WHO (2009) *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence provides expert guidance on* Buprenorphine (and other medicines used in agonist pharmacotherapy of opioid dependence, such as methadone).

Component 6: Accountability and evaluation

Example:

The legislation should provide for a proper system of accountability and evaluation, which should be established in the basic law or implementing regulations.

Article 6.

1. Counteracting drug addiction shall be performed by the National Bureau for Drug Prevention, hereinafter referred to as "the Bureau".
2. The Bureau shall be a state budget unit subordinate to the Minister competent for health matters.
3. The Bureau's tasks shall comprise the following:

……..

7) conducting periodical evaluations of prevention, treatment, rehabilitation and reintegration programs in terms of their effectiveness in reducing use of narcotic drugs, psychotropic substances or substitutes thereof;

……..

12) operating the national system of information on drugs and drug addiction as well as monitoring actions of counteracting drug addiction at national and international level, including:

a) collecting, gathering, exchanging information and documentation on counteracting drug addiction that is covered by public statistical research as well as editing and processing collected data,

….

k) evaluating the implementation of the National Programme for Counteracting Drug Addiction on a regular basis.

Discussion:

WHO guidance (1987) suggest the only part of an overall treatment program that might not be placed formally under the authority of the designated agency (see component 2) is evaluation, especially when it comes under a National Drug Control or treatment board. This might be better located in a broadly oriented planning office of the Board to ensure its independence.

Component 7: Delegation of regulatory powers

Legislation alone cannot make things happen. It requires administrative regulations, decrees, or other legal instruments for implementation of legislative policy, to apply technical detail to the program, and to adjust operations to respond to changing conditions, scientific advances, and other inevitable trends. The legislation must delegate specific authority to a specific administrative agency to adopt regulations in the area under consideration at that time. In the case of drug treatment programs, the legislation should delegate regulatory powers to the agency responsible for treatment program operations to ensure that they are modified and improved in line with demands and to consider technical and scientific advances in the field.

Example:

Operational areas that may be covered in ministerial orders or regulations are as follows:

- Treatment programs
    - procedures for the approval and registration/accreditation/certification of programs;
    - qualifications and duties of personnel;
    - powers of officers in charge;

- treatment procedures and record-keeping and reporting;
- relations with courts and other referral centers

- Standards for professional personnel
  - educational requirements
  - experience requirements
  - authority to prescribe therapeutic drugs

Component 8: Human rights: The fulfillment of civil, economic, social, and cultural rights protects the individual and advances achievement of treatment goals

People who use drugs have equal rights with other people and should not be discriminated against based on their dependence. Legislation should make provision for equitable, non-discriminatory entry to MAT and other treatment programs for drug dependence. Protection of these rights is found, variously, in State Constitutions and international and regional human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights. WHO guidelines (1987) emphasize "drug-dependent persons should not lose their civil rights because they are undergoing treatment."

Example:

Article 4. Basic Rights of Patients

Every patient has the right

(a) to a full course of high-quality treatment and follow-up support to be provided in accordance with good clinical practice;

(b) to treatment without discrimination;

(c) to meaningful participation in determining his or her own treatment goals, which may include but are not limited to abstinence or changes in drug use that minimize the harms of dependence;

(d) to meaningful participation in all treatment decisions, including when and how treatment is initiated and withdrawal from treatment;

(e) to exercise his or her rights as a patient, including:

(i) reporting, without retribution, any instances of suspected abuse, neglect, or exploitation of patients in the program;

(ii) a grievance and appeal process, in accordance with national laws and regulations;

(iii) input into the policies and services of drug dependence treatment programs; and

(iv) voluntary withdrawal from treatment at any time.

(f) to confidentiality of medical records and clinical test results; and

(g) to be fully informed, including but not limited to the right to receive information on:

(i) his or her state of health;

(ii) his or her rights and obligations as a patient, as specified in this Part and in applicable law;

(iii) the procedure for making a complaint about the services received through the program; and

(iv) cost and payment conditions and the availability of medical insurance and other possible subsidies.

Model law provision on basic rights of patients for the provision of treatment and follow up support (Network, 2010).

Discussion:

Legislation should declare it to be public policy to respect the rights of persons treated for drug dependence and establish mechanisms for the protection of their civil, political, economic, social, and cultural rights. In particular, legislation should provide for the protection by the law and through legal-judicial institutions (courts, tribunals) of the rights, welfare, property, and dignity of drug-dependent persons (WHO, 1987).

As noted in Section 1.3, failure to keep the contents of patient records confidential is a major barrier to effective MAT and other types of treatment for drug dependence. WHO guidelines (1987) state that "there are serious conflicts of public policy concerning the confidentiality of patient records in a treatment program that is part of an overall national campaign to combat drugs. Treatment personnel will wish to protect confidentiality to the same extent as in any other clinical setting. Yet, in the cases of diversion to treatment in criminal justice system, police often are allowed access to a person's treatment record, often kept in a central register, in order to determine eligibility for different types of treatment." However, police should not be permitted the use of patient information for purposes of identifying persons for arrest or surveillance. Except for circumstances involving child abuse and violence, confidentiality must be maintained.

Component 9: Amending, aligning of laws

When planning for legislative changes to achieve MAT access, it essential to assess the potential impact for all sectors of such changes on existing laws and policies. For example, when a public health law is modified to support MAT, are law enforcement laws and codes modified to harmonize with the revised public health law? A critical role of conducting an inventory is to identify other laws or policies that will need to be amended or deleted to ensure that new laws are not in conflict with other existing laws. Refer to the inventory in Chapter 2 to identify the full range of sectors.

Questions that will assist in this analysis include: What provisions in criminal law, without changes, would or might impede the purposes of the new law? What provisions in law concerning women or children, may be needed to bring such provisions in line with the new legislation? Do laws on confidentiality, informed consent, and other areas need revision?

1.1.6 Conclusion

Examination of existing legislation, gaps, and conflicts is an essential task for MAT advocates. Advocates should seek out lawyers in local communities willing to give advice on laws already in the statute books. Attention to the legal basis for treatment should be given early priority—and not relegated to the end of the process. In this regard, refer to Section 1.6 for strategies that will be useful for policy (and legislative) change processes.

1.1.7 References

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1.2 Policies that Directly Enable or Restrict Effective Access to MAT

This section describes the elements of the overall policy framework for effective MAT programming. The next section provides concrete guidance on specific policy document[8] provisions needed to create an enabling policy environment for MAT; this is a review of two types of policy barriers—restrictive policy provisions and the absence of needed proactive policy provisions—that may need to be overcome to create or strengthen an enabling MAT policy environment. **Annex for Section 1.2** sets out MAT policy components that reflect 'best practice' guidance according to materials referenced in this tool.

1.2.1 Policy document provisions necessary to enable MAT

Comprehensive, accessible, and sustainable MAT programs require the following proactive policy support:

- Country policy documents should expressly recognize and provide for the availability and accessibility of MAT services. Providing for MAT is essential to fulfill the country's obligations under the provisions of many international human rights instruments, including the International Covenant on Economic, Social, and Cultural Rights, the Convention on the Rights of the Child, and provisions of international drug conventions.
- Country policy documents need to recognize that methadone and buprenorphine are included in the WHO Model List of Essential Medicines.[9]
- Publicly conducted MAT programs require budgetary policy and continuing fiscal support. Where MAT has been implemented only on a pilot basis and/or relies entirely on external donor support (e.g., Global Fund to Fight AIDS, Tuberculosis and Malaria), successful program elements should be scaled up to meet anticipated treatment needs through multiple funding sources.
- Policy document provisions need to establish medically based entry requirements to MAT and other drug treatment; requirements should be equitable and non-discriminatory in practice.
- Policy document provisions need to establish and provide for minimum standards for MAT treatment program staffing and resources, including regulation of professional competence and adequacy of MAT facilities.
- Policy document provisions should protect the civil, economic, and human rights of all persons seeking MAT, both those currently in treatment and those leaving MAT, through legislation and, if necessary, recourse to courts and administrative tribunals.

1.2.2 Policy barriers to MAT

There are two types of policy barriers to MAT. The more easily detected of these are restrictive policies—policy document provisions that explicitly deny or rule out the broad directions described in 1.2.1 above; for example, a drug policy that expressly outlaws the importation of buprenorphine entirely or restricts if research purposes only. Related to outright prohibitions of critical components of MAT is the *problem of poorly drafted legislation* that does not respond to current science or international best practices. Much of the region's legislation passed after the collapse of the Soviet Union 'has been marred by a lack of clarity, causing medical personnel to follow outdated Soviet regulations' (Open Society Institute, 2009).

[8] As described more fully in Tool 1.1, the five categories of policy documents that support an overall public policy environment required for effective MAT are legislation, policies, regulations, guidelines and protocols, and operational plans.

[9] See http://www.who.int/medicines/publications/essentialmedicines/en/.

The second type of policy barrier reflects the absence of explicit policy provisions to provide, sustain, and/or expand access to MAT. Often these barriers are more difficult to detect, yet they may be as important as restrictive policies—or even more important—requiring a thorough assessment of the policy environment. The absence of explicit policy provisions can hamper the implementation and sustaining of MAT services, such as

1. Provider reluctance to offer potentially controversial services unless there are explicit policy documents that permit or even direct them to do so. While providers in some countries may feel free to offer services not explicitly banned or prohibited, the culture and practices of Eastern Europe and Eurasia often discourage this practice.
2. Reliance on decrees rather than legislation to establish MAT. While this may be sufficient to set up pilot programs, *there is no substitute for legislation to mandate the broad public policy and objectives in drug treatment (including MAT) programs*. In contrast to provisions of national governmental policies established by the executive branch of government, which can be overturned more easily by subsequent governments, the legislative provisions enacted by parliaments and legislatures establish a more sustainable public policy for MAT (WHO, 1999; WHO, 1987).
3. Ineffective or non-existent *coordination of the national strategic policy and plans.* National coordinating bodies or advisory committees have a key role in ensuring a country's effective, coordinated, and holistic drug treatment programs. Their composition and powers must be specified in national legislation.

Regional Experience

It is reported (EHRN, 2010; OSI, 2009; UNODC/Canadian Network, 2010) that Kazakhstan, Kyrgyzstan and Tajikistan have enacted no legislation requiring MAT therapy programs and rely on ministerial decrees and similar instruments to offer MAT.

Further work is needed to form a solid legal basis for OST [opioid substitution therapy] programming**:** In all of the countries decisions, regulatory documents and legal acts on substitution therapy seem to be made in response to short term needs, rather than being developed as part of long-term strategic planning and reform. Different pieces of legislation at different levels are often incompatible or directly contradict one another (EHRN, 2010.)

Refer to Section 1.4 for a discussion of legislation in context of best practices and lessons learned in addressing policy barriers to MAT services.

1.2.3 References

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Annex 1.2: MAT policy framework components

This annex set outs MAT policy components that reflect current 'best practice' guidance according to materials referenced in this tool. These components should be considered by analysts and advocates in assessing the policy documents currently in use. Annex A provides guidance for follow on action when such assessments reveal policy document provisions that are omitted, in conflict, or otherwise in need of enactment or amendment.

Authorization

In assessing the Authorization component, you should determine whether:

- Facilities (governmental/nongovernmental) are authorized to provide evidence-based treatment for drug dependence, either by direct dispensing or prescription. **Best practice:** both government and nongovernment facilities are authorized to provide evidence-based treatment for drug dependence.
- Facilities (governmental/nongovernmental) are authorized to provide methadone and/or buprenorphine for opioid dependence treatment. **Best practice:** medications are authorized for use at both government and nongovernment facilities.

Budget

In assessing the Budget component, you should determine whether:

- There are budgets and/or any explicit directives to allocate budget/financing for government provision of methadone and/or buprenorphine. **Best practice:** legislation or other policy documents authorizing MAT stipulate that government will pay for public services and instruct a government body to prepare MAT budgets.
- There are national estimates of the number of people who are opioid and drug dependent. **Best practice:** national estimates on illicit drug use and abuse are approved by a government entity and widely available.
- There are national targets or estimates of the number or percentage of opioid-dependent users who seek drug treatment using methadone and/or buprenorphine. **Best practice:** national targets or estimates are approved by a government entity and widely available.
- There are national targets or estimates of the number or the amount of methadone and/or buprenorphine that will be needed for drug treatment. **Best practice:** national targets or estimates are approved by a government entity and widely available.

Registration, scheduling, and procurement

In assessing the Registration/scheduling/procurement component, you should determine whether:

- Methadone and/or buprenorphine are included in the country's approved essential medication list. **Best practice:** these medications are explicitly included in the essential medication list.
- Methadone and/or buprenorphine are expressly registered or banned for use in substance dependence programs. **Best practice:** these medications are explicitly listed for use in opioid dependence treatment.
- Local country manufacture (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine is expressly permitted or banned. **Best practice:** if local manufacturing conditions permit, local manufacture of at least one of these medications should be explicitly permitted.
- Importation (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine is expressly permitted or banned. **Best practice:** importation of at least one of these medications is explicitly permitted. In the event that local manufacture is not feasible or permitted, importation for clinical use—as opposed to research purposes—is essential.

Participation

In assessing the Participation component, you should determine whether there are written, express provisions that either encourage or exclude:

- Active participation of injecting drug users as consultants in the development of policies and/or regulations and/or in program design, implementation, and/or monitoring. **Best practice:** active participation of IDU as consultants.
- Active participation of other civil society organizations—such as families of drug users or other patient groups, such as persons living with HIV and/or their advocates—as consultants in the development of policies and/or regulations and/or in program design, implementation, and/or monitoring. **Best practice:** active participation of these groups as consultants.

Storage, distribution and dispensing of controlled medications

Whenever possible, the wholesale and retail distribution should be restricted to those persons and enterprises having adequate storage facilities at their disposal. Training consistent with the level of service to be given is essential, including knowledge of how to store, handle, dispense, or distribute medications. The Conventions require that all people engaged in manufacture or distribution of controlled medications be licensed and establishments and premises where such activities take place are to be controlled through inspections.

In assessing the component of Storage, distribution and dispensing of controlled substances, determine whether there are written, express provisions:

- For storage of methadone and/or buprenorphine. **Best practice:** provisions are specified.
- That set quality monitoring and control standards for imported or manufactured methadone and/or buprenorphine. **Best practice:** standards are specified.
- That either allow or prohibit methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs (such as general hospitals or prisons). **Best practice:** any medical facility that treats MAT patients should be authorized to provide medication on at least an emergency basis (i.e., for the duration of time that the patient is unable to receive treatment at his/her usual treatment site).
- That either allow or prohibit authorized treatment facilities to dispense/prescribe methadone and/or buprenorphine for later use outside the treatment facility. **Best practice:** treatment facilities should be permitted to dispense "take away" doses for patients unable to come to the treatment site for short periods of time; treatment programs prescribe buprenorphine in an office-based primary care setting.
- That specify the numbers and/or locations of authorized treatment facilities to dispense methadone and/or buprenorphine. **Best practice:** there should be a publicly available listing of names and locations of authorized treatment facilities.

Clinical treatment and continuum of care

In assessing the component of Clinical treatment and continuum of care, determine whether there are express provisions that:

- Designate an authority in the treatment program as the formal coordinator to develop individual medical drug abuse treatment plans. **Best practice:** each patient needs an individualized treatment plan based on his/her needs for moving toward recovery; clinical norms or guidelines should explicitly state those responsible for the development of the treatment plans and treatment program staff who will work with the patient to achieve the treatment goals.

- Either allow or prohibit a treatment relationship between the drug treatment programs and the criminal justice system through drug courts or via direct agreements for treatment continuity in closed systems (incarceration). **Best practice:** detention facilities should be authorized to provide MAT through evidence-based best practices.
- Mandate or promote appropriate cooperation between drug treatment programs and law enforcement agencies. For example, permit referral to treatment instead of prosecution for nonviolent drug offenses, prohibit surveillance of drug treatment programs and arrest of patients as they enter or leave the treatment programs, ensure confidentiality of patient's information, and limit the requirement of drug treatment programs to report clients to law enforcement to special cases and through a court proceeding. **Best practice:** there should be explicit provisions for coordination and cooperation between drug treatment programs and law enforcement authorities.
- Describe the range and/or dosing levels of methadone and/or buprenorphine that are permitted to be prescribed for drug treatment. **Best practice:** clinical norms or guidelines should require individual dosing of controlled medications.

Further, determine whether there are express provisions for:

- Referral and counter-referral between treatment facilities and other agencies and services. **Best practice:** integrated services, but if that level of coordination is not in place, referral/counter-referral mechanisms should be explicitly stated.
- Community re-entry programs, with case management between closed facilities (e.g., in-patient treatment facilities, prisons, etc.) and the community. **Best practice:** community re-entry programs should be explicitly stated.
- Integration of services with standardized procedures and protocols to guide providers in the minimum services required by patients with a need for both treatment of opioid dependence and a co-occurring condition such as HIV or pregnancy. **Best practice:** integration of services with checklists/standardized procedures/protocols provided for healthcare providers.

Determine whether there are express provisions to ensure that

- Drug treatment programs establish an individualized treatment plan for each patient. **Best practice:** clinical guidelines should direct providers to establish an individualized treatment plan for each patient.
- Injecting drug users have access to HIV/AIDS prevention, care, and treatment services. **Best practice:** clinical guidelines should explicitly permit and encourage the full range of HIV/AIDS services for IDU.
- Injecting drug users have access to tuberculosis prevention, care, and treatment medical services. **Best practice:** clinical guidelines should explicitly permit and encourage the full range of TB-related services for IDU.
- Injecting drug users have access to hepatitis prevention, care, and treatment services. **Best practice:** clinical guidelines should explicitly permit and encourage the full range of hepatitis-prevention, care, and treatment services for IDU.
- Injecting drug users have access to psychological services. **Best practice:** clinical guidelines should include effective evidence-based psychological services for IDU.
- Injecting drug users have access to social services. **Best practice:** clinical guidelines should include social services, including case management for IDU.
- Determine whether there is explicit mention of the range and/or quality of care in services providing methadone and/or buprenorphine. **Best practice:** clinical guidelines for MAT should include quality assurance and quality improvement practices.

Standards of care

In assessing the Standards of care component, determine whether there are express provisions that

- Establish and provide for professional competence comprising education, training, and certification of medical personnel and other healthcare personnel who provide methadone and/or buprenorphine, as well as ancillary services in support of MAT. **Best practice:** evaluation tools to ensure professional competence of MAT service providers.
- Provide medical doctors and other healthcare personnel with basic and/or continuing training in the use of methadone and/or buprenorphine for the treatment of opioid dependence. **Best practice:** there should be a requirement for and a mechanism to provide continuing medical education and certification for MAT service providers.
- Require the same standards of ethical treatment for the treatment of drug dependence as other health conditions (e.g., patient's right to autonomy and self-determination, obligation for beneficence and non-malfeasance from treating staff). **Best practice:** clinical guidelines should explicitly guarantee standards of ethical treatment for MAT patients.
- Protect or exclude confidentiality of client medical records and/or medical information in general. **Best practice:** all medical records should be guaranteed confidentiality.
- Protect or exclude confidentiality of medical information in drug dependence treatment. **Best practice:** medical records in drug treatment are treated as confidential.
- Permit or prohibit healthcare providers from passing treatment information to law enforcement bodies. **Best practice:** healthcare providers should be explicitly prohibited from sharing treatment information with law enforcement bodies without the patient's consent or a court order.

Coverage and client access to MAT

In assessing the component for Coverage of the known IDU community and their access to MAT, determine whether there are explicit directives to

- Provide methadone and/or buprenorphine to clients based solely on a clinical diagnosis of opioid dependence **Best practice:** access to MAT based on clinical criteria.
- To restrict individuals seeking treatment to MAT because of their age, gender, length of illicit drug use, their past history of attempts at abstinence or unsuccessful treatment attempts, any kind of opioid-dependence complications, or psychiatric conditions. **Best practice:** any opioid-dependent injecting drug user who seeks MAT should be admitted for treatment.
- Restrict the number or location of medical clinics providing MAT. **Best practice:** no restriction of MAT clinic locations.
- Require review by a medically trained MAT certified clinician for dispensing MAT or prescription by a medically trained MAT certified clinician prescribing methadone and/or buprenorphine for an individual client. **Best practice:** access to MAT and MAT services based on a comprehensive clinical assessment of the patient as part of the MAT treatment orientation.

Women who inject drugs

In assessing the component regarding Women who inject drugs, determine whether there is explicit mention of a specific woman-centered treatment environment and services for women to include

- Women's specific needs for dosing levels of medications and/or other drug treatment services. **Best practice:** clinical guidelines should explicitly mention women's specific needs.
- Access to family planning and/or other reproductive health services by women who inject drugs. **Best practice:** women who inject drugs should be explicitly permitted access to voluntary family planning and reproductive health services, *and* mandatory use of family planning as a condition for receiving treatment should be explicitly prohibited.

- The rights of women in treatment for drug dependence to retain or regain custody of their children in cases of no child abuse. **Best practice:** every effort should be made to retain the family structure for women seeking treatment for their drug dependence—there should be explicit mechanisms for women in treatment to retain custody of their children; women in treatment need a mechanism to regain custody if they have lost it.
- Methadone and/or buprenorphine treatment for pregnant or lactating women who inject drugs. **Best practice:** clinical guidelines need to establish procedures for prescribing MAT for pregnant and lactating women.
- Access to prenatal care by women who inject drugs. **Best practice:** pregnant women who inject drugs are to be provided access to prenatal care.

Civil, economic, social, and cultural rights of people who use drugs

In assessing the component regarding Civil, economic, social, and cultural rights of people who use drugs, determine whether there are express provisions that permit or prohibit

- Mandatory testing for illicit drug use. **Best practice:** testing for illicit drug use is to be part of the treatment plan and performed under informed consent.
- Mandatory treatment for people who use illicit drugs. **Best practice:** treatment is mandated only by a court of law and use as an alternative to incarceration should not be permitted.
- Mandatory medical services or procedures (for example, HIV testing, contraceptive sterilization) for people who use opioids and because of their drug use. **Best practice:** medical services and procedures should be part of the treatment plan and performed under informed consent.
- Discrimination as a barrier to receiving medical services based on a medical or physical disability or mental health condition. **Best practice:** people who use drugs have an undeniable right to the access and receipt of medical services, whether there are express provisions that either guarantee or restrict the following:
    - Movement of people who use opioids (such as mandatory quarantine, detention) because of their drug use. **Best practice:** freedom of movement for individuals who use drugs is the same as individuals who do not use drugs.
    - Employment opportunities for people who use opioids because of their drug use. **Best practice:** employment opportunities (hiring, retention, promotion) for people who use drugs cannot put the public at risk (international regulations—a person cannot fly a plane if under the influence of alcohol—in other words, this provision needs to be reasonable).
    - Any other civil, social, or cultural benefits (such as voting, freedom of association, access to housing, education, custody of children) for people who use opioids because of their drug use. **Best practice:** restrictions on civil, social, or cultural rights because of drug use should not be permitted.

