Improving Access to Opioid Analgesics for Pain Relief in the Middle East

United States National Cancer Institute
Middle East Cancer Consortium (MECC)

Palliative Care in the Middle East
Larnaca, Cyprus
2-3 February 2004

World Health Organization Collaborating Center for
Policy and Communications in Cancer Care
Pain & Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
www.medsch.wisc.edu/painpolicy

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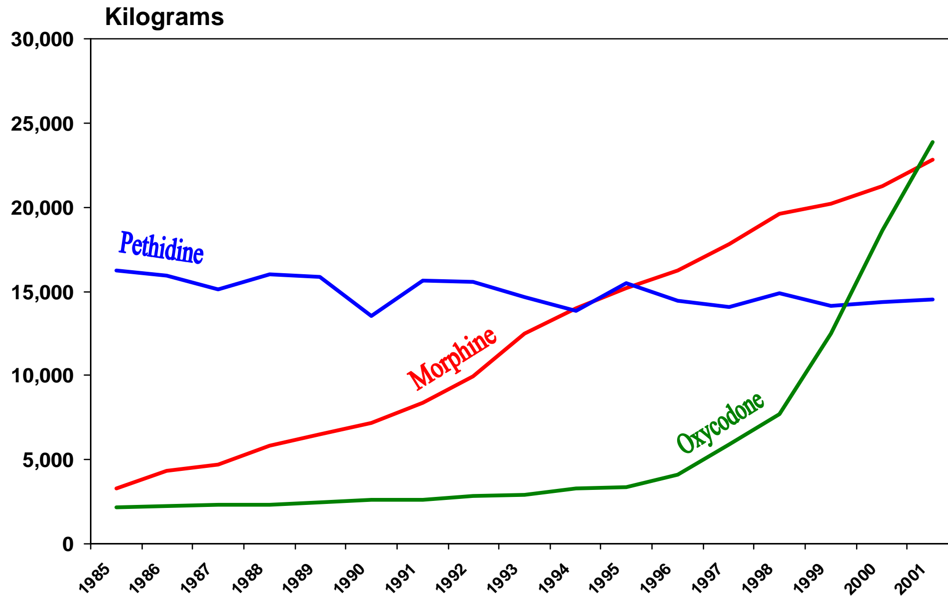
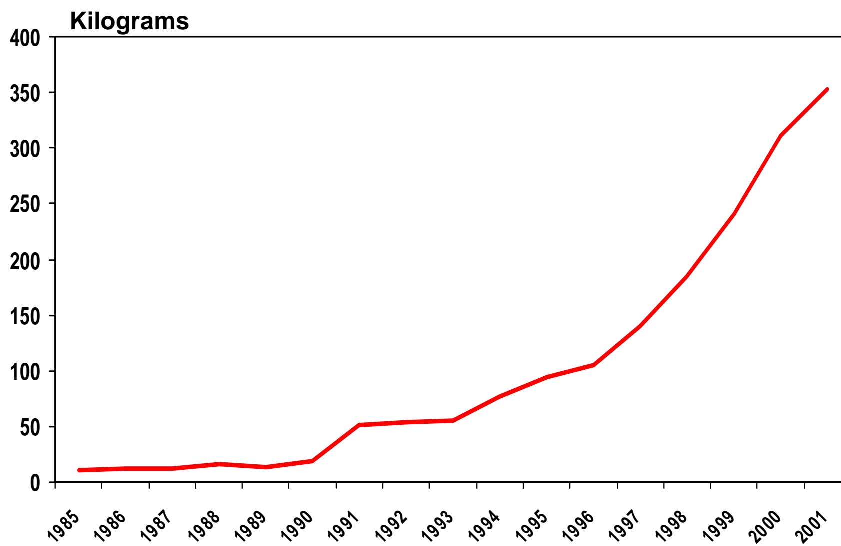
Global Consumption of Morphine, Pethidine & Oxycodone 1985-2001

