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Guide to Pain Management in Low-Resource Settings

Chapter 43
Resources for Ensuring Opioid Availability

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The purpose of this chapter is to provide perspective and tools that you can use to make opioid analgesics more available and accessible for the treatment of your patients' pain.

The availability of opioid analgesics depends on the system of drug control laws, regulations, and distribution in your country. Unless this system is able to safely distribute controlled medicines according to medical needs, clinicians will be unable to use opioid analgesics to relieve moderate to severe pain according to international health and regulatory guidelines and standards of modern medicine.

This chapter poses a number of questions that are relevant to a better understanding of how the system is supposed to function, and to identify and remove impediments to availability of opioids and patient access to pain relief. This is of utmost importance, since pain management of postoperative, cancer, and HIV/AIDS pain is virtually impossible without the availability of opioids. This does not imply that opioids are indicated for every type of pain. Opioids can be useful to treat patients with chronic pain from noncancer conditions, but the choice of therapies needs to be made on an individual basis, governed by a careful consideration of risks and benefits of treatment.

Case examples

Several real cases are offered to focus this chapter on the critical importance of availability and access to opioid analgesics for the relief of pain.

Case 1

A patient was initially given radiotherapy for her pain, but it was not effective as the disease progressed. Next she was given a weak pain-relieving medication, but her pain continued to worsen. Finally, she returned to the doctor in excruciating pain requesting medication that would end her life. She was given another weak pain medication along with antidepressants and sent home. She committed suicide. [Pain & Policy Studies Group]

Case 2

XX is a referral hospital for cancer management. The annual requirement of morphine is approximately 10,000 tablets of 20 mg. But the Institute has not been able to procure a single tablet … primarily due to the stringent state laws and multiplicity of licenses. After a lot of effort, the Institute had been able to obtain the licenses… and had approached a [manufacturer] for a supply of tablets … the [manufacturer] did not have tablets in stock and by the time the tablets could be arranged, the licenses had expired. The doctors at the Institute and the associated pain clinic have stopped prescribing morphine tablets because they would not be available. [Joranson et al. 2002]

Case 3

[T]here were several occasions when no morphine was available. Such situations normally arose as a result of the difficulties encountered when trying to obtain the required licences. At other times, manufacturers of the

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drugs simply did not have any stock to sell … a direct result of low and unpredictable demand. During these times, morphine stocks … would run out. In these emergencies, the clinic would resort to otherwise unethical and unacceptable cutback measures, implemented in such a way so as to minimize the effect on patients and families. … When these alternative treatments failed to achieve adequate pain relief, as was usually the case, the staff would share in the helplessness, anger, and frustration of the patients and their families. To communicate the intensity of the dread felt by staff and patients when a morphine shipment was delayed, and the joy when the morphine finally arrived, is not possible. [Rajagopal et al. 2001]

What do these cases illustrate?

These cases demonstrate some of the causes and the human impact of unrelieved severe pain when access to opioid analgesics is blocked. Such situations are tragic and never should be allowed to happen, but they do set the stage for this chapter that will describe a number of resources that can be used by health professionals and government in low-resource settings, or anywhere else, to improve availability and patient access to opioid analgesics such as oral morphine.

This chapter is based on the international studies and experience of the University of Wisconsin Pain and Policy Studies Group (PPSG) and many collaborators. Since 1996, the PPSG has been a World Health Organization Collaborating Center (WHOCC) with terms of reference to develop methods and resources that can be used to improve availability and access to essential opioid pain medicines.

The following questions and responses are intended to assist clinicians and advocates in their efforts to improve patient access to pain relief. Readers are encouraged to consult the resource materials referenced in the text and at the end, refer to other chapters in this book, and seek expert professional guidance on specific questions relating to clinical pharmacology, medicine, and law.

What is the principle of balance?