Also determine whether

- Drug dependence is classified as a disability and/or a mental health condition. **Best practice:** where policies explicitly protect disabled persons from discrimination, drug dependence should be classified as a disability to protect the rights of IDU.

1.3 Common Barriers to MAT Policy, Advocacy, and Implementation

1.3.1 Orientation

Understanding the common policy and advocacy barriers to MAT implementation is critical to the design of a long-term policy and program advocacy effort. The barriers listed below need to be understood and addressed in the local context to develop a local advocacy for the implementation and scale-up of MAT. These barriers and other arguments used to delegitimatize MAT can be documented during the process of doing policy inventory, policy assessment, and in the design and implementation of policy advocacy (Sections 2.1, 2.2, and 2.3 respectively).

The barriers described below were collected during the application of the *Inventory of Country Legislation, Policies, Regulations, Guidelines/ Protocols with Reference to International Best Practices*[10] by national consultants, as well as in subsequent group discussion of their experiences with the inventory tool and their perceptions of MAT and barriers to program implementation and expansion in their respective countries.[11] Country-specific information provided by consultants has been generalized to protect ongoing advocacy efforts and present a comprehensive list of arguments that need to be assessed for relevance in any country. Additional information was obtained from a literature review of previous studies of legal and policy frameworks for MAT and scientific articles on the current situation in the region.

1.3.2 Specific policy and advocacy barriers

Cultural and political environments

Stigmatization of IDU creates barriers to effective policy dialogue and results in discriminatory policies and practices. While stigma cannot be resolved by legislation or policy, discrimination can be resolved through implementation and enforcement of legislation or policy that addresses the legal rights of all, including IDU. Discrimination against IDU, in the form of criminalization of injecting drug use, is the primary contributor to barriers to effective prevention and treatment services. When drug dependence is viewed as a crime rather than a brain disease and a health issue, services for IDU become politically and socially untenable, especially in the context of competing needs for limited state resources. The less worthy criminal arguments will become more vocal as MAT programs move from donor funding to competing for limited state funding. In this competitive setting, lawmakers and budget developers often prioritize the support of noncontroversial services for constituents, rather than the public health needs of the community. There is the perception that people do not want to pay for drug treatment programs for IDU from their taxes (Focus group, 2009). Stigma and discrimination also limit the ability of IDU to participate in service design and policy advocacy. While IDU are among the most interested and critical stakeholders in MAT program development, implementation, and monitoring, because they are involved in behaviors that are classified as criminal, there are real or perceived barriers to their involvement in policy forums and political advocacy. (Focus group, 2009; Latypov, 2010).

Cultural and political environments are also influenced by political and cultural alliances and policies of dominant countries in the region. For example, in the Russian Federation, the fact that MAT is illegal is a common argument against the implementation of MAT in Eastern European countries. This political stance is influenced by and often correlated with the degree that a country is in political alignment with Russia or Western Europe on other issues (Aizberg, 2008; Focus group, 2009).

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[10] The *Inventory* covers 10 dimensions critical for MAT: authorization; budget; registration and procurement; coordination and participation; storage, distribution, and dispensing of controlled substances; continuum of care; standards of care; coverage and client eligibility; women who inject drugs; and civil, economic, social, and cultural rights of people who use drugs. See Tools 1.1 and 2.1for more details.

[11] National consultants from Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Tajikistan, and Uzbekistan met on December, 5, 2009 in Tbilisi; the national consultant from Albania could not attend the meeting. The Health Policy Initiative coordinator facilitated the discussion and prepared a summary report of the proceedings.

Legal and governance structure and philosophy

IDU are in a vulnerable position within the law and the general lack of legal aid and advocacy support (Focus group discussion, 2009). Because of these factors, law enforcement officers frequently use drug users as "sources' of information on drug dealers and users often become the source of bribes for corrupted officers. In addition, in many countries of the region officers who exceed their monthly targets for drug arrests are more likely to be promoted (Latypov, 2010). These actions deliberately target drug users and the barriers that act as deterrents to seeking medical and addiction services (Unique Identifier Code, 2007). The situation in the Central Asian Republics is further complicated by their locations along drug trafficking routes from Afghanistan to the Russian Federation and Europe and the resulting intertwining of drug use prevention and supply reduction strategies.

Because of the prevailing depth of concern about drug use and dependency treatment, multiple government sectors may seek to play a lead role in addressing these issues. Roles and responsibilities often are not clear and overall goals and philosophies can be contradictory, both among and between officials in health and other sectors, such as law enforcement (Focus group, 2009). An example of conflicting goals and philosophies is found in the argument raised about "substituting" one addiction (heroin) for another (methadone) and the potential for long-term MAT use rather than using MAT as a short-term treatment regimen to address withdrawal symptoms and promote abstinence from illicit drug use.

Information/communications

A study in Albania reported that new patients had heard from peers that "methadone is worse than heroin," "there is a high risk to long-term methadone users," "methadone damages the heart and the bones," and "methadone users can feel worse" (Aksion Plus, 2008). These issues need to be addressed as part of the treatment orientation. (Note—there is a basis for these myths—for example, high-dose methadone does cause cardiac arrhythmias. Also, methadone is highly addictive and some say the withdrawal symptoms are worse than heroin withdrawal.) Similar myths in the region reported by consultants include "methadone causes obesity" and "methadone contributes to the development of leukemia" (Focus group, 2009).

Access to evidence-based information about MAT in Russian and other national languages is also limited in the region. The majority of articles on opioid agonist therapy in Russian or on the Internet present arguments against MAT that are not evidence based and are sometimes just anecdotal (Focus group, 2009). The lack of documents about MAT in Russian and national languages is a commonly cited barrier to increasing awareness about opioid agonist therapy among policymakers, medical society and the general public (Aizberg, 2008; IAS, 2008).

Finally, media coverage of MAT programs and advocacy campaigns will be a critical factor in influencing the opinions of politicians and the general population (Focus group, 2009).

Advocacy and program design and implementation

Advocacy and program design can have unintended and negative consequences on MAT scale-up. Efforts to educate and influence providers and policymakers can create an advocacy backlash and be met with increased resistance to MAT (Focus group, 2009). And once programs or pilots are implemented, program design components, such as training and technical oversight, inventory and supply chain management, client accessibility, quality and spectrum of services, and community relations also will affect the success of the current program and future efforts for expansion of services. Failure to address these components can lead to real or perceived issues with diversion of MAT prescription medications into the black market; under-utilization; failure to reach and sustain treatment goals; and questions about program effectiveness by the general public, law enforcement, and politicians.

Two lessons learned in the region warrant special mention. It is a common story that the primary drivers of MAT programming are international donors. Governments often allow the implementation of "pilot" projects with these donor resources to fulfill the requirements for receipt of donor funding. However, throughout the region, there has not been much effort to establish a permanent legal framework for the provision of MAT. Negative attitudes toward IDU among government officials, law enforcement bodies, and the general public continue unabated, manifesting in barriers to evidence-based addiction treatment, lack of information on MAT, and a reluctance to legalize MAT prescription medications. The media publish inflammatory articles, such as reporting that police raids on places of drug use found methadone "syringes" from opioid agonist therapy programs scattered about and that drugs are leaking into the black market (Focus group discussion, 2009). Sole focus on the implementation of pilot programs without addressing the underlying legal and sociocultural frameworks will continue to impede sustainable and full-scale MAT implementation.

The other important lesson is that when pilot programs are not given the support and resources to be implemented successfully, MAT can became a "taboo" topic in the country, and officials who engaged in the project can unwittingly fuel long-term, strident opposition to MAT. One pilot project in the region was plagued by problems from the outset, including client accessibility barriers, limited technical support and staff training, failed supply chain management and inventory control, and limited attention to public relations and quality information. The pilot project received a negative evaluation and MAT has been suspended in the country (Focus group, 2009).

1.4 Recommendations

The following recommendations come primarily from the field experience of consultants who implemented the policy inventory tool. These recommendations were consolidated at a meeting of consultants from seven countries in December 2009. While in many cases these recommendations are the result of individual impressions, they resonated with consultants from throughout the region and can be a useful catalyst for country-specific discussion and analysis whenever MAT advocacy is considered. Where there was published support for the recommendations, we include the additional citation.

1.4.1 Cultural and political environments

Recognize the medical causes and treatments of drug dependence and de-stigmatize injection drug users (Focus group, 2009; Aizberg, 2008; IAS, 2008).

National legal codes should be revised to classify drug dependence as a disease and recognize drug dependence as a legally protected disability (Focus group, 2009; UNODC, Canadian HIV/AIDS Legal Network, 2010). Once IDU are legally protected from discrimination based on their drug use, national campaigns should be designed and conducted to combat stereotypes about drug users, examine how they are treated in society, and de-stigmatize drug dependency (IAS, 2008).

1.4.2 Legal and governance structure and philosophy

Provide legal aid to IDU

Establishing legal clinics for IDU can support them in circumstances where there is harassment from the police and in situations in which police and others exceed their authority or violate the law (Focus group discussion, 2009). In Kyrgyzstan, several legal clinics provide services to protect the rights of drug users. Over the last five years, the situation of detained drug users has improved. Drug users detained without any justification know that when they are represented by lawyers, their case is less likely to go to the court. Police also know this; several such cases have collapsed and prosecutors opened criminal proceedings against police officers. Police harassment of IDU, such as detaining drug users near methadone distribution points, has decreased (Focus group discussion, 2009).

Educate law enforcement bodies, medical students, and healthcare workers on MAT

In Kyrgyzstan the Ministry of Internal Affairs conducts a 48-hour training course for police to explain the specifics of MAT and reduce discrimination and stigma against IDU (Focus group, 2009).

MAT should be incorporated in the undergraduate and postgraduate curricula of medical students (Aizberg, 2008).

Develop a legal framework for MAT

The process of developing a legal framework for MAT provides the opportunity for policymakers to develop overall goals and philosophies for drug dependency services. It also provides the opportunity to align governance structures and roles and responsibilities across sectors.

1.4.3 Information/communications

Design and conduct evidence-based advocacy for MAT among physicians, government officials, the mass media, and the general public (Focus group discussion, 2009; Aizberg, 2008).

Evidence-based advocacy messages should be developed on various themes that speak to the concerns and needs of various stakeholder groups. Examples of positive messages regarding MAT could include the cost savings derived from MAT (cost of providing MAT vs. cost savings from not jailing IDU), crime reduction following drug treatment, decrease in disease transmission, and stabilizing individuals and families to allow former drug users to contribute to communities.

Engage mass media

Strategic communication with the mass media about MAT is crucial for a long-term promotion of the program (Latypov, et al., 2010). Successful programs in the region have included deliberate engagement and training of media to help ensure that press coverage is well informed by the evidence.

Collect and translate documents on MAT in Russian and national languages

Evidence-based articles on the advantages of MAT should be translated into Russian and other national languages and published on the Internet for all stakeholders and the general public (Focus group, 2009; Latypov, et al, 2010).

1.4.4 Advocacy and program design and implementation

Engage stakeholders in the design and implementation of advocacy efforts

To avoid backlash, advocacy messages must come from all key stakeholders, including the scientific community, officials, and community leaders. Advocacy campaigns must be indigenous and not perceived as being driven by external donors or governments (Focus group discussion, 2009; Aizberg, 2008).

Engage drug users in MAT program development, implementation, and monitoring

Drug users experience shortcomings of MAT firsthand. They can contribute to improving quality of care by providing feedback, organizing patient associations, advocating for MAT, conducting meetings with IDU not yet in treatment, and using "peer-to-peer" approaches to dispel myths about methadone and drug treatment (Focus group discussion, 2009; Latypov, et al, 2010; UNODC, Canadian HIV/AIDS Legal Network, 2010).

Ensure continuum of care (psychological and social support)

Invest resources to support qualified personnel to provide integrated psychological and social support (Focus group discussion, 2009). In Kyrgyzstan, the 2002 pilot project hired staff to provide methadone patients with psychological and social assistance to help them socialize and find jobs. Later in the pilot, some of those staff positions were eliminated and the quality of psychosocial support declined (Focus group discussion, 2009).

Advocacy for MAT is needed for healthcare professionals not yet involved in the program. New specialists must be trained in MAT to avoid a monopoly in provision of treatment (Focus group discussion, 2009).

Provide more intensive technical assistance for MAT staff in *new* programs (Focus group discussion, 2009; Latypov, et al, 2010)

The lack of sufficient technical assistance (TA) has been cited as contributing to the poor evaluation and subsequent discontinuance of MAT pilots in the region. TA should be country specific and include support for program monitoring and evaluation (Focus group discussion, 2009).

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1.5 Identification of Funding Requirements for Effective Drug Dependence Treatment Services

The WHO Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence (WHO, 2009) make the following recommendations concerning funding.[12]

> **Recommendation** *(Minimum standard*)—At the time of commencement of treatment services, there should be a realistic prospect of the service being financially viable.
>
> **Recommendation** *(Best Practice)*—To achieve optimal coverage and treatment outcomes, treatment of opioid dependence should be provided free of charge or covered by public healthcare insurance.

The WHO Guidelines (WHO, 2009) provide the following commentary regarding funding.
In each national situation, funding and equitable access to treatment should be ensured for the treatment approaches that are appropriate. In general, this means making the most cost-effective treatment widely available and accessible. The cost to patients of treatment for opioid dependence also influences the outcomes of treatment and can have unintended consequences.

- If costs are excessive, treatment will not be accessible to disadvantaged populations. Many opioid-dependent patients have difficulty paying for treatment and are not covered by health insurance schemes.
- Where patients have to pay for treatment, retention rates and health outcomes are worse than where treatment is free. Even small financial costs for treatment can be a significant disincentive.
- If higher doses of methadone and buprenorphine cost more than lower doses, patients may opt for too low a dose, resulting in poorer outcomes.
- In contrast, if patients pay the same price regardless of the dose, they may overstate their needs and sell their excess supply, which in turn may make staff reluctant to increase the medication dose when patients request it.
- If patients pay a dispensing fee to a pharmacist or clinic each time they collect their medication, they may collect their medication less frequently.

Although it is impossible to avoid all reverse incentives (i.e., those that have unintended and undesirable effects), making treatment both free and accessible will minimize them.

If a country has a public universal healthcare system, this should include access to opioid-dependence treatment. If a country has an insurance system, again, this should include access to opioid-dependence treatment, recognizing that long-term treatment will be needed in many cases.

Another aspect of treatment funding is sustainability. In many cases, pilot funding is used to launch treatment of opioid dependence. However, it is not appropriate to use short-term funding for long-term agonist maintenance treatment without a realistic prospect of people in treatment being able to access continuing pharmacotherapy at the end of the pilot phase. The development and maintenance of opioid treatment services evidently needs to take place within the broader system of healthcare financing and provisions in a given country. An understanding of the way health funds are raised and allocated in a country is therefore important for the appropriate planning of opioid treatment services.

[12] The text of this tool is an adapted replica of *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence* published by the World Health Organization in 2009. We acknowledge, with appreciation, the World Health Organization.

One particularly important potential barrier to treatment in many countries with relatively low resources is the reliance on private, out-of-pocket spending by households as the primary mechanism for paying for healthcare. Tax-based public health insurance schemes provide a more equitable mechanism for paying for health services, as well as a more suitable basis for developing and sustaining opioid treatment services at the population level.

Determining the total resources and associated costs needed to initiate and maintain a treatment service for opioid dependence should be a key element of strategic planning. Although cost estimates have been produced for a range of opioid-dependence treatment programs, they are largely restricted to the context of high-income countries, where costs and levels of funding for health may differ markedly from those found in low- and middle-income countries. For example, although estimates of staffing requirements will figure prominently in any resource-planning exercise, these labor costs may not represent as large a component of the total cost in low- and middle-income countries (due to lower salary levels); in contrast, the costs of purchasing and distributing medication, and fuel, utilities, and equipment comprise a relatively greater share of total costs in such countries.

WHO has methods and tools that can be used to assist such resource planning and program costing at the national level. (WHO, 2008)

1.5.1 References

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WHO. 2008. *Choosing Interventions that Are Cost Effective: Cost-it*. World Health Organization. Retrieved July 16, 2008, from http://www.who.int/choice/toolkit/cost_it/en/.

1.6 Models for Policy Change

The earlier sections of this tool describe the components of the policy framework for MAT, policies that enable or restrict access to MAT, common policy barriers and solutions, and funding requirements for successful MAT programs. This section addresses the process of policy change to expand MAT services. It builds on the conceptual framework described in *The Policy Circle: A Framework for Analyzing the Components of Family Planning, Reproductive Health, Maternal Health, and HIV/AIDS Policies*, developed by the POLICY Project.[13]

1.6.1 Policy models

Many models have been developed to describe policy change. Some are linear (see Lasswell, 1951 and Meier, 1991), others are iterative (see Grindle and Thomas, 1991), and others describe change in terms of policy streams (see Kingdon, 1984). They all share the common recognition that policies emerge from perceived problems and stress the importance of a wide range of stakeholders—not only policymakers, but also others in nonofficial roles—in proposing policies and acting on policy options.

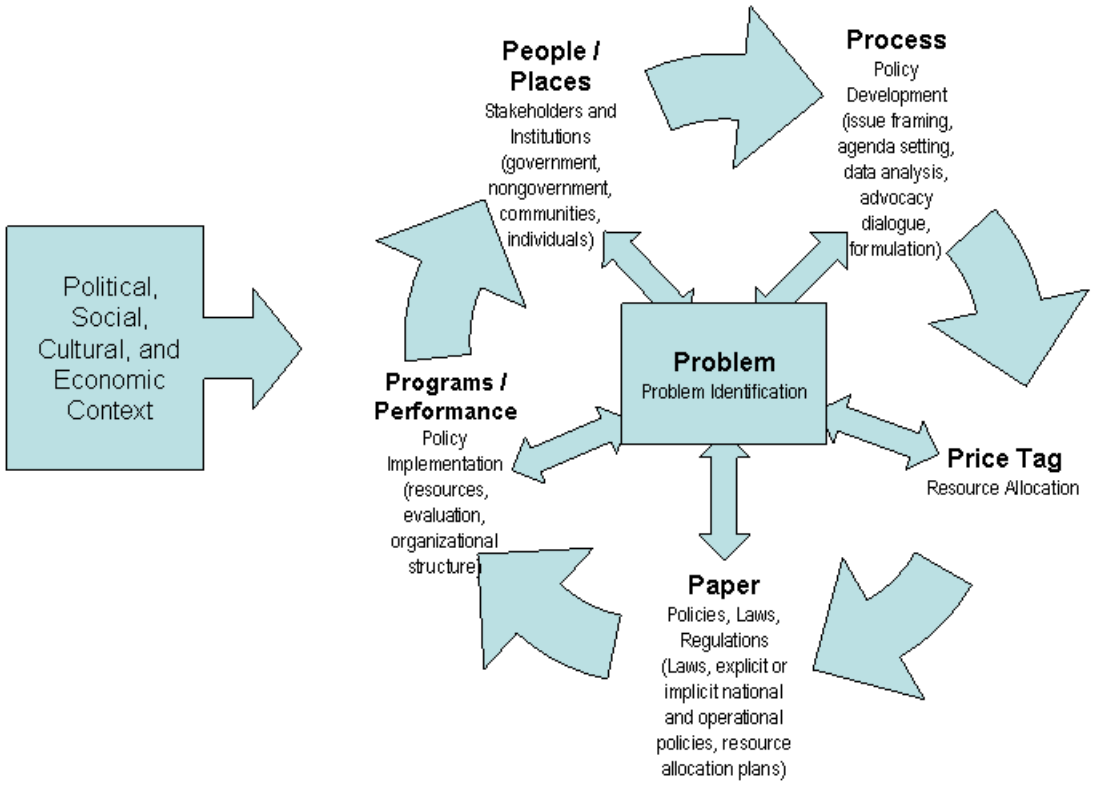
1.6.2 The Policy Circle Framework

The Policy Circle framework highlights six main components of policy, which play out against the backdrop of each country's unique political, cultural, social, and economic contexts:

- the **Problems** that arise requiring policy attention
- the **People** who participate in policy and the **Places** they represent
- the **Process** of policymaking
- the **Price Tag** of the policy (the cost of policy options and how resources are allocated)
- the **Paper** produced (actual laws and policies)
- the **Programs** that result from implementing policies and their **Performance** in achieving policy goals and objectives

Three of these components have already been discussed in some detail—the paper produced and the programs and their performance (Sections 1.1, 1.2), and the price tag (Section 1.5), as well as the political, cultural, social, and economic context (Section 1.4). This section will emphasize the identification of problems, the people who participate in policy and the places they represent, and the process of policymaking.

[13] The *Policy Circle* can be found in an interactive format at www.policyproject.com/policycd/. It includes policy analysis tools and other resources related to family planning, reproductive health, safe motherhood, and HIV/AIDS. Some tools also relate to gender, human rights, and youth/adolescent reproductive health, and some are specific to an individual component of the Policy Circle, while other tools address multiple components of the circle.

