Opioid Analgesics (Narcotics) in Asia:
Trends, Resources, Recommendations

Prepared for:

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About the Pain & Policy Studies Group

The Pain & Policy Studies Group mission is to promote "balance" in international, national and state pain policies to ensure adequate availability of opioid analgesics and their appropriate medical use for patient care while addressing diversion and abuse. The PPSG is designated the World Health Organization Collaborating Center for Policy and Communications in Cancer Care. Much of the PPSG's work, including new WHO Guidelines that are discussed later in this document, are available on their website at www.medsch.wisc.edu/painpolicy. As a WHO Collaborating Center, the PPSG provides technical assistance to governments in Africa, Asia, Europe, and Latin America, and established a WHO Demonstration Project in Calicut, India.

The PPSG also supports a global communications program to improve access to information about pain relief, palliative care, and pain policy, and publishes a WHO newsletter *Cancer Pain Release* (http://www.medsch.wisc.edu/WHOcancerpain/).

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SECTION I - CANCER PAIN RELIEF AND OPIOID AVAILABILITY IN THE WORLD

Relieving cancer pain

In 1986, the WHO said that implementation of currently available medical knowledge could relieve most pain due to cancer.[1] WHO recommended that health professionals use a three-step Analgesic Ladder to treat cancer pain and that governments make the drugs available. The successful implementation of the WHO Analgesic Ladder depends on the availability of drugs that are safe and effective in relieving chronic severe pain, such as morphine or other strong opioids including fentanyl, hydromorphone, methadone and oxycodone. However, the availability of these drugs varies greatly from country to country.

Monitoring progress

The WHO monitors countries' consumption of opioids as one indicator of national progress to improve cancer pain relief. Morphine is the principal indicator because it is the most widely available opioid analgesic for moderate to severe pain. Consumption trends for pethidine are included in this monograph because, although pethidine is not recommended for chronic pain, it is an opioid with the same control status as morphine, and its medical use is extensive. If governments can make pethidine available, they can also make morphine available.

Prior to 1986, the consumption of morphine throughout the world was low and stable. After 1986, the total global consumption of morphine began to increase substantially as some national governments and health professionals adopted the WHO Analgesic Ladder and as new opioid products became available more widely. It should be noted that medical use of morphine in some countries is mainly for cancer pain, but morphine and other opioids can be used for acute post-operative pain, AIDS pain, and chronic non-cancer pain.

Morphine consumption in the world

Only ten industrialized countries account for the vast majority (69%) of global morphine consumption: Australia, Austria, Brazil, Canada, France, Germany, Japan, Portugal, the United Kingdom, and the United States. These ten countries represent less than 10% of the world's population. The remaining countries of the world (a number of developed countries and all developing countries) consumed 31% of the morphine in 2000, compared to only 13% in 1999. In some countries, the lack of palliative care and opioids is particularly serious because, by the time most patients are diagnosed with cancer, they have late-stage cancer that is often accompanied by severe pain.

Inadequate opioid availability

Although many countries have experienced little change in morphine consumption since 1986, some have recently begun to increase their use of opioids for cancer pain relief. Nevertheless, global consumption remains extremely low in comparison to the medical need, and many national governments have yet to address this important health priority. According to a 1996 survey of governments by the International Narcotics Control Board (INCB),[2] injectable forms of morphine were more available than oral forms recommended by WHO, and approximately one-half of governments reported that morphine is not available in all hospitals that treat cancer patients. In addition, only 60% of governments surveyed had endorsed the WHO Analgesic Ladder. Success in implementing the WHO Analgesic Ladder has been limited by the lack of opioid analgesics, exaggerated fear of addiction, and excessively strict regulation of narcotic drugs; future success will depend on governmental efforts to address regulatory barriers and make opioids more available.

Impediments to availability

The INCB and the WHO have concluded that there are a number of impediments to the availability and use of opioid analgesics for cancer pain relief. Many government policies limit the quantity and duration of opioid prescriptions and impose special requirements for physicians who prescribe. National health priorities may not include cancer pain relief, as was evident in about half of the governments responding to the survey. In addition,

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[1] World Health Organization. *Cancer Pain Relief.* Geneva, Switzerland: World Health Organization; 1986.

