



Access to therapeutic opioid medications in Europe by 2011? Fifty years on from the Single Convention on Narcotic Drugs

“... the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering... adequate provision must be made to ensure the availability of narcotic drugs for such purposes.”

(Single Convention on Narcotic Drugs, 1961 as amended)

Nearly 50 years after the Single Convention on Narcotic Drugs, the importance of this statement continues to hold true and is reinforced by recent UN policy declarations (ECOSOC, 2006). However there continues to be ongoing problems with access to opioid analgesics for relief of pain globally. Cherny and his colleagues from the European Association for Palliative Care (EAPC) and the European Society of Medical Oncology (ESMO) Drug Policy Initiative have documented the current status in Europe of access to opioids for pain relief in an article published in the current issue of *Annals of Oncology*.¹

The authors reference the extensive work of the University of Wisconsin–Madison Pain and Policy Studies Group (PPSG), a WHO Collaborating Center for Policy and Communication in Cancer Care. PPSG has described the opioid consumption trends around the world, using consumption data reported by governments to the International Narcotics Control Board (INCB). Most of the countries of the world, including those in Eastern Europe, fall well below the European and global means for opioid consumption. While there has been a significant increase in opioid consumption in Western Europe, there has been little change in the last 20 years in Eastern Europe. There is evidence that in many European countries, particularly those in Eastern Europe, patient access to the opioid medicines recommended by the WHO to relieve cancer pain is profoundly restricted by inadequate formularies, excessive regulation and the attitudes and misconceptions of both clinicians and patients.

While there are clear disparities between Eastern and Western Europe, there is also variation within the two regions. Morphine (sustained or immediate release

[IR]) is available to the patient for less than 25% of the total cost in every Western European country except Iceland where patients pay 100% of the cost, perhaps a norm of their health care system. Turkey is the only Western European country without IR morphine, but does have available controlled release (CR) morphine and transdermal fentanyl, two preparations that are included in the International Association of Hospice and Palliative Care (IAHPC) list of essential drugs for palliative care. However, in that list, the IAHPC panel of experts recommended to the WHO that governments should not approve controlled release formulations of morphine, fentanyl or oxycodone, without first *guaranteeing* the wide availability of IR oral morphine.

The lack of IR morphine in Turkey is evident in many countries in Eastern Europe. No IR morphine is available in Albania although CR morphine is available. Belarus has no IR morphine but has CR morphine and TD fentanyl, as do Lithuania, Georgia, and the Ukraine (patients bear 100% of the cost of fentanyl in Georgia). While these are available in many Eastern European countries because of the marketing practice of pharmaceutical companies, the PPSG opioid consumption data for morphine (as shown in the paper) demonstrates a low level of consumption of CR morphine in these countries and the low level of fentanyl consumption is shown on the PPSG web site (<http://www.painpolicy.wisc.edu>). These data suggest that the national approval of a controlled-release opioid pharmaceutical does not necessarily lead to the appropriate use for analgesia, and may inadvertently minimize the importance of IR formulations.

Cherny and colleagues warn us that some aspects of their data, provided by practicing clinicians in 41 countries, may have deficits due to the selective nature of the survey process. On the other hand, the results are valuable perceptions of practice by these clinicians in their respective countries. The ESMO and EAPC survey is an important step; it is a window that can be used to continue the study, discussion and reform of regulatory barriers in Europe. It should be recalled that these laws were not enacted to prevent pain relief but rather to address drug abuse and diversion, an understandable concern about public health and safety of many governments.

The Single Convention establishes basic regulatory requirements but is not intended to impede medical practice and relief of pain and suffering. Indeed, the Single Convention specifies that governments must ensure the adequate availability of narcotic drugs for medical purposes. While the Single Convention mentions that governments may consider counterfoil prescription forms, it does not require them, and the WHO states that such additional measures should always be *balanced* against meeting medical needs.

The concept of balance in ensuring access to opioids while reducing the risk of diversion has been promoted by the WHO's (2000) *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*. Pain relief for cancer patients has increasingly become a priority as demonstrated by the 2008 World Cancer Declaration that focuses on the relief of cancer pain by 2020. The International Union for the Control of Cancer (UICC) is placing increased focus on this through its Global Access to Pain Relief Initiative (GAPRI) that will work to achieve this goal. The EAPC and WHO have commenced a new program to bring about Access to Therapeutic Opioid Medications in Europe to improve pain relief in Europe.

The authors make a number of recommendations to improve access to opioids. Adoption of the IAHPC essential opioids list is listed as a long-term goal with an immediate focus on ensuring access to IR morphine. Allowing emergency prescribing, ensuring easy and ready access to special prescription forms (where they are required), and allowing pharmacists to correct technical errors in discussion with the prescribing physician are also recommended. Importantly they call for reform of national policies to improve access. Engaging with a nation's competent authority can be an important part of this, as demonstrated by the PPSG's International Pain Policy Fellowship that pairs clinicians with representatives of the national competent authority to lead this process of change. The requisite knowledge base about pain policy and working with governments is now available in an on-line course from PPSG.

Reform of national policies should be preceded by a careful review of the actual laws and regulations to identify whether recommended access provisions are present, and to identify the excessively restrictive provisions that can be removed. In this way, the consensus needed to reform national policy will be based on evidence, a process described by the authors in a number of countries such as Romania. Following reform, one further step is essential: implementation of the policy reform. Implementation may be the hardest step as it would be false to state that the inadequate treatment of cancer pain is due entirely to regulatory restrictions. We know from experience that policy change alone does not bring about increased access. We need to address the low

priority of pain with health care, inadequate education, exaggerated fear of opioids and addiction, and problems in the supply chain for the medications.

A global pain relief initiative also runs a significant risk if it is limited to cancer pain as it may inadvertently increase disparities in pain treatment for those suffering from pain related to AIDS and other conditions for which the therapeutic use of opioids is indicated. This may be particularly true in sub-Saharan Africa where the number of patients with HIV-related pain is significant. However, even in Africa the burden of cancer is anticipated to overtake that of HIV, with cancer being the leading cause of death globally soon after 2020. The paucity of physicians in many countries including those of Africa makes access to opioids unlikely if prescribing is limited to physicians. The authors discuss the use of non-physician prescribing to improve access to opioid analgesics; the Single Convention requirement of 'medical prescriptions' does not disallow non-physician prescribing.

The challenge for the pain and palliative care communities is to bring about improved access to opioids. The PPSG has demonstrated that such an effort requires a working knowledge of international and national drug control policy and a commitment of pain and palliative care leaders to working cooperatively with government agencies. It may be optimistic to suggest that we can successfully address these problems globally by 2011, the 50th anniversary of the Single Convention. However, the 2020 goal of the UICC may be a more realistic objective, but it will require appropriate resources, leadership from individuals and their continental and national palliative care associations, and cooperation from government agencies responsible for drug regulation, cancer and HIV/AIDS.

Reference

1. Cherny NI, Baselga J, de Conno F, Radbruch L. Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative. *Ann Oncol* 2010; 21: 615–626.

James F Cleary, MB, BS, FACHPM

Associate Professor of Medicine

Paul Hutson, Pharm D

Associate Professor of Pharmacy

David Joranson, MSW

Distinguished Scientist and Founder

Pain and Policy Study Group, WHO Collaborating

Center for Policy and Communication in Cancer Care

University of Wisconsin Carbone Cancer Center

Madison, Wisconsin, USA

Corresponding author:

James F Cleary, Associate Professor of Medicine

E-mail: jfcleary@wisc.edu