

# **WHO Guidelines for Achieving Balance in National Opioids Control Policies**

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*International Association for the Study of Pain*

**Sydney, Australia**

**22 August, 2005**

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Comprehensive Cancer Center**

**WHO Collaborating Center for Policy and Communications in Cancer Care**



# PPSG Mission and Experience

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- **Improve policy/regulatory environment for pain mgt.**
  - Policy research, evaluation and development
  - Education and communications
- **15 years**
  - WHO Guidelines, workshops, publications
  - Asia, Africa, Eastern Europe, Latin America
  - China, Colombia, India, Indonesia, Italy, Malaysia, Mexico, Romania
- **Website resources**  
[www.medsch.wisc.edu/painpolicy](http://www.medsch.wisc.edu/painpolicy)

# Cancer → Pain → Opioids → Government

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- **Cancer increasing**
- **Shifting to less developed countries**
- **Often painful--diagnosed in late stage**
- **Pain destroys quality of life**
- **Cancer pain can be relieved**
- **Opioid analgesics essential**
- **Pain/palliative care depends on national narcotics control policy**

# Perspective on morphine availability

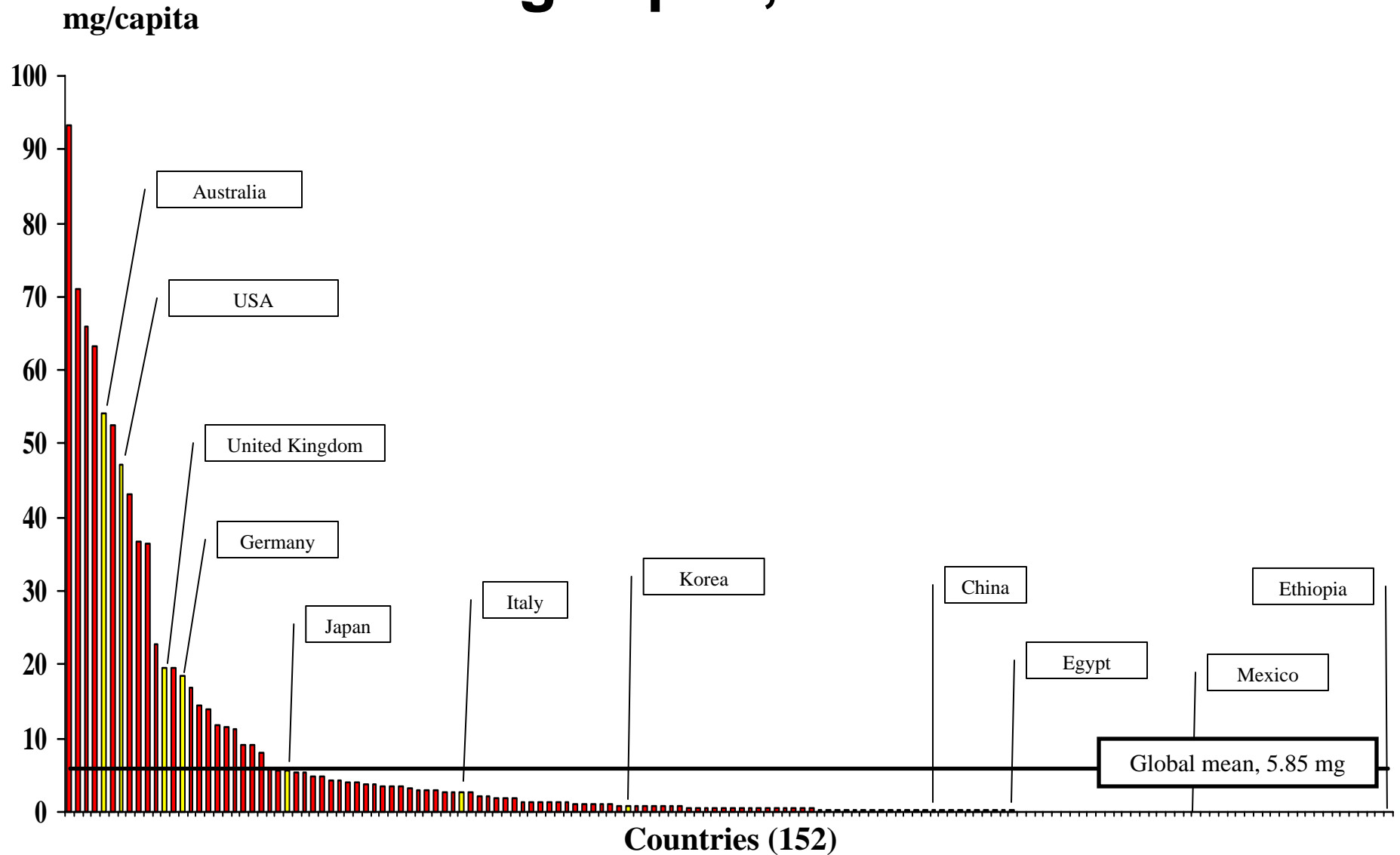
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- Morphine increased 10-fold in past 20 years
- In 2003, 6 countries accounted for 79 per cent
- Developing countries with 80 % of the population consumed 6 per cent of supply

