Featured Innovation

Improving Availability of Opioid Pain Medications:
Testing the Principle of Balance in Latin America

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Introduction

For a number of years, my colleagues and I have been working through a process to formulate an idea into a model that can be used to evaluate and then improve anti-drug abuse policies so they do not interfere with the use of opioid analgesics for pain relief. We refined this idea into the principle of "balance."

Our work started in Wisconsin and led ultimately to the development of policy evaluation guidelines that were endorsed by key agencies associated with the United Nations. Real world testing of the model with regulators and clinicians took place in several countries, including in Latin America.

Phase 1:
The Roots of Balance: Drug Diversion, Proposal to Legalize Heroin Prompts Collaboration Between Regulators and Clinicians

The principle of balance began to take shape in Wisconsin in the late 1970s due in part to an intergovernmental and multidisciplinary policy environment. I was administrator of the Wisconsin Controlled Substances Board (CSB), a state regulatory body established by the Wisconsin Legislature to manage the state's controlled substances policy. The CSB was unique among state agencies in that it was independent of any department, and its membership, by law, included a pharmacologist and a psychiatrist—recognition that drug regulatory decisions have scientific and clinical implications. I had previously been coordinator of a drug abuse treatment program where I had seen how "script doctors" could contribute to the drug abuse problem, and realized there was a lack of coordination among the government agencies that were supposed to address the problem. In response, the CSB developed a program to reduce the abuse of prescription controlled substances in the state.

The program was unique in several ways. Rather than establish additional prescription requirements as some states had, we formalized cooperation between a number of government regulatory agencies, including the CSB, Medicaid, the Medical and Pharmacy
Examining Boards, and the US Drug Enforcement Administration. We developed a systematic approach to analyzing and mapping data from a number of sources to identify the sources of diversion, including pharmacy thefts and physicians and pharmacists who prescribed or dispensed improperly. By the mid-1980s, the program successfully had reduced the illicit availability of prescription controlled substances in the state, and it had been recognized as an innovative model. In 1981, the Legislature officially added the diversion prevention and control program to the CSB’s permanent responsibilities.

A 1984 proposal in the US Congress to legalize one of the most stigmatized illicit drugs—heroin—stimulated the CSB’s interest in cancer pain relief. We simply could not understand why physicians and patients who already were reluctant to use morphine would suddenly embrace heroin as an analgesic. Pharmacologist member and CSB chairperson June L. Dahl, PhD, and I began developing the Wisconsin Cancer Pain Initiative (WCPI). At that time, Dr. Kathleen Foley, neurologist at Memorial Sloan-Kettering Cancer Center in New York City, was chairing a World Health Organization (WHO) expert committee that was preparing a global cancer pain relief program in which opioids such as morphine would be an essential component. Dr. Foley strongly encouraged our efforts to establish an initiative to improve cancer pain management. The WCPI was established in 1986 and was designated a WHO demonstration project; it became a model for other states to develop similar interdisciplinary pain initiatives.

The heroin proposal led us to explore more deeply the influences of drug abuse policy on pain management and opioid use. Indeed, Wisconsin physicians told us that they feared investigation by the Board for prescribing "too much" morphine. We had to admit that these fears could be due in part to the media coverage of the Board’s anti-diversion program and investigations of certain doctors. I learned first-hand that drug regulators can have a chilling effect on appropriate prescribing—a real, although unintended effect of the war on drugs. Later, we confirmed existence of these fears in a survey of Wisconsin physicians conducted by David Weissman. It became apparent that regulators and clinicians would need to learn from one another in order to improve pain management for patients.

The Board decided to improve the use of opioid analgesics that were already approved for medical use and easily available, rather than pursuing efforts to legalize heroin. By establishing the WCPI, the Board communicated to health professionals that it understood cancer pain was inadequately managed and that opioids were an essential part of cancer pain relief. We were strongly influenced by Charles S. Cleeland’s early work to identify barriers to cancer pain relief; we set out to identify more specifically the regulatory barriers affecting the prescribing and dispensing of opioid analgesics. Then we addressed these barriers by working with the state legislature and state medical and pharmacy boards to make several changes to achieve more balanced Wisconsin law and regulations.