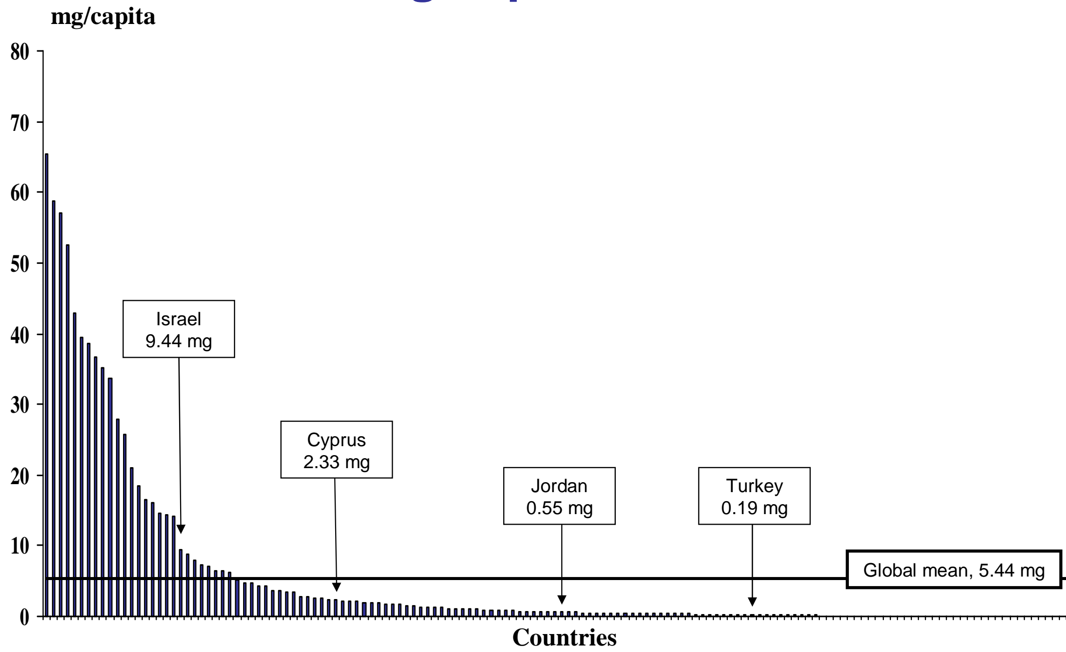


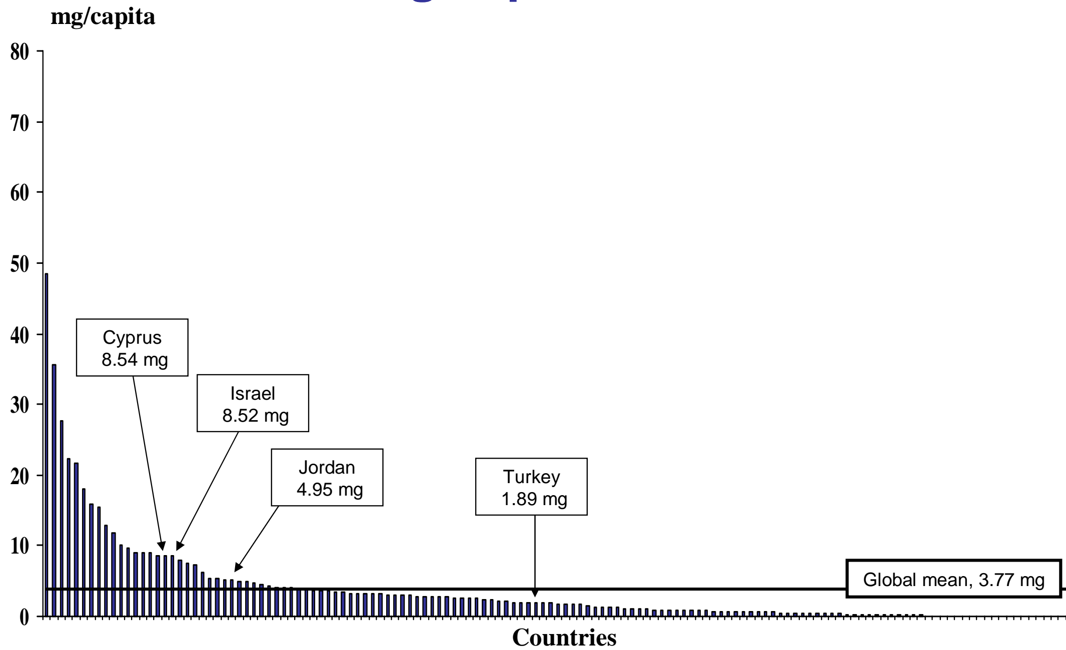
Source: International Narcotics Control Board

