

# **REFORMING ACCESS TO THERAPEUTIC OPIOIDS**

## **Tools for Rapid Policy Assessment and Response**

Prepared by Patricia Case, Zita Lazzarini and Scott Burris  
for the U.K. Department for International Development



# Rapid Policy Assessment and Response

## *A Tool for Mobilizing Local Capacity to Address Structural Risk Factors Endangering Health*

### Summary

Rapid Policy Assessment and Response (RPAR) is an intervention that mobilizes local knowledge and capacity to influence health policy. In RPAR, a research team in a country works with a Community Action Board (CAB) to collect three kinds of data: (1) laws and written policies relevant to health risks in the target populations; (2) existing data on the epidemiological situation and the operation of the relevant legal and service systems; and (3) qualitative interviews with police, judges, prosecutors, health care providers, pharmacists, patients and others who can describe how the laws are put into practice. The data collection and interpretation are guided by the CAB, which develops an action plan and final report. RPAR is designed to be used by people who do not have extensive experience in policy or qualitative research. The goals of RPAR are:

- (1) To catalogue written laws and policies and to collect data on their actual implementation;
- (2) To mobilize the stakeholder communities using this new knowledge to generate change that reduces health risk and increases access to care and services;
- (3) To build capacity of researchers to conduct implementation research; and
- (4) To disseminate the results of the research to policy makers and activists at the regional, national and international levels.

By combining the assessment of law on the books with research on how law is actually being applied on the streets, RPAR directly addresses the well-known gap between policy intent and implementation. By relying on local research capacity and leadership, the RPAR supports local capacity to produce change. RPAR emphasizes the link between formal policies and actual practices. It highlights the importance of and enables bottom-up change at the local level. It creates a means of holding states accountable not just for their formal policies but for the real practices that influence people's daily lives. It offers a means to mobilize communities to increase their participation and effectiveness in governing their own lives.

More information about RPAR is available at <http://www.rpar.org>.

This version of RPAR has been prepared for use in reforming laws, regulations and policies governing the importation, distribution, dispensing, administration and possession of opioid medicines for pain and drug dependency. It is designed to guide country stake-holders through a process of assessment, problem-solving, law reform and implementation to remove unnecessary barriers in policy and practice that impede patients' access to these essential medicines.

# **RAPID POLICY ASSESSMENT & RESPONSE: *ACCESS TO THERAPEUTIC OPIATES***



## **Module I: Project Planning & Community Action Boards**

*Tools*

## **Moderator's Guide**

The five Modules that follow include step-by-step instructions for organizing and conducting a Rapid Policy Assessment and Response (RPAR) in your country. The Tools modules include basic explanations of the Tools' purpose and the process for using them with the research team and the CAB. From time to time the Modules will also include "boxed" comments like this one, under the heading of "Moderator's Guide." The Moderator's Guide is intended to assist the research team in focusing and refining the collection and analysis of data throughout the process and in designing and implementing an action plan that will improve access to and utilization of opioid medicines.

Specifically, the Moderator's Guide will help you focus on:

- 1) Identifying the attitudinal, cultural, practice and other factors that suppress demand for pain medications or make health care providers unwilling or unable to provide them to patients as medically indicated;
- 2) Identifying the policy barriers that make it difficult to make, import, transport, store, dispense, administer, prescribe or possess opioid medicines in the dosages and amounts needed for good care;
- 3) Understanding how attitudes and policies interact to make the access problem more severe and difficult to solve;
- 4) Designing a regulatory system and an intervention/implementation plan that will create the most workable, locally appropriate set of rules and then teach all the stakeholders how and why it is important to use opioid medicines.

## **Moderator's Guide**

### **Scope of the Opioids RPAR**

The first decision to be made is how to deploy the RPAR in your country reform effort. We recommend that there be a national CAB, comprised of key stakeholders and champions in government, health care, public health, drug dependency, palliative care, consumer organizations and law enforcement. A national research team will coordinate the CAB and conduct the research. Working from the national level, it may be possible for the RPAR research team and national CAB to gather and analyze the necessary information about the current state of therapeutic opioid access, and the barriers and facilitators that need to be address to reform policies and implement new practices. As resources allow, a national RPAR may benefit from increasing the number of interviews of interactors and patients to address the diversity of situations across an entire country.

It should be noted, however, that mobilizing stakeholders is an important element of an RPAR project, and that a purely national RPAR may miss the opportunity to mobilize the knowledge, capacity and enthusiasm of champions and stakeholders across the country. It may therefore be desirable to conduct several local RPARs in major cities or representative rural areas, and to use the national CAB as the overall clearinghouse and coordinator of local data and action plans.

Use of the planning tools described in this Module should be adapted to fit the country plan for RPAR deployment.

# Telephone Mapping Exercise

The purpose of this exercise is to quickly identify or “map” the people who *influence* or have power over how opioids are used in the health care system to treat pain, relieve suffering and treat drug addiction and therefore over the lives of persons living with chronic pain, persons receiving hospice or palliative care, and those in need of drug-dependency treatment using medication assisted therapy (MAT). *Influence* is broadly defined and may be either a negative or positive effect on the daily lives or health of individuals. A person with influence and power over the over the lives of persons living with chronic pain, persons receiving hospice or palliative care, and those in need of drug-dependency treatment using MAT can be a Ministry of Health official who creates policy that affects the operation of pharmacies, hospitals, or clinics that treat these patients, a drug control official who investigates physicians who prescribe opioids, a hospital administrator known to be especially helpful, a prison warden who controls drug-dependency treatment in local jails and prisons, or a religious person who helps deliver hospice care. This exercise will be useful in quickly generating many names of people with both large and small roles in law, policy and practice related to therapeutic use of opioids; people your team may or may not be aware of. This list of names will be very useful in the future conduct of the RPAR as you consider who to add to the CABs or interview as key informants.

The technique is sometimes called “*snowball sampling*” and it is very simple. Make many copies of the attached form and then make an initial list of people to call. These initial people are sometimes called “seeds.” Pick someone in each category listed below or add additional categories you think may be useful. This exercise will work best if you only pick one seed for each category. Ideally, you would start with 8 seeds but if you want to add more you may, but don’t pick more than 10 seeds at the very most. This is meant to be a quick, short, flexible exercise.

## A. Possible Categories

- Health care professional who prescribe opioids
- Health care professional who dispenses opioids
- Hospital or hospice administrator
- Drug-dependency treatment professional
- Pharmaceutical company officer involved in importation, manufacture and/or distribution of controlled medicines
- Pharmacy professional who compounds or dispenses opioids
- Representative of regulatory agency that controls the legal importation, manufacture, movement, sale and dispensing of controlled drugs
- Representative of regulatory body that licenses and disciplines physicians, nurses, and others who may prescribe or dispense opioids
- Government officials
- Lawyers, judges, or prosecutors
- Police

After picking your initial seeds, which may be friends or people you have worked with in the past, call them and ask the following three questions (see telephone script below). This is meant to be an informal survey. Interviews should take no more than 5 minutes.

## **B. The telephone script**

Hi, my name is \_\_\_\_\_ and I am calling from \_\_\_\_\_. I am doing a quick, informal survey and I want to ask you three questions that will take no more than 5 minutes. May I continue?

1. Tell me the three people in your field with the most influence and/or power over how opioids are used in the health care system to treat pain, relieve suffering and treat drug addiction and therefore over the lives of persons living with chronic pain, persons receiving hospice or palliative care, and those in need of drug-dependency treatment using opioid substitution therapy (MAT). ...

*Write down the three names and their organizations and contact numbers, if available.  
Write down their names even if other people have mentioned them.*

2. Now, tell me the three people who are not in your field with the most influence and/or power over how opioids are used in the health care system to treat pain, relieve suffering and treat drug addiction and therefore over the lives of persons living with chronic pain, persons receiving hospice or palliative care, and those in need of drug-dependency treatment using MAT...

*Write down the three names and their organizations and contact numbers, if available.  
Write down their names even if other people have mentioned them.*

### **Prompts (use only if necessary)**

Lawyers?  
Pharmacy regulators?  
Educators?

3. Finally, tell me three people with influence or power over how opioids are used in the health care system that most people might not be aware of? This can include use of opioids to treat pain, relieve suffering and treat drug dependency.

*Write down the three names and their organizations and contact numbers, if available.  
Write down their names even if other people have mentioned them.*

Thank you so much for your time!

## **C. Organizing the responses**

Each round of telephone calling is called a wave. Wave 1 is finished when you have contacted all 8 initial seeds. Give each seed a unique number (Initial seeds will be #1 –8). The rest of this example will be based on the example of 8 seeds and 9 referrals from each seed.

The forms for the initial wave of calling will be labeled “Wave 1, Seed 1”, “Wave 1, Seed 2...etc.). Finish each wave before you start the next one, otherwise it will become very confusing.

If each seed gives nine referrals and assuming each referral is distinct, then you will have 72 calls to make in wave two. If you have already called someone, don’t call that person again. It is likely that some names will be mentioned many times; you only have to call them once. The referrals from wave 1 should be uniquely numbered. Since the initial seeds are number 1 – 8, the first referral will be number 9 and the next number 10 and so forth. These referrals become the seeds for the next wave. The form for the first referral will be labeled (Wave 2, seed 9) and the next (wave 2, seed 10).

If each seed (72) in wave II gives you nine referrals then you will have a list of 648 people and likely many will be repeats. Repeat the process with people who haven’t been called before for Wave 3. You will likely have what is known as saturation at that point in that very few new names are being added. This is a realistic place to stop.

#### **D. The Tally**

By now you have many forms and many names. One of the simplest things to do with this data is to list each name followed by the number of mentions. The people with the most mentions reflect a community consensus of influence. The people with the fewest mentions are also very interesting – they may also be important to consider for CAB membership.

# Telephone Mapping Exercise

Date: \_\_\_\_\_ Name called \_\_\_\_\_

Wave \_\_\_\_\_ Seed \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

## Less Well-known People

No. \_\_\_\_\_

No. \_\_\_\_\_

No. \_\_\_\_\_

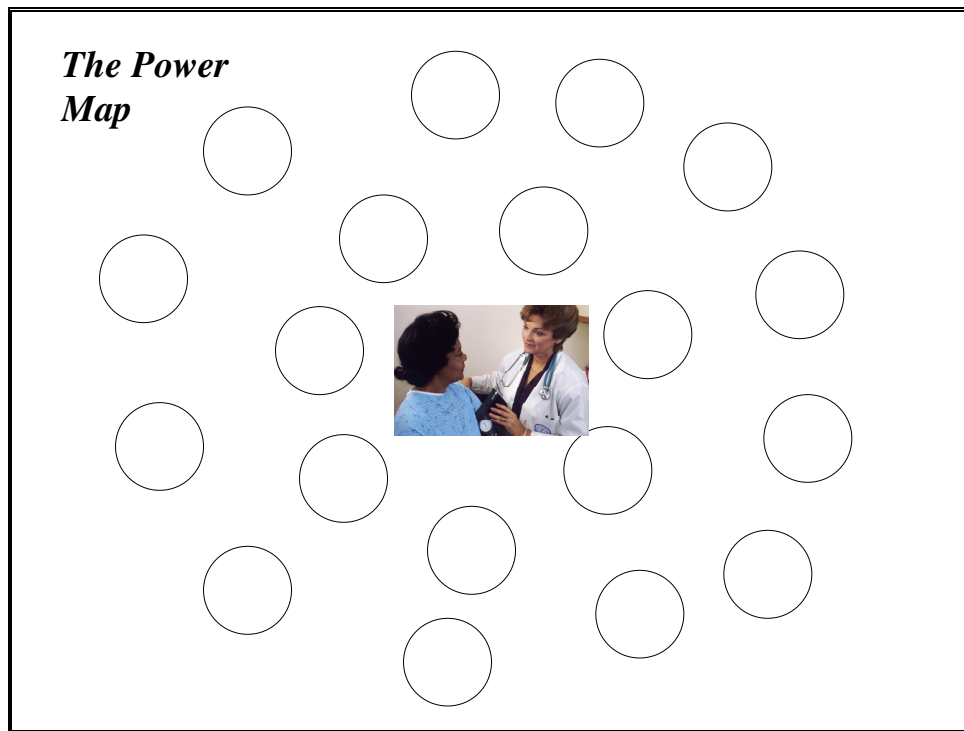
# The Power Map

A power map is a picture showing the *formal and informal organizations* that wield influence over (or “govern”) how opioids are used in the health care system and therefore over the lives of persons with a medical need for opioids.

**The power map is constructed using four basic steps described below.**

## Equipment Needed

PowerPoint or similar software and/or flip charts, pens and tape



A Blank Power Map

## Step 1: Identify the organizations that matter

### A. Identify organizations

*Try to identify organizations. If important individuals come up, list their organizations for now.*

### B. Refine the list

- a. Which of these organizations are really made up of some number of smaller units?

*Sometimes a large organization, like the police, is actually made of many units that operate more or less on their own, like a narcotics unit or a particular police station.*

- b. Are there organizations that, after discussion/reflection, should be added or removed?


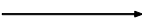

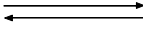
*Participants can decide what criteria to use to decide whether an organization is not important enough to include at this point.*

## Step 2: Chart the “influence connections” among the organizations

Which organizations influence which other ones?

Use arrow direction to indicate one way or two way influence

Use thickness of arrows to roughly indicate how powerful the influence is – large or slight

Strength and Direction of Influence		
	More Influence	Less Influence
One way		
Two way		

**Step 3: Write down what is known about the internal characteristics of each organization on a separate page/slide that looks like this:**

<p><b>Organization:</b></p> <ul style="list-style-type: none"> <li>• Resources</li>   <li>• Mentality</li>   <li>• Tools of Influence</li>   <li>• Key people</li> </ul>
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**Completing the Internal Characteristics form:**

This step focuses on gathering information about the key characteristics of each organization that determine its capacity to wield influence in your setting. These are:

- A. Identify the material resources of the target organization.

*Money, facilities, and equipment are important factors in an organization’s ability to wield influence. Poor organizations are not always weaker than rich ones, but resources are clearly helpful.*

- B. Identify the “mentality” that drives the organization.

*Every organization has a way of thinking about the issues it deals with that is more or less shared by its members and which helps the members to interpret what is happening in the environment and to collaborate in efforts to govern. Every organization has a way of thinking or “constitution” that governs how decisions are made within the group.*

- C. Identify the tools of influence used by the organization to accomplish its mission.

*Every organization has techniques or tools it uses to get others to obey them: legal organizations file lawsuits; police organizations arrest people; NGOs use personal connections or persuasion or expertise. Some tools are obvious, such as police use of force. Others are more subtle: any government agency can seek to get people to obey by using a social tool called “legitimacy,” which is the belief people have that they should obey the government just because it is the government.*

D. Identify the key people in the organization.

*In some organizations, many or all members of the organization can represent it in its dealings with other organizations. In others, there are one or a few people who actually make contact with other organizations, and so have an extra importance within the organization or the community.*

**Step 4: On the main slide/map, identify important groups (for example, cancer patients or drug users) who do not have an organization they can exert influence through**

*People in the community sometimes try to get things changed. But people who don't have an ongoing organization to work through will tend to have less effectiveness than people who are working together in an organized group over time.*

## Moderator's Guide

Your Power Map will be used throughout the RPAR process to capture and share the accumulating knowledge about the issue in your county. It will grow through the contributions and revisions of the team leaders, the team members, the CAB and the research participants.

At later CAB meetings you may want to revisit the Power Map, to add organizations, modify the directions and strengths of influence, or expand the information on the Internal Characteristics slide.

The Power Map is also a key tool to use when working on Analysis and Action Plan Forms 2, 3, and 4. The Power Map can help you identify new or innovative ways to cooperate with or try to change the behavior of various actors and organizations.

For example, if the CAB decides that a priority activity should be changing doctors' attitudes towards use of pain medication, it will be important to look back at the Power Map to identify which organizations (Universities, Medical Societies, pharmaceutical companies, large hospitals) play important roles in the training and continuing education of doctors. Gaining these organizations cooperation in endorsing, sponsoring, or requiring professional education on the medical uses of opioids and their important role in control of pain and treatment of drug dependency would be one way to change doctors' attitudes.

The Power Map might also remind you that doctors' behavior and attitudes toward pain medication are also influenced by the media's portrayal of the risk of addiction. Adopting a strategy that address both the formal and informal ways doctors are educated may, thus, be more successful than doing either one alone.

The power map is a fluid document. The power map will be used again and again throughout the RPAR process to refine or add information. As more information comes in from more perspectives, it will change. The research team should prepare a new edition of the map after each use.

## Problems and Solutions Exercise

Along the with Power Map, the Problems and Solutions Exercise is a means for the CAB members to exchange ideas about what policy and practice changes are needed to achieve satisfactory access to therapeutic opioids. It can consider everything from problems of drug importation and manufacture to the attitudes of doctors and patients towards pain medication.

### Equipment Needed

Problems and Solutions Form in Word software or a flip chart with pens and tape.

### Process

Ask every member of the CAB to quickly identify **one problem** that may be restricting the medically necessary use of opioids for treatment of pain or drug use, or for other uses identified in this RPAR, and **a possible solution** related to policy or policy implementation by health care providers, regulators or law enforcement. Write the ideas in Word or on a flip chart. Emphasize that

- this is a creative exercise, designed to get many ideas out on the table without judging how correct or important they are
- even speculation about possible problems is useful and welcome
- everyone must offer one idea that is different from the ones already offered
- there is no discussion of or comment on the problems and solutions offered
- you will not be recording who made what contribution

*The exercise should take only a few minutes. The goal is to get everyone to offer an idea, to build a team environment in which everyone feels entitled to participate. This is NOT the time to discuss or comment on the ideas.*

## **Moderator's Guide**

Note, the CAB and the research team will repeat the Problems and Solutions exercise multiple times during meetings and analysis of the data. At the beginning (in early CAB meetings) the facilitator should encourage participants to consider a wide variety of problems and possible solutions.

As the analysis process progresses (in later CAB meetings), the facilitator may want to narrow the question posed based, for example, on evidence from the research that most of the issues with access in that country are really about “overly restrictive regulations” or “pharmacists who refuse to stock or dispense opioids”. In either case the facilitator could ask all participants to identify a problem that is “part of” the main problem and then pose a solution to it.

*The goal is encourage creativity and participation. It is not a time to critique others' ideas or dwell on why a particular solution will not work.*



# Community Action Board

## *Purpose and Process*

A Community Action Board (CAB) is a group of people who have knowledge and interest in the medical use of opioids, the regulatory system that controls such use, and the needs of patients, as well as those experienced in public policy on these issues, health, local government and any other area the team thinks is important to the success of the RPAR project.

### **Purpose**

The purposes of the (CAB) are to:

- Organize and mobilize allies the important stakeholders at the local, provincial and national level
- Provide the research team with informational, social, moral and political support for the collection and analysis of policy data
- Collaborate with the research team to turn the data and analysis into an action plan, including specific proposals for legislation and regulatory change
- Implement the action plan

### **Process**

The CAB and the research team are collaborators on the RPAR project. The research team will meet with the CAB at least seven times. Each meeting is chaired by a member of the research team and has a specific agenda. In general, the research team uses each meeting to present data or information about the project to the CAB, and to learn more about the site and the priorities of the CAB. *After each Meeting*, the research team should organize the data collected from the CAB in the appropriate data organization form.

### **Moderator's Guide**

One of the most important goals that the research team should have in working with the CAB is to focus the CAB's discussions, analysis and planning on concrete issues that will move forward the process of developing and implementing a system of rules and regulations within the country that allow the balanced use of opioids medications and in educating physicians and patients about the important role of opioids in treatment of pain and drug dependency.

Module I describes a series of meetings with the CAB that stretch over the whole process of the RPAR. At each of these meetings you will have the opportunity to present new findings to the CAB from the research process and discuss these findings using the tools described in Modules I and IV.

Because each phase of the research produces different kinds of key findings, the CAB meetings

will focus on presenting and discussing these findings as they become available. All the key findings are important for the analysis process.

This schedule shows how to move through presentation and discussion of the types of key findings and their use in Analysis and Action planning over the course of the CAB meetings. Of course, since the RPAR research process will proceed somewhat differently in each setting, you can modify this schedule to fit your actual needs. It is important, however, to focus the CAB’s attention on these different areas of key findings and to use the findings with the analytical tools to identify, prioritize and refine strategy as part of the analysis and action planning.

<b>CAB meeting</b>	<b>Area of Key Findings</b>	<b>Goals and Exercises</b>
Meeting 1	Present preliminary results of :Medical Need Calculator	Demonstrate the gap between projected medical need and both supply and demand for opioids. Focus on possible reasons for gap and possible solutions.
Meeting 2	Present preliminary results of Module II, part II Opiate Access Policy Assessment	Focus on ways the country has or has not met criteria identified in treaty obligations and WHO list. Explore possible reasons and solutions.
Meeting 3	Present summary key findings from all of Module II, Law, Epidemiology, and Criminal Justice statistics.	Focus on identifying barriers in law, policy or enforcement and identifying possible solutions.
Meeting 4	Present preliminary key findings from interviews.	Focus on identifying barriers in culture, attitude, practices and implementation of law and policy that depress demand or promote excessively restrictive enforcement of existing regulations. Use Root Causes exercise to explore how attitudes and policies interact to make access problems more severe. Identify possible solutions.
Meeting 5	Present summary of all key findings.	Using the Root Causes and Priority Setting exercises focus the CAB on identifying interventions or plans for implementation that will create a workable, locally appropriate regulatory system and educate stakeholders how and why it is important to use opioid medicines.
Meeting 6	Present draft final report.	Using the Priority Setting and Power Map Action exercises develop strategies for action that will achieve the goals from Meeting 5.
Meeting 7		Assign responsibility for all identified priority interventions. Distribute Self-Evaluation Form.

# Community Action Board Meeting #1

**When:** As soon as possible after the beginning of the assessment

The goal for the first meeting is to:

- Introduce CAB to RPAR process
- Present basic information on opioid use in the country and outlines of opioid use regulatory system.
- Get CAB input on sources of existing epidemiological and legal data (Module II)
- Revise the research team's first version of the power map
- Generate one suggestion per CAB member for policy or practice change in the Problems and Solutions Exercise

*Agenda is included.*

**After the Meeting:**

- Organize the data you collected in the attached Sources of Existing Data form
- Prepare a new version of the Power Map

# **Community Action Board Meeting**

## **#1**

### ***Agenda***

- 1 – Introduction of members of Community Action Board and Research Team
- 2 – Brief summary of the RPAR methodology including the plan, timeline, activities and role of the CAB
- 3 – Brief summary of current medical use of opioids in the country, any areas where unmet needs may be identified, and the preliminary description of the policy situation, as necessary. Presentation of preliminary results of Medical Needs Calculator (Module II).
- 4 – Power Map Exercise
- 5 – Problems and Solutions Exercise – Focus on problems related to any gaps detected between estimated medical need for opioids and current supply and demand and identifying possible solutions.
- 6 – Identify sources of existing legal, criminal justice and epidemiological data
- 7 – Review agenda and date for next meeting
- 8 – Conclude meeting

## Existing Data Sources

### *CAB Meeting #1*

#### Sources of Existing Data

<b>Data Type</b>	<b>Source</b>	<b>Contact Person</b>
<b>Law on the Books</b>		
<b>Epidemiological Data Diseases</b>		
<b>HIV</b>		
<b>Cancer</b>		
<b>Chronic Pain</b>		
<b>Traumatic injuries (automobile, industrial, agricultural, other) requiring surgery, hospitalization, or setting broken bones)</b>		
<b>Surgeries requiring hospitalization</b>		
<b>Other Diseases Related to Severe Pain or Drug Dependency</b>		
<b>Overdoses</b>		
<b>Epidemiological data on prevalence of drug use and drug dependency treatment</b>		

<b>Drug use</b>		
<b>Drug dependency treatment</b>		
<b>Law Enforcement Data</b>		
<b>Arrests and convictions for diversion of opioids</b>		
<b>Seizures/closures of practices</b>		
<b>Investigations of physicians, pharmacists, hospitals, clinics, drug-dependency treatment centers</b>		
<b>Licensing actions against health professionals for prescribing or dispensing</b>		
<b>Importation &amp; Manufacturing Data</b>		
<b>Official estimates of opioid needs</b>		
<b>Official data on opioids imported</b>		
<b>Official data on opioids manufactured in country</b>		
<b>Official data on opioids dispensed</b>		
<b>Any other sources of data for opioid needs, imports, manufactured, or dispensed</b>		

*Add more rows or topics as needed.*

# Community Action Board Meeting #2

**When:** As soon as there are existing data (laws, law enforcement, and epidemiology) to present and the CAB can help identify prospective key informants.

The second meeting of the Community Action Board is intended to:

- Identify candidates for key informant interviews
- Review selected key findings from Module II, Law on the Books, Part I and Epidemiology, drug dependency treatment, criminal justice, and drug import/manufacture/distribution.
- Review the Module II, Part II Opiate Access Policy Assessment
- Review and discuss implications of existing data collection and Opiate Access Policy Assessment
- Revise the power map
- Generate one suggestion per CAB member for policy or practice change in the Problems and Solutions Exercise with focus on Opiate Access Policy Assessment.

*See Agenda attached.*

## **After the Meeting:**

- Organize the data you collected in the Power Map
- Candidate List and the System and Interactor Participants Candidate List
- Organize meeting notes

# **Community Action Board Meeting**

## **#2**

### ***Agenda***

- 1 – Identify candidates for Key Informant interviews
- 2- Present preliminary key findings of Module II.
- 3 - Review the Module II Part II Opiate Access Policy Assessment
- 4 – Review and discuss implications of existing data collection and Access Assessment
- 5- Revise power map
- 6 – Conduct Problems and Solutions Exercise – Focus on ways the country has or has satisfied the Opiate Access Policy Assessment and propose possible solutions.
- 7 – Resolve any outstanding problems with existing data collection
- 8 – Review agenda and date for next meeting.
- 9 – Conclude meeting.

# Community Action Board Meeting #2

## System and Interactor Participants Candidate List

*Please see pages 121 and 122 for complete list. Under each category of interview subject, the CAB should try to identify the best candidates for interviews and alternates, in case the first choice is not available.*

Rationale	Name	Organization	Contact Information
<u>Systems</u> Legal			
<u>Interactors</u> <u>Legal</u>			

<b>Rationale</b>	<b>Name</b>	<b>Organization</b>	<b>Contact Information</b>
<b><u>Systems</u></b> <b>Health Care</b>			
<b><u>Interactors</u></b> <b>Health care</b>			

<b>Rationale</b>	<b>Name</b>	<b>Organization</b>	<b>Contact Information</b>
<b>Systems Policy/regulatory</b>			
<b>Interactors Policy/regulatory</b>			
<b>Other locally important systems and interactors</b>			

# Community Action Board Meeting #3

**When:** Near the beginning of key informant interviews

The third meeting of the Community Action Board is intended to:

- Update or modify potential list of key informants based on community level feedback
- Present summary of key findings from all of Module II, Law, Epidemiology, Drug dependency treatment, Criminal justice and Drug manufacturing data collection
- Revise the power map
- Generate one suggestion per CAB member for policy or practice change in the Problems and Solutions Exercise – focus on barriers in law, policy or enforcement that make it difficult to make, import, transport, store, dispense, administer, prescribe or possess opioid medicines in the dosages and amounts needed for good care

*See attached agenda.*

## **After the Meeting:**

- Organize the data you collected in the System and Interactor Participants Candidate List and the Power Map
- Evaluate the CAB suggestion for RPAR and organize meeting notes

# **Community Action Board Meeting**

## **#3**

### **Agenda**

1 – Present summary of key findings from all of Module II: law, epidemiology, drug dependency treatment, criminal justice and drug manufacturing data collection

2 – Revise Power Map

3 – Conduct Problems and Solutions Exercise. Focus on identifying barriers in law, policy, or enforcement focus on barriers in law, policy or enforcement that make it difficult to make, import, transport, store, dispense, administer, prescribe or possess opioid medicines in the dosages and amounts needed for good care and on identifying possible solutions.

4 – Update list of systems and interactor key informants and suggestions for alternates

5 – Presentation of overall progress and timelines according to plan

6 – Review agenda and date for next meeting

7 – Conclude meeting

# Community Action Board Meeting #4

**When:** Near the end of qualitative data collection

The fourth meeting of the Community Action Board is intended to:

- Present preliminary key findings from key informant interviews
- Gather input on data yielded from finished key informant interviews
- Inform remaining system and interactor key informant interviews based on advice and suggestions from community members
- Revise the Power Map
- Introduce Root Causes Exercise (Module IV) to analyze problems identified in Problems and Solutions Exercises in meetings 1-3. Focus on identifying barriers in culture, attitude, practices and implementation of law and policy that depress demand or promote excessively restrictive enforcement of existing regulations. Use Root Causes exercise to explore how attitudes and policies interact to make access problems more severe.

*See attached agenda.*

## **After the Meeting:**

- Organize the data you collected in the System and Interactor Participants Candidate List, the Power Map and the appropriate forms of the Root Causes Exercise
- Evaluate the CAB suggestions and organize meeting notes

# **Community Action Board Meeting**

## **#4**

### ***Agenda***

- 1 -- Present preliminary key findings from key informant interviews
- 2 – Summary and discussion of key informant data
- 3 – Revise Power Map
- 4 – Conduct Root Causes Exercise based on problems selected from earlier Problems and Solutions exercises. Focus on identifying barriers in culture, attitude, practices and implementation of law and policy that depress demand or promote excessively restrictive enforcement of existing regulations. Use Root Causes exercise to explore how attitudes and policies interact to make access problems more severe.
- 5 – Identify more system and interactor key informants as necessary
- 6 – Review agenda and date for next meeting
- 7 – Conclude meeting

# Community Action Board Meeting #5 Workshop

**When:** About the 4<sup>th</sup> week of action planning and analysis, after the research team has made substantial progress organizing the data

The fifth meeting of the Community Action Board is a *half-day to full day* workshop intended to:

- Present summary of all Key Findings
- Update the Module II, Part II Opiate Access Policy Assessment (based on qualitative data key findings)
- Conduct the Root Causes Exercise to analyze problems developed in RPAR data collection
- Identify solutions for that will create a workable, locally appropriate regulatory system and educate stakeholders about how and why it is important to use opioid medicines.
- Conduct Priority-Setting Exercise to select interventions or implementations plans that will achieve these goals.

*See attached agenda.*

## **After the Meeting:**

- Record results using the forms for the Root Causes and Priority-Setting Exercises
- Evaluate the CAB suggestion for RPAR and add new notes as needed for the RPAR.

# **Community Action Board Meeting**

## **#5**

### **Workshop**

#### ***Agenda***

*This meeting, and meeting 6, are workshops, expected to require a half day to a full day of work.*

1 – Present summary of all key (includes Key Findings from qualitative data collections (interviews). If in written form they can be ready to insert into final report.

2 – Update the Module II Part II Opiate Access Policy Assessment (based on qualitative findings)

3 -- Conduct Root Causes Exercise, again focusing on how attitudes and policies interact to make access problems more severe.

4 -- Identification of potential solutions (law, policy, and practice interventions or reforms)

5 –Conduct Priority-Setting Exercise to select interventions or implementations plans that will t will create a workable, locally appropriate regulatory system and educate stakeholders about how and why it is important to use opioid medicines.

6 – Review agenda and date for next meeting

7 – Conclude meeting

# Community Action Board Meeting #6 Workshop

**When:** About 2 weeks after CAB meeting 5

The sixth meeting of the Community Action Board is a *half-day to full day* workshop intended to

- Conduct the Priority-Setting Exercise Again
- Compare the two sets of results and agree on priorities for action
- Conduct Power Map Action Exercise to develop strategies for action
- Present first draft of final report

**After the Meeting:**

- Organize the data you collected in the appropriate forms from Module IV.
- Integrate CAB ideas into the Final Report draft

# **Community Action Board Meeting #6 Workshop**

## *Agenda*

- 1 – Present / distribute first draft of final report, request comments returned by the next CAB meeting.
- 2 - Repeat Priority-Setting Exercise
- 3– Compare results with previous exercise
- 4 – Review and revise prioritized list of potential solutions
- 5 – Conduct Power Map Action Exercise. Focus on developing strategies that will create a workable, locally appropriate regulatory system and educate stakeholders about how and why it is important to use opioid medicines.
- 6 – Plan implementation using Analysis and Action Plan Form 3
- 7 – Review agenda and date for next meeting
- 8 – Conclude meeting

# **Community Action Board Meeting #7**

**When:** About 3 weeks after CAB meeting 6, near the conclusion of the RPAR

The seventh meeting of the Community Action board is intended to:

- Gather feedback on final report
- Allocate responsibility for disseminating and implementing the Action Plan and Final Report
- Plan future meetings of implementation group
- Distribute copies of Self-Evaluation Form (Analysis and Action Plan Form 5)
- Conclude RPAR and describe evaluation activities

**After the Meeting:**

- Integrate CAB suggestions in final draft of Report and Action Plan

# **Community Action Board Meeting #7**

## **Topic:**

- 1 – Present and discuss final report
- 2 – Repeat and revise implementation roles and responsibilities plan (Form 3)
- 3 – Set date and time for next meeting of CAB or successor group with responsibility for Implementation
- 4 – Distribute copies of Self-Evaluation Form (Analysis and Action Plan Form 5)
- 5 – End of RPAR, explanation of evaluation

# **RAPID POLICY ASSESSMENT & RESPONSE: *ACCESS TO THERAPEUTIC OPIATES***



## **Module II: Existing Data**

### ***Topic Areas:***

***(1) Law on the Books***

***(2) Epidemiology***

***(3) Law Enforcement***

### ***Tools***

# RAPID POLICY ASSESSMENT AND RESPONSE

## *Module II*

### *Topic Area (1) Laws*

In this part of Module II of the RPAR, researchers gather and analyze the law relevant to therapeutic use of opioids in pain relief, palliative care, and treatment of drug addiction.

