

# Opioid Availability

---

Fraser Black  
INCTR Annual Meeting  
Sao Paulo, March 2007



Thanks specifically to:  
Dave Joranson  
Dr. James Cleary  
Jody Garthwaite

*in collaboration with:*

Pain & Policy Studies Group  
University of Wisconsin Comprehensive Cancer Center  
World Health Organization Collaborating Center  
[www.medsch.wisc.edu/painpolicy](http://www.medsch.wisc.edu/painpolicy)



**INCTR**  
International  
Network  
for Cancer Treatment and Research

**New!**  
[Country Profiles on Opioid Availability](#)

[About the PPSG](#) | [US Pain Policy Resources](#) | [International Pain Policy Resources](#) | [Cancer Pain Release](#) | [Glossary](#) | [Bibliography](#) | [Related Links](#) | [Search](#) | [Feedback](#)

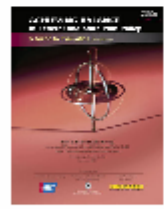
# Welcome to the Pain & Policy Studies Group

University of Wisconsin Paul P. Carbone  
Comprehensive Cancer Center



World Health Organization Collaborating Center  
for Policy and Communications in Cancer Care

**2006 Achieving Balance Reports**  
*Progress Report Card*      *Evaluation Guide (State profiles)*



[Click here to see the reports and supplemental materials](#)

## United States

- ["Drug Crime is a Source of Abused Pain Medications in the United States"](#) (2005 JPSM article)

# Take Home Messages

- Opioids are effective for the treatment of pain (and dyspnea)
- Lack of access for patients to opioids exists in many countries due to medical misconceptions as well as economic and regulatory barriers
- Opioid availability for patients **can** be improved
- Tools, guidelines and experience exist which can help in that process

# WHO Foundation Measures for Implementing Cancer Pain Relief Programs

## **Education**

*Of the public, healthcare professionals (doctors, nurses, pharmacists) & others (healthcare policy makers, administrators, drug regulators)*

## **Drug Availability**

*Changes in healthcare regulations/legislation to improve drug availability (especially of opioids)*

## **Government Policy**

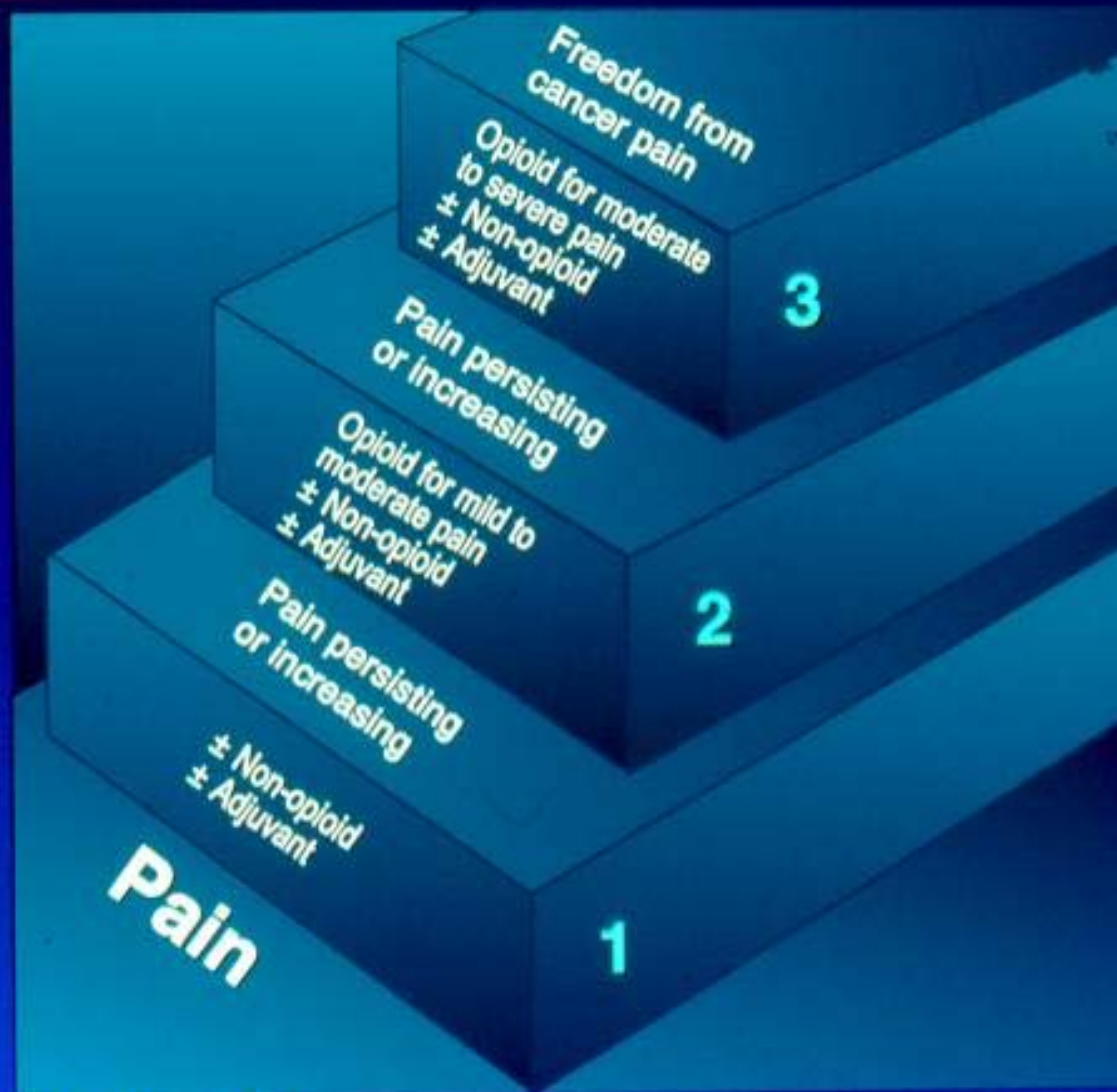
*National or state policy emphasizing the need to alleviate chronic cancer pain*