[2] International Narcotics Control Board. *Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs.* Vienna, Austria: United Nations; 1996. *Available at* http://www.incb.org/e/ar/1995/suppl1en.pdf

health professionals, narcotic regulators and legislators may not realize there is a need for pain relief; they may be mainly concerned about narcotic addiction and diversion. In fact, 43% of governments that responded to the INCB survey said that they require physicians to report to the government those patients who are prescribed opioid analgesics.

SECTION II - EFFORTS TO IMPROVE OPIOID AVAILABILITY IN THE WORLD

The WHO and the INCB are addressing the unmet need for opioid analgesics, as well as the impediments to their adequate availability.

WHO activities to improve availability

The WHO recommends that national governments implement a three-part strategy to make cancer pain relief and palliative care a priority: (1) establish a national policy that supports pain relief and palliative care; (2) develop educational programs for the public and health professionals; and (3) ensure the availability of needed drugs for the treatment of pain and other symptoms. The WHO Collaborating Center for Policy and Communications in Cancer Care provides technical assistance to governments and health professionals to evaluate impediments to opioid availability and to monitor the progress to improve opioid availability while preventing diversion. In 2000, the WHO published guidelines for evaluating national opioids control policy for "balance."

INCB activities to improve availability

The INCB is the international narcotics regulatory authority for the United Nations. The INCB monitors national governments' implementation of the 1961 Single Convention on Narcotic Drugs, as amended, a treaty that governs availability of narcotic drugs in the world.

According to the Single Convention, opioids (narcotic drugs) are indispensable for the treatment of pain and suffering, and governments should ensure their adequate availability for all medical and scientific purposes while preventing addiction and diversion. Thus, it is the responsibility of national governments (because most governments are parties to this treaty) not only to prevent misuse and diversion but also to ensure availability of opioids for medical needs. The INCB reports that, despite the large number of transactions of narcotic drugs, there was no diversion reported in 1999.[3] The INCB and other United Nations organizations, such as the Commission on Narcotic Drugs, have recognized that opioids are not sufficiently available in the world. The INCB has requested all national governments to (a) re-evaluate their medical needs for opioids, (b) identify and address impediments, and (c) communicate with health professionals to determine the unmet medical need for opioid analgesics.

WHOCC activities to improve availability

As a WHO Collaborating Center, the Pain and Policy Studies Group (PPSG) provides technical assistance to governments in Africa, Asia, Europe, and Latin America, and established a WHO Demonstration Project in Calicut, India. The World Health Organization Collaborating Center efforts to improve opioid availability are summarized in annual reports available at http://www.medsch.wisc.edu/painpolicy/publicat/annrepts.htm.