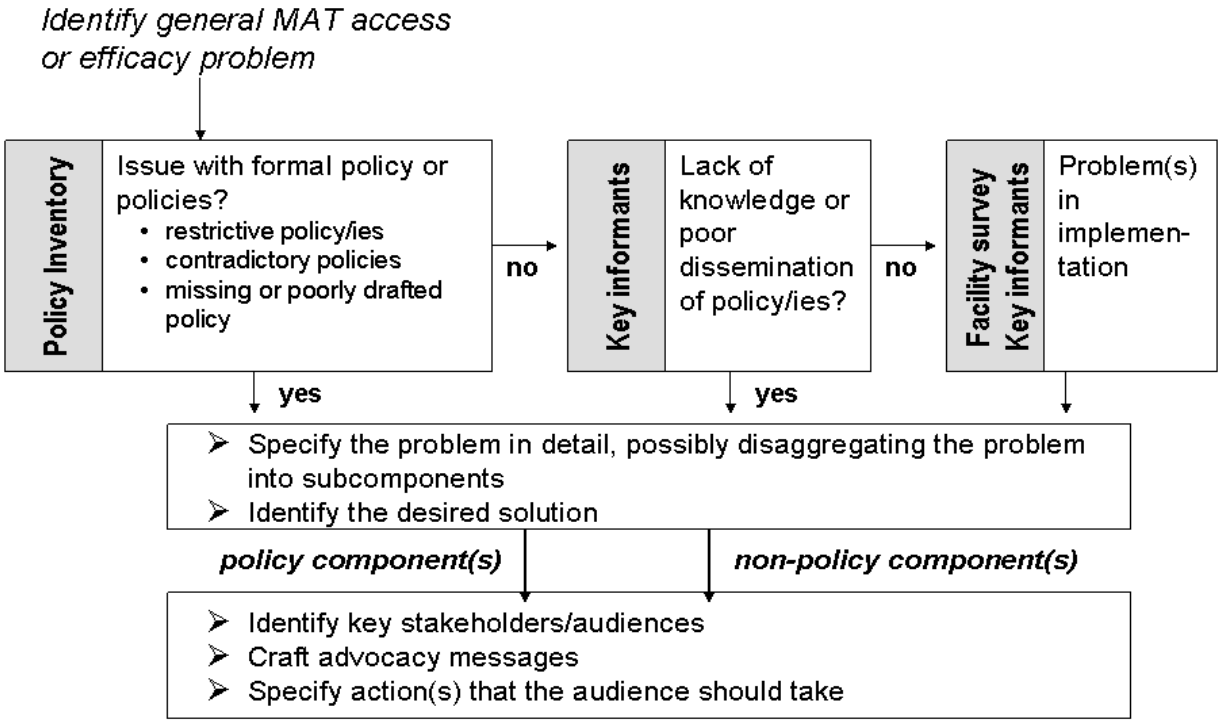


The political, social, cultural, and economic context

Policymaking does not take place in a vacuum. Different countries have their own political systems, forms of government, social and cultural traditions, and economic systems and levels of development. It is important to ascertain whether the political situation is stable or whether the government is working in a crisis mode. In addition to these general contextual issues that affect any policy change, MAT policy reform faces the specific political, social, and economic barriers described in Section 1.3, including stigma against injection drug users, political and cultural alliances and policies of dominant countries in the region, lack of access to up-to-date scientific information, uneven or hostile mass media coverage, and fledgling design and implementation of both advocacy efforts and MAT programs.

The problem

The Policy Circle begins with the problem that needs to be addressed through policy change. The general problem addressed by this Toolkit is access to quality MAT services. To tackle such a broad issue, advocates must identify which specific problem or problems contributing to the overall lack of or access to MAT services they wish to address first. Utilizing the policy inventory and assessment tools and methodologies presented here will provide analysis of the evidence that will underpin any effort to change policy; this evidence will help to measure the extent of the problem and suggest feasible and cost-effective policy responses.



People: Individual stakeholders

Many people are affected by MAT policies and programs—legislators who enact laws; economists who design national budgets, law enforcement officials and the court systems responsible for maintaining public order, clinicians who set standards of care and provide services, people who need and use those services, and their families and the communities in which they live. Each has some interest or "stake" in MAT. These stakeholders (the people involved in and/or affected by policymaking) and the institutions (the places) they represent are central to policy change. Some of their roles were described in Sections 1.1 and 1.2 under "participation."

Individual stakeholders come from within and outside of government. Public sector stakeholders can include politicians (heads of state and legislators); government bureaucrats and technicians from various sectors (e.g., health, education, finance, local government); and staff who implement public programs. Stakeholders from outside of government can include members of civil society organizations; support groups (e.g., groups of injection drug users or people living with HIV, women's health advocacy groups) or networks of these groups; and faith-based organizations. They also may include researchers and opinion leaders, such as media personalities. Individual beneficiaries of policy can also be involved in calling for policy change.

Places: Stakeholder institutions

Individual stakeholders not only have their own ideas and opinions, they also exercise responsibilities within their institutions. As described in Section 1.1, various parts of government play key roles in formal policymaking, including the executive branch (the head of state and the ministerial or departmental agencies of government); the legislative branch (the Parliament, congress or equivalent); and the judicial branch. In some countries, local governments have their own policymaking structures. Program implementers also play important roles in policymaking—for example, the Ministry of Health. The strength of institutions involved in policymaking can have a direct impact on the success of the policies and programs.

Institutions outside of the government play a role in policymaking by acting as advocates for policy change; providing data for decisionmaking; and providing funding for policy research, policy dialogue and formulation, and implementation. Finally, international organizations also play a role in supporting—and influencing—policymaking.

- **The expanded role of nongovernmental stakeholders in policy:** In the past, policymaking was concentrated in the hands of policymakers and a few influential people and organizations outside of government. Over the past decade, policymaking increasingly has included the participation of a wider range of stakeholders outside of government.

  It is not enough that nongovernmental stakeholders are kept informed as policies are developed. To be effective advocates, they should be included as contributing members of government bodies, consult and engage in policy dialogue with policymakers, and participate in multisectoral coordination mechanisms (UNFPA, 1999). Excluding injection drug users and others affected by drug use from MAT policy formulation runs the risk of developing an unresponsive policy or one that does not have broad social and political support. MAT advocates may find it useful to adapt the principle of Greater Involvement of People Living with HIV/AIDS (GIPA) in policymaking and program implementation, including application of the continuum of participation geared to ensuring the active involvement of people living with HIV (PLHIV) in decisionmaking and policymaking (UNAIDS, 1999). PLHIV advocates and activists have played an enormous role in making AIDS treatment available in developing countries (AFSC, 2003; TAC, 2003). IDU advocates could do the same for MAT.

  International organizations and donors are also important stakeholders in policy development and implementation. Donor funds often drive policy agendas. Most notably, the Global Fund asks countries in which injecting drug use is a principal driver of HIV transmission to include harm reduction and substitution treatment in their HIV/AIDS grants applications and encourages applicants to consider interventions to ensure a more supportive policy environment.[14]

- **The importance of policy champions:** High-level support within government is crucial for policy change to occur. While many stakeholders can and should be involved in advocacy, it is especially important to identify and support "policy champions." A policy champion can be anyone who is committed to an enabling policy environment for MAT and will use his/her convictions to motivate others to act on or participate in policy development and reform. Being an effective policy champion requires not only positive personality characteristics to engage and communicate with others, but also a solid understanding of the scientific and human rights arguments for MAT. Policy champions can come from any stakeholder group; what is important is that they have access to key decisionmakers. Generally, the higher level the policy champion, the more likely he or she will have a positive impact on the policy issue.

- **Analysis of people/places:** Stakeholder analysis is a useful tool for understanding the people and places (institutions) that can facilitate or block the desired policy reform. In its simplest form, a stakeholder matrix will list relevant individuals and organizations or groups; their reasons for their interest in MAT; knowledge about MAT; resources they can bring to bear on behalf of or in opposition to MAT (including access to information, human and financial resources, legal or moral authority, etc.); their capacity to mobilize resources; and their position on MAT. The tool is best used when stakeholders from different sectors are brought together to conduct a comprehensive analysis that includes government, politicians, nongovernmental organizations, the commercial sector (including private medical practice), other civil society groups, and possibly international donors.[15]

[14] See Global Fund, Harm Reduction Information Note, May 2010. Downloaded from http://www.theglobalfund.org/documents/rounds/10/R10_InfoNote_HarmReduction_en.pdf

[15] See the *Policy Stakeholder Analysis Tool*, http://www.policyproject.com/policycd/documents/stakeholder.doc.

The process: Policy development

Once the specific problem requiring a policy solution has been identified, the process of policy development includes how the problem is framed by various stakeholders, how to get it onto the policymaking agenda, and formulating the policy document. Moving the process along requires advocacy and policy dialogue by stakeholders, as well as data analysis at each step of the way.

- **Issue framing:** The way a problem is stated or an issue is framed influences the types of solutions proposed. Often, policy stakeholders take different sides of the drug use/dependency issue, with some advocating a law enforcement philosophy and others a medical condition and treatment philosophy. Issue framing—that is, describing the problem and its proposed solutions—sets the terms for policy debate and may influence the eventual outcome. Knowing likely arguments against MAT (see Section 1.3) will help advocates frame the issue in the best possible way from the outset.
- **Agenda setting:** Stakeholders outside of government can advocate for MAT policy reform, but government policymakers must become engaged in the process for the needed policy change to happen. Government policymaking bodies follow fixed calendars and terms of office. Health and welfare in general, and MAT in particular, are only a few of the myriad issues simultaneously clamoring for policymakers' attention. Clear issue framing, strong evidence to substantiate the problem, and effective policy champions are all needed to set MAT on the policy agenda.
- **Policy formulation:** Policy formulation is the part of the process by which proposed actions are articulated, debated, and drafted into language for a law or policy. See Section 1.1 for more details.
- **Advocacy and policy dialogue:** Both advocacy and policy dialogue are important for policy. In advocacy, stakeholders promote issues and their positions on the issues. Advocacy is more likely to succeed if networks of organizations and individuals join forces.[16] The media also can play an influential role by highlighting issues that need to be addressed and stimulating public discourse—even deciding which issues will receive public attention and which will not. Sections 1.3 and 1.4 highlight media opposition to MAT in the region and offer suggestions on engaging the media in a positive manner.

  Policy dialogue involves discussions among stakeholders to raise issues, share perspectives, find common ground and, if possible, reach agreement or consensus on policy solutions. Policy dialogue takes place among policymakers, advocates, other nongovernmental stakeholders, other politicians, and beneficiaries (see Section 1.1 on "participation").
- **Data analysis:** Lack of information is a common barrier to MAT policy reform (see Sections 1.3 and 1.4). Policymakers weigh their decisions on a number of criteria, including the technical merits of the issue; potential effects of the policy on political relationships within the bureaucracy and between groups in government and their beneficiaries; potential impact of the policy change on the regime's stability and support; perceived severity of the problem, and whether or not the government is in crisis; and pressure, support, or opposition from international aid agencies (Thomas and Grindle, 1994). Data analysis expands from the technical aspects of MAT to the political costs and benefits of policy reform.

The price tag

Price refers to the financial, physical, and human resources needed to implement policies, plans, and programs. It is crucial when developing or analyzing a MAT policy to consider the level of resources necessary for proper implementation, whether those resources already are available and allocated or need to be added, and any potential unintended consequences that funding decisions may have on program outcomes. Section 1.5 provides further discussion of international funding guidelines for MAT programs, including the issues around fee for service for patients, ensuring sustainable funding for dependency

[16] See *Networking for Policy Change* (POLICY, 1999), an advocacy training manual.

resources that will be needed over the long term, and the role of cost forecasting in strategic planning. Section 1.1 addresses the inclusion of budgeting for MAT into the law or policy document.

The paper: policies, laws, and regulations

Policy formulation culminates in promulgation of formal policy documents that provide a broad framework for MAT programs. These include legislation, policies, regulations, guidelines and protocols, and operational plans. Section 1.1 provides a detailed description of the roles and forms policy can take and a detailed description of the components needed for legislation.

The programs and performance: Policy implementation

Policies require strategic plans, operational policies and, ultimately, programs to ensure that the intent of the policy is carried out. Program encompasses organizational structure (including the lead implementing agency or body), resources, activities, and monitoring and evaluation of performance to assess whether goals of the policies and implementation plans have been met.

Policy implementation is political as well as technical and requires some of the same steps as policy development. The process of policy implementation is often left to technicians, including upper and mid-level managers. They may not be knowledgeable about MAT or even about established routines of the government, such as annual budget cycles.

Scaling up MAT programs (i.e., moving beyond pilot programs to broad access to treatment) faces a number of implementation challenges:[17]

- Generating and maintaining the support of community and government leaders;
- Ensuring sufficient present and future budgets and human resources;
- Adjusting the objectives, procedures, systems, and structures of agencies responsible for MAT implementation;
- Developing or reforming operational policies; and
- Monitoring progress and alerting decisionmakers and program managers to snags and intended and unintended consequences.

1.6.3 Summary

The *Policy Circle* presents a simple framework with easy-to-remember components. This simplicity is not intended to imply that formulating policy is simple—indeed, each component is complex and requires significant work. There will be many challenges. Perhaps the problem was not well articulated through adequate policy analysis. Perhaps there is strong opposition or differences of opinion on how to address the problem. There may have been insufficient efforts to consult those who will be affected by the policy change. Perhaps the policy document is vague or lacks an implementation strategy. Resources for implementation may be inadequate. Using the *Policy Circle* and related tools can help identify what aspects of policy or the policy process need to be addressed to solve an identified problem.

There is no hard and fast rule as to how much time each component will take, because it depends on the context and the issue to be addressed. Small or lower-level policy changes may be resolved more quickly than more comprehensive changes. Finally, MAT problems may need to be addressed by more than one policy. What is considered first as an adequate policy solution may not succeed, and the problem may need to be addressed through further policy reform—going back to the "Problem" and beginning the cycle again.

[17] For more detail, see the Implementing Policy Change Project framework that divides policy implementation into six tasks, some similar to the components of the Policy Circle (USAID, 2000).

1.6.4 References

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Annex 1.6: Description of the policy circle tools

In addition to the tools provided in Chapter 2, the following tools listed below may be helpful in implementation of MAT advocacy and policy reform. They are listed in alphabetical order. All of these and additional tools are available on the Policy Circle CD. [*]

Tool Name	Description
Advocacy Tools and Guidelines: Promoting Policy Change Manual	This training guide familiarizes program managers with key advocacy concepts and techniques. It suggests a framework for identifying policy goals, creating a plan of action, and effectively building a case for change.
Advocacy Training Manual (Networking for Policy Change: An Advocacy Training Manual)	The Advocacy Training Manual describes the building blocks of advocacy and includes background notes, learning objectives, and handouts. It can easily be adapted to MAT advocacy efforts.
Guidelines for Conducting a Stakeholder Analysis	The Guidelines were developed by the PHRplus Project to provide users with a framework for assessing key actors and their interests, knowledge, positions, alliances, resources, power, and importance.
HIV/AIDS Toolkit: Building Political Commitment for Effective HIV/AIDS Policies and Programs	The POLICY Project HIV/AIDS Toolkit contains five modules to assist activists interested in increasing political commitment for effective HIV/AIDS policies and programs.
Human Rights Approach	The Human Rights Approach to health issues includes identifying the health problem, identifying the related national norm or policy, comparing this policy with the human rights standard, researching a human rights solution, proposing a new rights-based policy, and advocating for its adoption
Human Rights Matrix	The Human Rights Matrix is a searchable database linking international human rights instruments, country parties, and specific human rights issues important to reproductive and maternal health, family planning, and HIV/AIDS.
Implementing Policy Change	This is a series of documents based on a project to improve policy implementation and democratic governance in developing countries. It includes technical notes, research notes, working papers, case studies, and monographs.
Monitoring the Policy Reform Process	This paper outlines the importance of policy reform, monitoring systems and tools for achieving policy reform, characteristics of good monitoring systems, identifying 'milestone events' in the policy reform process, approaches to monitoring policy reform, and other issues related to monitoring policy reform.
Planning and Finance Checklist	The Planning and Finance Checklist specifies key elements of the planning process and asks multiple-choice questions to determine whether the plan has adequately addressed these issues.
Policy Characteristics Checklist	The Policy Characteristics Checklist assesses the various aspects of policy. It poses the following questions, for example: Where did the impetus for policy change come from? What is the nature of the costs and benefits, and who bears them? How complex are the changes?
Policy Stakeholder Analysis Matrix	The Policy Stakeholder Analysis Matrix is used to analyze the stakeholders related to a specific issue. It assesses the group or organization and their potential vested interest in the policy reform, level of knowledge about the issue, available resources, capacity for resource mobilization, and position on the issue.

[*] Numerous tools exist to assess each component of the Policy Circle. Some were developed under the POLICY Project. Others were developed by other projects or organizations. Many of the tools are available at www.policyproject.com and also on the Policy Circle CD. Others are available through links to external websites.

Tool Name	Description
Political Mapping	PolicyMaker software is available at www.polimap.com. PolicyMaker is a rapid assessment method for analyzing and managing the politics of public policy.
Stakeholder Analysis	The Stakeholder Analysis document outlines an "objective" and systematic process for collecting and analyzing data about key health reform stakeholders.
Summary of Regulations and Policy Issues	The Summary of Regulations and Policy Issues provides a framework for assessing the population policy environment, including its legal, political, economic, demographic, ecological, cultural, and technological elements. The framework helps users identify the influences of obstacles and facilitators in each environmental element. It also provides a matrix to assess various issues and their impact and to propose strategies for change.
Understanding Steps to Passing a Law or Policy	This document provides clear details of the steps included in passing a law or policy, using the processes followed in Jamaica and Ukraine as examples. The document outlines the institutions and steps involved in drafting and submitting legislation for approval.

CHAPTER 2: MAT POLICY ADVOCACY TOOLS

The following tools in this chapter can be used separately or as a combined toolkit.

- **Tool 2.1.1** Inventory of Documents
- **Tool 2.1.2** Inventory Scoring Form
- **Tool 2.1.3** Quick Reference Matrix
- **Tool 2.2.1** Part A: MAT policy assessment index: Facility-based survey
- **Tool 2.2.2** Part B: MAT policy assessment index: Key informant interview
- **Tool 2.3.1** MAT policy stakeholder analysis worksheet
- **Tool 2.3.2** Political, social, cultural, and economic contexts worksheet
- **Tool 2.3.3** Problem identification/Advocacy prioritization worksheet
- **Tool 2.3.4** Target audience identification worksheet

2.1 Inventory of Country Legislation, Policies, Regulations, Guidelines/ Protocols with Reference to International Best Practices

Background on inventory of documents pertaining to medication-assisted therapy for opioid-dependence

Medication-assisted treatment (MAT) is used as part of a comprehensive treatment program for those individuals who are opioid dependent. The term includes the use of approved medications (e.g., methadone, buprenorphine, naltrexone) for treatment for opioid dependence. Medication can be used individually for patients seeking opioid detoxification or maintenance treatment. MAT may be provided in a variety of healthcare or program settings and in conjunction with a behavioral health treatment component, such as psychosocial treatment and support. Methadone and buprenorphine are controlled medications—drugs for which availability and access are restricted and distribution is strictly regulated because of their potential for abuse. The focus of this Inventory is to collect country policy documents concerning the availability and use of methadone, and/or buprenorphine, or other effective medications used as components of comprehensive treatment programs for opioid dependence.

Written policy documents (see table below) set the stage for program implementation, but by themselves cannot guarantee program success. In other words, documents are necessary but not sufficient for policy implementation and effective programs. The Inventory is meant to be the first step in a comprehensive review that can help guide advocacy efforts to achieve their ultimate objective of widely accessible and high-quality MAT programs. The purpose of the Inventory is to compile a reference library of policy documents addressing specific aspects of internationally accepted "best practices" for MAT for later analysis. As such, it does not assess the adequacy of the documents' provisions, *their* quality, or *the* extent to which they have been put into practice. For example, item 2.1 asks if there are any directives to allocate government budget for MAT. If there is a budget-related document or authorization with a line item for MAT, the data collector should check "yes," denoting that a line item budget has been mandated, and should attach the relevant policy document(s), noting the section or clause that refers to MAT. The data collector should not attempt to judge whether the amount of budget is sufficient to respond to the need for MAT in the country or whether the allotted resources were spent effectively on MAT. These analyses will be conducted later, after the reference library of documents and other information have been compiled.

The Inventory has two additional tools: the Inventory Scoring Form and Quick Reference Matrix, used to compare current policies with best practices. The Inventory Scoring Form analyzes or scores documents referenced in the aggregate in the Inventory and its sections are organized in accordance with Inventory content areas. The Matrix provides a snapshot of existing policies that can be compared against the internationally recognized best practices. These three tools form a package that can be used either as part of the Toolkit or independently to measure areas of strength and weakness in the country's policy/program environment and measure change in the environment over time. This allows for conducting a diagnosis, establishing a baseline, advocating for necessary changes, and evaluating the impact of advocacy efforts.

The Inventory is designed to be applied in Eastern Europe and Eurasia. While there is no single set of standards that encompasses all 'best practices' for every situation and circumstance, the Inventory identifies and embraces the content of the source references cited in below as representing and containing up-to-date explication of core concepts considered favorable for advancing MAT and overall drug treatment goals.

List of publications setting out internationally stated principles, standards, or guidelines, considered to state best practice guidance

WHO – *Guidelines for Assessing and Revising National Legislation on Treatment of Drug- and Alcohol-dependent Persons.* 1987. By W.J. Curran, A.E. Arif, and D.C. Jayasuriya, published in World Health Organization, International Digest of Health Legislation, Vol. 38, Supplement 1, 1987. Includes surveys of legislation, suggests alternative legislative provisions, and covers a wide range of subjects dealing with the role of legislation.

UNAIDS – *Advocacy Guide: HIV/AIDS Prevention among Injecting Drug Users*. 2004.
http://www.unodc.org/documents/hiv-aids/advocacy%20guide%20on%20prev%20for%20IDU.pdf

WHO – *Substitution Maintenance Therapy in the Management of Opioid Dependence and HIV/AIDS Prevention.* 2004.
www.who.int/substance_abuse/publications/en/PositionPaper_English.pdf
Position paper developed by the United Nations Office on Drugs and Crime, Joint United Nations Programme on HIV/AIDS.

WHO – *Access to Controlled Medications Programme*. 2007.
www.who.int/medicinedocs/index/assoc/s14860e/s14860e.pdf

WHO – *Principles of Drug Dependence Treatment.* 2008.
www.who.int/substance_abuse/publications/principles_drug_dependence_treatment.pdf
Discussion paper developed by the United Nations Office on Drugs and Crime.

WHO – *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence* . 2009.
http://www.who.int/substance_abuse/publications/drugs/en/index.html
Reviews the use of medications in combination with psychosocial support in the treatment of people dependent on heroin or other opioids. The Guidelines contain specific recommendations on the range of issues faced in organizing treatment systems, managing treatment programs, and treating people dependent on opioids.

WHO – *Technical Guide for Countries to Set Targets for Universal Access to HIV Prevention, Treatment and Care for Injecting Drug Users (IDUs)*. 2009
http://www.who.int/hiv/pub/idu/OMSTargetSettingGuide.pdf
Developed by the United Nations Office on Drugs and Crime.

Effective access to MAT depends not only on a positive policy environment that enables programs to provide methadone and/or buprenorphine but also on the absence of negative policies and practices that might keep otherwise motivated people from seeking therapy—such as the fear of being arrested or losing their job if seen at a treatment facility or identified as a person who uses drugs. Therefore, the Inventory includes a final section on key documents that may not have a direct impact on the availability of MAT services and medications but could affect whether people in need of these services seek them out.

Profile of team to complete the inventory tools

The contents of the Inventory are wide ranging, from authorization to offer MAT services, to scheduling and procurement of methadone and/or buprenorphine, to clinical procedures and continuum of care, to the civil and social rights of people who use drugs. The policy documents to be collected range from national legislation (and in some cases, the Constitution itself) to clinical guidelines and operational plans.