# Cancer → Pain ← Opioids

- Increasing incidence
- Shifting to less developed countries
- Often painful
- Diagnosed in late stage
- Pain destroys quality of life
- Cancer pain can be relieved
- Opioid analgesics essential



# WHO Three-Step Analgesic Ladder



# Evidence and the WHO Analgesic Ladder

- 10 year prospective validation study reported in 1995 confirms effectiveness

*Pain 1995;63(1): 65-76*

- Morphine remains gold standard for moderate or severe cancer pain

Cochrane Database of Systematic Reviews, 2003

- Strong opioids at 1st step well tolerated in advanced cancer pain

*Journal Pain Symptom Management 2004; 27(5): 409-416*

# WHO Three-Step Analgesic Ladder



**Treatment gap exists however if there is inadequate availability of opioid analgesics.**

“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”

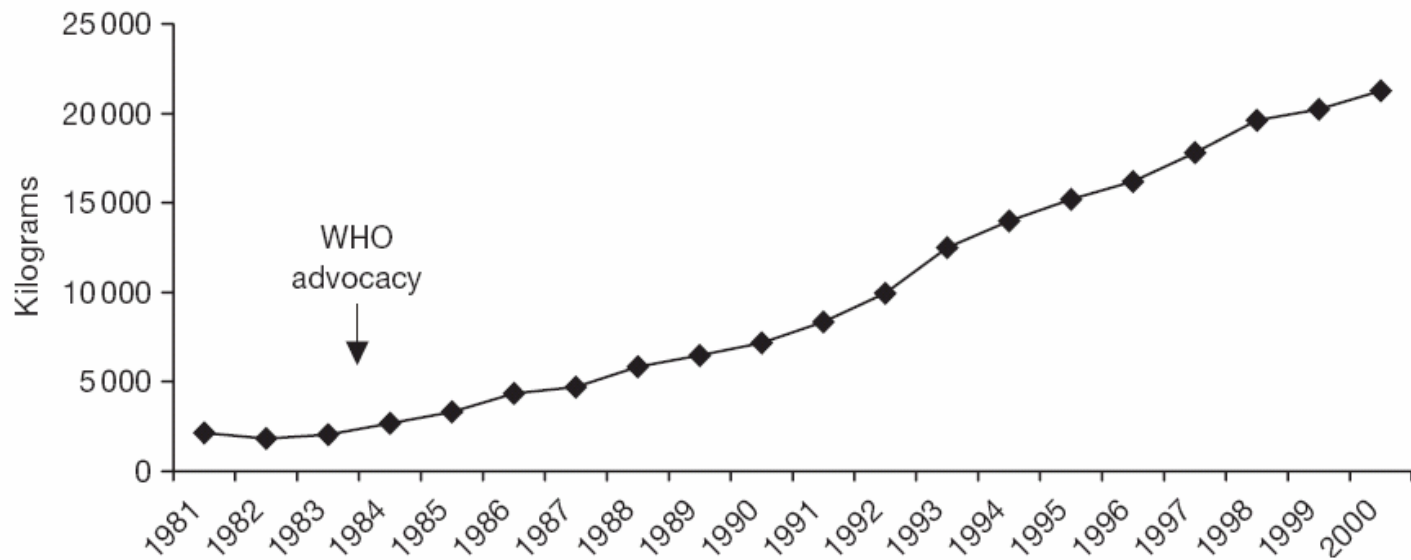
**World Health Organization, 2002**

# Cancer → Pain ← Opioids

- Increasing incidence
- Shifting to less developed countries
- Often painful
- Diagnosed in late stage
- Pain destroys quality of life
- Cancer pain can be relieved
- Opioid analgesics essential
- Governments have two responsibilities
  - To control abuse of narcotics
  - To ensure availability of opioid analgesics



# Global Consumption of Morphine 1981-2000



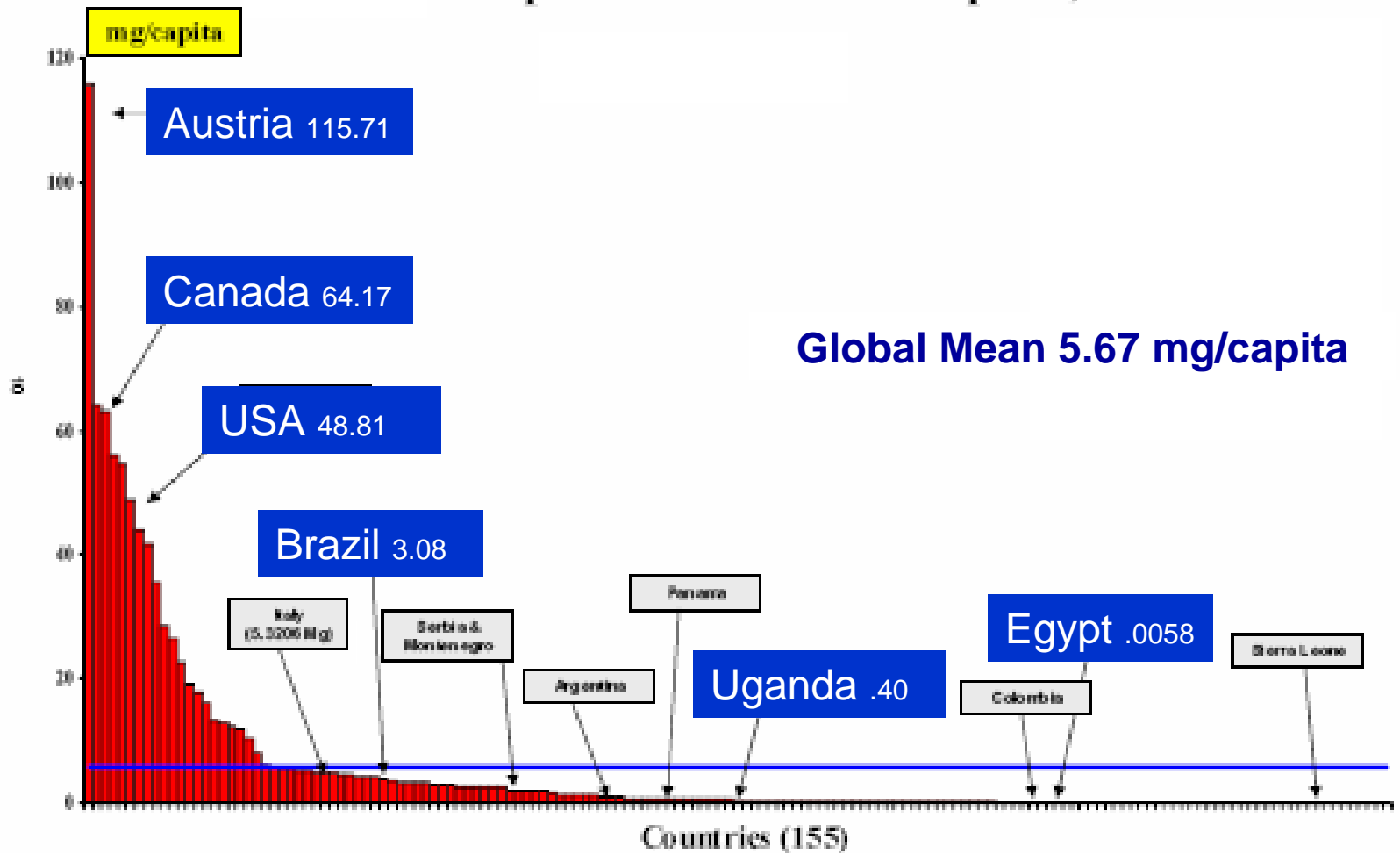
# The Reality

In many countries, consumption of opioid analgesics remains extremely low in comparison to medical need, and many national governments have yet to address this important deficit.