Efforts to improve opioid availability should be guided by the drug regulatory principle of "balance." Balance is an internationally accepted medical, ethical, and legal principle stating that opioids are indispensable for relief of pain and suffering and that they also have a potential for abuse. The principle recognizes that efforts to prevent illegal activities and abuse should not interfere with the adequate availability of opioid analgesics to relieve pain and suffering. International agreements that are binding on governments have recognized for decades that narcotic drugs, i.e. opioids, are indispensable for the relief of pain and suffering and that governments are obligated to ensure their adequate availability for medical and scientific purposes.

What is the world situation regarding the availability of opioids such as oral morphine for people in pain?

Throughout the world every day, millions of people including older adults and children experience pain from surgery, trauma, cancer, AIDS, sickle cell anemia, and a range of other diseases that may include severe pain. The incidence of cancer and HIV/AIDS is shifting to low- and middle-income countries. Clinicians understand only too well how unrelieved severe pain can destroy quality of life and sometimes even the will to live.

Some—but not all—of the wealthier countries have fairly good opioid availability, and therefore patients have access to opioid analgesics. However, the reality is that most of the world's population lacks access to these indispensable medicines. Lack of access is especially serious in settings with limited resources and an inadequate health care infrastructure. A number of organizations with an interest in pain, palliative care, cancer, and HIV/AIDS are working to address these problems.

Why are controlled drugs such as oral morphine important?

While other chapters address this question in more detail, it is important to note that a variety of drug and nondrug therapies, including surgical procedures, radiation, and behavioral techniques, can be useful in treating pain and providing palliative care. Pain is treated with a combination of drug and nondrug measures. The WHO has determined that pharmacological treatment, including opioids and nonopioids, is the mainstay for relieving pain due to cancer and HIV/AIDS.

Opioids block the transmission of pain in the pathways of the nervous system. Some opioids, such as fentanyl, morphine, hydromorphone, and oxycodone can relieve moderate to severe and escalating pain. These opioid agonists lack a "ceiling effect" so that the dose can be increased to relieve increasing pain, keeping in mind side effects. International health and regulatory bodies do not recommend a maximum dose for opioid analgesics. Some other opioids and nonopioid analgesics do have a ceiling effect and, especially in the absence of opioid agonists, may be overused to try to achieve an effect of which they are not capable.

There is agreement that several opioid agonists in different dosage forms should be available to allow clinicians to change opioids, doses, and routes of administration to maximize efficacy and minimize side effects. The goal is to ensure the availability of these important pain relief medicines at an affordable cost, when and where needed by patients. A number of opioids are listed on the WHO and International Association for Hospice and Palliative Care (IAHPC) lists of essential medicines.

Do opioids have a potential for abuse?

Yes, opioids do have an abuse potential and therefore are "controlled" under international, national, and state laws and regulations. Many controlled opioids are also designated as essential medicines; they are safe and effective—indeed indispensable—for the relief of severe pain.

There is a legal tradition to classify opioids as "narcotic drugs," "dangerous substances," and even as "poisons." "Controlled substances" is a less stigmatizing term. The movement of controlled substances is subject to government regulatory controls such as licensing, secure storage, inventory, recordkeeping, and reporting of procurement, storage, distribution, and dispensing. A medical prescription is required to provide patients with lawful access to controlled medicines.

The manner in which regulatory requirements are administered differs greatly from country to country, and even from state to state and among institutions. But it should be understood that the purpose of opioid regulations should not only be to prevent unauthorized use and diversion from the supply chain. The purpose is also to ensure medical and patient access. However, it has been well documented that some national and provincial/state regulations are more restrictive than is necessary and impede or completely block access, hampering the ability of pain and palliative care clinicians to practice modern medicine.

Although international agreements recognize that national governments may be more restrictive, regulatory controls over opioid analgesics are not balanced if they interfere in legitimate medical treatment of patients. Tools for assessing balance in national laws and regulations and for bringing about change are discussed later in this chapter.

How should prescription opioid analgesics be handled safely?

