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Special Article

Ensuring Opioid Availability: Methods and Resources

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Abstract
The pain and palliative care fields are encouraged to learn about government drug control policy and to engage with their governments to examine these policies and their implementation in order to address impediments to patient access to pain management. Although pain management is a necessary part of palliative care, it is often impossible because strict national and state regulations block access to opioid analgesics. It is important for us to know that in adhering to international drug treaties, governments often concentrate on drug control to the exclusion of their obligation to ensure opioid availability for medical and scientific purposes. Indeed, international health and regulatory authorities are increasingly concerned about wide disparities in national consumption of opioid analgesics and have called on governments to address barriers in their national laws and regulations that govern the prescribing of opioid analgesics. The Pain & Policy Studies Group (PPSG) has developed methods and resources to assist governments and pain and palliative care groups to examine national policies and make regulatory changes. Romania, India, and Italy are examples. The PPSG is developing several new resources, including a training program for Fellows from low- and middle-income countries, enhanced support of collaborators working on opioid availability, an internet course in international pain policy, an improved website with policy resources and country profiles, and new approaches to the study of opioid consumption indicators.

Key Words: Opioid analgesics; pain management; pain policy; palliative care

Introduction

Established in 1996 at the University of Wisconsin Comprehensive Cancer Center (now the Paul P. Carbone Comprehensive Cancer Center in the University of Wisconsin School of Medicine and Public Health), the Pain & Policy Studies Group (PPSG) has been developing methods to evaluate and improve national policies that govern availability and access to the medicines that are essential for relieving severe pain throughout the world. The PPSG was recently redesignated as a World Health Organization (WHO) Collaborating Center (WHOCC) until 2010. This article summarizes policy evaluation methods and their application in several countries and describes additional resources PPSG is developing to support improved access to pain relief medicines. (This article addresses policy evaluation in countries other than the USA; for results of PPSG's evaluation of policy in the USA, please see http://www.painpolicy.wisc.edu/Achieving_Balance/index.html.)

Why Concentrate on Opioid Analgesics?

More than 20 years ago, international health authorities concluded that most pain due to cancer could be relieved using a simple analgesic method and that every national government should institute a cancer pain relief program.[1] The WHO recommended an analgesic method that has also been endorsed for relief of pain due to HIV/AIDS.[2] The method depends on the availability and patient access to morphine and other opioids.

Recognizing that opioids are controlled strictly as narcotic drugs because of a potential for abuse and drug dependence, the WHO recommended that governments evaluate their drug control policies and practices to ensure that patients receive the opioid medications that are necessary for pain relief,[3] and even encouraged health care workers to report to the appropriate authorities any instance in which oral opioids are not available for cancer patients.[1]

International health and regulatory organizations monitor opioid consumption reports made by national governments as an indicator of pain treatment. The International Narcotics Control Board repeatedly has expressed concern about the disparity in opioid consumption: most countries have low consumption and a subset of developed countries consume the vast majority of the supply.[4] Most governments of the world have also expressed concern: the World Health Assembly and the United Nations Economic and Social Council have recently adopted resolutions calling on all governments to take steps to ensure the availability of essential medicines, particularly opioids.[5, 6]

It is important to note that governments must adhere to specific provisions of the United Nations treaty that regulates opioids: the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol.[7] Most governments are familiar with the drug *control* requirements; however, few observe the mandate to ensure *availability* of controlled drugs for medical and scientific purposes.

Indeed, the fact that governments regulate essential opioid analgesics as narcotic drugs is precisely the reason why those who are dedicated to improving pain relief and palliative care for HIV/AIDS and cancer *must* learn about the drug regulatory system and prepare to work with their governments. As expressed so clearly by the WHO:

"A palliative care program cannot exist unless it is based on a rational national drug policy, including…regulations that allow ready access of suffering patients to opioids."[8] (p. 87)

Any attempt to address adequate availability and accessibility of opioid analgesics should take a public health systems approach, the elements of which parallel those of patient care: *examination* of national and sometimes state-controlled drug policy and distribution systems; *diagnosis* of weaknesses and blockages; prescription of the necessary *treatments*; *monitoring* of outcomes; and re-treatment if necessary. The distribution system is only as strong as its weakest link. Fig. 1 illustrates the basic elements of an opioid distribution system in which information about the requirement for opioids moves upward from the patient, and the adequate amount of medications move downward.

In 2000, the WHO published a document aimed at improving availability of opioid analgesics in the world, titled "Achieving Balance in National Opioids Control Policy: Guidelines for Assessment."[9] Now available in 22 languages (Arabic, Bulgarian, Chinese, English, French, German, Hindi, Indonesian, Italian, Lithuanian, Mongolian, Polish, Portuguese, Romanian, Russian, Serbian, Spanish, Swahili, Tagalog, Turkish, Ukrainian, and Vietnamese), this document provides 16 criteria that can be used by national governments and health

professionals to assess the national opioids control policies and their administration to determine if there are undue restrictions, and if they contain the provisions, procedures, and cooperation that are necessary to ensure the availability of opioid analgesics. The guidelines are derived from the international principle of "Balance" in drug control policy, which asserts that governments have an obligation not only to prevent drug abuse, but also to ensure the availability of opioid analgesics for medical purposes, and further, that efforts to prevent drug abuse and diversion must not interfere with the adequate availability of opioid analgesics for patients' pain relief.