Phase 2:
Developing a Method to Evaluate National Policies

In 1989, I moved to the University of Wisconsin Pain Research Group and WHO Collaborating Center directed by Dr. Cleeland, to pursue study of drug policies and pain

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management and develop models for policy evaluation. At that time, we defined "balance" simply as "preventing diversion and abuse of prescription drugs while assuring their availability for legitimate medical purposes." By 1990, my colleagues and I had concluded that federal controlled substances law was reasonably well balanced because it recognized that narcotic drugs were necessary, that their availability should be ensured, and that there were few unduly restrictive provisions. We also concluded that most state drug laws were not balanced. State drug laws emphasized the abuse potential of opioids but lacked recognition of their medical value; they also had more restrictions on prescribing than federal policy. For example, some states limited the amount of opiates that could be prescribed at one time, required cumbersome triplicate prescriptions, and used terminology erroneously, suggesting that patients who were physically dependent on opioids were addicts.

By 1992, I was learning from the late Robert T. Angarola, a Washington, DC lawyer with expertise in international drug policy, about the international narcotics control treaty called the Single Convention on Narcotic Drugs, 1961. Most governments are party to this treaty, which means that each government must make its national policies conform to the treaty. Even as the Single Convention was mainly focused on preventing trafficking in narcotics, it also made two critically important declarations about medical use of narcotic drugs that all governments are supposed to follow: narcotic drugs are indispensable for the relief of pain and suffering, and governments are obligated to ensure their adequate availability for all medical and scientific purposes [italics added]. Indeed, in 1989 the International Narcotics Control Board (INCB), the principal international narcotic regulatory authority responsible for implementation and monitoring of the Single Convention, had requested all governments in the world to evaluate their laws and regulations for unduly restrictive narcotics regulations that might interfere with use of opioids for cancer pain relief. Clearly, the INCB could be an ally with health professionals in efforts to improve the availability of opioids for cancer pain relief.

I started the Pain & Policy Studies Group (PPSG) in 1996, in part to pursue the study of international and national opioids policy. The WHO and the Pan American Health Organization (PAHO) designated the PPSG a Collaborating Center for Policy and Communications in Cancer Care. Dr. Jan Stjernswärd, director of the WHO Cancer Unit encouraged us to continue work on opioid availability and asked us to become involved in the Congressos of the Latin American Palliative Care Association. Consequently, we initially began testing our approach to evaluating policy according to the principle of balance in Latin America.

Two Case Examples

Colombia

Ms. Liliana De Lima, MHA, a highly respected leader in palliative care from Colombia, has been an important collaborator in this work. When I met Ms. De Lima, she was working to
obtain opioid analgesics such as morphine for the terminally ill cancer patients at her hospice called La Viga, in Cali, Colombia. This was no small task; in Bogotá, government officials in charge of the war on drugs were wary of making morphine available for medical use for fear it would be diverted and lead to another controversy about drugs. Ms. De Lima convinced them; she developed access to the regulators, described the effects of unrelieved pain and supported her argument with guidelines from WHO. She also developed the first state cancer pain initiative in Latin America, in her state, El Valle del Cauca, using the WCPI as a model.

For many of us in the United States, mention of Colombia often brings to mind illicit drugs. Now when I think of Colombia, I think of a country whose government is also working to make opioids available for cancer pain relief. This reflects the principle of balance.

**Mexico**

Ms. De Lima was a Fellow with the PPSG for one year in 1996. This was a valuable experience for us; we collaborated on a project to try out our early policy evaluation criteria on the national narcotics policies of Mexico. We already had been learning about the inadequate availability of opioids through research, participation in several pain conferences of the Mexican Association for the Study and Treatment of Pain, and meetings with the Mexico National Cancer Institute, as well as representatives of the Ministry of Health and its narcotic regulators. For this project, we obtained and analyzed Mexico's narcotics ("estupefacientes") laws and regulations. The results of this pilot indicated that we could use our approach to evaluate the policies of another country. For example, our analysis had identified the absence of certain key provisions, as well as the presence of unduly restrictive policies in Mexico narcotics regulations: a prescription for opioids could not be for more than a five-day supply; to obtain more, the patient had to make a written request to the national narcotics regulator in Mexico City. National policy also required physicians to use a complex triplicate prescription form that was available only in Mexico City.

In 1997, we prepared a preliminary analysis that included suggestions for modifying these policies. We disseminated these results to health professionals and regulators who were working to improve national narcotic regulations in Mexico.