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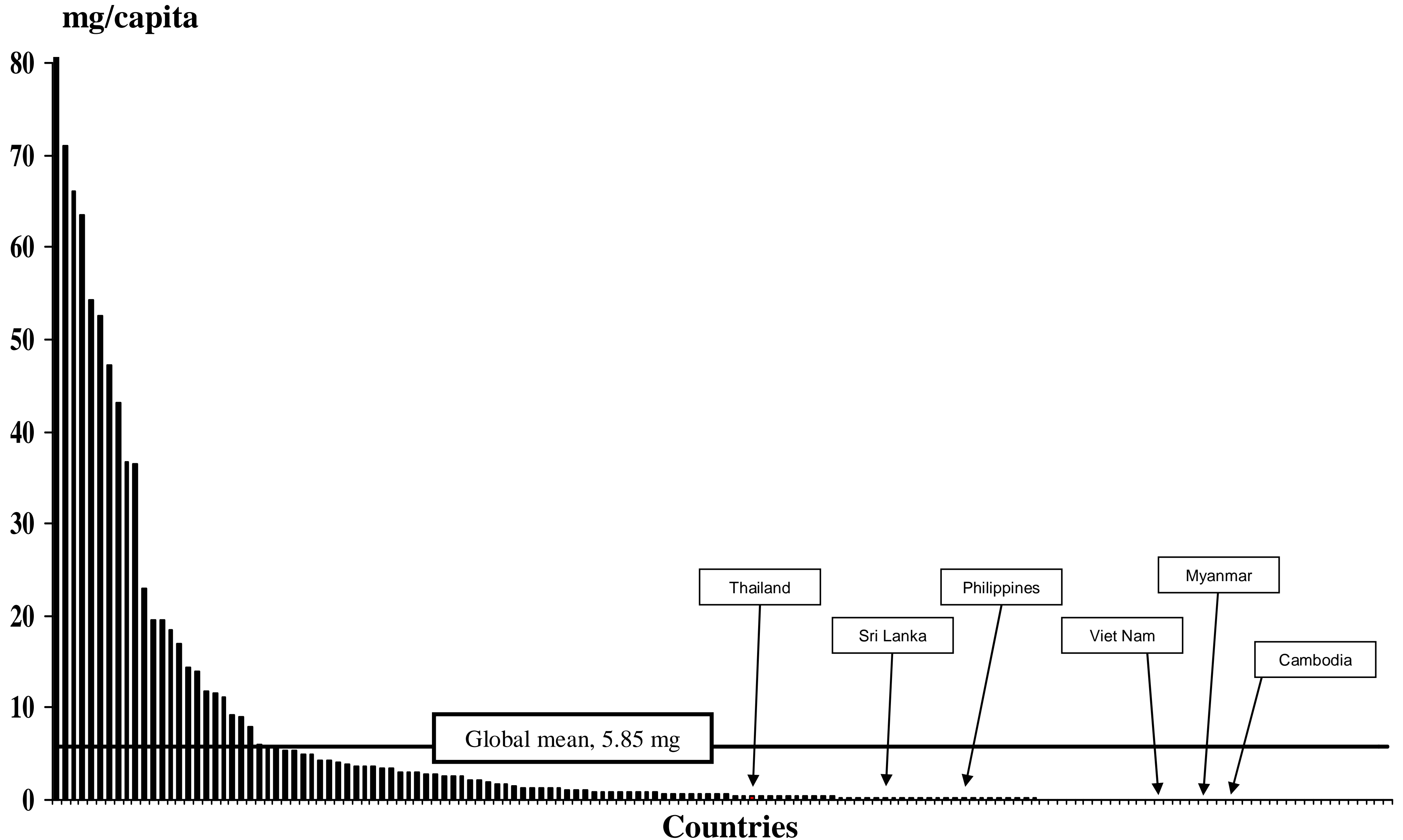
[3] International Narcotics Control Board. *Report of the International Narcotics Control Board for 1999*. New York, NY: United Nations; 2000. *Available at* http://www.incb.org/e/ar/1999/

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

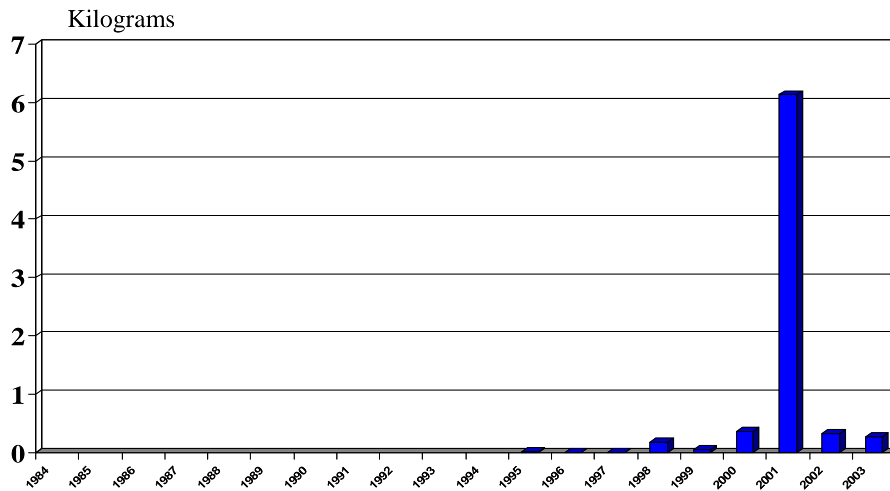
Per Capita Global Consumption of Morphine, 2003