## Conclusion:

*Availability continues to be inadequate,  
especially in developing countries*

# Global Consumption of Morphine mg/capita, 2003

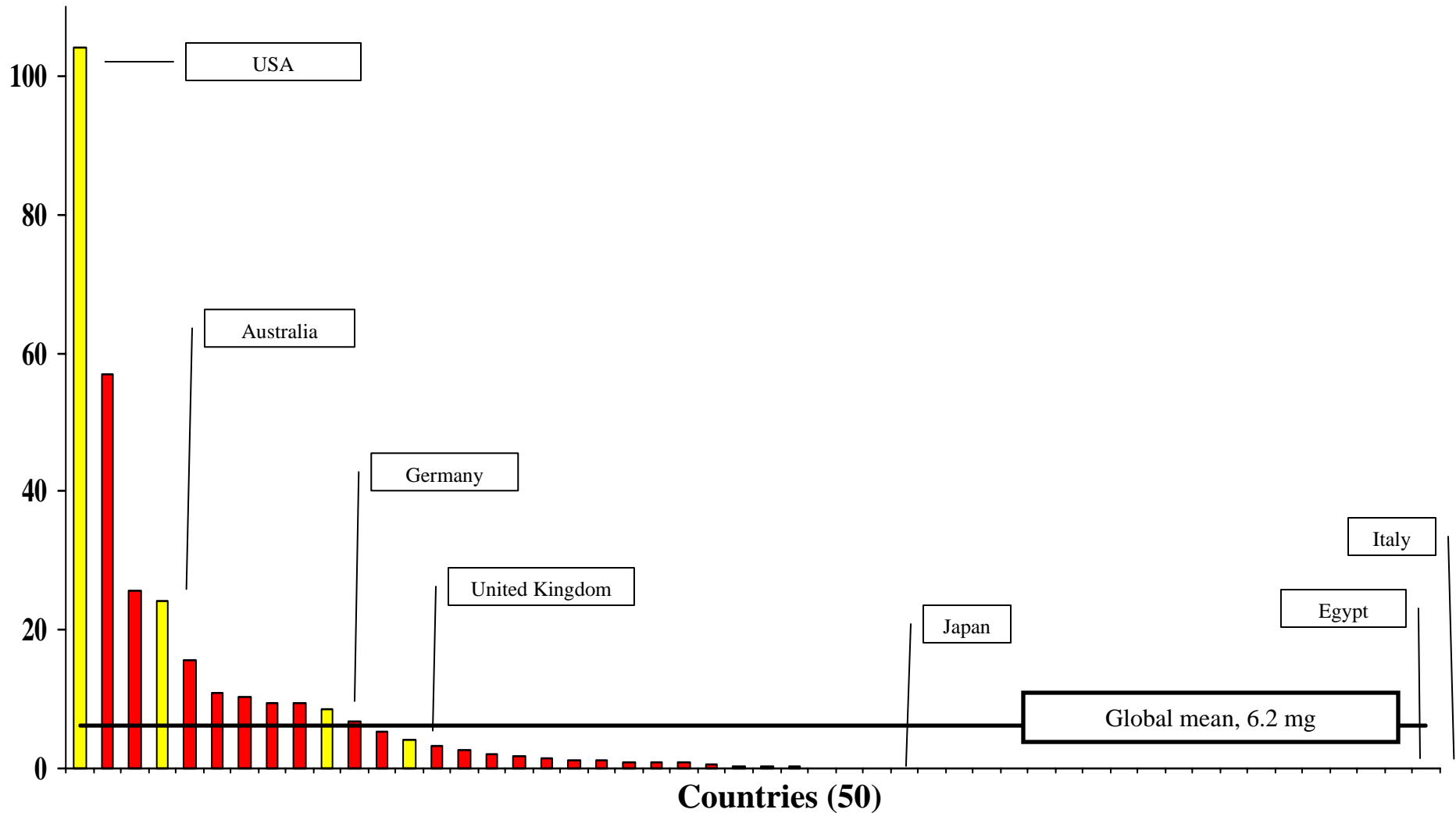


Source: International Narcotics Control Board; United Nations Demographic Yearbook  
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