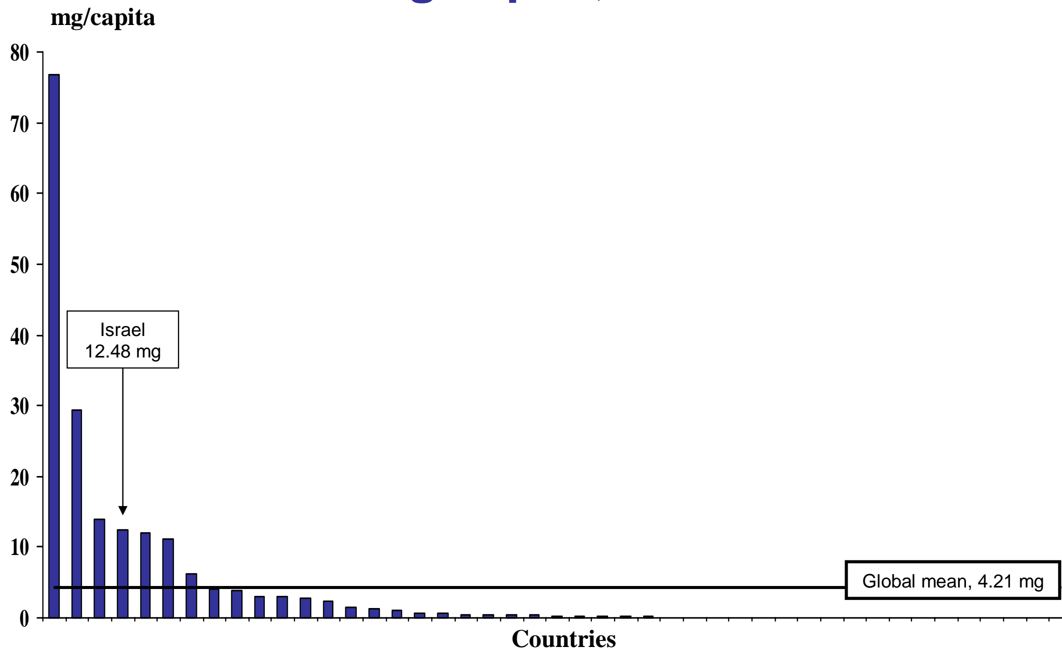
Global Consumption of Fentanyl 1985-2001