#### **For purposes of the RPAR, “law” consists of:**

- Constitutions and any treaties that have the force of law
- Statutes passed by the national or regional legislature
- Ordinances (statutes) passed by local legislative bodies
- Administrative regulations with the force of law, issued by administrative agencies at the national, regional or local level
- Court decisions interpreting laws or regulations
- Executive orders or decrees with some binding effect issued by executive officers at the national, regional or local level
- Internal documents created by agencies to guide their enforcement or interpretation of laws and regulations
- Guidance on the interpretation of laws issued for the public by an agency or executive body
- Standard operating procedures, manuals or other documents defining enforcement practices, agency interpretation of laws or guidelines for public behavior
- Guidelines, “best practices,” published by medical professionals’ organizations intended to shape physician and other care-giver behavior in use of opiates.

#### **Definitions of drugs and drug names in the RPAR**

- National and international documents refer to the drugs that are the focus of this RPAR variously as “opiates”, “opioids”, “narcotics”, and even “psychotropic substances”
- This RPAR, focuses on the use of drugs to treat pain, relieve suffering, and to replace the opioidss of addiction
- The drugs included are those on the WHO Essential Medicines List (15<sup>th</sup>) and additional important pain medications. Drugs include: : Buprenorphine, Codeine, Diazepam, Ephedrine, Ergometrine, Fentanyl, Hydromorphone (Dilaudid), Morphine, Methadone, Naloxone, Oxycodone, Phenobarbital, and Pethidine (Demerol) as well as any other opioids of local significance, as defined by the local research team.

#### **Purpose:**

The information collected will provide a foundation upon which to build the remaining research of the RPAR. The laws you collect will help define the policy issues to be addressed in

qualitative research and the work of the CAB. Change in law may be a major goal of the Action Plan.

### **Process:**

This tool requires standard legal research using the normal methods and resources in the site country.

## **Part I: Collecting the laws, policies and practice guidelines**

### **Find and describe a broad range of laws, policy and practice guidelines that influence the therapeutic use of opioids in pain relief, palliative care, and treatment of drug addiction.**

Part I asks you to answer a series of questions about how the law, as written and enacted, regulates therapeutic opioids and to find and describe the individual laws and policies that govern a particular area or that address a particular question. The following five steps will take you through this process and the forms on the following pages guide you in describing the provisions.

**Step 1:** Answer the specific questions about the control and use of therapeutic opioids by referring to all the domains of law and policy listed below.

*This step asks you to review multiple areas of law, regulation and policy in order to answer each question. If the existing laws create ambiguity, and make a “yes” or “no” answer difficult, you can explain the differences below the question.*

**Step 2:** Identify laws and obtain the complete citation in correct local format.

*As you collect data, compare what you find with the domains below to ensure you are finding all that is required. If you find laws not mentioned below, but which you think may be relevant, include those in topic area 14.*

*Because you are collecting a broad range of documents that fall within the RPAR definition of “law,” there may be more than one provision applicable to a domain or topics within a domain. For example, drug control acts, medical practice acts, professional guidelines, and pharmacy regulations may all express official positions on the legitimacy of opioid use for pain control and drug-dependency treatment or on specific limitations placed on prescriptions for opioids. Be sure to collect the full range of relevant laws.*

**Step 3:** Copy the law.

*We expect that virtually all laws will be available for electronic cutting and pasting. If not, please copy the printed versions of the most important provisions and provide a more detailed summary in Step 4.*

*If you find an English translation of the statute, please copy that also.*

**Step 4** Enter information about the law into the box provided in this section, including: citation, type of provision, text of law, narrative summary and questions for practice.

**Citation** *(the correct way the provision is identified in national, regional or local codes) usually includes the name of the law (e.g., “Narcotics Control Act”), name of the source (e.g., Criminal Code), volume, page, year, and other locating information*

**Type of provision:** *Distinguish whether the rule is a statute/law, an administrative regulation with the force of law, an executive directive from an agency or official (e.g., a presidential decree), a written policy of an agency without the force of law, a written standard operating procedure or other management directive of a law enforcement agency, or a form of legal guidance issued by a law enforcement agency.*

**Text of law:** *include all the relevant text.*

**Narrative summary:** *in your own words give a brief description of what the law says relevant to the domains in question. Do not include speculation about the application or enforcement of the law in this section. Make sure your narrative addresses all the key topics in each domain. Note any particularly important elements (e.g., methadone is listed as a controlled substance, or possession of up to a gram of heroin is not a crime)*

*The purpose of the narrative is to succinctly summarize key points for your later work with the CAB and final report. Because you will have copies of the law, there is no need for lengthy discussion or detailed paraphrasing of the law.*

*You may wish to create more than one summary box for a domain or topic within a domain.*

**Questions for practice:** *include any questions about how the law is applied that are particularly relevant. For example, if methadone is listed among drugs with legitimate medical purposes, yet there are no opioid substitution programs in the country, there may be other reasons that the medical, drug-dependency treatment, and law enforcement communities have had for failing to adopt MAT or for blocking proposed programs. A question for practice might be: what is preventing health officials from establishing programs for MAT? Is the law, as enforced in this context – the “law on the streets” different from the apparent law on the books you have documented?*

**Step 5:** Important note: CAB meetings and research in Module III may lead to more areas of relevant law being identified, and require additional legal research.

*For each new area of law identified, repeat steps 2-4.*

## **Part II: Analyzing the laws, policies, and practices.**

### ***Step 1: Assessing compliance with treaty obligations and WHO essential medicines recommendations.***

At the conclusion of Part I, you will have collected a large body of laws and policies. In order to make sense of these, you have to analyze them in some way to determine the most significant elements of the law in relation to efforts to guarantee access to therapeutic opioids.

*Compare the information you collected with twenty-two criteria listed to determine whether the national government has taken the necessary steps to comply with the Single Convention on Narcotic Drugs (1961) as amended 1972 (Single Convention) using the 16 criteria identified by the World Health Organization and additional criteria addressing access to opioid substitution therapy (MAT) and specific drugs availability. You will be asked to review the government's response to the requirements of the Single Convention and the WHO Essential Medicines list, answer a series of questions, and, assuming the materials have been identified in step 1 provide cross references to the portions of laws, policies, or practice guidelines that satisfy the treaty requirements. If the source of your answer to any question is not included in Part I, then provide the full description of the source of the supporting information, and a summary of what it says.*

*For all “no” answers in Step 1 of the Analysis (Assessing compliance with treaty obligations and WHO essential medicine recommendations) enter the criteria number, source and brief description of the problem into the **Key Findings Form – Law on the Books: Key Findings from Part II: Treaty and WHO Recommendations Checklist** on page 105. You should also make an entry onto the Key Findings Form for all ambiguous answers to the Criteria Checklist. In other words, if you cannot determine whether national laws and policies satisfy the treaty obligations or WHO essential medicines list, enter that on the Key Findings Form. This form, and the other Key Findings Forms, provides the basis for Module IV Analysis and Action Planning. **It is crucial to include as Key Findings (and law and policy problems) all instances where national laws and policies do not satisfy the criteria in this section or where you cannot determine if the criteria are satisfied.***

### ***Step 2: Identify Key Findings.***

For each topic area of Module II (“law on the books”, epidemiology, and criminal justice statistics) you will be asked to analyze the data you collect to identify “Key Findings.”

The goal of this step is to identify the important information aspects of law, policy or practice that could influence access to therapeutic opioids and that will guide further

qualitative research during the RPAR. In identifying “key findings” in the “law on the books” section, you should look for: 1) laws, policies or guidelines that are not consistent with balanced access to therapeutic opioids; 2) laws, policies or guidelines that are neutral or supportive of access but where there is reason to believe that actual practice differs significantly from what is written; 3) laws, policies or guidelines that are new, and therefore actual practice may be unknown; 4) laws, policies or guidelines that are confusing or conflict with one another in a way that could be interpreted to restrict access in cases where opioids are medically indicated for treatment of pain, palliative care, or drug-dependency treatment; 5) other findings that you, the CAB, or interview subjects believe are significant..

For example:

- Methadone or buprenorphine are included in the list of drugs with no legitimate medical purpose;
- Pharmacists’ discretion to dispense is poorly defined;
- It is a crime for a physician to “unreasonably” or “unnecessarily” prescribe a controlled substance.

Once you have identified other “key findings” from the law on the books section using the 5 types of guidance above, record those key findings and their sources onto the **Law on the Books: Key Findings from Part I** form on page (106).

### ***Key Findings Forms:***

Through out this Module you will find several slightly different Key Findings Forms. Please note that there are specific Key Findings Forms for law Parts I and II. These are designed to help researchers identify the most important law and policy barriers to access to therapeutic opioids based on your collection of the “law on the books” and your completion of the Opiate Access Policy Assessment. There is also a Key Findings Form at the end of the module for use in organizing the epidemiology and law enforcement data. It is always important to identify the source, or supporting document for each key finding. In the case of laws, this could be by including the legal citation, for a policy, by including the title, date, and source of the policy document. The information on these forms will be used to help you organize and present data to the CAB and to begin the Analysis and Action Planning process covered in Module IV. You **must** identify, organize and prioritize the key findings as part of the systematic Analysis process.

## Moderator's Guide

Concepts similar to the “key findings” described here are common in policy research and development work. For examples of another system of identifying key findings, see the Pain Policy Study Group's (PPSG) website. In their national summaries of law and policy they often highlight important points in a way similar to the “key findings” found in the RPAR.

For specific examples, see their analysis of the laws and regulations of the State of Michigan (U.S.), at: [http://www.painpolicy.wisc.edu/domestic/state\\_profiles/Michigan/MI\\_complete.pdf](http://www.painpolicy.wisc.edu/domestic/state_profiles/Michigan/MI_complete.pdf). At this site you can see the analysis of one jurisdiction's laws, regulations and professional practice provisions. First, you find the provisions listed, with the official citations. Second, the evaluation criteria used by PPSG are presented on two Tables (those that *enhance* pain management and those that *impede* pain management). On one axis of each Table are the criteria, while the other lists the types of legal provisions (statutes, regulations, other government policies). Marks in the cells of the Table indicate where and how criteria are satisfied, or how possible barriers are created. Finally, there is a complete reproduction of the legal provisions with highlighted sections and annotations indicating precisely which sections of the laws, regulations and policies satisfy the evaluation criteria.

Users of these tools could use a similar process in reviewing their laws to identify provisions that are helpful for building a balanced approach to regulation and those which are not and need to be changed. The results of this process are both key findings and important targets for reform or revision of laws and regulations.

# The Domains of Law in the RPAR

**Purpose:** *The domains of law in the RPAR outline the areas of law that you should review in answering the questions related to laws, policies and guidelines.*

*For this RPAR focusing on access to therapeutic opioids this involves two parts. The first is designed to collect citations, text, and summaries of a broad range of laws that can influence access to therapeutic opioids by persons in need of pain treatment as well as those who would benefit from MAT as part of drug-dependency treatment programs.*

*The second part is designed to analyze the laws, policies and guidelines to determine the most important aspects for improving access to therapeutic opioids. The first step of the analysis will measure how completely the jurisdiction in question has reformed their laws to comply with the treaty (Single Convention on Narcotic Drugs).<sup>1</sup> The next step will identify key findings in the laws, policies and guidelines that may impede access to therapeutic opioids.*

## **Domains of law:**

- Control of opioids:
  - Controlled substances law
  - National formulary or pharmacopeia
  - National estimate process for INCB
  - Tax law related to import and movement of drugs
- Practice of medicine, pharmacy, nursing and other professions
  - Medical practice acts
  - Licensing and discipline of medical professionals
  - Licensing or operating of hospices, hospitals, clinics that treat patients for pain
  - Pharmacy regulations (related to prescription, use, or distribution of opioids)
  - Professional codes and standards related to use of opioids, relief of pain, and prevention or treatment of drug addiction
- Reimbursement for health care
  - Right to health care/ right to pain relief and / or palliative care
  - Health insurance provisions
- Patient rights
  - Privacy of medical information
  - Anti-discrimination provisions
  - National provisions related to international human rights norms
- Other laws
  - International drug control agreements
  - Relevant law applicable to minors
  - Other laws identified by CAB or Module III research that influence availability or safety of therapeutic opioids.

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<sup>1</sup> Part II of this instrument uses the criteria and approach developed by the Pain Policy Study Group at University of Wisconsin (Joranson D, et al) as part of the system of analysis. A complete explanation of their tools and results of their work is available at <http://www.painpolicy.wisc.edu/>. Used with permission.

**Part I:**

**In this part you will be asked to answer a series of questions about what the law, policies, and guidelines of your country actually say. The goal here is to collect a comprehensive record of what the county's official positions are in order to measure those against actual implementation and internationally recognized best practices.**

Therefore, for the question: "Does the law, policies or guidelines indicate that pain management recognized as part of general medical practice?" you should only answer "Yes" if you can find documented evidence for that official position. In the case of "laws" that would be the text and citation of the law itself. For policies, it would be the actual policy in writing, with a date it was issued or was effective and the administrative source for the policy. For a guideline, it would be a copy of the guideline itself, with the source, date of issue or effectiveness, and the full name of the government agency or professional organization that issued the guideline.

**This section is NOT trying to identify how laws, policies or guidelines are actually implemented (that is covered in Module III). However, if you already believe that implementation is a problem for any specific provision, you can indicate this in the "Questions for practice" section of the collection boxes for each law.**

# RAPID POLICY ASSESSMENT AND RESPONSE

## Module II Topic Area (1)

### Law on the Books

#### COLLECTION INSTRUMENT

#### Part I: Laws, Policies and Practices that Govern use of Opiates<sup>2</sup>

##### Directions:

The goal of this section is to answer specific questions about the law as it is written and to collect and summarize the actual text of the laws. Some questions, such as the first, ask you to collect a published list or “schedule” of controlled substances. Subsequent questions ask for details related to the schedule. Most of the remaining questions ask a direct question about the law, policy or professional standards. The collection instrument is designed to help you both collect the actual text of the materials and to provide quickly accessible answers based on those materials. Where there are multiple laws, policies or standards that address a specific question, collect all the materials and summarize them using the boxes. If the laws and other materials collected reveal ambiguities or even conflicts, this is important information for your analysis. The answers to these questions and the materials collected here will be helpful in the analysis and dissemination of your findings.

- 1) Answer the following questions based on your review of all the domains of law described on above.
- 2) For each question identify the specific laws or other legal provisions that support you answer and fill out one of the “collection boxes” for each law or other legal provision. In some cases you will find one law or provision that answers the question, but in other cases there may be multiple provisions. Fill out a “collection box” for each separate law or provision.
- 3) Sometimes you may find that different provisions conflict and that they might lead you answer “yes” and “no” to the question. Include an brief explanation in the space provided under “Comments” to explain conflicts or ambiguities in the law or other provisions.
- 4) This section is NOT meant to document actual practice or implementation where that differs from the law as it is written. However, you can make notes in the “Questions for practice” section of the “collection box” about implementation concerns you are aware of.
- 5) The “collection box” looks like this:

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<sup>2</sup> Part II of this instrument includes some of the criteria developed and used by the Pain Policy Study Group at the University of Wisconsin (Joranson D, et al) to measure compliance by United States jurisdictions (States and District of Columbia).

**SAMPLE**

<b>1.1</b>	<b><i>Drug use, possession and sale</i></b>
<b><i>Citation</i></b>	
<b><i>Type of provision</i></b>	
<b><i>Text of law</i></b>	
<b><i>Narrative summary</i></b>	
<b><i>Question for practice</i></b>	

**For more specific directions on filling out the box, see pages 40-43.**

**1.0 Controlled Substances**

**1.1 Schedule of Controlled Substances,**

1.1.1 Under the Single Convention, countries are required to compile a list or “schedule” of prohibited drugs. Find the most recent version of this schedule and identify which drugs are regulated. Attach the full list if possible then answer the specific questions regarding drugs that are relevant to the treatment of pain, relief of suffering, effective drug-dependency treatment, and the main drugs of abuse:

1.1.2 Determine the status of the drugs listed below (mostly opiates and synthetic opiates)

	<b>Drug Name</b>	<b>Schedule (I-V)</b>
a.	Buprenorphine	_____
b.	Codeine	_____
c.	Diazepam	_____
d.	Ephedrine	_____

- e. Ergometrine \_\_\_\_\_
- f. Fentanyl \_\_\_\_\_
- g. Hydromorphone (Dilaudid) \_\_\_\_\_
- h. Morphine \_\_\_\_\_
- i. Methadone \_\_\_\_\_
- j. Naloxone \_\_\_\_\_
- k. Oxycodone \_\_\_\_\_
- l. Phenobarbital \_\_\_\_\_
- m. Pethidine (Demerol) \_\_\_\_\_
- n. Heroin \_\_\_\_\_
- o. Opium \_\_\_\_\_
- p. Home-made opiates \_\_\_\_\_

1.1.3 Based on the list or “schedule” what are the minimum quantities (usually by weight) that may legally be possessed for each drug? For some drugs there will be no minimum, any detectable trace of the drug presents possible criminal penalties. For others, the schedule may set a threshold below which possession is decriminalized.

1.1.4 What are the penalties for use, possession, sale, manufacture, and diversion (if separate)?

Comment: \_\_\_\_\_

1.1.5 Are physicians and pharmacists specifically included or excluded from laws prohibiting distributing, transferring, or “turning over” controlled substances?

Comment: \_\_\_\_\_

1.1.6 Does the law make it a crime for physicians or other health care professionals to improperly or unnecessarily prescribe opioids?

Comment: \_\_\_\_\_

1.1.7 Are there non-criminal penalties, such as where possession is punishable by a fine or administrative penalty?

Comment: \_\_\_\_\_

1.1.8 For each relevant drug, are there different penalties for repeat offenders? (If so, what are they?)

Comment: \_\_\_\_\_

1.1.9 If you have not done so already, identify and summarize any available executive decrees, agency policies or other laws relating to drug possession or the enforcement of drug possession laws.

Comment: \_\_\_\_\_

<b>1.1</b>	<b>Schedule of Controlled Substances,</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**1.2 Authority and responsibility for regulating controlled substances. What agencies are charged with making regulations concerning and or enforcing:**

**1.2.1 Under the terms of the 1961 Convention, countries agree to designate a “competent authority” to oversee controlled drug regulation. Indicate which agency or other body the law designates**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.2            Scheduling and rescheduling of controlled substances (amending the schedule, adding new drugs, moving drugs from one list to another)?**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.3            Drug-dependency treatment?**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.4            Illegal drug use?**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.5 Approval of opioid medications for medical use?**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.6 Compiling and amending the national formulary or pharmacopeia**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.7 Compiling of estimates and reports to INCB**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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**1.2.8 Importation, manufacture and transportation of opioid drugs for medical use?**

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**Within this agency, what individual is currently responsible for key activities (give name and contact information)?**

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<b>1.2</b>	<b>Authority and responsibility for regulating controlled substances</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**1.3 National formulary or pharmacopeia**

1.3.1 Does the country have a national formulary or pharmacopeia?

Yes \_\_\_\_\_ No \_\_\_\_\_

Please attach a copy of the sections of the formulary relevant to opioids and opioid substitution therapy: \_\_\_\_\_

1.3.2 For each of the following drugs, indicate whether it is on the national formulary, what doses are provided and how it is administered?

<b>Drug name</b>	<b>In Formulary? (Y/N)</b>	<b>Doses</b>	<b>How administered? (oral, parenteral,</b>

			etc)
<b>WHO Essential Medicines List (15<sup>th</sup>)</b>			
Buprenorphine			
Codeine			
Diazepam			
Ephedrine			
Ergometrine			
Methadone			
Morphine			
Naloxone			
Phenobarbital			
Fentanyl			
Hydromorphone hydrochloride (Dilaudid)			
Oxycodone			
Pethidine (Demerol)			
Others (add as many as needed)			

1.3.3 Does the law set out a process for establishing the national formulary or pharmacopeia?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.3.4 Does the law specify how the national formulary or pharmacopeia can be amended?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>1.3</b>	<b>National formulary or pharmacopeia</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

#### 1.4 Compiling estimates for INCB

1.4.1 Does the law set out a process for compiling national estimates for INCB?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

1.4.2 What kinds of data does the law require the authority in charge of estimates to use to establish need for opiates and opiate substitutes?

\_\_\_\_\_  
\_\_\_\_\_

1.4.3 Does the law require the authority in charge of estimates to file an amended estimate when regional or local supplies are insufficient?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

<b>1.4</b>	<b>Compiling estimates for INCB</b>
<b>Citation</b>	
<b>Type of</b>	

<b>provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

### 1.5 Status crimes related to drug use

1.5.1 Does the law formally make it a crime to be a drug user?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.5.2 Being in the company of drug users?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.5.3 Other activities related to status as drug user?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.5.4 If you have not done so already, identify and summarize any available executive decrees, agency policies or other laws relating to the status of being a drug user.

Comment: \_\_\_\_\_

<b>1.5</b>	<b>Status crimes related to drug use</b>
<b>Citation</b>	
<b>Type of provision</b>	

<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**1.6 Registration of drug users or “addicts”**

1.6.1 When must a person be registered with government as a drug user or “addict?”

Comment: \_\_\_\_\_

\_\_\_\_\_

1.6.2 What types of professionals or others are authorized or required to identify people to be placed in such a registry (e.g., police, physicians)?

Comment: \_\_\_\_\_

\_\_\_\_\_

1.6.3 Who is authorized or required to maintain the registry?

Comment: \_\_\_\_\_

\_\_\_\_\_

1.6.4 What types of professionals or others have access to the registry?

Comment: \_\_\_\_\_

\_\_\_\_\_

<b>1.6</b>	<b>Registration of drug users or “addicts”</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	

<b>Narrative summary</b>	
<b>Question for practice</b>	

**1.7 Mandatory drug testing of suspected drug users.**

1.7.1 Does the law allow testing of a person suspected of drug use without his or her consent?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

1.7.2 When or under what circumstances can a person be tested for drug use without his or her consent?

Comment: \_\_\_\_\_

\_\_\_\_\_

1.7.3 What is the process for legally ordering a drug test and what officials are authorized to conduct such testing?

Comment: \_\_\_\_\_

\_\_\_\_\_

<b>1.7</b>	<b>Mandatory testing of suspected drug users</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	

<b>Question for practice</b>	
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**1.8 Laws concerning promotion or facilitation of drug use**

1.8.1 Does the law address activities deemed to promote or facilitate drug use?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.8.2 Does the law specifically address harm reduction activities in terms of promotion or facilitation of drug use?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>1.8</b>	<b>Promotion or facilitation of drug use</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**1.9 Naloxone or other treatment for drug overdose**

1.9.1 Is naloxone is a “scheduled drug” or “controlled substance”?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.9.2 Does the law govern use of naloxone in the treatment of drug overdose?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.9.3 Can naloxone be provided legally to drug user as part of an overdose prevention program?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.9.4 Who may be provided with naloxone and by whom? (for example, may non-physician outreach workers give drug users naloxone to use on in case of an overdose?)

\_\_\_\_\_

1.9.5 Repeat items 1-3 for any other medication used in the area to treat drug overdose.

\_\_\_\_\_

<b>1.9</b>	<b>Naloxone or other treatment for drug overdose</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

### **1.10 Needle exchange programs (NEPs)**

1.10.1 Are NEPs authorized by law, forbidden by law, or neither?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.10.2 If needle exchanges are allowed, identify all provisions governing their approval, operation or other oversight.

Comment: \_\_\_\_\_

<b>1.10</b>	<b>Needle Exchange Programs (NEPs)</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

### 1.11 Drug treatment as an alternative to incarceration

1.11.1 Does the law include drug treatment as an alternative to trial and/or incarceration for those arrested/convicted for drug-related crimes?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.11.2 Does the law make opioid substitution therapy (MAT) available to those serving alternatives to incarceration?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.11.3 Does the law make MAT available to those in jail or pre-trial detention?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.11.4 Does the law make MAT available to those in prison?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>1.11</b>	<b>Drug treatment as an alternative to incarceration</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

### 1.12 Tax law related to import and movement of drugs

1.12.1 Does the law tax import of opiates and opiate substitutes?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.12.2 Does the law tax movement of opiates or opiate substitutes from one region, province, state, or oblast to another (this may include state or regional laws, or other provisions at a lower level than national tax law)?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

1.12.3 Does the law in any other way limit or control movement of lawfully manufactured or obtained opiates or opiate substitutes from one region to another or one institution or another, such as by requiring special permits or licenses?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

<b>1.12</b>	<b>Tax law related to opiates or opiate substitutes</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**2.0 Legal provisions related to pain management and treatment of opiate addiction**

**2.0 Using opioids in medical practice**

**Include provisions related to physicians, nurses, and other allied health professionals who prescribe opioids (see below for questions specific to pharmacists and others who may dispense opioids)**

2. 1 Does the law recognize pain management as part of general medical practice?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

2.1.1 Does the law recognize medical use of opioids as part of legitimate medical practice?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

2.1.1.1 For pain?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.1.1.2 for drug-dependency treatment?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.1.2 Does the law define medical use of opioids to be outside legitimate medical practice?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.1.2.1 For pain?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.1.2.2 For drug-dependency treatment?

2.1.3 Does the law explicitly encourage pain management?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.1.4 Does the law describe opioids as a treatment of last resort?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>2.0</b>	<b>Using opioids in medical practice</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

2.2. What health care professionals are authorized to prescribe and administer opioids and how are prescriptions limited?

2.2.1 List health care professionals authorized to prescribe opioids:

List: \_\_\_\_\_

2.2.1.a. Does the law or regulations limit the authority to prescribe by requiring consultation with a second health care professional?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.b. Through specific prescription limitations?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.c. Is there a time limit on prescriptions' validity?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.d. Are practitioners subject to additional prescription requirements, if so, what are they?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.e Are there provisions that prohibit or limit prescribing opioids to persons who are or have a history of drug addiction or dependence?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.e.1. Does the law define “addiction,” “dependence,” or “tolerance”?  
Provide legal definitions.

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.2.1.e.2 Do the legal definitions overlap in a way that would confuse “addiction” with “dependence” or “tolerance”?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>2.2</b>	<b>Prescribing opioids</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

2.2.2. List health care professionals authorized to administer opioids:

List: \_\_\_\_\_

2.2.2.a. Does the law or regulations limit the authority to administer opioids?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>2.2.1</b>	<b>Administering opioids</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

2.3 Are there other provisions that may impede pain management?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

2.4 Are there other provisions that may impede use of MAT?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>2.2.3</b>	<b>Other provisions</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	

<b>Narrative summary</b>	
<b>Question for practice</b>	

### 3.0 Dispensing opioids

3.1 Does the law limit who may dispense opioids?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

3.1.1 List what types of practitioners may dispense opioids:

List: \_\_\_\_\_

3.1.2 Does the law grant different authority to “pharmacists”, “assistant pharmacists”, or “pharmacy technicians” or other ?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

3.2 Who has authority for licensing of pharmacies and pharmacists?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

3.3 Does the law relating to pharmacists and pharmacies consider the relief of pain a legitimate part of pharmacists’ practice?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

3.3.1 Does the same law recognize the use of opioids for pain relief a legitimate part of pharmacists' practice?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.3.2 Does the law relating to pharmacists and pharmacies consider the use of opiates or opiate substitutes to treat drug addiction a legitimate part of pharmacists' practice?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.4 Does the law relating to pharmacists and pharmacies create any additional restrictions for prescriptions for opioids?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.4.1 Require the purchaser to present identification?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.4.2 Limit the length of prescription validity or refills?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.4.3 Require record keeping of prescriptions?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.5 Are pharmacists subject to inspection, review, or additional scrutiny for, or related to, prescriptions of opiates or opiate substitutes?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

3.0	Dispensing opioids
Citation	
Type of provision	
Text of law	
Narrative summary	
Question for practice	

**4.0 Licensing and discipline of medical and allied health professionals (may be part of medical practice acts )**

4.1 Who has authority to license and discipline medical professionals who prescribe, dispense or administer opiates or opiate substitutes?

Physicians: \_\_\_\_\_

Nurses: \_\_\_\_\_

Pharmacists: \_\_\_\_\_

Other health care professionals (list by job category and licensing authority) :

\_\_\_\_\_

4.2 Are licensing and disciplinary bodies authorized to review “legitimacy” of health care professionals’ prescription or administration of opioids?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

h4.2.1 Is the amount prescribed alone used to determine legitimacy?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

4.2.1.1 Number of prescriptions written by a practitioner?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

4.2.1.2 Number of patients on specific drugs?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

4.2.1.3 Size of the dosage for individual patients?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

4.3 What are the penalties if a physician or other prescriber is investigated by the licensing or disciplinary body and found to have improperly/illegally prescribed?

\_\_\_\_\_  
\_\_\_\_\_

<b>4.0</b>	<b>Licensing and discipline of medical and allied health professionals</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**5.0 Licensing or operating of hospices, hospitals, clinics that treat patients for pain or for drug-dependency treatment (may be in medical practice acts, public health codes, or elsewhere)**

5.1 Who has the authority for licensing of institutions that treat patients for pain and for drug-dependency treatment:

5.1.1 Hospitals?

---

5.1.2 Hospices?

---

5.1.3 Drug-dependency treatment programs?

---

5.2 How are the requirements for licensure or operation different for :

5.2.1 .Hospitals?

---

5.2.2 Hospices?

---

5.2.3 Other facilities specializing in pain management or palliative care?

---

<b>5.0</b>	<b>Licensing or operating of hospices, hospitals, clinics that treat patients for pain or for drug-dependency treatment</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

## 6.0 Operation of drug-dependency treatment programs

### *Definitions for the following terms:*

**Medication-assisted Treatment (MAT)** is the use of methadone, buprenorphine or other medically appropriate opioid medicine to treat opioid dependency.

**Detoxification** is a short-term course of treatment with a defined end point using methadone, buprenorphine or suboxone during the acute withdrawal phase, with the goal of having the patient free of all opioid drugs at the conclusion of the treatment.

**Long-term MAT** is continuous, ongoing treatment using methadone, buprenorphine or other medically appropriate opioid medicine, conducted with the goal of patient remaining free of non-prescribed opioid drugs throughout the treatment.

6.1 What laws regulate operation of drug-dependency treatment programs?  
Identify any law regulating the establishment and operation of drug-dependency treatment programs, including:

6.1.1 What individuals or organizations may operate programs?

6.1.2 What licenses or other approvals are required for such programs?

6.1.3 Are these rules different for different types of programs (detoxification, in-patient treatment, out-patient treatment, long term MAT, behavioral modification, twelve step, or other modalities)?

<b>6.1</b>	<b>Operation of drug-dependency treatment programs</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

## 6.2 Medication-assisted detoxification and MAT:

6.2.1 Are methadone, buprenorphine, and any other opioid drug currently used to treat drug dependency “scheduled drugs” or “controlled substances” ?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

6.2.2 Is the use of opioid medicines in drug dependency treatment recognized as a legitimate medical use of opioids?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

6.2.3 What laws and regulations govern MAT?

(Be specific as to licensing/permitting required under controlled substances laws; record-keeping and other rules governing prescribing and dispensing; rules on security of the drug to avoid diversion; note regulations applicable specifically to long-term MAT)

\_\_\_\_\_

<b>6.2</b>	<b>MAT</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

6.3 Answer the following questions using the law you have identified “yes” or “no” and provide supporting laws or policies: (unless the law is different)

6.3.1 Are there restrictions on who may prescribe MAT or long-term MAT?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

6.3.2 Where can medication-assisted therapy be delivered:

6.3.2.1 Only government approved clinics	Yes	No
6.3.2.2 Physicians' private offices?	Yes	No
6.3.2.3 Pharmacies?	Yes	No
6.3.2.4 Emergency rooms?	Yes	No
6.3.2.5 Other?		

List \_\_\_\_\_

Comments: \_\_\_\_\_

6.3.3 Can MAT be used for (indicate all that apply):

6.3.3.1 Only for detoxification?	Yes
6.3.3.2 Only for post-detoxification long-term treatment?	Yes
6.3.3.3 For both detoxification and long-term treatment?	Yes

6.3.4 Are there time limits on how long MAT can be used for long-term treatment?

Yes \_\_\_\_ No \_\_\_\_

If Yes, how long? \_\_\_\_\_

Comment: \_\_\_\_\_

6.3.5 Are there time limits on how long MAT can be used for detoxification?

Yes \_\_\_\_ No \_\_\_\_

If Yes, how long? \_\_\_\_\_

Comment: \_\_\_\_\_

6.3.6 Are there official policies or guidelines indicating a priority or preference for weaning drug users off MAT?

Yes \_\_\_\_ No \_\_\_\_

Comment: \_\_\_\_\_

**7.0 Professional codes and standards related to use of opioids, relief of pain, and prevention or treatment of drug addiction.**

7.1 Is pain management recognized as a subspecialty in medicine?

7.1.1 What is the name of the accreditation organization?

\_\_\_\_\_

7.1.2 Do they certify or license individuals?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.1.3 Do they provide guidelines, standards or professional codes for treatment in addition to those described in the medical practice acts above?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.1.4 Include their standards or professional codes to answer the questions related to opioid, pain management, and drug-dependency treatment contained in question 6, above.

