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

I. Cancer pain relief and opioid availability in the world ... 1
II. Efforts to improve opioid availability in the world ... 2
III. Key publications about opioid availability ... 3
IV. Opioid consumption trends in selected Asian countries ... 5
V. Consumption of opioid analgesics ... 6
VI. Status of adherence to conventions, receipt of statistics, and estimates ... 28
VII. Estimated requirements for selected opioids ... 29
VIII. Competent authorities ... 30
IX. Bibliography ... 32
Annex 1. Cancer pain relief: With a guide to opioid availability ... 33
Annex 2. Achieving balance in national opioids control policy, Guidelines for assessment 45
Annex 3. INCB report conclusions and recommendations ... 53

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About the Pain & Policy Studies Group

The Pain & Policy Studies Group (PPSG) mission is to study and educate about the need for "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 (WHO) 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 the PPSG website at www.medsch.wisc.edu/painpolicy.

The PPSG 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/).

Relevant websites

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

- WHO Newsletter *Cancer Pain Release*
  www.whocancerpain.wisc.edu

- World Health Organization (WHO)
  www.who.int/home-page/

- International Narcotics Control Board
  www.incb.org/

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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 which 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

The vast majority (69%) of the increased consumption of morphine has been in only ten industrialized countries: 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) represent approximately 90% of the world's population, yet 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 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

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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

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, 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, public and professional education, and drug availability; (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." (See Section III - Key Publications)

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

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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/

determine the unmet medical need for opioid analgesics. The INCB conclusions and recommendations are provided in ANNEX 3.

WHOCC activities to improve availability

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 WHOCC efforts to improve opioid availability are summarized in annual reports available at http://www.medsch.wisc.edu/painpolicy/publicat/annrepts.htm.

SECTION III. KEY PUBLICATIONS ABOUT OPIOID AVAILABILITY

There are three authoritative publications that are relevant to health professionals and government regulators. These are publications of the WHO and the INCB, and are summarized below.

World Health Organization. ***Cancer Pain Relief: With A Guide to Opioid Availability.*** **Geneva: Author, 1996.**

This Guide explains the system that is used to make morphine and other opioids available for the patients who need these medications for pain. The Guide is for the use of regulators and health care professionals, and is intended to promote communication between them. It briefly reviews the problem of cancer and pain, the necessity of having opioid analgesics available to treat pain, and the WHO strategy for cancer pain relief. The Guide explains how the opioid distribution system should work within the legal framework of international treaty and national narcotic control laws. Particular attention is given to the role of the national estimate of medical need for opioids, and the steps which are necessary to obtain a supply of opioids either by domestic manufacture or by import. This publication offers guidelines for appropriate regulation of health care professionals who handle opioids, paying special attention to the need to balance concerns about drug abuse with the needs of patients for pain relief.

World Health Organization publications can be obtained from Distribution and Sales, World Health Organization, 1211 Geneva 27, Switzerland. This document is published in English, French and Spanish. The part of this publication relating to opioid availability is on the PPSG website at http://www.medsch.wisc.edu/painpolicy/publicat/cprguid.htm and is also contained in **ANNEX 1** *of this monograph.*

World Health Organization. ***Achieving Balance in National Opioids Control Policy: Guidelines for Assessment*****. Geneva: Author, 2000.**

In 2000, WHO issued "Achieving Balance in National Opioids Control Policy: Guidelines for Assessment," which provides 16 guidelines that can be used by governments and health professionals to assess the national opioids control policies of any country. The document can be used to determine if national policies contain provisions and procedures that are necessary to ensure the availability of opioid analgesics that are essential for the relief of pain. The guidelines are derived from the international principle of "balance" in drug control policy. This principle, which is carefully and extensively documented in the publication, asserts (1) that governments not only have an obligation to prevent drug abuse, but also to ensure the availability of opioid analgesics for medical purposes, and (2) that efforts to prevent drug abuse and diversion must not interfere with the adequate availability of opioid analgesics for patients' pain relief.

The Guidelines are available on the WHO website at http://www.who.int/medicines/library/qsm/who-edm-qsm-2000-4/who-edm-qsm-2000-4.htm and on the PPSG website at http://www.medsch.wisc.edu/painpolicy/publicat/00whoabi/00whoabi.htm. Excerpts of this publication are also available in **ANNEX 2** *of this monograph.*

International Narcotics Control Board. ***Report of the International Narcotics Control Board for 1995: Availability of Opiates for Medical Needs.*** **New York: United Nations, 1996.**

The International Narcotics Control Board is responsible for monitoring governments' compliance with the Single Convention on Narcotic Drugs, 1961. The Board recognizes that the regulatory control of narcotics should not interfere with the availability of opioids for medical purposes, including pain management, and works with national governments to ensure that opioids are sufficiently available to meet medical needs, as defined by individual governments.

In 1995, the INCB surveyed all governments in the world to find out how they responded to the Board's 1989 recommendations to identify and address barriers to opioid availability for medical and scientific purposes, and to collect data on the status of opioid availability worldwide. This publication reports the results of that survey, concluding that a small but significant number of governments are making efforts to improve the availability of opioids for medical use, but that a number of problems remain which governments must address. The INCB makes a number of recommendations that form a blueprint for national and international actions to improve the situation.

INCB reports are United Nations publications and may be obtained from bookstores and distributors throughout the world. Consult your bookstore or write to: United Nations, Sales Section, New York or Geneva. (If there is difficulty obtaining a publication, contact the INCB at Vienna International Centre, P.O. Box 500, A-1400, Vienna, Austria, Fax 43 1 21345-5867) This document is published in English, French and Spanish. Available at http://www.incb.org/e/ar/1995/suppl1en.pdf. The Conclusions and Recommendations section of this publication are contained in **ANNEX 3** *of this monograph.*

SECTION IV - OPIOID CONSUMPTION TRENDS IN SELECTED ASIAN COUNTRIES

Interpretation of INCB consumption data

Morphine consumption statistics are used by the WHO as a broad indicator of progress to improve cancer pain relief. Morphine is indispensable for the medical management of moderate to severe pain. WHO considers opioids such as morphine to be "essential drugs" and the WHO three-step Analgesic Ladder includes morphine on the third step of the ladder. Morphine is the most widely available strong opioid in the world. Therefore, many countries' morphine consumption statistics are good general indicators of progress to improve cancer pain. Although pethidine is not recommended due to toxic metabolites and short duration of action, it is nevertheless used widely mainly for acute post surgical pain, and sometimes also cancer pain.

The following consumption data come from the INCB.[4] Each year the INCB receives reports from national governments on narcotics consumed for medical purposes. For statistical purposes, "consumption" is that amount of a narcotic drug that has been distributed to the retail level in a country, that is, to hospitals and pharmacies in a country for medical use; patients do not necessarily use this amount in a particular year. On these graphs, no consumption statistics may be provided for a given year because a government did not submit a report to the INCB.

The statistics for morphine consumption reported in this monograph do not include amounts that are used for manufacturing combination products that contain a small amount of morphine but which are subject to less restrictive control than single-entity morphine. All statistics represent the actual amount of Schedule II preparations only.

National consumption statistics may vary widely according to medical, economic and social factors. *There is no ideal consumption rate or amount which is officially implied to be ideal.* However, it is generally acknowledged that opioids are underused throughout the world; even in the most economically advanced countries, the use of opioids for relief of pain due to cancer remains inadequate.

There are a number of cautions that should be used in interpreting the data. In some countries, morphine is used for painful conditions other than cancer, such as surgery or chronic non-cancer conditions. Increased consumption of morphine may not necessarily reflect improved pain management; rather, more institutions may be using morphine and more patients being treated with less than effective doses. Increased consumption may also be an indicator of a shift to morphine from pethidine or other less suitable drugs, such as pentazocine. The INCB provides the WHOCC with data on the consumption of other important opioids that should be used for the treatment of moderate to severe pain, such as fentanyl and oxycodone. Therefore, this monograph reports global consumption statistics for morphine, pethidine, oxycodone and fentanyl. The per capita consumption of morphine and pethidine is reported globally and for individual countries.

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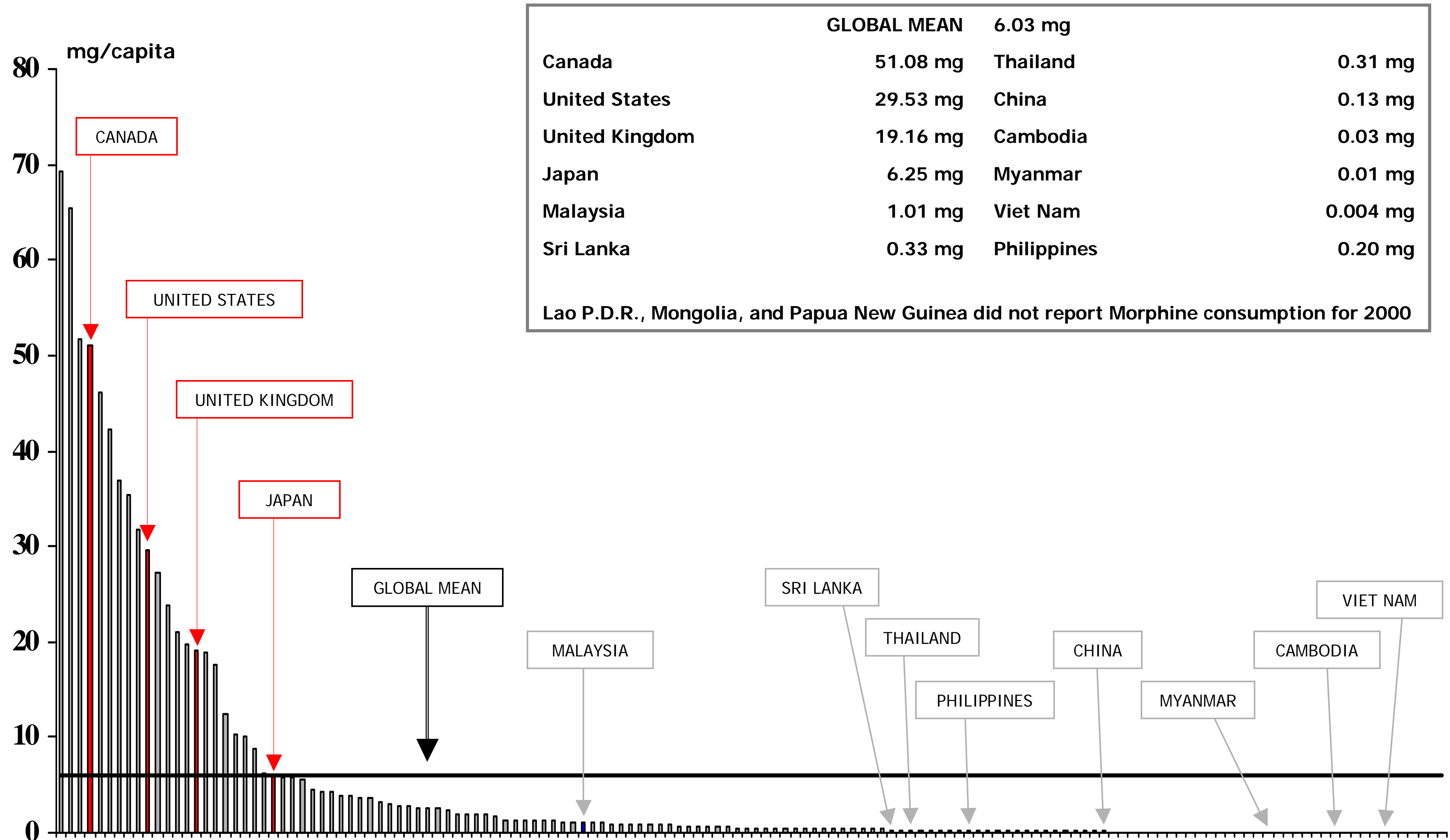
[4] See, for example, International Narcotics Control Board. *Narcotic Drugs: Estimated World Requirements for 2001-Statistics for 1999.* New York, NY: UN; 2001. Sales number E/F/S.01.XI.2 (This publication is in English, French, and Spanish.)