International Narcotics Control Board, 1996

**Do patients in your country have adequate access to the opioids they need?**

# Morphine Global Consumption, 2004



Source: International Narcotics Control Board; United Nations Demographic Yearbook; IPI Pain & Policy Studies Group; University of Wisconsin/WBC Collaborating Center, 2006

The global mean is calculated by adding the individual mg/capita statistics for all countries and then dividing by the number of countries.

# Reality remains ...

In 2003, 6 countries accounted for 79 per cent of global consumption of morphine. Developing countries, which represent about 80 per cent of the world's population, accounted for only about 6 per cent of global consumption of morphine.

- *INCB Annual Report for 2004*

# Three types of barriers to opioid availability

- Economic
- Medical/Nursing
- Regulatory



# Impediments to Availability

- Low priority for pain management in health care systems
- Greatly exaggerated fears of addiction
- Overly restrictive national drug control policies
- Government policies that limit the quantity and duration of opioid prescriptions
- Problems in procurement, manufacture and distribution of opioids
- Cost to patients and families

# International Narcotics Control Board (INCB)

- Independent, quasi-judicial monitoring body
- Established in 1968 in accordance with the Single Convention on Narcotic Drugs, 1961
- Implementation of the United Nations international drug control conventions
- Based in Vienna
- 13 members from different countries



# INCB has requested all national governments

- Re-evaluate their medical needs for opioids
- Identify and address impediments
- Communicate with health professionals to determine the unmet medical need for opioid analgesics

**Has your government done this?**

# INCB Annual Report for 2004

“In view of the continued inadequate global consumption of opiates for the treatment of pain, the Board reiterates that it would **welcome a further increase in global demand for opiates.** The Board encourages governments to take steps to **increase the medical use of opiates** in their countries in order to meet their real needs for the treatment of pain.”

