The World Health Organization Paves the Way for Action to Free People from the Shackles of Pain

Willem Scholten, PharmD, MPA*

Helena Nygren-Krug, LLB, LLM, LLM†

Howard A. Zucker, MD, JD‡

For about 80% of the world's population, pain relief when needed is a right yet to be realized. If policies on opioid use were better balanced to enable access to pain relief, rather than merely focusing on potential abuse, human suffering could be significantly and readily alleviated.

Barriers that prevent people from accessing pain medications stem from efforts to limit opium trade (mainly for nonmedical purposes) because of its detrimental effects on the populations of many countries, especially in 19th century Asia. The Shanghai conference of 1919 was a first step towards international control of opium. In 1912, the first Opium Convention was signed in The Hague, Netherlands. Since then, governments appear to be primarily concerned about the possibility that people would become dependent on psychoactive substances and about the harm that these could do to them. Often, they seem to have forgotten about the medical benefit of these substances.

In the decades that followed, more international drug conventions and national and local drug legislation were adopted. We can now see evidence that these regulations have not sufficiently prevented people from taking drugs and becoming dependent on them. Nevertheless, many countries have implemented the treaties in their domestic laws more strictly than the conventions require, impeding access to controlled medicines for legitimate medical purposes.

At the same time as the legislative process aimed at preventing drug abuse evolved, the fear of drug dependence spread in society, both among health professionals and ordinary people. Physicians started avoiding prescribing opioids and lost the knowledge of how to use them. A number of medical schools no longer teach opioid prescribing. Myths began to grow around opioid medication. Doctors inexperienced in the use of opioids did not know how to initiate, titrate, and withdraw the medication. Faced with undesirable outcomes in patients (e.g., respiratory depression after a rapid increase in dose), physicians became reluctant to prescribe these medicines. This led to further mystification, including the widespread belief that morphine hastens death, although this has been refuted (1). One may argue, conversely, that freedom from pain prolongs life.

A few countries have good access to medicines that are controlled under international drug conventions[1] whereas a number of countries have mediocre access. However, in most countries, controlled medicines, and especially opioids, are hardly available, or not at all available. Figure 1 shows the legal per capita consumption of morphine for each country. It clearly shows that only 10–20 countries have good or reasonable access. In all other countries, including in a number of rich countries, availability is

From the *Departments of Medicines Policy and Standards; †Sustainable Development and Healthy Environments; and the Cluster of ‡Health Technology and Pharmaceuticals, World Health Organization, Geneva, Switzerland.

Accepted for publication April 5, 2007.

Address correspondence to Willem Scholten, PharmD, MPA, Technical Officer, Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland. Address e-mail to schottenw@who.int.

DOI: 10.1213/01.ane.0000267542.72315.34

[1]Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; Convention on Psychotropic Substances, 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