Safe handling of controlled substances can prevent diversion, misuse, and injury. All those who handle controlled opioid analgesics, including manufacturers, distributors, physicians, pharmacists, nurses, patients, and family members, should know and respect that opioids are to be distributed, prescribed and dispensed only for a medical purpose such as relief of pain or medical treatment of opioid dependence/addiction. Controlled medicines should be used only by the person for whom they are prescribed and according to the physician's instructions.

It is important to keep prescribed medicines in the original container because the label has the prescription information that establishes in the eyes of the law the patient's right to possess a controlled drug. The label on the original container should have the instructions for use, as well safety-related warnings. Controlled medicines should always be stored out of sight to prevent theft, and kept out of reach of children to avoid accidental ingestion.

National requirements vary for returning or disposing of unused or "leftover" medicines. Additional information about requirements for secure disposal and ways to avoid harm to others and the environment should be obtained from the relevant government authorities.

What should be done if pain medicines are diverted?

In some cases, opioid analgesics are unlawfully stolen or "diverted" from various points along the drug distribution system, and then sold for nonmedical purposes, including to abusers. Abuse of essential medicines, especially if publicity is sensational and unbalanced, can

lead to overreactions and more restrictions on essential medicines that can undermine confidence in their therapeutic use. When diversion occurs, the response should be quick and balanced, i.e., the person or persons responsible should be held accountable, without interrupting patient access to pain relief. National leaders in pain management and palliative care should discuss balanced approaches to diversion with the government before it happens.

How can I find out about the opioids that are used in my country?

The PPSG has posted on its website extensive information about the consumption trends of selected opioids in each country. Governments are required to report consumption statistics to the U.N. International Narcotics Control Board (INCB). The INCB in turn provides the data to the PPSG/WHOCC. "Consumption" means the amount of opioids that are distributed by manufacturers or distributors to the retail level in the country, such as to physicians, pharmacies, hospitals, hospices, pain clinics, and palliative care programs. Opioid consumption statistics are an indicator of the capacity of a country to relieve moderate to severe pain.

The opioid consumption trend graphs include information for fentanyl, hydromorphone, methadone (also considered essential for the treatment of opioid dependence), morphine, oxycodone, and pethidine (meperidine). These data do not tell us which dosage forms of the opioid are being consumed in a particular country.

If the graphs for a country show no consumption of a particular opioid, this is an indicator that the drug may not available, or it could be a problem in reporting. The consumption statistics are updated annually by the PPSG as new data are received. These statistics can be used to study the consumption trends for the strong opioids in the world, a region, your country, or any country. Opioid consumption statistics can be used in the evaluation of long-term outcomes of efforts to improve availability.

Consumption statistics can be found in the Country Profiles on the PPSG website. Users can download the graphs and tables of data and use them for presentations without special permission, with appropriate citation. Examples of slide presentations relevant to international and national pain policy are available at http://www.painpolicy.wisc.edu/internat/conferences.htm.

What are the reasons for inadequate availability and access?

The lack of opioid analgesics in a country is not a "supply side" problem. According to the INCB, the United Nations' principal regulatory body for narcotic drugs, there is no insufficiency of raw materials for manufacturing opioid medicines. Instead, the problem is the result of system barriers within countries that result in a low or sometimes nonexistent demand for opioids.

The INCB periodically surveys national governments, in consultation with the WHO, to explore the status of opioid availability and the reasons why they are not adequately available. Governments have reported that the following barriers contribute to the lack of availability of opioids in their countries:

- Concerns about addiction;
- Insufficient training of health care professionals;
- Regulatory restrictions on opioid manufacture, distribution, prescribing, or dispensing;
- Health care professionals' reluctance to stock opioids because of concerns about legal sanctions.

These factors and interaction among them can act as a vicious circle—low national availability can lead to low medical use, resulting in weak demand, which in turn fosters continued low availability. Insufficient medical education about pain, combined with regulatory restrictions and exaggerated concerns about opioid analgesics and addiction, may conspire to maintain the status quo. However, it is possible to break out of this cycle if there is leadership both from health professionals and government.

What can the "National Competent Authority" do to improve availability and access?