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

# Global Consumption of Oxycodone mg/capita, 2003

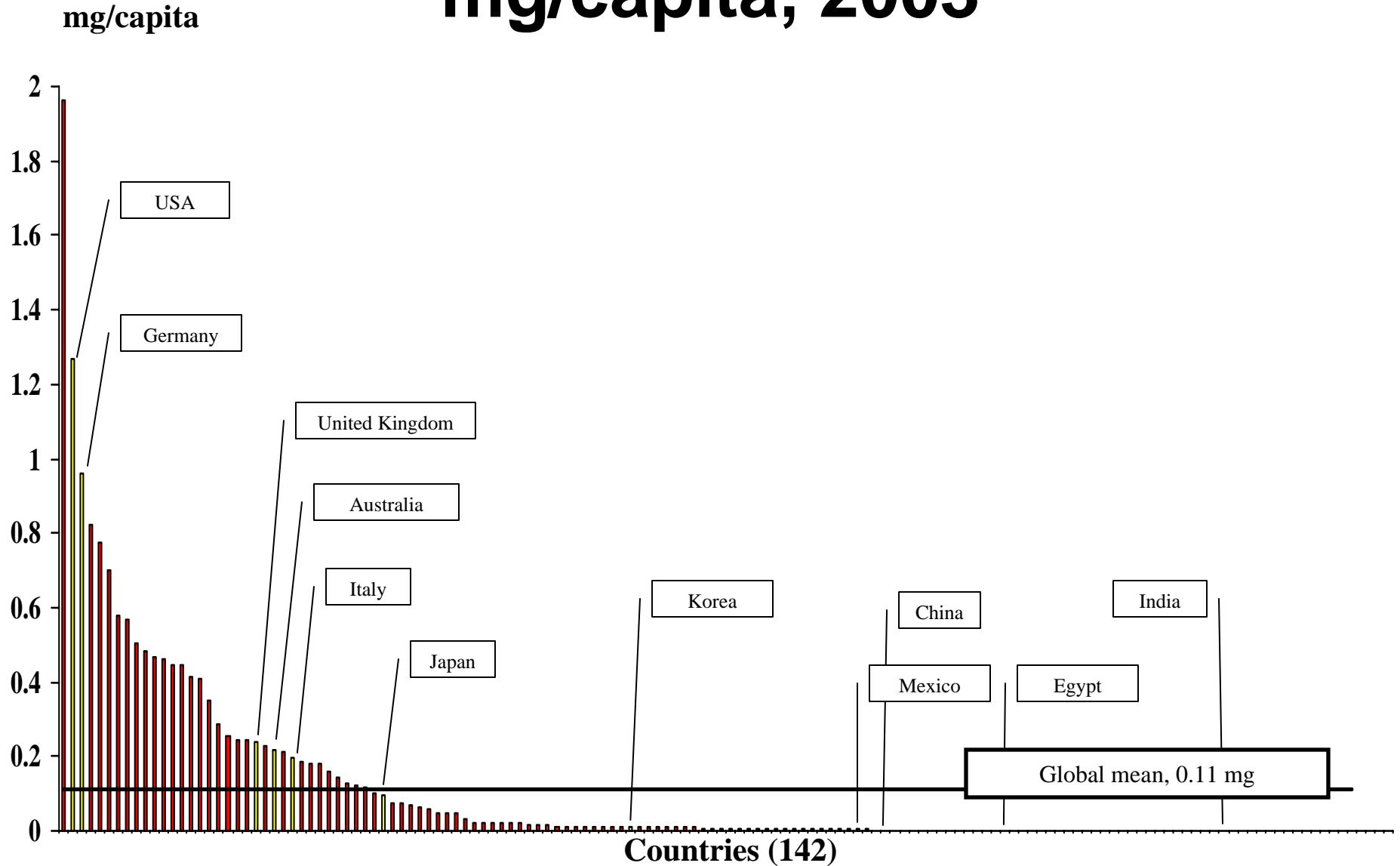
mg/capita



Source: International Narcotics Control Board; United Nations "Demographic Yearbook  
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