COUNTRY	MG/CAPITA	COUNTRY	MG/CAPITA	COUNTRY	MG/CAPITA
Austria	93.20109	Cyprus	1.768061	Tuvalu	0.2
Falkland Islands	71	Tunisia	1.74813	Turkey	0.159676
Canada	66.01489	British Virgin Islands	1.4	Philippines	0.158391
Denmark	63.39678	St. Vincent & the Grenadines	1.389831	Venezuela	0.158129
Australia	54.1915	Namibia	1.376166	El Salvador	0.150325
New Zealand	52.61075	Montserrat	1.333333	Azerbaijan	0.138585
U.S.A..	47.19575	Bahrain	1.327561	Cameroon	0.136107
France	43.07664	Saint Lucia	1.231293	Peru	0.134398
Norway	36.64219	Paraguay	1.070664	Egypt	0.130201
Iceland	36.45263	Lebanon	0.994063	Uzbekistan	0.12938
Sweden	22.84515	Croatia	0.969854	Morocco	0.114247
United Kingdom	19.60578	Cuba	0.950347	Syrian Arab Republic	0.104019
Switzerland	19.55221	Colombia	0.948559	Burundi	0.095134
Germany	18.39137	Argentina	0.894348	Swaziland	0.091682
Netherlands	16.99962	Dem. Peop. Rep. of Korea	0.892499	Uganda	0.089948
Gibraltar	14.37037	Singapore	0.849452	Kazakhstan	0.088328
Belgium	13.96535	Cook Islands	0.833333	Turkmenistan	0.086864
Portugal	11.89495	Netherlands Antilles	0.801843	Kyrgyzstan	0.076877
Saint Helena	11.6	Armenia	0.755829	Maldives	0.066667
Ireland	11.21656	Jamaica	0.6869	Solomon Islands	0.066667
Luxembourg	9.117914	Macao	0.672527	Wallis & Futuna Islands	0.066667
Cayman Islands	9.078947	United Arab Emirates	0.666551	Libyan Arab Jamahiriya	0.063483
Spain	7.975951	Romania	0.662121	Serbia and Montenegro	0.057658
Czech Republic	5.908355	Belarus	0.654116	Viet Nam	0.056189
Poland	5.680655	Russian Federation	0.644167	Dominica	0.051282
Japan	5.614838	Brunei Darussalam	0.611111	Djibouti	0.04699
Slovenia	5.308853	Greece	0.549283	Lesotho	0.037347
Israel	5.273243	Suriname	0.5338	Kenya	0.034895
Malta	4.859335	Vanuatu	0.514851	Myanmar	0.032652
Finland	4.849075	Thailand	0.50329	Mexico	0.031357
Brazil	4.358624	Panama	0.432657	Guyana	0.02231
French Polynesia	4.270042	Mozambique	0.42595	Cambodia	0.020775
Estonia	4.020695	Saudi Arabia	0.425599	Zambia	0.020435
Bulgaria	3.941616	Turks and Caicos Islands	0.421053	Senegal	0.01767
Slovakia	3.743604	Mauritius	0.410684	Indonesia	0.014719
South Africa	3.729242	Dominican Republic	0.407661	Rwanda	0.012026
Bahamas	3.605863	Republic of Moldova	0.40014	Iraq	0.01052
Andorra	3.477612	Qatar	0.373942	Angola	0.007832
Seychelles	3.4	Jordan	0.338414	Yemen	0.007077
Hungary	3.105638	Grenada	0.320988	Cape Verde	0.006742
Republic of Korea	2.995842	Oman	0.318452	Guinea	0.005581
Hong Kong SAR	2.947979	Tonga	0.313725	Comoros	0.00551
Barbados	2.843284	Marshall Islands	0.288462	Sierra Leone	0.005467
Lithuania	2.779851	Nicaragua	0.287663	Algeria	0.004098
Costa Rica	2.651134	Sri Lanka	0.287169	Madagascar	0.003893
Italy	2.588846	Albania	0.278347	Benin	0.003758
Chile	2.555808	Ecuador	0.271718	Eritrea	0.00208
Georgia	2.228752	Republic of Palau	0.25	Côte d'Ivoire	0.001615
Latvia	2.076563	Mongolia	0.221519	Haiti	0.00111
Ukraine	1.880037	China	0.218912	Nigeria	0.000518
		Kuwait	0.21632	Ethiopia	0.000253