Key to breaking the cycle and improving availability and access is the National Competent Authority (NCA). This is an agency in every country, often located in the Ministry of Health. It is intended to be responsible for implementing the government's international narcotics treaty obligations to ensure adequate availability of narcotic drugs for medical and scientific purposes. The Country Profiles on the PPSG website provide contact information for the NCA for each country.

The NCAs have been asked by the INCB to work with health professionals to determine and anticipate adequately future medical needs for opioid analgesics so that the necessary amounts can be imported and

manufactured. The "estimates system" administered by the NCA and the INCB is designed to estimate unmet needs for opioids and then authorize their acquisition. Each year, the NCA prepares and submits to the INCB the estimated requirements of the quantities of each opioid that will be needed in the country.

Only when the national estimate is increased or expanded to include other opioids can there be a change in the overall amounts that are imported, manufactured, distributed, and dispensed to patients. However, if there is little public interest in obtaining pain relief or medical interest in providing it, there may be little justification for increasing availability.

When controlled drugs are needed for humanitarian emergencies, the usual time-consuming regulatory procedures governing exports and imports can be abbreviated to expedite increased availability and access; further information is available from the INCB and the WHO.

Are there recommendations for educators and professional organizations to address opioid availability problems?

Yes. The INCB, in consultation with the WHO, has recommended a strong role for educational institutions and nongovernmental health care organizations—including the International Association for the Study of Pain (IASP)—to teach students in health care professions and licensed practitioners about the use of opioid analgesics, their control, and *correct* use of terms related to dependence. Furthermore, health care professionals and their organizations have been requested to establish ongoing communication with their governments about unmet needs for opioid analgesics and to help identify impediments to availability and access.

Where can a clinician find information about how to improve opioid availability and access?

Although there are numerous guidelines and educational curricula that address pain and palliative care, clinical training materials often do not describe the drug control system and the steps necessary to obtain and distribute opioid analgesics. Obtaining and *sustaining* access to opioid analgesics in any country depends on learning about the context of international and national drug control laws and regulations, how these are implemented in the distribution system, how they can be evaluated, and then working with government to make necessary changes in policy and administration.

With support from the National Hospice and Palliative Care Organization and the Foundation for Hospices in Sub-Saharan Africa, the PPSG developed an Internet course titled "Increasing patient access to pain medicines around the world: a framework to improve national policies that govern drug distribution." The course was developed to make available this specialized information to clinicians, government administrators, drug regulatory personnel, national health policy advisors, health policy scholars, and to those who develop clinical guidelines and training materials for pain management and palliative care.

The course has seven lessons, each with required readings and extensive citations (see Table 1). The course explains why patients and clinicians have a right to expect that their national drug regulatory system should make opioids available, and explains how this goal can be accomplished.

Do health professionals already have skills that can be used to address opioid availability?

If you have medical training, you already have relevant medical knowledge that can be applied in the drug regulatory policy and systems arena. For example, you may appreciate the need for pain relief among patients with various diseases and conditions. You may know about the drugs and their uses. The medical model is also a solid problem-solving approach that can be applied to the diagnosis of barriers to opioid availability and access, and to formulating action strategies, or treatments, as if the opioid distribution system in your country is your patient. Using this knowledge and skill, you can become an effective leader to work with government to examine, diagnose, and then decide on and implement the treatments necessary to correct the problems.

What tools are available to help diagnose regulatory problems in my country?

