GdPO Global Drug Policy Observatory
reportingmonitoringanalysis

Swansea University
Prifysgol Abertawe

GDPO Situation Analysis

December 2013

Untreated pain in the lower and middle-income countries

Katherine Pettus, PhD.

More than 5.5 billion people (83% of the world's population) in over 150 countries have low to non-existent access to morphine and other controlled medicines for pain relief, palliative care or opioid dependency. Although access to morphine has increased exponentially over the last two decades, global inequalities in access to pain relief are stark. Ninety per cent of the global consumption of morphine, fentanyl and oxycodone registered in 2009 occurred in Australia, Canada, New Zealand, the United States and several European countries (See Map below). All these medicines are 'scheduled' and controlled under the UN 1961 Single Convention on Narcotic Drugs. Widespread lack of access in lower and middle-income countries (LMICs), however, underlines the serious limitations of the current regulatory regime.

Impact

- According to WHO, the realization of the Millennium Development Goal 8, 'providing access to affordable essential drugs in developing countries', is likely to be a more distant prospect for opioid analgesics than for any other class of medicines.
- More than 1 million AIDS patients, 5.5 million cancer patients, and 800,000 trauma victims have little or no access to treatment for moderate, severe, or acute pain each year.
- Untreated pain affects the physical, psychological, social, and financial health of individuals, families and communities, profoundly impacting their quality of life.
- The prevalence of untreated pain is likely to increase as the population ages in many developed nations, and with the increasing global burden of chronic disease, cancer and HIV/AIDS.
- The need for inexpensive oral morphine is particularly acute in developing and resource poor countries where most patients only seek medical attention when disease has advanced beyond the possibility of cure and is causing severe pain.
- Pain relief restores quality of life and in many cases allows patients to return to work, participate in community life, and care for their families.
- In restricted and acute situations, patients and their families may resort to illegal markets for heroin and other painkillers, risking arrest, imprisonment, and related harms.

Background

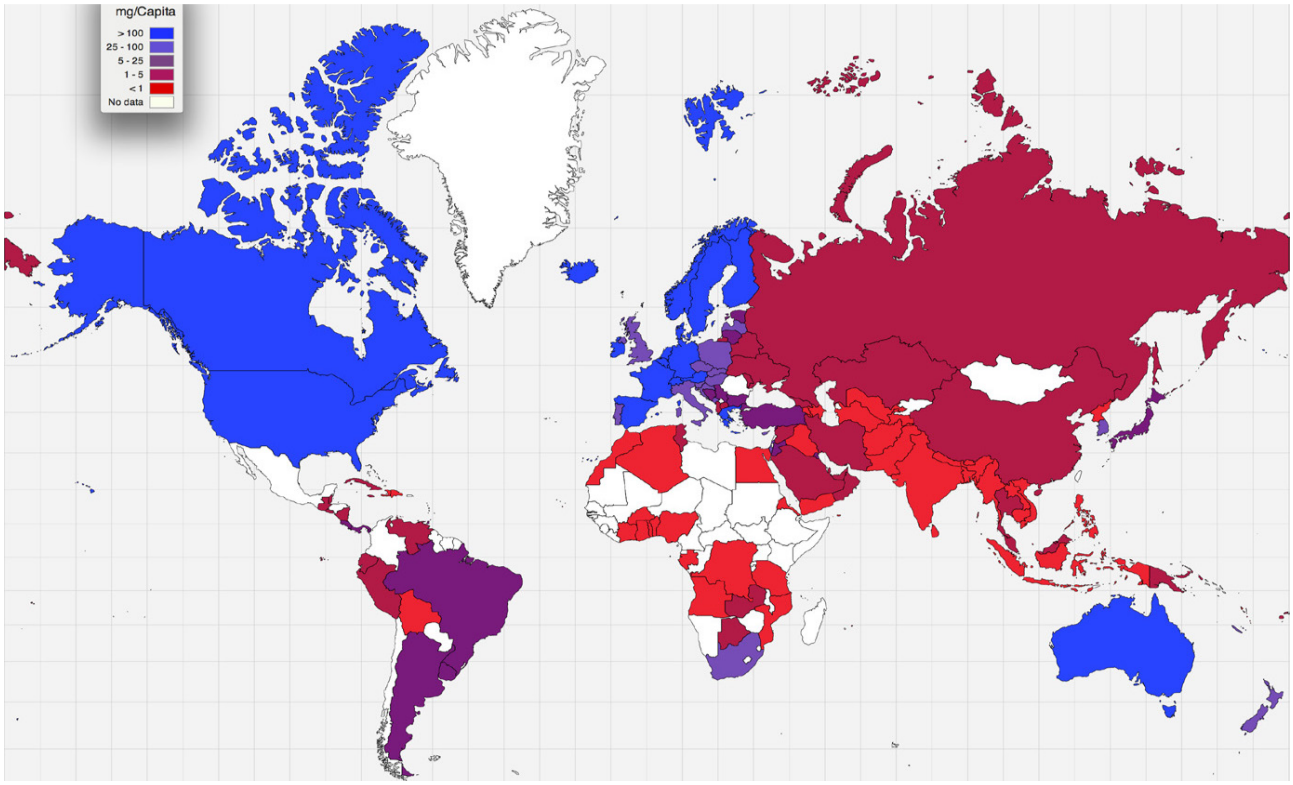
The Single Convention on Narcotic Drugs is a multi-lateral treaty that obliges each of its 185 signatories to pass laws and regulations that define and control all legal and illegal activities relating to narcotic drugs in their territories. The International Narcotics Control Board (INCB or Board), a treaty body established by the Single Convention, oversees what it interprets to be treaty compliance from its headquarters in Vienna. To be in compliance, countries' domestic laws must conform to the treaty's minimum surveillance and enforcement provisions regarding all controlled narcotics, including medicines.