Per Capita Global Consumption of Morphine, 2000



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

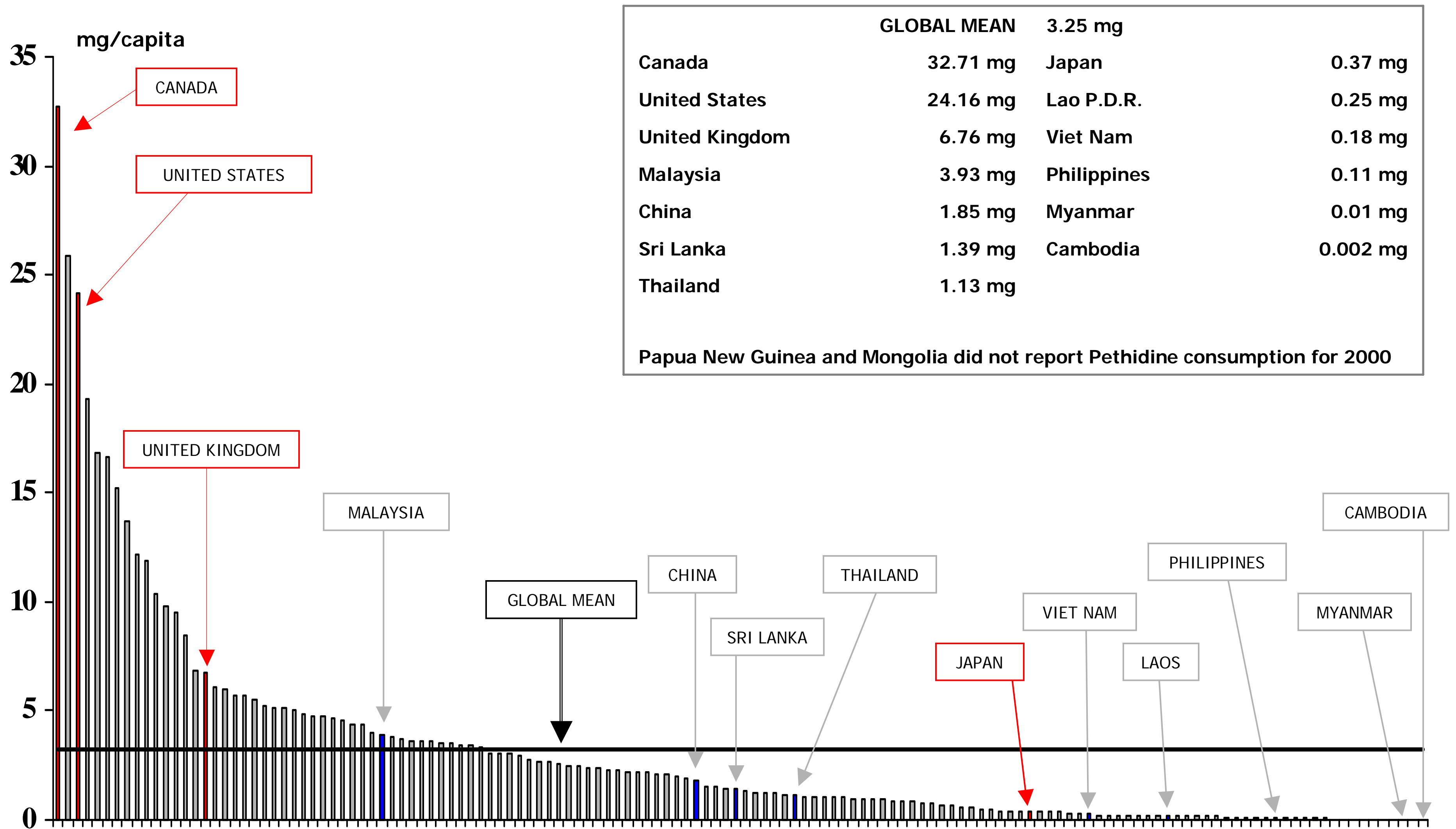
Morphine Consumption: JICWELS participating countries* and the World, 2000 (mg/capita)

Country	mg/capita
Denmark	69.3633
Portugal	65.4668
Australia	51.6755
Canada	51.0839
Austria	46.0939
New Zealand	42.3243
Iceland	36.7948
France	35.3562
Norway	31.8172
United States of America	29.5269
Sweden	27.1492
Gibraltar	23.8519
Switzerland	21.0640
Ireland	19.7783
United Kingdom	19.1616
Luxembourg	18.7813
Germany	17.6222
Belgium	12.4722
Israel	10.3290
Netherlands	10.0413
Spain	8.8175
Japan	6.2519
Czech Republic	6.0565
Finland	5.8696
Slovenia	5.7897
New Caledonia	5.6455
Hungary	4.5839
Slovakia	4.2189
Estonia	4.2081
Namibia	3.8534
Form.Yug. Rep.of Macedonia	3.8009
Poland	3.6249
South Africa	3.5442
Andorra	3.2501
Italy	3.0816
Croatia	2.7667
Bulgaria	2.7305
Hong Kong SAR	2.6595
Chile	2.6415
Lithuania	2.6387
Brazil	2.4205
Costa Rica	1.9519
Malta	1.9008
Republic of Korea	1.8754
Bahamas	1.8261
Argentina	1.6438
Georgia	1.3160
Russian Federation	1.3044
Latvia	1.2792
Barbados	1.2412
Singapore	1.2270
Tunisia	1.0665
Malaysia	***1.0112***
Fiji	1.0000
Macao	0.9802
Seychelles	0.9737
Netherlands Antilles	0.9488
Cuba	0.9359
Lebanon	0.8701
Belarus	0.8201
Uruguay	0.8193
Saudi Arabia	0.8084
Ukraine	0.7957
Colombia	0.7363
Oman	0.7240
Greece	0.6820
Bahrain	0.6746
Armenia	0.5677
Tonga	0.4545
Sierra Leone	0.4540
United Arab Emirates	0.4428
Qatar	0.4248
Saint Kitts and Nevis	0.4207
Jamaica	0.4201
Bosnia and Herzegovina	0.3759
Kazakhstan	0.3666
Kuwait	0.3590
Brunei Darussalam	0.3546
Jordan	0.3529
Suriname	0.3465
Nicaragua	0.3405
Kiribati	0.3373
Cook Islands	0.3352
Sri Lanka	***0.3282***
Dominican Republic	0.3186
Thailand	***0.3134***
Turkey	0.2738
Marshall Islands	0.2549
Yugoslavia	0.2284
Peru	0.1988
Philippines	***0.1968***
Vanuatu	0.1929
Montserrat	0.1896
Egypt	0.1893
Botswana	0.1869
Zambia	0.1865
Paraguay	0.1820
Antigua and Barbuda	0.1692
Azerbaijan	0.1679
Nauru	0.1667
Mauritius	0.1619
Venezuela	0.1609
Samoa	0.1406
Ecuador	0.1297
China	***0.1265***
Iran (Islamic Republic of)	0.1175
Uganda	0.0840
Morocco	0.0809
Grenada	0.0690
Iraq	0.0662
Libyan Arab Jamahiriya	0.0582
Albania	0.0536
Republic of Palau	0.0526
Kyrgyzstan	0.0517
Bolivia	0.0509
Syrian Arab Republic	0.0438
Algeria	0.0357
Senegal	0.0336
Kenya	0.0326
Pakistan	0.0291
Cambodia	***0.0283***
Dem. Rep. of the Congo	0.0175
Guyana	0.0142
Nepal	0.0137
Sudan	0.0110
Yemen	0.0103
Mexico	0.0101
Myanmar	***0.0095***
Sao Tome and Principe	0.0072
Bhutan	0.0072
Cape Verde	0.0070
Indonesia	0.0061
Viet Nam	***0.0040***
United Republic of Tanzania	0.0037
Eritrea	0.0036
Mozambique	0.0032
Burundi	0.0008
Ethiopia	0.0000

* ***JICWELS participating countries are indicated in bold and italics***

- Countries not represented on this list did not report to the INCB for 2000

Per Capita Global Consumption of Pethidine, 2000



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Pethidine Consumption: JICWELS participating countries* and the World, 2000 (mg/capita)