\_\_\_\_\_

7.2 Is palliative care recognized as a subspecialty?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.2.1 What is the name of the accreditation organization?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.2.2 Do they certify or license individuals?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.2.3 Do they provide guidelines, standards or professional codes for treatment in addition to those described in the medical practice acts above?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.2.4 Include their standards or professional codes to answer the questions related to opioid, pain management, and drug-dependency treatment contained in question 6, above.

\_\_\_\_\_

7.3 Is treatment of drug addiction recognized as a subspecialty?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.3.1 What is the name of the accreditation organization?

\_\_\_\_\_

7.3.2 Do they certify or license individuals?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.3.3 Do they provide guidelines, standards or professional codes for treatment in addition to those described in the medical practice acts above?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

7.3.4 Include their standards or professional codes to answer the questions related to opioid, pain management, and drug-dependency treatment contained in question 6, above.

\_\_\_\_\_

<b>7.0</b>	<b>Professional codes and standard related to use of opioids, relief of pain, and prevention or treatment of drug addiction.</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

## **8.0 Reimbursement for health care**

8.1 Does the law establish a “right to health care”?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

<b>8.1</b>	<b>Right to health care</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**8.2 Right to treatment for HIV/AIDS**

8.2.1 Does the law establish a right to HIV/AIDS medicines, specifically anti-retrovirals and drugs for adequate pain management when necessary?

Yes \_\_\_\_\_ No\_\_\_\_\_

Comments: \_\_\_\_\_

8.2.2 Does the law indicate how to allocate scarce resources to HIV/AIDS medicines, or for use of resources for different types of treatment for persons with HIV? (such as by setting up criteria for allocating anti-retroviral treatment or setting priorities for types of patients - for example giving pregnant women priority for ARVs)?

Yes \_\_\_\_\_ No\_\_\_\_\_

Comments: \_\_\_\_\_

8.2.3 Does the law indicate how to allocate opioid replacement therapy for persons with HIV/AIDS (for example by prioritizing access to methadone for patients already on ARVs)?

Yes \_\_\_\_\_ No\_\_\_\_\_

Comments: \_\_\_\_\_

<b>8.2</b>	<b>Right to treatment for HIV/AIDS</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**8.3 Access to drug-dependency treatment**

8.3.1 Is there a legal right to drug-dependency treatment?

Yes \_\_\_\_\_ No\_\_\_\_\_

Comments: \_\_\_\_\_

8.3.2 Identify any law governing the payment of the costs of drug-dependency treatment, including any provisions on government-paid treatment, eligibility for aid and time limitations on state-paid treatment.

\_\_\_\_\_

<b>8.3</b>	<b>Access to drug-dependency treatment</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

8. 4 Does the law recognize a right to treatment for pain or palliative care?

Yes \_\_\_\_\_ No\_\_\_\_\_

Comments: \_\_\_\_\_

8.4.1 Is the right limited to care related to specific diseases?

Cancer? Yes \_\_ No\_\_\_

AIDS? Yes \_\_ No\_\_\_

Other? List \_\_\_\_\_

<b>8.4</b>	<b>Right to pain treatment of palliative care</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

8.5 Is there a national health insurance system?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

8.5.1 Does the national health insurance system provide access to care for:

Primary health care? Yes \_\_ No\_\_

HIV/AIDS? Yes \_\_ No\_\_

Cancer? Yes \_\_ No\_\_

Pain management? Yes \_\_ No\_\_

Palliative care? Yes \_\_ No\_\_

Hospice care? Yes \_\_ No\_\_

Drug-dependency treatment? Yes \_\_ No\_\_

8.5.2 Does the national health insurance system require patients to pay doctor, hospital, or laboratory fees, purchase medicines, or be responsible for any portion of the cost of the care listed above?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

8.5.3 Does the national health insurance system require use of an identity card?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

8.5.4 Does the national health insurance system prohibit treatment of any kind of patients?

What does this mean? (for example, are non-citizens, internal migrants barred from receiving government funded care?).

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

8.5.5 Is there a system of private insurance that pays for the care listed below?

Primary health care? Yes \_\_ No\_\_

HIV/AIDS? Yes \_\_ No\_\_

Cancer? Yes \_\_ No\_\_

Pain management? Yes \_\_ No\_\_

Palliative care? Yes \_\_ No\_\_

Hospice care? Yes \_\_ No\_\_

Drug-dependency treatment? Yes \_\_ No\_\_

8.5.6 What provision does the law make for care for people who are not covered by national health insurance or private insurance?

Primary health care? \_\_\_\_\_

HIV/AIDS? \_\_\_\_\_

Cancer? \_\_\_\_\_

Pain management? \_\_\_\_\_

Palliative care? \_\_\_\_\_

Hospice care? \_\_\_\_\_

Drug-dependency treatment?  
\_\_\_\_\_

<b>8.5</b>	<b>Is there a national health insurance system?</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

## **9.0 Privacy of medical information**

### **9.1 Medical information generally**

9.1.1 Does the law protect personally identifiable medical information?

Yes \_\_\_ No\_\_\_

9.1.2 Are there penalties for disclosing personally identifiable medical information without patient consent or justification under the law?

Yes \_\_\_\_ No\_\_\_\_

Comments: \_\_\_\_\_

9.1.3 What are the penalties? \_\_\_\_\_

<b>9.1</b>	<b>Medical information generally</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

9.1.4 Does the law define personally identifiable medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.4.1 Are prescriptions (and the personal information contained in them) for opiates, opiate substitutes or other narcotics included in the definition of personally indefinable medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.4.2 Are HIV/AIDS related information included in the definition of personally identifiable medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.4.3 Is information related to drug addiction or drug-dependency treatment included in the definition of personally identifiable medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.4.4 Do these types of information or any other receive **additional protections** beyond what is granted other medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.4.5 Do any of these types of information receive **less** protection than what is granted other medical information?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

9.1.5 When may a physician/health care worker disclose personally identifiable health care information to others (such as)

- Health department
- Other health care workers involved in care
- Law enforcement officers who may have been exposed
- Institutional workers who may have been exposed
- Patient's family
- Patient's regular sex partners
- Patient's casual sex partners
- Law enforcement / courts for use as evidence
- Other individuals at risk of infection/exposure
- Researchers
- Others (list)

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<b>9.1.4-5</b>	<b>Medical Information – special protections or exceptions by disease</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	

<b>Question for practice</b>	
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**10.0 Anti-discrimination provisions and human rights provisions**

**10.1 Anti-discrimination or human rights protection for people with disabilities**

10.1.1 Are there specific anti-discrimination provisions or human rights provisions prohibiting discrimination against persons with disabilities?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

10.1.2 Does the law or policy define “persons with disabilities”?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

10.1.2.1 Does the definition of disabilities include those with terminal disease, cancer, or chronic pain?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

10.1.2.2 Does the definition include persons with HIV/AIDS?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

10.1.2.3 Does the definition include those who use or are addicted to narcotics?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

10.1.3 For all disabilities defined above:

10.1.3.1 Describe the forms of discrimination prohibited (e.g., employment, public programs, and professional services)

\_\_\_\_\_

10.1.3.1 What are the enforcement mechanisms and remedies (money damages, fines, etc)?

\_\_\_\_\_

<b>10.1</b>	<b>Specific anti-discrimination or human rights protection for people with disabilities</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

## 10.2 Other anti-discrimination laws or human rights provisions

10.2.1 Are there any other anti-discrimination laws or human rights provisions that are or could in the future be construed to guarantee that all people be treated fairly, or provide protection to people in medical need of treatment with opioids, or people in need of drug-dependency treatment, in gaining access to that treatment or against discrimination in housing, access to public services/facilities, access to private services/facilities employment or other areas.?

Yes \_\_\_\_\_ No \_\_\_\_\_

Comments: \_\_\_\_\_

10.2.2 What are the enforcement mechanisms and remedies (money damages, fines, etc)?

---

<b>10.2</b>	Other anti-discrimination laws or human rights provisions
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**10.3 Government agencies enforcing anti-discrimination provisions or human rights provisions**

10.3.1 What government agency or body oversees or enforces anti-discrimination or human rights provisions?

---

10.3.2 Does this agency or body also interpret the law related to anti-discrimination and human rights?

---

<b>10.3</b>	<b>Government agencies enforcing anti-discrimination or human rights provisions</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for</b>	

<b>practice</b>	
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### 11.0 International treaties and national law

11.1 Identify international human rights conventions and treaties to which the country is a signatory.

---

11.2 What status do these treaties have in relation to national law?

---

11.3 Do the provisions of the treaties take priority over national or local laws, and are their provisions enforceable or binding?

---

<b>11.0</b>	<b>International human rights treaties and national law</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

### 12.0 International narcotics control treaties

12.1 Which international narcotic and psychotropic substances treaties has the country signed and ratified?

---

12.2 What status do these treaties have in relation to national law?

---

12.3 Do the provisions of the treaties take priority over national or local laws, and are their provisions enforceable or binding?

---

<b>12.0</b>	<b>International narcotics treaties</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

#### 12.4 Bilateral or regional agreements on drug control

12.4.1 Determine whether the country has participated in any bilateral agreements on drug control and describe any agreements.

<b>12.4</b>	<b>Bilateral or regional agreements on drug control</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

#### 13.0 Relevant law applicable to minors

##### 13.1 Relevant law applicable to minors in the health care system.

13.1.1 May minors provide legal consent to care for HIV/STD or drug addiction without a parent's permission?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

13.1.2 May a minor legally obtain sterile syringes from NEPs, pharmacies or other sources without a parent's permission?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

13.1.3 May minors legally obtain other types of health care without a parent's permission?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>13.0</b>	<b>Minors in the health care system</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

13.2.5 Are minors eligible for substance abuse treatment or other alternatives to incarceration available to other drug users?

Yes \_\_\_\_ No \_\_\_\_

Comments: \_\_\_\_\_

<b>13.2.5</b>	<b>Substance abuse treatment for minors in criminal justice system</b>
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	

**14.0 Other laws identified by CAB or Module III research that influence availability or safety of therapeutic opioids.**

14.1 Document any other laws identified by CAB or Module III research that influence availability or safety of therapeutic opioids.

<b>14.0</b>	<b>Other laws that influence</b> availability or safety of therapeutic opioids.
<b>Citation</b>	
<b>Type of provision</b>	
<b>Text of law</b>	
<b>Narrative summary</b>	
<b>Question for practice</b>	



## Part II: Analysis

### 1: Criteria for assessing compliance with treaty obligations and WHO essential medicine recommendations: a checklist

*This section asks you to evaluate your law in terms of 16 criteria measuring a State's compliance with the Single Convention on Narcotic Drugs (1961, 1975) and additional criteria assessing the State's provisions governing medication-assisted therapy (MAT).*

*Criteria 1.1-1.16<sup>3</sup> Focus on whether the country has taken steps to reform their laws to comply with the treaty.*

*Criteria 1.17-19 measure the government's efforts to create access to medication-assisted therapy.*

*Criteria 1.20-1.22 evaluate the government's formulary in relation to WHO essential medicine recommendations.*

#### 1. Compliance with Single Convention and WHO essential medicines recommendations

1.1 Has the government conducted an examination to determine if there are overly restrictive provisions in the national (and state, if applicable) drug control policies that impede prescribing, dispensing, or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.2 Is there a provision in national drug control policies that recognizes that narcotic drugs are absolutely necessary for the relief of pain and suffering?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<sup>3</sup> Based on the criteria and approach developed by the Pain Policy Study Group (PPSG) at University of Wisconsin (Joranson D, et al). A complete explanation of their tools and results of their work is available at : [www.painpolicy.wisc.edu/](http://www.painpolicy.wisc.edu/) . Used with permission.

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.3 Is there a provision in national drug control policies that establishes that it is the government's obligation to make adequate provision to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.4a Has the government established administrative authority for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.4b Are there adequate personnel (employees) available for the implementation of this responsibility?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
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<b>Specific text supporting the answer, if applicable</b>	
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1.5a Does the government have a method to estimate realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief, palliative care and medication assisted therapy for drug users?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.5b Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.5c Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.6 Does the government furnish annual estimates to the INCB of need for narcotic drugs for the next year in a timely way?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.7 If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a supplementary estimate?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.8 Does the government submit to the INCB in a timely way the required annual statistical reports respecting production, manufacture, trade, use and stocks of narcotic drugs?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.9a Has the government informed health professionals about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.9b Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.10 Is there cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1. 11. Has the government taken steps, in cooperation with licensees, to ensure that there are no shortages of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

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1.12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will maximize physical access of patients to pain relief medications?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.13a Has the government established a national cancer control program to which it allocates health care resources?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.13b Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing education programs and by its inclusion in medical, pharmacy, and nursing curriculum?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.14. Is there terminology in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.16 Are there prescription requirements in the national drug control policy that may unduly restrict physician and patient access to pain relief?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

**Additional questions related to access to medication-assisted therapy**

1.17. Is medication-assisted therapy recognized as legitimate medical practice?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.18 Are there provisions in national drug control policy that may unduly restrict physician and patient access to medication-assisted therapy?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.19 If medication-assisted therapy is a relatively new treatment modality in the State, has the government taken steps to educate physicians, drug control authorities, and patients about its use and availability?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

**Additional questions related to types and dosages of opiates and opiate substitutes made available by law in the country.**

1.20. Does the national formulary or pharmacopeia include all of the minimum list of opiates and opiate substitutes included in the WHO Essential Medicines List (15<sup>th</sup>) and in the doses described? Drugs such as: Buprenorphine, codeine, diazepam, ephedrine, ergometrine, methadone, morphine, naloxone, phenobarbital?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.21 Does the national formulary or pharmacopeia include all of the following opiates and opiate substitutes beyond the WHO Essential Medicines List: Drugs such as: Fentanyl, hydromorphone hydrochloride (Dilaudid), oxycodone, and pethidine (Demerol)?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

1.22 Does the national formulary or pharmacopeia include any other opiates or opiate substitutes (if so, please list)?

Yes \_\_\_\_ No \_\_\_\_ Information not available \_\_\_\_

<b>Source of information</b>	
<b>Specific text supporting the answer, if applicable</b>	

### Identify Key Findings from the Checklist

For all “no” answers in Step 1 of the Analysis (Assessing compliance with treaty obligations and WHO essential medicine recommendations) enter the criteria number, source and brief description of the problem into the **Key Findings Form – Law on the**

**Books: Key Findings from Part II: Treaty and WHO Recommendations Checklist,** below. You should also make an entry onto the Key Findings Form for all ambiguous answers to the Criteria Checklist. In other words, if you cannot determine whether national laws and policies satisfy the treaty obligations or WHO essential medicines list, enter that on the Key Findings Form. This form, and the other Key Findings Forms, provides the basis for Module IV Analysis and Action Planning. It is crucial to include as Key Findings (and law and policy problems) all instances where national laws and policies do not satisfy the criteria in this section or where you cannot determine if the criteria are satisfied.

## **2: Other key findings**

### **Identify Key Findings from the information about the law collected in Part I.**

Review the law collected to identify “key findings”.

The goal of this step is to identify the important information aspects of law, policy or practice that could influence access to therapeutic opioids and that will guide further qualitative research during the RPAR.

In identifying “key findings” in the “law on the books section, you should look for: 1) laws, policies or guidelines that are not consistent with balanced access to therapeutic opioids; 2) laws, policies or guidelines that are neutral or supportive of access but where there is any reason to believe that actual practice differs significantly from what is written; 3) laws, policies or guidelines that are new, and therefore actual practice may be unknown; 4) laws, policies or guidelines that are confusing or conflict with one another in a way that could be interpreted to restrict access in cases where opioids are medically indicated for treatment of pain, palliative care, or drug-dependency treatment; 5) other findings that you, the CAB, or interview subjects believe are significant.

Once you have identified other “key findings” from the law on the books section using the 5 types of guidance above, record those key findings and their sources onto the form **Law on the Books: Key Findings from Part I.**

#### ***Key Findings Forms:***

*Use the Key Findings forms on the next two pages to record key findings. It is always important to identify the source, or supporting document for each key finding. In the case of laws, this could be by including the legal citation, for a policy, by including the title, date, and source of the policy document.*





# **Epidemiological Data on Disease/Injuries, Drug Use, and Drug-Dependency Treatment, Law Enforcement Data, Manufacturing and Importing Data, and National Estimates of Opiate Needs**

## *Topic Areas (2) and (3)*

In this part of Module II of the RPAR, researchers gather and analyze

- Existing data on the prevalence and distribution of disease, injuries, surgical procedures in the country and the community
- Existing data on the numbers of drug users, types of drugs used, and drug dependency treatment availability;
- Existing data about law enforcement related to enforcement of laws on illegal drug use and diversion of opioids
- Existing data on import, manufacture, storage, sale, and dispensing of opiates and opiate substitutes
- Existing data on national estimates of need for opiates and opiate substitutes

### **Purpose:**

The information collected will provide a foundation upon which to build the remaining research of the RPAR. Data on HIV and other significant diseases is essential to assessing the severity of the health policy problem in the country. Criminal justice statistics are an important measure of crime, the extent of the country's reliance on incarceration, and the extent of drug use.

### **Process:**

This tool includes the following three steps:

#### ***Step 1:*** Obtain data

*Be sure that each table or other data item you find is clearly labeled as to source and time period covered.*

*As you collect data, compare what you find with the domains below to check how well you are doing. Do NOT stop just because you find one source of data covering a topic on the list, because different sources may have different statistics on the same disease or behavior.*

*We expect that most of the data sources you find will be in tables or contain tables. There is no need to re-enter the data or create new tables in most cases.*

*Reports and published epidemiological studies or reviews will often include analysis and discussion of the most important data and trends in the epidemic. Part of the work of this Module is to identify and summarize these expert assessments.*

**Step 2:** Assign a number or other identifier to each data source or set of data and fill out the Data Evaluation Form for each one. Sometimes one source, such as a national AIDS center, will provide more than one set of data. Evaluate each set independently.

**Step 3:** Review the data and identify and list key findings on the Key Findings Form.

# Step 1: Obtaining Data

## *Topic Area (2): Epidemiology*

### **Epidemiology of Relevant Diseases and Drug Requirement Estimates**

The purpose of this section is to help you collect data on the scope of the need for pain treatment, palliative care and medication-assisted therapy. The section asks for several recent years of your national estimates for opioid requirements as provided to the INCB. In addition, the section asks you to collect data on specific diseases, behaviors and institutions that might serve as indicators for making an accurate estimate of opioid needs, revising current estimates, or establishing new areas of need (e.g. MAT).

Timeframe: Provide the last ten years (if possible) of estimates for opioids submitted by the government to the INCB.

Domains: For each disease listed, try to obtain data covering the past ten years for:

- the country
- particularly important cities or regions within the country

#### Directions:

For each disease/event listed, collect

1) Statistics:

- a) Prevalence rates and numbers (actual and / or estimated)
- b) Incidence rates and numbers where available or feasible (actual or estimated)

2) Documents analyzing or discussing the statistics, especially those that:

- a) Identify the most important data
- b) Summarize any trends or important points identified in epidemiological reports or studies.

#### Diseases:

- HIV/AIDS
- Cancer
- Chronic pain

- Traumatic injuries (automobile, industrial, agricultural, or others requiring surgery, hospitalization or setting broken bones)
- Surgeries requiring hospitalization
- Other diseases that could require treatment with opioids

Sentinel Events:

- Overdose data (linked to opioids)
- Fatal
- Non-fatal

# Epidemiology of Drug Use and Drug-Dependency Treatment

## Characteristics of drug use

This RPAR focuses on use of opioids, as drugs of addiction, as legal therapeutic replacement therapy, and as legally prescribed pain relief for acute and chronic pain including palliative care. Although there may be many other interesting data on drug use, injected and non-injected, the goal of this RPAR is more limited.

Domains: For each category of drug use, try to obtain data covering the past ten years for

- the country
- particularly important cities or regions

## Directions:

For each drug listed, collect:

### 1) Statistics:

*Depending on the question, the statistics collected will be quantities of drugs needed, or seized by law enforcement agencies, or numbers of beds available, or other units of measurement.*

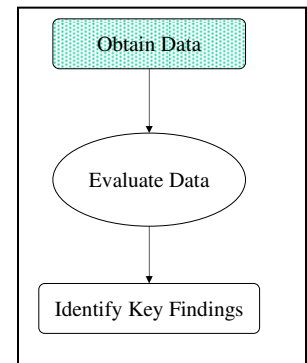
- a) Prevalence rates and numbers (actual and / or estimated)
- b) Incidence rates and numbers where available or feasible (actual or estimated)

### 2) Documents analyzing or discussing the statistics, especially those that:

- a) Identify the most important data
- b) Summarize any trends or important points identified in epidemiological reports or studies.

### 1.0 Legally prescribed opioids (prescribed and administered by health care provider)

*These data are important for use in calculating potential unmet medical needs for treatment of pain and drug-dependency.*



1.1 Copies of the estimates (for the last ten years) supplied by the Competent Authority in your country to the INCB as required by Arts. 19 and 20 of the 1961 Convention. These include (but are not limited to):

Art. 19

- 1.1.1 the quantities of drugs to be consumed for medical and scientific purposes;
- 1.1.2 the quantities of drugs to be used in manufacturing of other drugs;
- 1.1.3 the quantities of drugs held at the end of the year prior;
- 1.1.4 the quantities of drugs needed for addition to special stocks;
- 1.1.5 the area and locations of all opium cultivated;
- 1.1.6 the approximate amount of opium to be cultivated;
- 1.1.7 the number of manufacturing facilities making synthetic drugs;
- 1.1.8 the quantities of synthetic drugs to be manufactured

Art. 20

- 1.1.9 the actual amount of drugs consumed for medical and scientific purposes;
- 1.1.10 the actual amount of drugs used in manufacturing of other drugs;
- 1.1.11 consumption of drugs
- 1.1.12 import and export of drugs and poppy straw;
- 1.1.13 seizures of drugs and disposal thereof
- 1.1.14 the actual quantities of drugs held at the end of the year prior;
- 1.1.15 ascertainable areas of opium cultivated;

1.2 For each drug, obtain the official estimates numbers compiled by the Competent Authority in your country.

1.3 Collect any other sources of data on the amounts of each drug manufactured, imported, prescribed, sold, or administered.

- a. Buprenorphine
- b. Codeine
- c. Diazepam
- d. Ephedrine
- e. Ergometrine
- f. Fentanyl
- g. Hydromorphone (Dilaudid)
- h. Morphine
- i. Methadone
- j. Naloxone
- k. Oxycodone
- l. Phenobarbital
- m. Pethidine (Demerol)
- n. [Other locally important drugs]

2.0 Diverted or illegally obtained prescription opioids:

*These data may be collected in terms of illegal prescriptions written and detected, or milligrams illegally dispensed, or amounts seized. Ideally collect data that will be comparable over time.*

- a. Buprenorphine
- b. Codeine
- c. Diazepam
- d. Ephedrine
- e. Ergometrine
- f. Fentanyl
- g. Hydromorphone (Dilaudid)
- h. Morphine
- i. Methadone
- j. Naloxone
- k. Oxycodone
- l. Phenobarbital
- m. Pethidine (Demerol)
- n. [Other locally important drugs]

### **3.0 Illegal opioids**

3.1 Heroin

3.2 Opium

3.3 Home-made opiates (e.g., Kompot)

### **4.0 Drug-dependency treatment availability**

4.1 What kinds of drug-dependency treatment programs exist for treatment of opioid addiction?

*Please specify if they are “public” or “private” or “both*

4.2 Numbers of “beds” and/or clinics available for drug-dependency treatment (opioid addiction)

4.2.1 Inpatient detoxification?

4.2.2 Outpatient detoxification?

4.2.3 Inpatient treatment (post-detoxification)?

4.2.4 Outpatient treatment (post detoxification)?

4.2.5 MAT in inpatient detoxification?

4.2.6 MAT in outpatient detoxification?

4.2.7 Long-term MAT in inpatient treatment (post detoxification)?

4.2.8 Long-term MAT in outpatient treatment (post detoxification)?

4.3 Utilization: Numbers of beds occupied in the most recent year (trying to see if there is excess capacity or a shortage)?

4.3.1 Inpatient detoxification?

4.3.2 Outpatient detoxification?

4.3.3 Inpatient treatment (post-detoxification)?

4.3.4 Outpatient treatment (post detoxification)?

4.3.5 MAT in inpatient detoxification?

4.3.6 MAT in outpatient detoxification?

4.3.7 Long-term MAT in inpatient treatment (post detoxification)?

4.3.8 Long-term MAT in outpatient treatment (post detoxification)?

4.4 Waiting times to treatment (“waiting lists”).

4.4.1 If the numbers of drug users seeking treatment exceeds the number of available beds, how long are the waiting times to enter treatment?

4.4.2 Does this vary geographically?

4.4.3 If there are no data on how long the “time” to treatment is, are there data on how long the lists are in terms of numbers of names? Or how many drug users awaiting treatment finally enter treatment?

## **5.0 Pain treatment availability**

*This section tries to measure the adequacy of specialized sites where experts manage patients with pain (“pain clinics”, hospices, palliative care teams in acute care hospitals).*

5.1 How many hospices exist?

5.1.1 How many individual hospice beds does this include?

5.2 How many specialized “pain clinics” exist?

5.2.1 How many patients do they see annually?

5.3 How many acute care hospitals have specialized palliative care teams?

5.3.1 How many patients are treated annually?

5.4 How many long-term care institutions (nursing homes, rehabilitation facilities) have or are served by palliative care teams?

5.4.1 How many patients do they treat annually?

## Step 2: Evaluate Data

### Topic Area (2)

**Assign a number or other identifier to the data source and fill out the Data Evaluation Form for each source.**

For each source from which you have obtained data, and for distinct sets of data from a single source, use the Data Evaluation Form to record source, citation, and any important information about the reliability or availability of the information.

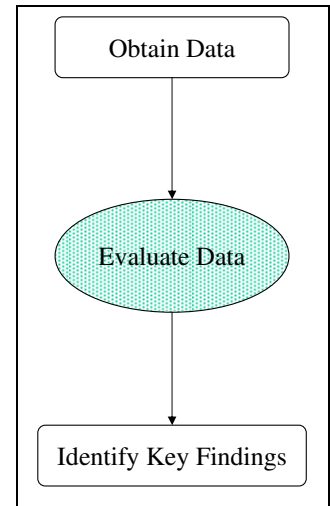
**Complete citation -** For all data, make sure you have a complete citation for the source. Then assign a number or other unique identifier to the source. This number will allow you to identify the source easily, and to refer to the source in other tables and forms. Record both citation and source on the data evaluation form.

A single source, may provide more than one relevant data set. For example, a national AIDS center may have data taken from a telephone survey on sexual behavior and also data taken from a registry of AIDS cases. In such cases, assign a different identifier to each data set and evaluate them separately.

In the box on disease or topic give a short description of the basic subject matter of the source. For example “Cumulative AIDS cases since 1995”.

In the box on limitations on validity, record any limitations on the validity or accuracy of the data of which you are aware. For example, if official sources estimate drug users using only those identified and registered with the state narcological institute, this would be important to note along with a comment that the actual number of (non-registered) drug users is likely to be much higher. “Non-registered users are not included in state estimate. Local treatment officials estimate 5-10 non-registered/each registered drug users in Kaliningrad.”

In the box on notes on access record any barriers to access you encountered. For example, “Arrest data were only available in paper files stored in basement of police station” or “It took 4 written requests to get permission to inspect data”. Or, conversely, note where data is publicly available in useable format. For example “On-line data available, search possible by year, type of crime, etc.”



## Data Evaluation Form

Source and Citation	Disease or topic	Limitations on validity	Notes on access

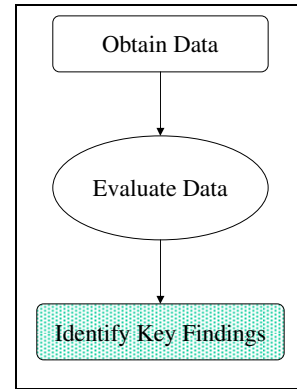
## Step 3: Identify Key Findings

### Topic Area (2)

#### Review the Data and Identify and List Key Findings on the Key Findings Form

At the end of each part of this module, we ask researchers to review the data they have collected to identify key findings. Researchers will have available the published statistics as well as the discussion and analysis in any published papers. The goal of this step is to identify the important information that can be used in the RPAR.

The Key Findings form will be used to prepare your presentation for the CAB and as part of your action planning process.



Key findings from Topic Area (2) will focus on using available data to estimate the actual medical need there is in your country for therapeutic opioids and comparing that amount to the actual amounts of opioids that are manufactured, imported, prescribed, sold and used in your country. If your medical need is greater than the amount that is currently used, you will have identified “unmet needs” for therapeutic opioids in the form of untreated pain. Your findings about the adequacy of the supply of opioids to treat a reasonable estimate of the medical need in your country will be a key finding for your use in the analysis of the law, policy and practice situation in your country.

Of course there can be many reasons for unmet needs including both “supply” and “demand” side reasons. For example, if your Competent Authority cannot or does not have accurate measures of the prevalence of diseases or injuries that require treatment with opioids, or does not use adequate dosing schedules in combination with prevalence data, then you may have a problem in terms of supply – your country’s estimates for opioids needed will not be high enough and no matter what patients or doctors do, they will not be able to get enough opioids. On the other hand, even if adequate estimates are submitted to INCB and opioids are imported, if doctors and patients are afraid of opioids, or it is too stigmatizing to purchase opioids, then you may have a problem in terms of demand – doctors won’t prescribe and patients won’t take sufficient opioids for medical needs.

You will use the Medical Need Calculator to estimate the amount of opioids that would be necessary to meet the medical need in your country if physicians and patients used opioid medicines to meet those medical needs. The Medical Need Calculator is based on a formula developed by several experts in pain, palliative care and policy.<sup>9</sup>

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<sup>9</sup> Basic methods for estimating morphine costs were developed by Foley et al. Foley K, Wagner J, Joranson D, Gelband H: Pain control for people with cancer and AIDS. Chapter 52, Disease Control Priorities for Developing Countries (2<sup>nd</sup> edition) [www.dcp2.org/pubs/DCP/52/FullText](http://www.dcp2.org/pubs/DCP/52/FullText) accessed May 2007. Suzanne Gelders built on the formula to create a simple estimate of national need. Gelders, S. “Access to Controlled Medications: Current issues on the availability and use of opioid analgesics, palliative care and selected controlled medications.” Background Report for the WHO Access to Controlled Medications Programme, September 2007.

### Medical Need Calculator

“The theoretical needs of a number of countries has been calculated using the mortality figures for cancer, AIDS and injuries, and assuming that only a certain number of those groups will require morphine for pain relief. It is assumed that of all cancer patients dying within one year 80% will require a total of 90 days of pain relief with 75 mg of morphine, of all AIDS patients dying within one year 50% will require a total of 90 days of pain relief with 75 mg of morphine, and of all patients dying of injuries within one year 15% will require a total of 5 days of pain relief with 75 mg of morphine.”<sup>10</sup>

1. Use the data collected in Topic Area (2) to complete the following formula:

[Number of cancer deaths in year X] X 80% X 90 days X 75mg morphine = annual cancer need

[Number of AIDS deaths in year X] X 50% X 90 days X 75mg morphine = annual AIDS need

[Number of injury deaths in year X] X 15% X 5 days X 75mg morphine = annual injury need

Annual cancer need + annual AIDS need + annual injury need = annual morphine need

2. Compare with reports of annual morphine consumption; add in consumption of other opioids for pain.

3. Need – actual consumption = unmet need

4. Enter this into key finding form for use in Module IV.

*Note, the medical need calculator could be adapted to estimate need for MAT. That calculation would also represent an important key finding.*

You may also identify other key findings from this section. Note the important, relevant conclusions of the studies and reports you reviewed, these will usually appear in “Discussion” “Findings” “Conclusions” sections of the report. Not all findings or conclusions of all reports will be relevant to this project, but some may be. Additionally, you must look at the actual data for important findings. Some examples follow.

Important information to look for:

- Trends (changes over time) – are the estimates of untreated pain getting better or worse over time? Are there trends in diseases (such

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<sup>10</sup> S. Gelders op cit. at 34(citing Foley K, Wagner J, Joranson D, Gelband H: Pain control for people with cancer and AIDS. Chapter 52, Disease Control Priorities for Developing Countries (2<sup>nd</sup> edition) [www.dcp2.org/pubs/DCP/52/FullText](http://www.dcp2.org/pubs/DCP/52/FullText) accessed May 2007).

as HIV or cancer diagnoses) that suggest that more people may need pain treatment than in prior years? Has the number of drug users seeking treatment increased greatly?

- Changes geographically. Are different parts of the city, region or country reporting higher levels of disease that was previously rare?
- Absolute numbers can also be noteworthy, even if the numbers do not represent a trend or change. For example, are there focal points that indicate especially significant needs, such as a significant drop in imports of opioids with no compensating manufacturing that point to possible severe shortages?