The Single Convention classifies narcotics producing plants and related pharmaceuticals into Schedules that reflect perceived 'potential for abuse'. Although morphine is on the WHO's list of Essential Medicines, and is considered the 'gold standard' for treating severe pain, it is a Schedule I narcotic, subject to the strictest national and international control.

For a country's pharmacies to receive any medical opioid medicines, duly designated national authorities must estimate the national need for pain medicines and submit that data to the INCB on an annual basis. The Board must approve the estimates before Health Ministries can place orders and before pharmacies can receive stocks. Eligibility for the annual quota requires the designated authorities to submit accurate (and acceptable to the INCB) 'statistical returns' that track actual national consumption.

A country's *real* epidemiological need for medical opioids, as opposed to the estimate generated for INCB purposes, is based on its current and projected burden of communicable and non-communicable disease. This metric, set against INCB country consumption data, reveals the gap of untreated pain in countries whose public health and regulatory infrastructures are unable to meet the drug control conventions' requirements to simultaneously provide and control narcotic drugs.

OPIOID CONSUMPTION MAP – MORPHINE EQUIVALENCE (WITHOUT METHADONE), MG/CAPITA, 2011



Source: Opioid Consumption Data, INCB, Estimated Requirements for 2013, Statistics for 2011, New York: United Nations, 2013.

Analysis

The preamble to the Single Convention on Narcotic Drugs states 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.' This statement makes universal provision a treaty obligation for member states. The other treaty obligation is to prevent illicit production, trafficking, and consumption of many of the same substances, including controlled medicines. In order to accomplish both these aims *at the same time*, countries must have effective regulatory, public health, *and* law enforcement systems. Few LMICs have all three.

This compulsory centralized system prevents states parties from engaging in free trade in scheduled medicines to meet their national health needs. One treaty historian commented that, 'the estimate system introduced for the first time into a general convention the essential principles of a planned economy on a world scale for a particular industry'.[1] The goal of controlling and regulating the licit global trade in controlled medicines is to 'balance' licit demand with global supply. Theoretically, this allows the INCB to identify *illicit* demand and supply. It can be argued then that t*he purpose of the INCBs 'estimates' and 'statistical returns' system is not to ensure adequate provision of medical opioids for pain relief, but to detect diversion and abuse of controlled medicines to illicit supply chains and to 'dry up' illicit supplies.*

Legal and Cultural Barriers to Access in the LMICs

Low- and middle-income countries that lack the requisite health, regulatory, and educational infrastructures to meet the Single Convention's complex regulatory standards often ban scheduled medications outright.