Then, in 1997, PPSG sponsored a consultation for Dr. Araceli Garcia, the chief narcotics regulator, Dr. Sylvia Allende, a palliative care physician from the Mexican National Cancer Institute, and Mrs. Cathy Carvell, a volunteer nurse and pain relief advocate working with Dr. Allende. All three visited the PPSG for a week. We reviewed INCB and WHO resource materials that were available in Spanish, and discussed (in Spanish with translation) the medical need for opioids, Mexico national policies, and our analysis of them. Dr. Garcia was very interested in comparing the drug regulatory system in Mexico with the US system. We got to know one another, and together we developed a better understanding of the importance of national policy to permit patient access to opioid analgesics. Soon thereafter, the Mexican government eliminated the five-day requirement, simplified the prescription forms, and made them available in all the states of Mexico. We have been told that the week
of regulator-clinician consultation contributed to the policy changes that were made; of course, there were many other factors, including contemporaneous national meetings in Mexico aimed at reforming national opioids policy. This experience confirmed not only the value of our policy analysis, but it also reaffirmed the value of cooperation between clinicians and regulators. Subsequently, our national-level experience was enlarged with similar projects in China, India, Indonesia, and Malaysia.\textsuperscript{14,15}

**Phase 3: Engaging with International Organizations**

**International Narcotics Control Board (INCB)**

The INCB can have a tremendous effect on national governments' narcotics policy and administration. In 1995, the INCB asked me to assist in a survey of all governments to assess the reasons for low availability of opioid analgesics and prepare a report with recommendations. Sixty-five governments responded to the survey. The findings were distressing: governments reported that opioids were not sufficiently available for medical purposes; the injectable forms of morphine were more available than the oral form that was recommended by the WHO; many hospitals with cancer programs did not stock morphine; there were many shortages of opioids in hospitals so that opioid pain medications were not available to patients.

Keeping in mind that the INCB monitors the degree to which governments are in compliance with the Single Convention, it was clear that the INCB's conclusions and recommendations could be influential. The report\textsuperscript{16} was published in English, French, and Spanish and was sent to the narcotic authorities of every government in the world. The report communicated to government narcotic regulators in official terms the need to have balanced narcotics policies. The INCB requested that governments evaluate whether their national laws recognized that medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering—a key element of the principle of balance. The Board observed that "...while there have been efforts by some governments to ensure the availability of narcotic drugs for medical and scientific purposes, it appears that many others have yet to focus on that obligation." They went further, commenting on the administrative capability of every country's national drug control program: "... an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes."\textsuperscript{17} Additionally, the report recommended that governments and health professionals cooperate to ensure that opioids are adequately available while preventing abuse.

**World Health Organization**

The interest of international organizations in the problem of inadequate availability of opioids for cancer pain relief continued to grow. The WHO asked PPSG for assistance in preparing a publication about cancer pain relief that would focus for the first time on opioid availability.\textsuperscript{18} This small booklet has been translated into 17 languages, including Spanish. Its
value is that the WHO, a key source of guidance for health professionals throughout the world, re-emphasizes that opioid analgesics must be available for cancer pain relief; it explains regulatory control and distribution system for opioids, discusses the need to identify and address barriers, and strongly encourages regulators and health professionals to communicate.

By the late 1990s, there was little doubt that the principal international organizations were on record and positioned correctly and consistently in terms of their overall policy. The official reports had been sent to governments. Is it reasonable to expect national governments to take action upon the receipt of a report? Exactly how does one evaluate a national drug control law? What do you look for? How do you tell if the law has the correct provisions; how do you identify reliably the regulatory barriers? How should we engage with health professionals?

Technical support was available from UN drug control authorities to help governments evaluate national policies about abuse and trafficking of illicit drugs, but there was not as yet any guidance for the other side of the balance equation. PPSG's prior work with regulators and clinicians in Mexico and other countries placed us in a unique position to suggest the next steps.

Developing Guidelines to Achieve Balanced National Policies

In 1998, PPSG began exploring with the WHO Office for Essential Drugs and Medicines Policy the feasibility of developing guidelines for governments and health professionals to evaluate national drug control policy. This WHO Office had for a number of years supported educational programs for regulators about cancer pain relief and opioid availability. Mr. Tokuo Yoshida, a former narcotic regulator with the Japanese government, agreed to support a project to develop guidelines. Our preparations were systematic. First, with the help of Ms. Maria Monterosso, a lawyer from Colombia, we conducted an in-depth review of all the treaty language and relevant reports published by the UN, INCB, and WHO to identify language relating to the principle of balance. Then, we identified and described in more detail the principle of balance and prepared criteria—a series of prescriptive "should" statements that could be used to evaluate national policy.