Country	mg/capita
Canada	32.7097
Barbados	25.9038
United States of America	24.1636
Denmark	19.2628
Australia	16.8298
Bahamas	16.6493
Cook Islands	15.1955
Israel	13.6565
New Zealand	12.2157
Gibraltar	11.8889
Czech Republic	10.3224
Antigua and Barbuda	9.8000
Saint Kitts and Nevis	8.4633
Switzerland	6.8590
United Kingdom	6.7587
Botswana	6.1032
Norway	6.0328
Estonia	5.7454
Ireland	5.6814
Mauritius	5.5511
Malta	5.2195
Bahrain	5.1374
Poland	5.1312
Grenada	5.0099
Guyana	4.8354
South Africa	4.7700
Montserrat	4.7402
Jordan	4.6192
Kuwait	4.5801
Hong Kong SAR	4.3799
Netherlands Antilles	4.3674
Jamaica	3.9822
Malaysia	***3.9339***
Cyprus	3.8375
Qatar	3.7009
Brazil	3.6067
Singapore	3.6006
Seychelles	3.5868
Republic of Palau	3.5263
Hungary	3.5093
Samoa	3.4558
Bulgaria	3.3780
Namibia	3.3029
Oman	3.0866
Greece	3.0514
Slovakia	3.0488
Republic of Korea	2.9261
Turks and Caicos Islands	2.7059
Libyan Arab Jamahiriya	2.6654
Lithuania	2.6008
Portugal	2.4817
Uruguay	2.4698
Tonga	2.3535
United Arab Emirates	2.3312
Fiji	2.3071
Germany	2.2800
Belgium	2.2212
Spain	2.2044
Anguilla	2.1818
Lebanon	2.1107
Zambia	2.0517
Brunei Darussalam	1.9947
Turkey	1.9313
China	***1.8519***
Saudi Arabia	1.5354
Netherlands	1.5337
Finland	1.4558
Sri Lanka	***1.3920***
Egypt	1.3599
New Caledonia	1.2372
Vanuatu	1.2081
Cuba	1.2057
Albania	1.1493
Thailand	***1.1269***
Chile	1.0912
Luxembourg	1.0259
Cape Verde	1.0187
Kenya	1.0108
Suriname	1.0051
Kiribati	0.9880
Venezuela	0.9179
Croatia	0.9135
Iran (Islamic Republic of)	0.8623
Colombia	0.8398
Syrian Arab Republic	0.8247
Andorra	0.7897
United Republic of Tanzania	0.7151
Panama	0.6706
Marshall Islands	0.6275
Tunisia	0.5524
Morocco	0.5361
Benin	0.5049
Nauru	0.5000
Uganda	0.3958
Yemen	0.3862
Italy	0.3809
Japan	0.3718
Georgia	0.3577
Peru	0.3531
Sweden	0.3472
Costa Rica	0.3151
Nepal	0.2703
Lao Peop. Dem. Rep.	***0.2501***
Macao	0.2216
Bolivia	0.2208
Togo	0.2096
France	0.1989
India	0.1880
Pakistan	0.1818
Viet Nam	***0.1769***
Sudan	0.1671
Indonesia	0.1611
Argentina	0.1481
Iraq	0.1460
Paraguay	0.1456
Nicaragua	0.1364
Guatemala	0.1223
Dominican Republic	0.1209
Mozambique	0.1148
Madagascar	0.1064
Philippines	***0.1055***
Iceland	0.1031
Ethiopia	0.0716
Eritrea	0.0678
Latvia	0.0547
Burkina Faso	0.0453
Dem. Rep. of the Congo	0.0352
Bosnia and Herzegovina	0.0322
Sao Tome and Principe	0.0217
Burundi	0.0183
Bhutan	0.0120
Myanmar	***0.0116***
Mali	0.0047
Cambodia	***0.0021***

**** JICWELS participating countries are indicated in bold and italics***

- Countries not represented on this list did not report to the INCB for 2000

Consumption of Selected Opioid Analgesics, 2000

(mg/capita)

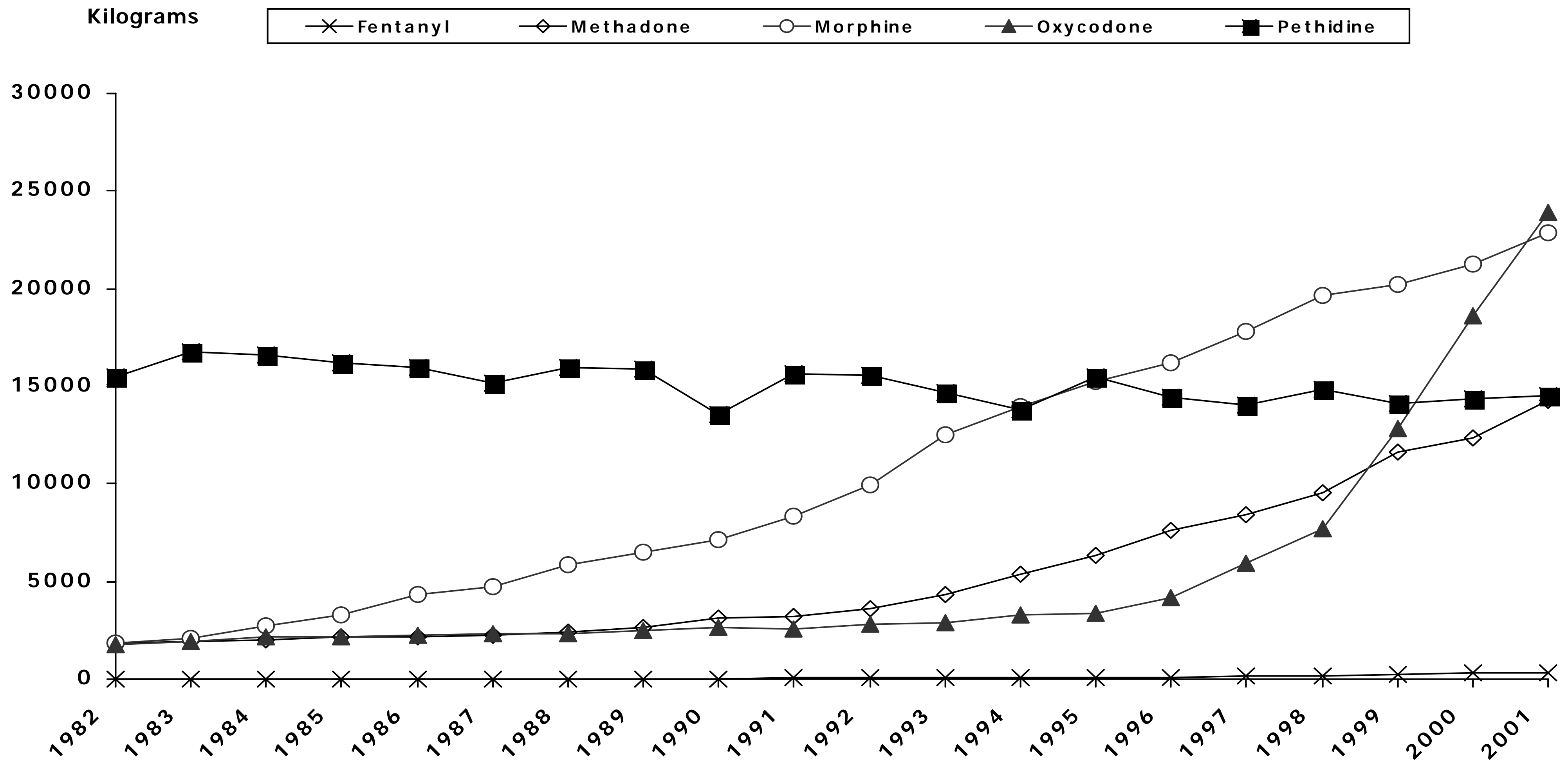
	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Global mean	0.06	6.26	6.03	3.24	3.25
Canada	0.33	15.37	51.08	19.14	32.71
Japan	0.01		6.25	0.00	0.37
United Kingdom	0.26	8.49	19.16	0.95	6.76
United States	0.59	18.30	29.53	60.98	24.16
Cambodia	--	--	0.03	--	0.002
People's Republic of China	0.0005	0.01	0.13	--	1.85
Lao People's Democratic Republic	0.0003	--	--	--	0.25
Malaysia	0.0003	--	1.01	--	3.93
Mongolia	--	--	--	--	--
Myanmar	--	--	0.01	--	0.01
Papua New Guinea	--	--	--	--	--
Philippines	0.0001	0.0001	0.20	--	0.11
Sri Lanka	0.0002	0.01	0.33	--	1.39
Thailand	0.0034	1.11	0.31	--	1.13
Viet Nam	0.0011	--	0.004	--	0.18

-- = No consumption information reported for 2000.
Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Notes: 1) 2001 mg/capita information is not provided as population data was not available
2) Data are rounded