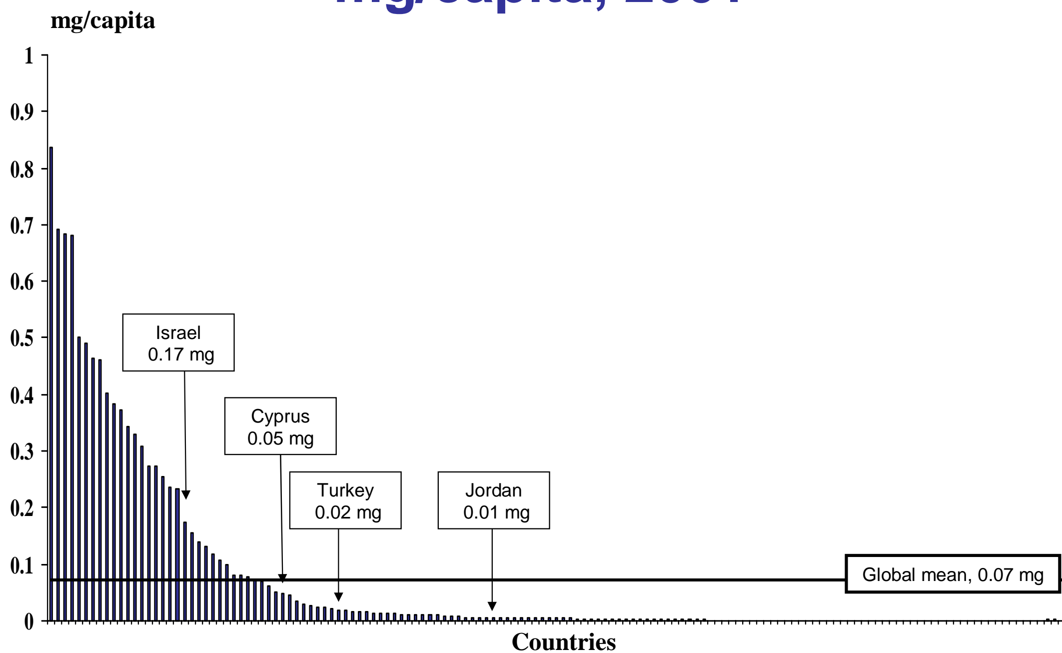


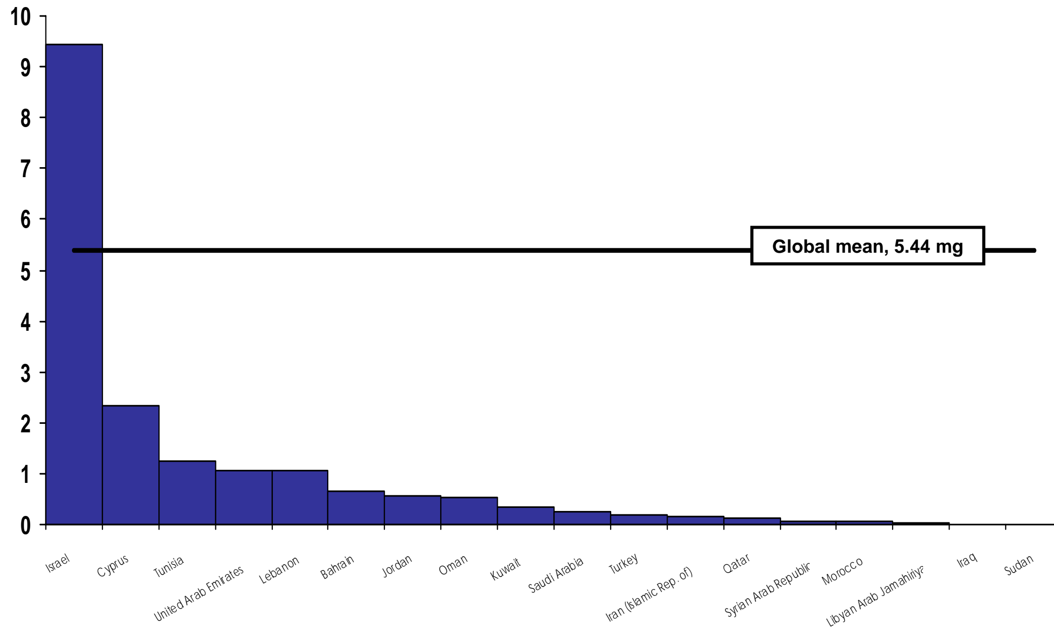
Source: International Narcotics Control Board