"The Central Principle of 'balance' represents a dual imperative of governments to establish a system of control to prevent abuse, trafficking, and diversion of narcotic drugs while, at the same time, ensuring their medical availability. While opioid analgesics are controlled drugs, they are also essential drugs and are absolutely necessary for the relief of pain. Opioids, including those in the therapeutic group of morphine, should be accessible to all patients who need them for relief of pain. Governments must take steps to ensure the adequate availability of opioids for medical and scientific purposes. These steps include empowering medical practitioners to provide opioids in the course of professional practice, allowing them to prescribe, dispense and administer according to the individual medical needs of patients, and ensuring that a sufficient supply of opioids is available to meet medical..."
demand.

When misused, opioids pose a threat to society; a system of control is necessary to prevent abuse, trafficking, and diversion, but the system of control is not intended to diminish the medical usefulness of opioids, nor interfere in their legitimate medical uses and patient care. Indeed, governments have been asked to identify and remove impediments to the availability and medical use of opioid analgesics.20

Here we called on our earlier experiences in policy evaluation and cooperation between regulators and clinicians in Mexico and other countries.21 To make the guidelines practical, we included a checklist that regulators could use to assess their own national policies, as well as suggestions for how to use the guidelines.

To further enhance the credibility of the guidelines, WHO and PPSG brought together a working group of experts to review the guidelines. The group included a representative of the INCB Secretariat, as well as pain experts and national narcotic regulators from around the world (Table 2).

Table 2: Members of World Health Organization Working Group

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<thead>
<tr>
<th>Name</th>
<th>Organization</th>
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<tbody>
<tr>
<td>Tokuo Yoshida</td>
<td>World Health Organization</td>
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<tr>
<td>David E. Joranson</td>
<td>World Health Organization Collaborating Centre</td>
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<td>Carmen Selva</td>
<td>International Narcotics Control Board Secretariat</td>
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<td>Liliana De Lima</td>
<td>Pan American Health Organization</td>
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<td>Romesh Bhattacharji</td>
<td>Narcotics Commissioner of India</td>
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<tr>
<td>Gu Wei-Ping</td>
<td>State Drug Administration, People's Republic of China</td>
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<tr>
<td>Claudio Blengini</td>
<td>Pain and Palliative Care Specialist, Italy</td>
</tr>
<tr>
<td>Philip Emafo</td>
<td>WHO Expert Advisory Panel on Drug Dependence, Nigeria</td>
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<tr>
<td>Alan Nixon</td>
<td>Palliative Care Specialist, Saudi Arabia</td>
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**WHO Guidelines for Achieving Balance**

The new WHO document which resulted from this work, *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment* (referred to here as "the Guidelines") was issued in 2000 and quickly translated into Spanish, French, and Italian.22 The 16 Guidelines cover three
distinct topic areas: (1) assessing national policy, (2) estimating annual requirements for opioids, and (3) administering an effective system for distributing opioids to the patients. The Guidelines emphasize the need to define responsibility at every level of the drug distribution system, (importer, manufacturer, distributor, hospital, pharmacy, hospice, palliative care program, physician) in an effort to ensure that opioid analgesics are available to all patients who need them. The Guidelines encourage governmental representatives of narcotic regulation and cancer control to work with medical institutions and health professionals in palliative care to obtain information about the needs for opioids, and to make changes that may be necessary in national policies and administration to achieve the important public health goal of relieving pain. In addition, the document includes the following suggestions for how regulators and clinicians could work together to evaluate their national policies and improve opioid availability and patient access:

- As an educational tool to learn about the role of national government and its drug control policy with respect to making opioid analgesics available for pain relief
- As a standardized policy evaluation tool to identify strengths and weaknesses in national drug control policy
- As a method to formulate new policies or improve existing policies

In 2002, the INCB gave its official endorsement to the Guidelines.23

But of what value are policy guidelines if they are not put into practice, and only are put on the shelf? Our first effort to meet this challenge and breathe some life into the guidelines was in Latin America.

Phase 4: Guideline Implementation: A Workshop for Latin American Regulators and Clinicians

Ms. De Lima and I had for several years been working with colleagues in Latin America to raise awareness about the need in this region to identify and address regulatory issues as a part of palliative care. We did this by presenting workshops, sometimes including national narcotic regulators, at the conferences of the Latin American Association for Palliative Care.24,25 This activity did contribute to awareness of regulatory barriers in several countries, and even some progress in regulatory reforms. However, we also concluded that this approach was not strong or direct enough to produce very much change because it lacked specificity and cooperative work between regulators and clinicians.