Global Consumption of Opioid Analgesics

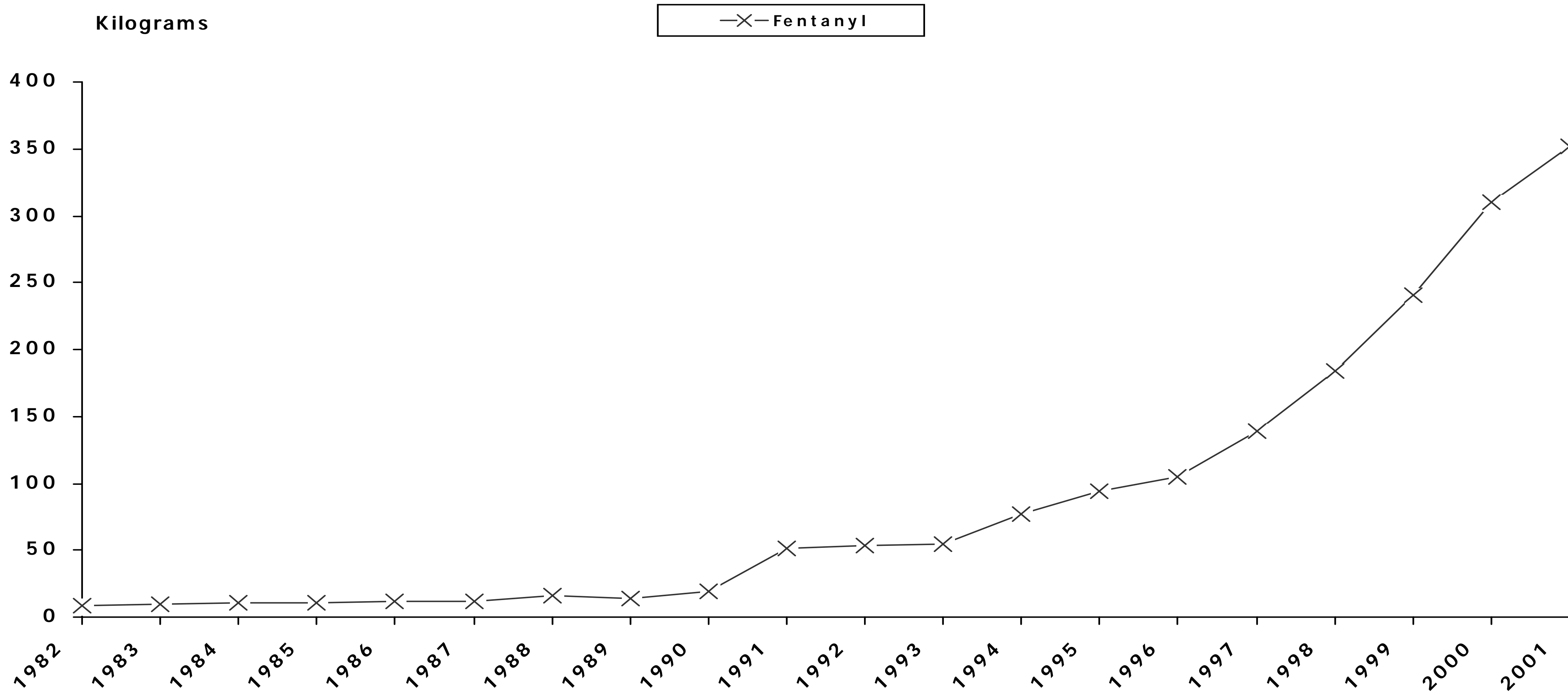
1982 - 2001



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2003

Global Consumption of Opioid Analgesics

1982 - 2001



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 2000
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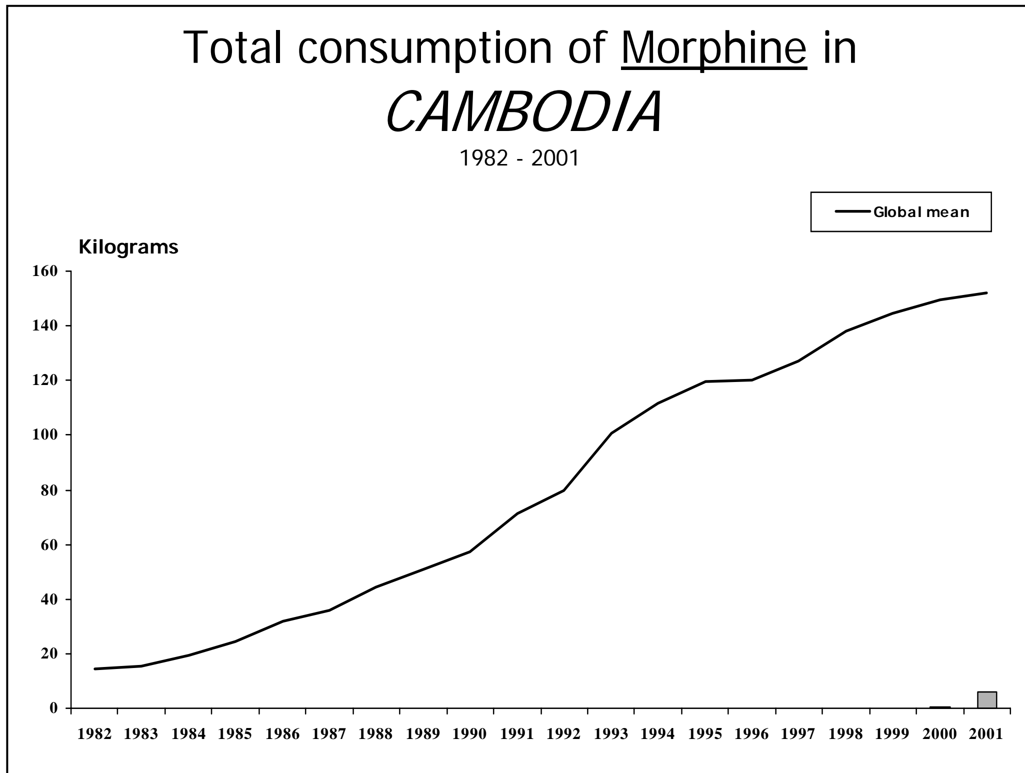
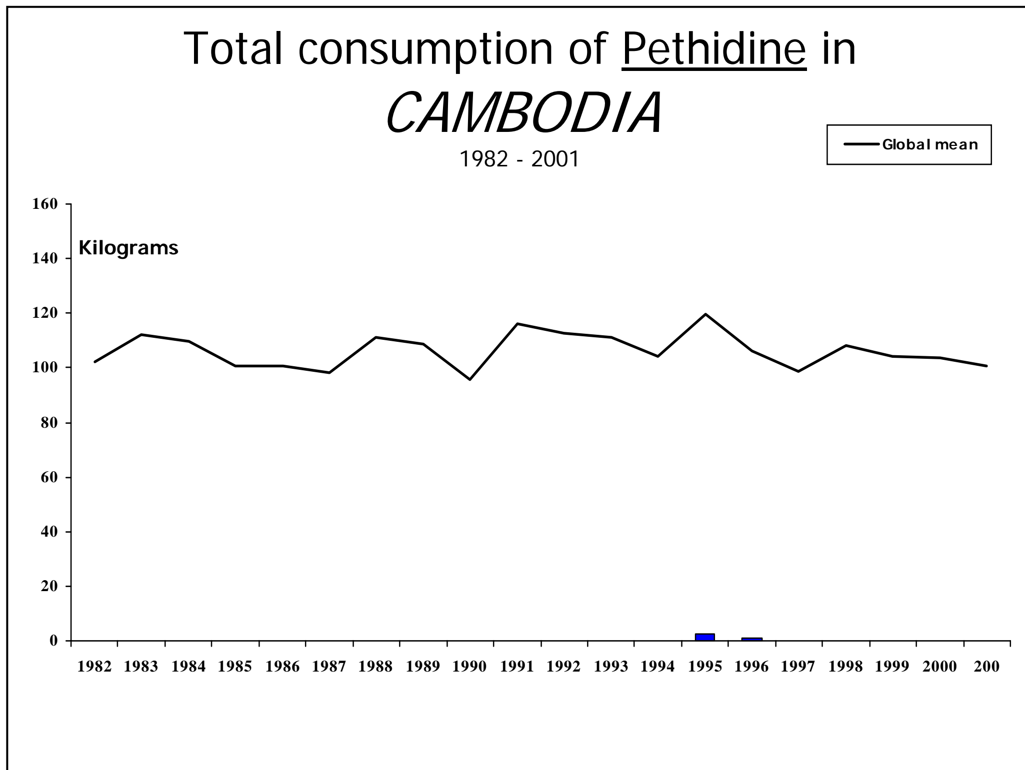
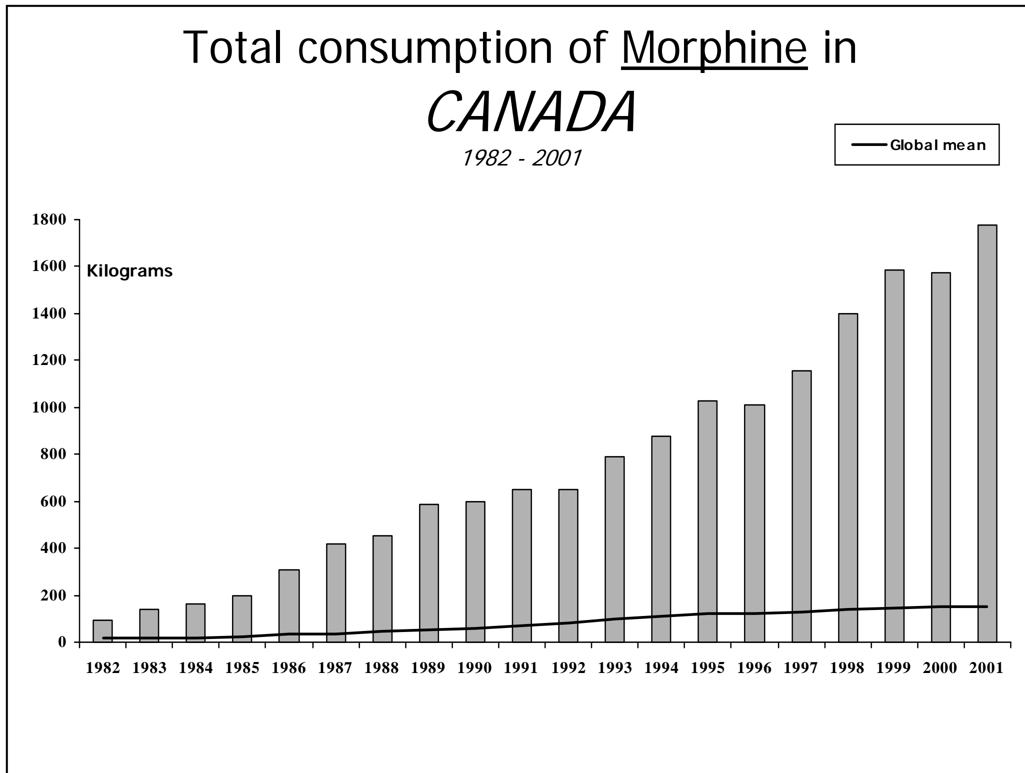
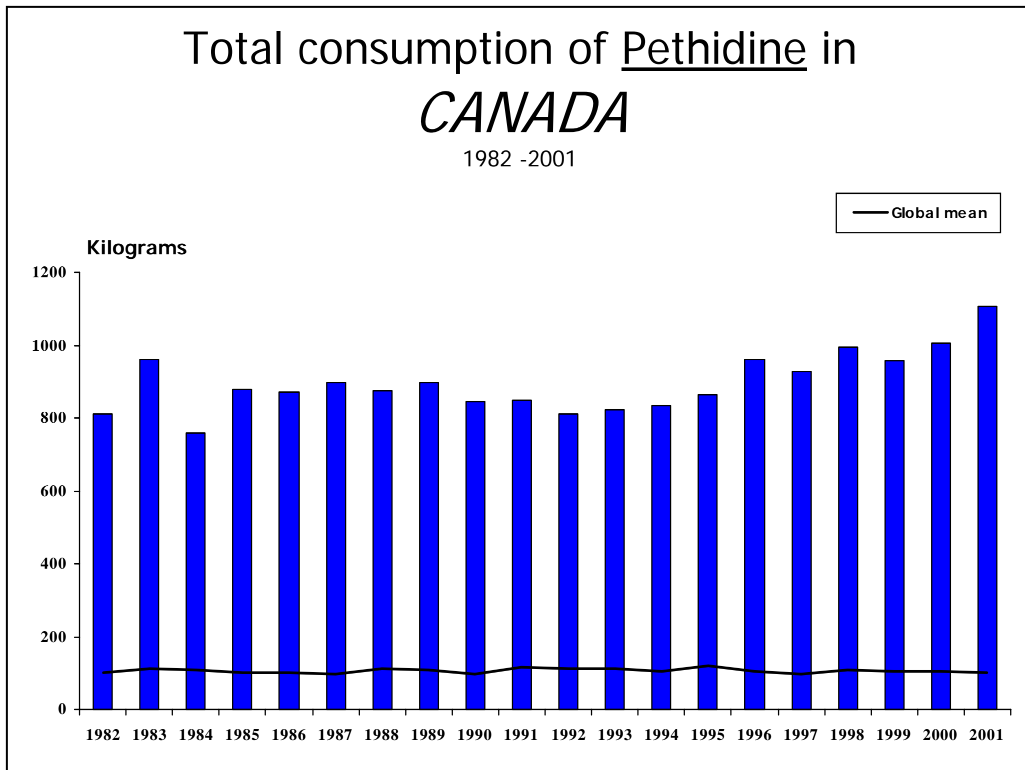
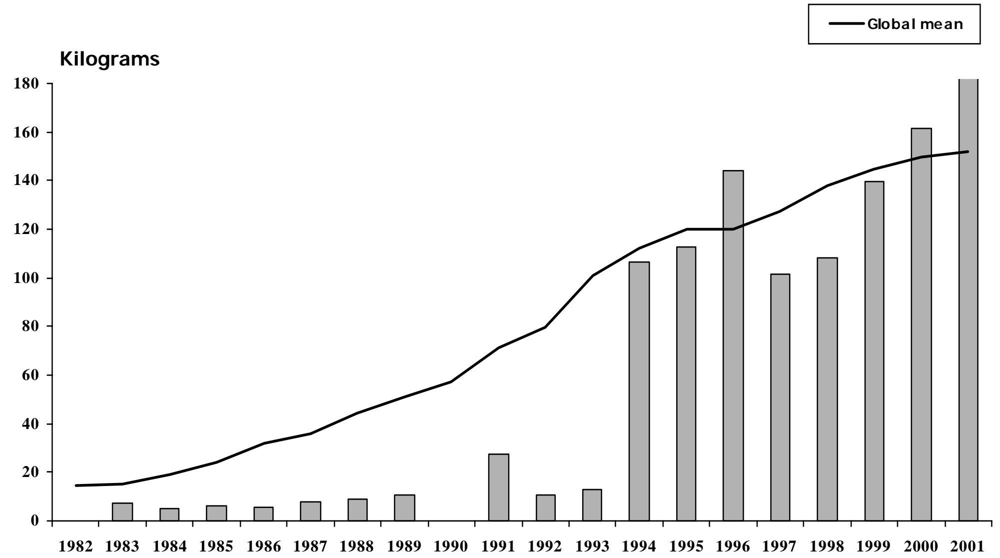
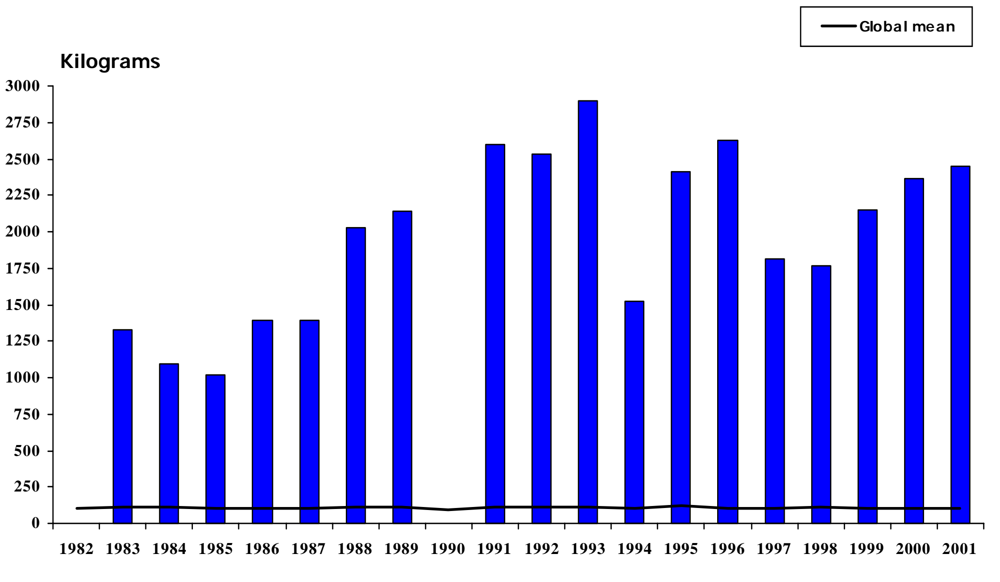