Example of a Rational National Process: Romania

A systematic collaborative effort between palliative care experts and the PPSG was undertaken to improve opioid availability and patient access in Romania, with very promising results.[10] Following a six-country workshop about opioid availability for palliative care in Budapest, Hungary in February 2002, the PPSG identified Romania as having good potential to address regulatory barriers, evidenced by a continuing trend of very low consumption of opioid analgesics in spite of steady development of palliative care in the country, and unduly strict narcotic regulations that blocked access to opioid pain medications. There were well-trained palliative care professionals who were eager to work with the government to evaluate policy and improve patient access to pain medications. And finally, the Ministry of Health (MOH) announced its decision to appoint a special MOH Commission to explore what regulatory changes were necessary to improve patient access.

In 2003, with funding from the Open Society Institute (OSI) and the United States Cancer Pain Relief Committee, the PPSG devoted three years to a project that included Romanian health care practitioners, the MOH and its commission, European experts from Spain and France, and the WHO. Following an invitation from the MOH Commission, the PPSG collaborated to evaluate national policy and regulations and develop a set of policy recommendations that were presented personally to the Minister of Health in July 2003. During the next two years, the MOH drafted a revised narcotics control law, which was adopted by Parliament in November 2005. In early 2007, the MOH issued new regulations to implement the new law governing prescribing of opioid analgesics. The regulations are a vast simplification of the old administrative process required for patients to obtain opioids for pain relief.

However, modifying a national policy by itself is not sufficient to improve patient access to opioid analgesics. Romanian colleagues recognized that there are vital additional steps that must be taken, so they are developing a program to disseminate the new policies to the public, health care practitioners, regulators, and police. They are also developing, with the input of international experts, a nationwide program to educate doctors and pharmacists about modern pain management that will now be allowed under the new national policies. Finally, there will be follow-up evaluation to measure the impact, such as changes in consumption of opioids. There should also be evaluations of institutional indicators, individual patient pain level and opioid consumption.

Other International Progress

Progress in India

Elsewhere in this issue, Rajagopal and Joranson describe in more detail the important progress and the challenges in India to improve national policy and opioid availability for patients who need pain relief. The PPSG and its WHOCC have worked collaboratively for a number of years with Indian pain and palliative care experts, government officials, and nongovernmental organizations to examine the complex regulatory policy and administrative structure aimed at addiction and trafficking but which has blocked access to essential analgesics such as morphine, and thereby limited the development of true palliative care. A combination of efforts beginning in the mid-1990s has led to significant improvements in policy and opioid availability, but only in some places. In Kerala, for example, elimination of a national requirement for pharmacy licenses, simplification of state narcotic regulations, and a new licensing mechanism have led to a major increase in the number of community-based palliative care centers with oral morphine and increased patient access to pain relief, with little if any misuse or diversion.[11, 12]

Progress in Italy

In 1999, the PPSG assisted a workgroup appointed by the Italian MOH to identify and address barriers to

opioid availability. Many Italian colleagues have been and continue to be involved in these efforts that resulted in revision of national law and drug registration procedures, the addition of opioid analgesics to the list of reimbursable drugs, a simplified triplicate prescription form that eliminated the need to complete each copy manually, an increase in the amount that could be prescribed from eight days to one month, allowance for two drugs or dosage units on each prescription (instead of one), and allocation of government funds for coordination of physician education and public awareness about cancer pain management.[13]

New Tools for Pain Policy Advocacy

In light of the serious lack of access to opioid pain medicines in most of the world,[4] there is a need to increase advocacy with the governmental bodies that make the drug control laws and regulations. The PPSG is developing methods to evaluate and improve national policies, and is also making these tools available so they can be used by individuals, government officials, and nongovernmental organizations.

In 2006, the PPSG redesigned and expanded the international part of its website (new URL: www.painpolicy.wisc.edu) to include more comprehensive information, including global, regional, and national opioid consumption and country profiles.

International Pain Policy Fellowship

In order to expand the number of pain relief and palliative care professionals advocating for opioid availability, the PPSG developed an International Pain Policy Fellowship (IPPF), supported by a grant from the OSI. For the first IPPF training session, held in October 2006, the eight Fellows (from Argentina, Colombia, Nigeria, Panama, Serbia, Sierra Leone, Uganda, and Vietnam) came to Madison for a weeklong learner-centered training program. At the end of the week, the Fellows prepared detailed national action plans that will guide their activities to improve patient access to opioid analgesics for the next two years, in collaboration with the PPSG.