Because it is unlikely that a single person will have the policy and content area expertise to complete the entire Inventory, it is recommended that participating countries assemble a team of knowledgeable individuals who collectively can cover the content areas listed below. The country team will need a team leader to work with the project to identify appropriate members and ensure balance and composition of the team.

Content areas include the following:

- MAT policies and operational plans
- HIV prevention, care, and treatment
- National health systems
- Scheduling, registration, importation, and local manufacturing of controlled substances, in particular methadone and/or buprenorphine
- Budgeting
- Procurement and supply chain management
- Prison, jail, and policing procedures and practices related to drug use and MAT
- Clinical service delivery guidelines and standards of care for drug dependence
- Human rights

Ideally, the team would include no more than five to six members. In some countries, a few individuals may be able to cover all of these content areas. Although more than one content area can be filled out by the same individual, it is important that the team include a member of the community who is a person living with HIV, someone who injects drugs with knowledge of MAT programs, and/or a former or current drug user with linkages to the drug-using community and knowledge of one or more of the above-mentioned content areas.

Instructions for filling out the inventory tools

The Inventory considers five types of documents: legislation, policies, regulations, guidelines, and operational plans. They are defined as follows.

Types of documents that determine or otherwise affect medication-assisted treatment and/or delivery of comprehensive substance abuse treatment services

Legislation: Laws and other documents enacted or originated by the **Legislative branch** of government, such as Parliament, National Assembly. Also includes customs (importation) codes.

Policies: High-level documents issued by the **Executive branch** of government, such as the President, Prime Minister and other Cabinet ministers. Includes edicts, Presidential or Ministerial decrees, national strategies, programs.

Regulations: Documents issued by **line ministries and departments** that specify how laws, decrees, and other high-level policies should be put into practice. Includes orders, resolutions, rulings.

Guidelines, protocols: Published documents prepared by **professional associations** (e.g., medical, pharmacy, nursing, and dispensers) that specify the content and delivery of services.

Operational plans: Published documents prepared by **departments and programs** (e.g., National Treatment Program) usually on an annual or biennial basis, that specify the type and number of program activities to be conducted, such as training events, supervision schedules, commodities, and/or purchases.

For each item in the inventory, determine whether or not the country has enacted or issued pertinent legislation, policies, regulations, guidelines, and/or operational plans. *Do not assess the adequacy of the existing policy documents*. Answer "yes" or "no" for each type of policy document, for each item in the inventory.

For every "yes" answer, **include the full citation and attach a copy (English-language if possible) of the relevant document(s)**. Many documents may pertain to more than one item in the inventory. Each discrete document should be attached only once. For ease of filling out the inventory, the documents may be numbered and referred to by number. If a numbering system is used, prepare a separate attachment that lists for each number the **full title of the document** (e.g., "Requirements and Procedures for Providing Substitution Therapy to People with Drug Dependence in the Kyrgyz Republic"), its **official number** (e.g., Ministry of Health Order #71) and **date of publication** (e.g., 03/13/2001). Each time a policy document is referenced in the inventory, in the "notes" section, record its **title or number**, the **page number** where the specific reference is found and the **chapter or provision number** (if any). If a numbering system is used, **a separate attachment** listing the full title of the document with its number must be included.

If it is not possible to locate a physical copy of the policy document, use the "notes" section to describe it in detail—for example, exact name of the document, date of publication, registry number, etc. Use the description in lieu of the actual document only as a last resort: the quality of the subsequent in-depth assessment of the policy environment and recommendations for advocacy will depend in large part on analysis of the actual policy texts.

Note that more often than not, the documents that pertain to the various subjects in the inventory will not be in a law, regulation, or policy that uses the terms 'drug treatment' or 'Medication-assisted Treatment' in its title. Rather, many of the relevant documents will be trade, procurement, or customs documents or will be part of a criminal law that uses a different title. Therefore, it is desirable that the team filling out the inventory have broad knowledge not only about health programs but also about laws, regulations, and policies dealing with controlled substances (see "Profile of team to complete the inventory tools" above.)

Definition of terms

Drug dependence and MAT

Different countries may use different terms to describe substance abuse and MAT, and even different documents from the same country may use different terms to refer to the same concept. The data collector should be mindful of these variations and not restrict the search to a single, precise term.

Drug dependence: This term refers to people who use opioid drugs and have reached the clinical stage of drug dependence as defined by the DSM-IV or ICD-10 codes. Other terms employed to refer to people who use drugs may include the following:

- Drug addiction
- Drug addicts; People who are addicted to drugs
- Injecting drug users
- People who use non-medical drugs; People who use drugs for non-medical purposes
- Illicit drug use; Illegal drug use

Treatment for drug dependence: There are many forms of treatment for drug dependence, and not all of them follow international recommendations or best practices. The Inventory team should collect all policy documents that refer to treatment for drug dependence, whether or not the content of that treatment is specified or follows international guidelines. The team also should collect policy documents that refer specifically to MAT, as described below.

Medication-assisted treatment (MAT): According to the 2009 WHO guidelines, the medications of choice for MAT are either methadone or buprenorphine. Other medications may be used for opioid detoxification and treatment *but they are not included in this Inventory*. To simplify the document review, reference to treatment of opioid dependence or opioid drug abuse must explicitly name either methadone and/or buprenorphine.

Mention: The purpose of the Inventory is to collect all documents that expressly allow or prohibit specific practices as described in each item. The term "mention" includes both permission and prohibition. Pay attention to the entire phrase: for example, a document that states "public facilities may provide treatment" mentions government but not nongovernment facilities. However, if the document states "only government facilities may provide treatment," it explicitly mentions public facilities and implicitly notes nongovernment facilities (i.e., non-government facilities would be prohibited because *only* public facilities are permitted).

Registration, scheduling, and procurement

There are several documents a national government may use to control or specify which drugs and other pharmaceutical products may be used in the country. The Inventory includes two of these: the *Approved Drug List*, and the *Essential Drug (or Medicine) List*. In addition, the government may specify which drugs are approved for local manufacture and which are approved for importation. Alternatively, the government may explicitly indicate by law or regulation the use of controlled medications.

Approved Drug List: The Approved Drug List is the largest, most extensive listing of medical pharmaceuticals that are permitted for use in the country. It typically is maintained by the equivalent of the U.S. Food and Drug Administration (FDA, part of HHS). The Approved Drug list usually includes generic formulations as well as brand name drugs; it also covers both drugs that can be sold or distributed "over-the-counter" (i.e., without a physician's prescription) and those that require a physician's prescription. The Approved Drug List typically does not include drugs still being tested for safety and efficacy or those permitted only for research purposes.

For example, Methadone is registered in the United States. It is available as a concentrate, powder, and tablet, or already in solution. But only the solution is dispensed in the treatment of opioid dependence by federal law; the tablet is used in pain management by prescription. The FDA lists its active ingredients (Methadone Hydrochloride) and several brand names (e.g., Methadose, Westadone) registered by different manufacturers.

If the consultant has difficulty locating the country's Approved Drug List, he/she might contact the local office of one of the large transnational pharmaceutical companies. Bayer-Schering, GlaxoSmithKline, and other companies often have local offices to ensure that their products can be imported, distributed, and sold. They would know who to contact for the Approved Drug List.

Essential Drug List: Many countries also maintain an Essential Drug List. Most are adapted from the World Health Organization (WHO) *Model Lists of Essential Medicines*, which are updated every two years. The WHO model list includes a **core list** of minimum medicines for a basic healthcare system to address public health concerns and a **complementary list** of essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, specialist medical care, and/or specialist training are needed.

Methadone and buprenorphine are listed in the WHO Model Lists under section 24.5 Medicines Used in Substance Dependence Programmes, with the notation, "*The medicines should only be used within an established support programme."*

The Essential Drug List is usually smaller than the Approved Drug List—in other words, all of the drugs on the Essential Drug List should also be found on the Approved Drug List, but the reverse is not the case—not all drugs on the Approved Drug List will be found on the Essential Drug List.

Countries may use their Essential Drug List in different ways. Some countries may require that government health programs purchase only drugs listed in the Essential Drug List; on the other hand, private sector organizations may purchase any drugs that are on the Approved Drug List, whether or not they are on the Essential List. Other countries may require that government programs stock *all* of the drugs on the Essential Drug List. And some countries may not specify their own Essential Drug List, but instead direct their government health programs to use the WHO Model Lists as reference.

More than 150 countries have published an official essential drugs or medicines list. For example, Kyrgyzstan developed its first list of essential drugs in 1996, based on WHO guidelines, and revised the list in 1998, 2001, and 2003. Georgia developed an Essential Drugs List in 1995, which lists more than 250 generic drugs.

Local manufacture and importation: The drugs distributed and used in a country may include some products that are manufactured locally (in-country) and others that are imported from another country. The decision to manufacture locally vs. import is based on many considerations, including costs and type of laboratory installations required to manufacture the product. Government approvals to manufacture a drug locally (sometimes with imported raw materials) and/or to import the finished product may be found in different policy documents. In some cases, the approvals are indicated in the Approved Drug List and/or Essential Drug List. In other cases, approvals may be issued by special documents. Since methadone and buprenorphine are controlled substances, special approvals for their manufacture and/or importation are required to conform to international conventions. For example, the government of Kazakhstan issues an annual resolution, "*On the requirement of the Republic of Kazakhstan in narcotic drugs, psychotropic substances and precursors*," which specifies quotas limiting the amount of each controlled substance that may be imported during that year.

Participation

Active participation: New policies, guidelines, and other procedures are usually developed by a group of people working together, rather than by a single individual. Often a governmental office or agency is responsible for deciding who should participate in that group and ensuring that the group meets and accomplishes the task. Other organizations or individuals may be invited to observe the meetings, comment on draft documents before they are officially approved, or receive the final documents before they are formally circulated. An organization is considered to be an *active* participant if it contributes directly to discussions, votes on the outcomes, or has another way of making its positions known and considered. An organization invited to observe the process would not be considered an active participant unless there was an additional mechanism to ensure that its opinions were considered in the debate; similarly, an organization receiving a pre-publication copy of an approved document would not be an active participant.

Tool 2.1.1 Inventory of Documents

Country: _____ Date completed: _____

Name of data collector _____

Position: _____

Contact information for data collector:
Email address:_____

Telephone/fax: _____

Instructions to data collector:

Please fill out this page and indicate the best way to contact you (email, telephone, fax, etc.) should we need further information from you.

Refer to the instructions page for directions on how to fill out the inventory. The inventory includes 10 content areas. Please provide information only on those areas that you are familiar with and leave the others blank. Within the areas that you are familiar with, please be sure to answer "yes" or "no" to each item. All data collectors should address the open-ended question number 11 at the end of the inventory.

When you have completed the inventory, please send all the pages and all the documents you have referenced to [team leader should fill this in before distributing to team members].

1. Authorization			
1.1a	Is there any *mention* [see definition of terms] of *treatment* [see definition of terms] in government facilities for *drug dependence* [see definition of terms], in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.1b	*If yes to any in 1.1a*, is there any mention of treatment for drug dependence in government facilities with *methadone and/or buprenorphine*, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.2a	Is there any mention of treatment in non-government facilities for drug dependence, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.2b	*If yes to any in 1.2a*, is there any mention of treatment for drug dependence in non-government facilities with methadone and/or buprenorphine, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

1.3	*If any document in 1.2b allows non-government facilities to treat drug dependence with methadone and/or buprenorphine*, is there explicit mention of licensing, provider qualifications or other requirements for non-government services providing methadone and/or buprenorphine, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
1.4	*If any document in 1.2b allows non-government facilities to treat drug dependence with methadone and/or buprenorphine*, is there express mention of prices that non-government services are permitted to charge for methadone and/or buprenorphine, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

2. Budget			
2.1	Are there budgets and/or any explicit directives to allocate budget/financing for government provision of methadone and/or buprenorphine, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
2.2	Are there national estimates of the number of people who are drug dependent?		
	[ ] Yes → Attach document(s) [ ] No	Notes:	

2.3	Are there national targets or estimates of the number or percentage of drug users who will or should receive methadone and/or buprenorphine treatment, in [check each]?		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
2.4	Are there national targets or estimates of the number or the amount of methadone and/or buprenorphine that will be needed for drug treatment settings, in [check each]?		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

3. Registration, scheduling and procurement			
3.1	Is *methadone* included in the country's approved drug list, as found in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

3.2	Is *methadone* expressly registered or banned for use in substance dependence programs, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.3	Is ***buprenorphine*** included in the country's approved drug list, as found in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.4	Is ***buprenorphine*** expressly registered or banned for use in substance dependence programs, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.5	Are methadone and/or buprenorphine (either one or both) included in the country's own essential drug list, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

3.6	Is local country manufacture (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine expressly permitted or banned, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
3.7	Is importation (subject to licensing, oversight, etc.) of either methadone and/or buprenorphine expressly permitted or banned, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

4. Participation			
4.1	Are there written, express provisions that either encourage or exclude active participation of injecting drug users in the development of policies and/or regulations in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

4.2	Are there written, express provisions that either encourage or exclude active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, in the development of policies and/or regulations in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
4.3	Are there written, express provisions that either encourage or exclude active participation of injecting drug users in program design, implementation and/or monitoring in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
4.4	Are there written, express provisions that either encourage or exclude active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, in program design, implementation and/or monitoring in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

5. Storage, distribution and dispensing of controlled substances			
5.1	Are there written, express provisions for storage of methadone and/or buprenorphine, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
5.2	Are there written, express provisions that either allow or prohibit methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs (such as in general hospitals or in prisons), in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
5.3	Are there written, express provisions that either allow or prohibit authorized treatment facilities to dispense methadone and/or buprenorphine for later use outside the treatment facility, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

5.4	Are there written, express provisions that specify the numbers and/or locations of authorized treatment facilities to dispense methadone and/or buprenorphine, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6. Clinical Treatment and Continuum of Care			
6.1	Are there express provisions that designate some authority as the formal coordinator to develop individual medical drug abuse treatment plans, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.2	Is there explicit mention of the range and/or quality of care in services providing methadone and/or buprenorphine, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6.3	Are there express provisions for referral and counter-referral between treatment facilities and other agencies and services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.4	Are there express provisions for referral and/or case management between closed facilities (e.g., in-patient treatment facilities, prisons, etc.) and the community, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.5	Are there express provisions for integration of services and standardized procedures for patients with both need for treatment of opioid dependence and another health or medical condition such as HIV, pregnancy, etc., in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6.6	Are there express provisions that either allow or prohibit patients receiving methadone or buprenorphine treatment prior to imprisonment to continue treatment while in prison or other closed facility, or to start treatment while in prison, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.7	Are there express provisions that mandate or promote cooperation between drug treatment programs and law enforcement agencies, for example to permit referral to treatment instead of prosecution for minor drug offences, to ensure confidentiality of patient's information, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.8	Are there express provisions to ensure that drug treatment programs establish an individualized treatment plan for each patient, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

6.9	Are there express provisions that describe the range and/or dosing levels of methadone and/or buprenorphine that are permitted to be prescribed for drug treatment, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.10	Are there express provisions to ensure that injecting drug users have access to HIV and AIDS prevention, care and treatment medical services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.11	Are there express provisions to ensure that injecting drug users have access to Tuberculosis prevention, care and treatment medical services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.12	Are there express provisions to ensure that injecting drug users have access to Hepatitis prevention, care and treatment services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document:		

	Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.13	Are there express provisions to ensure that injecting drug users have access to psychological services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
6.14	Are there express provisions to ensure that injecting drug users have access to social services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

7. Standards of care			
7.1	Are there express provisions that establish and provide for professional competence of medical personnel and other health personnel who provide methadone and/or buprenorphine, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.2	Are there express provisions to provide medical doctors and other health personnel with basic and/or continuing training in the use of methadone and/or buprenorphine for the treatment of opioid dependence, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Operational plans	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.3	Are there express provisions that require the same standards of ethical treatment in to the treatment of drug dependence as other health care conditions (e.g. patient's right to autonomy and self determination, obligation for beneficence and non-malfeasance from treating staff), in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

7.4	Are there express provisions that protect or exclude confidentiality of client medical records and/or medical information in general, in [check all]		
Policy documents	Constitution	[ ] Yes → Attach document(s)	[ ] No
	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.5	Are there express provisions that protect or exclude confidentiality of medical information in drug dependence treatment, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
7.6	Are there express provisions that permit or prohibit health care providers from passing treatment information to law enforcement bodies, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

8. Coverage and client access to treatment			
8.1	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their age, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.2	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their gender, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.3	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of length of illicit drug use, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.4	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of their past history of attempts at abstinence or unsuccessful treatment attempts, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found:		

	Chapter or provision number of relevant reference:		
8.5	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of any kind of opioid dependence complications, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.6	Are there express (explicit) directives to offer or restrict methadone and/or buprenorphine to clients because of psychiatric conditions, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
8.7	Are there express (explicit) directives to require review by a medical commission or prescription by a psychiatrist for dispensing or prescribing methadone and/or buprenorphine for an individual client, in [check each]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

9. Women who inject drugs			
9.1	Is there explicit mention of women's specific needs for dosing levels of medications and/or other drug treatment services, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.2	Is there explicit mention of access to family planning and/or other reproductive health services by women who inject drugs, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.3	Is there explicit mention of the rights of women in treatment for drug dependence to retain or regain custody of their children except in cases of child abuse, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
9.4	Is there explicit mention of methadone and/or buprenorphine treatment for pregnant or lactating women who inject drugs, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

9.5 Is there explicit mention of access to prenatal care by women who inject drugs, in [check all]			
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10. Civil, economic, social and cultural rights of people who use drugs			
10.1 Are there express provisions that permit or prohibit mandatory testing for illicit drug use, in [check all]			
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.2 Are there express provisions that permit or prohibit <u>mandatory treatment</u> for people who use illicit drugs, in [check all]			
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.3	Are there express provisions that permit or prohibit other mandatory medical services or procedures (for example, HIV testing, contraceptive sterilization) for people who use opioids and because of their drug use, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.4	Are there express provisions that either guarantee or restrict the free movement of people who use opioids (such as mandatory quarantine, detention) because of their drug use, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.5	Are there express provisions that either guarantee or restrict employment opportunities for people who use opioids because of their drug use, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.6	Are there express provisions that either permit or prohibit discrimination based on medical or physical disability, in [check all]		
Policy documents	Constitution	[ ] Yes → Attach document(s)	[ ] No
	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.7	Are there express provisions that either permit or prohibit discrimination based on mental health condition, in [check all]		
Policy documents	Constitution	[ ] Yes → Attach document(s)	[ ] No
	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		
10.8	Is drug dependence classified as a disability and/or a mental health condition, in [check all]		
Policy documents	Constitution	[ ] Yes → Attach document(s)	[ ] No
	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

10.9	Are there express provisions that either guarantee or restrict any other civil, social or cultural benefits (such as voting, freedom of association, access to housing, education, custody of children) for people who use opioids because of their drug use, in [check all]		
Policy documents	Legislation	[ ] Yes → Attach document(s)	[ ] No
	High-level policies	[ ] Yes → Attach document(s)	[ ] No
	Regulations	[ ] Yes → Attach document(s)	[ ] No
	Guidelines and/or protocols	[ ] Yes → Attach document(s)	[ ] No
	Notes on Document: Title or number: Page number where reference for this item is found: Chapter or provision number of relevant reference:		

11. Please use the space below for any other remarks or observations about the areas covered in this inventory or to describe important topics concerning MAT, especially methadone and/or buprenorphine, that were not included in the inventory. Attach any related materials – e.g. press release, brochures, news articles, declarations.

_____

_____

_____

_____

_____

_____

_____

Background on inventory scoring form for documents pertaining to medication-assisted therapy for opioid dependence

The first step of the Inventory is to compile a reference library of documents addressing specific aspects of internationally accepted "best practices" for MAT using methadone or buprenorphine. The second step is to analyze or score the compiled documents.

Before beginning to score the individual items, the analyst should take time to become familiar with all of the documents in the reference library, especially if they were compiled by other people. For each item in the Inventory, the analyst should re-read the documents specifically referenced for that item and score them in the aggregate. Also include any other document(s) in the reference library that pertain to the item, even if they were not noted in the original inventory form.

Different documents may conflict with one another. For example, Methadone may be listed as an illicit drug in one document and permitted as a controlled substance in another. In this case, in Section 3 (Registration, scheduling and procurement) under item 3.1, two response options should be checked: "Methadone is expressly registered or scheduled" and "Methadone is expressly banned or prohibited." The relevant document(s) and sections should be cited in the box for each checked option.

If no written documents pertaining to the aspect in question were discovered (i.e., all document types were checked as "no") and none of the other documents in the reference library is applicable, check the last box for the item ("No mention of methadone in the policy documents").

At least one response option should be checked for each inventory item. The last box, "No mention…" should be checked only if none of the previous boxes were checked.

The analyst may find that a particular document that was classified in the first stage of the inventory as a "regulation" is in fact a "guideline," or vice-versa. The analyst should correct and make note of any documents that were misclassified by type.

In a few cases, the analyst will be asked to include a specific piece of information from the document(s). For example, item 2.4 asks about published estimates of the number of people potentially in need of MAT. If such an estimate exists, it should be included on the score sheet. Similarly, items 3.6 and 3.7 ask about authorization of local country manufacture and importation of methadone and buprenorphine. If authorization exists and if the authorized manufacturers and/or importers are listed, they should be included on the score sheet in the spaces provided.

The analyst should confine the ratings to what is contained in the written documents. He/she should not attempt to assess the adequacy of their content—for example, whether the estimated number of drug-dependent people potentially in need of MAT (item 2.4) is reasonable or whether the specification of range and/or quality of care of MAT services (item 6.1) meets the latest international standards. In addition, the analyst's ratings should not be influenced by how well the policy provisions have been circulated, support for or opposition to them, or the extent to which they have been put into practice. These more subjective ratings can be collected through key informant interviews and direct observation during Policy Assessment Index (PAI) application (See Tool 2.2.2).

Tool 2.1.2 Inventory Scoring Form

Country: _____ Date completed: _____

Name of analyst _____

Position: _____

Contact information for analyst:
Email address: _____

Telephone/fax: _____

Instructions to analyst:
Please fill out this page and indicate the best way to contact you (email, telephone, fax, etc.) should we need further information from you.

Refer to the instructions page for directions on how to score the inventory. The inventory includes 10 content areas. Please be sure to score all items for all content areas and read all cited documents, even if you are already familiar with their provisions.

When you have completed scoring the inventory, please send all the pages to [team leader should fill this in before distributing to team members].