WHO/EDM/QSM/2000.4  
ENGLISH ONLY  
DISTRIBUTION: GENERAL

NARCOTIC & PSYCHOTROPIC  
DRUGS

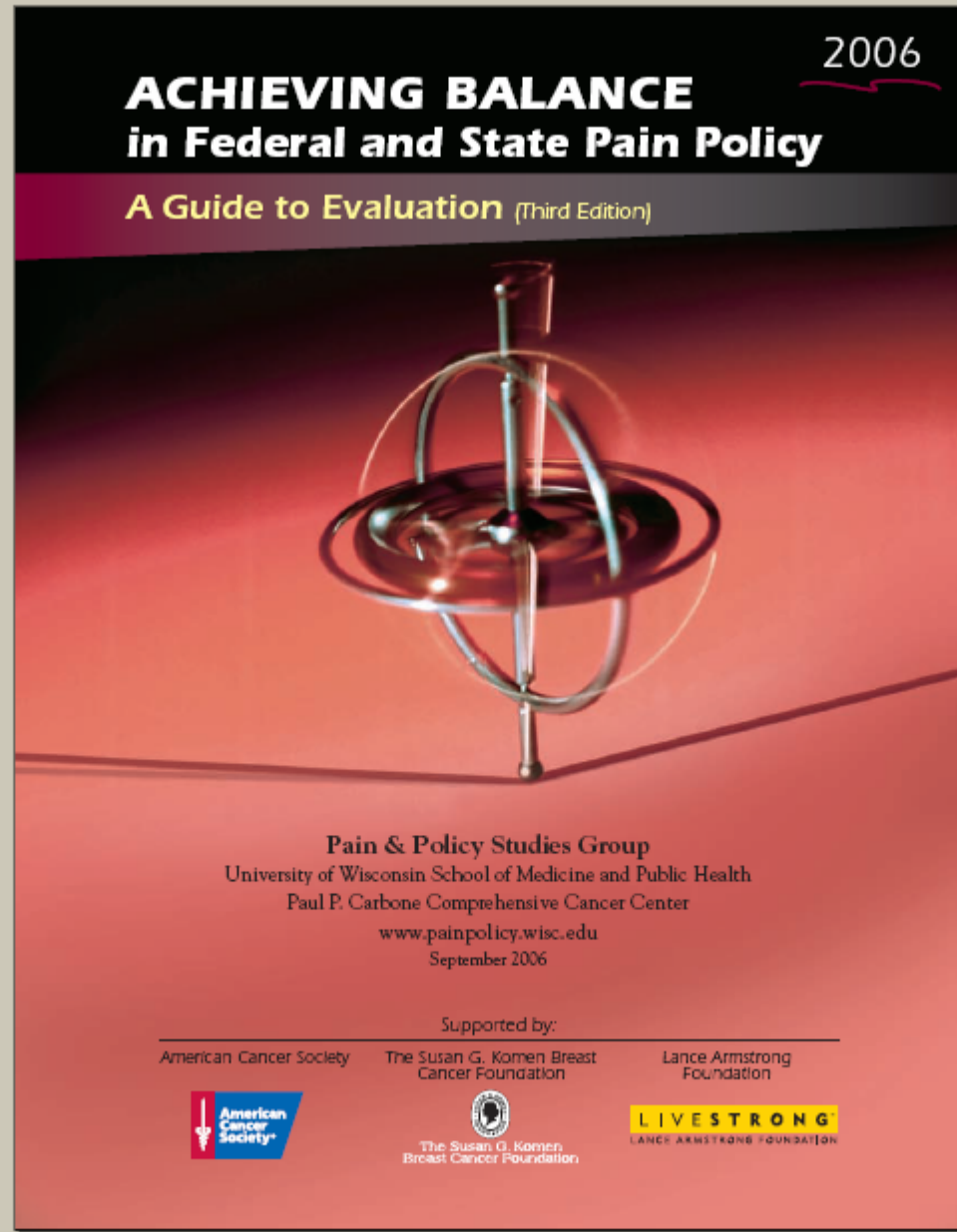
ACHIEVING  
BALANCE IN  
NATIONAL OPIOIDS  
CONTROL POLICY

GUIDELINES FOR ASSESSMENT



World Health  
Organization

<http://www.painpolicy.wisc.edu>



2006

# ACHIEVING BALANCE in Federal and State Pain Policy

A Guide to Evaluation (Third Edition)



**Pain & Policy Studies Group**  
 University of Wisconsin School of Medicine and Public Health  
 Paul P. Carbone Comprehensive Cancer Center  
[www.painpolicy.wisc.edu](http://www.painpolicy.wisc.edu)  
 September 2006

Supported by:

American Cancer Society

The Susan G. Komen Breast Cancer Foundation

Lance Armstrong Foundation



# How to evaluate drug policy ...

- Identify person or committee to study the guidelines
- Obtain additional information from key resources
- Obtain up-to-date copies of your national drug control policies and study them
- Use the self-assessment checklist to assess the policies
- Prepare a country specific action plan
- Establish dialogue with policy-makers to make the necessary changes

# Assessment Guidelines

- Total of 16 areas of reflection and assessment:
  - Six relate to national laws and regulations
  - Ten relate to administrative policies, directives and practices that implement national laws and regulations.

# Common characteristics of countries that improve opioid policy

**Recognition:** that regulations interfere with patient access to pain relief

**Leadership** : Specialists; NGOs, Cancer survivors, family members, politicians

**Government willingness:** to study needs and barriers  
Commission; Task Force; study Public report and recommendations

# Demonstration Project India

Objective:

“To overcome regulatory barriers and to improve availability and access to opioid analgesics for Indian patients with painful conditions such as cancer and, increasingly, HIV/AIDS.”



# Demonstration Project India

An action plan was prepared that included:

- Development of guidelines for obtaining morphine
- Preparation of a plan for simplifying regulations over morphine
- Sponsorship of workshops on morphine availability with state governments and healthcare professionals

# Demonstration Project India

## Outcomes:

- Thirteen states and territories adopted the model
- Number required licenses reduced from 5 to 2
- National morphine increased by 383% in 2 yrs
- Uninterrupted supply of morphine secured
- "Buffer Stock" of 50 kg for domestic need
- Seven manufacturing units in India

# Uganda Experience

- First African country to recognize palliative care as an essential clinical service
- Changed its national legislation to make opioids more available



# Uganda Experience

- In 2004 further modified its policy to permit nurses prescribe morphine
- Programs of morphine "sensitization"



# Take Home Messages

- Opioids are effective for the treatment of pain (and dyspnea)
- Lack of access for patients to opioids exists in many countries due to medical misconceptions as well as economic and regulatory barriers
- Opioid availability for patients **can** be improved
- Tools, guidelines and experience exist which can help in that process

# Final Words ....

“Freedom from pain should be seen as a right of every cancer patient and access to pain therapy as a measure of respect for this right”