Total consumption of Morphine in
CAMBODIA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

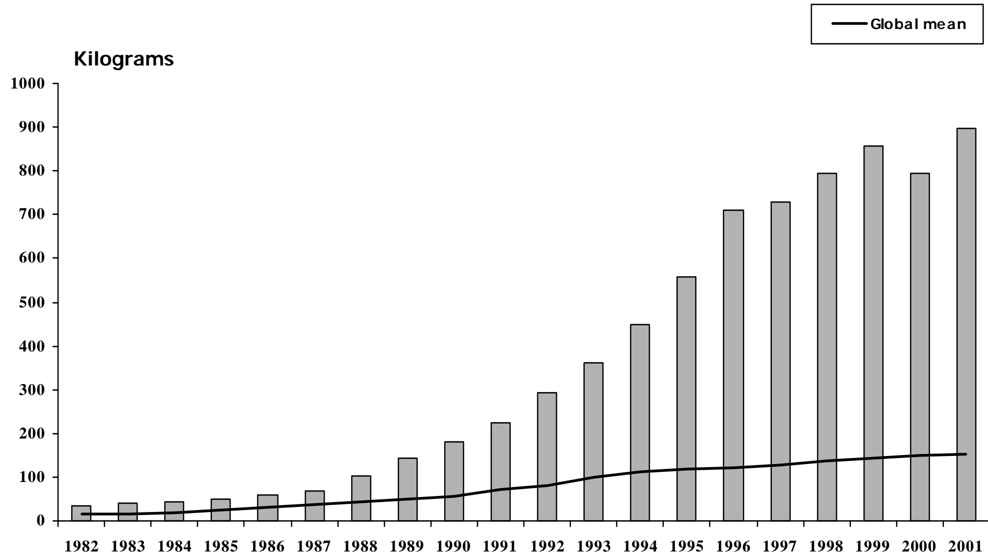

Total consumption of Pethidine in
CAMBODIA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 200

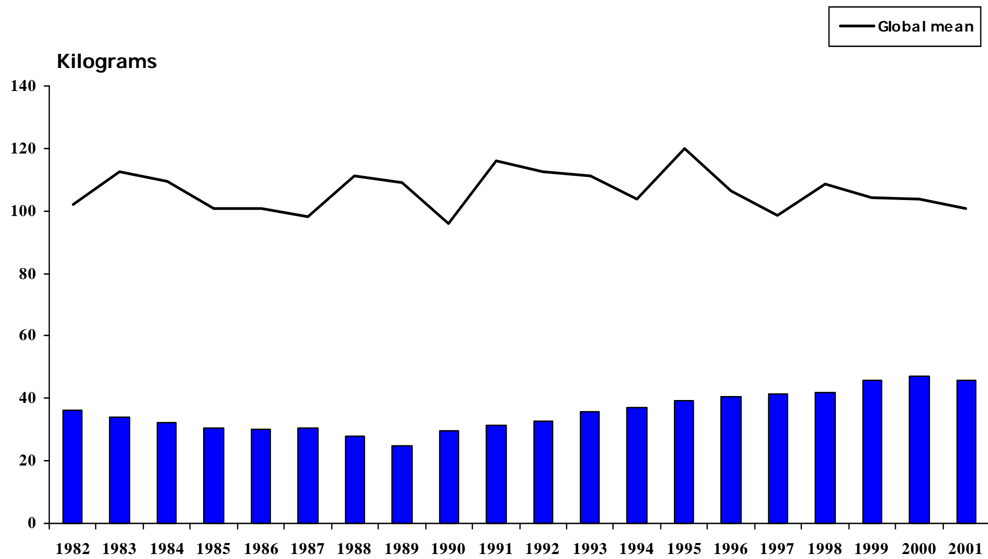

Total consumption of Morphine in
CANADA
1982 - 2001
Global mean
Kilograms
1800
1600
1400
1200
1000
800
600
400
200
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

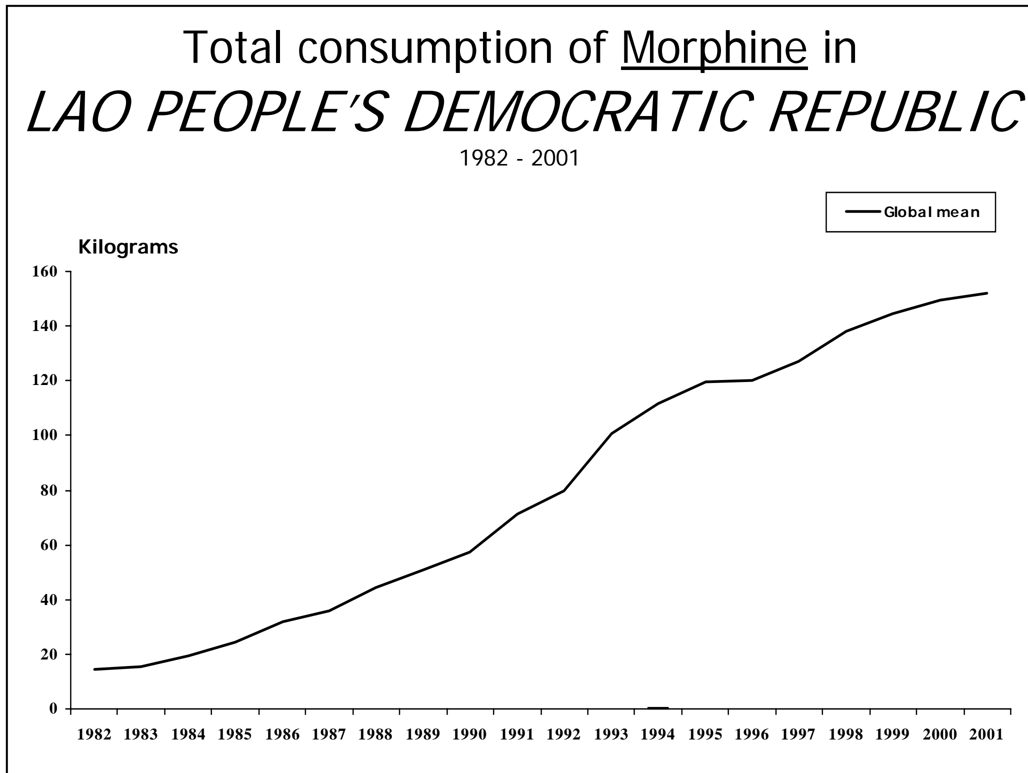

Total consumption of Pethidine in
CANADA
1982 -2001
Global mean
Kilograms
1200
1000
800
600
400
200
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