Information about drug control policy and systems barriers is often new to the health professional, so the WHO has published *Cancer Pain Relief with a Guide*

Table 1
Lessons in the PPSG Internet Course*

Lesson 1:	Understanding the Relationship between Pain and Drug Control Policy
Lesson 2:	The Role of International and National Law and Organizations
Lesson 3:	Barriers to Opioid Availability and Access
Lesson 4:	WHO Guidelines to Evaluate National Opioids Control Policy
Lesson 5:	WHO Guidelines to Evaluate National Administrative Systems for Estimating Opioid Requirements and Reporting Consumption Statistics
Lesson 6:	WHO Guidelines on Procurement and Distribution Systems for Opioid Analgesics
Lesson 7:	How to Make Change in Your Country

* This is a self-paced noncredit course that can be taken at any one time or over a period of time. It may take between 10 and 12 hours to complete. Each lesson has a pre-test and post-test; links to background reading and many authoritative resources are provided. A certificate is issued upon successful completion. The welcome and sign-in page is found at http://www.painpolicy.wisc.edu/on-line_course/welcome.htm. The course is available only in English at present.

to Opioid Availability, which explains basics of policy, as well as *Guidelines for Achieving Balance in National Opioids Control Policy.* The WHO *Guidelines for Achieving Balance* provides a framework for diagnosis of impediments in national drug control laws that has been used extensively around the world. These guidelines and the diagnostic checklist are available in 22 languages on the PPSG website at http://www.painpolicy.wisc.edu/publicat/00whoabi/00whoabi.htm.

From a practical point of view, what can clinicians and government regulators do to improve cooperation?

Table 2 presents recommendations from the WHO *Guidelines for Achieving Balance* about how health professionals and drug regulators can cooperate through exchange of information and perspectives and establishment of mechanisms of communications and engagement.

Do health professionals have beliefs or attitudes that might interfere with addressing opioid availability?

Possibly. Misinformation about the addictive potential of opioids and confusing terminology have led to exaggerated concerns about the use of opioid analgesics and overly strict regulations that impede efforts to improve access to appropriate treatment for moderate to severe pain.

Decades ago, experts said that mere exposure to morphine would inevitably result in "addiction." At that time, addiction researchers studied the withdrawal syndrome that occurs when opioid use is stopped abruptly. Today in the field of pain management, we know that physical dependence is an expected adaptation of the body to the presence of an opioid analgesic, and that the withdrawal syndrome can be managed if the opioid is stopped. The WHO no longer uses the term "addiction." The current terminology is "dependence syndrome," which is a biopsychosocial condition, the markers of which are maladaptive behavior, compulsive use, and continued use despite harm. However, in referring to dependence syndrome, use of the term "dependence" by itself has the possibility of being confused with physical dependence. Under these circumstances, it is important to be clear in clinical and scientific communications whether one is referring to a diagnosis characterized by maladaptive behavior, or to physiological adaptation.

The notion that morphine should only be used as a last resort is based on an outdated view of opioids and addiction. Indeed, efforts to prevent dependence/addiction that were based on this now outdated understanding have led to excessively strict prescribing restrictions that impede access. Examples include strict limits on patient diagnoses that are eligible for opioid analgesics, restrictions on dosing and prescription amount, and complex prescription forms that require multiple approvals and are difficult to obtain. These matters are discussed more fully in the PPSG Internet course; articles about progress to remove barriers in a number of countries appear on the PPSG website.

If I want to assume more of a leadership role in my country, is specialized training available?

Yes. In addition to the Internet course, the PPSG sponsors an International Pain Policy Fellowship (IPPF), with support from the International Palliative Care

Initiative of the Open Society Institute and the Lance Armstrong Foundation. The purpose of the IPPF is to prepare leaders from low- and middle-income countries to become change agents, and to develop plans to improve patient access to opioid pain medicines in their countries. Fellows are selected through a competitive application process and spend a week in training with the PPSG and other international experts. In some cases, a representative of the NCA accompanies the Fellow to facilitate cooperation with the government drug regulators.

The Fellows study the Internet course, diagram and diagnose impediments in their country's drug distribution system, learn to use WHO tools to assess national drug control laws, and develop their own action plans to improve opioid availability and access. During the 2-year fellowship, the Fellows implement their action plans with technical assistance from the PPSG. Please visit the PPSG website for announcements, or go to http://www.painpolicy.wisc.edu/newslist.htm to sign up for email announcements from the PPSG.