Where not proscribed, structural and human resources barriers to dispensing or obtaining opioids include

- ineffective drug distribution systems,
- lack of pain management policies,
- inadequate training of health care workers,
- restrictive licensing,
- cumbersome dispensing procedures
- limitations on the formulation and quantity of medicine that can be prescribed.

Cultural barriers to prescription and consumption of pain medication are based on historical trauma, lack of knowledge, and fear of addiction. Although authorities often cite fear of diversion of medical opioids as justification for over-regulation, studies show that diversion of oral morphine is low to non-existent in developing countries.

Cost

Unlike many other medicines, morphine is not under patent protection and can be produced inexpensively in sufficient quantities to meet actual global need. However, low profit margins typically realized from selling immediate release oral morphine are often further reduced by market volatility resulting from burdensome regulatory requirements. Global retail prices for morphine, fentanyl and other opioids vary dramatically and can make medicines unaffordable for citizens of low-and middle- income countries.

National governments such as Uganda, Mongolia and Kenya, and state governments such as Kerala in India, subsidize production and distribution of morphine at no cost to their citizens. Oral morphine is not difficult or dangerous to administer when used correctly. Nurse prescribers can be trained, as they are currently in Uganda, to provide it to patients and families.

What Next?

Concerned civil society advocates are developing a strategy requesting states parties to add a fourth pillar to the three pillar approach of the Commission on Narcotic Drugs (CND) – the central policy making body for the UN drug control system. The CND currently prioritizes demand reduction, supply reduction, and money laundering. The proposed fourth pillar would prioritize equitable access to controlled medicines for the relief of pain and suffering, in line with international human rights obligations. The issue must become a priority for major CND donors who provide the funding streams for the United Nations Office on Drugs and Crime (UNODC) sub-programmes for technical assistance and training. *UNODC currently has no sub-programme or staffing to address this issue area*.

1 See 'Twenty Years of narcotics Control under the United nations. Review of the Work of the Commission on Narcotic Drugs from its 1st to its 20th Session, *Bulletin On Narcotics*, 1966 http://www.unodc.org/unodc/en/data-and-analysis/bulletin/bulletin_1966-01-01_1_page002.html#n13

- The African Union is leading on the promotion of intergovernmental collaboration between drug control agencies and health ministries to increase access to medical opioids for palliative care and harm reduction on the continent. The African Common Position on Controlled Substances and Access to Pain Management Drugs, taken at Addis Ababa in 2012, encourages Member States to develop effective joint operations, arrangements, and standards to be applied regionally to build capacity and remove barriers to access to pain medicine. This innovative initiative is currently unfunded.

- Donor funded NGOs such as the Pain Policy Studies Group at the University of Wisconsin, the Union for International Cancer Control, Human Rights Watch, and the International Association for Hospice and Palliative Care, consult in selected partner countries to help regulators, physicians, and health officials identify barriers, revise over-stringent regulations, and educate health personnel about safe and effective use of opioids.

- Global advocates for improved access to pain medicines for palliative care and opioid dependency are promoting a 2014 World Health Assembly resolution recommending that member states integrate palliative care into their national health systems. Since palliative care entails the use of strong opioids for pain control, a successful outcome would give more international visibility to the issue of equitable access to controlled medicines.

supported by

OPEN SOCIETY FOUNDATIONS

About the Global Drug Policy Observatory

The Global Drug Policy Observatory aims to promote evidence and human rights based drug policy through the comprehensive and rigorous reporting, monitoring and analysis of policy developments at national and international levels. Acting as a platform from which to reach out to and engage with broad and diverse audiences, the initiative aims to help improve the sophistication and horizons of the current policy debate among the media and elite opinion formers as well as within law enforcement and policy making communities. The Observatory engages in a range of research activities that explore not only the dynamics and implications of existing and emerging policy issues, but also the processes behind policy shifts at various levels of governance.

Global Drug Policy Observatory

Research Institute for Arts and Humanities

Room 201 James Callaghan Building

Swansea University

Singleton Park, Swansea SA2 8PP

Tel: +44 (0)1792 604293

www.swansea.ac.uk/gdpo

@gdpo_swan

GdPO Global Drug Policy Observatory

reportingmonitoringanalysis