While participating in the 1998 palliative care Congresso in Concepción, Chile, organized by Dr. Eduardo Bruera, Ms. De Lima and I gave a proposal to the head of cancer control for PAHO that PPSG and PAHO collaboratively sponsor a workshop to improve the capacity of Latin American governments to ensure the availability of opioid analgesics for palliative care. This effort would be the first time that health professionals and narcotic regulators would be brought together in this way in Latin America. In addition, it would be a cross-
cultural event, bringing together North and South American professionals, to conduct a workshop in Spanish, with all of the challenges such international work implies.

We chose PAHO as a partner in this venture for two reasons. First, to be able to address narcotic control policies, the workshop needed the participation of narcotics regulators in their official capacity as representatives of government. As the arm of the WHO in the Americas, PAHO has direct relationships with governments and can invite them through official channels to participate in such meetings. Second, to be credible with national Ministries of Health, the workshop needed the imprimatur of the WHO. Further, PAHO had developed an interest in opioid analgesics; with Ms. De Lima's assistance, PAHO had been developing a WHO/PAHO palliative care plan for the region and had recognized that the success of this initiative would depend in part on the adequate availability of opioid analgesics for patient care.

The workshop proposal built on our previous work to develop policy evaluation guidelines, but now the task was to bring the right people together, to use the guidelines to identify regulatory barriers, and to develop national action plans to improve national policies and ultimately, opioid availability. PAHO accepted the proposal and began planning. Six Andean countries were selected: Bolivia, Chile, Colombia, Ecuador, Peru, and Venezuela. PAHO proceeded to invite a total of 28 regulators and health professionals in cancer and palliative care from the region.

The three-day workshop was held in Quito, Ecuador in December 2000, shortly after the Guidelines were issued; a Spanish translation was prepared for the workshop. The workshop objectives were to sensitize regulators about the need for balanced policy, to educate clinicians about the necessary steps to obtain opioids, and to develop work plans to ensure their availability to patients for palliative care. (In our discussions about opioids for pain, we used the term "opioides" rather than "estupefacientes," preferring the scientific rather than legal term and to move away from erroneously perpetuating the notion that these drugs' mechanism of action is "stupefaction.")

The faculty was comprised of representatives of the WHO, INCB, PAHO, and PPSG. We invited the INCB to clarify how the international regulatory system should work to ensure the availability of opioid analgesics and to emphasize the need for balanced national drug control policies. As the key international narcotics regulatory agency to which these regulators must provide estimates of need and reports of consumption, its presence lent powerful credibility to the notion of balance. In this way, national narcotic regulators who are accustomed mainly to control issues would know there was support at the highest international level for identifying policies that interfered with patient care and they would know first-hand that the INCB was recommending that governments work to make narcotic drugs more rather than less available in their countries.

'Taller de Reguladores: Asegurando Disponibilidad de Analgesicos Opioides para Cuidados Paliativos (Regulators' Workshop: Assuring Availability of Opioid Analgesics for Palliative Care).

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Content and Organization of the Workshop

Over the course of three days, the program included a number of elements. Introductory plenary presentations addressed the prevalence of cancer in Latin America, the WHO program for cancer and palliative care, the role of opioids as essential medicines in pain relief and palliative care and trends in their availability in the Andean region, clarification of issues relating to drug dependence in relation to medical use of opioids, and the role of the Single Convention and the INCB in availability of opioids. Then, the participants gave prepared talks about the status of opioid availability and legal requirements for prescribing opioids in their respective countries. The participants reviewed extensive background materials they had been sent before the meeting. They identified regulatory issues such as the requirement to use a special prescription form and restrictions on the amount of a prescription. These plenary talks were followed by a review of each guideline, with discussion about how they contributed to ensuring availability and patient access through balanced national policies, annual estimation of the amounts of opioids needed in the country for medical purposes, and administration of an effective drug distribution system.

With this preparation, the participants split off into country teams and selected a coordinator and a reporter. Each country team completed the Guidelines checklist to identify regulatory barriers to opioid availability. After this, the teams remained together, first identifying the problems and barriers, and then developing action plans, including objectives, priorities and timelines, and needs for assistance. The faculty circulated among the teams, checking on progress and offering suggestions. The workshop concluded with reports about the action plans from each country team. The program was interspersed with coffee breaks, meals, and a reception.