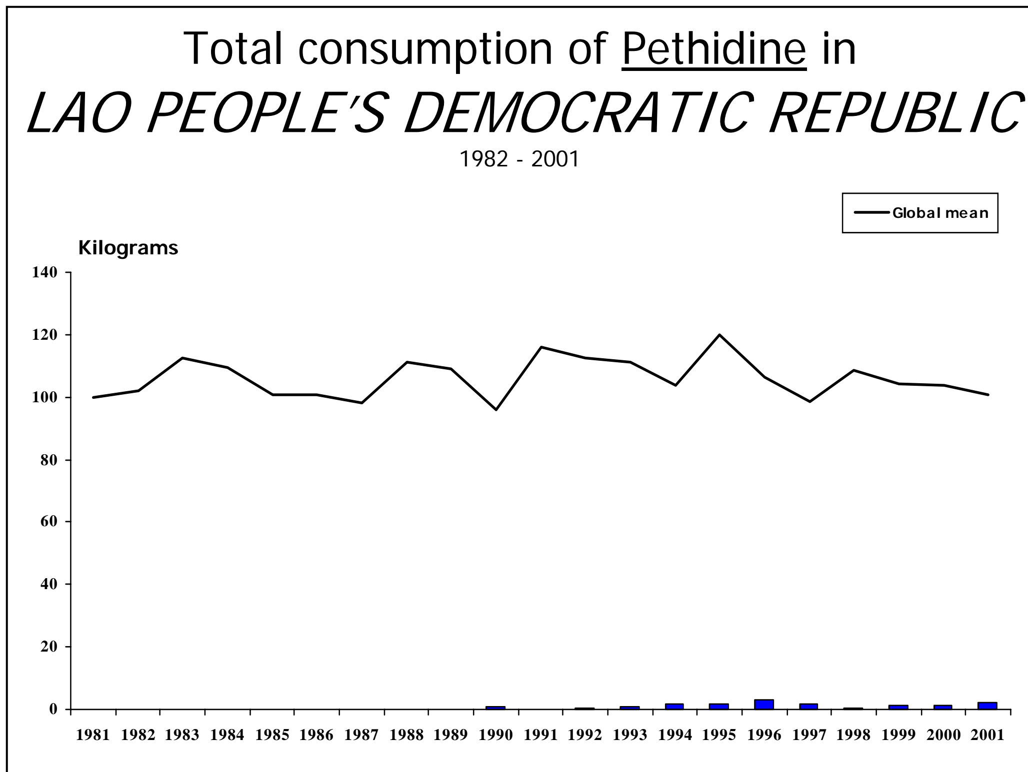

Total consumption of Morphine in
PEOPLE'S REPUBLIC OF CHINA
1982 -2001
Global mean
Kilograms
180
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

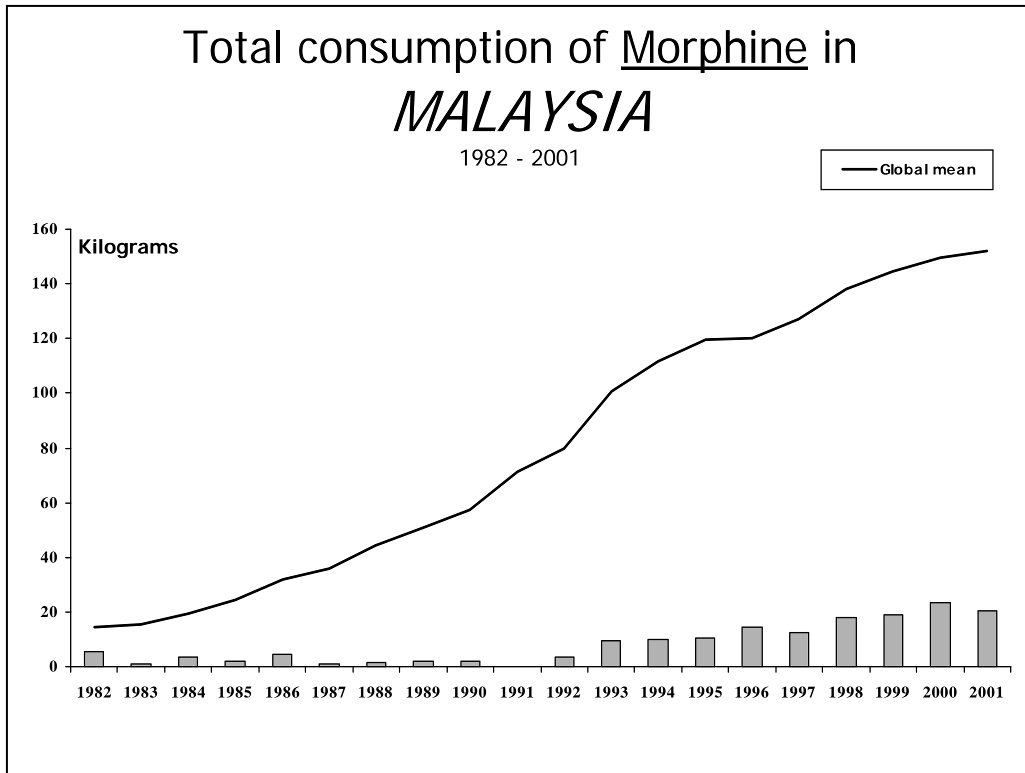

Total consumption of Pethidine in
PEOPLE'S REPUBLIC OF CHINA
1982 - 2001
Global mean
Kilograms
3000
2750
2500
2250
2000
1750
1500
1250
1000
750
500
250
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

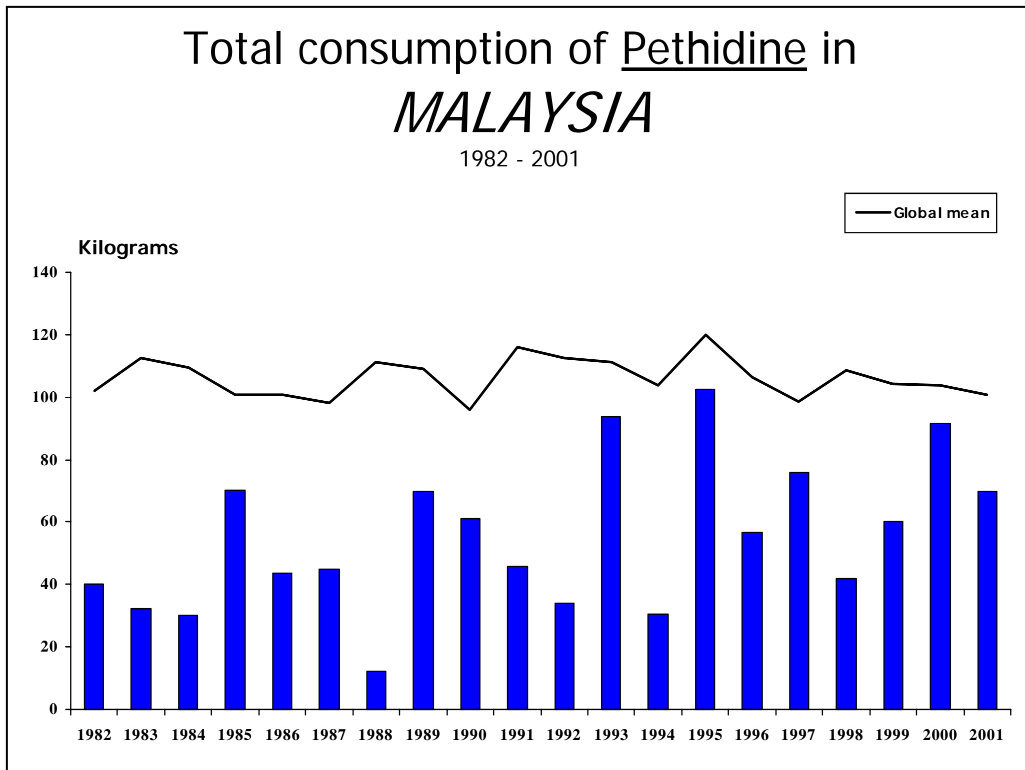

Total consumption of Morphine in
JAPAN
1982 - 2001
Global mean
Kilograms
1000
900
800
700
600
500
400
300
200
100
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

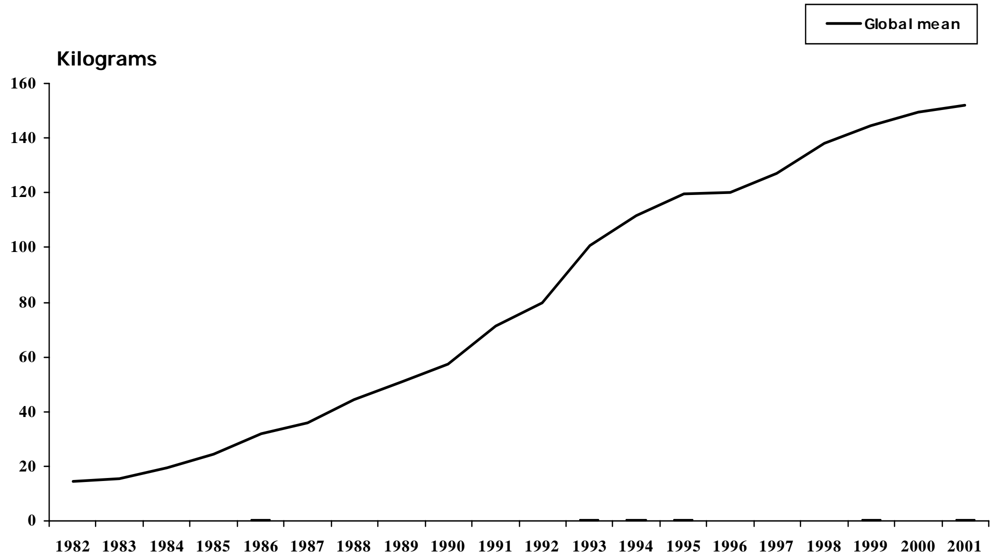

Total consumption of Pethidine in
JAPAN
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

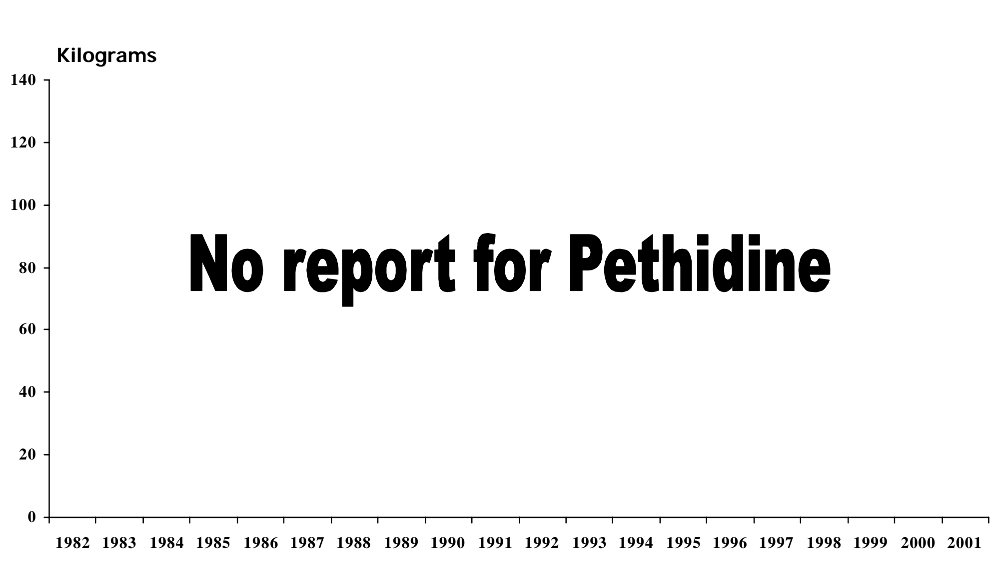

Total consumption of Morphine in
LAO PEOPLE'S DEMOCRATIC REPUBLIC
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