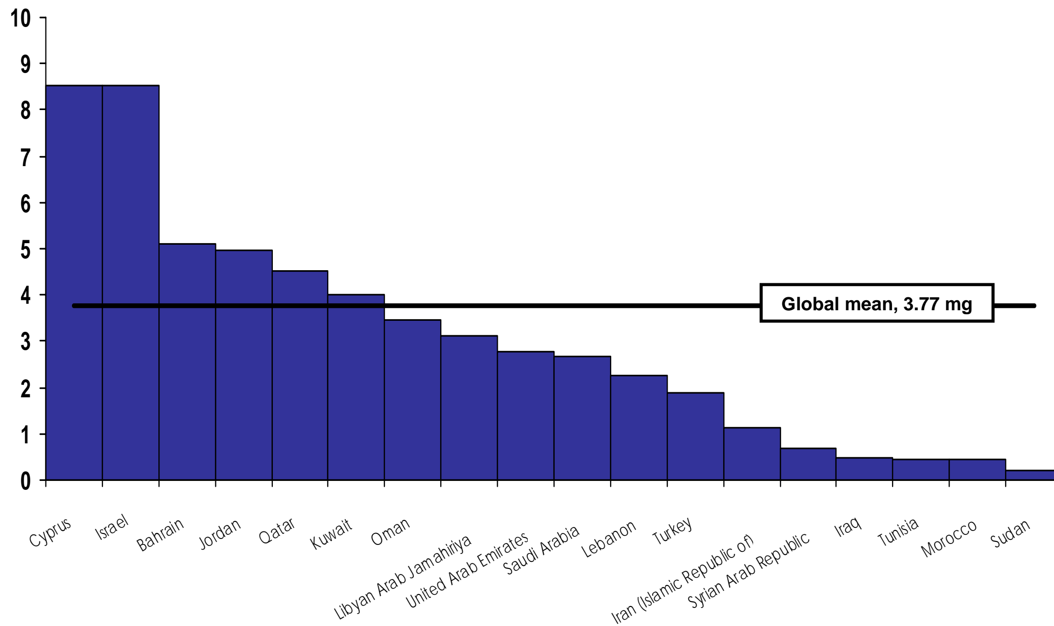

Global Consumption of Morphine
mg/capita, 2001
mg/capita
80
70
60
50
40
30
20
10
0
Israel
9.44 mg
Cyprus
2.33 mg
Jordan
0.55 mg
Turkey
0.19 mg
Global mean, 5.44 mg
Countries
Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001


Global Consumption of Pethidine
mg/capita, 2001
mg/capita
80
70
60
50
40
30
20
10
0
Cyprus
8.54 mg
Israel
8.52 mg
Jordan
4.95 mg
Turkey
1.89 mg
Global mean, 3.77 mg
Countries
Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001

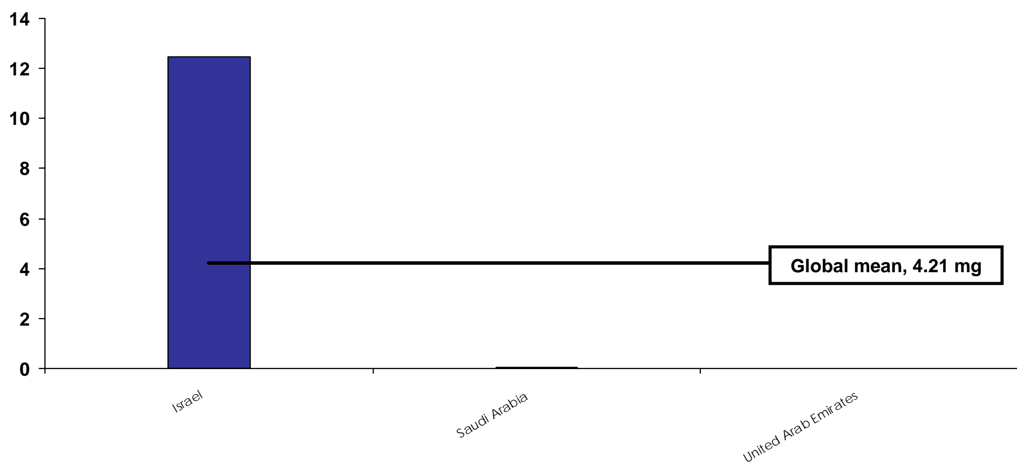

Global Consumption of Oxycodone
mg/capita, 2001
mg/capita
80
70
60
50
40
30
20
10
0
Israel
12.48 mg
Global mean, 4.21 mg
Countries
Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001


Global Consumption of Fentanyl
mg/capita, 2001
mg/capita
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Israel
0.17 mg
Cyprus
0.05 mg
Turkey
0.02 mg
Jordan
0.01 mg
Global mean, 0.07 mg
Countries
Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2001


Consumption of Morphine in the region
mg/capita, 2001
10
9
8
7
6
5
4
3
2
1
0
Global mean, 5.44 mg
Israel
Cyprus
Tunisia
United Arab Emirates
Lebanon
Bahrain
Jordan
Oman
Kuwait
Saudi Arabia
Turkey
Iran (Islamic Rep. of)
Qatar
Syrian Arab Republic
Morocco
Libyan Arab Jamahiriya
Iraq
Sudan
Source: International Narcotics Control Board; United Nations Demographic Yearbook