# Step 1: Obtaining Data

## Topic Area (3): Criminal Justice Statistics

Domains: For each area of criminal justice statistics listed, try to obtain data covering the past ten years for

- the country
- particularly important cities or regions

For each crime listed, collect:

1) Statistics:

- a) Arrests
- b) Prosecutions
- c) Convictions
- d) Sentences

2) Analysis and discussion

- a) Identifying the most important data
- b) Summarizing any trends or important points identified in criminological reports or studies.

1.0 Criminal law domains:

1.1 Violation of drug laws (possession, sale, manufacture, trafficking)

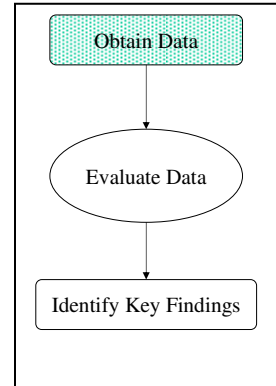
- By type of drug (e.g. arrest and conviction data for all crimes involving heroin)
- By type of crime (e.g. for criminal possession charges for all drugs\*)
- Where possible include data on the drugs listed below
  - Heroin
  - Kompott
  - Other opioids
  - Diverted prescription drugs (opioids)

1.2 Illegal prescribing of opioids – crime (data on physicians investigated, arrested, sentenced by criminal authorities),

- Numbers of investigations
- Numbers of arrests, prosecutions and sentencing

1.3 Illegal dispensing (violation of pharmacy regulations or controlled substances laws related to sale or distribution of opioids)

- Numbers of investigations



- Numbers of arrests, prosecutions, sentencing

#### 1.4 Prosecutions for harm reduction related activities

- Overall
- NEP operation
- Providing information
- Other

#### 1.5 Sentencing for all the drug crimes listed, by offense where possible

- Length of sentences
- Alternative sentencing including diversion to treatment

#### 2.0 Data on civil law suits:

- Are there data on numbers and outcomes of anti-discrimination claims brought by persons denied pain treatment or access to drug-dependency treatment?
- Are there data on numbers and outcomes of suits by physicians who have been investigated by drug control authorities or fear regulation or infringement on medical practice?

#### 3.0 Data on licensing actions or cases in which professionals have been disciplined for prescription of opioids (data on number of physicians/pharmacist/others investigated or sanctioned, by licensing boards)

- Types of professionals investigated or sanctioned
- Numbers of investigations
- Numbers of license sanctions (limitations, suspensions, revocations)
- Are there cases where health care professionals have been disciplined for “good faith” prescription of opioids?

## Step 2: Evaluate Data

### Topic Area (3)

**Assign a number or other identifier to the data source and fill out the Data Evaluation Form.**

For each source from which you have obtained data, and for distinct sets of data from a single source, use the Data Evaluation Form to record source, citation, and any important information about the reliability or availability of the information.

*Complete citation - For all data, make sure you have a complete citation for the source. Then assign a number or other unique identifier to the source. This number will allow you to identify the source easily, and to refer to the source in other tables and forms. Record both citation and source on the data evaluation form.*

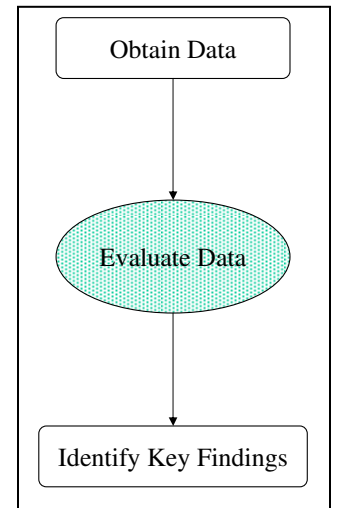
*A single source, may provide more than one relevant data set. In such cases, assign a different identifier to each data set and evaluate them separately.*

*In the box on disease or topic give a short description of the basic subject matter of the source.*

*In the box on limitations on validity, record any limitations on the validity or accuracy of the data of which you are aware.*

*In the box on notes on access record any barriers to access you encountered.*

See form in previous section.



## Step 3: Identify Key Findings

### Topic Area (3)

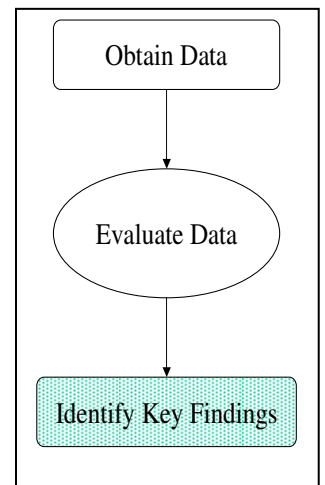
#### Review the Data and Identify and List Key Findings on the Key Findings Form

At the end of each part of this module, we ask researchers to review the data they have collected to identify key findings and enter those key findings in the Key Findings form. Researchers will have available the published statistics as well as the discussion and analysis in any published papers. The goal of this step is to identify the important information that can be used in the RPAR.

The Key Findings form will be used to prepare your presentation for the CAB and as part of your analysis and action planning process.

Key findings in this area will focus on identifying whether law enforcement practices are directly affecting doctors who prescribe pain medication or MAT, or pharmacists, or other health professionals. Specifically, you should look at several areas of the data you collected:

- Investigations of doctors for diversion of opioids (illegal prescription, distribution, or sale);
- Closures of doctors' practices or offices by officials investigating diversion;
- Arrests, prosecutions, convictions, incarcerations of doctors for diversion;
- Licensing sanctions or other professional sanctions against doctors for diversion;
- Investigations of pharmacists for diversion of opioids (illegal prescription, distribution, or sale);
- Closures of pharmacies by officials investigating diversion;
- Arrests, prosecutions, convictions, incarcerations of pharmacists for diversion;
- Licensing sanctions or other professional sanctions against pharmacists for diversion;
- Investigations of other health care professionals for diversion of opioids (illegal prescription, distribution, or sale);
- Arrests, prosecutions, convictions, incarcerations of other health care professionals for diversion;
- Licensing sanctions or other professional sanctions against other health care professionals for diversion;



If some health care professionals are being investigated, arrested or jailed for prescribing or dispensing opioids, then other health professionals may become even more reluctant to prescribe or dispense opioids, for fear of the potential consequences. This could be a key finding of your project.

## Moderator's Guide

It may be difficult, when collecting criminal justice or regulatory enforcement statistics, to separate those investigations, arrests and prosecutions which were related to illegal drug markets from those related to suspected diversion of legal drugs. However, it is important to try to do so, as the impact on physicians' attitudes is likely to be very different. In some countries this is possible, because drug control authorities have the capacity to track legally manufactured or imported drugs throughout the supply chain. If such tracking is possible, then diversion data are available.

Ultimately, it is also important to try to separate investigations, arrests, closures and prosecutions where the health care professional was acting in "good faith", from those in which the professional was knowingly diverting drugs for profit or to support his or her (or others') own addiction. This may be more difficult and may require more detailed investigation into the records of professional licensing agencies (for doctors or pharmacists). Professional licensing organizations usually keep more detailed records of the reasons for investigations of professionals and the findings from those investigations.

The most serious impact, sometimes called "the most chilling effect", of regulatory action on physicians' or pharmacists' attitudes and behavior – in other words the most likely to discourage all use of opioids – is usually where the authorities investigate, arrest, and prosecute doctors (or pharmacists) who are acting in good faith in prescribing or dispensing pain medication. In these cases investigations may be triggered because they have large numbers of patients taking opioids or some patients on high doses of opioids.

Now it is also possible for there to be a chilling effect on physicians or pharmacists based purely on fear of law enforcement or regulatory actions, even in the absence of any evidence of such actions. Evidence you collect in this section, combined with interview data in Module III, should help you sort out whether you have a problem based on investigations or arrests, or one based on fear and rumor. Clarifying this will help you identify the best solutions.

When reviewing these data to identify key findings you should do several things. One is to note the important, relevant conclusions of the studies and reports you reviewed, these will usually appear in "Discussion" "Findings" "Conclusions" sections of the report. Not all findings or conclusions of all reports will be relevant to this project, but some may be. Additionally, you must look at the actual data for important findings. Some examples follow.

Important information to look for:

- Trends (changes over time) of the same crime or law enforcement activity. For example, are the numbers of cases of arrests for diversion of drugs from pharmacies increasing or decreasing over time? Are the number of physicians under investigation up or down or remaining approximately steady?
- Changes geographically. Are different parts of the country reporting crimes, prosecutions, or other law enforcement actions that were previously rare?
- Absolute numbers can also be noteworthy, even if the numbers do not represent a trend or change. For example, are there focal points, age, ethnic, or risk groups where the law enforcement activity appears to be concentrated?

The Key Findings form will be used to prepare your presentation for the CAB and as part of your action planning process.

See form in previous section.

# **RAPID POLICY ASSESSMENT AND RESPONSE: *ACCESS TO THERAPEUTIC OPIATES***



## Module III: Qualitative Data

### ***Key Informant Interviews Tools***

# Qualitative Data: Key Informants

## *Module III: Tools*

### Purposes

The overall purpose of this Module is to collect evidence on the actual implementation of laws and policies governing access to therapeutic opioids for treatment of pain, drug addiction and palliative care. Specifically, Module III will help you to assess the actual implementation of the Single Convention on Narcotic Drugs (1961) as amended in 1972 (“the Single Convention”) and to identify differences between law “on the books” compared to implementation of the law “on the streets” – i.e., in practice. Qualitative interviews will be used with key informants to assess practice and identify barriers to the medical use of opioid drugs. The module is designed to learn about these key domains:

- Policies and regulations related to the medical use of opioids
- Enforcement of laws, regulations and policies related to the medical use of opioids from multiple perspectives
- Clinical practice and norms in prescribing and opioid medications
- Practical availability of opioid medications
- Facilitators and barriers to access to opioid medications and clinical, drug-dependency treatment and harm reduction services
- Attitudes towards opioid medications, and stigma and its institutional expressions from multiple perspectives
- Ongoing education in pain control and the medical use of opioid drugs
- Police behavior towards people who are in possession of prescribed or non-prescribed opioids, who have HIV, cancer or other diseases with pain, or are drug-dependency treatment patients.

### Intended Products

1. Qualitative data regarding practical enforcement of laws, regulations, and policies related to opioid medications from multiple perspectives.
2. Qualitative data on accessibility and availability of opioid drugs and structural barriers to opioid drugs, if any, that may contribute to suffering. .
3. Qualitative data on stigma and social attitudes as they apply to people who either receive opioid drugs as patients or use opioid drugs illicitly.

# **Module III**

## **Qualitative Data: Key Informants**

### *Tools*

#### **Introduction to the module**

Module III interviews cover the following topic areas:

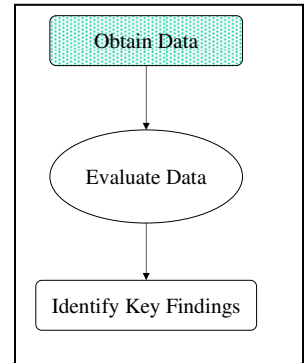
1. Questions on Practice: Policy and Drug Control
2. Questions on Practice: Clinicians
3. Questions on Practice: Pharmacists and Pharmacies
4. Questions on Practice: Drug-dependency Treatment
5. Questions on Practice: Police and Prisons

# Step 1: Obtain Data

## *Key Informants*

### Dimensions of opioid regulation and therapeutic use

This RPAR focuses on therapeutic use of opioids, as legal therapeutic replacement therapy for the treatment of drug-dependency, and as legally prescribed pain relief for acute and chronic pain including palliative care. Although people will say many interesting things about drug use, injected and non-injected, the goal of this RPAR is more limited in focus.



## Key Informant Interviews

1. There will be a total of 39 System and Interactor interviews (SI) (see Table A below) and 26 Patient-Level (PL) key informant interviews (see Table B).
2. The topic guides are separate; make sure you use the right one; either the topic guide for Systems and Interactor key informants, or the one for “Patient-Level” key informants (Pain patients and drug users).
3. Every day you should plan your interviews. Pack all the required materials in a bag; things such as extra batteries, interview guides, incentives, pens, paper, and anything else you might need to conduct interviews.
4. Qualitative interviewing is meant to produce exploratory data. Interview guides are meant to be just guides, not rigid questionnaire forms. Asking additional follow-up questions related to the comments of the participant is encouraged after asking the main questions. Prompts are written to make sure that certain areas are covered, but do not need to be asked again if the respondent has already covered that topic completely.
5. If new questions occur to the interviewer or new areas not covered on the Guide open up that are related to the experiences of pain patients and drug users with enforcement of laws related to opioids, barriers to obtaining opioid medications, aspects of drug-dependency treatment and MAT, or other areas, the interviewer is strongly encouraged to pursue those topics. Avoid “yes or no” questions and always aim to encourage the participant to say more and tell stories about their experiences. We want the participants’ own words; avoid excessive prompting or “putting words in the mouths” of respondents.
6. When you have recruited someone to interview, the order of the process is this:

- 1) Conduct the informed consent process, answering all questions the respondent may have.
  - 2) Conduct the demographic screening sheet – a short battery of structured questions that will enable you to assign a category of interview
  - 3) Conduct the qualitative interview and audio record the interview.
7. After every interview, download, label the audio file correctly with the date of interview, write summary notes, and begin to organize your data by entering findings into a table that corresponds to our numbered topic areas. You may have to listen to relevant parts of the audio file in order to remember how people responded. Be sure to find a confidential space to do this.

## Number and Type of Interviews

You have learned about system, interactor and patient-level key informant interviews in the training. We are asking you to recruit and interview particular types of people as well. For system and interactor (SI) interviews, if you are unable to recruit a type of person you may interview another type of person. For example, if there is no medication-assisted drug-dependency treatment available, then you will not be able to recruit drug-dependency treatment patients using methadone. You should recruit drug-dependency treatment patients who used illegal opioids as they represent potential methadone patients and their perspective will be valuable. Be sure that you have exhausted the possibilities for recruitment before you make a substitution. It will be a much better assessment if you adhere as closely as possible to the numbers in Tables A and B. In choosing an alternative person to interview, choose someone with a role or relationship to opioid medications or substance use that is as similar as possible to that of the person you were supposed to interview.

**Key informants inclusion criteria:** Key informants will be recruited from known contacts, on the street, from programs or wherever you are likely to find knowledgeable and talkative interview participants who are willing to share their knowledge. Inclusion criteria for key informant interviews are as follows:

- 1) Willing and able to independently consent to be interviewed
- 2) Is 18 years old or above
- 3) Meets one of the sampling category criteria
- 4) Is reported to be aware of issues relating to opioid medications, pain control or drug-dependency treatment in the system where s/he is active
- 5) Has direct knowledge of relevant events in the country where this study is taking place.

Please see the following page for number and categories of interviews.

**A. System and Interactor Key Informant Interviews**

<b>System/Interactor</b>	<b>Number</b>
<b>Legal systems</b>	
Judge	1
Person responsible for INCB estimates (the “Competent National Authority”)	1
Drug control authority (not INCB person) official	1
Customs or border authority official	1
<b>Legal interactors</b>	
Police	
Local police officer	1
Drug enforcement officer	1
Prosecutor	1
Customs agent – one who would inspect/approve shipments of medical opioids	1
<b>Health care systems</b>	
Cancer clinic director	1
HIV clinic director	1
Pain clinic director	1
Hospice/palliative care clinic director	1
Drug-dependency treatment clinic director	1
Prison health official (national)	1
Pharmacy owners or managers	1
<b>Health care interactors</b>	
Clinicians at cancer clinics	2
Clinicians at HIV clinics	2
Clinicians with chronic pain patients	2
Clinicians at hospices/palliative care clinics	2
Clinicians in drug-dependency treatment programs	2
Clinician in prison health	1
Dispensing pharmacists	2
Pharmacy staff	2
<b>Policy and regulatory systems</b>	
Pharmacy board practice regulator	1
Medical board practice regulator	1
Other systems level regulators	1
<b>Policy and regulatory interactors</b>	
Pharmacy board investigative/disciplinary staff	1
Medical board investigative/disciplinary staff	1
<b>Other locally important systems/interactors</b>	
Systems	2
Interactors	2
<b>Total</b>	<b>39</b>

## ***B. Patient-Level Key Informant Interviews***

<b>Patient-Level</b>	<b>Number</b>
<b>Pain Patients</b>	
Cancer patients with pain	2
HIV patients with pain	2
Chronic pain patients (ex: back injury, arthritis)	2
Hospice/palliative care patients with pain (self or relative)	2
Pain patients with concurrent addictive disease	2
Pain patients with a history of opioid misuse	2
<b>Drug-dependency Treatment Patients</b>	
Potential drug-dependency treatment patients (e.g. on a waiting list)	2
Medication-assisted therapy (MAT) patients	4
Other drug-dependency treatment patients	2
<b>Substance users (opioid misuse)</b>	2
<b>Other locally important categories</b>	4
<b>Total</b>	<b>26</b>

### **General Directions**

Collect data on each of the questions asked below, unless the subject does not want to answer, or does not have information relevant to the specific question. Informants might answer several questions at once. In that case the questions are there to remind you to collect information on each one. Also, for some questions, prompts are included to help you get more complete information if the informant gives very brief answers. Some respondents may feel that they have little “official” knowledge, but our aim is to elicit multiple perspectives so to the extent possible, ask questions of all. For example, a police officer may feel that s/he has little knowledge of pharmacy practice, but discovering what a police officer knows and doesn’t know is equally important in evaluating implementation of drug policy.

### **Definitions**

In working with sampling categories the key is definitions and inclusion criteria. Before recruiting key informants, please write clear and careful definitions for each category of key informant even if “everyone knows” what a good definition is for the category. For example, the category “Pain patient with a history of opioid misuse” could mean someone who last misused opioids a year ago or twenty years ago. What is the difference between the two cases? Is there one? Should the three interviews be specified as “history of opioid misuse within the last five years”?

Another example is the concept “Pain patient”. Not all patients experience chronic pain, some experience intermittent pain or pain related to a single surgery. If all of the pain patient interviews are limited to just those experiencing chronic pain, important contrasts will be missed. Careful specification of the concept “Pain patient” and important subcategories of the concept will greatly improve the quality and comprehensiveness of the data collected. Discussions

between investigators about the definitions of each category often reveal important theoretical distinctions and areas in need of clarity. Writing out expanded definitions is a critically important and interesting step and should not be skipped.

Definitions will be sharpened as interviews are conducted. In many ways, new definitions and distinctions between groups will emerge as interviews proceed. Nevertheless, investigators should attempt to clarify who they are trying to recruit ahead of time, but can flexibly change definitions and inclusion criteria as they proceed. Where a definition cannot be known or agreed upon in advance, it is completely acceptable to use self-definition. In that case, inclusion criteria might be written as “Persons (male or female) who self-identify as injection drug users and report injecting heroin at least twice in the last 12 months”.

Here’s another example that includes a definition and a time frame. Try to put time frames in every definition so that the behavior of interest is current. Twelve months is about the right time frame to capture current behaviors, and also captures people who may intermittently work in the sex industry. Several examples follow below. In addition, other constraints may be added (such as age, residence, or gender).

**Ex. 1. Injection Drug User:** A person who has injected heroin at least twice in the last 12 months

The next example has additional constraints. Note that the definitions are for the purposes of this study, and are constructed to provide guidance to interviewers and not to define all injection drug users.

**Ex. 2. Injection Drug User:** A person over 18 who has injected heroin at least twice in the last 12 months and is a resident of <the study area>.

The investigative team should write clear definitions with time frames for all categories in Table B (even if the definitions are quite open) before initiating recruitment or interviews. The interviewers should be provided with clear, written guidance about whom they may or may not recruit. In cases where the definitions of particular categories are unclear, investigators may wish to add other definitional questions to the module and allow the respondents to provide their perspective. One example of a definitional question might be:

**Ex 1.** What do you think is the difference is between patients with chronic severe unremitting pain and those who experience severe intermittent pain. How would you define the differences?

## **Data processing**

All interviews should be digitally recorded using a high quality digital recorder. Immediately following the interview:

- 1) Download the audio file onto a secure computer and electronically label the file.
- 2) Write brief process notes about how the interview went and your thoughts and impressions of the interview. Store the process notes and the cover sheet in a file.

3) Transcribe the audio recording completely. After the transcript is finished, have a second person listen to the interview with the transcript and check for errors in transcription. No matter how skilled the transcriptionist is, there will always be errors. After correcting the transcript, save the final version with the word FINAL in the file name.

4) Make frequent back-ups of all electronic files.

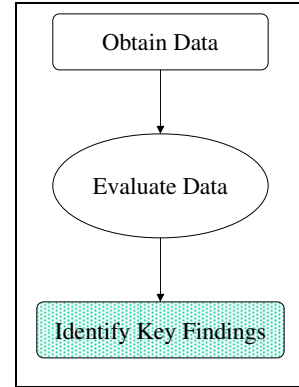
## Step 3: Identify Key Findings

### *Key Informants*

#### Review the Data and Identify and List Key Findings on the Key Findings Form

By now, you will have thick transcripts with a significant amount of information on each topic. Throughout the RPAR, we ask researchers to review the data they have collected to identify key findings. It is sometimes confusing to assess what is a key finding.

A useful way to do this is to use the Topic Guide as a guide to key findings. Using the transcripts, identify key quotes that will represent the key points a respondent made about a particular topic or sub-topic area. After reading through all of the transcripts, begin to organize key findings. A key finding may represent the majority “voice” or a single dissenting opinion.



In qualitative research, contrast is an important concept. You will not be able to summarize this data as you might summarize statistical data, by saying that 60 percent of the sample said one thing and 40 percent said another. Instead it is the narratives, the stories, and the explanations that are critical in providing context about policy regarding opioids in the study area. Finding the most important narratives will require many re-readings of the transcripts.

Once you have a sense of key concepts from readings of the transcripts, use the key findings forms to organize the data. The easiest way to use the forms is on the computer, so that you may expand the boxes. Include exemplar quotes and contrasting quotes to illustrate the range of findings. Always include the ID number of transcripts where a quote may be found. See box below for an example of a key finding.

### Example: Using the Key Finding Form

Topic Area or sub-area	Key Findings	Exemplar quotes <sup>11</sup>
<p>Topic Area 3, “Availability of Injectable Morphine” (Q 3.12.8)</p>	<p>Most pharmacists felt that injectable morphine was widely available in the pharmacies in the city.</p>	<p>“Injectable morphine is just one of those drugs that is so important for pain control it is always available here in the city” (SI032909)</p> <p><b>Contrast quotes:</b> One pharmacist disagreed, saying “Inject able morphine is never available in pharmacies. With the conflict nearby, pharmacists make a lot more money selling it “out the back door” to militia members for their wounded so that cancer patients in the city can never get it” (SI022709).</p> <p>Another pharmacist felt that the morphine sold as injectable was adulterated, saying “Well, they sell it but most of the injectable morphine sold is watered down, so patients often insist on tablets even though injectable may be more appropriate. That is why injectable morphine is always available but tablets are never available” (SI022209)</p>

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<sup>11</sup> Place quotes in quotation marks and ID number in parentheses after each quote. For example: “This is a quote” (POL220309KI)

## **Systems and Interactor Key Informant Interview Guide**

- 1) Demographic Screening Sheet**
- 2) Interview Topic Guide**
- 3) Key Findings Form**

## Systems and Interactor Cover Sheet

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
           (day)      (month)      (year)

Study ID: SI \_\_\_\_ - \_\_\_\_

Interviewer name: \_\_\_\_\_

Category Number: \_\_\_\_\_

### *System and Interactor Category Numbers*

Category number	System/Interactor	Category number	
	<b>Legal systems</b>		<b>Policy and regulatory systems</b>
1.	Judge	23.	Pharmacy board practice regulator
2.	Person responsible for INCB estimates	24.	Medical board practice regulator
3.	Drug control authority official	25.	Other systems level regulators
4.	Customs or border authority official		<b>Policy and regulatory interactors</b>
	<b>Legal interactors</b>	26.	Pharmacy board investigative/disciplinary staff
5.	Police	27.	Medical board investigative/disciplinary staff
6.	Prosecutor		<b>Other systems and interactors</b>
7.	Customs agent	28.	Other systems
	<b>Health care systems</b>	29.	Other Interactors
8.	Cancer clinic director		
9.	HIV clinic director		
10.	Pain clinic director		
11.	Hospice/palliative care clinic director		
12.	Drug-dependency treatment clinic director		
13.	Prison health official (national)		
14.	Pharmacy owner or manager		
	<b>Health Care Interactors</b>		
15.	Clinicians at cancer clinics		
16.	Clinicians at HIV clinics		
17.	Clinicians with chronic pain patients		
18.	Clinicians at hospices/palliative care clinics		
19.	Clinicians in drug-dependency treatment programs		
20.	Clinician in prison health		
21.	Dispensing pharmacists		
22.	Pharmacy staff		

Comments:

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**INTERVIEWER: CODE RESPONDENT GENDER**

G. \_\_\_\_\_

Female = 1, Male = 2, Other (specify: \_\_\_\_\_) =3

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I just have a few questions to begin:

1. How old are you? (in years): 1. \_\_\_\_\_
2. Where were you born? 2. \_\_\_\_\_  
(either city in country, or country if outside study area)
3. What is your organization's official name? 3. \_\_\_\_\_
4. What is your official job title? 4. \_\_\_\_\_
5. How long have you been in your current professional position? (in years, code as 01 if < 1 year) 5. \_\_\_\_\_
6. What percent of your clients/patients/people you deal with are .....  
(READ LIST. Check here if no direct contact with below categories \_\_\_\_\_)
  - 6.a. Cancer patients with pain 6.a. \_\_\_\_\_
  - 6.b. HIV patients with pain 6.b. \_\_\_\_\_
  - 6.c. Patients with chronic pain 6.c. \_\_\_\_\_
  - 6.d. Hospice/palliative care patients 6.d. \_\_\_\_\_
  - 6.e. Pain patients with co-morbid addictive disease 6.e. \_\_\_\_\_
  - 6.f. Pain patients with a history of opioid misuse 6.f. \_\_\_\_\_
  - 6.g. Drug-dependency treatment patients 6.g. \_\_\_\_\_
  - 6.h. Illicit opioid users (not in treatment) 6.h. \_\_\_\_\_

# **System and Interactor Key Informant Interview Guide**

## *Questions on Practice: Policy and Regulation Topic Area 1*

**To the interviewer:** This set of questions is designed to get specific information from the informant about what actually takes place with respect to enforcement of laws, policies and regulations relevant to opioid drugs.

### **Road map**

Section One. Ask ALL

Section Two. Ask only Policy and Regulatory systems and interactors.

Section Three. Ask only Border and Customs systems and interactors

Section Four. Ask only the person responsible for provision of INCB estimates.

### Section One: Ask All.

#### **Opiate drugs and the government**

1.1. To your knowledge, has the government conducted an examination to determine if there are overly restrictive provisions in the national (and state, if applicable) drug control policies that impede prescribing, dispensing, or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? Please say more...

1.2. To your knowledge, has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities? Please say more...

1.3. To your knowledge, do you think the government has informed health professionals about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? Please say more....

1.4. To your knowledge, do you think the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids? Please say more...

1.5. [Insert here any important questions identified as a result of Module II or in the CAB process]

If not going on to subsections, thank respondent for participating in the interview.

## Section Two: Ask only Policy and Regulatory systems and interactors

### **Medical Regulations**

1.6. Tell me about how laws, polices and regulations concerning clinican’s use of opioid drugs are enforced?

#### *Prompts*

- *Elicit details of the day to day practice of enforcement*

1.7. Tell me about how laws, polices and regulations concerning clinican’s use of opioid drugs are investigated?

#### *Prompts*

- *Elicit details of the day to day practice of investigation*

1.8. About how many enforcement actions against clinicians in <the study area> were conducted in the last year?

#### *Prompts*

- *Elicit details of the enforcement actions, narratives of cases.*

1.9. Do laws, regulations and policies relating to clinicians create any additional restrictions for prescribing opioids? Tell me about them...

#### *Prompts*

- *Elicit each barrier, for example, do regulations ...*
  - *Require the purchaser to present identification?*
  - *Limit the length of prescription validity or refill*
  - *Require record keeping of prescriptions?*
  - *Require that a patient be “terminal” for pain relief?*
  - *Require a particular diagnosis?*
  - *Limits on dosage or type of drug?*
- *Probe for differences by drug type or dose*

1.10. Are clinicians subject to inspection, review, or additional scrutiny for, or related to, prescriptions of opiates or opiate substitutes?

1.11. Do licensing and disciplinary bodies review patterns and “legitimacy” of pharmacist’s dispensing of opioids?

1.11.1. (If Yes) How is legitimacy determined? Tell me more about that...

#### *Prompts*

- *Is the number of prescriptions for opioids written by the physician assessed?*
- *Is the number of patients on specific opioid drugs assessed?*

- *Is the size of the dosage for individual patients assessed?*

## **Pharmacy Regulations**

1.12. Tell me about how laws, polices and regulations concerning pharmacists dispensing of opioid drugs are enforced?

### *Prompts*

- *Elicit details of the day to day practice of enforcement*

1.13. Tell me about how laws, polices and regulations concerning pharmacists dispensing of opioid drugs are investigated?

### *Prompt*

- *Elicit details of the day to day practice of investigation*

1.14. About how many enforcement actions against pharmacists in (the study area) were conducted in the last year?

### *Prompt*

- *Elicit details of the enforcement actions, narratives of cases.*

1.15. Do laws relating to pharmacists and pharmacies create any additional restrictions for dispensing opioids? Tell me about them...

### *Prompts*

- *Elicit each barrier, for example, do regulations ...*
  - *Require the purchaser to present identification?*
  - *Limit the length of prescription validity or refill*
  - *Require record keeping of prescriptions?*
  - *Require that a patient be “terminal” for pain relief?*
  - *Require a particular diagnosis?*
  - *Limits on dosage or type of drug?*
- *Probe for differences by drug type or dose*

1.16. Are pharmacists subject to inspection, review, or additional scrutiny for, or related to, prescriptions of opiates or opiate substitutes?

1.17. Do licensing and disciplinary bodies review patterns and “legitimacy” of pharmacist’s dispensing of opioids?

1.17.1. (If Yes) How is legitimacy determined? Tell me more about that...

### *Prompts*

- *Is the number of prescriptions for opioids dispensed by the pharmacist assessed?*
- *Is the number of patients on specific opioid drugs assessed?*

- *Is the size of the dosage for individual patients assessed?*

1.18. What do you consider is the biggest barrier for pharmacists and clinicians in the use of opioid medications?

1.19. What do you consider is the biggest barrier for patients in the use of opioid medications?

1.20. [Insert here any important questions identified as a result of Module II or in the CAB process]

Thank the respondent for their participation in the interview

### Section 3. Ask only Border and Customs systems and interactors

#### **Shipment**

1.21. When medical supplies of medical drugs containing opioids are shipped across the border into this country, what are the procedures that you take to pass the shipment through transit?

*Prompt*

- *Do procedures differ by type of drug. Please say more...*

1.22. What steps or procedures are taken to assure that the shipment is legitimate?

*Prompts*

- *How is legitimacy assessed?*
- *How is inspection of shipments conducted?*

1.23. What are the barriers to the shipment of medical drugs containing opioids into this country?

#### **Diversion**

1.24. What steps or procedures are implemented at the border to prevent diversion of medical supplies of opioid drugs?

*Prompts*

- *Do procedures differ by type of drug? Please say more...*

1.25. In your opinion, about what percentage of shipments into this country of medical drugs containing opioids are diverted to the illegal market?

1.26. What do you consider is the biggest barrier for pharmacists and physicians in the use of opioid medications?

1.27. [Insert here any important questions identified as a result of Module II or in the CAB process]

Thank respondent for their participation in the interview

Section Four. Ask only the person responsible (“the Competent National Authority”) for INCB estimates

1.28. Tell me about your role in developing the INCB estimates....

*Prompt*

- *How do you generate the estimate?*

1.29. If you have other duties in your job, about what percent of your overall time do you spend in your role as the Competent National Authority?

1.30. Do you feel that you have adequate resources (including personnel) to carry out your duties?

1.31. Are you responsible for submitting the data required by the Single Convention on Narcotic Drugs? How often do you submit the data to the INCB?

1.32. Are you satisfied with the method your country uses for collecting statistics on past year imports, exports, production, manufacture, utilization, consumption, stocks and seizures? Please say more...

1.33. Has your government approached you to ask about improving the method of estimation and collecting statistics?

1.34. What is the procedure, in the event your country falls short of needed narcotic drugs, for requesting a supplemental amount?

1.35. Is there a person at the INCB you can contact if you have a question about any of your duties as the Competent National Authority?

1.36. What do you consider is the biggest barrier for pharmacists and physicians in the use of opioid medications?

1.37. [Insert here any important questions identified as a result of Module II or in the CAB process]

## System and Interactor Key Key Informant Interview Guide

### *Questions on Practice: Clinicians* *Topic Area 2*

**To the interviewer:** This set of questions is designed to get specific information from the informant about what actually takes place in clinical practice with respect to the use of opioid drugs in treatment. We want to get data on how regulations and policies that might affect the use of opioid drugs in practice and how clinical decisions are made about the use of opioid drugs. Ask all respondents the questions in the Section One, and only clinicians in the Section Two.