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

# Global Consumption of Fentanyl mg/capita, 2003



Source: International Narcotics Control Board; United Nations "Demographic Yearbook  
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

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

## INCB → Governments (2004)

“...the Board...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.”

### Conclusion:

*International regulatory authorities recognize there is inadequate availability, that it is not a supply problem but weak demand coupled with barriers in national policies.*

# **Barriers responsible for inadequate availability of opioids**

**(INCB, 2002)**

- 1. Inadequate method for assessing needs**
- 2. Unduly restrictive regulations**
- 3. Burdensome administrative procedures**
- 4. Excessive concerns about addiction**
- 5. Fear of investigation, penalties**
- 6. Lack of medical training in pain relief**

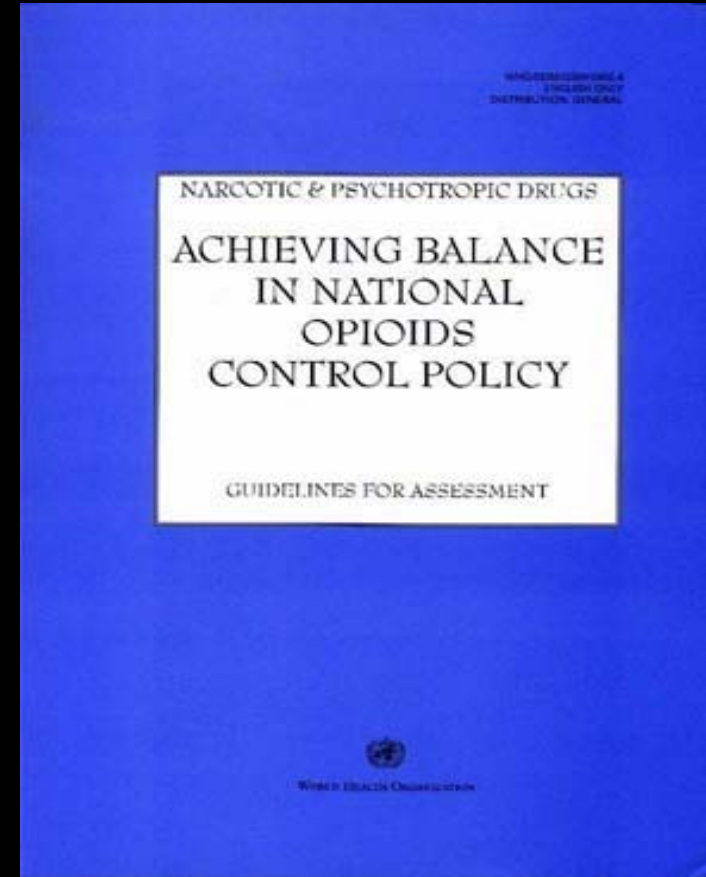
# National opioid policies

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- Opioids regulated by anti-narcotics laws
- Laws developed before pain movement emerged
- Purpose is drug trafficking, not medical use
- National policies are unique, often outdated
- Great variation in prescription requirements
- Gov'ts are obligated to ensure availability
- Little awareness about how to ensure availability
- INCB recommends evaluation of national policies

# WHO Guidelines for Achieving Balance in National Opioids Control Policy (2000)

- ✓ For governments and health professionals
- ✓ Explains need, rationale and imperative
- ✓ 16 criteria
- ✓ Simplified Checklist



[www.medsch.wisc.edu/painpolicy](http://www.medsch.wisc.edu/painpolicy)

# **The Principle of “Balance”**

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- **Opioids safe and effective, essential medicine; availability must be ensured**
- **Opioids have potential for abuse; control system needed to prevent diversion**
- **Efforts to address abuse and diversion must not interfere with medical practice and patient care**