Source: International Narcotics Control Board

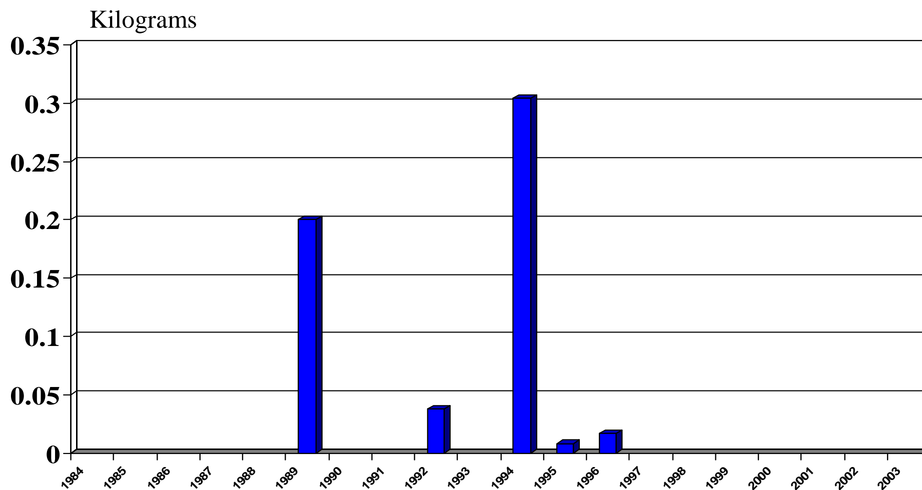
By: Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center, World Health Organization Collaborating Center for Policy & Communications in Cancer Care, ppsg@med.wisc.edu, www.medsch.wisc.edu/painpolicy , 2005

Total Consumption of Morphine
- Kingdom of Cambodia -
1984 - 2003



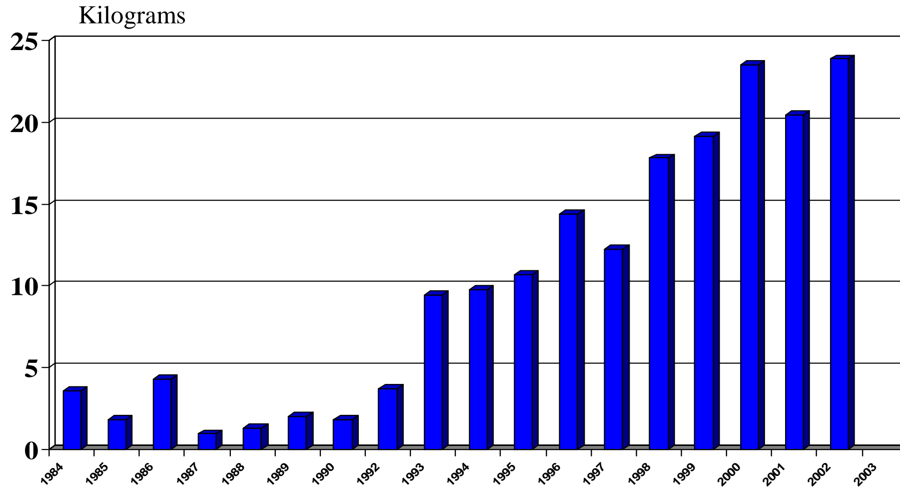
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- Lao Peoples Democratic Republic -
1984 - 2003