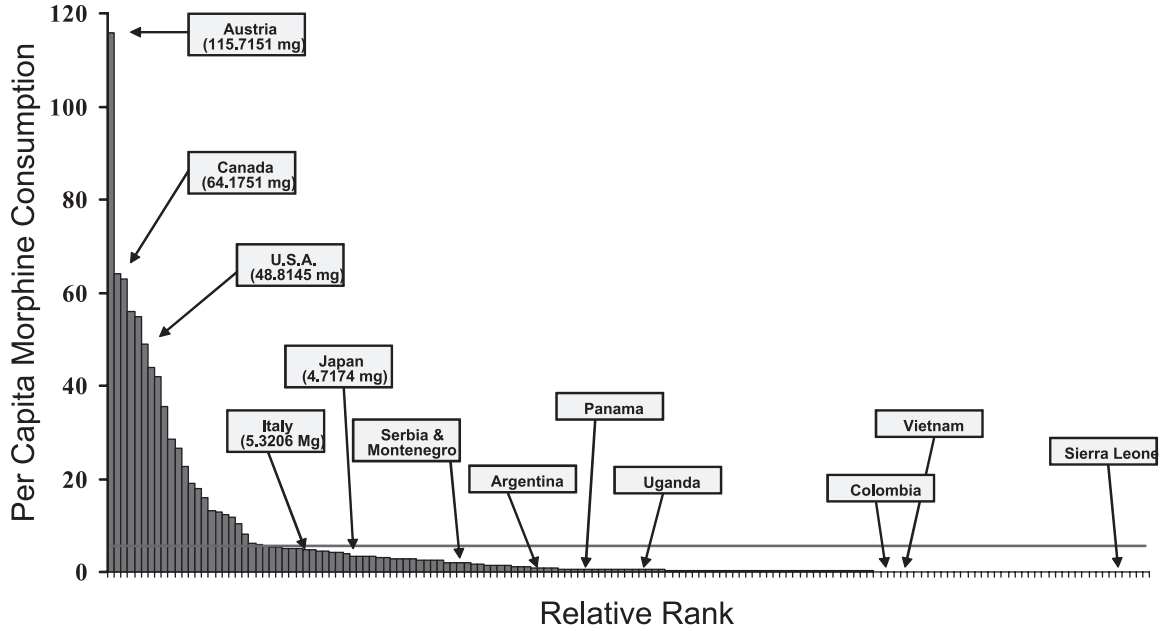

Figure 1. Global morphine consumption per capita, 2004. The global mean (5.67 mg per capita) is calculated by adding the individual mg/capita statistics for all countries and then dividing by the number of countries. Data from 155 countries. Source: International Narcotics Control Board. United Nations Demographic Yearbook. By: Pain and Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2006.

a problem. Admittedly, this graph does not show other opioids used in medicine, but drafting a graph that would include those other opioids would not change the essence.

Drug control goes beyond opioids for analgesics. Controlled medicines also include opioids for the treatment of opioid dependence, and some nonopioids. Preliminary estimates show that, every year, 4.8 million people suffering from moderate to severe pain caused by cancer do not receive treatment. For moderate to severe pain experienced during end-stage Acquired Immuno Deficiency Syndrome (AIDS), an estimated 1.4 million receive no treatment annually.[2] For other causes of pain, we can assume that those estimations are in the millions.

Substitution therapy of opioid dependence decreases the mortality rate of opioid-dependent patients considerably. (In France, a reduction of more than 90% was observed after its introduction in the 1990s.)[3] It also decreases the transmission of bloodborne diseases like HIV and hepatitis C virus since it reduces the use of contaminated needles. The use of injected drugs and contaminated needles is known to be the cause of new infections in 30% of all new HIV cases outside sub-Saharan Africa (420,000 cases annually)[4] With regard to the medicines used in emergency obstetric care no accurate figures have yet been collected, but access to ephedrine and ergometrine are reportedly problematic.

The health impact of the lack of access to controlled medicines can be expressed even more forthrightly: cancer causes 12% of all deaths and 80% of terminal-stage cancer patients suffer moderate to severe pain. Of terminal-stage patients, 80% will have no access to the analgesics they need. This means that the lives of 7.7%[5] of the world's population, or 576 million of the roughly 6 billion people living today, will end without adequate analgesia. Similar estimates suggest that a further 36 million HIV patients die in pain.[6]

In summary, of the people living now, at least 600 million will experience one or more of the negative health impacts mentioned above during their lifetime as a result of not being able to obtain medicines controlled under international drug control treaties.

Although the drug conventions are often implemented in a way that hampers access to these medicines, their stated objective includes the availability of controlled medicines in medical practice. For example, the Preamble to the Single Convention on Narcotic Drugs, i.e., the convention that regulates most opioids, says "Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes . . . ." The Preamble of the Convention on Psychotropic Substances uses similar wording and adds ". . . that their availability for such purposes should not be unduly restricted . . . ."

[2]Based on number of cancer and HIV/AIDS deaths in 2001, World Health Report 2002 and INCB statistics.

[3]Information from Dr. Patrizia Carrieri, INSERM, Marseille, France.

[4]UNAIDS Global Facts and Figures 2006.

[5]0.12 multiplied by 0.8 multiplied by 0.8.

[6]These are rough estimates, that would need to be adjusted for increasing mortality from cancer and pain from other causes.

Another important legal instrument, to which 193 states are parties, is the constitution of the World Health Organization (WHO). It recognizes "the enjoyment of the highest attainable standard of health [as] one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[7] It defines health broadly as including physical, social and mental well-being. Importantly, in this context, when the United Nations Committee on Economic, Social, and Cultural Rights issued its interpretation of the above, it included access to essential medicines as part of the state parties' core obligations and referred explicitly to the WHO Model List of Essential Medicines.[8–10] This list includes those medicines that satisfy the priority health care needs of the population and are intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Another important development came in 2005, when the World Health Assembly, the highest governing body of the WHO, adopted a resolution asking WHO and the International Narcotics Control Board (INCB) to help countries to improve access to opioid analgesics.[11] A similar call was made by the Economic and Social Council.[12] In response, WHO developed the *Access to Controlled Medications Program* (ACMP) in consultation with the INCB.[13] With INCB, WHO agreed that WHO will operate the program solely.