1. Authorization
1.1a Government facilities are authorized to provide treatment for drug dependence
[ ] Government facilities are authorized to provide drug treatment *Citations*:
[ ] Government facilities are expressly banned or prohibited from providing drug treatment *Citations*:
[ ] No mention of drug treatment in government facilities in policy documents
1.1b Government facilities are authorized to provide methadone for drug dependence
[ ] Government facilities are authorized to provide methadone treatment for opioid dependence *Citations*:
[ ] Government facilities are expressly banned or prohibited from providing methadone treatment for opioid dependence *Citations*:
[ ] No mention of methadone treatment for opioid dependence for drug treatment in government facilities in policy documents
1.1c Government facilities are authorized to provide buprenorphine for drug dependence
[ ] Government facilities are authorized to provide buprenorphine treatment for opioid dependence *Citations*:
[ ] Government facilities are expressly banned or prohibited from providing buprenorphine treatment for opioid dependence *Citations*:
[ ] No mention of buprenorphine treatment for opioid dependence for drug treatment in government facilities in policy documents
1.2a Non-government facilities are authorized to provide treatment for drug dependence
[ ] Non-Government facilities are authorized to provide drug treatment *Citations*:
[ ] Non-Government facilities are expressly banned or prohibited from providing drug treatment *Citations*:
[ ] No mention of drug treatment in non-government facilities in policy documents
1.2b Non-government facilities are authorized to provide methadone for drug dependence
[ ] Non-Government facilities are authorized to provide methadone treatment for opioid dependence *Citations*:
[ ] Non-Government facilities are expressly banned or prohibited from providing methadone treatment for opioid dependence *Citations*:
[ ] No mention of methadone treatment for opioid dependence for drug treatment in non-government facilities in documents
1.2c Non-government facilities are authorized to provide buprenorphine for drug dependence
[ ] Non-Government facilities are authorized to provide buprenorphine treatment for opioid dependence *Citations*:
[ ] Non-Government facilities are expressly banned or prohibited from providing buprenorphine treatment for opioid dependence *Citations*:
[ ] No mention of buprenorphine treatment for opioid dependence for drug treatment in non-government facilities in documents

1.3	Licensing, provider qualifications or other requirements for non-government services providing methadone and/or buprenorphine are provided
[ ] Licensing, provider qualifications are specified *Citations*:	
[ ] Non-government services are not permitted to provide MAT using methadone or buprenorphine	
[ ] No mention of licensing, provider qualifications in policy documents	
1.4	Prices that non-government services providing methadone and/or buprenorphine are allowed to charge are specified
[ ] Prices are specified → prices: *Citations*:	
[ ] Non-government services are not permitted to provide MAT using methadone or buprenorphine	
[ ] No mention of prices in policy documents	

2. Budget	
2.1	There are budgets and/or explicit directives to allocate budget/financing for government provision of methadone and/or buprenorphine.
[ ] There are directives to allocate budgeting/ financing for government provision of methadone and/or buprenorphine treatment for opioid dependence *Citations*:	
[ ] No mention of budget allocation in policy documents	
2.2	There are national estimates of the number of people who are opioid drug dependent.
[ ] Yes → Number of drug dependent people: __ __ __ __ __ __ [ ] No	Source, year:
2.3	There are national targets or estimates of the number or percentage of opioid dependent drug users who will or should receive methadone and/or buprenorphine treatment.
[ ] Yes → Estimated use of MAT using methadone or buprenorphine: [ ] No	Source, year:
2.4	There are national targets or estimates of the number or the amount of methadone and/or buprenorphine that will be needed for drug treatment settings.
[ ] Yes → Estimated medications needed: [ ] No	Source, year:

3. Registration, scheduling and procurement	
3.1	*Methadone* is included in the country's approved drug list.
[ ] Methadone is expressly registered or scheduled *Citations*:	
[ ] Methadone is expressly banned or prohibited *Citations*:	
[ ] No mention of methadone in the country's approved drug list	

3.2 *Methadone* is expressly registered and/or scheduled for use in opioid dependence treatment programs.	
[ ] Methadone is expressly registered or scheduled <u>for opioid dependence treatment</u> *Citations*:	
[ ] Methadone is expressly banned or prohibited <u>for opioid dependence treatment</u> *Citations*:	
[ ] No mention of methadone <u>for opioid dependence treatment</u> in policy documents	
3.3 *Buprenorphine* is included in the country's approved drug list.	
[ ] Buprenorphine is expressly registered or scheduled for opioid dependence treatment *Citations*:	
[ ] Buprenorphine is expressly banned or prohibited for opioid dependence treatment *Citations*:	
[ ] No mention of buprenorphine in the country's approved drug list	
3.4 *Buprenorphine* is expressly registered and/or scheduled for use in opioid dependence treatment programs.	
[ ] Buprenorphine is expressly registered or scheduled <u>for opioid dependence treatment</u> *Citations*:	
[ ] Buprenorphine is expressly banned or prohibited <u>for opioid dependence treatment</u> *Citations*:	
[ ] No mention of buprenorphine <u>for opioid dependence treatment</u> in policy documents	
3.5 Methadone and/or buprenorphine are included in the country's own essential drug list.	
Methadone: [ ] Yes [ ] No Buprenorphine: [ ] Yes [ ] No	Source, year:
3.6 Local country manufacture of methadone and/or buprenorphine is authorized or permitted.	
[ ] Local manufacture of methadone is allowed [ ] Local manufacture of methadone is banned [ ] No mention of local manufacture	Authorized manufacturers:
[ ] Local manufacture of buprenorphine is allowed [ ] Local manufacture of buprenorphine is banned [ ] No mention of local manufacture	Authorized manufacturers:
Citations:	
3.7 Importation of methadone and/or buprenorphine is authorized or permitted.	
[ ] Import of methadone is allowed [ ] Import of methadone is banned [ ] No mention of import	Authorized importers:
[ ] Import of buprenorphine is allowed [ ] Import of buprenorphine is banned [ ] No mention of import	Authorized importers:
Citations:	

4. Participation
4.1 There are written, express provisions that encourage active participation as consultants of injecting drug users in the development of policies and/or regulations.
[ ] Yes → Mechanism: [ ] No
Citations:
4.2 There are written, express provisions that encourage active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, as consultants in the development of policies and/or regulations.
[ ] Yes → Mechanism: [ ] No
Citations:
4.3 There are written, express provisions that encourage active participation of injecting drug users as consultants in program design, implementation and/or monitoring.
[ ] Yes → Mechanism: [ ] No
Citations:
4.4 There are written, express provisions that encourage active participation of other civil society organizations such as families of drug users, other patient groups such as persons living with HIV and/or their advocates, as consultants in program design, implementation and/or monitoring.
[ ] Yes → Mechanism: [ ] No
Citations:

5. Storage, distribution and dispensing of controlled medications
5.1 There are written, express provisions for storage of controlled medications in general and/or methadone and/or buprenorphine in particular.
[ ] Yes → Mechanism: [ ] No
Citations:

5.2 There are written, express provisions that allow methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs.	
[ ] Methadone and/or buprenorphine are <u>allowed</u> in (specify): [ ] Methadone and/or buprenorphine are <u>prohibited</u> in (specify): [ ] No provisions exist regarding methadone and/or buprenorphine use inside medical facilities other than dedicated substance dependence treatment programs	
Citations:	
5.3 There are written, express provisions that allow authorized treatment facilities to dispense or prescribe methadone and/or buprenorphine for later use outside the treatment facility.	
[ ] Treatment facilities are <u>allowed</u> to dispense MAT for use outside the facility [ ] Methadone and/or buprenorphine are <u>prohibited</u> from dispensing MAT for use outside the facility [ ] No provisions exist regarding dispensing MAT for use outside the facility	
Citations:	
5.4 There are written, express provisions that specify the numbers and/or locations of authorized treatment facilities to dispense or prescribe methadone and/or buprenorphine.	
[ ] Yes [ ] No mention of identification of suppliers	Authorized number or locations:
Citations:	

6. Clinical treatment and Continuum of care	
6.1 There are express provisions that designate some authority as the formal coordinator to develop individual medical drug abuse treatment plans.	
[ ] Yes [ ] No	Citation:
6.2 There is express mention of the range and/or quality of care in services providing methadone and/or buprenorphine.in the treatment for opioid dependence.	
[ ] Yes [ ] No	Citation:
6.3 There are express provisions for referral and counter-referral between treatment facilities and other agencies and services.	
[ ] Yes [ ] No	Citation:
6.4 There are express provisions for referral and/or case management between closed facilities (e.g. in-patient treatment facilities, prisons, etc.) and the community.	
[ ] Yes [ ] No	Citation:

6.5	There are express provisions for integration of services and standardized procedures for patients with both need for treatment of opioid dependence and another health or medical condition such as HIV, pregnancy, etc.
[ ] Yes [ ] No	Citation:
6.6	There are written, express provisions that allow patients receiving methadone treatment prior to imprisonment to continue treatment while in prison or other closed facility, or to start treatment while in prison.
[ ] Yes [ ] No	Citation:
6.7	There are express provisions that mandate or promote cooperation between drug treatment programs and criminal justice system, for example to permit referral to treatment instead of prosecution for non-violent drug offences.
[ ] Yes [ ] No	Citation:
6.8	There are written, express provisions to ensure that drug treatment programs establish an individualized treatment plan for each patient.
[ ] Yes [ ] No	Citation:
6.9	There are express provisions that describe the range and/or dosing levels of methadone and/or buprenorphine, that are permitted to be prescribed for opioid dependence.
[ ] Yes [ ] No	Citation:
6.10	There are written, express provisions to ensure that injecting drug users have access to HIV and AIDS prevention, care and treatment medical services.
[ ] Yes [ ] No	Citation:
6.11	There are written, express provisions to ensure that injecting drug users have access to Tuberculosis prevention, care and treatment medical services.
[ ] Yes [ ] No	Citation:
6.12	There are written, express provisions to ensure that injecting drug users have access to Hepatitis prevention, care and treatment services.
[ ] Yes [ ] No	Citation:
6.13	There are written, express provisions to ensure that injecting drug users have access to psychological services.
[ ] Yes [ ] No	Citation:
6.14	There are written, express provisions to ensure that injecting drug users have access to social services including case management.
[ ] Yes [ ] No	Citation:

7. Standards of care	
7.1 There are express provisions that establish and provide for professional competence of medical personnel and other health personnel who provide methadone and/or buprenorphine in the treatment for opioid dependence.	
[ ] Yes [ ] No	Citation:
7.2 There are express provisions to provide medical doctors and other health personnel with basic and/or continuing training in the use of methadone and/or buprenorphine for the treatment of opioid dependence.	
[ ] Yes [ ] No	Citation:
7.3 There are express provisions that require the same standards of ethical treatment in to the treatment of drug dependence as other health care conditions.	
[ ] Yes [ ] No	Citation:
7.4 There are express provisions that protect confidentiality of client medical records and/or medical information in general.	
[ ] Medical records are explicitly protected [ ] No provisions exist regarding confidentiality of medical records	
Citations:	
7.5 There are express provisions that protect confidentiality of medical information in drug dependence treatment.	
[ ] Medical information in drug dependence treatment is explicitly protected [ ] Medical information in drug dependence treatment is explicitly excluded from protection [ ] No provisions exist regarding dispensing confidentiality of medical information in drug dependence treatment	
Citations:	
7.6 There are express provisions that prohibit health care providers from providing treatment information to law enforcement bodies without specific court authorization.	
[ ] Health care providers are explicitly prohibited from passing treatment information to law enforcement without court authorization [ ] Health care providers are explicitly allowed to pass treatment information to law enforcement without court authorization [ ] No provisions exist regarding passing treatment information to law enforcement	
Citations:	

8. Coverage and client access to treatment	
8.1 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment, to clients because of their age.	
[ ] MAT is explicitly available to all who need it regardless of age	
[ ] Age restrictions on MAT are specified	Excluded ages:
[ ] No mention of age restrictions	
Citations:	
8.2 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of their gender.	
[ ] MAT is explicitly available to all who need it regardless of gender	

[ ] Gender restrictions on MAT are specified	Gender restrictions:
[ ] No mention of gender restrictions	
Citations:	
8.3 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment clients because of length of illicit drug use.	
[ ] MAT is explicitly available to all who need it regardless of length of drug use	
[ ] Restrictions because of length of use are specified	Restrictions:
[ ] No mention of restrictions for length of use	
Citations:	
8.4 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of their history of attempts at abstinence or unsuccessful treatment attempts.	
[ ] MAT is explicitly available to all who need it regardless of past history	
[ ] Restrictions because of past history are specified	Restrictions:
[ ] No mention of restrictions because of past history	
Citations:	
8.5 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of any kind of opioid dependence complications.	
[ ] MAT is explicitly available to all who need it regardless of dependence complications	
[ ] Restrictions because of dependence complications are specified	Restrictions:
[ ] No mention of restrictions because of dependence complications	
8.6 There are no restrictions to offer or restrict methadone and/or buprenorphine treatment to clients because of psychiatric conditions.	
[ ] MAT is explicitly available to all who need it regardless of psychiatric conditions	
[ ] Restrictions because of psychiatric conditions are specified	Restrictions:
[ ] No mention of restrictions because of psychiatric conditions	
Citations:	
8.7 There is no requirement of review by a medical commission or prescription by a psychiatrist for dispensing or prescribing methadone and/or buprenorphine in the treatment for opioid dependence, for an individual client.	
[ ] MAT is explicitly available to all who need it without medical or psychiatric review	
[ ] Review by medical commission or psychiatrist is explicitly required	Specifications:
[ ] No mention of review	
Citations:	

9. Women who inject drugs	
9.1 There is explicit mention of women's specific needs for dosing levels of medications and/or other drug treatment services.	
[ ] There are special dosing guidelines for women	Citation:
[ ] No mention of special dosing guidelines for women	
9.2 There are express provisions to ensure that women injection drug users can obtain family planning and other reproductive health services.	
[ ] Access to FP/RH is guaranteed but use is not required	Citations:
[ ] FP use is required of women in treatment	Citations:
[ ] No mention of access to FP/RH	
9.3 There are express provisions to protect or promote the rights of women in treatment for drug dependence to retain or regain custody of their children for cases without child abuse.	
[ ] Custody rights of women in treatment are explicitly protected	Citations:
[ ] Custody rights are explicitly denied to women in treatment	Citations:
[ ] No mention of custody rights	
9.4 There are written, express provisions to ensure that pregnant or lactating women have access to methadone and/or buprenorphine treatment.	
[ ] Pregnant/lactating women are guaranteed access to methadone and/or buprenorphine	Citations:
[ ] Pregnant/lactating women are restricted in access to methadone and/or buprenorphine	Citations:
[ ] No mention of pregnancy/lactation	
9.5 There are express provisions to ensure that pregnant women who use drugs have the same access to prenatal care as any other pregnant women.	
[ ] Access to prenatal care is protected	Citation:
[ ] No mention of access to prenatal care	

10. Civil, economic, social and cultural rights of people who use drugs	
10.1 Mandatory testing for illicit drug use.	
[ ] Mandatory testing for illicit drug use is permitted	Citations:
[ ] Mandatory testing for illicit drug use is prohibited	Citations:
[ ] No mention of mandatory testing for illicit drug use	

10.2 Mandatory treatment for illicit drug use.	
[ ] Mandatory treatment for illicit drug use is permitted	Citations:
[ ] Mandatory treatment for illicit drug use is prohibited	Citations:
[ ] No mention of mandatory treatment for illicit drug use	
10.3 Imposition of medical services or procedures (such as mandatory HIV testing, contraceptive sterilization) on people who use opioids because of their drug use.	
[ ] Mandatory medical procedures for drug users are explicitly specified	Citations:
[ ] Mandatory medical procedures for drug users are explicitly prohibited	Citations:
[ ] No mention of mandatory medical procedures because of drug use	
10.4 Restrictions on the free movement of people who use opioids (such as mandatory quarantine, detention) because of their drug use.	
[ ] Movement of drug users is explicitly restricted	Citations:
[ ] Free movement of drug users is explicitly protected	Citations:
[ ] No mention of free movement of drug users	
10.5 Restrictions on employment opportunities for people who use opioids because of their drug use.	
[ ] Restrictions on employment for drug users are explicitly permitted	Citations:
[ ] Restrictions on employment for drug users are explicitly prohibited	Citations:
[ ] No mention of employment restrictions because of drug use	
10.6 Discrimination based on medical or physical disability is prohibited.	
[ ] Discrimination based on medical or physical disability is explicitly prohibited	Citations:
[ ] Discrimination based on medical or physical disability is explicitly allowed	Citations:
[ ] No mention of protection from discrimination based on medical or physical disability	
10.7 Discrimination based on mental health condition is prohibited.	
[ ] Discrimination based on mental health condition is explicitly prohibited	Citations:
[ ] Discrimination based on mental health condition is explicitly allowed	Citations:
[ ] No mention of protection from discrimination based on mental health	

10.8 Is drug dependence classified as a disability and/or a mental health condition?	
[ ] Yes [ ] No	
Citations:	
10.9 Restrictions on other civil, social or cultural benefits (such as voting, freedom of association, access to housing, education, custody of children) for people who use opioids because of their drug use.	
[ ] Restrictions on other rights and/or benefits are explicitly permitted	Citations:
[ ] Restrictions on other rights and/or benefits are explicitly prohibited	Citations:
[ ] No mention of restrictions on other rights and/or benefits because of drug use	

Hints from Malika

1. Before starting to score, skim every document from the beginning to end. You may find a lot of useful information for multiple items.
2. Re-read each item twice before you start to answer it, to make sure you understand what is being asked.
3. Begin each item by reviewing the national consultant's attachments. Check the attachments carefully – you may find that some attachments listed by the consultant do not relate to the item in question and/or that attachments to other items may have important information for the item in question.
4. Do not forget to put the page number and section title of each source along with its citation.
5. Print out all documents that are related to the substitution therapy. You will have a lot of detailed questions on this issue!
6. The actual scoring will take two or three times longer than you think it will.

This work is not boring! Enjoy it ☺

Background on quick reference matrix for policy documents pertaining to medication-assisted therapy using Methadone or Buprenorphine in the treatment of opioid dependence

The *Quick Reference Matrix* provides an easy way for policymakers, program managers, advocates, and other stakeholders to see which policy documents are especially important for content areas. This tool represents a snapshot of the information collected for the Inventory and can be used as an illustrative chart during the identification of advocacy strategies or the development of action plans for implementing advocacy strategies. It should be filled in only after the Inventory has been completed—after the reference library of documents has been compiled and the Inventory has been scored.

1. Identify which of the documents in the reference library are the most relevant for MAT using methadone or buprenorphine, either because they enable effective treatment programs to be designed, implemented, and used by those who need drug treatment services or because they pose significant obstacles or barriers to the design, implementation, and/or use of MAT services.

   Each policy document should be listed only once in Column 1, even if it is relevant for more than one content area. Include its full title, official number and the date that it was adopted or disseminated. Use one line per document.

2. The 10 policy or content areas are listed in columns 2–11. Beginning with the first listed policy document, identify which policy area or areas it covers. Fill in that cell or cells with the page number and chapter/section number where the policy text can be found. (Do not fill in the actual text and do not specify which particular questions within the policy area are addressed.) When the line for the first listed policy document has been completed, go on to the second policy document and continue until the last line has been completed.

3. Every listed policy document should be cross-referenced to at least one MAT policy area. Some policy documents may be cross-referenced to more than one policy area. There may be some policy areas that are not covered by any document in the reference library.

Tool/Instrument	Level of Detail	Uses
Reference library: Original policy documents	Highest	• Citations to support policy arguments • Specify policy clauses that should be changed
Policy inventory: Scored	High	• Assess overall adequacy of policy environment • Identify policy barriers, contradictory policies, and/or policy gaps
Quick reference matrix	Lowest	• Quick identification of relevant policy documents • Facilitate use of reference library and Inventory

Tool 2.1.3 Quick Reference Matrix

Key Documents: Title, Date, Official Number	Policy Area									
	Authorization	Budget	Registration	Participation	Distribution	Treatment	Standards	Coverage	Women	Rights

2.2 Policy Assessment Index

Background

Medication-assisted treatment (MAT) is used as part of a comprehensive treatment program for those individuals who are opioid dependent. The term includes the use of approved medications (e.g., methadone, buprenorphine, naltrexone) for treatment for opioid dependence. Medication can be used individually for patients seeking opioid detoxification or maintenance treatment. Despite considerable evidence that MAT using methadone or buprenorphine enhances HIV prevention, care, and treatment, as well as other health outcomes, and leads to substantial cost savings in healthcare and criminal justice, widely differing views among policymakers, law enforcement, the medical community, and the general public often inhibit the scale-up and coverage of this important therapy.

The MAT *Policy Assessment Index* explores experiences and opinions related to (1) the coverage of MAT using methadone or buprenorphine; (2) quality of care provided by MAT using methadone or buprenorphine; (3) involvement of civil society, including people who use drugs, in policy dialogue related to MAT using methadone or buprenorphine; and (4) stigma, harassment, and human rights violations that people who use drugs face in accessing services. The Index consists of two sections—facility-based interviews with clients, service providers, and managers and key informant interviews with clients, service providers, and other key informants. The facility-based interviews focus on quality of care of MAT using methadone or buprenorphine and the provision of health services. The key informant interviews include opinions regarding coverage of MAT services, involvement of civil society, and human rights considerations.

The *Policy Assessment Index* complements the *Inventory of Country Legislation, Policies, Regulations, Guidelines/ Protocols with Reference to International Best Practices*. The *Inventory* compiles a reference library of written policy documents addressing specific aspects of internationally accepted "best practices" for MAT using methadone or buprenorphine that sets the stage for program implementation. The *Index* provides an "on-the-ground" assessment of program success. Used together, the two tools support a comprehensive review that can help guide advocacy efforts to achieve their ultimate objective of widely accessible and high-quality MAT programs using methadone or buprenorphine. The information collected will help treatment providers, people who use drugs, advocates, and policymakers make concrete recommendations to introduce, scale up, and improve access to quality services for treatment of opioid dependence.

Tool 2.2.1 Part A: MAT policy assessment index: Facility-based survey

Overview

The purpose of the facility-based survey is to collect information on quality of care and fees charged to/paid by clients. These data are most reliably captured at the point of service from actual program clients and providers.

Critical elements of quality of care in MAT using methadone or buprenorphine include setting and monitoring client dose, client-provider interactions and opportunity for discussion, dispensing procedures, and problems with stockouts or low stock levels at the facility. These should be assessed from both the client and provider perspectives.

There are several ways to collect facility-based information, including gathering information from "mystery" clients, medical record review, direct observation of the client-provider interaction, client intercept interviews, and interviews with service providers and managers. Each has its own strengths and limitations.