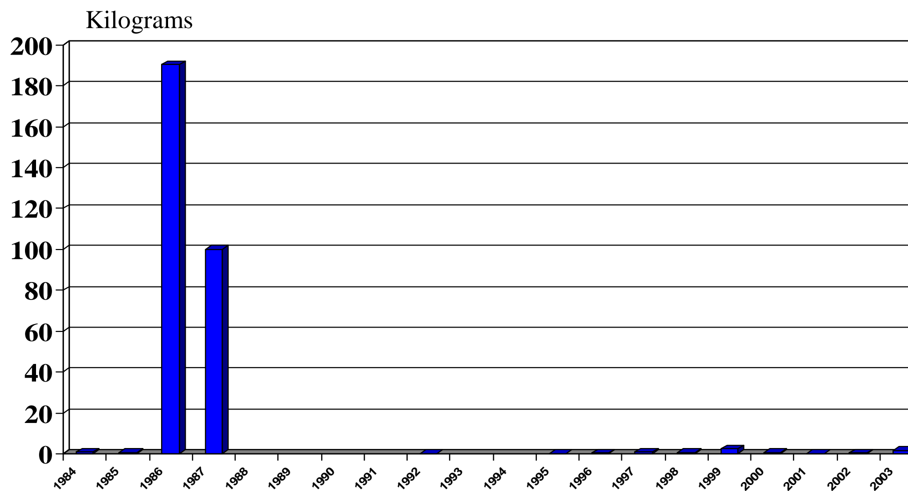
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- Malaysia -
1984 - 2003



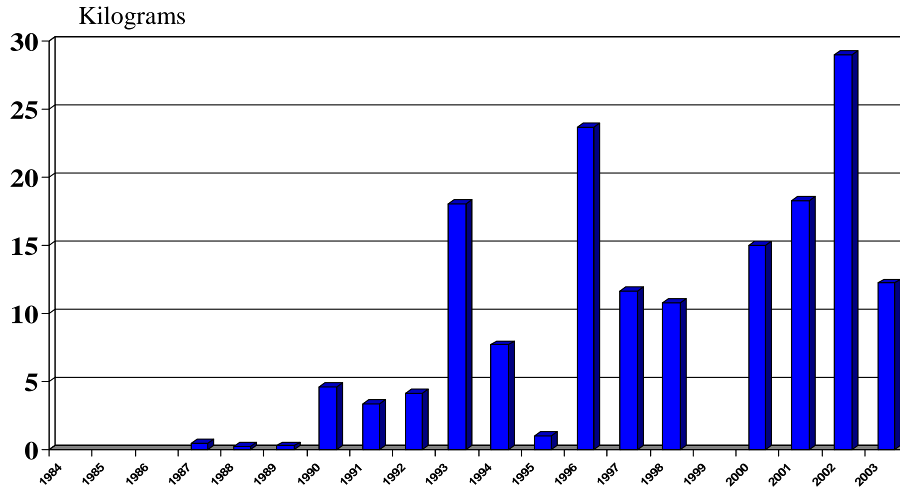
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- The Union of Myanmar -
1984 - 2003



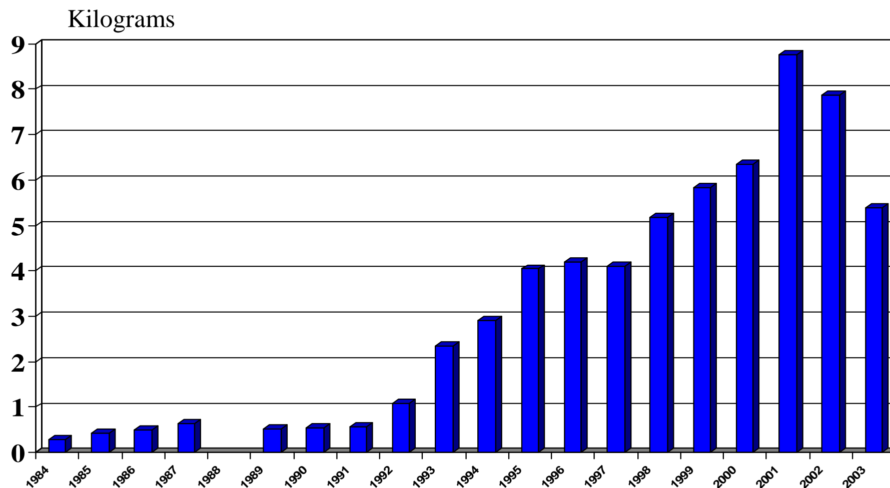
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- Republic of the Philippines -
1984 - 2003