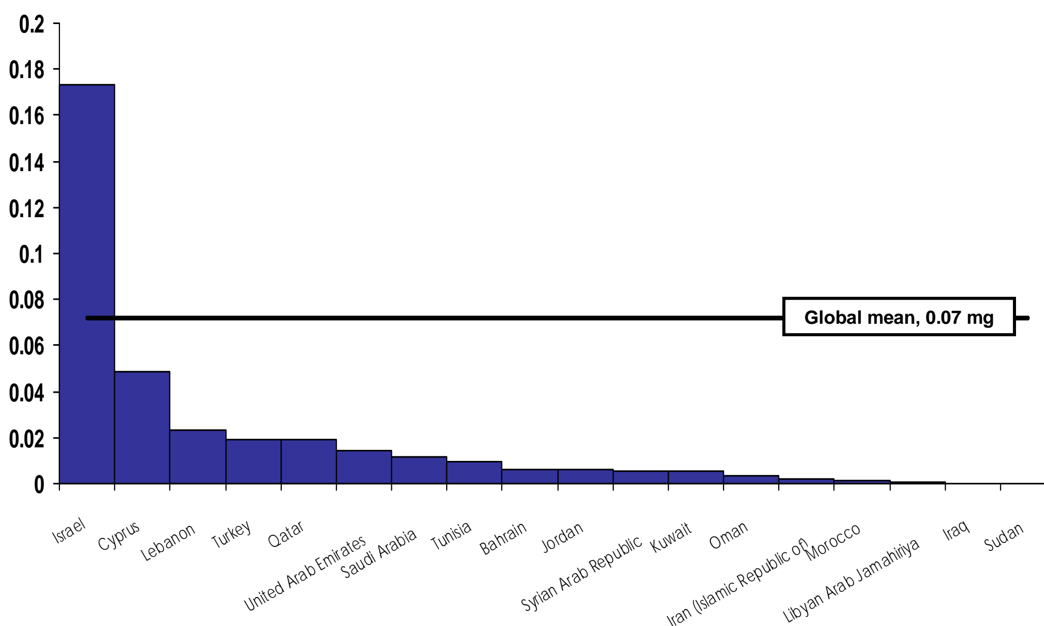

Consumption of Pethidine in the region
mg/capita, 2001
10
9
8
7
6
5
4
3
2
1
0
Global mean, 3.77 mg
Cyprus
Israel
Bahrain
Jordan
Qatar
Kuwait
Oman
Libyan Arab Jamahiriya
United Arab Emirates
Saudi Arabia
Lebanon
Turkey
Iran (Islamic Republic of)
Syrian Arab Republic
Iraq
Tunisia
Morocco
Sudan
Source: International Narcotics Control Board; United Nations Demographic Yearbook

Consumption of Oxycodone in the region mg/capita, 2001



Source: International Narcotics Control Board; United Nations Demographic Yearbook

Consumption of Fentanyl in the region mg/capita, 2001



Source: International Narcotics Control Board; United Nations Demographic Yearbook

Consumption of opioids in the region mg/capita, 2001

	Morphine	Pethidine	Oxycodone	Fentanyl
Cyprus	2.33	8.54	--	0.05
Egypt	--	--	--	--
Israel	9.44	8.52	12.48	0.17
Jordan	0.55	4.95	--	0.01
Turkey	0.19	1.89	--	0.02

Source: International Narcotics Control Board

-- = no report

Status of Adherence to Conventions

Receipt of Statistics, and Estimates

	Adherence		Consumption Statistics for 2001	Estimated requirements for 2003
	Single Convention 1961	As amended 1961/72		
Cyprus	●	●	●	●
Egypt	●	●		●
Israel	●	●	●	●
Jordan	●	●	●	●
Turkey	●	●	●	●

Source: International Narcotics Control Board, Estimated World Requirements for 2003 – Statistics for 2001

"Competent Authorities"

(National administrators of Single Convention on Narcotic Drugs)

Cyprus	Egypt	Israel
Director **Pharmaceutical Services** **Ministry of Health** 1475 Lefkosia (Nicosia) Cyprus Tel: 357 22-407 107 Fax: 357 22-407 149	**Central Administration for Pharmaceutical Affairs** **Narcotic Department** **Ministry of Health** 22, El-Falaky Street Cairo Egypt Tel: 202-7949802/202-7945159 Fax: 202-7942627/202-7945151	**The Pharmaceutical Administration** **Ministry of Health** P.O. Box 1176 Jerusalem 91010 Israel Tel: 972 2-5681215/972 2-5681344 Fax: 972 2-6725827/972 2-6725820

Jordan	Turkey
Drugs Directorate **Ministry of Health** P.O. Box 86 Amman Jordan Tel: 962 6-5693104/962 6-5693109 Fax: 962 6-5665232/962 6-5688373	**General Directorate of Medicine and Pharmaceutical Affairs** **Ministry of Health** Ankara Turkey Tel: 90 312-2302794/90 312-2302769 Fax: 90 312-2301610

Source: International Narcotics Control Board

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

[1] World Health Organization. *Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*. Geneva, Switzerland: World Health Organization; 2000. (Available at http://www.who.int/medicines/library/qsm/who-edm-qsm-2000-4/who-edm-qsm-2000-4.htm).