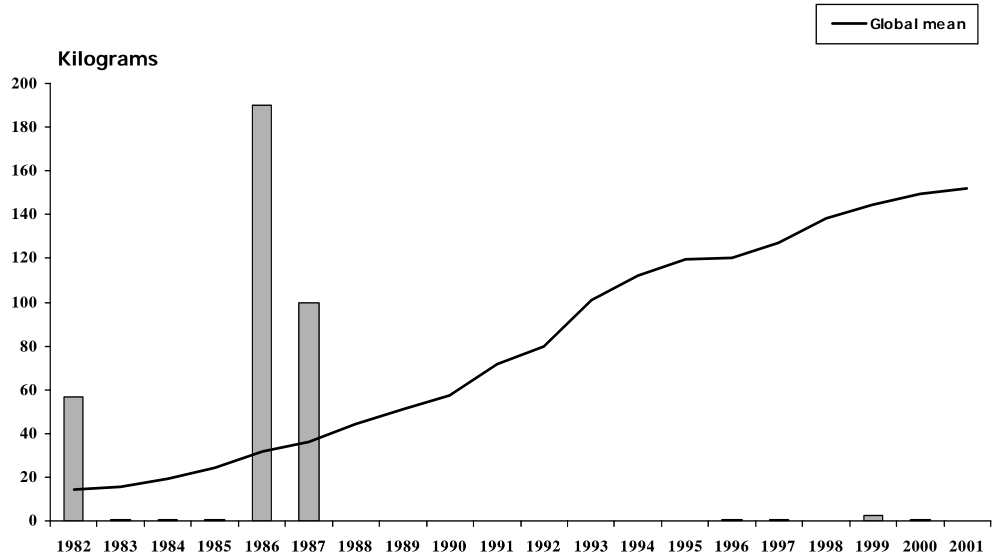

Total consumption of Pethidine in
LAO PEOPLE'S DEMOCRATIC REPUBLIC
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

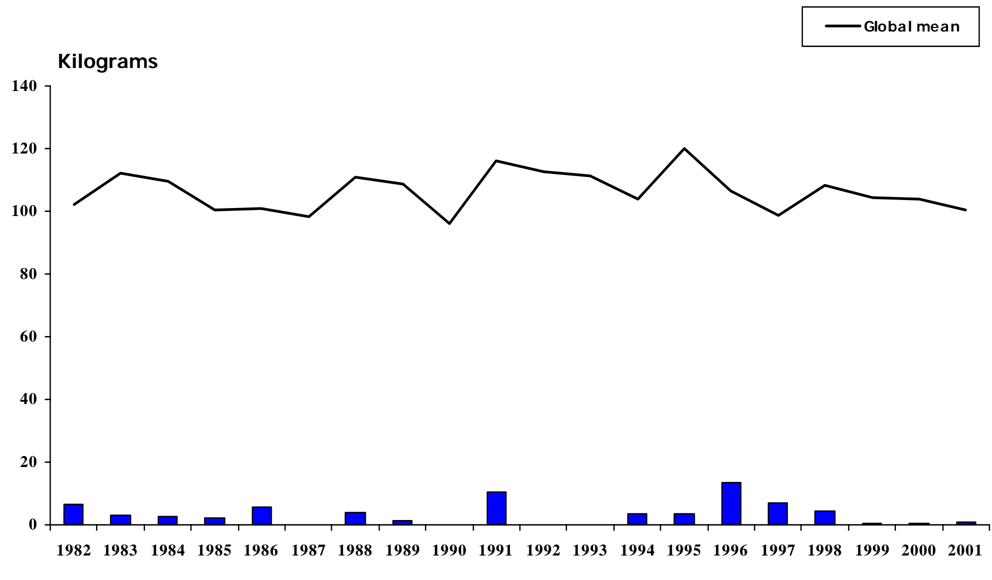

Total consumption of Morphine in
MALAYSIA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

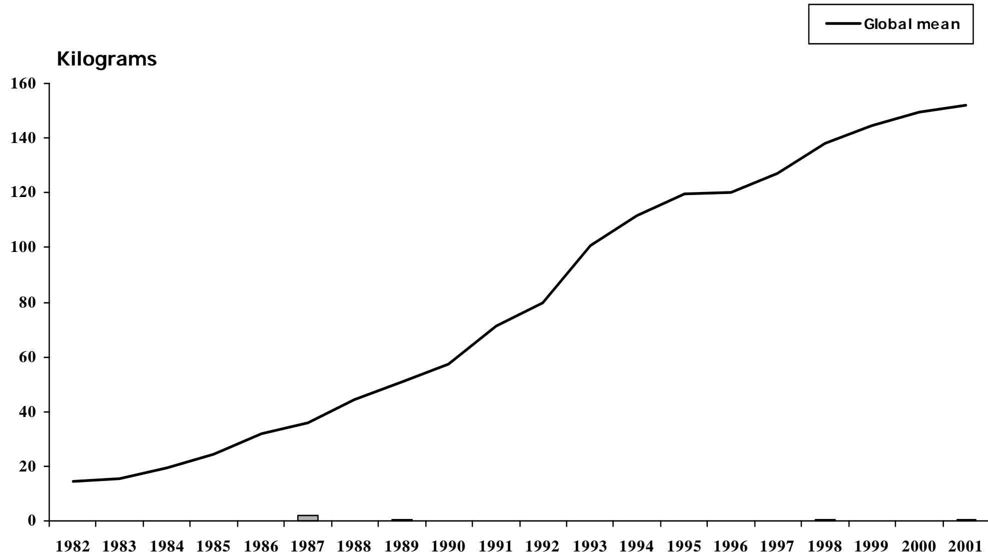

Total consumption of Pethidine in
MALAYSIA
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

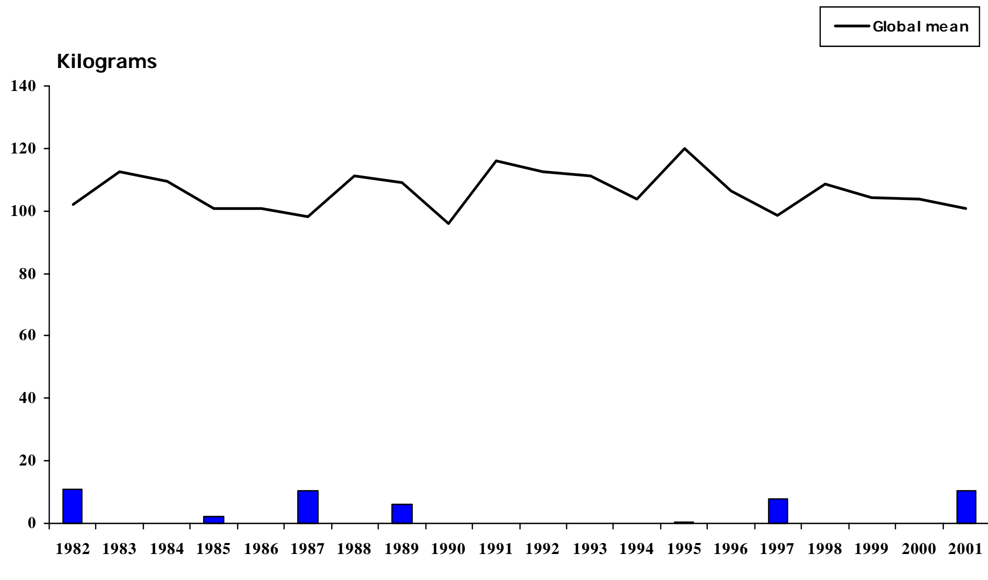

Total consumption of Morphine in
MONGOLIA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

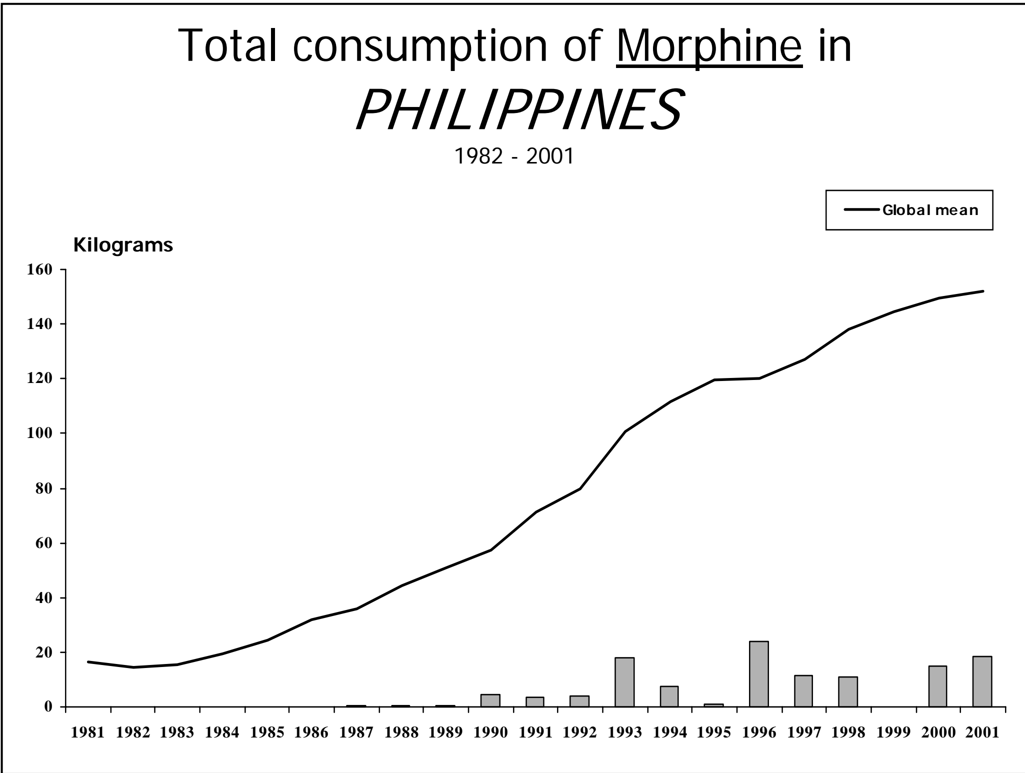

Total consumption of Pethidine in
MONGOLIA
1982 - 2001
Kilograms
140
120
100
80
60
40
20
0
No report for Pethidine
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