# **What to expect from a national drug control agency**

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- **Assess needs, consult with experts**
- **Submit estimated requirements**
- **Amend as needed**
- **Issue licenses**
- **Manage importation, manufacture**
- **Report statistics**
- **Identify and remove undue restrictions**

# Using WHO Guidelines in Eastern Europe

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- WHO workshop in Budapest (2002)
- WHO Guidelines to evaluate national policy
- Severe restrictions in Romania
  - Complicated procedures
  - Dose and time limits
  - Incurable cancer, not AIDS
- Patients often die before obtaining morphine
- 35 year-old anti-narcotics law



# Romania: A Work in Progress

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- **MoH Palliative Care Commission**
- **Evaluate national policy**
- **PPSG invited to help**



[www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm](http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm)

WHO/EDM/QSM/2000.4

**Bulgarian**

**English**

**French**

**German**

**Italian**

**Lithuanian**

MEDICAMENTE  
NARCOTICE & PSIHOTROPICE

ATINGEREA  
ECHILIBRULUI IN  
POLITICA NATIONALA  
DE CONTROL A  
OPIOIDELOR

INSTRUCTIUNI DE EVALUARE

**Mongolian**

**Polish**

**Romanian**

**Russian**

**Spanish**

**Turkish**

**Ukrainian**



**Organizatia Mondiala a  
Sanatatii**

*Colectivul de Specialisti in Terapia Durerii si Ingrijiri Paliative*

*Pain & Policy Studies Group,  
Centrul OMS, Universitatea Wisconsin*

**Recomandari catre  
Ministerul Sanatatii**

16 iulie 2003

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*Commission of Specialists in Pain Therapy and Palliative Care*

*Pain & Policy Studies Group,  
WHO Centre, Wisconsin University*

**Recommendations to the  
Ministry of Health**

16 July 2003



# Who were the partners?

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- **Ministry of Health**
  - The Minister
  - Pharmacist/lawyer
  - Legislation drafting specialist
- **Palliative Care Commission**
  - Dr. Daniela Mosoiu and other pall care experts
  - Senior oncologist and pharmacologist
- **PPSG**
- **Open Society Institute**
- **US Cancer Pain Relief Committee**

# **Essential elements of the Romania project**

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- **Strong foundation of palliative care**
- **Evidence of impact on patients**
- **Palliative care leadership**
- **Government willingness to evaluate policy**
- **WHO/INCB guidelines**
- **Guidance from WHOCC**
- **Progress in other countries**

# Progress from around the world

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1. <u>France</u> :	7 days	28 days
2. <u>Mexico</u> :	5 days	30 days
3. <u>Italy</u> :	8 days	1 month
4. <u>Germany</u> :	1 day	no limit
5. <u>Poland</u> :	100 mg	8.0 grams
6. <u>Peru</u> :	1 day	14 days
7. <u>India</u> :	4 licenses	1 license
8. <u>Uganda</u> :	No <u>M</u>	<u>M</u> + RN Rx
9. <u>Romania</u> :	3 days/strict	????

# **Policy can be viewed as the patient**

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## **Policy**

1. Evaluation
2. Identify issues
3. Action plan
4. Evaluate outcomes

## **Patient**

1. Examination
2. Diagnosis
3. Treatment plan
4. Follow up visits

# Future direction of PPSG

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- **Regional/national policy initiatives**
  - Eastern Europe, former Soviet Union
  - Africa
  - India
- **Expanded website** [www.medsch.wisc.edu/painpolicy](http://www.medsch.wisc.edu/painpolicy)
  - Internet courses
  - Country profiles, opioid trends
  - More guidelines translations
- **Leadership development**
- **Distance consultation and assistance**

# Closing thoughts

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- **Regulatory barriers can and must be removed**
- **Cooperation between medicine and government is necessary**
- **Education of policy makers, health professionals and regulators is essential**
- **WHO Guidelines are a useful framework**



## **A closing question...**

**Is it morally acceptable  
to deny pain relief  
to the sick and dying  
in a vain effort to  
protect society from drug abuse?**

**Thank you!**

**Pain & Policy Studies Group**

**WHO Collaborating Center**

**Univ. of Wisconsin Comprehensive Cancer Center**

**[www.medsch.wisc.edu/painpolicy](http://www.medsch.wisc.edu/painpolicy)**