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EXECUTIVE SUMMARY

The World Health Organization (WHO) has determined that the inadequate management of pain due to cancer is a serious public health problem in the world. Worldwide, there are 10 million new cases of cancer and 6 million deaths annually from this noncommunicable disease *(1)*. Twenty years from now, the global burden of cancer will double. The incidence of cancer, presently greatest in developed countries, will shift to developing countries, reflecting better prevention strategies in the developed world. The WHO Programme on Cancer Control has estimated that by the year 2020, approximately 70% of the annual 20 million new cancer cases will occur in developing countries *(1)*, where most patients are diagnosed when the disease is already in the late stages. Pain is prevalent in cancer, but especially in the late stages, near the end of life.

Tragically, cancer pain frequently goes untreated; when it is treated, relief is often inadequate. Yet, the WHO has demonstrated that most, if not all, pain due to cancer *could* be relieved if we implemented *existing* medical knowledge and treatments. There is a treatment gap: it is the difference between what can be done, and what *is* done about cancer pain. The treatment gap can be narrowed by educating and training health care workers, and by increasing access to pain relief and palliative care services. However, much of the treatment gap, especially in developing countries, is defined by the inadequate availability and use of pain medications, in particular the opioid analgesics.

Although there are many drug and non-drug pain treatments, the opioid analgesics such as codeine and morphine are *absolutely necessary* for the management of pain due to cancer. When cancer pain is moderate to severe, there is no substitute for opioids in the therapeutic group of morphine. The International Narcotics Control Board (INCB)[1], the international body that monitors, inter alia, global availability of narcotic drugs, emphasizes that these drugs must be available for pain relief.

Opioids are classified as narcotic drugs because they have a potential for abuse. As a consequence, they are regulated by international treaties and national drug control policies. The INCB, the WHO and national governments report that opioids are not sufficiently available for medical purposes. There are a number of reasons, including the low priority for pain management in health care systems, greatly exaggerated fears of addiction, overly restrictive national drug control policies, and problems in procurement, manufacture and distribution of opioids.

In some countries, governments and health care professionals have been working together to improve cancer pain management and palliative care; some have begun to identify and correct overly restrictive regulatory control over the medical use of opioid analgesics. Other countries have yet to address these matters. These Guidelines can be used by governments to determine whether their national drug control policies have established the legal and administrative framework to ensure the medical availability of opioid analgesics, according to international treaties and the recommendations of the INCB and the WHO.

A 1995 INCB report *(3)* stated:
"...an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes" (p.14).

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[1] The International Narcotics Control Board is an independent treaty-based body that monitors implementation of the Single Convention on Narcotic Drugs, 1961, and other related treaties. For a description of the Board and its activities see: INCB, 1999 *(2)*.

SECTION I
PURPOSE AND AUDIENCE

The purpose of these self-assessment Guidelines is to encourage governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability.[2] These Guidelines may also be used to develop balanced national (including state, provincial or territorial authorities where relevant) drug control policies where none already exist. (See Annex 1 for definition of "national policy.") "Balance" refers to the dual purpose of preventing illegal trafficking and diversion, while ensuring their availability for medical and scientific purposes, in particular for the treatment of pain and suffering (see Section VII for further discussion).

This document is intended for those who make national drug control policy, as well as those who implement it. It may also be used by health care professionals and their organizations to encourage cooperation with governments and to facilitate further education.