The program recognizes similar obstacles to access as those identified by Brennan et al. in this issue of Anesthesia and Analgesia. (2) As a result, the ACMP will address the broad range of the impediments to appropriate use of controlled medications, including.[14]

- improving access to effective treatment by reviewing legislation and administrative procedures
- educating health care professionals, law enforcement staff and others regarding current best practices and scientific evidence, and encouraging their adherence to these
- developing normative clinical guidelines
- promoting a better understanding of international drug control treaties
- helping to ensure an uninterrupted supply of controlled medications at affordable prices
- assisting governments to make realistic estimates of future needs for opioid analgesics and to compile reliable statistics on past consumption
- performing surveys on the accessibility, availability, affordability and use of the medicines and substances involved.

Because access to controlled medicines is wider than access to opioid analgesics only, the program will include all medicines controlled under the drug conventions listed on the WHO Model List of Essential Medicines. These include the medicines and medicine classes of opioid analgesics, opioids for substitution therapy of opioid dependence, ephedrine and ergometrine, benzodiazepines, and phenobarbital. These medicines are used in many areas of medicine, including oncology, palliative care (for cancer, HIV patients, and others), anesthesiology, surgery, trauma, treatment of dependence, neurology, obstetrics, psychiatry, and general medicine. Basically, the obstacles to address are the same for all these areas of medicine and therefore, the program will cooperate with all these medical specializations and with many others involved, including patients, pharmacists, and nurse associations.

As the numbers of affected patients make clear, impeded access is a huge problem. Therefore, the ACMP will involve other organizations to enable the work to take place on a scale that can make a real difference. WHO is currently developing the operational plan for the first 6 yr of the program. However, it is expected that it will take a much longer period to reach the more than 150 countries where access to controlled medicines is a problem. Initially, the ACMP will work in countries where change has begun to take place in one way or another, and will use the experience of countries, such as Romania, Uganda, and some Indian states, that have made important improvements over the past year. Gradually, the program will move on to other countries. If improvement were to depend entirely on the actions of the ACMP, global change would take an estimated 15–20 yr. It is hoped that, at a certain stage, countries will copy the successful efforts of other countries on their own initiative.

For too long now, pain relief has remained a distant reality for millions of people. The barriers are many, and stem mainly from the skewed focus on limiting potential drug abuse rather than on relieving human suffering. But there are also widespread myths that need to be dispelled, such as the idea that newborns do not feel pain. Although the signals that children

[7]Off. Rec. Wld Hlth Org., **2**, 100. (Accessed through www.who.int/governance/eb/constitution/en/index.html).

[8]International Covenant on Economic, Social and Cultural Rights, Article 12. (Accessed through www.ohchr.org/english/law/cescr.htm).

[9]General Comment 14, on the right to the highest attainable standard of health (art. 12), 2000. (Accessed through www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument).

[10]WHO Model List of Essential Meds, 14th Edition, Geneva, 2005. (Accessed through www.who.int/medicines/publications/essentialmedicines/en/index.html).

[11]Resolution WHA 58.22, 2005. (Accessed through www.w9ho.int/gb/ebwha/pdf_files/WHA58/WHA58_22-en.pdf).

[12]Resolution ECOSOC 2005/25. (Accessed through www.un.org/docs/ecosoc/documents/2005/resolutions/Resolution%202005-25.pdf).

[13]WHO, Framework of the Access to Controlled Medications Program, 2007. (Accessed through www.who.int/medicines/areas/quality_safety/AccessControlledMedicinesProgr.Framework.pdf).

[14]The ACMP often uses the word medications to include the whole process of making medicines available from the beginning to the end, the administration of medicines inclusive.

give when in pain may be different from those of adults, thus making the diagnosis more challenging, the best interests of the child must prevail[15] and relief must be provided.

The human suffering due to lack of pain relief is an affront to human dignity. Every effort must be made to remedy this situation. WHO, through its ACMP, will support governments in the realization of their obligation under the right to "the enjoyment of the highest attainable standard of health," to make essential medicines accessible. WHO welcomes collaboration with others in this important endeavor.

[15]The principle of the best interest of the child to be a primary consideration and guide all actions is enshrined in the UN Convention on the Rights of the Child (1990).

REFERENCES

1. Porthenoy RK, Sibirceva U, Smout R, Horn S, Connor S, Blum RH, Spence C, Fine PG. Opioid use and survival at the end of life: a survey of a hospice population. J Pain Symptom Manage 2006;32:532–40.
2. Brennan F, Carr DB, Cousins MJ. Pain management: a fundamental human right. Anesth Analg 2007;105:205–21.