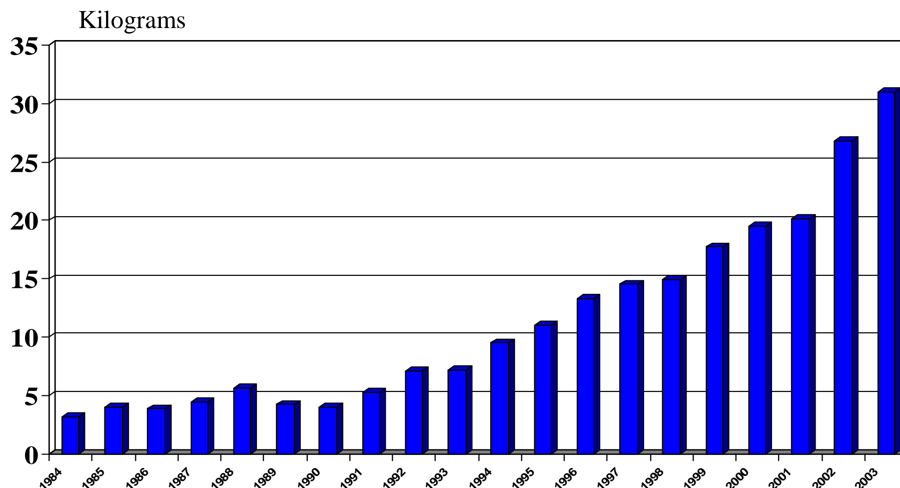
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- Democratic Socialist Republic of Sri Lanka -
1984 - 2003



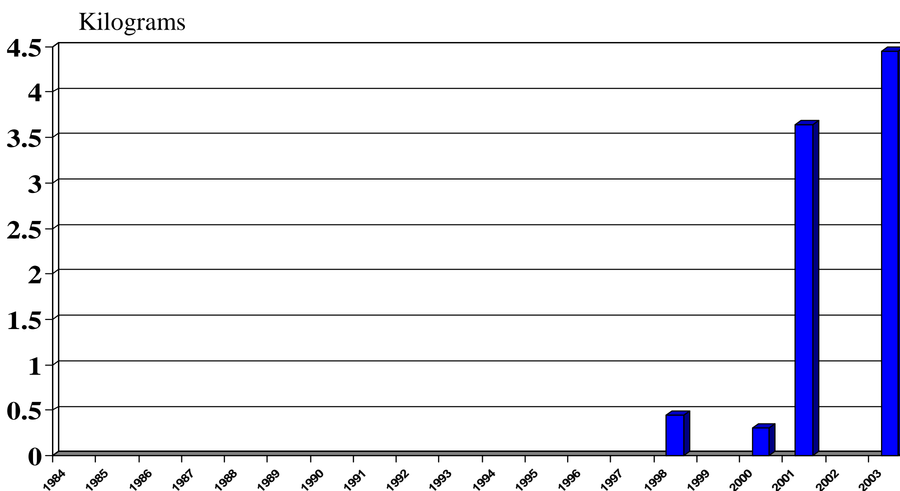
Source: International Narcotics Control Board; United Nations "Demographic Yearbook
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005

Total Consumption of Morphine
- Kingdom of Thailand -
1984 - 2003



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

Total Consumption of Morphine
- Socialist Republic of Viet Nam -
1984 - 2003



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

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NARCOTIC & PSYCHOTROPIC DRUGS

ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY

GUIDELINES FOR ASSESSMENT

WORLD HEALTH ORGANIZATION

* 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

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[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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