#### Section One. Ask All.

##### **Attitudes towards the use of opioid medications**

- 2.1. What are your thoughts on the use of opioid medications for pain control? Are they absolutely necessary or a treatment of last resort?
- 2.2. Are there particular opioids that are more useful than others, and ones to avoid?
- 2.3. Tell me your opinion about the potential for addiction when using medically prescribed opioids for either pain control or MAT? Is it a concern?

##### **Availability of opioid medications**

*Interviewer Instructions: The next few questions are about the availability and retail cost of opioid medications. Ask the following three questions for each drug, and carefully probe for the reasons underlying variability in availability, limitations on supply, fluctuations in retail price, and practical restriction or limitations to prescribing the drug.*

2.4. Ask the following questions for each drug

- 1) Is [drug/dose where specified] available at all times in <the study area>?
- 2) Is there an adequate supply of [drug/dose] in <the study area> to address need? To address demand?
- 3) What is the approximate retail price of [drug/dose where specified] <the study area>?
- 4) Are there practical restrictions or limitations to prescribing [drug/dose where specified]?

- |        |               |                   |
|--------|---------------|-------------------|
| 2.4.1. | Buprenorphine | Appropriate doses |
| 2.4.2. | Codeine       | Tablet 30 mg      |
| 2.4.3. | Diazepam      | Appropriate doses |
| 2.4.4. | Ephedrine     | Appropriate doses |
| 2.4.5. | Ergometrine   | Appropriate doses |

2.4.6.	Fentanyl	Appropriate doses	
2.4.7.	Hydromorphone (Dilaudid)	Appropriate doses	
2.4.8.	Morphine	Injectable	10 mg/1 ml ampoule
2.4.9.	Morphine	Oral Liquid	10 mg/5 ml
2.4.10.	Morphine	Tablet	10 mg
2.4.11.	Morphine	Tablet/Prolonged Release	10 mg
2.4.12.	Morphine	Tablet/Prolonged Release	30 mg
2.4.13.	Morphine	Tablet/Prolonged Release	60 mg
2.4.14.	Methadone	Oral Liquid	5 mg/5 ml
2.4.15.	Methadone	Oral Liquid	10 mg/5 ml
2.4.16.	Naloxone	Injectable	400 mcg/1 ml ampoule
2.4.17.	Oxycodone	Appropriate doses	
2.4.18.	Phenobarbital	Appropriate doses	
2.4.19.	Pethidine (Demerol)	Appropriate doses	

## Regulation

2.5. Do licensing and disciplinary bodies review patterns and “legitimacy” of clinicians prescription or administration of opioids?

2.5.1. (If Yes) How is legitimacy determined? Tell me more about that...

### Prompts

- *Is the number of prescriptions for opioids written by a physician assessed?*
- *Is the number of patients on specific opioid drugs in a practice assessed?*
- *Is the size of the dosage for individual patients assessed?*

## Education

2.6. In general, how do physicians and other clinicians in this country get training or education in pain control methods?

2.7. In general, how do physicians and other clinicians in this country receive training in the use of MAT or other addiction management techniques?

2.8. Are the following recognized as specialties or subspecialties of medical practice?  
Pain control?  
Palliative care?  
Drug addiction ?

2.9. In your opinion are there sufficient practitioners in <the study area>with experience and expertise in:  
Pain control?  
Palliative care?  
Drug addiction ?

- 2.10. Are they licensed/accredited/certified as specialists in...?  
Pain control?  
Palliative care?  
Drug addiction ?

## Section 2. Ask Only Clinicians

All others skip to next topic area

### **Education**

- 2.11. What year did you graduate from medical school or clinical training program (e.g. nursing)?
- 2.12. In your medical education, about how many (hours or courses) did you receive in clinical care and management of pain? Was it adequate?
- 2.13. In the last year, what kinds of continuing education did you receive in pain management techniques?

#### *Prompt*

- *What was the source (university, government, NGOs, pharmaceutical companies) of that training?*

- 2.14. In your medical education, about how many (hours or courses) did you receive in clinical care and management of drug addiction?
- 2.15. What was your general training in the use of MAT?
- 2.16. In the last year, what kinds of continuing education did you receive in the clinical care and management of drug addiction?

#### *Prompts*

- *What was the source (university, government, NGO, pharmaceutical companies) of that training?*
- *How much of your education or training in this topic included consideration of MAT?*

### **Clinical practice (ask only those who can prescribe opioid medications)**

- 2.17. Tell me what happens when you prescribe an opioid medication to a patient.

#### *Prompt*

- *Are there extra steps you have to take related to regulations?*

We are interested in the issue of clinical discretion, and how you make clinical choices when prescribing opioid drugs.

2.18. In practice, in what situations do you decide to limit the strength (in milligrams) of opioid drugs that you will prescribe, even if the lower dose may be less medically effective? Tell me more about that....

*Prompts*

- *Does it depend on personal characteristics of the patient? Probe age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or status as a drug-dependency treatment patient and other differences?*

2.18.1. (If Yes) Tell me about the last time you limited the dose of an v drug....

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details.*
- *Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences.*

2.19. In practice, in what situations do you decide not to prescribe opioid drugs for pain control to patients, even if it may be medically indicated? Tell me more about that....

*Prompts*

- *Does it depend on personal characteristics of the patient? Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or status as a drug-dependency treatment patient and other differences?*

2.19.1. (If yes) Tell me about the last time you decided not to prescribe opioid sfor pain....

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details.*
- *Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences.*

2.20. In practice, in what situations do you decide to restrict the length of time a prescription is valid or the amount of medication that can be obtained at one time? Tell me more about that....

*Prompts*

- *Does it depend on personal characteristics of the patient? Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or status as a drug-dependency treatment patient and other differences?*

2.20.1. (If Yes) Tell me about the last time you restricted the length of time a prescription is valid or the amount of medication that can be obtained at one time....

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details.*
- *Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences.*

2.21. Have you ever been **unable** to prescribe a needed opioid to a patient?

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details.*
- *What happened to the patient?*
- *Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences*

2.22. Have you ever prescribed an opioid (analgesic) that your patient was **not able** to have it filled?

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details.*
- *What happened to the patient?*
- *Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences*

2.23. Given equal levels of pain and in the absence of allergy, are there situations or types of people to whom you would **not** prescribe each of the following drugs. Please give a brief description of situations that you would not prescribe these drugs.

- Buprenorphine
- Codeine
- Diazepam
- Ephedrine
- Ergometrine
- Fentanyl
- Hydromorphone (Dilaudid)
- Morphine
- Methadone
- Naloxone
- Oxycodone
- Phenobarbital
- Pethidine (Demerol)
- [Other locally important drugs]

2.24. In addition to characteristics of the patient, or the patient's disease, are there other factors, such as the regulatory or licensing system, that would influence your clinical decisions in prescribing opioid s?

2.25. What happens to clinicians who “over-prescribe” opioid s?

*Prompts*

- *What happens to clinicians who are investigated?*
- *How is “over-prescription” determined?*

2.26. Have you heard about any actions taken against clinicians who over-prescribe opioid s? (If Yes) Tell me what happened ....

*Prompts*

- *Was his/her practice interrupted or closed?*
- *Did his/her patients find out?*
- *Was his/her license affected?*
- *Was he/she prosecuted?*

2.27. Have you ever been investigated for over-prescription of opioids? Tell me more about that ....

*Prompt*

- *Elicit story with details*

**Data Collection**

2.28. Has the government collected data from you in the effort to establish the medical need for opioids:

- For pain control?
- For palliative care?
- For drug-dependency treatment?
- For prison health?

2.29. What do you consider the biggest barrier to prescribing opioid medications?

2.30. [Insert here any important questions identified as a result of Module II or in the CAB process]

2.31. Who should I talk to next for more information about opioid sand medical practice?

## System and Interactor Key Informant Interview Guide

### *Questions on Practice: Pharmacists and Pharmacies* *Topic Area 3*

**To the interviewer:** This set of questions is designed to get specific information from the informant about what actually takes place in pharmacy practice with respect to the dispensation of opioid drugs. Ask all respondents the questions in the Section One, and only pharmacists or those who can dispense opioid medications in the Section Two.

#### Section One. Ask All.

##### **Regulations**

- 3.1. Do laws relating to pharmacists and pharmacies create any additional restrictions for dispensing opioid s? Tell me about them...

##### *Prompts*

- *Elicit each barrier, for example, do regulations ...*
  - *Require the purchaser to present identification?*
  - *Limit the length of prescription validity or refill*
  - *Require record keeping of prescriptions?*
- *Probe for differences by drug type or dose*

- 3.2. Are pharmacists subject to inspection, review, or additional scrutiny for, or related to, prescriptions of opiates or opiate substitutes?

- 3.3. Do licensing and disciplinary bodies review patterns and “legitimacy” of pharmacist’s dispensing of opioid s?

- 3.3.1. (If Yes) How is legitimacy determined? Tell me more about that...

##### *Prompts*

- *Is the number of prescriptions for opioids dispensed by the pharmacist assessed?*
- *Is the number of patients on specific opioid drugs assessed?*
- *Is the size of the dosage for individual patients assessed?*

##### **Education**

- 3.4. In general, how do pharmacists in this country get training or education in pain control medication and methods?

- 3.5. In general, how do pharmacists in this country receive training or education in dispensing MAT medications, or other addiction management techniques?

## Section Two. Ask Only Those Who Work in Pharmacies

All others skip to next topic area

### **Availability of Opiate Medications in Pharmacy**

*Interviewer Instructions: The next few questions are about the availability of opioid medications. Ask the following question for each drug/dose, and carefully probe for the reasons underlying variability in availability, limitations on supply, and practical restriction or limitations to dispensing the drug.*

3.6. Ask the following questions for each drug

- 1) Is [drug/dose where specified] available at all times in <the study area>?
- 2) Is there an adequate supply of [drug/dose where specified] in <the study area> to address need? To address demand?
- 3) What is the approximate retail price of [drug/dose where specified] in <the study area>?
- 4) Are there practical restrictions or limitations to prescribing [drug/dose where specified]?

3.6.1.	Buprenorphine	Appropriate doses	
3.6.2.	Codeine	Tablet	30 mg
3.6.3.	Diazepam	Appropriate doses	
3.6.4.	Ephedrine	Appropriate doses	
3.6.5.	Ergometrine	Appropriate doses	
3.6.6.	Fentanyl	Appropriate doses	
3.6.7.	Hydromorphone (Dilaudid)	Appropriate doses	
3.6.8.	Morphine	Injectable	10 mg/1 ml ampoule
3.6.9.	Morphine	Oral Liquid	10 mg/5 ml
3.6.10.	Morphine	Tablet	10 mg
3.6.11.	Morphine	Tablet/Prolonged Release	10 mg
3.6.12.	Morphine	Tablet/Prolonged Release	30 mg
3.6.13.	Morphine	Tablet/Prolonged Release	60 mg
3.6.14.	Methadone	Oral Liquid	5 mg/5 ml
3.6.15.	Methadone	Oral Liquid	10 mg/5 ml
3.6.16.	Naloxone	Injectable	400 mcg/1 ml ampoule
3.6.17.	Oxycodone	Appropriate doses	
3.6.18.	Phenobarbital	Appropriate doses	
3.6.19.	Pethidine (Demerol)	Appropriate doses	

### **Diversion control**

- 3.7. What practices are implemented in the pharmacy to prevent diversion of opioid drugs by individuals coming into the pharmacy?

*Prompt*

- *Elicit all practices large and small, both legally required and specific to this pharmacy*

3.8. What practices are implemented in the pharmacy to prevent diversions of drugs by staff?

*Prompt*

- *Elicit all practices large and small, both legally required and specific to this pharmacy*

3.9. What practices are implemented in the pharmacy to prevent pharmacy theft by non-patients?

*Prompt*

- *Elicit all practices large and small, both legally required and specific to this pharmacy*

### **Data Collection**

3.10. Has the government collected data from your pharmacy in the effort to establish the medical need for opioid s:

- For pain control?
- For palliative care?
- For drug-dependency treatment?
- For prison health?

Please say more...

*Prompts*

- *When was the last data collection effort?*
- *What kinds of information were you asked to provide?*

### Section Two. Ask Only Pharmacists and Others Who Can Dispense Opiate Medications .

All others skip to next topic area

### **Education**

3.11. What year did you graduate from a pharmacy school or training program?

3.12. In your pharmacy education, about how many (hours or courses) did you receive in pain medications and management of pain?

3.13. In the last year, what kinds of continuing education did you receive in pain medications?

*Prompts*

- *What was the source (university, government, NGOs, pharmaceutical companies) of that training?*
- 3.14. In your pharmacy education, about how many (hours or courses) did you receive in medications for and management of drug addiction?
- 3.15. What proportion of your training was related to MAT medications?
- 3.16. In the last year, what kinds of continuing education did you receive in the medications for and management of drug addiction?

*Prompts*

- *What was the source (university, government, NGOs, pharmaceutical companies) of that training?*
- *How much of your education or training in this topic included consideration of MAT?*

**Obtaining opioid s**

- 3.17. When a patient comes into your pharmacy with a prescription for opioid s, what happens?

*Prompts*

- *Elicit the story, and the steps*
  - *Are there additional procedures the patient or the pharmacist must go through to obtain the medication?*
- 3.18. In practice, in what situations do you decide **not** to dispense opioid drugs even if the patient has a legitimate prescription for opioid s? Tell me more about that....

*Prompts*

- *Does it depend on personal characteristics of the patient? Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or status as a drug-dependency treatment patient and other differences?*

- 3.18.1.(If Yes) Tell me about the last time you decided not to dispense opioid s....

*Prompts*

- *Elicit the story, when this happened, what drug(s) were involved and other details. Probe for age, gender, minority status, migrant status, occupational group, co-morbid addictive disease or history of substance abuse, pain or drug-dependency treatment patient status and other differences.*

## Reporting

3.19. Are you required to record or report opioid prescriptions?

If yes,

3.19.1. How do you record opioid prescriptions?

3.19.2. To what agency or office must you report opioid prescriptions?

3.19.3. What does this agency do with the reported prescriptions?

3.19.4. Are there any consequences for pharmacists that report many prescriptions?

3.19.5. Are there any consequences for pharmacists who fail to report prescriptions?

3.20. What do you consider the biggest barrier to dispensing opioid medications?

3.21. [Insert here any important questions identified as a result of Module II or in the CAB process]

3.22. Who should I talk to next for more information about opioid and pharmacy practice?

## System and Interactor Key Informant Interview Guide

### *Questions on Practice: Drug-dependency Treatment* Topic Area 4

**To the interviewer:** These questions are designed to get specific information from the respondent about MAT and other drug-dependency treatment therapy.

#### Key Definitions

**Medication-assisted Treatment (MAT)** is the use of methadone, buprenorphine or other medically appropriate opioid medicine to treat opioid dependency.

**Detoxification** is a short-term course of treatment with a defined end point using methadone, buprenorphine or suboxone during the acute withdrawal phase, with the goal of having the patient free of all opioid drugs at the conclusion of the treatment.

**Long-term MAT** is continuous, ongoing treatment using methadone, buprenorphine or other medically appropriate opioid medicine, conducted with the goal of patient remaining free of non-prescribed opioid drugs throughout the treatment

#### Section One. Ask all

#### **Drug-dependency treatment programs**

4.1. Tell me what kinds of drug-dependency treatment are available in <the study area>? (ask all questions related to table)

Type of treatment	Available? Y/N	If not available, why not?
Counseling only		
Detoxification (without MAT)		
Detoxification (with MAT)		
Long term in-patient treatment (without MAT)		
Long term in-patient treatment (with MAT)		
Long term out-patient treatment (without MAT)		
Long term out-patient treatment (with MAT)		
Behavioral modification		
Other modalities		

4.2. Tell me about the opioid drugs that are available for use in drug-dependency treatment in <the study area>? (ask all questions related to table)

Type of Medicaton	Available? Y/N	If not available, why not?
Methadone		
Buprenorphine		
Suboxone		
Other opioid medications		

### Capacity of drug-dependency treatment programs

4.3. (If detoxification with MAT available), Tell me about detoxification with MAT treatment. In general, how long is the treatment course? Tell me more about this form...

#### Prompts

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*
- *How is the treatment paid for? About how much does it cost?*

4.4. (If long term in-patient treatment with MAT available), Tell me about long term in-patient treatment with MAT In general, how long is the treatment course? Tell me more about this form...

#### Prompts

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*
- *How is the treatment paid for? About how much does it cost?*

4.5. (If long term out-patient treatment with MAT available), Tell me about long term out-patient treatment with MAT In general, how long is the treatment course? Tell me more about this form...

#### Prompts

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*
- *How is the treatment paid for? About how much does it cost?*

4.6. (If methadone available) What are the government requirements to be a licensed provider for methadone treatment?

4.7. (If buprenorphine available) What are the government requirements to be a licensed provider for methadone treatment?

4.8. What are professional and care-taking staff like at treatment facilities that use MAT?

*Prompts*

- *Are there adequate professional staff?*
- *Are they well trained, and experienced?*
- *Are there adequate care-taking staff?*
- *Are they well trained?*

**MAT and Drug Addiction**

- 4.9. What are your thoughts on the use of MAT for treatment of opioid addiction? Is it an effective form of drug-dependency treatment?

**Education**

- 4.10. In general, how do drug-dependency treatment specialists in this country get training or education in pain control methods?
- 4.11. (If MAT available) In general, how do drug-dependency treatment specialists in this country receive training in the use of MAT or other addiction management techniques?
- 4.12. In your opinion, are the sufficient drug-dependency treatment specialists using MAT to meet the needs of **existing** programs? Please say more....
- 4.13. In your opinion, are there sufficient drug-dependency treatment specialists using MAT to meet the needs of programs to **reach all those** who would benefit from drug-dependency treatment?

Section 2. Ask only Drug-dependency Treatment Systems and Interactors

All others skip to next topic area

**MAT and drug-dependency treatment practice**

- 4.14. What has been your clinical experience in using MAT for the treatment of opioid addiction?

*Prompts*

- *Elicit stories*

- 4.15. Clinically, what kinds of patients are **not** appropriate candidates for MAT?

*Prompts*

- *Elicit stories*

- 4.16. How does someone enroll in MAT therapy? What are the procedures and steps involved in participation?

*Prompts*

- *Elicit all the steps – do they have to get a blood test? Fill out extra forms? Agree to be fingerprinted?*
- *Are these procedures different from programs not using MAT?*

## **Data Collection**

4.17. Has the government collected data from you in the effort to establish the medical need for opioid sin drug-dependency treatment? Please say more...

### *Prompts*

- *When was the last data collection effort?*
  - *What kinds of information were you asked to provide?*
- 4.18. What do you consider the biggest barrier to using opioid medications in drug-dependency treatment practice?
- 4.19. What do you consider the biggest barrier for patients to using opioid medications in drug-dependency treatment?
- 4.20. [Insert here any important questions identified as a result of Module II or in the CAB process]
- 4.21. Who should I talk to next for more information about opioid sand drug-dependency treatment?
- 4.22. (If there is no MAT in the study area) Are there providers of other forms of drug-dependency treatment that I can talk to about the possibility of their becoming providers of MAT drug-treatment? Who should I talk to?

System and Interactor  
Key Informant Interview Guide

***Questions on Practice: Police and Prisons***  
***Topic Area 5***

***To the interviewer:*** This topic area is designed to get specific information from the informant about what actually takes place between police and people who use opioids, whether by prescription or illegally. We are also interested in general attitudes towards patients using opioids. We want to get data on how and when police choose to arrest drug users, whether or not there are special circumstances surrounding arrests of drug users, and opioid medications in prison.

**General Attitudes**

5.1. In general, how do people treat substance users (SUs)?

*Prompts*

- *Are they afraid of SUs?*
- *If it is known that you are an SU, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*

5.2. In general, how do people treat people with HIV?

*Prompts*

- *Are they afraid of people with HIV/AIDS?*
- *If it is known that you are an SU, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*

5.3. In general, how do people treat drug-dependency treatment patients? How do they treat those enrolled in MAT programs?

*Prompts*

- *Are they afraid of people in drug-dependency treatment?*
- *If it is known that you are in drug-dependency treatment, will you lose your job, house/friends/medical care/state benefits/ chance to go to school?*
- *Do people consider MAT programs to be “real” drug-dependency treatment?*

5.4. In general, how do people treat people with cancer?

*Prompts*

- *Are they afraid of people with cancer?*
- *If it is known that you have cancer, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*
- *Do people believe that cancer is contagious?*

## SUs and law enforcement

5.5. Tell me about how police treat illicit substance users (SUs)?

### *Prompts*

- *Do police treat different kinds of drug users differently? Probe for age, gender, minority status, migrant status, occupational group, and pain or drug-dependency treatment patient status and other differences*
- *Does it depend on characteristics of the defendant?*
- *Which characteristics (i.e. age, gender, ethnicity, race, location)?*
- *Do police treat men and women differently?*

5.6. Do police target people they suspect of being SUs?

### *Prompts*

- *What happens if a suspected SU is a drug-dependency treatment patient?*
- *What happens if a suspected SU is a pain patient?*
- *What happens if a suspected SU is an HIV patient?*

5.7. Tell me what happens when police arrest an SU in possession of opioid drugs?

### *Prompt*

- *Are the police afraid of SUs?*

5.8. Tell me what happens when police arrest an SU in possession of syringes.

### *Prompt*

- *Are police afraid of being stuck by syringes or other health consequences from being in contact with SUs?*

5.9. Do police use known sites of drug-dependency treatment programs, pain clinics, or syringe exchanges or other harm reduction programs to identify SU-clients for stops, questioning, or arrest?

5.10. Do police take money, drugs, sex, or other items from SUs in exchange for release or to avoid arrest?

5.11. Do police ever detain SUs and turn them over to drug-dependency treatment facilities?

5.12. Do police use physical violence or force against SUs?

### *Prompt*

- *Do they use physical violence or force against SUs instead of arresting them?*

5.13. Tell me what happens to SUs who primarily use medical opioid purchased from others.

*Prompt*

- *Do the police treat people using pills differently than people who use injected opioids.*

### **Function of legal system**

5.14. Tell me about the impact of law enforcement efforts to control drug use on the function of legal system?

*Prompts*

- *Has there been a change or a trend over time in arrests for drug use?*
- *Are law enforcement efforts working?*

5.15. Tell me about the impact of law enforcement efforts to control diversion of medical supplies of opioid drugs on the function of legal system?

*Prompts*

- *Has there been a change or trend overtime in arrests for diversion of medical supplies of opioid drugs?*
- *Are law enforcement efforts working?*

5.16. Tell me about the impact of law enforcement efforts on narcotics trafficking?

*Prompts*

- *Has there been a change or trend overtime in arrests for narcotics trafficking?*
- *Are law enforcement efforts working?*

5.17. Tell me about people in the legal system taking money, drugs, sex, or other items in order to affect the outcome of legal troubles...

*Prompts*

- *Are people with medical prescriptions for opioid drugs ever targeted?*
- *How about substance users? Persons in MAT drug-dependency treatment? Cancer patients?*

### **Institutional Pressure**

5.18. Tell me about the bureaucratic or institutional pressures that encourage or discourage arrests of drug users and traffickers?

*Prompts*

- *Are there arrest quotas?*
- *Pressure from politicians or higher level officials?*

- *Media attention?*

5.19. Is it different for people, such as medical staff who may divert medical supplies of opioid drugs?

5.20. What would make the criminal system more effective in reducing drug use?

### **Drug-dependency treatment patients and law enforcement**

5.21. Tell me more about how police treat people who are enrolled in drug-dependency treatment programs? (Please give me some specific examples)

5.22. [Insert here any important questions identified as a result of Module II or in the CAB process]

5.23. Who should I talk to next for more information on police practice?

Ask only respondents with prison health experience and the  
judge the following questions  
All others skip to the next topic

### **Protection of rights of defendants**

5.1. Tell me what happens to defendants [in the following categories] when they are taken to court and the prisons?

- Persons enrolled in MAT drug-dependency treatment programs
- Persons with prescriptions for opioid medications for pain
- Persons who use illegal opioid drugs

### **Opiate prescriptions in prison**

5.2. In general, do people have regular access to a clinician such as a nurse or physician while in prison?

5.3. Do people with legitimate medical prescriptions for either pain medication or MAT medications receive their medications in prisons? Tell me how that works....

#### *Prompts*

- *About how long does it take before they receive their medication (in hours, days?)*
- *What happens to the supply of medication they had in their possession?*
- *Are there formal or informal costs for access to medications?*

5.4. Is there a difference in access to personal opioid medications if someone is in pre-trial detention or post-conviction?

5.5. If someone is in opioid withdrawal when they are detained, what happens to them?

*Prompts*

- *Are they treated or detoxified? How? By whom?*
- *Is there a formal or informal cost to the prisoner for this?*

5.6. Do prisons, jails and detention areas have a supply of naloxone available?

*Prompt*

- *Who is trained to administer it? Under what circumstances?*

5.7. If SUs, persons enrolled in MAT drug-dependency treatment, or persons with a prescription for pain medication feel their rights have been violated, what are their options for complaining to the police department or the legal system?

**Prison/jail conditions**

5.8. Tell me about the kinds of places (and their conditions) SUs are confined in if they get into trouble?

*Prompts*

- *Jail*
- *Prison*
- *Mandatory drug-dependency treatment*

**Drug-dependency treatment in prisons and jails**

5.11. Are there drug-dependency treatment programs in jails and prison? (If Yes) Tell me more about them....

*Prompts*

- *Is drug-dependency treatment required or coerced?*
- *Does receiving drug-dependency treatment depend on a particular characteristic, such as good behavior?*
- *What types of programs are there?*

5.12. Is MAT drug-dependency treatment using methadone or buprenorphine readily available in jails and prison?

*Prompts*

- *Is MAT treatment readily available in jails and prison for long-term treatment of drug dependency?*
- *Is there a limitation on the dose of methadone or buprenorphine someone may receive in prison or jail?*

**Opiates and prison health**

5.13. Tell me how chronic pain is treated in prison health programs?

*Prompts*

- *Are opioid sused for pain control?*
- *How are opioid medications dispensed to prisoners?*

5.14. Are hospice services or palliative care available in prison? Tell me more about them...

**Other programs in prison**

5.16. Are there HIV/AIDS education programs in prisons? (If Yes) Tell me more about them?

5.17. Are there programs in prison to “rehabilitate” prisoners or prevent recidivism, teach trades, continue education, and teach anger management or parenting skills? (If Yes) Tell me more about them...

5.18. Are there programs for people getting out of prison, to help them find jobs, housing, medical care, drug-dependency treatment, or other necessities? (If Yes) Tell me more about them....

**Data Collection**

5.19. Has the government collected data from you or your program in the effort to establish the medical need for opioid sin prison health? Please say more...

*Prompts*

- *When was the last data collection effort?*
- *What kinds of information were you asked to provide?*

5.20. In the practice of prison health, what has been the most important barrier to the clinical use of opioid medications?

5.21. Who should I talk to next for more information about prison health issues?

5.22. [Insert here any important questions identified as a result of Module II or in the CAB process]

Thank respondent for their participation in the interview

# Key Findings Form

## Key Informant Interviews

Topic Area or sub-area	Key Findings	Exemplar quotes <sup>12</sup>
		Contrast quote:
		Contrast quote:
		Contrast quote:
		Contrast quote:
		Contrast quote:

<sup>12</sup> Place quotes in quotation marks and ID number in parentheses after each quote. For example: "This is a quote" (SI220309)

## **Patient-Level Key Informant Interview Guide**

- 1) Demographic Screening Sheet**
- 2) Interview Topic Guide**
- 3) Key Findings Form**

## Patient-Level Cover Sheet

Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
           (day)      (month)      (year)

Study ID: PL \_\_\_\_\_

Interviewer name: \_\_\_\_\_

Category Number: \_\_\_\_\_

*Patient-Level Category Numbers*

Category number	Patient Level
	<b>Pain Patients</b>
1.	Cancer patients with pain
2.	HIV patients with pain
3.	Chronic pain patients (ex: back injury, arthritis)
4.	Hospice/palliative care patients with pain (self or relative)
5.	Pain patients with concurrent addictive disease
6.	Pain patients with a history of opioid misuse
	<b>Drug-dependency treatment Patients</b>
7.	Potential drug-dependency treatment patients (e.g. on a waiting list)
8.	MAT drug-dependency Patients
9.	Other drug-dependency treatment patients
	<b>Substance Users</b>
10.	Substance users (opioid misuse)
	<b>Others</b>
11.	Other locally important categories

Interviewer comments:

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**INTERVIEWER: CODE RESPONDENT GENDER**

G. \_\_\_\_\_

Female = 1, Male = 2, Other (specify: \_\_\_\_\_) =3

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I have just a few questions to begin....

1. How old are you? (in years): 1. \_\_\_\_\_

2. Where were you born? 2. \_\_\_\_\_  
(either city in country, or country if outside study area)

**Pain**

3. Have you ever been told by a doctor or a health practitioner that you have any of the following diseases:

(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

3.1. Cancer of any kind 3.1. \_\_\_\_\_

3.2. HIV 3.2. \_\_\_\_\_

3.3. Osteoarthritis 3.3. \_\_\_\_\_

3.4. Any condition resulting in pain 3.4. \_\_\_\_\_

3.4.1. Specify: \_\_\_\_\_

4. In the last year, have you been treated for pain?  
(IF NO, SKIP TO 5, Yes = 1, No = 2, Don't Know = 3, Decline = 9)

4.1. What condition(s) were associated with the pain that you were treated for in the last year?

Specify:

\_\_\_\_\_

4.2. Which prescribed drugs have you used in the last year to alleviate pain?

Specify:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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**Hospice and Palliative Care**

5. Have you or a close relative ever been in hospice or palliative care? 5. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

**Substance Use**

6. Have you ever used an illegal drug? 6. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)  
(IF NO, SKIP TO 10)

6.1. (If YES) Have you ever used an illegal opioid drug? 6.1. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)  
(IF NO, SKIP TO 7)

6.2. (If YES) Have you used an illegal drug in the last 30 days? 6.2. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)  
(IF NO, SKIP TO 7)

6.2.1. (IF YES) On how many days of the last 30 days 6.2.1. \_\_\_\_\_  
have you used any illegal drug?

6.2.2. (IF YES) How many days in the last 30 days 6.2.2. \_\_\_\_\_  
did you inject an illegal drug?

6.2.3. Which drugs have you used, injected or non-injected,  
in the last 30 days? (LIST ALL)

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**Drug-dependency treatment**

7. Have you ever been in a drug-dependency treatment program? 7. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)  
(IF NO, SKIP TO 8)

7.1. (If YES) When was the last time you were in a drug-dependency treatment

program of any kind?

7.1. Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
(month) (year)

7.2. Have you ever been treated for drug dependence with methadone? 7.2. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

7.2.1.(IF YES) Are you currently enrolled in a drug treatment program using methadone? 7.2.1. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

7.3. Have you ever been treated for drug dependence with buprenorphine? 7.3 \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

7.3.1. (IF YES) Are you currently enrolled in a drug-dependency treatment program using buprenorphine? 7.3.1. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

8. Would you like to be in a drug-dependency treatment program? 8. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

9. Are you currently on a waiting list to enroll in a drug-dependency treatment program? 9. \_\_\_\_\_  
(Yes = 1, No = 2, Don't Know = 3, Decline = 9)

9.1. (IF YES) How long have you been on the list? 9.1. \_\_\_\_\_

10. Thank you! These are all the questions I have in this section. Before we go on to the next section, do you have any additional comments on this part or anything else we have talked about?

Comments:

## Patient Level Key Informant Interview Guide

### *Questions on Experience: Clinicians and Pharmacists Topic Area 1*

**To the interviewer:** This set of questions is designed to get specific information from the respondent about what actually takes place in physician practice with respect to the use of opioid drugs in treatment. We want to get data on how regulations and policies that might affect the use of opioid drugs in practice and what the experience is of patients who are treated with opioid drugs.

#### Availability of opioid medications - Experience

1.1. Have you ever received a prescription for an opioid drug from a clinician such as a nurse or physician to treat pain?

IF NO, Skip to 1.20., IF YES Continue

1.2. Tell me about the last time you received a prescription for pain...

#### *Prompts*

- *Elicit story – date, condition treated, drug prescribed, details of the episode*

1.3. Did you feel your pain was treated adequately in this episode? Please say more...

1.4. Did the clinician restrict your access to the drug by limiting the type of drug s/he would prescribe, the dose of the drug, or the length of the prescription? Please say more...

#### *Prompts*

- *Probe: Did the limitation depend on patient characteristics such as gender, type of pain, patient diagnosis?*
- *Required to return and pay for an office visit in order to get a refill.*

1.5. What happened when you went to the pharmacy to obtain the drug? Tell me more about that...

#### *Prompts*

- *What drug was prescribed?*
- *Elicit story and probe for details*

1.6. Were there any procedures that you had to go through, such as presenting identification to get the drug?

#### *Prompt*

- *Elicit story and probe for details*

1.7. Is that drug available in all pharmacies? Was it easy to obtain? Please say more...

1.8. Tell me about a time that was different from that one....

*Prompts*

- *Elicit story – date, condition treated, drug prescribed, details of the episode*
- *Probe for contrasts with the first story – what was different?*

1.9. Did you feel your pain was treated adequately in this episode? Please say more...

1.10. Did the clinician restrict your access to the drug by limiting the type of drug s/he would prescribe, the dose of the drug, or the length of the prescription? Please say more...