This document accomplishes its purpose in several ways:

I. Background information is presented about the global problem of inadequate cancer pain relief (Section II);
II. Information is provided about why opioids (i.e., narcotic drugs, opiates[3]) are needed for the medical management of pain (Section III);
III. Information is given about the inadequate availability of opioid analgesics in most countries (Section IV);
IV. The reasons for inadequate availability are given, with specific reference to the overly restrictive regulation of pain medications under some national drug control policies (Section V);
V. A rationale is presented for governments to assess national policies for balance (Section VI);
VI. The method that was used to develop guidelines for conducting a self-assessment is described (Section VII);
VII. The Guidelines are presented to encourage consensus in the adoption of balanced national drug control policy. They are based on international medical and regulatory consensus that national drug control policy should be balanced (Section IX);
VIII. A checklist of questions is provided to guide the self-assessment (Section X);
IX. Reference information is provided on page 28-29;
X. Ordering information for key resources is provided in Annex 2; and
XI. A directory of the government offices responsible for narcotic regulation (National Competent Authorities) is available from the INCB at the following:

website http://www.incb.org
telephone +43-1-26060-4277, facsimile +43-1-26060-5867/5868

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[2] There are three levels of barriers to adequate pain management: economic, medical and regulatory. While these Guidelines focus solely on regulatory issues, it is well understood that economic and medical barriers play major roles in the inadequate treatment of pain. For example, in some countries, for economic reasons, health care professionals are encouraged to use more expensive and less effective pharmaceutical products. This may exacerbate inadequate availability, both for the health care system in general, and for the individual patient. In some countries, scarce medical resources are spent on expensive curative treatments that are futile for patients with late-stage cancer *(4)*. Such policies preclude the provision of palliative care. Finally, medical education that does not address pain management contributes to inadequate pain management.

[3] See Annex 1 for an explanation of "opiate" and "opioids," and other key terms used in this publication.

SECTION X
SELF-ASSESSMENT CHECKLIST

Governments or other interested groups, including health care professionals, may use the following checklist to guide their analysis of national drug control policies. Please note that some inquiry may be needed prior to answering the questions contained on this checklist.

1. Has the government conducted an examination to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments?

• Yes • No • Information not available

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are absolutely necessary for the relief of pain and suffering?

• Yes • No • Information not available

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make adequate provision to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering?

• Yes • No • Information not available

4a. Has the government established administrative authority for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics?[11]

• Yes • No • Information not available

4b. Are adequate personnel (employees) available for the implementation of this responsibility?

• Yes • No • Information not available

5a. Does the government have a method to estimate realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care?

• Yes • No • Information not available

[11] **In some cases, the government's policy may be found in either the law or administrative policies, or in both.**

5b. Has the government critically examined its method for assessing medical needs for narcotic drugs, as requested by the INCB?

- Yes
- No
- Information not available

5c. Has the government established a satisfactory system to collect information about medical need for opioid analgesics from relevant facilities?

- Yes
- No
- Information not available

6. Does the government furnish annual estimates to the INCB of need for narcotic drugs for the next year in a timely way?

- Yes
- No
- Information not available

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a supplementary estimate?

- Yes
- No
- Information not available

8. Does the government submit to the INCB in a timely way the required annual statistical reports respecting production, manufacture, trade, use and stocks of narcotic drugs?

- Yes
- No
- Information not available

9a. Has the government informed health professionals about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns?

- Yes
- No
- Information not available

9b. Has the government identified and addressed concerns of health care professionals about being investigated for prescribing opioids?

- Yes
- No
- Information not available

10. Is there cooperation between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes?

- Yes
- No
- Information not available

11. Has the government taken steps, in cooperation with licensees, to ensure that there are no shortages of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems?

• Yes • No • Information not available

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will maximize physical access of patients to pain relief medications?

•Yes • No • Information not available

13a. Has the government established a national cancer control programme to which it allocates health care resources?

• Yes • No • Information not available

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing education programmes and by its inclusion in medical, pharmacy and nursing curriculum?

• Yes • No • Information not available

14. Is there terminology in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?

• Yes • No • Information not available

15. Are there provisions in national drug control policy that restrict the amount of drug prescribed or the duration of treatment?

• Yes • No • Information not available

16. Are there prescription requirements in national drug control policy that may unduly restrict physician and patient access to pain relief?

• Yes • No • Information not available

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Fax: 1-608-263-0259

http://www.medsch.wisc.edu/painpolicy/
http://www.medsch.wisc.edu/WHOcancerpain/