Methodology	Strengths	Limitations/Challenges
Mystery client (observer posing as client)	• Direct observation of client-provider interaction • Ease of data collection	• Cannot be used to monitor continuing care • May be difficult to implement in closed communities
Medical record review	• Provides longitudinal record of dosing • Does not disrupt patient flow	• Depends on completeness and legibility of written record • Does not include client-provider interaction • Privacy issues (client name)
Direct observation of client-provider interaction	• Direct observation of client-provider interaction in real time • Ease of data collection	• May alter provider's and/or client's behavior • Does not capture longitudinal information • Privacy issues
Client intercept interviews, coupled with provider interview	• Accurate recall of current visit • Does not disrupt patient flow • Ease of data collection	• Possible difficulties recalling past events • Possible selection bias
Provider interviews, coupled with client intercept	• Insight into provider perspective • Does not disrupt patient flow • Ease of data collection	• Possible difficulties recalling past events • Possible reporting bias

Client intercept interviews—usually administered after the visit has been completed—coupled with provider interviews, generally yield good overall information, within the shortest timeframe and at the lowest cost.

Preparing for the facility-based survey

Simple preparations are essential to ensure that the right people are interviewed under proper conditions that safeguard privacy and do not impede patient flow/functioning of the facility. Clients should be interviewed immediately upon finishing their visit; providers should be interviewed after operating hours. To avoid interviewing the same client more than once, all client interviews should be completed during the same day if possible.

The survey supervisor should visit the facility in advance of the fieldwork and fill out the *Facility Information* form. At that time, he/she can meet with facility staff to explain the purpose of the survey and answer their questions. A "normal" workday should be chosen for the client interviews; it may be preferable to avoid the last day before the weekend or a major holiday and the first day after the weekend or holiday. Provider interviews should be conducted after all client interviews have been conducted and may be scheduled over several days.

The *Facility Information Form* should be filled out for each facility in the system, regardless of whether all facilities or a sample of facilities will be surveyed. Part 1 can be completed through a telephone or email interview with the clinic manager or other knowledgeable informant. Criteria for selecting facilities for survey will depend on the policy issues of interest. If the purpose is to understand the "typical" facility and client experience, facilities would be selected proportional to size. If the purpose is to understand the range of facilities and client experience, purposive sampling would be more appropriate. In this case, it might be of interest to compare facilities in the capital city with facilities in other locations, facilities that have been operating a longer time with those that started more recently, public sector with private sector facilities, or larger facilities with smaller facilities.

Once the facilities have been selected for survey, the survey manager should visit each facility in person to complete Part 2 of the Facility Information Form. This will enable interviewers to be stationed appropriately, and the supplementary information (e.g., presence of police and/or others inside or outside of the facility) may be useful for providing security for interviews. Direct observations of presence of client information (client rights, educational information, etc.) can be compared against client and staff responses.

Ethics review

Client interviews will likely require approval by an Institutional Review Board (IRB) or comparable ethics review committee in the country where the survey will be conducted. If the survey is funded by U.S. government funds, IRB approval also will be required in the United States. Ethics review is required for any biomedical or behavioral research involving humans—particularly when vulnerable groups such as drug users are involved in the research—with the aim of protecting the rights and welfare of the research participants.

Client interviews

For statistical reliability, we recommend at least 100 interviews per facility. If the facility serves fewer than 100 clients, all clients should be approached for interview (a census). If the facility serves more than 100 clients, a quota sample should be interviewed, as follows. Different kinds of clients may have different experiences—for example women vs. men, ethnic minorities, or even clients who come in the early morning vs. those who come later in the day. To capture the "typical" client experience or the range of typical experiences, we recommend that a minimum of 25 clients be interviewed for each specific group (or all clients if there are fewer than 25 in that group) and that interviews be spaced out over the day more or less in the same proportion in which clients come in for treatment. This may require posting more interviewers during the peak attendance hours than at other times of day. Assigning quotas will ensure that enough interviews of each type are conducted.

Illustration: Clinic A provides methadone treatment to 300 clients, including 30 ethnic minority men, 50 women (all ethnicities), and 220 non-minority men. Approximately 60 percent of all clients come for their doses in the early morning, with the remainder coming in late morning or afternoon. The following interview/quota schedule is proposed for a total of 100 interviews:

Group	Time	Quota	# Interviewers
Non-minority men	Early morning	30	3
Non-minority men	Late morning	10	2
Non-minority men	Afternoon	10	1
Minority men	All day	25	1
Women	All day	25	1

Interviewers should be instructed to approach the first client who passes their station and continue interviewing until they complete their assigned quota. Care should be taken to avoid interviewer selection bias (for example, not approaching clients who look to be in a hurry or who are poorly dressed, etc.).

Provider interviews

It is important to interview the full range of facility staff who provide client services and/or supervise or manage those who provide services. In many facilities, there may be only one or two of each kind of service provider, and some providers may fill multiple roles (e.g., attending physician also supervises non-clinicians). If there are three or fewer of any kind of service provider (e.g., physicians, nurses, counselors), all should be interviewed. If there is a large number (e.g., volunteers), a sample can be chosen, taking care to represent different sub-groups (e.g., men and women).

Data entry and analysis

Any standard computer package can be used for data entry (Excel, SPSS, STATA, etc.). Double data entry verification is recommended, along with range checks for accuracy. The survey is designed for analysis with simple descriptive statistics, such as frequencies and cross-tabulations by clinics and/or client characteristics. Responses to the last question ("Those are all the questions I have. Before we finish, is there anything you would like to tell me about the services here, such as what could be done to make the services better or what you especially like about your treatment here?") should be transcribed into a separate text file.

There probably will be too few provider interviews for meaningful statistical analysis. Provider responses should be compared with client responses and where relevant, also compared with direct observation. For example, for the question regarding information on how to take medications (verbal, written, or both), if providers say that written information is given to clients, but clients say they received only verbal instructions and observation of the facility confirms this—there are no client educational materials in plain view—the addition of written instructions could be included in a strategy to improve quality of care.

Preliminary findings should be shared with clinic staff and patients for feedback and discussion before the final report is prepared. Care should be taken to ensure that responses cannot be traced back to specific respondents—for example, attributing a comment to the "Social Worker at Clinic X" will identify that staff person to anyone familiar with the system, even if names are not given.

The survey supervisor should visit the facility in advance of the fieldwork and fill out the *Facility Information* form. At that time, a team member can meet with facility staff to explain the purpose of the survey and answer their questions. A "normal" workday should be chosen for the client interviews; it may be preferable to avoid the last day before the weekend or a major holiday and the first day after the weekend or holiday. Provider interviews should be conducted after all client interviews and may be scheduled over several days.

Facility Information
Part I

Name: _____

Address: _____

Contact person: _____

Telephone/fax/email: _____

Ownership [ ] Public [ ] Private [ ] NGO

Providing MAT since ___ ___ ___ ___ year/___ ___ month

Hours of operation:

Day	Dispensing methadone		Other client services		Emergency care	
	Open	Close	Open	Close	Open	Close
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						

Approximate client volume for dispensing methadone, weekdays (modify as appropriate):

Time of Day	Starting	Ending	# Men	# Women
Early morning				
Late morning				
Early afternoon				
Late afternoon				
Evening/night				
Total daily client load for dispensing medication				

Number of staff working at facility (modify as appropriate):

Attending Physicians: ____
Nurses: _____
Counselors/psychotherapists/psychologists/social workers: _____
Volunteers/patient advocates; _____
Pharmacists/medication dispensers: _____
Supervisors (not included above): _____
Clinic managers (not included above); _____
Other: _____

Part 2

Description of location(s) suitable for client exit interviews (easy access to clients before they leave facility, provide adequate auditory privacy, do not impede patient flow):

_____

_____

_____

Maximum number of interviewers who can be accommodated simultaneously: _____

Additional observations (modify as appropriate):

Identifying information visible from street: _____

Presence of outsiders (e.g. police, others) near entrance: _____

Presence of outsiders (e.g. police, others) inside facility: _____

Operating hours posted inside in plain view [ ] Yes [ ] No

Fees/prices posted inside in plain view [ ] Yes [ ] No

Client rights posted inside in plain view [ ] Yes [ ] No

Educational materials posted inside in plain view [ ] Yes → describe
[ ] No

Take-away information inside in plain view [ ] Yes → describe
[ ] No

Number of private rooms for counseling: _____

Other: _____

Other: _____

Client intercept questionnaire

Informed consent instructions

Good morning/afternoon/evening. My name is _____ and I work with _____. We are visiting facilities like this one to learn about their practices. The purpose of our work is to make recommendations to expand drug dependence treatment services and improve the quality of services provided throughout [country]. This work is funded by [name of funder – for example, the US Agency for International Development (USAID)]. Information from clients such as yourself is critical to the work. We invite you to take part in a short survey to answer a few questions about yourself and the services you receive here.

- **All information will be kept confidential.** We will not ask for your name or for any other information that could identify you. We will not share your answers with the staff working at this facility or any other authorities. Our report will combine all the interviews we collect.
- **Taking part in this activity is entirely voluntary.** The interview should take no more than 15 minutes of your time. You are free to decline to answer any question or to terminate the interview at any time.
- **We anticipate no risk to you as a result of your participation in this survey** other than the inconvenience of the time to complete the questionnaire.
- Do you consent to participate in the survey? [If signed consent is required by local IRB: By signing/initialing this form, you indicate that you have been fully informed about the project and that you understand it, and you are voluntarily choosing to take part in this survey.]

[ ] Consent to participate [ ] Decline to participate (Thank client and terminate interview.)

Identification number: ___ ___ ___

City: _____ Country: _____

Date (year/month/day): 20 __ __/ __ __/ __ __

Time interview started: __ __ : __ __

Gender: [ ] Male [ ] Female

1. How old are you? __ __ years

2. How long have you been coming to this facility for drug treatment?
   [ ] Less than one month (including first visit)
   [ ] 1-6 months
   [ ] 7-12 months
   [ ] More than one year

3. From the time you set out, how long does it usually take to get here?
   __ hours __ __ minutes

4. What medication(s) did you get today? [Check all that apply]
   [ ] Methadone → Was it [ ] Oral tablet
   [ ] Liquid
   How many milligrams? _____

   [ ] Buprenorphine → Was it [ ] Oral tablet
   [ ] Liquid
   How many milligrams? _____

   [ ] Other(s) → specify: _____

5. Did you take (swallow) all the medications here or are you taking some away to use later?
   [ ] Took all medications at the facility
   [ ] Taking some medications away to use later

6. When you first started getting [methadone/buprenorphine] at this facility, were you offered a choice of medication?
   [ ] Yes [ ] No [ ] Don't remember

7. What statement best describes your experience when you first started getting [methadone/ buprenorphine] at this facility? (Read all and check only one)
   [ ] Treatment options and doses were fully explained, I was given opportunity to ask questions and I was satisfied with the information and my choice if treatment
   [ ] Treatment options and doses were explained and I was given opportunity to ask questions, but I felt as though I was being 'talked down' to
   [ ] Treatment options and doses were explained but I did not have opportunity to ask all the questions I wanted
   [ ] I was told what I would be getting with little or no explanation of why, and I had little or no opportunity to ask questions
   [ ] Don't remember

8. Since you first starting getting [methadone/buprenorphine] at this facility, have you always received the same dose that you got today?
   [ ] Yes
   [ ] No → Did you start out at a lower or a higher dose?
   [ ] Started out at a lower dose
   [ ] Started out at a higher dose
   [ ] Don't know/don't remember

9. When was the last time you were checked or evaluated to make sure you were getting a dose that you are satisfied with?
   [ ] Within the last month/month and a half
   [ ] Two months or longer ago
   [ ] Never checked
   [ ] Don't know/don't remember

10. Since you began treatment at this facility, has anyone ever asked you about the following conditions or told you that you needed to be careful because of any of these conditions?

    Your age (65 years or older)
    [ ] Yes [ ] No [ ] Don't know/don't remember
    Liver, renal, or pulmonary disease,
    [ ] Yes [ ] No [ ] Don't know/don't remember
    Pregnancy (ask only of women)
    [ ] Yes [ ] No [ ] Don't know/don't remember
    Menopause (ask only of women)
    [ ] Yes [ ] No [ ] Don't know/don't remember
    HIV treatment
    [ ] Yes [ ] No [ ] Don't know/don't remember
    TB treatment
    [ ] Yes [ ] No [ ] Don't know/don't remember
    Dependency on high doses of opioid
    [ ] Yes [ ] No [ ] Don't know/don't remember
    Psychiatric/mental illness
    [ ] Yes [ ] No [ ] Don't know/don't remember

11. Since you began treatment at this facility, have you…
    Discussed your treatment plan and dosing with your doctor or other service provider
    [ ] Yes [ ] No [ ] Don't remember

    Received information on how to take your medications, either in writing and/or verbally
    [ ] Printed [ ] Verbal [ ] Both printed and verbal [ ] Neither

    Been informed, either in writing or verbally, that if you believe you are not being treated fairly or that you are not getting the services you need, you can meet with someone with authority to address the situation
    [ ] Printed [ ] Verbal [ ] Both printed and verbal [ ] Neither

12. At any time in the last 6 months, did you ever experience any of the following problems at this facility:
    Dismissed/not given MAT medication because the facility was out of methadone and/or buprenorphine
    [ ] Yes [ ] No [ ] Don't remember
    Given a reduced dose of methadone and/or buprenorphine because the facility was low on MAT medicines
    [ ] Yes [ ] No [ ] Don't remember
    Given a different MAT medication because the facility was out of your usual medicines
    [ ] Yes [ ] No [ ] Don't remember

13. Over the <u>last month</u> (in the last four weeks), have you had to come in every day, seven days a week, for your MAT medication or have you been given any "take-away" doses?
    [ ] Had to come in every day, seven days a week
    [ ] Was given "take-away" doses → When were you given take-away doses (check all)
    [ ] Before the weekend
    [ ] Other times

14. What did you have to do before the first time you were given a take-away dose – for example, did you have to make a special request or were they offered to you without request? Were you given any reason or conditions for getting take-away doses? Anything else?

    _____

    _____

    _____

    [ ] Have never received a take-away dose

15. How much in all did you pay for today's visit? _____
    Is this the same, more, or less than you usually pay?
    [ ] Same
    [ ] More
    [ ] Less
    [ ] Did not pay anything → Do you usually pay?
    [ ] No
    [ ] Yes → how much do you usually pay? _____

16. Do you usually pay at every visit, once a week, once a month or on another schedule?
    [ ] Every visit
    [ ] Once a week
    [ ] Once a month
    [ ] Other schedule: specify _____
    [ ] Do not pay/get services for free

17. Those are all the questions I have. Before we finish, is there anything you would like to tell me about the services here, such as what could be done to make the services better or what you especially like about your treatment here?

    _____

    _____

    _____

    _____

    _____

THANK YOU!

Note time interview finished __ __: __ __

Provider/manager questionnaire

Informed consent instructions

Good morning/afternoon/evening. My name is _____ and I work with _____. We are visiting facilities like this one to learn about their practices from both clients and staff. The purpose of our work is to make recommendations to expand drug dependence treatment services and improve the quality of services provided throughout [country]. This work is funded by [name of funder – for example, the US Agency for International Development (USAID)]. We would like to interview you about the services provided here.

- **All information will be kept confidential.** We will not ask for your name. We will not share your answers with other staff working at this facility or any other authorities. Our report will combine all the interviews we collect.
- **Taking part in this activity is entirely voluntary.** The interview should take no more than 20 minutes of your time. You are free to decline to answer any question or to terminate the interview at any time.
- **We anticipate no risk to you as a result of your participation in this survey** other than the inconvenience of the time to complete the questionnaire.
- Do you consent to participate in the survey?

[ ] Consent to participate [ ] Decline to participate (Thank client and terminate interview.)

Identification number: ___ ___ ___

City: _____ Country: _____

1. What is your position/function in the drug treatment program at this facility?
   [ ] Attending physician
   [ ] Drug treatment counselor
   [ ] Facility manager
   [ ] Nurse
   [ ] Volunteer
   [ ] Other: specify: _____

2. How long have you been working in the drug treatment program at this facility?
   [ ] Less than 6 months
   [ ] 7-12 months
   [ ] 1-2 years
   [ ] More than 2 years

3. Are methadone and buprenorphine available at this facility?
   [ ] Only methadone is available → skip to Question 5
   [ ] Only buprenorphine is available → skip to Question 6
   [ ] Both methadone and buprenorphine are available

4. If both methadone and buprenorphine are available at this facility, how is the choice made between methadone and buprenorphine for a specific client/patient?
   [ ] Based on client's choice
   [ ] Based on doctor's opinion
   [ ] Client and physician discuss and come to joint decision
   [ ] Based on availability
   [ ] Don't know

5. What is the usual maintenance dose of methadone at this facility?
   [ ] Less than 20 mg/day
   [ ] Between 20 and 40 mg/day
   [ ] Between 40 and 80 mg/day
   [ ] More than 80 mg/day
   [ ] Don't know

6. What is the usual maintenance dose of buprenorphine at this facility?
   [ ] Less than 4 mg/day
   [ ] Between 4 and 8 mg/day
   [ ] Between 8 and 12 mg/day
   [ ] Between 12 and 24 mg/day
   [ ] Don't know
   [ ] Buprenorphine is not available at this facility

7. At this facility, do all patients receive the same dose, or are patient doses individualized?
   [ ] All patients are given the same dose → skip to Question 11
   [ ] Doses are individualized

8. How is the patient's dose established? (Do not read options)
   [ ] Slowly titrated according to response
   [ ] Other: specify _____

9. How often are clients reassessed during titration? (Do not read options)
   [ ] At least once weekly during titration
   [ ] Other: specify _____

10. How often are clients reassessed after the daily dosage is stabilized? (Do not read options)
    [ ] At least once monthly after the daily dosage is stabilized
    [ ] Other: specify _____

11. As a general rule are special considerations or precautions followed when setting the dose for any of the following (read each one):

    Elderly clients (≥ 65 years)
    [ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
    Patients with liver, renal, or pulmonary disease,
    [ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
    Pregnant women
    [ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
    Women in menopause
    [ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know

HIV positive clients, receiving HAART
[ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
TB positive clients, receiving TB medications
[ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
Clients dependent to high doses of opioid
[ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know
Clients who are diagnosed with psychiatric/mental illness
[ ] Yes [ ] No [ ] Ineligible for treatment [ ] Don't know

12. Are clients always required to take their daily dose of [methadone/buprenorphine] at the facility, or are take-away doses sometimes allowed?
    [ ] All clients have to take their daily dose at the facility → skip to Question 16
    [ ] Take-away doses are sometimes allowed

13. When are take away doses allowed? (Do not read. Check or record all mentioned)
    [ ] During or before the week-end
    [ ] Other: specify _____

14. What factors are considered in allowing a client to receive take-away doses (Do not read. Check or record all mentioned)
    [ ] Time on treatment
    [ ] To reward "good behavior"
    [ ] Other: specify _____

15. What is the maximum number of days allowed for take-away doses? ___ ___ days
    [ ] Don't know

16. If a client is unable to collect his/her own dose/s, can another person collect the dose/s on his/her behalf? (Do not read, check only one)
    [ ] No
    [ ] Yes, if the client provides proof that this is his/her intention
    [ ] Yes, if approved by the clinic → What factors are considered in approving another person to collect the dose/s (check all mentioned)
        [ ] Only under exceptional circumstances (specify _____)
        [ ] Time on treatment
        [ ] To reward "good behavior"
        [ ] Other: specify _____
    [ ] Don't know

17. How is dispensing information or guidelines provided to clients at this facility – verbally? In pamphlets? Posted on the walls? Any other way? (Check all that apply)
    [ ] Verbally
    [ ] Written/printed materials → Are printed materials available in different languages?
        [ ] Yes
        [ ] No
        Are printed materials in stock today?
        [ ] Yes
        [ ] No
        [ ] Don't know
    [ ] Posted on the walls
    [ ] Other: specify _____

18. How does this facility respond to special needs of people with communication difficulties (e.g., people who are deaf or blind, people with low level of literacy, developmentally disabled, etc.)? (Write down response)

_____

_____

19. What procedures are followed to encourage clients to discuss their treatment plan and dosing? (Write down response)

_____

_____

20. What can a client do or whom can he or she talk with if he/she feels that he/she is not getting the services he/she needs or is being treated unfairly? (Write down response)

_____

_____

21. And if after this (refer to question 20), the client is still not satisfied, what other options are open to him or her? (Write down response).

_____

_____

22. At any time in the last six months, did this facility experience a "stock out" or lack of sufficient supplies of (methadone/buprenorphine)?
    [ ] Yes
    [ ] No → go to Question 24
    [ ] Don't know/not sure → go to Question 24

23. How did the facility deal with the "stock out"/ lack of medicines? Anything else? (Do not read; mark all that apply)
    [ ] dismissing some clients until the clinic was able to fulfill again the demand
    [ ] dismissing all clients until the clinic was able to fulfill again the demand
    [ ] reducing the dose of methadone and/or buprenorphine for some clients
    [ ] reducing the dose of methadone and/or buprenorphine for all clients
    [ ] Borrowed stock from another facility
    [ ] Other: specify _____
    [ ] Don't know

24. Now I would like to ask about the prices charged in this facility.
    What is the average monthly price for (methadone, buprenorphine)
    Methadone (per month) _____
    Buprenorphine (per month) _____
    [ ] Don't know

And how much does the facility charge for services? _____
[ ] Don't know
Are any additional fees charged? _____
[ ] Don't know

25. What does the facility do if a client cannot pay or has problems paying the fees? (Write down response)

_____

_____

26. Overall, how would you rate the ability of this facility to provide clients with adequate dosing and avoid unfair restrictions?
    [ ] Strongly positive
    [ ] Somewhat positive
    [ ] Neither positive nor negative
    [ ] Somewhat negative
    [ ] Strongly negative

27. What are the major obstacles to providing adequate dosing, in terms of legislation, policies, regulations, and/or guidelines?

_____

_____

28. What are the supportive processes or mechanisms to providing adequate dosing in terms of legislation, policies, regulations, and/or guidelines?

_____

_____

29. Do you believe you have had adequate training to perform your job? How often do you have the opportunity to receive further training?

_____

_____

30. Before we finish, do you have any comments about what could be done to make the services better or what you think is especially positive about this facility?

_____

_____

THANK YOU!

Tool 2.2.2 Part B: MAT policy assessment index: Key informant interview

Orientation

An estimated 3.7 million people inject drugs in the E&E region, the vast majority of whom are dependent on heroin or related opioid drugs. This is close to four times higher than the overall prevalence of injecting drug use worldwide. Sixty-two percent of the HIV epidemic in this region is attributable to injecting drug use, with the epidemic increasingly affecting women. In 2006, women accounted for about 40 percent of reported new HIV cases; more than 35 percent of HIV-positive women were infected through sharing of contaminated injecting equipment, and another 50 percent were infected via unprotected sex with an infected IDU.