*Prompts*

- *Probe: Did the limitation depend on patient characteristics such as gender, type of pain, patient diagnosis?*
- *Required to return and pay for an office visit in order to get a refill?*

1.11. What happened when you went to the pharmacy to obtain the drug? Tell me more about that...

*Prompts*

- *What drug was prescribed?*
- *Elicit story and probe for details*

1.12. Were there any procedures that you had to go through, such as presenting identification to get the drug?

*Prompt*

- *Elicit story and probe for details*

1.13. Is that drug available in all pharmacies? Was it easy to obtain? Please say more...

1.14. Was it difficult to find a clinician who could treat your pain? Tell me more about that...

1.15. In your opinion are there sufficient practitioners in <the study area>with experience and expertise in:

- Pain control?
- Palliative care?
- Drug addiction ?

1.16. How available are opioid drugs in <the study area>? Did you ever have trouble obtaining a drug you had a prescription for because of inadequate supplies? Please say more....

1.17. In your experience are the following drugs available at all times in <the study area> pharmacies? Tell me more about that...

- a. Buprenorphine
- b. Codeine
- c. Diazepam
- d. Ephedrine
- e. Ergometrine
- f. Fentanyl
- g. Hydromorphone (Dilaudid)
- h. Morphine
- i. Methadone
- j. Naloxone
- k. Oxycodone
- l. Phenobarbital
- m. Pethidine (Demerol)
- n. [Other locally important drugs]

1.18. Are any of those drugs too expensive for you to buy? Please say more...

1.19. Have you ever been denied a prescription for pain medication that contained opioids? Tell me more about that....

*Prompts*

- *Elicit story – date, condition treated, details of the episode*
- *Did the denial depend on patient characteristics such as a history of opioid misuse?*

1.20. Have you ever concealed your opioid use or misuse history from a clinician because you were concerned that s/he would not prescribe appropriate opioid medication? Tell me more about that...

*Prompt*

- *Elicit story and get details of the episode*

1.21. Have you ever obtained or purchased an opioid medication not prescribed to you from someone else to control your physical pain? Tell me more about that....

*Prompt*

- *Elicit story and get details of an episode – why did this happen?*

1.22. Have you ever purchased an illicit drug to control your physical pain? Tell me more about that....

*Prompt*

- *Elicit story and get details of an episode – why did this happen?*

1.23. What do you think is the biggest barrier to obtaining opioid medications?

1.24. [Insert here any important questions identified as a result of Module II or in the CAB process]

**Patient Level  
Key Informant Interview Guide**

***Questions on Experience: Drug-dependency Treatment  
Topic Area 2***

**To the interviewer:** These questions are designed to get specific information from the respondent about MAT and other drug-dependency treatment therapy.

**Key Definitions**

**Medication-assisted Treatment (MAT)** is the use of methadone, buprenorphine or other medically appropriate opioid medicine to treat opioid dependency.

**Detoxification** is a short-term course of treatment with a defined end point using methadone, buprenorphine or suboxone during the acute withdrawal phase, with the goal of having the patient free of all opioid drugs at the conclusion of the treatment.

**Long-term MAT** is continuous, ongoing treatment using methadone, buprenorphine or other medically appropriate opioid medicine, conducted with the goal of patient remaining free of non-prescribed opioid drugs throughout the treatment

**Drug-dependency treatment programs**

2.1. To your knowledge, what kinds of drug-dependency treatment are available in <the study area>? (ask all questions related to table)

Type of treatment	Available? Y/N	If not available, why not?
Counseling only		
Detoxification (without MAT)		
Detoxification (with MAT)		
Long term in-patient treatment (without MAT)		
Long term in-patient treatment (with MAT)		
Long term out-patient treatment (without MAT)		
Long term out-patient treatment (with MAT)		
Behavioral modification		
Other modalities		

2.2. Tell me about the opioid drugs that are available for use in drug-dependency treatment in <the study area>? (ask all questions related to table)

Type of Medicaton	Available? Y/N	If not available, why not?
Methadone		
Buprenorphine		
Suboxone		
Other opioid medications		

2.3. Have you ever wanted to enroll or been enrolled in a drug-dependency treatment program for opioid misuse?

IF NO, thank the respondent for participating in the interview and ask if they have any comments on the interview.

IF YES, Continue

### Capacity of drug-dependency treatment programs

2.4. (If detoxification with MAT treatment available), Tell me about detoxification with MAT treatment. In general, how long is the treatment course? Tell me more about this form...

#### Prompts

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*
- *How is the treatment paid for? About how much does it cost?*

2.5. Have you ever been in a detoxification with MAT treatment program? (If Yes) Tell me about the last time you were in this kind of program...

#### Prompts

- *Was it difficult to enroll in the program?*
- *Is there a waiting list? How long were you on the waiting list?*
- *How much does it cost?*
- *Was it effective?*
- *Elicit details of the last treatment episode*

2.6. (If long term in-patient treatment with MAT available), Tell me about long term in-patient treatment with MAT. In general, how long is the treatment course? Tell me more about this form...

#### Prompts

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*

- *How is the treatment paid for? About how much does it cost?*

2.7. Have you ever been in a long term in-patient treatment with MAT program? (If Yes) Tell me about the last time you were in this kind of program...

*Prompts*

- *Was it difficult to enroll in the program?*
- *Is there a waiting list? How long were you on the waiting list?*
- *How much does it cost?*
- *Was it effective?*
- *Elicit details of the last treatment episode*

2.8. (If long term out-patient treatment with MAT is available), Tell me about long term out-patient treatment with MAT. In general, how long is the treatment course? Tell me more about this form...

*Prompts*

- *How many spaces are there in this kind of drug-dependency treatment?*
- *Is there a waiting list?*
- *How is the treatment paid for? About how much does it cost?*

2.9. Have you ever been in a long term out-patient treatment with MAT program? (If yes) Tell me about the last time you were in this kind of program...

*Prompts*

- *Was it difficult to enroll in the program?*
- *Is there a waiting list? How long were you on the waiting list?*
- *How much does it cost?*
- *Was it effective?*
- *Elicit details of the last treatment episode*

2.10. (If any personal experience with MAT) To your knowledge, were there any patients with pain who were enrolled in programs you have been in as a way to have their pain treated? Please say more....

2.11. In general, how does someone enroll in MAT therapy? What are the procedures and steps involved in participation?

*Prompts*

- *Elicit all the steps – do they have to get a blood test? Fill out extra forms? Agree to be fingerprinted?*
- *Are these procedures different from non-MAT programs?*

2.12. To your knowledge, what are professional and care-taking staff like at treatment facilities?

*Prompts*

- *Are there adequate professional staff?*
- *Are they well trained, and experienced?*
- *Are there adequate care-taking staff?*
- *Are they well trained?*

2.13. Have you ever wanted to enroll in a drug-dependency treatment program using MAT and couldn't? (If Yes) Tell me what happened...

*Prompt*

- *What were the barriers to enrollment? Cost? Waiting lists?*

2.14. What are your thoughts on using MAT to treat opioid addiction? Is it an effective form of drug-dependency treatment? Please say more...

2.15. What do you think is the biggest barrier to enrolling in drug-dependency treatment programs using MAT in <the study area>?

2.16. [Insert here any important questions identified as a result of Module II or in the CAB process]

## *Questions on Experience: Police and Prisons*

### *Topic Area 3*

**To the interviewer:** This topic area is designed to get specific information from the respondent about what actually takes place between police and pain patients or substance users (SU) and how police treat people who have pain medications. We want to get data on how and when police choose to arrest SU and whether or not there are special circumstances surrounding arrests of persons suspected of substance use.

#### **General Attitudes**

3.1. In general, how do people treat drug-dependency treatment patients? How do they treat those enrolled in MAT programs?

##### *Prompts*

- *Are they afraid of people in drug-dependency treatment?*
- *If it is known that you are in drug-dependency treatment, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*
- *Do people consider MAT programs to be “real” drug-dependency treatment?*

3.2. In general, how do people treat people with cancer?

##### *Prompts*

- *Are they afraid of people with cancer?*
- *If it is known that you have cancer, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*
- *Do people believe that cancer is contagious?*

3.3. In general, how do people treat people with HIV?

##### *Prompts*

- *Are they afraid of people with HIV/AIDS?*
- *If it is known that you are an SU, will you lose your job house/friends/medical care/state benefits/ chance to go to school?*

#### **SUs and law enforcement**

3.5. Tell me about how police treat illicit substance users (SUs)?

##### *Prompts*

- *Do police treat different kinds of drug users differently? Probe for age, gender, minority status, migrant status, occupational group, and pain or drug-dependency treatment patient status and other differences*

- *Does it depend on characteristics of the defendant?*
- *Which characteristics (i.e. age, gender, ethnicity, race, location)?*
- *Do police treat men and women differently?*

3.6. Do police target people they suspect of being SUs?

*Prompts*

- *What happens if a suspected SU is a drug-dependency treatment patient?*
- *What happens if a suspected SU is a pain patient?*
- *What happens if a suspected SU is an HIV patient?*

3.7. Tell me what happens when police arrest an SU in possession of opioid drugs?

*Prompts*

- *Are the police afraid of SUs?*

3.8. Tell me what happens when police arrest an SU in possession of syringes.

*Prompts*

- *Are police afraid of being stuck by syringes or other health consequences from being in contact with SUs?*

3.9. Do police take money, drugs, sex, or other items from SUs in exchange for release or to avoid arrest?

3.10. Do police ever detain SUs and turn them over to treatment facilities?

3.11. Do police use physical violence or force against SUs?

*Prompt*

- *Do they use physical violence or force against SUs instead of arresting them?*

3.12. Do people in the legal system take money, drugs, sex, or other items in order to affect the outcome of legal troubles?

*Prompts*

- *Are people with medical prescriptions for opioid drugs ever targeted?*
- *How about substance users? Persons in MAT drug-dependency treatment? Cancer patients?*

3.13. [Insert here any important questions identified in the CAB process]

### **SUs and law enforcement - Experience**

3.14. Have you ever been detained or arrested by the police for any reason? (If Yes) Tell me more about that....

*Prompts*

- *Elicit stories and probe for details*
- *Probe for experience related to opioid medication*
- *What happened to the medication in their possession?*
- *Did they receive their medication in detention?*
- *Did they experience withdrawal in detention?*

**IF NO, thank the respondent for participating in the interview and ask if they have any comments on the interview.**

**IF YES, continue with only people detained or arrested by police because of substance use or related to pain medication.**

3.15. Tell me about an experience that you have had with the police in the past five years because of your substance use or related to your pain medication.

*Prompts*

- *Elicit stories and probe for details*
- *Probe for experience related to opioid medication*

3.16. Tell me about a time that you had an experience with the police that was different than that one.

*Prompts*

- *Elicit stories and probe for details*
- *Probe for experience related to opioid medication*
- *Probe for contrasts to the first story – what was different?*

3.17. In your encounters with the police, do you feel that the police treated you differently from other SUs because of some characteristic of yours such as your gender, ethnicity, medical conditions, medications or something else?

*Prompts*

- *Elicit stories and probe for details and contrasts*
- *Probe for experience related to opioid medication*
- *Probe for contrasts to the first story – what was different?*

3.18. [Insert here any important questions identified in the CAB process]

**Opiate prescriptions in prison**

**Prison/jail conditions**

3.19. Tell me about the kinds of places (and their conditions) that people can be confined in if they get into trouble with the law?

*Prompts*

- *Jail*
- *Prison*
- *Mandatory drug-dependency treatment*

3.20. In general, do people in prison have regular access to a clinician?

3.21. Do people with legitimate medical prescriptions for either pain medication or MAT medications receive their medications in prisons? Tell me how that works....

*Prompts*

- *About how long does it take before they receive their medication (in hours, days?)*
- *What happens to the supply of medication they had in their possession?*
- *Are there formal or informal costs for access to medications?*

3.22. If someone is in opioid withdrawal when they are detained, what happens to them?

*Prompts*

- *Are they treated or detoxified? How? By whom?*
- *Is there a formal or informal cost to the prisoner for this?*

### **Pain treatment in prisons and jails**

3.23. Tell me how chronic or other pain is treated in prison or jail?

*Prompts*

- *Are opioids used for pain control?*
- *How are opioid medications dispensed to prisoners?*

3.24. Are hospice services or palliative care available in prison? Tell me more about them...

### **Pain treatment in prisons and jails - experience**

3.25. Did you receive treatment for chronic other pain in prison? (If yes) Tell me about your experience of pain treatment in jail or prison....

*Prompts*

- *Probe for the narrative, the details, what medications were they treated with, how medications were dispensed and were opioids used for treatment*

3.26. In your experience, with prison or jail, what was the most important barrier to receiving opioid medications for pain while you were incarcerated?

## **Drug-dependency treatment in prisons and jails**

3.27. Are there drug-dependency treatment programs in jails and prison? (If Yes) Tell me more about them....

### *Prompts*

- *Is drug-dependency treatment required or coerced?*
- *Does receiving drug-dependency treatment depend on a particular characteristic, such as good behavior?*
- *What types of programs are there?*

3.28. Is MAT drug-dependency treatment using methadone or buprenorphine readily available in jails and prison?

### *Prompts*

- *Is MAT readily available in jails and prison for long-term treatment drug-dependency treatment?*
- *Is there a limitation on the dose of methadone or buprenorphine someone may receive in prison or jail?*

3.29. Is it possible to choose enrolling in a drug-dependency treatment program instead of going to prison?

### *Prompt*

- *Are MAT programs one of the alternatives offered?*

## **Drug-dependency treatment in prisons and jails - experience**

3.30. Did you receive drug-dependency treatment in jail or prison? (If yes) Tell me about your experience of drug-dependency treatment in jail or prison....

### *Prompts*

- *Probe for the narrative, the details, what medications were they treated with*
- *If MAT, probe for details on MAT therapy, how they received it, was it available for Long-term treatment therapy?*

3.31. In your experience, with prison or jail, what was the most important barrier to receiving MAT therapy while you were incarcerated?

3.32. [Insert here any important questions identified as a result of Module II or in the CAB process]

3.33. This is the end of the interview. Do you have any other comments about this interview or anything else?

## Key Findings Form

### Key Informant Interviews

Topic Area or sub-area	Key Findings	Exemplar quotes <sup>13</sup>
		<b>Contrast quote:</b>
		<b>Contrast quote:</b>
		<b>Contrast quote:</b>
		<b>Contrast quote:</b>
		<b>Contrast quote:</b>

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<sup>13</sup> Place quotes in quotation marks and ID number in parentheses after each quote. For example: “This is a quote” (SI220309)

# **RAPID POLICY ASSESSMENT & RESPONSE: *ACCESS TO THERAPEUTIC OPIATES***

## **Module IV: Analysis, Action Plan, & Report**

*Tools*

# Analysis, Action Plan, & Report Tools

## Purpose:

The purpose of this module is

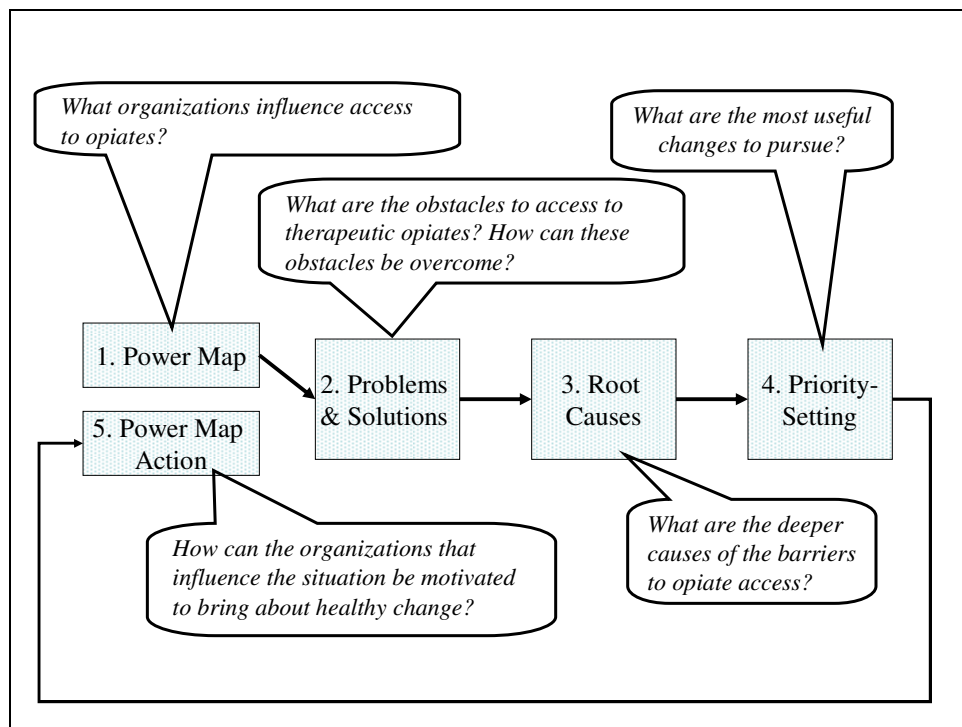
1. To organize the data obtained from the other modules, and
2. To work with the CAB to produce the Action Plan and Final Report.

## Process:

During the process you will:

- Organize main findings for presentation to the CAB
- Work with the CAB to
  - identify problems in law, policy, and practice that interfere with access to therapeutic opioids for pain treatment, palliative care, or treatment of opioid addiction;
  - Identify the root causes of problems in the Root Causes Exercise;
  - Identify possible solutions to problems and root causes;
  - Prioritize and evaluate possible solutions in the Priority Setting Exercise;
  - Develop strategies to successfully bring about changes in law, policy and practice in the Power Map Action Exercise
- Plan implementation of these strategies and recommendations

Produce a final report summarizing findings, making recommendations for solutions or interventions, and describing an action plan for implementation.



The Five Steps of Policy Analysis in RPAR

## Organizing Data for the CAB

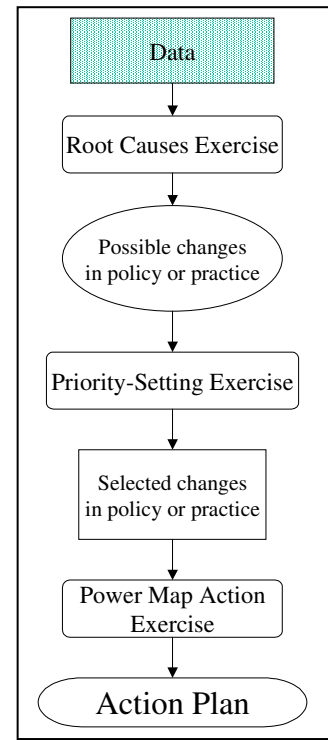
**When:** Before CAB meeting # 5

**Purpose:** To convey the chief findings of the RPAR research to the CAB.

**Process:**

Record (1) key findings from Modules II and III and (2) relevant results of earlier Problems and Solutions and Root Causes Exercises into the Key Findings column on the Analysis and Action Plan Form 1.

Modules II and III include Key Findings Forms for all types of data: law, epidemiology, drug dependency treatment, manufacturing, criminal justice statistics, and qualitative data from Key Informant interviews. Key Findings from all these domains are important to the Analysis and Action Planning process.



### Moderators' Guide

In Modules I and IV the CAB and the research team work together to use data collected in the RPAR to:

- 1) Identify the attitudinal, cultural, practice and other factors that suppress demand for pain meds or make health care providers unwilling or unable to provide them to patients as medically indicated;
- 2) Identify the policy barriers that make it difficult to make, import, transport, store, dispense, administer, prescribe or possess opioid medicines in the dosages and amounts needed for good care
- 3) Understand how attitudes and policies interact to make the access problem more severe and difficult to solve; and
- 4) Design a regulatory system and an intervention / implementation plan that will create the most workable, locally appropriate set of rules and then teach all the stakeholders how and why it is important to use opioid medicines.

You should use the forms and tools in Module IV to explicitly address each one of these issues, to focus the CAB's discussion on these steps, and to facilitate design and implementation of interventions to create a system that works in your country to achieve these goals.

# RAPID POLICY ASSESSMENT AND RESPONSE

## Analysis and Action Plan Form 1

Key Findings	Law, Policy or Practice Problems	Root Causes	Possible Responses

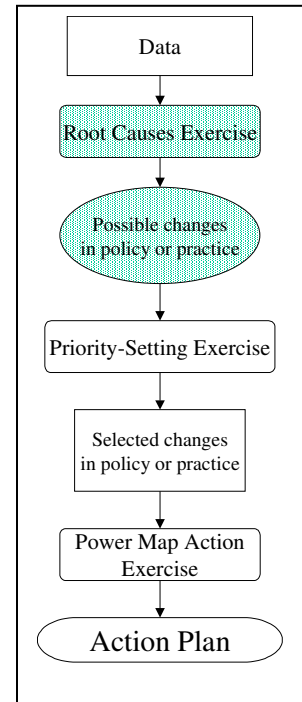
# Root Causes Exercise

**When:** CAB meeting # 5

**Purpose:** To describe a web of factors that govern the medical use of opioids; to identify “pressure points” where significant gains could be made from policy or practice change; and to outline what those changes should be and what implementation barriers changes are likely to face.

**Process:**

- 1) The CAB reviews the chief findings set out in Analysis and Action Plan Form 1.
- 2) The most serious problems (e.g., untreated cancer pain, lack of medication-assisted therapy for persons addicted to opioids, or few pharmacies willing to stock and dispense opioids) are entered into the bottom row of the Root Causes Form.
- 3) Causes of the problems are entered higher on the form, and then causes of causes and so on, until participants feel they have mapped the issues.



**Prompts and Probable Responses:**

*Prompt: Why are patients with cancer receiving inadequate treatment for cancer pain?*

*Response: Because doctors are afraid to prescribe opioids in the amounts necessary to treat their pain. [Add “doctors are afraid to prescribe” to Root Causes Form]*

*Prompt: Why are doctors afraid to prescribe opioids?*

*Response: Because they are afraid they will allow their patients to become addicted or that they will be investigated by the drug control authorities. [Add, “doctors fear they will contribute to addiction” and “doctors fear drug control authorities” to Root Causes Form]*

*Prompt: What happens to a doctor if the drug control authorities investigate him or her?*

*Response: Their practice will be closed and patients driven away. [Add “doctors fear losing patients or their practice” to Root Causes Form]*

*Prompt: Is this mostly a law and policy problem, a practice problem, or an attitude problem? What part of the*

*problem is the actual law and what part is that doctors fear how the law is implemented or how drug control authorities interpret the law?*

*Response: [the answer will vary depending on the national laws and the local situation. The goal is to help the CAB distinguish where the law, itself, is the problem from where the problem is in the interpretation of the law, or fears about the law.]*

- 1) Identify laws, policies, and implementation practices that are acting as important “root causes” of the problems in column 1 of Form 1. Enter results in columns 2 and 3 of Form 1.

*Prompt: What laws, policies, and practices on this root-causes picture seem to be causing the most harm?*

- 2) Identify changes in laws, policies or practices that are needed to alter root causes of problems. Record possible responses in column 4 of Form 1.

*Be as specific as possible in describing the changes needed to the law, policy or practice at this point. If it is appropriate, include “draft language” for a new law, regulation or policy. You do not have to put “draft language” on the form. Make a separate document for specific changes that you keep with Form 1.*

## Moderator's Guide

Usually the CAB and research team will identify a mixture of law, policy and practice problems at various stages of the Root Causes exercise. It is important to identify both problems with how the law/policy is actually written, and how they put into practice or implemented. Different kinds of problems require different responses. For example, if the problem is in overly restrictive regulations, it may be necessary to revise the regulations. If, however, the problem is in how regulators interpret or apply the regulations, it may be possible to work with regulatory staff so that they recognize ensuring access to opioids as one of their duties.

The Root Causes exercise should be used to move the discussion from a range of issues that emerged from the key findings to specifically identifying which ones are most important for achieving systemic change. Ideally this will include:

- \* Identification of the specific policies that have to be changed;
- \* An outline of the changes needed (or draft language, if that is appropriate);

In the next exercise, the Priority Setting exercise, you will identify the major implementation obstacles likely to arise with efforts at policy change – attitudes, training, habits, money, logistics – and, later you will make plans for dealing with those – (how to identify and work with allies who can help, facilitators in organizations, champions inside or outside the government, etc) ;

# RAPID POLICY ASSESSMENT AND RESPONSE

## Root Causes Form

The diagram shows a central circle at the bottom, with four rounded rectangular boxes on either side. Above this base, there are several more rounded rectangular boxes arranged in a web-like structure, with some boxes having dotted outlines, suggesting they are to be filled in by participants.

### Moderator's Guide

Practical advice for doing this exercise:

The Root Causes Exercise works best when done using a large format writing surface so that everyone participating can see the gradual development of a “web” of “causes” and can help identify law, policy and practice problems. Possible tools include a paper flip chart, chalk board, white board, or smart board, or even large pieces of paper that can be taped to the wall and written on. Ideally, whatever format is used can be saved as part of the CAB process data, either by saving the final product or having someone copy the final “web” onto a paper format (see above) or a computer.

## Priority-Setting Exercise

**When:** CAB meeting # 5 & 6

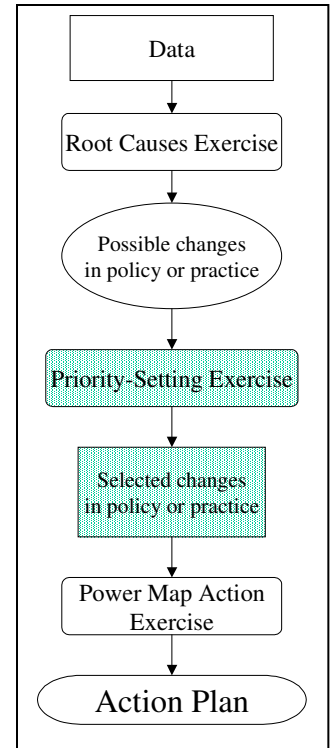
**Purpose:** To identify the most useful and attainable policy and practice changes available to the CAB

**Process:**

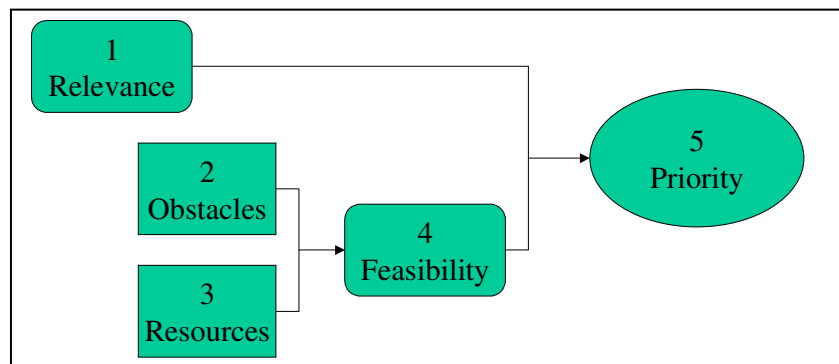
*The process of setting priorities among possible targets and methods of change can be more or less formalized. The exercise described in the body of the text below uses a more formal set of steps in which the CAB as a group performs the prioritization using Analysis and Action Plan Form 2. A less formal approach is set out in the text box. The research team should decide what approach or combination of approaches makes the most sense for a particular CAB.*

Using Analysis and Action Plan Form 2, list possible responses drawn from Form 1. Through group discussion:

- 1) Evaluate each potential response for relevance. Relevance is expressed in a score, with “1” being very relevant and “3” being the least relevant.
- 2) Describe obstacles (political, economic, and social) to successfully implementing the response.
- 3) List resources needed to implement the response.
- 4) Evaluate feasibility by considering both obstacles and resources. Feasibility is expressed as a score with “1” being the most feasible and “3” the least.
- 5) Prioritize each response by combining Relevance and Feasibility.



Priority Setting Criteria



The highest-scoring items represent the group's preferred action options for change in policy or practice.

### **Dot-Voting: An Alternative Approach to Setting Priorities**

- (1) Using Analysis and Action Plan Form 2, list possible responses drawn from Form 1. The responses should also be entered onto one or more flip chart pages and displayed on the wall.
- (2) Discuss the Priority Setting Criteria as a group.
- (3) Ask each individual CAB member to determine their own ratings, using Analysis and Action Plan Form 2 if they wish.
- (4) After ten or fifteen minutes, give each member of the research team and the CAB five small adhesive dots.
- (5) Instruct the participants to place dots next to the solutions they think have the highest priority. They may select five different solutions or weight their preference by putting two or more dots at the same point.
- (6) The "score" for each solution represents the group's aggregate assessment of its priority. The product is a set of preferred action options.

**RAPID POLICY ASSESSMENT AND RESPONSE  
Analysis and Action Plan – Form 2**

		<b>Relevance (1)</b>	<b>Obstacles (2)</b>	<b>Resources (3)</b>	<b>Feasibility (4)</b>	<b>Priority (5)</b>
<b>Response 1</b>						
<b>Response 2</b>						
<b>Response 3</b>						
<b>Response 4</b>						
<b>Response 5</b>						
<b>Response 6</b>						
<b>Response 7</b>						
<b>Response 8</b>						

## **Moderator's Guide**

You should use this exercise primarily to guide the CAB and the research team in determining which interventions or responses will be the highest priority.

Using either Form 2 or the dot-voting method will achieve this goal.

However, a secondary goal, is to fully explore and define the potential implementation barriers to each intervention and to begin to explore how those might be overcome. Form 2 provides the most explicit way to do this, since the potential barriers and resources are specifically discussed. If the dot-voting method is used, the research team or the CAB will still have to spend some time identifying and discussing possible barriers and what resources might be available to overcome them.

Therefore, one outcome of this exercise, however, it is conducted, is to create a list for each priority intervention, of barriers to its adoption or implementation and of resources that will be needed to overcome those barriers.

“Feasibility” is one of the measures in this exercise because there will be some proposed changes, that currently face such overwhelming barriers that they may not be achievable using the resources available. The goal of the interventions need not be perfect solutions to all the access problems, but workable or better solutions.

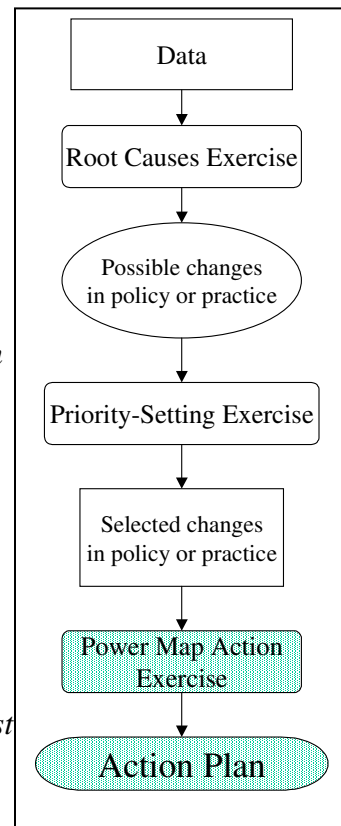
## Power Map Action Exercise and Action Plan

**When:** CAB meeting # 6 & 7

**Purpose:** To develop strategies to successfully bring about policy and practice changes, and to incorporate them into a draft Action Plan

**Process:**

- 1) *Distribute or display the latest version of the Power Map*
- 2) *Review the priority responses identified using Form 2 and the Priority-Setting Exercise. Enter the priority responses in column 1 of the Power Map Action Exercise Form 3.*
- 3) *For each priority response, use the Power Map and the Power Map Action Exercise Form 3 to list organizations that must cooperate in order to bring about the change in policy or policy implementation.*
  - *For each response, begin by listing an organization/key person whose cooperation is needed and filling in the rest of the row.*
  - *Then repeat in the rows below for the important organizations/key people who can influence the first organization.*



**Prompts:**

What are the organizations whose practices we want to change?

What organizations do we need to support us?

Are there key people we need to reach in that organization?

What organizations can influence the organizations we want to change?

Are there any important groups that don't have an organization to work through – "missing organizations"?

4) *For each organization, identify:*

- Any key individuals
- Existing organizations that could influence the target organization to change or support change
- Organizations that don't exist (“missing organizations”) but could potentially be created to give voice to important people who are now unrepresented in governance, such as cancer patients
- “Resource strategies”: Ways to influence the target organization by changing the flow or its resources (e.g., finding money for poor organizations, or rewarding hospitals that provide effective pain control or include MAT in their drug-dependency treatment programs)
- “Tool strategies”: Ways to influence the target organization by changing the tools it uses to get things done (e.g., creating a program to divert drug suspects from jail to treatment programs that can include MAT)
- “Mentality strategies”: Ways to influence the target organization by changing its culture (e.g., educating physicians about effective pain control; dispelling myths about addiction; educating pharmacists and regulators about the critical role of opioids in treating acute and chronic pain as well as in drug-dependency treatment).

*Move on to a new response when the group is satisfied it has the information it needs to go on to Analysis and Action Plan Form 4.*

5) *Using Analysis and Action Plan Form 4, take the solutions and strategies developed in previous steps and begin to form an Action Plan. For each of the responses and strategies listed in the Power Map Action Exercise Form 3, decide:*

- The specific steps that must be taken to implement the response
- The resources needed to implement the response
- What individuals and organizations agree to take action to implement the response and be responsible for future action
- The time frame for action
- And indicators that will show whether there has been progress towards achieving the goal “indicators of success”
- Enter these into columns 1-6 on Analysis and Action Plan Form 4

*Analysis and Action Plan Form 4 provides important information to be used in the monthly self-evaluation recommended for each response that the team prioritizes. The Self-Evaluation process is described in the coming pages.*

### Moderator's Guide

The goal of this exercise is to help you translate your priority interventions into concrete plans for implementing policy or practice changes that will produce a regulatory system that will create the most workable, locally appropriate set of rules governing access to opioid medicines and which will educate all the stakeholders regarding how and why it is important to use opioid medicines.