Each country team came to the meeting well prepared, some extensively so, and eager to explore the topic. They gave a good picture of the situation in their countries. It was clear that some countries had begun to make progress in palliative care and had already been trying to address regulatory barriers. The immediate achievement of the workshop in bringing together these players for three consecutive days of work was to make opioid availability for palliative care a more visible priority and to begin empowering the teams to work together to identify and solve problems. Several dynamics occurred that are worth noting. Most participants were personally interested in improving cancer pain relief in their country; for them the workshop validated their interest and pointed out ways they could help. For some this was a new area of public health and drug control about which they were provided a conceptual framework, practical tools for making change as well as contact with the people who could help make change.

Since the meeting in Quito, Ms. De Lima and staff members of the PPSG have had periodic communication with the team leaders. In 2002, we had the opportunity to meet again with most of the country team representatives during a Latin American palliative care conference in Guadalajara, Mexico where we gave an update on progress and issues in opioid availability in the region.27 PPSG sponsored an informal get-together to hear about some of the progress since the workshop in Quito:

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• In Venezuela, the Ministry of Health had held a national workshop on the importance of pain relief and opioid availability, in which both health professionals and regulators participated.

• In Peru, legislation had been adopted that changed the amount of opioid medication that could legally be prescribed to an outpatient at one time from a 24-hour supply to a 15-day supply.

• In Colombia, to follow up on their action plan, an executive group was formed, which identified and removed barriers in the drug distribution process, and created a National Network of Pain Relief to address opioid availability through regional workshops and training of physicians about opioids.

Despite the availability of international guidelines, national leadership and workshops, making change in policy is a slow process. Change is sometimes hampered by the difficulty busy professionals have in taking on additional priorities; frequent elections usually result in changes in governmental personnel; competition (or lack of cooperation) between key groups and individuals can interfere with the power of consensus. In my experience, the factors underlying slow progress are similar throughout the world: the generally low priority of pain management and palliative care in health care and in professional education, lack of public awareness, insufficient resources and high medication costs, regulatory barriers, and erroneous beliefs about opioids that impede the willingness of governments and health professionals to modify their policies and practices.

Phase 5: Looking Ahead

Have we progressed from where we were 10 or 15 years ago? Yes, we have made progress. We no longer rely on conferences to achieve our objectives. Our understanding of regulatory barriers is better. We have a template—the WHO Guidelines—for evaluating national policy on opioid availability that has been approved by the WHO and the INCB. We have a growing body of experience demonstrating that engaging clinicians and regulators in a cooperative process to address policy can influence the governmental policy change process. However, although some Latin American countries have changed their policies and increased their use of opioids in the last ten years, Figure 1 shows that in 2000, most were below the global mean of 5.5 milligrams per capita.

The next crucial step to improve patient access to pain medications in Latin America is refinement and implementation of the action plans made in Quito, but this step is endangered. Without dedicated resources, it is difficult to maintain follow-up communication to monitor progress and provide encouragement and technical assistance. For example, it would be useful to have support for developing Spanish-language materials to monitor opioid consumption trends in addition to periodic in-country meetings with the teams to go over progress and issues and plan next steps. It would be useful to have workshops at the national and state level to focus attention on the practical aspects of
patient access, including for home care, and to define more specifically the type and amounts of opioids that are needed for pain medications in the programs that are prepared to use them. Technical assistance and training are necessary to prepare clinicians and programs to use opioids and to inform their government of the quantities of opioids that will be needed. We should devise economically sustainable methods to meet those needs, as is being done in India. The challenge is to develop the resources necessary to advance past this initial progress and to make the relief of pain a reality for patients in Latin America, as well as in other regions of the developing world.

**In Sum**

We have learned from and built on our early experiences. Since the workshop in Quito, PPSG and the WHO have sponsored two more regional opioid availability workshops for teams from six countries in Eastern Europe and five in Sub-Saharan Africa. Initial indications are that our approach of guideline-regulator-clinician workshops can be successful in changing policy. Time and monitoring will tell whether regulators and clinicians will implement the action plans and improve availability of opioids to the patients who need them.

Our belief is that change in policy and availability depends upon practical policy guidance and developing meaningful partnerships among the stakeholders in palliative care and drug regulation. We have the policy guidance. Now we need the partnership. **These two groups must talk to each other before opioids will be adequately available for patient care.** The partnership must exist at several levels: international, regional, national, and state. This partnership is particularly essential if misuse and diversion of opioid analgesics occurs—regulators who understand the use of opioids to relieve pain are less likely to take actions that interfere with medical practice and patient care. While there is now some recognition of the need for these partnerships, there is a very long way to go before patients have adequate access to adequate pain relief. Readers' suggestions are welcome.

**References:**


Figure 1: Global Per Capita Consumption of Morphine, 2000.