International Experts Collaboration

Another PPSG effort aimed at accelerating progress in opioid availability is the establishment, also with OSI support, of a pool of experts with prior experience in palliative care and opioid availability who are interested in further advancement of opioid availability at the national level. An International Experts Collaboration (IEC) was formed in 2006; several members were able to participate in the IPPF and will be able to provide ongoing mentorship to Fellows as they work to implement their action plans. In addition, the PPSG will collaborate with the IEC members to support their efforts abroad, including speaker support for presentations at relevant international and national meetings and other technical assistance as needed.

Internet Course

Yet another PPSG effort aimed at accelerating progress is the development of a course on international pain policy that will be easily accessible from the PPSG website. Supported by the National Hospice and Palliative Care Organization and the Foundation for Hospices in Sub-Saharan Africa, the course will be useful for health professionals and government officials who want to learn more about the relation between disease, pain, policy, and government and what can be done to improve availability and access to pain relief medications in their country. The curriculum will be similar in content to that of the IPPF and is planned to be available in 2007.

Essential Elements of National Policy

In our work abroad, the PPSG occasionally encounters the question, “Is there a model law our country could adopt that would solve our opioid availability problems?” To our knowledge, there is no “one-size fits all” model that would neatly fit the needs of all countries. Indeed, our experience tells us that there is great variability among national laws in the world, because each national drug control law is unique in so many ways. The reasons for this uniqueness stem from how different societies and cultures handle national drug control policies relating to opioids, from procurement, licensing and distribution to prescribing and dispensing to patients.

It would be inappropriate to replace these unique national approaches with a standard model law. Consequently, we continue to rely on internationally accepted criteria to assess national policy to identify those provisions that can either enhance or interfere in availability and access within the existing national frameworks. That said, we do recognize that some key elements of national policy are often missing and that recommended language would be helpful. Consequently, with funding assistance from the OSI, the PPSG will be developing “essential elements of a modern national opioids control policy” that will represent reasonable expectations for the contents of a national policy aimed at improving opioid availability. The elements will be based on provisions and official interpretations of international treaties and expert guidance from international health and regulatory bodies.

A New Metric for Studying Opioid Consumption

Opioid consumption statistics are a valuable contribution to problem identification and outcomes evaluation, but these statistics can be cumbersome and inaccurate, especially when morphine and several other opioids of differing strengths need to be considered to obtain a more complete picture of a country's opioid consumption. There are important research questions such as how would we adjust our understanding of global and national trends if we could study a single metric that would combine the reported consumption of all the principal opioids used for severe pain, not just one or two? How would this affect our understanding of where global progress in pain management has occurred, or not; how would it affect country rankings and our understanding of the global disparities according to income, mortality, and opioid requirements? The PPSG, with support from the OSI, is developing a single metric that will be used to conduct these studies.

Mind the Gaps

Experts in pain management and palliative care are very familiar with the gap between what is known about pain relief and what is actually done in terms of practice and care. There is another gap, and it is the subject of this article: the gap between the need to relieve severe pain in millions of patients and the unavailability of opioids with which to do it. This gap remains wide for most of the world's population, especially, but not only, in developing countries. International authorities have correctly pointed out that this problem is not due to inadequate supply of opioids—so the answer is not to calculate how much is needed and then simply provide the amount to each country. Elsewhere in this issue, Rajagopal and Joranson describe the failure of one such supply side solution.

Instead, the world authorities point to the weak demand from many countries. This weak demand is due to many factors that are familiar to readers, including the low national priority of pain relief and palliative care, problems with high cost of medicines and reimbursement, and restrictions in national policy that block opioid availability and patient access to essential pain relief medicines.

The Future

Looking ahead realistically, we recognize that there will always be many unmet needs and limited resources that need to be allocated strategically. Consequently, the PPSG plans to focus its limited international resources on policy evaluation that can make a difference, on education of health professionals about working with government, on making resources available online, and on providing technical assistance, especially where change is possible. By “possible” we mean where there is leadership by “champions” and where government is willing to examine their policies and administration. Such was the case in Italy, Romania, and India.

We and many other colleagues have often heard about how the exaggerated fear of addiction blocks regulatory reform and pain relief. Indeed, the WHO's own past statements have contributed to misunderstanding of addiction/dependence. Because WHO is the world's authoritative body on drug dependence, we encourage the WHO to consider mounting a communications initiative on the scale of some of its other efforts to address public health problems to convince governments, regulators, professionals, and the public that opioids need to be used to manage pain of cancer and AIDS and can be used without a significant risk of addiction/dependence.

Conclusion

The emerging work of an increasing number of colleagues around the world to improve access to essential pain medicines and address regulatory barriers to opioid availability in cooperation with governments is beginning to achieve some positive results, but there is a long way to go. The PPSG is committed to continue its work to support this critically important effort.

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Figure 1 – Distribution system that ensures patient access to opioids