This form is intended to help you plan each response in your Action Plan. In completing Form 4, it is important to identify all the small steps necessary to achieve the goal.

For example, if the hoped for goal is to change the regulations regarding pharmacy investigations, do not write "Change the regulations" in column 2. Think about what smaller steps would be necessary before you achieve that goal ... You might list: "(1) draft a letter with local pharmacists outlining their concerns about investigators' practices; (2) ask local physicians to persuade medical society to write a letter to pharmacy board in support of pharmacists' request; (3) meet with regional drug control authorities to confirm their support for access to opioids for medical purposes and address their concerns about pharmacies; (4) arrange a meeting with the pharmacy board regulator to discuss problems that inspections are causing; (5) request pharmacy board support in changing regulations; (6) work with coalition of pharmacists, physicians, drug control authorities, and pharmacy board to change regulations at the agency level." These steps will be more helpful.

Also, it is important to identify ways to measure progress towards achieving the overall goal of the response – "indicators of success" in column 6. In the above example, you might write: "(1) Was a draft a letter written? (2) Were local pharmacists contacted?" (3) How many agreed to join a letter? (4) How many signed the letter? (5) How many local physicians were contacted? (6) Did the medical society agree to write a letter of support? (7) Were drug control authorities contacted to discuss pharmacists and medical society concerns? (8) Was a meeting held with regional drug control authorities? (9) What concerns did drug control authorities have? (10) Was there a meeting with the pharmacy board? (11) Which parties agree to work as a coalition to change regulations?

*The Action Plan combines the ideas for change with specific assessments of the resources and commitments needed to carry out effective advocacy. The Action Plan can take a variety of forms, but regardless of the form, it represents a commitment by the community to begin implementing identified responses.*

*Ideally, the organization or person who agrees to be responsible will use the "indicators" of success that the team identifies, continue to work with other members of the CAB or the research team, and seek help if they encounter unexpected difficulties in implementing the response as part of the Action Plan.*

**RAPID POLICY ASSESSMENT AND RESPONSE**  
**Analysis and Action Plan – Form 3**  
**Power Map Action Exercise Form 3**

Response number	Target organization and key people	Organizations and key people that could influence the target		Resource strategies	Tool strategies	Mentality strategies
		Existing	Missing			
<b>1</b>						
<b>2</b>						
<b>3</b>						
<b>4</b>						

**RAPID POLICY ASSESSMENT AND RESPONSE  
Analysis and Action Plan – Form 4**

<b>Response Number</b>	<b>What needs to be done (specific steps or tasks)</b>	<b>Resources Needed</b>	<b>Time Frame</b>	<b>Responsible person or agency</b>	<b>Indicators of Success (measurable progress towards completion)</b>
1					
2					
3					
4					
5					

## **Self-Evaluation Analysis and Action Plan Form 5**

***Purposes:***     ***To keep track of progress towards achieving the priority responses included in the Analysis and Action Plan. To help the person responsible for each response to identify if and why progress has slowed or stopped and to seek sources of assistance. To allow the lead investigator to track overall progress and assist those working on responses who encounter problems. To facilitate overall evaluation of changes.***

Analysis and Action Plan Form 4 creates a list of prioritized responses, identifies persons who are responsible for each response, and defines measurable indicators of progress or success. You will use Form 4 to begin the Self-Evaluation process which is described in this section. The Self-Evaluation process is repeated periodically throughout the year following completion of the RPAR. Information generated in the Self-Evaluations process will help all parties who are working on the RPAR responses and will facilitate overall evaluation.

***Process:***       ***The Self-Evaluation Process includes the following steps:***

- Step 1:***        At the last CAB meeting the research team distributes the Self-Evaluation Form (Analysis and Action Plan form 5 and describes the self-evaluation process).
- Step 2:***        In order to report progress on the responses, each person who is responsible for a response completes Form 5 monthly and sends it to the lead investigator.
- Step 3:***        The lead investigator responds to problems or delays and coordinates others who can help.
- Step 4:***        One year interview: One year after completion of the Action Plan, the local investigator (or someone else who has taken on this role) conducts a short qualitative interview with all the persons responsible for action. The interview covers similar questions, but tries to identify what has worked and why and what has not worked and why not. Results of the interviews could be used by DIFD/PEPFAR to refine additional efforts in that country.

**Self-Evaluation Form**  
**Analysis and Action Plan Form 5**  
 (to be submitted monthly)

<b>Name of responsible person/organization:</b>	
<b>Response # :</b>	<b>Name of Response:</b>
Has there been progress in implementing this response? (Y/N)	
Which measurable indicators have been achieved?	
Which have not?	
What are the reasons that they have not?	
What steps have been taken to overcome any challenges?	
What old or new contacts have been asked for help in the process?	
What, if anything, does the responsible person think could be done to move forward the stalled responses?	

# The Final Report

**When:** Weeks 1-36

**Purpose:**

- To assist research team assemble and review key information and issues during the RPAR
- To present data to and highlight policy issues for the CAB meetings 2-7
- To produce a final report summarizing findings, making recommendations for solutions or interventions, and describing an action plan for implementation.
- To provide a document that can be used for local, regional or national advocacy

**Process:**

**Step 1:** Identify key findings from existing and qualitative data collection modules (Modules II and III) and present to CAB as described in Module I

- Existing data : law on the books, epidemiology, and criminal justice
  - Present at CAB meetings #2 & 3 (weeks 1-18)
- Qualitative data: Key informant interviews
  - Present at CAB meeting #4 (weeks 14-26)

**Step 2:** Identify law, policy, and practice problems related to ensuring access to therapeutic opioids.

- Use the power map, problems and solutions exercises, and root cause analysis developed with the CAB at regular meetings #1-6 (weeks 1-29)

**Step 3:** Organize the findings, issues, and law, policy, and practice problems into a preliminary draft report

- Discuss draft report at CAB meeting # 5 (weeks 23-27)

**Step 4:** Integrate prioritized solutions and plans for implementation into the draft report

- Use the Priority-Setting Exercise (CAB meetings #5 and 6)
- Distribute revised draft report at CAB meeting #6 (weeks 27-29)

**Step 5:** Draft and distribute final report (weeks 32-36).

- Collect feedback on draft report from CAB at meeting #7
- Include details of final action plan
- Distribute report through the medical professional, law enforcement and regulatory networks and through other local, regional, and national networks as appropriate

These steps are intended to help the research team organize the collection of data for and drafting of the report. They are not meant to limit the team to a single form for the final report, or a single method for collecting information and drafting the report.

First, the time frame for each step is estimated, but some steps will overlap throughout the RPAR. For example, the team should be able to identify most of the key findings from the

existing data (**Step 1**) during or soon after completion of existing data collection at week 13, but new sources of problematic law or policy may be identified later during the qualitative data collection.

Second, other steps may include using information that is developed in an iterative process by the CAB at more than one meeting. For example, the power map and problems and solutions exercise will be conducted at almost every CAB meeting and the draft and final reports should reflect the changing results.


## **The Form of the Final Report**

There is no single best model for a final report in every country. The research team should outline the final report in a form that best meets their local needs for communicating data and supporting advocacy. The research team should review relevant models of reports and advocacy documents for ideas and guidance. The following are a few guidelines to creating an effective report:

- Organize the report to emphasize the most important policy issues
  - The report is not an epidemiological summary or a descriptive piece about the law
  - The report should illustrate the relationship between access to therapeutic opioids in the community and law, policy and practice problems identified within the regulatory and law enforcement processes.
  - Findings and recommendations should be clearly related and succinctly set out
  - Usually, an effective report focuses on a few key problems and recommendations, but when little has been done in the past a comprehensive and detailed report with a long list of recommendations may be useful
- Offer detailed plans for action and implementation
  - The report provides an opportunity to explain the recommendations, plan for action and implementation developed by the CAB
  - It is intended to guide the decisions and actions of people who may not have been involved in the CAB or even had a prior knowledge of the problems created by lack of access to therapeutic opioids
  - Detailed recommendations may look, and be, more feasible
  - Document community involvement in the process and action plan
- Link the goals of this project to other projects for improving the diagnosis and treatment of pain and treatment of drug addiction and to other projects to improve public health
  - Indicate how data from this project might be used by other projects
  - Describe other gaps in law, policy, practice and / or locally important data that are relevant to developing effective systems to regulate drugs, educating health care and law enforcement professionals about public health goals, and providing adequate national supply of opioids to meet medical and public health needs; and identify those that need additional resources, advocacy or research

For examples of final reports, visit [www.rpar.org](http://www.rpar.org).

# **RAPID POLICY ASSESSMENT & RESPONSE: *ACCESS TO THERAPEUTIC OPIATES***



## **Module V: Research Ethics**

### ***Tools***

# **Research Ethics**

## *Purpose and Process*

### **Purpose**

- To describe need for ethical oversight of research studies involving humans
- To explain ethical principles that guide research
- To describe important documents relevant to policy research
- To present basic requirements for ethical review
- To facilitate identification and discussion of ethical issues arising in this research
- To train all staff and research team in human subject and information protection procedures for this project and each site.

# Why is Ethical Oversight of Research Studies Involving Humans Important?

Research can be defined as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”<sup>14</sup> A human subject is “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”<sup>15</sup> Research involving human subjects includes a wide variety of scientific endeavors including: basic (non-clinical) science using biological samples, randomized clinical trials of new drugs or devices, epidemiological research of population health and behavior, and policy behavioral research involving surveys, observation, and interviews.

Human subject research has produced important new basic scientific knowledge, established the effectiveness of life saving treatments and vaccines, and advanced our understanding of behavioral and structural factors’ role in health. Not all research, of course, leads to important discoveries. Sometimes research exposes subjects to real or potential risks. Regulation of human subjects’ research aims to reduce these risks and prevent exploitation of research subjects while promoting ethical and well-designed research studies.

Historically, some research has exposed human subjects to real or potential harm, often without their full consent and sometimes without their knowledge. Examples include the Nazi doctors’ experiments that involved exposing concentration camp prisoners to wounds, unnecessary surgery, infectious agents, and extremes of heat, cold, altitude, or other dangerous situations to document the impact on the human body even to the point of causing death. Other examples include the Tuskegee syphilis study in which African-American men with syphilis were deceived about their diagnosis, denied effective treatment when it became available, and observed for up to 30 years untreated. Additionally, throughout the 1940s, 50s, and early 60s, many well-respected researchers conducted studies involving patients without their fully informed consent and some exposed patients to much greater risks from experimental interventions than they would have faced with standard treatment.<sup>16</sup>

Instances of abuse and harm led to calls for oversight. Regulation, as it has developed in the U.S., has included oversight from courts and regulatory bodies within the government, and from the development of ethical codes and voluntary standards. Ultimately, federal regulation combined with international standards, currently define the requirements for U.S.-based researchers working in other countries. This section introduces the basic principles, documents, and requirements for ethical review of human subject research and identifies some of the potential ethical issues of policy research in particular.

## The Basic Ethical Principles that Guide Research

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<sup>14</sup> 45 (US) Code of Federal Regulations (CFR) 46.102(d).

<sup>15</sup> 45 (US) Code of Federal Regulations (CFR) 46.102(f).

<sup>16</sup> H. K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine*, 274 (1966): 1354-1360.

In the past thirty years a consensus has emerged on basic ethical principles that should guide biomedical research, these are *respect for persons, beneficence and justice*. They appear explicitly stated in the Belmont Report, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, and are reflected less explicitly in each of the important documents described in the next section. What follows is an excerpt from the most recent CIOMS guidelines describing the basic principles.

*“Respect for persons* incorporates at least two fundamental ethical considerations, namely:

- a) respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination; and
- b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

*Beneficence* refers to the ethical obligation to maximize benefits and to minimize harms. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, *nonmaleficence* (do no harm).

*Justice* refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability. "Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provision must be made for the protection of the rights and welfare of vulnerable persons.

Sponsors of research or investigators cannot, in general, be held accountable for unjust conditions where the research is conducted, but they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities. Neither should they take advantage of the relative inability of low-resource countries or vulnerable populations to protect their own interests, by conducting research inexpensively and avoiding complex regulatory systems of industrialized countries in order to develop products for the lucrative markets of those countries.

In general, the research project should leave low-resource countries or communities better off than previously or, at least, no worse off. It should be responsive to their health needs and priorities in that any product developed is made reasonably available to them, and as far as

possible leave the population in a better position to obtain effective health care and protect its own health.

Justice requires also that the research be responsive to the health conditions or needs of vulnerable subjects. The subjects selected should be the least vulnerable necessary to accomplish the purposes of the research. Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subject is representative.”<sup>17</sup>

## Important Documents

The current CIOMS guidelines describe many of the key international documents related to human subjects’ research.

“The first international instrument on the ethics of medical research, the Nuremberg Code, was promulgated in 1947 as a consequence of the trial of physicians (the Doctors’ Trial) who had conducted atrocious experiments on unconsenting prisoners and detainees during the second world war. The Code, designed to protect the integrity of the research subject, set out conditions for the ethical conduct of research involving human subjects, emphasizing their voluntary consent to research.

The Universal Declaration of Human Rights was adopted by the General Assembly of the United Nations in 1948. To give the Declaration legal as well as moral force, the General Assembly adopted in 1966 the International Covenant on Civil and Political Rights. Article 7 of the Covenant states “*No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation*”. It is through this statement that society expresses the fundamental human value that is held to govern all research involving human subjects – the protection of the rights and welfare of all human subjects of scientific experimentation.

*The Declaration of Helsinki, issued by the World Medical Association in 1964, is the fundamental document in the field of ethics in biomedical research and has influenced the formulation of international, regional and national legislation and codes of conduct. The Declaration, amended several times, most recently in 2000 (Appendix 2), is a comprehensive international statement of the ethics of research involving human subjects. It sets out ethical guidelines for physicians engaged in both clinical and nonclinical biomedical research.*

Since the publication of the CIOMS 1993 Guidelines, several international organizations have issued ethical guidance on clinical trials. This has included, from the World Health Organization, in 1995, *Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products*; and from the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), in 1996, *Guideline on Good Clinical*

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<sup>17</sup> Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, World Health Organization, 2002, available at: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm).

*Practice*, designed to ensure that data generated from clinical trials are mutually acceptable to regulatory authorities in the European Union, Japan and the United States of America. The Joint United Nations Programme on HIV/AIDS published in 2000 the UNAIDS Guidance Document *Ethical Considerations in HIV Preventive Vaccine Research*.

*In 2001 the Council of Ministers of the European Union adopted a Directive on clinical trials, which will be binding in law in the countries of the Union from 2004. The Council of Europe, with more than 40 member States, is developing a Protocol on Biomedical Research, which will be an additional protocol to the Council's 1997 Convention on Human Rights and Biomedicine.*

Not specifically concerned with biomedical research involving human subjects but clearly pertinent, as noted above, are international human rights instruments. These are mainly the Universal Declaration of Human Rights, which, particularly in its science provisions, was highly influenced by the Nuremberg Code; the International Covenant on Civil and Political Rights; and the International Covenant on Economic, Social and Cultural Rights. Since the Nuremberg experience, human rights law has expanded to include the protection of women (Convention on the Elimination of All Forms of Discrimination Against Women) and children (Convention on the Rights of the Child). These and other such international instruments endorse in terms of human rights the general ethical principles that underlie the CIOMS International Ethical Guidelines.”<sup>18</sup>

In addition to these international instruments, the United States has produced key documents of international import. The first, The Belmont Report, was published April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, reporting to the Secretary of Health, Education and Welfare. The Belmont Report is a statement of “basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.”<sup>19</sup> Although not itself binding, and originally only a statement of departmental policy, the Belmont Report also provided the guiding principles for the development of the federal regulations that govern research in the US, referred to as the Common Rule.”<sup>20</sup>

The Common Rule and institutional policies designed to comply with US federal regulations have direct impact only on U.S. researchers and institutions. However, they also have an enormous impact on research conducted around the world by U.S. researchers or funded by U.S. institutions since they require such research to adhere to U.S. standards for review and approval, *in addition to*, local and international requirements.

*See documents and web sources at the end of this section.*

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<sup>18</sup> Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, World Health Organization, 2002, available at: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm).

<sup>19</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. April 18, 1979. Available at: <http://ohsr.od.nih.gov/guidelines/belmont.html>.

<sup>20</sup> 45 CFR 46, and 21 CFR (governing the Food and Drug Administration's activities).

## The Basic Requirements of Ethical Review

### General Requirements

As a general rule all research involving human subjects should conform to the international standards for research described in CIOMS and Helsinki, as well as respecting human rights, and complying with relevant local (national) law regarding the rights of research subjects and the responsibilities of investigators.

The primary responsibility for ensuring research is ethical and conforms to local, national and international standards rests with the investigators. It is the responsibility of the investigator to ensure that all persons involved in the project have a sufficient understanding of ethical issues in research to protect the rights of subjects during the project. First, investigators and staff must familiarizing themselves with the basic documents governing research and understand the steps necessary to protect subjects in their particular protocol. Additionally, a local board or committee whose mandate is to provide ethical review of new and ongoing protocols involving human subjects can assist investigators to identify ethical issues and solutions through the process of local review of their research plan. Local review may result in dialog between investigators and the committee to identify potential ethical issues, reduce research risks, protect subjects' confidentiality and physical well-being, and provide adequate procedures to meet requirements. In the U.S., such committees are usually called an Institutional Review Board(s) (IRB).

### Research involving U.S. institutions

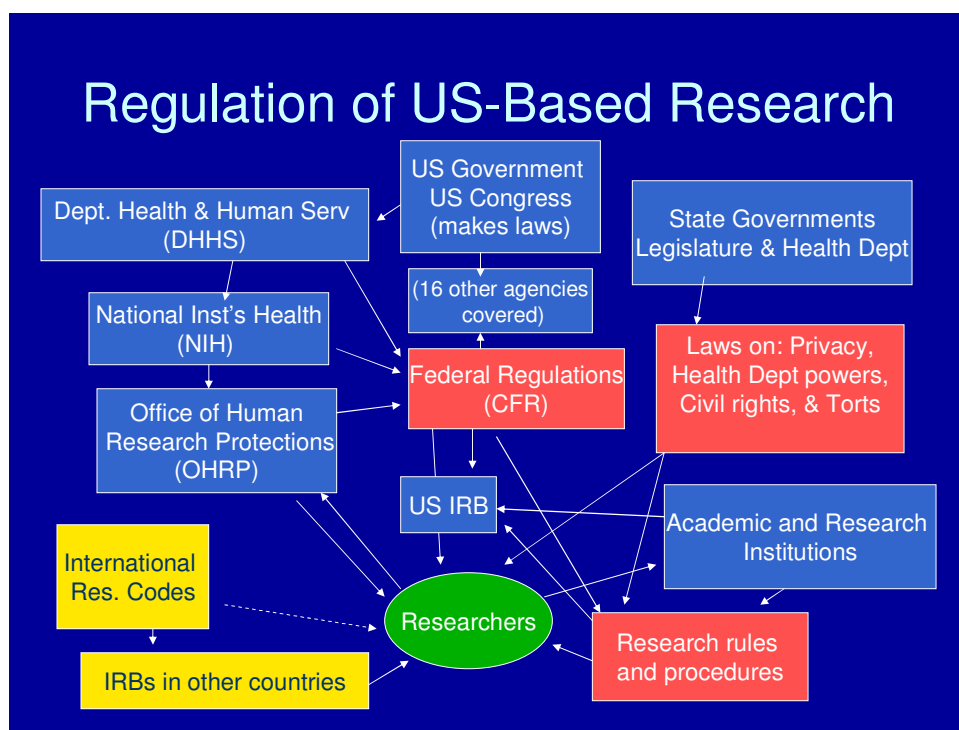
For research funded by the United States government or involving U.S. institutions the specific requirements that must be met through ethical review include:

- obtaining prior ethical review and approval by an IRB within the US;
- minimizing research risks in relation to possible benefits;
- ensuring that the informed consent process and documentation is sufficient for fully informed and voluntary consent by research subjects or their legally authorized representatives;
- informing subjects of their rights as research subjects to withdraw from the study at any time;
- selecting subjects fairly;
- protecting confidential or identifying information about subjects;
- establishing safety monitoring, where appropriate;
- protecting vulnerable populations;
- re-reviewing the study at least once a year to monitor compliance with ethical rules and identify unanticipated risks.

Additionally, for research occurring outside the U.S., the study must also be reviewed by a local ethics committee or board (IRB) or the U.S. IRB must be advised by someone who is aware of ethical issues in the site where the research will occur.

The complex structure of institutions and documents that govern human subject research involving U.S. and foreign institutions is displayed in the following diagram. For the purposes of the RPAR it is important to know that:

- U.S. regulations cover even policy research relying mainly on interview data;
- The project must be reviewed both in the U.S. and by a committee or board that has knowledge of the local research environment (usually an in-country research ethics committee registered with the NIH);
- That the research must comply with both the international documents discussed above and the U.S. federal regulations; and
- For policy research, meeting these requirements should be easily achievable.



### *Informed Consent*

Researchers and staff should be aware of the basic requirements of informed consent wherever they are responsible for recruiting subjects and / or obtaining informed consent from subjects, documenting informed consent, designing research protocols, or storing research data and informed consent documentation.

***Informed consent is a process, not a form.*** Although, federal regulations and most projects require that research subjects sign and complete very specific informed consent forms

and that investigators maintain records of such forms, subjects actually give fully informed and voluntary consent, only as part of a process. The *informed consent process* includes 1) disclosure of information about the project by someone involved in the project, or by documents prepared for this purpose; 2) discussion of the purpose, procedures, and other aspects of the project by the potential subject and the project representative including enough time for the subject to ask any questions she has; and 3) deliberation of the risks and benefits of the project by the potential subject. If, after weighing all these, the subject chooses to enroll, then she or he signs the consent form, a copy is given to the subject and another stored in the research records.

In order for informed consent to be possible, the subject must meet at least two pre-conditions – that the subject have the capacity to make an informed decision and that the decision be made free of coercion. Additionally, the researcher must provide sufficient information to the subject to make an informed choice. First, in order to have the capacity to make a decision, the potential subject must be capable of *understanding* the risks and benefits of the study, *deliberating* the balance of risks and benefits in the context of his or her own life, and *communicating* a choice clearly to the investigator or staff. Thus, adults are assumed to be able to give consent unless there is evidence that they are unable to understand, deliberate or communicate. Children, however, are assumed not capable of consent, and permission to enter research is usually necessary from their parent or legal guardian. Adults with mental disabilities, dementia, mental illness, or those unconscious or heavily medicated, may or may not be able to give consent and must be evaluated on a case-by-case basis. The second precondition is that the subject must make the decision whether or not to participate freely, voluntarily and without coercion.

If both these pre-conditions are present, then the subject must be fully informed. This means that they have been presented the following information and have had an opportunity to ask questions and receive answers to those questions. Informed consent should include:

- the purpose of the study;
- reasonably foreseeable risk and discomforts to the subject;
- potential benefits to subjects;
- how risks will be minimized including protection of confidential information;
- possible alternative (non-research) procedures or treatments;
- participation is voluntary;
- subject may withdraw at any time;
- if the study poses greater than minimal risk, the subject should receive any information about potential compensation for harm or medical treatment;
- who to contact with questions about the research and their rights as subjects.

Documentation of informed consent is usually required, by a form that lists all the above information at a level of language understandable to the potential subjects, and is signed by the subject. Some institutions require a witness's signature or the signature of the person obtaining the consent.

Protecting subject's confidentiality

In many research projects, including those involving mainly interviews or surveys, the only risk to subjects is that confidential or sensitive information about them will be improperly disclosed. In all studies researchers have an obligation to protect subject identities and information. Common measures to protect information include:

- conducting interviews in private or in settings where the information disclosed cannot be overheard by other persons;
- keeping the identities of all research subjects confidential, even the fact that an individual *is* a research subject should be protected;
- identifying research data by code rather than name;
- not using names or other identifiable information in any published or circulated summary of the data or discussion of the results;
- storing research data, including informed consent forms in locked rooms or file cabinets, or on pass-word protected computers, to limit outsider's access to information;
- educating staff not to share interesting anecdotes from the research outside of the research setting.

#### **Confidentiality in research:**

Interviewers may know their research subjects from other settings such as street outreach, health clinics, on-going therapy groups, or other settings. They may have even recruited subjects in those settings. However, in all cases interviewers should not acknowledge the identity of a subject as a participant in a study in any setting, unless the subject identifies himself as such. Interviewers may even encounter research subjects socially at a later time. Once again, interviewers should not acknowledge their previous contact with the subject unless the subject does so.

### **Ethical Issues in Policy Research and this Project**

#### *Avoiding harm to subjects and others*

Although policy research focusing on behavior is relatively low risk in comparison to some types of clinical trials or behavioral research, any research related to drug use or other illegal behavior poses some risks to subjects. For those not engaging in illegal activity themselves, the main risk is that sensitive or critical information revealed in an interview might be disclosed to their colleagues, friends, or associates. Or, there might be some possible stigma associated with working with the researchers identified with an “AIDS project” or a “drug user project.”

For subjects engaged in or knowledgeable about illegal behaviors such as drug use, potential risks include both disclosure of stigmatizing information and potential legal risks if law enforcement authorities use information obtained in research for criminal justice purposes. These subjects, who may be reluctant to talk to researchers, deserve protection from possible mis-use of their information. For example, collecting data without personally identifiable information on subjects may be one way to insulate them from harm. Subjects could give their initials or use pseudonyms. Other precautionary measures include not recording precise locations where

subjects were interviewed or illegal activity occurred so as to prevent police use of the information to conduct surveillance or make arrests.

Finally, in some cases the potential for harm comes from the implications of the results of the research. In these cases, researchers must balance the probable benefits of the research against the possible harms that might occur from documentation of the results.

**Case Study: do no harm – an ethical dilemma in prison**

During planning for an investigation of HIV in a prison researchers were concerned that a backlash would result from prison staff and administration if the researchers revealed that there was injection drug use and sex in the prison. On balance the team decided that research was vital to convince policy makers and politicians to implement penal reform.

*Neutrality*

Researchers will need to have a non-judgmental stance. This means respecting the life choices that informants have made and any opinions they hold. During a rapid assessment, researchers should never attempt to change the behavior, beliefs or attitudes of an informant. Where conflict exists in a locality, either between individuals or political groups, researchers should avoid being associated with either side.

**Case study: neutrality - an ethical dilemma**

During street interviews with young heroin injectors, a researcher was often asked whether she thought they should be tested for HIV. Rather than express her own opinion about HIV testing, at the end of the interview she would give the interviewee a card with contact details for a free, confidential HIV testing and counseling service.

*Consent*

Informants should normally give their consent to being involved in the study. Where researchers record the identity of the respondent, consent is required. However, where researchers are only observing behavior, or where they have been advised not to explain what they are doing by a key informant, *and* the identity of the subject of the information is not recorded, the researcher must assess the most ethical course of action.

### **Case study: informed consent - an ethical dilemma**

During research in a Baltic country, members of the team became involved in a conversation at a party. The young person they spoke to revealed, during the conversation, that she was involved in sex work and used drugs. She spoke quite openly about her experience and provided useful information about sex work and drug use in the city. However, the members of the research team did not reveal to the young person that they were researchers or the nature of their work. Since there was no informed consent, the researchers were faced with the ethical dilemma of whether or not to use the useful information.

#### *Feedback*

Those people who were involved in the rapid assessment should be given a chance to comment on the findings. As well as being ethical, this is often a useful final check on the validity of any results and the feasibility of any recommendations.

#### *Consequences*

Researchers should always be aware of the consequences of their actions. What seems ethical in strict research terms may have unethical consequences for others.

### **Example: Alcohol and ethics, Ireland**

Research team members were interested in how 'poitin' is made. 'Poitin' is a home-made spirit that a lot of young people drink in our community. The only person who could show them how to make the drink was currently undergoing alcohol treatment. The team was aware that by asking this person prepare the drink, they could be placing the individual in a situation where she might be tempted to drink the solution. This ethical dilemma was solved when the opportunity arose to witness the 'poitin' production by individuals not in alcohol treatment.

#### *Protecting Human Subjects in Policy Research and this Project*

Investigators should develop a plan specific to their research project that foresees potential risks to research subjects (and staff), adopts means to reduce risks and establishes procedures to ensure that risks are minimized and subjects are protected throughout the course of the research project.

**See Protection of Human Subjects in the next section of this Module.**

## **Documents and Sources:**

The Belmont Report. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979, available at:  
<http://ohsr.od.nih.gov/guidelines/belmont.html>

Code of Federal Regulations (US) 45 CFR Part 46, available at:  
<http://www.nihtraining.com/ohsr/site/guidelines/45cfr46.html>

Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. CIOMS, World Health Organization, 2002, available at: [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm)

Nuremberg Code, 1947. available at: <http://ohsr.od.nih.gov/guidelines/nuremberg.html>

Universal Declaration of Human Rights, 1948. available at:  
<http://www.un.org/Overview/rights.html>

World Medical Association, Declaration of Helsinki, available at:  
<http://www.wma.net/e/policy/pdf/17c.pdf>

# RESEARCH ETHICS

## Tools

### *Materials Included:*

Human subject and information protection protocol

How to Obtain Informed Consent

# Human Subject and Information Protection Protocol

## Purposes:

- To summarize procedures to protect the safety and identity of human subjects in this research;
- To ensure that information is collected accurately, attributed correctly (when applicable), and protected from unintended disclosure;
- To ensure that national and international standards for research ethics are met and appropriate documentation maintained to establish compliance.

## Human Subject Protection Protocol and Protecting Information and Identities:

Key principles:

- Consent of subjects to participate;
- Protection of confidentiality;
- Limited disclosure with attribution when specifically permitted;
- Anonymity of subjects and records where highly sensitive information is collected.

## Process:

Observe the following requirements while collecting data from research subjects in the RPAR.

1. All subjects must give voluntary informed consent to participate.
2. Recruited subjects will be told that participation is fully voluntary and interviews or groups participation can be ended at any time without any penalty or adverse consequences to the subject's medical care, psychological services, or participation in other programs.
3. Every subject must go through the informed consent process and have the opportunity to have all their questions answered. This is a basic premise of ethical research. Many international and domestic research rules require that subjects sign a consent form and that the investigators keep a copy of the signed consent form to prove that each subject has consented. However, a project like this, which involves minimal risk to subjects and collects only interview data, may not be required to keep signed consent forms, if those forms are the only record a subject's identity. Check with your local or national Research Ethics authority to determine if your project qualifies for such an exception. Otherwise, collect signed consent forms and store them in a secure place as described below.
4. System and interactor informants will also be asked for permission to refer to them by name or professional title. The last page of the consent form includes a permission

statement. Copies of this page should be kept in a locked cabinet in the local research office. Interviewers will clearly note that informant has or has not given permission to use his or her name.

5. Any informant possibly engaged in illegal or otherwise sensitive activities will remain anonymous in the recorded data from the interview.
6. Any form (such as a list of potential key informants) that contains names should not designate people by status (such as “injection drug user”) but instead indicate areas of expertise (e.g., “has information about drug use”).
7. Research data and forms granting or refusing permission to use people’s names and / or titles will be kept in a locked office, file cabinet, or on password protected computers.
8. Research team personnel will refrain from talking about interviews results in public in any way that could reveal the identities of participants who have not given such permission (researchers should be particularly careful of discussions in restaurants, institutional settings, elevators or on the street).
9. Research team personnel will protect participants from being identified as part of the project unless the participant has given permission for such identification.
10. Research team personnel who know subjects from other settings will not identify them as subjects without their permission.

### **Monitoring of the project**

The investigators are responsible for ensuring that research subjects are protected from harm and that the subject and information protection protocol is followed. The following steps should be undertaken to monitor compliance with subject protection.

1. All researchers, staff and field workers should be trained about the details of this plan and the means to protect subjects.
2. The primary investigator should review the data collection, recording and storage techniques of staff and fieldworkers throughout the RPAR.

## How to Obtain Informed Consent

### Screening Subjects and Obtaining Informed Consent:

The informed consent process begins with recruiting. You must identify yourself as a researcher and ask permission of any potential subject before you recruit them into the study. In order to determine if a potential subject is eligible for the study you must ask him some basic questions to determine if he meets the “inclusion criteria” for the study. This first stage is called “screening”. You will need to ask potential subjects several questions to determine if they are eligible for the study. If you determine that they are eligible, the next phase is the informed consent phase. First, we will review screening, then we will review the informed consent process for the interview.

### Screening Overview

#### Summary of Steps:

1. Introduce yourself, say you are a researcher.
2. Ask permission to talk to the subject.
3. Briefly describe the study.
4. Ask permission to determine eligibility by asking screening questions.
5. Ask screening questions and determine if subject is eligible according to the inclusion criteria.
6. Decide if you want the potential subject as an actual subject.