Pearls of wisdom

- Today's regulatory requirements for "narcotic drugs" were developed long ago, well before pain relief became a priority, before opioids were designated essential medicines by the WHO, and at a time when morphine was thought to cause addiction in anyone exposed to it.
- More recently, the WHO and the INCB have encouraged governments to provide patients with trouble-free access to oral opioid analgesics, and the WHO has updated its definition of dependence syndrome. Still, opioid analgesics continue to be inaccessible to most of the world's population.
- The U.N. drug regulatory and health authorities have recognized the lack of availability of opioid analgesics, have urged governments to examine national laws and regulations for barriers to opioid availability, and have asked health professionals and the IASP to work together to cooperate to

Table 2
Examples of cooperation between government and health care professionals

Government regulatory authorities can:
Inform health professionals about trends in drug trafficking and abuse.
Explain the framework of drug control policy and administration in the country including how the estimated requirements for opioid analgesics are prepared.
Create mechanisms such as a task force or commission to examine ways that national drug control policy and its administration could help to improve availability and access while maintaining adequate control.
Endorse World Health Organization guidelines for management of pain.
Support national guidelines for pain management.
Inform health professionals about legal requirements and discuss any concerns.
Explore ways to provide an adequate number of outlets to maximize patient access.
Collaborate with other government organizations, e.g., in cancer and AIDS planning for services, and to support medical education, education of patients and the general public.
Health professionals can:
Provide the government with information about the needs for various opioids for pain management and palliative care in the country.
Identify needs to address any barriers in the regulatory system.
Provide information about modern pain management, current knowledge about opioid analgesics in treating pain, and knowledge and attitudinal barriers to their optimal use.
Demonstrate understanding of the international narcotic conventions and the obligation of governments to ensure adequate availability of opioid analgesics, while also preventing abuse and diversion.
Provide information about WHO guidelines that can be used in self-assessment of the national opioids control policy.
Assist in providing information to estimate the amounts of various opioids that are needed to satisfy actual needs.
Identify impediments and weaknesses in the distribution system that lead to shortages.
Support the government's efforts to obtain adequate personnel to administer drug control functions under the Single Convention.
Explain health professionals' concerns about prescription requirements and the possibility of investigation.

educate health workers and to ensure adequate patient access to pain relief.

- Pain and palliative care experts report that the absence of a clear statement about the governmental obligation under international agreements to ensure adequate opioid availability in national laws makes it difficult to convince regulators. PPSG studies show that the U.N. model drug control laws that should provide balanced guidance to governments also lack such language.
- Traditionally, most countries have used pethidine (meperidine) for pain relief, with the thought that such a short-acting opioid would be less addictive. But since the regulatory controls for morphine and other strong opioids are the same as for pethidine, it should be possible for health professionals and the NCA to figure out how to make available other opioids where they are needed.
- The resources provided in this chapter offer a starting point as well as encouragement to work with colleagues, professional organizations, and government to correct the conditions that block efforts to relieve pain and suffering.

In closing, here are a few tips:

Be alert to new opportunities and resources. There may be opportunities in your country for synergistic partnerships with government and nongovernment public health organizations that advocate the use of methadone for treatment of intravenous drug users to reduce the spread of HIV/AIDS. The international controls on morphine and methadone are the same, and the regulatory steps to make them available and accessible in a country should be similar to those for opioid analgesics.

The WHO is developing an Access to Controlled Medicines Program to provide additional support for efforts to improve medical access to opioid analgesics as well as other essential medicines that are controlled drugs.

Pain relief is becoming recognized as a human right. As the right to pain relief becomes more widely recognized, there may be additional opportunities for collaboration with human rights advocates. Human rights advocates understand that working with government is necessary. The work outlined here to evaluate and reform outdated drug control policies is an integral part of making the human right to pain relief a reality.

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Recommended websites

Pain & Policy Studies Group: www.painpolicy.wisc.edu/

World Health Organization: www.who.int/medicines/

International Narcotics Control Board: www.incb.org

International Association for Hospice and Palliative Care: www.hospicecare.com/