Medication-assisted treatment (MAT) is used to help those individuals who are opioid dependent. The term is used to cover any treatment for opioid dependence that includes an approved medication for opioid detoxification or maintenance treatment, may be provided through a variety of settings, and usually also includes psychosocial treatment and support.

One of the key components of MAT is Opioid Substitution Therapy (OST), using methadone or buprenorphine. OST has been endorsed by WHO, UNAIDS, UNODC, The Global Fund, and researchers and healthcare professionals around the world. WHO now includes methadone and buprenorphine in its model list of essential medicines.

Part B of the MAT Policy Assessment Index explores four key dimensions related to (1) the coverage of OST services; (2) quality of care provided by OST services; (3) the involvement of civil society, including people who use drugs, in policy dialogue related to OST; and (4) the extent of stigma, harassment, and human rights violation that people who use drugs face in accessing services. The information collected will help treatment providers, people who use drugs, advocates, and policymakers make concrete recommendations to introduce, scale up, and improve access to quality services for treatment of opioid dependence.

Part B consists of two sections—key informant interviews with clients, service providers, and other key informants, and facility-based interviews with clients and service providers and managers. The key informant interview includes coverage of OST services, involvement of civil society, and human rights considerations. The facility-based interviews focus on quality of care of OST services.

The **key informant interview** consists of four sections:

- **Section 1** addresses the types of facilities that offer methadone and/or buprenorphine therapy, where they are located, who is eligible to receive therapy, prices charged, and other factors that determine whether people who need MAT can really obtain it.
- **Section 2** addresses the constituencies and level of involvement of civil society in developing policies related to MAT and the challenges they face. The pertinent question is: Are people who use drugs meaningfully involved in consultative processes, as well as in decisionmaking or policymaking bodies and advisory structures dealing with issues related to MAT?
- **Section 3** asks the respondent to comment on attitudes and behaviors in the country toward drug use and drug users, and the extent of stigma, harassment, and other human rights violation occurring against drug users, including examples of such violations.
- **Section 4** asks the respondent to identify specific barriers and opportunities to making methadone therapy available and accessible for opioid users in his/her country.

Selection of respondents

The purpose of the key informant interviews is to understand the opinions of the wide range of stakeholders involved in MAT policies and programs. Respondents should come from within and outside of government. Public sector stakeholders can include legislators and other policymakers; government bureaucrats and technicians from various sectors and local government, law enforcement, and the courts; and treatment program staff. Respondents outside of government should include members of civil society organizations; support groups or networks (e.g., injection drug users, people living with HIV, women's health advocates); and faith-based organizations. Researchers and opinion leaders also may be included. Representatives of international organizations and donors are also important stakeholders in MAT policy and programs.

We recommend that the team form an advisory group to identify potential respondents and make introductions. At least 15 to a maximum of 25 respondents can be managed to include a range of stakeholders, including those who are resistant to MAT.

If possible, a single interviewer should conduct all interviews. He/she should have enough status to interview high-level officials and yet be sensitive to marginalized groups such as injection drug users. It is important that the interviewer not be seen as identified with or an advocate for a particular point of view concerning MAT.

Data entry and analysis

The key informant questionnaire is designed to be administered as a standardized interview; if respondents are agreeable, it may be useful to audio-record the interviews and transcribe responses to open-ended questions later.

The sample will be too small and too varied for statistical analysis. Analyses should look for areas of agreement and disagreement among respondents and seek to compare respondents' opinions and perceptions against objective measures, such as actual policy documents or clinic norms.

Key informant interview

Informed consent instructions

Good morning/afternoon/evening. My name is _____ and I work with _____. We are interviewing knowledgeable people such as yourself to learn about the availability of drug dependence services in [country], the policies around drug dependence treatment and the groups that participated in developing the policies, and attitudes towards people who use drugs. The purpose of our work is to make recommendations to expand drug dependence treatment services and improve the quality of services provided in [country]. This work is funded by the US Agency for International Development (USAID) [or other donor]. We invite you to take part in a survey about these topics.

- **All information will be kept confidential.** We will not ask for your name or for any other information that could identify you. We will not share your answers with anyone outside the project. Our report will combine all the interviews we collect and not single out any individual.
- **Taking part in this activity is entirely voluntary.** The interview should take no more than 30 minutes of your time. You are free to decline to answer any question or to terminate the interview at any time.
- **We anticipate no risk to you as a result of your participation in this survey** other than the inconvenience of the time to complete the questionnaire.
- Do you consent to participate in the survey?

[ ] Consent to participate [ ] Decline to participate (Thank client and terminate interview.)

Informant information:
City/country: _____

Gender: [ ] Male [ ] Female

Personal/professional affiliation(s) (Check at least one and all that apply)

[ ] MAT Client
[ ] Policy maker: specify _____
[ ] MAT service provider
[ ] Law enforcement, criminal justice
[ ] Harm reduction organization
[ ] Organization of drug users
[ ] Organization of people living with HIV
[ ] Organization of families of drug users
[ ] Other advocacy group: specify _____
[ ] Organization of health professionals: specify _____
[ ] Organization of lawyers
[ ] Human rights or civil liberty organization
[ ] Other: specify _____

Part 1. Availability of methadone and/or buprenorphine to those who need MAT

The first part asks you to comment on the types of facilities that actually offer methadone and/or buprenorphine therapy, where they are located, who is eligible to receive therapy, prices charged and other factors that determine whether people who need MAT can really obtain methadone and/or buprenorphine in your country.

1. Which of the following types of public facilities currently provide methadone and/or buprenorphine therapy:

   Hospitals
   [ ] Yes [ ] No [ ] Don't know

   Specialized Inpatient Clinics
   [ ] Yes [ ] No [ ] Don't know

   Outpatient Clinics in the capital city/regional centers
   [ ] Yes [ ] No [ ] Don't know

   Community based services
   [ ] Yes [ ] No [ ] Don't know

   [ ] No public facilities provide methadone or buprenorphine therapy → Go to #17

1a. In addition to the above, is methadone and/or buprenorphine therapy available in:

   Tuberculosis health facilities
   [ ] Yes [ ] No [ ] Don't know

   Maternity hospitals
   [ ] Yes [ ] No [ ] Don't know

   Prison
   [ ] Yes [ ] No [ ] Don't know

   Pre-trial detention
   [ ] Yes [ ] No [ ] Don't know

   Other public settings: specify: _____

2. Describe the geographic distribution of public facilities that provide methadone and/or buprenorphine therapy.
   - [ ] No public facilities provide methadone or buprenorphine therapy
   - [ ] Few public facilities and/or only in the capital city/regional centers provide methadone and/or buprenorphine
   - [ ] Public facilities provide methadone and/or buprenorphine in most large urban areas
   - [ ] Public facilities provide methadone and/or buprenorphine throughout the country
   - [ ] Don't know/no opinion

3. Who qualify for treatment of opioid dependence in public facilities?
   - [ ] all patients dependent on opioids
   - [ ] injecting opioid users only
   - [ ] HIV positive patients only
   - [ ] HIV negative patients only
   - [ ] Only pregnant women
   - [ ] Only if over the age of ____years
   - [ ] Other: please specify
   - [ ] There are no public facilities providing methadone and/or buprenorphine therapy

4. Do public facilities give priority to certain clients to begin methadone and/or buprenorphine therapy?
    [ ] HIV-positive clients
    [ ] TB-positive clients
    [ ] Pregnant women
    [ ] Others: specify _____
    [ ] Don't know
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy

5. Do public facilities require their clients to be registered as drug users with their local law enforcement agency, as a condition to begin methadone and/or buprenorphine therapy?
    [ ] Yes
    [ ] No
    [ ] Don't know
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy

6. How would you characterize the prices charged by public facilities for methadone and/or buprenorphine therapy?
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    [ ] Free to all
    [ ] Very affordable - Most people who need such therapy can pay
    [ ] Somewhat affordable - At least half the people who need such therapy can afford the prices
    [ ] Unaffordable - Most people who need such therapy cannot afford the prices)

7. Do people who cannot afford to pay get fee waivers at public facilities?
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    [ ] Free to all
    [ ] Yes – and most people who need them, get them
    [ ] Yes – but only some people get them
    [ ] No
    [ ] Don't know

8. Do public facilities in the larger urban areas have waiting lists to begin methadone and/or buprenorphine therapy?
    [ ] Most have waiting lists
    [ ] Some have waiting lists
    [ ] Very few have waiting lists
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    [ ] Don't know

9. In general, how long does it take to begin methadone and/or buprenorphine therapy in public facilities in the larger urban areas?
    [ ] 2 months or more
    [ ] 1-2 months
    [ ] Less than 1 month
    [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    [ ] Don't know

10. Do public facilities in the smaller urban areas have waiting lists to begin methadone and/or buprenorphine therapy?
    - [ ] Most have waiting lists
    - [ ] Some have waiting lists
    - [ ] Very few have waiting lists
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    - [ ] Don't know

11. In general, how long does it take to begin methadone and/or buprenorphine therapy in public facilities in the smaller urban areas?
    - [ ] 2 months or more
    - [ ] 1-2 months
    - [ ] Less than 1 month
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    - [ ] Don't know

12. In general, how well are public facilities in the larger urban areas staffed to provide MAT?
    - [ ] There are usually enough staff for the client volume during clinic hours
    - [ ] There are occasional staff shortages during clinic hours
    - [ ] There are frequent staff shortages during clinic hours
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy

13. In general, how well are public facilities in the smaller urban areas staffed to provide MAT?
    - [ ] There are usually enough staff for the client volume during clinic hours
    - [ ] There are occasional staff shortages during clinic hours
    - [ ] There are frequent staff shortages during clinic hours
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy

14. In general, how well are public facilities in the larger urban areas supplied/ stocked with methadone and/or buprenorphine?
    - [ ] There are usually adequate stocks on hand
    - [ ] There is occasional lack of stock/stock-outs (the demand for methadone and/or buprenorphine cannot be fulfilled from the current (on hand) inventory).
    - [ ] There are frequent stock-outs and/or low stock levels
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy

15. In general, how well are public facilities in the smaller urban areas supplied/ stocked with methadone and/or buprenorphine?
    - [ ] There are usually adequate stocks on hand
    - [ ] There are occasional stock-outs (the situation where the demand for methadone and/or buprenorphine cannot be fulfilled from the current (on hand) inventory).
    - [ ] There are frequent stock-outs and/or low stock levels
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy

16. Which of the following types of private facilities provide methadone and/or buprenorphine therapy

    Hospitals

    [ ] Yes [ ] No [ ] Don't know

    Specialized Inpatient Clinics

    [ ] Yes [ ] No [ ] Don't know

    Outpatient Clinics in the capital city/regional centers

    [ ] Yes [ ] No [ ] Don't know

    Community based services

    [ ] Yes [ ] No [ ] Don't know

    [ ] No private facilities provide methadone or buprenorphine therapy → Go to #27

17. Describe the number and geographic distribution of <u>private facilities</u> that provide methadone and/or buprenorphine therapy.
    - [ ] No private facilities provide methadone or buprenorphine therapy
    - [ ] Few private sector facilities and/or only in the capital city/regional centers provide methadone or buprenorphine therapy
    - [ ] Private sector facilities provide methadone and/or buprenorphine in most large urban areas
    - [ ] Private sector facilities provide methadone and/or buprenorphine throughout the country
    - [ ] Don't know/no opinion

18. Who qualifies for treatment of opioid dependence in private facilities?
    - [ ] all patients dependent on opioids
    - [ ] injecting opioid users only
    - [ ] HIV positive patients only
    - [ ] HIV negative patients only
    - [ ] Only pregnant women
    - [ ] Only if over the age of ____years
    - [ ] Other: please specify
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

19. Do private facilities give priority to certain clients to begin methadone and/or buprenorphine therapy?
    - [ ] HIV-positive clients
    - [ ] TB-positive clients
    - [ ] Pregnant women
    - [ ] Others [Please specify _____]
    - [ ] Don't know
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

20. Do private facilities have waiting lists to begin methadone and/or buprenorphine therapy?
    - [ ] Most have waiting lists
    - [ ] Some have waiting lists
    - [ ] Very few have waiting lists
    - [ ] There are no public facilities providing methadone and/or buprenorphine therapy
    - [ ] Don't know

21. In general, how long does it take to begin methadone and/or buprenorphine therapy in private facilities?
    - [ ] 2 months or more
    - [ ] 1-2 months
    - [ ] Less than 1 month
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

22. Do private facilities require their clients to be registered as drug users with their local law enforcement agency, as a condition to begin methadone and/or buprenorphine therapy?
    - [ ] Yes
    - [ ] No
    - [ ] Don't know
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

23. In general, how well are private facilities staffed to provide MAT?
    - [ ] There are usually enough staff for the client volume during clinic hours
    - [ ] There are occasional staff shortages during clinic hours
    - [ ] There are frequent staff shortages during clinic hours
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

24. In general, how well are private facilities stocked with methadone and/or buprenorphine?
    - [ ] There are usually adequate medicines on hand
    - [ ] There is occasional lack of medicines/ stock-outs (where the demand for methadone and/or buprenorphine cannot be fulfilled from the current (on hand) inventory).
    - [ ] There are frequent low and/or lack of medicines
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

25. How would you characterize the prices charged by private facilities for methadone and/or buprenorphine therapy?
    - [ ] Free to all
    - [ ] Very affordable - Most people who need such therapy can pay
    - [ ] Somewhat affordable - At least half the people who need such therapy can afford the prices
    - [ ] Unaffordable - Most people who need such therapy cannot afford the prices
    - [ ] There are no private facilities providing methadone and/or buprenorphine therapy

26. Overall, how would you rate the legislation, policies, regulations, guidelines around public and/or private facilities making methadone and/or buprenorphine available to the majority of people who need them?
    - [ ] Strongly favorable
    - [ ] Somewhat favorable
    - [ ] Neither favorable nor unfavorable
    - [ ] Somewhat unfavorable
    - [ ] Strongly unfavorable

27. What are the major obstacles to making methadone and/or buprenorphine available through public and/or private facilities to the majority of people who need these therapies?

_____

_____

_____

28. What are the major factors or processes that support making methadone and/or buprenorphine available through public and/or private facilities to the majority of people who need these therapies?

_____

_____

_____

Part 2. Participation of civil society in developing MAT policies, legislation, regulations, guidelines

The term 'civil society' covers a wide range of organizations of different sizes, with diverse constituencies and interests.[18] Civil society organizations are established voluntarily by those seeking to promote their concerns, values, or identities and are autonomous from the state.

Part 2 asks you to comment on the constituencies and level of involvement of civil society in developing policies related to MAT and the challenges they face. This includes whether people who use drugs are meaningfully involved in consultative processes, as well as in decision-making or policy-making bodies and advisory structures dealing with issues related to MAT.

1. For each of the following civil society organizations and constituencies, please tell me if they have been or are currently involved in developing legislation, policies or regulations related to drug use, and particularly methadone and buprenorphine:

People who are currently using drugs
- [ ] Yes → including women who currently use drugs? [ ] Yes [ ] No
- [ ] No
- [ ] Don't know

People who formerly used drugs
- [ ] Yes → including women who formerly used drugs? [ ] Yes [ ] No
- [ ] No
- [ ] Don't know

Families of people who use drugs
- [ ] Yes
- [ ] No
- [ ] Don't know

Persons living with HIV
- [ ] Yes
- [ ] No
- [ ] Don't know

Religious based organizations
- [ ] Yes
- [ ] No
- [ ] Don't know

Organizations of concerned citizens
- [ ] Yes → specify: _____
- [ ] No
- [ ] Don't know

Immigrants
- [ ] Yes
- [ ] No
- [ ] Don't know

Others
- [ ] Yes → specify: _____
- [ ] No
- [ ] Don't know

[18] 'Civil society' includes AIDS service organizations, groups of people living with HIV and AIDS, youth organizations, women's organization, business, trade unions, professional and scientific organizations, sports organizations and a wide spectrum of religions and faith-based organizations.

2. Now I would like to ask you about formal mechanisms that promote participation of civil society into the process of developing legislation, policies regulations or guidelines related to drug use and particularly access to methadone and buprenorphine.

2a. Are there any mechanisms to provide civil society with information in matters related to MAT services?
[ ] Yes → please describe

_____

_____

[ ] No
[ ] Don't know

2b. Are there any mechanisms to build capacity of civil society to gather and analyze data and information, to support their involvement in the development of policies and/or regulations related to drug use and particularly methadone and buprenorphine?
[ ] Yes → please describe

_____

_____

[ ] No
[ ] Don't know

2c. Are there financial resources to facilitate civil society participation in the development of policies and/or regulations related to drug use and particularly methadone and buprenorphine?
[ ] Yes → please describe

_____

_____

[ ] No
[ ] Don't know

2d. Are there formalized mechanisms to assist policy makers and/or government employees to engage with civil society, especially with people who use drugs?
[ ] Yes → please describe

_____

_____

[ ] No
[ ] Don't know

2e. Are there formalized procedures to ensure the meaningful involvement of people who currently use or previously used drugs on boards, committees and oversight and evaluation mechanisms that advise and oversee programs and services affecting them?
[ ] Yes → please describe

_____

_____

[ ] No
[ ] Don't know

3. Which of the following statements best describes the level of involvement of people who use drugs, PHA organizations and/or their advocates in the development of legislation, policies, regulations or guidelines related to drug use and particularly to access to methadone and buprenorphine? (Read all statements, check only one)
    - [ ] People who use drugs, PHA organizations and/or their advocates are involved at the early stages of policy development and participates in joint analysis and development of MAT programs
    - [ ] People who use drugs, PHA organizations and/or their advocates are asked to provide comments to policies and regulations at a later stage and after major decisions have been made
    - [ ] People who use drugs, PHA organizations and/or their advocates are consulted by policy makers, who define the issues and who may or may not modify the policy and/or regulation in light of civil society response
    - [ ] People who use drugs, PHA organizations and/or their advocates are told what is going to happen or has already happened

4. Overall, how would you rate the adequacy of existing procedures regarding meaningful involvement of civil society, and particularly of people who use drugs, in the development of policies and/or regulations related to drug use and particularly to access to methadone and buprenorphine?
    - [ ] Strongly favorable
    - [ ] Somewhat favorable
    - [ ] Neither favorable nor unfavorable
    - [ ] Somewhat unfavorable
    - [ ] Strongly unfavorable

5. What are the major obstacles regarding meaningful involvement of civil society, and particularly of people who use drugs, in the development of legislation, policies, regulations or guidelines related to drug use and particularly methadone and buprenorphine?

_____

_____

_____

_____

6. What are the major supportive processes or mechanisms regarding meaningful involvement of civil society, and particularly of people who use drugs, in the development of legislation, policies, regulations or guidelines related to drug use and particularly methadone and buprenorphine?

_____

_____

_____

_____

7. In particular, what kind of challenges or achievements, if any, has your community encountered with regard to access to information, public participation in decision-making and access to justice in matters related to access to and quality of MAT services? If appropriate, please provide a description underlining those experiences you think could be most useful to consider to improve the current situation, and/or identify a specific change or modification to policy, legislation, regulation, or guideline that was the direct result of the involvement of civil society.

_____

_____

_____

_____

Part 3: Social and legal attitudes towards people who use drugs

Drug use is often accompanied by stigma and discrimination. People who use illicit drugs may face harassment, discrimination, and abuse. Part 3 asks you to comment on attitudes and behaviors in your country toward drug use and drug users, and the extent of stigma, harassment, and other human rights violation against drug users, including examples of such violations.

1. For each of the following statements, please tell me if you strongly agree, somewhat agree, somewhat disagree, or strongly disagree.

   a. People who use drugs are treated as criminals
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   b. People who use drugs are required to register with the authorities
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   c. People who use drugs are deprived of some legal and civil rights, such as voting rights, employment rights, the ability to get a driver's license, etc.
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   d. People who use drugs are treated as mentally ill.
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   e. Drug dependence is considered as a chronic medical condition and people dependent on drugs are treated as patients like any other.
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   f. People who use drugs are highly stigmatized by society.
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree
      [ ] Strongly disagree
      [ ] Don't know/ no opinion
   g. People who use or are perceived to use drugs are often denied medical treatment.
      [ ] Strongly agree
      [ ] Somewhat agree
      [ ] Somewhat disagree

[ ] Strongly disagree
[ ] Don't know/ no opinion

h. People who use drugs are subjected to compulsory detoxification and/or drug treatment.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

i. It is permissible to expel people who use or are perceived to use drugs from school.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

j. It is permissible to dismiss or deny employment to people who use or are perceived to use drugs.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

k. People who use drugs or used drugs in the past are subjected to policy surveillance.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

l. People who use or are perceived to use drugs lose parental rights to their children.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

m. People who use or are perceived to use drugs are not allowed to adopt children.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

n. Mandatory drug testing is permitted for school admission or continued enrollment.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

o. Mandatory drug testing is permitted for employment or continued employment.
[ ] Strongly agree
[ ] Somewhat agree
[ ] Somewhat disagree
[ ] Strongly disagree
[ ] Don't know/ no opinion

p. Women who use or are perceived to use drugs may be sterilized or forced to terminate pregnancy.
   [ ] Strongly agree
   [ ] Somewhat agree
   [ ] Somewhat disagree
   [ ] Strongly disagree
   [ ] Don't know/ no opinion

2. Do you personally know of specific examples or cases where someone has been treated unfairly because he or she uses or is perceived to use drugs?
   [ ] Yes → please describe

   _____

   _____

   [ ] No
   [ ] Don't know

3. What recourse would a person have, if he or she was treated unfairly because of drug use or suspected drug use?

   _____

   _____

   [ ] No recourse
   [ ] Don't know

4. Overall, how would you rate the adequacy of existing legislation, policies, and regulations in protecting people who use or have used drugs, or are perceived to use or to have used drugs, from unfair treatment?
   [ ] Strongly favorable
   [ ] Somewhat favorable
   [ ] Neither favorable or unfavorable
   [ ] Somewhat unfavorable
   [ ] Strongly unfavorable

5. What are the major obstacles to reforming practices or policies to protect to people who use or have used drugs, or are perceived to use or to have used drugs from discrimination and/or unfair treatment?

_____

_____

   [ ] Don't know

6. What are the major supportive processes or mechanisms to reform practices or policies to protect to people who use or have used drugs, or are perceived to use or to have used drugs from discrimination and/or unfair treatment?

_____

_____

   [ ] Don't know

Part 4: Overall

1. For each of the following factors, would you say that it is an important barrier, somewhat of a barrier or not at all a barrier to making methadone therapy available and accessible for opioid users in your country?