*NOTE, this script is designed for use with “patient informants”, those with direct experience as patients who might have experienced or been treated for significant pain or for those knowledgeable about drug use. When screening for system or interactor informants, the interviewer must still make sure that the potential subject meets the inclusion criteria through screening questions, but the inclusion criteria will usually be based on professional experience (“Based on my notes, you are a physician who treats patients with cancer and chronic pain. Is that true?”), rather than personal behavior.*

#### Script:

**1. “Hello, my name is (                    ) and I am a researcher conducting a study. I would like to talk to you about the study. May I talk to you about it?”**

- Wait for respondent to clearly say YES – if respondent says YES, continue.
- If respondent says NO or does not respond, say thank you and walk away

**2. “We are conducting a study of laws and policies governing the medical use of opioids for treatment of pain and drug addiction. I think I would like to interview you but first I have**

**to ask you some personal questions to determine whether you are eligible for the study. May I ask you some personal questions?”**

- Wait for respondent to clearly say YES – if respondent says YES, continue.
- If the respondent has questions, answer them fully and then ask again if you may ask some personal questions.
- If respondent says NO or does not respond, say thank you and walk away.

**3. “For this part of the study we are interviewing people who have experienced pain from cancer, HIV, or other serious diseases, or who have been treated for drug addiction, so I am going to ask you a few more questions about your experiences while being treated for pain or for drug addiction ...”**

- **ASK ALL POTENTIAL RECRUITS:** How old are you? (subjects must be at least 18; for visibly older subjects, asking “are you at least 18 years old?” may be more polite)
- If YES: Ask the appropriate screening questions as follows. If the person meets broad inclusion criteria you can figure out the appropriate category during the interview. Only ask the one or two questions in the appropriate section not all of them.

**a) If you think the person is a patient with cancer pain, HIV-related pain, or chronic pain ask:**

- “Have you been treated for cancer [HIV, or chronic pain]”?
- If, YES:
- “During your treatment, did you experience pain that was ...[insert here the definitions for patients with cancer pain, HIV-related pain or chronic pain that the research team has developed following the table and guide on pages 134-135] .... ?
- If [the patient meets the inclusion criteria for cancer pain, HIV-related pain or chronic pain] then go on to the next step. If not, thank him or her for their time and move on.

**b) If you think the person is an injection drug user of opioids, and therefore might fit the criteria for current or potential medication-assisted therapy patient, ask:**

- “Have you ... [insert here the definition of “potential or current drug-dependency treatment patient” that the research team has developed following the table and guide on pages 134-135] ... ?
- If YES, then subject meets definition of [potential drug-dependency treatment patient or medication-assisted therapy patient].

**4. ASK any other questions that may be necessary to determine eligibility and decide whether person is eligible.**

*NOTE: For this project you can also decide not to interview a person who may be eligible just because he is not talkative enough, too intoxicated, because you don't think s/he knows enough or for any other reason at all. Just tell them that they are not eligible if you decide not to interview them for any reason. Do not ever tell potential respondents the requirements for being in the study. If you tell a potential respondent the requirements, they may lie to you about their experiences to enroll in the study or tell others what the eligibility requirements are.*

**IF NOT ELIGIBLE** say, “According to our research protocol you are not eligible for a longer interview but thank you very much for your time. Here is (a very small incentive like a candy bar or pen) as a small gift. Thanks again.”

**IF ELIGIBLE:** say "You qualify for our study and I would like to conduct a longer interview with you. We can either do it right now or schedule it for later....."

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***IMPORTANT NOTE:** Before interviewing the person you must conduct a full informed consent process with that person. The above protocol is to obtain consent to ask only the screening questions. The process below describes the informed consent process for the interview.*

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**Obtaining Informed Consent**

After completing the screening questions, you have to determine whether or not you want the individual as an actual subject. For this project you want to get subjects who will be the most helpful (not necessarily the most representative).

*NOTE, When you have screened the subject and decided that he or she would be a good subject, you must still go through the informed consent process with the subject, explaining the project, obtaining consent, and completing the consent forms. The easiest and most reliable way to begin explaining the study is to READ the consent form to the subject. You should stop after each section of the form and ask the subject if she/he has any questions and then answer them to the*

*best of your ability. If you cannot answer the questions accurately, tell the truth. The subject can refuse to participate at any time.*

### **Summary of Steps:**

1. Re-introduce yourself (if interview is done at a later time)
2. Tell them you need to explain the purposes of the study, answer their questions, and get his or her consent to continue with the interview.
3. Give him or her a copy of the form to follow along with.
4. Read the informed consent form, stop after each section and ask if the subject has any questions, answer those questions.
5. When the reading and questions are completed, ask if the subject agrees to participate, and ask him or her to sign the form using no more than initials.
6. Keep a copy of the form and give the subject to keep a copy. Save your copy and return it to the principle investigator to file. The subject is required to take the copy.

### **Script:**

1. **“Hello, my name is ( ), and I have made this appointment with you to talk about the study on the medical use of opioids and policy which we talked about. The study interview will take about 2 hours, is this a good time to talk?”**

Wait for the respondent to say YES.

2. **“Before we get started I need to explain the study to you, and answer any questions you may have. I would like to record the consent process, is that alright? After we are finished, and if you agree to participate, I will give you a copy of the consent for if you want it and I will note that you have agreed to participate. Can I begin?”**

WAIT for the respondent to say YES

3. Give subject a copy of the form.
4. [Read the form, pause at the end of each section, and ask]  
**“Do you have any questions about his section?”**
5. [When reading and questions are finished]  
**“Based on what we have discussed, would you like to be in the study?”**

If respondent says YES,

**“Thank you for agreeing to be in our study. You may have a copy of the consent form, but you do not need to keep it if you do not want to. The form does include names and phone numbers of the researchers conducting the study. You can call, email, or write them if you have additional questions.”**

6. Save one copy of consent AND return it to the local Principle Investigator to file and save. This is very important, the project cannot use data from interview subjects from whom we do not have consent documented in our files. Give the other copy to the respondent and begin interview.

**RAPID POLICY ASSESSMENT AND RESPONSE:  
*ACCESS TO THERAPEUTIC OPIATES***



**Appendix 1**

***Supplemental Tools***

## 1.0. Introduction

The RPAR process is an adaptable method of quickly assessing policy, laws, and practice as related to access to therapeutic opioids, identifying barriers and facilitators of access, developing a collaborative action plan, and implementing key interventions. The main set of RPAR tools has been tested in multiple countries with a focus on a variety of health policy issues.

RPAR teams may wish to explore a number of important issues related to opioid access policy more deeply, and the goal of this appendix is to provide resources and in some cases, tools, that may be of assistance in gathering more information. RPAR teams may choose to use the tools in this appendix if they feel that the data gathered may be useful, or they may not use them. As part of the organization of the RPAR, engaged dialog about these issues will be useful, whether or not further data collection is pursued.

Topics include:

2.0. Internet Infrastructure Assessment. The goal of this section is to assess the level of internet accessibility and informational infrastructure.

3.0. Inventory Assessment of Opioid Medications. The goal of this section is to assess the inventories of opioid drugs available at points, such as hospital or retail pharmacies, where patients may purchase them.

4.0. Community Readiness-to-change Assessments. The goal of this section is to assess readiness-to-change on the part of policy makers or others in a community.

Additional resources such as websites, online training courses and references are provided in each section as a way of framing the issues. While the material provided cannot represent all methods or references available, they serve as a useful starting point in working to create policy change and interventions. Wherever possible, links to full-text versions of articles and references are provided.

## 2.0. Internet Infrastructure Assessment

Wireless and internet infrastructure or lack thereof can be a significant barrier to increasing access to opioid medications. Without reliable access to the internet, legislators, policymakers, physicians, pharmacists and others cannot access vital and timely professional materials related to opioid medications access. Legislators can't review model laws or collaborate with international bodies, physicians can't review the latest standards of practice or most current journal articles on treatment of pain, palmists do not have access to online courses or relevant research related to opioid medications, drug-dependency treatment specialists cannot review WHO or UNDOC materials on methadone or buprenorphine, and all are deprived of the collaborative networking with colleagues in other communities or internationally.

The international expansion of information availability and the consequent transition from paper and postal mail to electronic documents and e-mail has substantively changed professional relationships around the world for communication, collaboration and the exchange of information. This accelerating transition has great potential for improving opioid medication-assisted care, but in some developing countries, infrastructure supporting the transition is sometimes lacking. George Sadowsky referred this digital divide in 1996 as “information poverty”, saying

*“In developing countries, information poverty is one of the more significant and insidious obstacles to effective exploitation of information processing and other types of technology. Lack of adequate information regarding developments in other countries and other environments is often not noticed, and in the absence of new information, old techniques and procedures are continued without conscious knowledge of alternatives.”*<sup>21</sup>

Information poverty continues to be a critical issue in the world and information infrastructure is an especially important linchpin in assuring access to therapeutic opioids.

One assessment that may be useful in RPAR projects is to assess the status of internet and wireless infrastructure through community “staging” of the information infrastructure by using a standardized staging form to evaluate the stage of information infrastructure. Moving the entire community to an improved stage is one approach that could be an effective, but very challenging, intervention, another may be to simply improve information access for pharmacists, physicians and policy makers. Staging can provide important insights into gaps in the information infrastructure and actionable points. A simple, adaptable, qualitative staging scheme is included in section 2.2. and 2.3. Tools.

There are multiple methods that are more rigorous, quantitative and nuanced assessments. One example is the MOSAIC method, developed by researchers at the International Telecommunications Union (ITU) of the United Nations. ITU is the leading United Nations agency for information and communication technology issues. The MOSAIC methods assigns a numerical score, provides a deep understanding across six axes, and derived scores can be

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<sup>21</sup> Sadowsky, George. The Internet and Developing Countries. *On the Internet*, International Internet Society, 1996. Available at: <http://www.isoc.org/oti/articles/1196/sadowsky.html>

compared across countries. For an excellent review and comparison of quantitative methods to assess “e-readiness” see the bridges.org report entitled *E-readiness Assessment Tools Comparison, 2005*, available for download online at: <http://www.bridges.org/publication/128> Several of the methods could be easily adapted for RPAR projects.

## 2.1. Additional Resources

### References

Barja G, Gigler B-S. The concept of information poverty and how to measure it. In: Galperin H, Mariscal J, editors. *Digital Poverty- Latin American and Caribbean Perspectives*. Warwickshire, United Kingdom: Practical Action Publishing; 2007.

Hawkins R. Ten Lessons for ICT and Education in the Developing World. In: Kirkman G, Cornelius PK, editor. *The Global Information Technology Report 2001–2002: Readiness for the Networked World*. Oxford: Oxford University Press; 2002.

Ngini CU, Furnell SM, Ghita BV. Assessing the global accessibility of the Internet. *Internet Research* 2002, 12: 329 – 338. Available at: <http://www.emeraldinsight.com/Insight/viewContentItem.do?contentType=Article&contentId=863755>

Norris P. The Worldwide Digital Divide: Information Poverty, the Internet and Development. Paper presented at the Annual Meeting of the Political Studies Association of the UK, London School of Economics and Political Science, 10-13th April 2000. Complete paper available at: <http://ksghome.harvard.edu/~pnorris/Acrobat/psa2000dig.pdf>

### Journals

The Electronic Journal of Information Systems in Developing Countries  
Online is available at: <http://www.ejisd.org/ojs2/index.php/ejisd>

### Data

One publication of the ITU that includes basic data for internet infrastructure for 154 countries, such as the proportion of households with the internet, posted online in 2009. **Measuring The Information Society – The ICT Development Index, 2009 Edition**. The data is available at: <http://www.itu.int/publications/publications.aspx?lang=en&media=electronic&parent=D-IND-ICTOI-2009>

### Other online resources

Bridges. org. **A Guide to Free IT**. This online guide lists sources of free, donated, or low-cost computers, web hosting and email services, and how to enlist tech-saavy volunteers. Full text of the document is available at: <http://www.bridges.org/publication/95>

## 2.2. Included Tools

On the following page is a simple qualitative staging form to assess through discussion the stage of a community in adopting information technology and infrastructure. The stages and the form are designed as discussion guides, and are meant to be flexible and adaptable to local conditions. To following steps may be taken to use the form.

1. First, adapt the stages to local conditions. For example, if there is no broadband access in the country, delete sections related to broadband from the stage.
2. Gather together a diverse group of knowledgeable people and engage in discussion about the level of internet infrastructure. It is likely that gaps will be identified, but it is also likely that more information is required.
3. This assessment probably will require two meetings. Assign information gathering tasks to different members of the group to find out more.
4. Reconvene the group, exchange information that was obtained and assign a stage number to the community under consideration. Keep careful notes about the two meetings and provide the information to the CAB for their consideration as part of planning for action.

### 2.3. Access to the Internet: Community Staging Tool

Stage	Residential	Commercial	Public
0	There is no way to obtain internet access residentially	There is no way for businesses to obtain access to the internet.	There is either no way for the public or educational institutions and hospitals to access the internet  or  A sole public internet access point ("internet cafe") may be operating.  Schools and colleges may have sporadic and unreliable internet service that is carefully monitored  Email is used by very few.
1	Some residences may be able to obtain access to the internet either through dial-up or via satellite but with difficulty and at a high price.  Email is used by few.	Some businesses may be able to obtain access to the internet either through dial-up or via satellite but with difficulty and at a high price.  Email is used by few.	More than one "internet cafe" is operating in the area so that the public may pay to obtain access to the internet but service is sporadic.  Email is used by few.
2	Dial-up service is available from at least two ISPs across the community.  Affordable dial-up, wireless or broadband internet access service is available in the community's population center(s) from a single provider.  Email is used by some people.	Some of the businesses have affordable internet access.  Email is used by some people.	Most of the schools, government and healthcare facilities have <u>affordable</u> internet access and staff members are able to access the internet within their institutions.  Multiple internet cafes provide reliable service for public access.  Email is used by some people.
3	The community's large population center(s) have affordable access to the internet.  Affordable internet access is available in some small population centers and rural areas from providers.  Email is used by many people.	Affordable internet services with are available to most of the business market, schools, government offices and health care facilities.  Several businesses provide WiFi hotspots in their establishments.  Email is used by many people	WiFi hot spots are available at several public facilities.  A public or private center that provides some access to video teleconferencing, high-speed printing, and other ancillary services is located in the community  Email is used by many people
4	Residential internet use is common and accessible.  WiFi is widely available for laptops.  Email is used by most people.	Businesses maintain websites and have an online presence.  Electronic medical records are used to insure efficient care  Email is used by most people.	Telemedicine is used in rural areas to improve practice.  Affordable access to video teleconferencing facilities is available in the community. Most local governments allow individuals and entities to pay fees, complete forms and applications and register for services on-line.  Email is used by most people.

### 3.0. Inventory Assessment of Opioid Medications

At the other end of the supply chain for opioid medications are the shelves of the pharmacy. If opioid medications are not in stock, for whatever reason, there simply cannot be effective “access to therapeutic opioids” in the area. Tracking retail availability of medications is often done with computers or the use of RFID tags (see supply chain paper) but if the RPAR is being conducted in an area of resource limitations, RFID or computer tracking of medications may not be possible. The question to be answered is simple, although getting the answers may be challenging. The question to be considered is: Today, are there stocks of opioid medications available in pharmacies, hospital pharmacies or other points where patients may obtain opioid medications in the country or particular areas of interest.

Ancillary questions might include: What price do the patients pay? Are the pharmacies or other sources of opioid drugs well-stocked?

Reasons for a lack of inventory available in sources of opioid medications such as hospital or retail pharmacies may include diversion, fraudulent paperwork, or high retail prices. A simpler explanation may be that lack of medication supplies at the patient access level is a result of poor inventory control methods. Inventory methods to prevent “stock-outs” or running out of supplies are many, and following an assessment of inventory at the retail level in pharmacies and intervention to improve inventory methods may be effective in increasing access to therapeutic opioids. Inventory methods used in the developing world include web-based and stock card methods.

Partners in Health recently implemented a **web-based inventory** software program in rural Haiti.<sup>22</sup> The computer based inventory software system has been successful; after implementation, drug stock-outs fell to 1.1%. If the RPAR area has sufficient electronic infrastructure and computer literacy, implementing a web-based inventory system for stock management may be a very important facilitator of access to opioid medications. Contact Partners in Health, listed in the Resources section below, for more information on the program and software.

The World Health Organization offers a management training manual with training in the use of a **paper-based drug stock** inventory method that may be useful in areas where there is insufficient computer equipment or expertise to use a web-based system. Entitled *Management of Drugs at Health Centre Level - Training Manual*<sup>23</sup>, the document includes practical training exercises in inventory management, detailed training in inventory and procurement and is a very

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<sup>22</sup> Berger EJ, Jazayeri D, Sauveur M, Manasse JJ, Plancher I, Fiefe M, Laurat G, Samahel Joseph S, Kathryn Kempton K, Hamish S F Fraser HSF. Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti. *AMIA Annu Symp Proc.* 2007; 2007: 46–50.

<sup>23</sup> World Health Organisation. *Management of Drugs at the Health Centre Level – Training Manual.* 2004. Full text available at: <http://www.who.int/medicinedocs/en/d/Js7919e/2.html>

useful approach in resource-poor areas. The full text of the 84 page manual can be downloaded from the WHO website from this link: <http://www.who.int/medicinedocs/en/d/Js7919e/2.html>.

In sections 3.2. and 3.3. is a simple **visual verification of physical inventory** and retail costs of drugs assessment tool. This kind of assessment is important to confirm the presence of opioid medications at the points where patients may obtain them. One excellent example of a study to confirm physical availability of medications in pharmacies is found in Gulyaev G, Nurgozhin T, Hafner G *et al.* *Survey on Prices and Availability of Pharmaceuticals in the Pharmacies of Karaganda City, Kazakhstan.* 2002. USAID/ZdravPlus Project. Full text available at: [http://pdf.usaid.gov/pdf\\_docs/PNACW564.pdf](http://pdf.usaid.gov/pdf_docs/PNACW564.pdf).

Results of the study in Kazakhstan suggested several interventions to improve access to essential medications and pharmacy practice. In this project, in addition to practice recommendations providing consumers with information about which pharmacies had the most reliable supplies or lowest cost would be an important intervention to improve access to pharmaceuticals.

### 3.1. Additional Resources

#### References

Berger EJ, Jazayeri D, Sauveur M, Manasse JJ, Plancher I, Fiefe M, Laurat G, Samahel Joseph S, Kathryn Kempton K, Hamish S F Fraser HSF. Implementation and evaluation of a web based system for pharmacy stock management in rural Haiti. *AMIA Annu Symp Proc.* 2007; 2007: 46–50. Full text available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?tool=pubmed&pubmedid=18693795>

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Gulyaev G, Nurgozhin T, Hafner G *et al.* *Survey on Prices and Availability of Pharmaceuticals in the Pharmacies of Karaganda City, Kazakhstan.* 2002. USAID/ZdravPlus Project. Full text available at: [http://pdf.usaid.gov/pdf\\_docs/PNACW564.pdf](http://pdf.usaid.gov/pdf_docs/PNACW564.pdf).

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Selva, C. International control of opioids for medical use. *European Journal of Palliative Care* 1997; 4: 194-198. Available at: <http://www.painpolicy.wisc.edu/internat/selva.htm>

World Health Organisation. *Management of Drugs at the Health Centre Level – Training Manual.* 2004. Full text available at: <http://www.who.int/medicinedocs/en/d/Js7919e/2.html>

#### Other Online Resources

Online Course: Pain & Policy Studies Group. Increasing Patient Access to Pain Medicines around the World: A Framework to Improve National Policies that Govern Drug Distribution. This course focuses on a policy framework for understanding policy change and drug distribution. University of Wisconsin Paul P. Carbone Comprehensive Cancer Center. Madison, Wisconsin, 2008. This course is available at: [http://www.painpolicy.wisc.edu/on-line\\_course/welcome.htm](http://www.painpolicy.wisc.edu/on-line_course/welcome.htm)

Online Course: USAID and Information & Knowledge for Optimal Health (INFO) Project. Fostering Change in Health Services. This course focuses on changes in clinical practices, behavioral practices of providers, and management practices at service delivery sites. This course is available at: <http://www.infoforhealth.org/elearning/fosteringchange.shtml>

Online Course: USAID and Information & Knowledge for Optimal Health (INFO) Project. Logistics for Health Commodities. Learners who take this course will be oriented to key concepts in supply chain logistics for health commodities, and basic principles of logistics. This course is available at: <http://www.infoforhealth.org/elearning/logistics.shtml>

### Websites

Partners in Health. Website: <http://www.pih.org/home.html>

### 3.2. Included Tools

On the following page is a form to support a visual verification study of opioid drugs available at purchase points, such as retail pharmacies, hospital pharmacies, or other places where patients may obtain opioid medications. This assessment is intended to be conducted once to provide a “snapshot” of the inventory available in a community.

To use this form, take the following steps.

1. Adapt the form to local conditions. For example, if methadone is illegal in your country, then delete methadone from the form.
2. Organize a list of all the places that dispense opioid drugs to patients in the area. Places might include pharmacies, clinics, drug treatment programs and hospital pharmacies. Organize the list so that each purchase point is only listed once. Use Table 2 to help define the area and organize the list.
3. Identify the researchers who will be conducting the survey. The survey teams should have at least two people on the team and at least one member should have medical expertise. It is better to have many teams operating in a shorter period of time than to have one team conducting all the surveys over a longer period of time.
4. Choose the area to assess. Surveying all of the pharmacies in a small area would give a 100 percent assessment of availability in that small area. We estimate that each team can conduct about 4 – 6 survey’s a day. Write out the definition of your study area, with street boundaries, and include the definition in your research files.
5. Arrive at the pharmacy and engage with the manager. There are a number of strategies to ensure cooperation that could be used. One is to ask the head of the pharmacy association or a health official for that area to arrange the visits or provide a letter of support in advance.
6. There should be one survey form per place surveyed, fill out a face page and a survey form for each place. All medications should be visually verified; members of the research team must be able to see the medication. Report by the pharmacist is insufficient.
7. Only the medications on the list should be verified, other medications are not included in this study. If a dosage is listed on the form, only medications at that dosage should be included. For example, only codeine in 30 mg doses is on the list; if codeine is available, but in 10 mg pills, then it would not be included. If the dose is not specified, then whatever dosage is available should be recorded and the formulation noted.

Visual Verification Survey: Medication Stocks Instruments  
Face Page

Date: \_\_\_\_\_ Place: \_\_\_\_\_

Category: \_\_\_\_\_

Team members: \_\_\_\_\_

Comments on any aspect of the process:

Table 1. Formulary Medications Available on Shelves

Drug	Formulation	Number Available	Retail Price per piece	Notes
Buprenorphine				
Codeine, Tablet	30 mg			
Diazepam				
Ephedrine				
Ergometrine				
Fentanyl				
Hydromorphone (Dilaudid).				
Morphine, Injectable	10 mg/1 ml ampoule			
Morphine, Oral Liquid	10 mg/5 ml			
Morphine, Tablet	10 mg			
Morphine, Tablet Prolonged Release	10 mg			
Morphine, Tablet Prolonged Release	30 mg			
Morphine, Tablet Prolonged Release	60 mg			
Methadone, Oral Liquid	5 mg/5 ml			
Methadone, Oral Liquid	10 mg/5 ml			
Naloxone, Injectable	400 mcg/1 ml ampoule			
Oxycodone				
Phenobarbital				
Pethidine (Demerol)				

Table 2. Organizing the Survey. Sources of Opioid Medications For Patients

1. Define area to be surveyed:

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2. Define Categories. Categories are types of places where patients may purchase opioid drugs. Make as many categories as needed.

**Category Example Listing**

Category 1 = Retail pharmacy

Category 2 = Hospital pharmacy

Category 3 = \_\_\_\_\_

Category 4 = \_\_\_\_\_

3. Create list of sources of opioid medications and arrange list so that each source only appears once, in the category that *best* describes it.

## 4.0 Community Readiness-to-Change Assessments

Another activity that an RPAR team may wish to undertake is one or more Community Readiness-to-Change assessments. Readiness is the degree to which a community is willing to take action on a specific issue, or change. Without readiness-to-change assessments and an essential understanding of where different communities are in terms of their readiness, implemented interventions to change policy may be inappropriate or mis-targeted. The typical presentation of readiness-to-change data is in terms of stages of change and depending on the stage of a community, effective interventions will vary. There will be more discussion of stages below, but first, some definitions of terms.

*What is community?* This is an excellent question, as there are many different definitions and on-going debate about the meaning of the word community. For the purposes of the RPAR, community is defined as a group of people organized around common values and social cohesion living in a shared geographic location. Social cohesion can be thought of as the “ties that bind” or that which brings people together. This definition community suggests that there are multiple communities in a geographic area, and an individual person usually belongs to many communities. Communities can be affiliational, consisting of social clubs, religious organizations or professional groups such as clinicians or pharmacists. Communities can be related to identity, there can be communities organized around tribal, ethnic, sexual or gender identities, or they can be based on micro-geographic divisions, such as neighborhood communities or sub-areas of neighborhoods. There are also large communities of nations and communities existing unbounded by geography on the internet, but in this discussion we are focusing on smaller and geographically based communities.

*Stages of Change:* Prochaska and DiClemente developed the Transtheoretical Model of Change in 1977<sup>24</sup>, and published an article in 1983 apply that model to smoking cessation<sup>25</sup>. They conceptualized each of 5 stages of change as distinct, and proposed that the effectiveness of health interventions with smokers depended on which stage they were in. They argued for “stage-based” intervention. For example, if a smoker was in the “pre-contemplative” stage, or not really thinking about quitting smoking, then an effective intervention is risk education but if a smoker is in the action stage, or actively working to quit smoking, ensuring their access to supportive medication or nicotine patches is much more effective than risk education in that stage, although the approach has garnered some criticism<sup>26</sup>. Stage-based interventional design is one of the most prominent approaches to individual intervention.

Stage-based interventions are an excellent approach to community change as well, and the RPAR process includes many elements of stage assessment. Others have conceptualized a stage-based

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<sup>24</sup> Prochaska JO, DiClemente CC. The transtheoretical approach. In: Norcross JC, Goldfried MR, (eds). *Handbook of Psychotherapy Integration*. 2nd ed. New York: Oxford University Press; 2005. p.147-171.

<sup>25</sup> Prochaska JO, DiClemente CC. Stages and processes of self-change in smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology* 1983, 5: 390-395.

<sup>26</sup> Riemsma RP, Pattenden J, Bridle C, Sowden AJ, Mather L, Watt IS, Walker A. Systematic review of the effectiveness of stage based interventions to promote smoking cessation. *BMJ* 2003 May 31;326(7400):1175-7.

intervention at the community-level and have developed, refined, and tested methods to assess community readiness-to-change as a necessary first step.

*What Does “Readiness” Mean?* Pleastad et al. when considering community-level readiness-to-change staging, defined readiness as the degree to which a community is prepared to take action on an issue. They characterize readiness as a concept that (1) is very issue-specific, (2) is measurable, (3) is measurable across multiple dimensions, (4) may vary across dimensions, (5) may vary across different segments of a community, (6) can be increased successfully, and (7) is essential knowledge for the development of strategies and interventions. Matching an intervention to a community’s level of readiness is absolutely essential for success. Interventions must be challenging enough to move a community forward in its level of readiness.

*Community Readiness-to-Change Theory and Assessment.* The Tri-ethnic Center for Prevention Research at Colorado State University has developed, tested and refined a 9-stage model of community change and associated assessments<sup>27</sup> that has broad applications for looking at community level stages of change and identifying stage-based interventions. The model suggests that by moving communities to the next stage, readiness can be increased. The Tri-ethnic Center’s assessment is measured across six dimensions of readiness, and yields quantitative scores, which are helpful for comparing readiness across communities. The model is intuitive and the methods of assessment are brief, accessible and ideal for rapid assessment projects. See Table 1 on the following page for the summary of potential interventions that might be associated with each stage.

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<sup>27</sup> Edwards RW, Jumper-Thurman P, Plested BA, Oetting ER, Swanson L. Community readiness: Research to practice. *Journal of Community Psychology* 2000, 28:291-307. Full text available at: <http://www.colostate.edu/Dept/TEC/article3.htm>

Table 1. Stages of Community Readiness and Associated Intervention Strategies

From: Edwards RW, Jumper-Thurman P, Plested BA, Oetting ER, Swanson L. Community readiness: Research to practice. *Journal of Community Psychology* 2000, 28:291-307. Full text available at: <http://www.colostate.edu/Dept/TEC/article3.htm>

<p><b>1. No Awareness</b>  <u>Goal:</u> Raise awareness of the issue  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• One on one visits with community leaders and members.</li> <li>• Visit existing and established small groups to inform them of the issue.</li> <li>• Make one-on-one phone calls to friends and potential supporters</li> </ul>	<p><b>5. Preparation</b>  <u>Goal:</u> Gather existing information to help plan strategies  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Conduct community surveys and present in-depth local statistics .</li> <li>• Sponsor a community event to kick off the effort.</li> <li>• Publicize the costs of the problem to the community.</li> <li>• Conduct public forums to develop strategies.</li> <li>• Utilize key leaders and influential people to speak to groups and to participate in local radio and television shows.</li> </ul>
<p><b>2. Denial</b>  <u>Goal:</u> Raise awareness that the problem or issue exists in the community  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Continue one-on-one visits and encourage those you've talked with to assist.</li> <li>• Discuss descriptive local incidents related to the issue</li> <li>• Approach and engage local education/health outreach programs to assist in the effort with flyers, posters, or brochures.</li> <li>• Present information to community groups.</li> </ul>	<p><b>6. Initiation</b>  <u>Goal:</u> Provide community-specific information  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Conduct in-service training for professionals and para-professionals.</li> <li>• Attend meetings to provide updates on progress of the effort.</li> <li>• Conduct consumer interviews to identify service gaps and improve existing services.</li> <li>• Begin library or internet search for resources and/or funding.</li> </ul>
<p><b>3. Vague Awareness</b>  <u>Goal:</u> Raise awareness that the community can do something about the problem  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Post flyers, posters, and billboards.</li> <li>• Conduct informal local surveys/interviews with community people by phone or door to door.</li> <li>• Publish newspaper editorials and articles with general information - but relate information to local situation.</li> </ul>	<p><b>7. Stabilization</b>  <u>Goal:</u> Stabilize efforts/program  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Plan community events to maintain support for the issue.</li> <li>• Conduct training for community professionals.</li> <li>• Conduct training for community members.</li> <li>• Introduce program evaluation through training and newspaper articles.</li> <li>• Conduct quarterly meetings to review progress and modify strategies.</li> <li>• Begin networking between service providers and community systems</li> </ul>
<p><b>4. Preplanning</b>  <u>Goal:</u> Raise awareness with concrete ideas to combat condition  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Visit and develop support from community leaders in the cause.</li> <li>• Review existing efforts in community (curriculum, programs, activities, etc.) to determine who benefits and what the degree of success has been.</li> <li>• Conduct local focus groups to develop strategies.</li> <li>• Increase media exposure through radio public service announcements.</li> </ul>	<p><b>8. Confirmation/expansion</b>  <u>Goal:</u> Expand and enhance service  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Formalize the networking with letters of agreement.</li> <li>• Prepare a Community Risk Assessment Profile.</li> <li>• Publish a localized Program Services Directory.</li> <li>• Maintain a comprehensive database.</li> <li>• Begin to initiate policy change through support of local city officials.</li> <li>• Conduct media outreach on specific data and trends related to the issue.</li> </ul>
	<p><b>9. High Level of Community Ownership</b>  <u>Goal:</u> Maintain momentum and continue growth  <u>Strategies:</u></p> <ul style="list-style-type: none"> <li>• Diversify funding resources.</li> <li>• Continue more advanced training of professional and para-professionals.</li> <li>• Continue re-assessment of issue and progress made.</li> <li>• Utilize external evaluation and use feedback for program modification.</li> <li>• Track outcome data for use with future grant requests.</li> <li>• Continue progress reports for benefit of community leaders and local sponsorship.</li> </ul>

### Included tools

Fortunately, with extensively available tools online, there is no need to replicate a tool here. To conduct a community readiness-to-change assessment, follow these steps.

1. Familiarize yourself with the concepts, assessments and tools of community readiness to change assessment. First, download the 70 page handbook, *Community Readiness: A Handbook for Successful Change*. The handbook is available free of charge as an electronic document or is available in hard copy for a small charge. The handbook download page of the Tri-ethnic Center for Prevention Research is here:  
<http://triethniccenter.colostate.edu/CRhandbook.shtml>.

Another resource is the Center's slideshow about the Community Readiness Model, available here: [http://www.triethniccenter.colostate.edu/docs/CR\\_Presentation.pdf](http://www.triethniccenter.colostate.edu/docs/CR_Presentation.pdf)

2. Define the change that you are seeking. For example, you may be interested in expanding drug treatment services using MAT or changing regulations that limit the prescription of pain medication to cancer patients.

3. Define the communities you will be assessing. For example, in a city, there may be two main religious groups, each with different levels of readiness to change with respect to increasing access to pain medications for cancer patients. Conducting a brief readiness-to-change assessment in each religious community will help you craft a more nuanced and targeted Action Plan for creating change in both communities. Other communities including in a series of assessments might be patient self-help groups, a poor neighborhoods and wealthy ones, sports organizations or social clubs.

4. Use the methods and tools outlined in the Handbook to conduct the assessments and the results of the assessments to inform the development of the Action Plan.

## **3.1 Additional Resources**

### References

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Applications of Community Readiness-to-Change Assessments

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