Legislation, policies or regulations that prohibit prescription of methadone	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Too few facilities that offer methadone	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Eligibility or inclusion criteria that prevent many people who want and need therapy from getting it	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Concerns about lack of confidentiality and protection of personal information on the part of clients or potential clients	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Clients have to be included on a drug user registration system before they can receive services	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Not enough providers trained to deliver methadone therapy and/or other needed services (such as counseling)	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Not enough funding for methadone therapy	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Limited and/or lack of government policy support for OST	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Stigma, discrimination and/or moralistic views of drug use among key decision-makers and/or opinion leaders	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Decision makers not familiar with the evidence base of the effectiveness of OST	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
High cost of methadone medication	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Others: specify	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	

2. For each of the following factors, would you say that it is an important barrier, somewhat of a barrier or not at all a barrier to making buprenorphine therapy available and accessible for opioid users in your country?

Legislation, policies or regulations that prohibit prescription of buprenorphine	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Too few facilities that offer buprenorphine	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Eligibility or inclusion criteria that prevent many people who want and need therapy from getting it	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Concerns about lack of confidentiality and protection of personal information on the part of clients or potential clients	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Clients have to be included on a drug user registration system before they can receive services	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Not enough providers trained to deliver buprenorphine therapy and/or other needed services (such as counseling)	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Not enough funding for buprenorphine therapy	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Limited and/or lack of government policy support for OST	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Stigma, discrimination and/or moralistic views of drug use among key decision-makers and/or opinion leaders	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Decision makers not familiar with the evidence base of the effectiveness of OST	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
High cost of buprenorphine medication	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	
Others: specify	Important barrier	
	Somewhat of a barrier	
	Not at all a barrier	

Prepared By:

Name: _____

Title: _____

Department: _____

City/State: _____

Country: _____

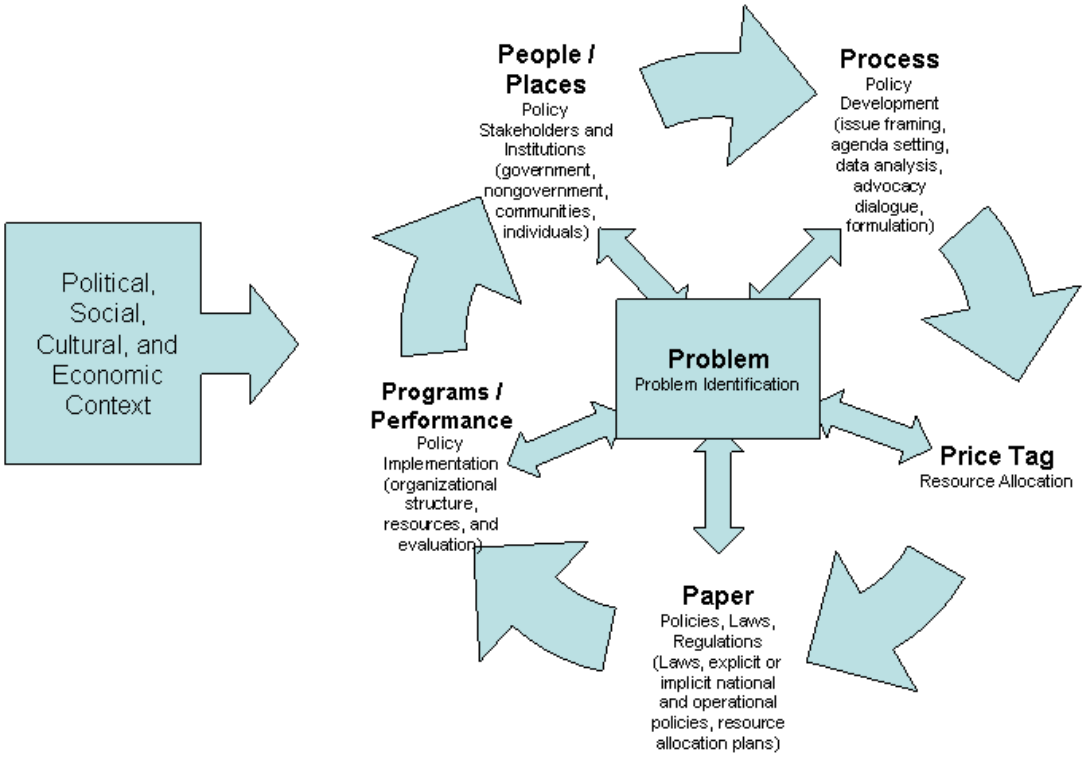
Email: _____

Telephone: _____

2.3 Policy Advocacy Planning Worksheets

Lessons learned from the field of policy advocacy have identified the importance of developing a coordinated, strategic, evidence-based advocacy strategy; this should be a strategy that has clear goals and objectives, addresses the needs of stakeholders, and is informed by a country's social, political, and economic contexts.

The following collection of worksheets is presented as a simple tool to guide the development of an advocacy strategy within the policy circle framework to incrementally increase access to MAT.



These worksheets are a highly summarized outline for developing an advocacy strategy. More in-depth information can be found in the following source documents.

Leading Voices in Securing Reproductive Health Supplies: An Advocacy Guide and Toolkit.
www.rhsupplies.org/fileadmin/user_upload/toolkit/Advocacy_Guide_and_Toolkit.pdf

Networking for Policy Change: An Advocacy Training Manual.
www.policyproject.com/pubs/advocacymanual.cfm

People/places: Stakeholder engagement

Advocacy steering committee/initiative group of stakeholders

The first step in policy advocacy will be to form or identify an informal committee or initiative group. Strategic engagement of stakeholders is critical to informing the design of an advocacy strategy. Look for individuals or organizations that have experience in policy development, advocacy, monitoring, and implementation; who understand the context of MAT (including opposition / opportunities); and who are providers and clients of MAT or drug addiction services.

Composition of this committee / initiative group must strike a balance between a broad inclusion of stakeholders, including those who are resistant to MAT, and establishing a functional advisory body. While it is important to incorporate a range of expertise and opinion, try to include individuals who can work together constructively. Consider the different skills of individuals who design and implement policies; advocate for policy reform; and come from government agencies, nongovernment groups, and international donors. Also consider the point at which law enforcement will be involved. Is law enforcement positioned to be an effective part of the advocacy process, or would they be considered a target audience for advocacy efforts?

A decision also needs to be made as to the role of the advocacy steering committee. Will the committee simply be convened to help develop an advocacy strategy or will it be involved more in implementation?

A decision will also need to be made on how—and if—other planning processes and groups are informed of the activities related to MAT advocacy. For example, will it be beneficial to keep the CCM / National AIDS Committee informed, or would these bodies try to block advocacy activities?

Keep this group at a reasonable size (12–15 max) and make sure that individuals who agree to participate have a clear understanding of the expectations for their roles and the time and resources that participation may require.

Tool 2.3.1 MAT policy stakeholder analysis worksheet

This tool is used to focus on one specific issue. It is best used when stakeholders from different sectors are brought together to conduct a more comprehensive analysis.[19] Expand the tool as necessary

Complete name of the organization or group. Please indicate if it is a national, regional or oblast/local group.	Identify reason or nature of group's or individual's interest in MAT.	Indicate the level of knowledge about MAT. (Enter low, medium or high)	Identify specific resources held by group or to which it has access. (Resources include staff and volunteers, financial, technology, information, legal, religious/moral or others)	Estimate of which and how easily groups can mobilize resources in pursuit of improving access to MAT. (Enter low, medium or high)	**Position on MAT** (Enter one rating only. If not known, enter DK for "Don't Know.")		
					Support +3 Very strong support +2 Moderate support +1 Weak support	Neutral Enter 0	Oppose -3 Very strong opposition -2 Moderately opposed -1 Weakly opposed
Government Sector							
Political Sector							
Commercial Sector							

[19]Adapted from Brinkerhoff, D. and B. Crosby, "Managing Policy Reform: Concepts and Tools for Decision-makers in Developing and Transitioning Countries", Kumarian Press, CT, 2002 and POLICY, "*Networking for Policy Change: An Advocacy Training Manual*, 1999.

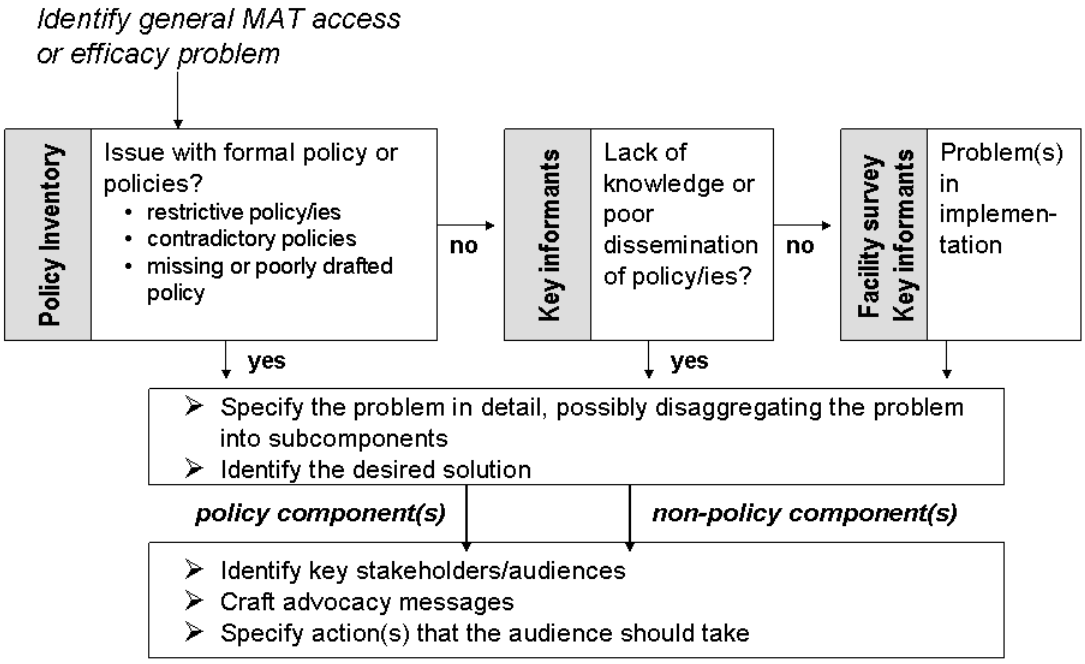
Non-Governmental Sector							
Other Groups from Civil Society							
International Donors							

Date:

Problem identification

The first step of this process is to engage stakeholders to identify problems without assigning cause or solution. Once the problem has been identified, explore whether it is related to policy (restrictive, contradictory, or missing); dissemination of existing policy; or implementation of existing policy.

Political, social, cultural, and economic contexts



It will be important for the steering committee to come to a common understanding of the general context and issues affecting the provision of MAT and the specific context for the problems identified. Given the dynamic nature of MAT policy, this information should be assessed against current realities and will come from sources such as existing assessments, key informants, and official documents. Using a format similar to the worksheet provided, summarize:

- Laws, policies, and regulations related to MAT (draw from policy inventory);
- Epidemiological data on HIV and drug use;
- Demand for MAT (official estimates, information from advocates, clients, providers….); determine whether there is a difference in these estimates, and if so, why;
- Current state of drug treatment (providers, methods, coverage, quality, barriers to access); and
- Donor and government financing of MAT and other drug treatment / HIV prevention for IDU.

Much of this information may seem obvious to local advocates, but documenting a common understanding will help to identify positive and negative factors contributing to MAT access, assess strategic alternatives, and craft advocacy strategies to address barriers to access.

Tool 2.3.2 Political, social, cultural, and economic contexts worksheet

Country / Jurisdiction:

Laws, policies, and regulations related to MAT:

Epidemiological data on HIV and injection drug use:

Demand for MAT:

Current state of addiction treatment (providers, methods, coverage, quality, barriers to access):

Donor and government financing of MAT and other drug treatment / HIV prevention for IDUs:

Process

A critical element in the success of any advocacy effort is a thorough understanding of the policy process. An in-depth knowledge of the policy environment can help advocates identify and recognize advocacy opportunities and critical points of entry, so as to both influence the policy process and guide the selection of advocacy issues.

In many countries, government and political leaders remain skeptical, if not fearful, of NGOs and other representatives of civil society participating in the policy arena. There is a common perception among policymakers that civil society lacks the experience, skills, and knowledge required for policy analysis and formulation. This perception can lead to a reluctance or refusal to listen to or collaborate with networks in their advocacy efforts. Consequently, it is vital that advocates demonstrate a clear and accurate understanding of the process followed and the players involved in making policy decisions.

In addition, advocates should monitor the political, economic, sociocultural, and technological environment to keep abreast of emerging issues and the positions of government. Opportunities to influence policy and policymakers can arise or disappear at any time.

The group should answer the following questions:

Issue Framing

1. How can we frame our problem/solution so it becomes a priority for policymakers to address?
2. How can the problem be framed to guide the terms of the policy debate in the direction that we want?

Agenda Setting

1. How are ideas or issues generated for new or revised policies?
2. How is a proposed issue introduced into the formal decisionmaking process?
3. Can the problem/solution be introduced at different levels of policymaking to increase pressure to address the issue?

Policy Formulation

1. What is the process for discussing, debating, and perhaps, altering the proposal? Who are the players involved?
2. How is the proposal approved or rejected?
3. If approved, what are the steps to move the proposal to the next level of decisionmaking?
4. Once the proposal is finalized, what are the implementation steps? Who are the players involved?
5. What is the process for identifying and addressing barriers or challenges to implementation?

Advocacy prioritization

There is no right or wrong way to prioritize advocacy efforts. Of real importance is keeping in mind the ultimate goal of increasing access to quality MAT services and coming to agreement on an incremental strategy to achieve that goal.

This worksheet provides an example of a format that can be used to identify each advocacy need and consolidate information that has been gathered about the context and the process to weigh and prioritize advocacy activities.

Through a participatory process, the advocacy steering committee / initiative group of stakeholders should summarize and agree on a common list of the policy issues under problem identification. Using the information gathered from policy inventories; policy assessment indexes; the political, social, and economic contexts; and relevant information from the policy process, members of the steering committee can assign numeric values to columns A through D and total their scores in column E.

By definition, the scoring will be subjective, which is why a membership of broad and diverse experience on the steering committee will be valuable. Scores can then be collected and averaged for the group to determine a final prioritization; the highest scores in column E will be the top priority issues to address.

Once the worksheet has been completed, it is important to assess whether or not it makes sense. Consider the following:

- Which advocacy issues rank highest (column E)? Does it make sense to address these issues first? Is there a logical sequencing of advocacy that either confirms this ranking or requires prioritization of issues with a lower score?
- For advocacy issues that rank lower but are really important, consider breaking the issues into smaller, incremental steps and score each step.

Finally, revisit the issue prioritization process regularly, especially if there is a significant change in political climate or resources available to implement policy advocacy.

Tool 2.3.3 Problem identification/Advocacy prioritization worksheet

Specific Issue	What Needs to Be Changed	A	B	C	D	E
List all barriers to MAT access	• Policy – good, bad, nonexistent • Implementation of existing policy • Other	Potential that addressing this issue would improve MAT access: Scale of 10--1 (Strong—weak)	Time needed to change: Scale of 10-1 (Short—long)	Financial and human resources required for change: Scale of 10-1 (Low—high)	Strength of opposition: Scale of 10--1 (Weak—strong)	Priority Ranking: (Add values of columns A, B, C, D and enter total)

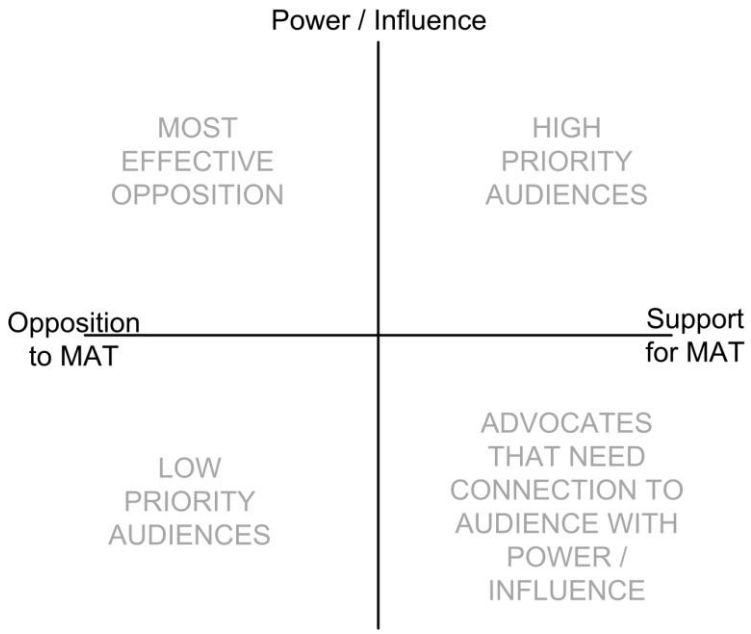
Target audience identification

For each prioritized advocacy issue, there will be critical audiences that need to be targeted with advocacy messages. Target audiences include decisionmakers and individuals or mechanisms that influence decisionmakers. Consider political leaders, legislators, officials of national and/or local government agencies, donors, national / local media, religious and traditional leaders, civic and non-profit organizations, and groups representing current and potential users of MAT services.

As they are identified, document critical information about each audience. This information will help to inform advocacy messages and strategies.

- **Level of knowledge about MAT.** Is the audience well informed or does it lack accurate information? What are the sources of information the audience uses for learning about MAT?
- **Level of demonstrated support for MAT.** Has the audience actively and/or publicly supported MAT? Describe examples…
- **Level of demonstrated opposition toward MAT.** Has the audience actively and/or publicly opposed MAT? Describe the reasons given for such opposition.
- **Undecided or unknown.** Has the audience failed to declare its position on MAT? What are the issues that remain unanswered?
- **Potential benefits to the audience.** How might the audience benefit on a personal, professional, or political level from supporting access to MAT?
- **Potential threats to the audience.** How might the audience be threatened?
- **Find shared values.** Is there a "we" message possible? Might there be a way to frame the issue, drawing on the values that are important to both the audience and MAT advocates?

As an exhaustive list of audiences is compiled, time and resources may dictate that audiences be prioritized. Which one is most critical to accomplishing the advocacy outcome identified? Consider the audiences' influence on decisionmaking, the relative "distance" they need to be moved to become advocates, the strength of the benefit and shared value between MAT advocates and the audience, and the cost and time required to gain their support. It can be helpful to place audiences on a chart and draw lines between audiences linked with each other.



Tool 2.3.4 Target audience identification worksheet

Prioritized advocacy issue: Final outcome desired:

Audience: Role: (direct decision maker or influencer of decision maker – *if influencer,* identify decision maker and relationship between decision maker and audience)			
Level of knowledge / source of information on MAT	Support / opposition / unknown	Benefit / danger to audience for supporting MAT	Shared value between MAT advocates and audience

Audience: Role: (direct decision maker or influencer of decision maker – *if influencer,* identify decision maker and relationship between decision maker and audience)			
Level of knowledge / source of information on MAT	Support / opposition / unknown	Benefit / danger to audience for supporting MAT	Shared value between MAT advocates and audience

Audience: Role: (direct decision maker or influencer of decision maker – *if influencer,* identify decision maker and relationship between decision maker and audience)			
Level of knowledge / source of information on MAT	Support / opposition / unknown	Benefit /danger to audience for supporting MAT	Shared value between MAT advocates and audience

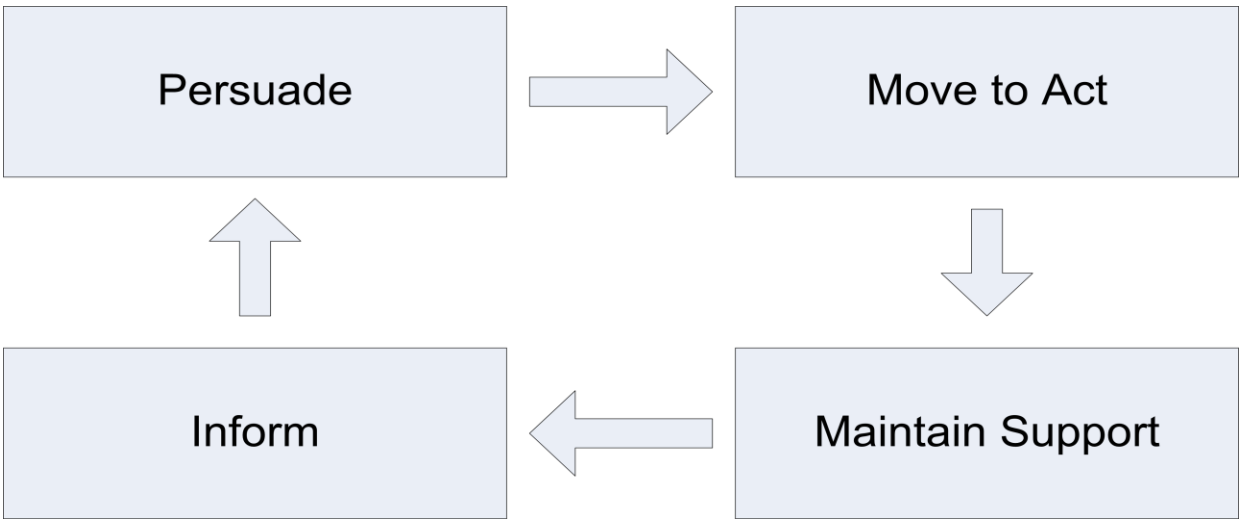
Add additional audience assessments as necessary.

Repeat for each prioritized advocacy issue.

Stakeholder mapping

As audiences are identified, carefully match the audience with stakeholder(s) that have credibility with that particular audience and message(s) that resonate with the audience's concerns.

To move an audience to action, stakeholders need information to develop a thorough understanding of the issue, the position of the audience, and the desired advocacy action. Once an audience is informed, the advocacy strategy seeks to persuade the audience to feel strongly about the issue, adopt the desired position, and move to action.



Successful messages

Each message must inform, persuade the audience to feel strongly about the issue, persuade it to adopt the desired position, and finally, persuade it to move to action. For each message developed, ask if it is tailored to the specific audience to accomplish these tasks (inform, persuade, move, maintain). Consider the following:

1. Have all of the key audiences been covered by a credible stakeholder and advocacy message? Have contextual issues been addressed or incorporated?
2. Are advocacy goals clear and attainable?
3. What is the timeline for achieving each advocacy goal? Are there specific events or processes that need to be taken into consideration when considering timelines (elections, parliamentary processes, holidays, opposition advocacy campaigns, etc.)?
4. How will achieving the listed advocacy goals move the group to its final advocacy outcome? (Clarify or describe the outcome.)
5. After these goals are achieved, what are the next steps?

Now that you have a basic advocacy strategy in place, make sure that individuals know their responsibilities and timelines; create a process for feedback, reporting, and adjusting the process based on successes or challenges; keep track of each incremental step; and keep planning for future advocacy.

COMPLETE LIST OF REFERENCES

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