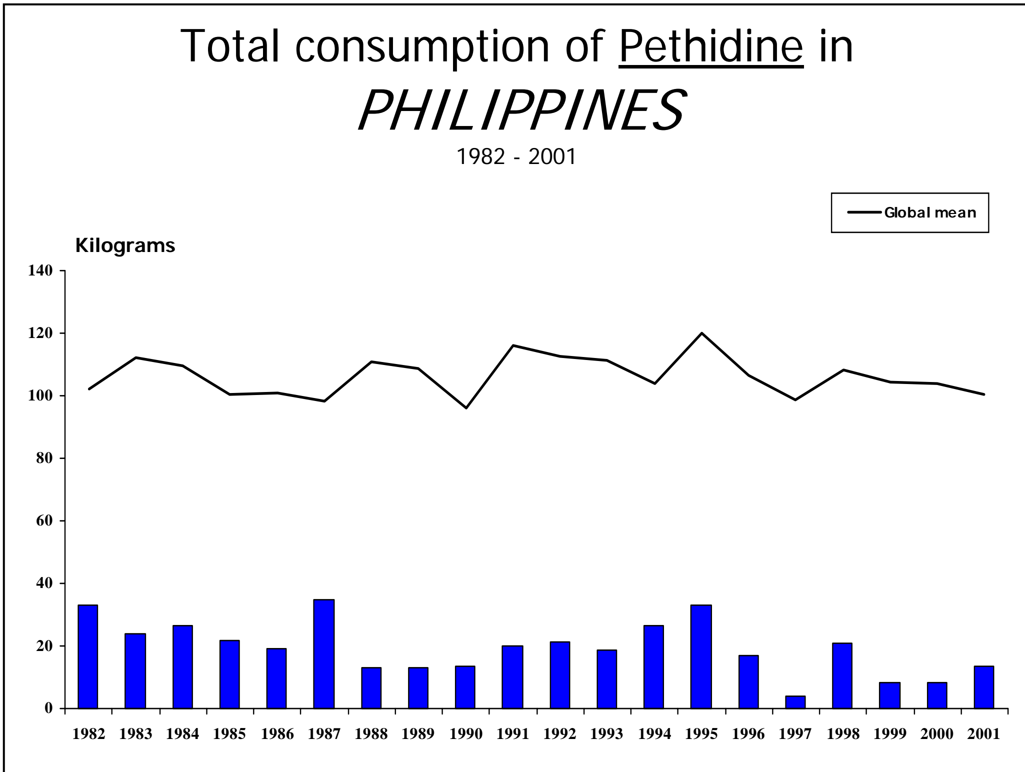

Total consumption of Morphine in
MYANMAR
1982 - 2001
Global mean
Kilograms
200
180
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

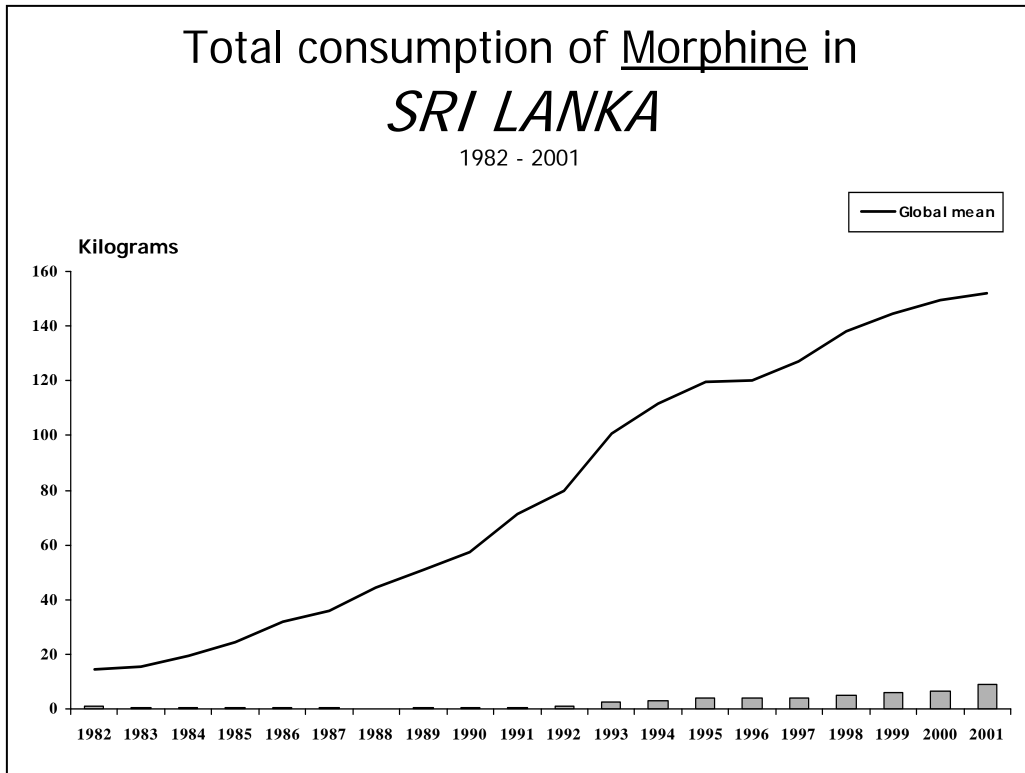

Total consumption of Pethidine in
MYANMAR
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

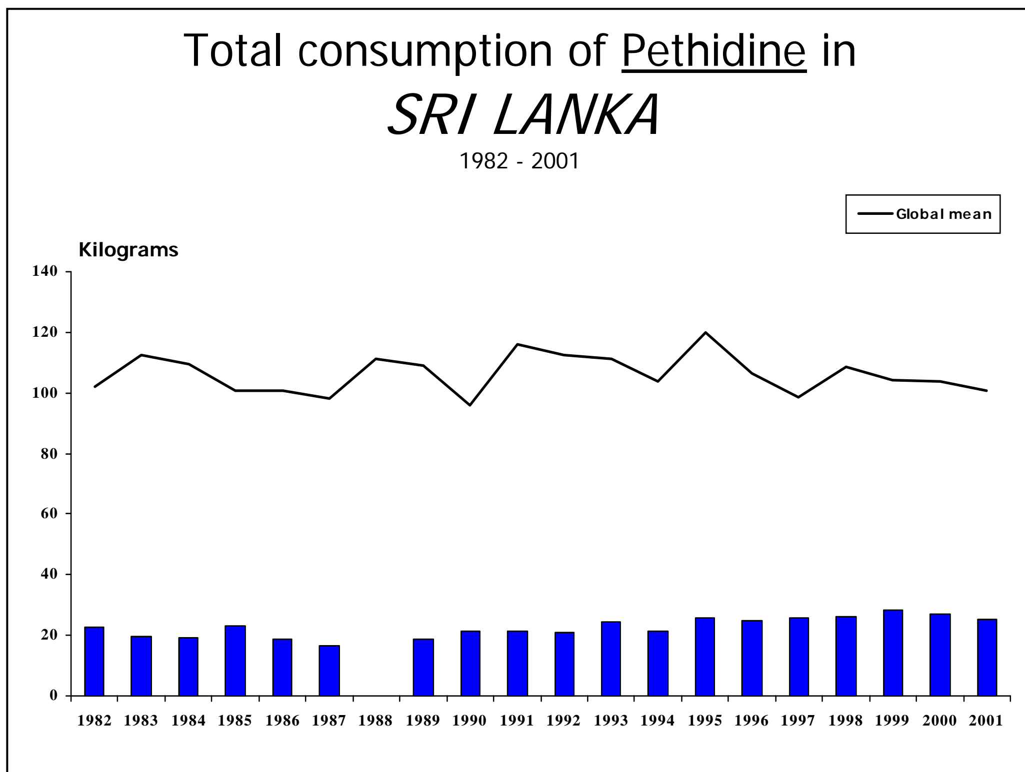

Total consumption of Morphine in
PAPUA NEW GUINEA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

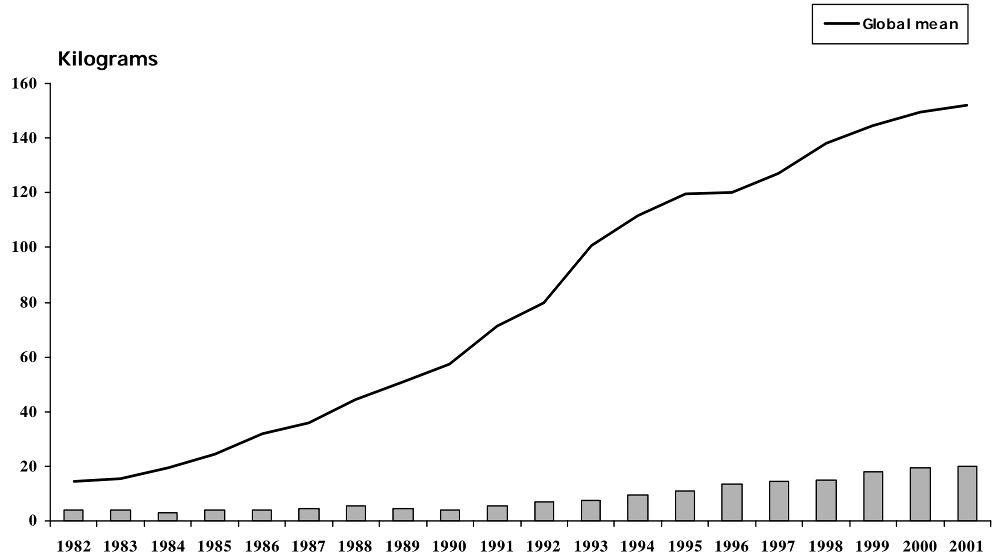

Total consumption of Pethidine in
PAPUA NEW GUINEA
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

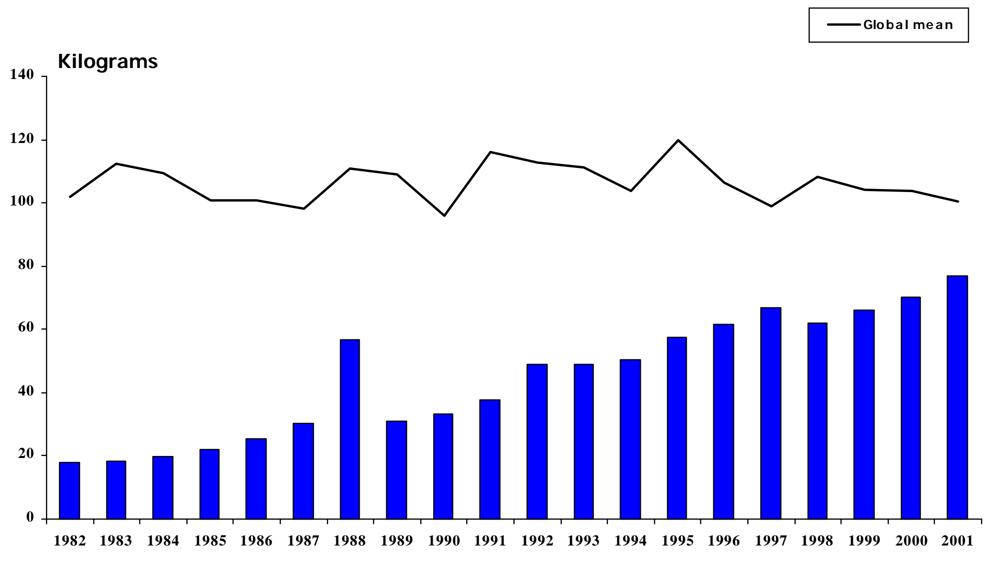

Total consumption of Morphine in
PHILIPPINES
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

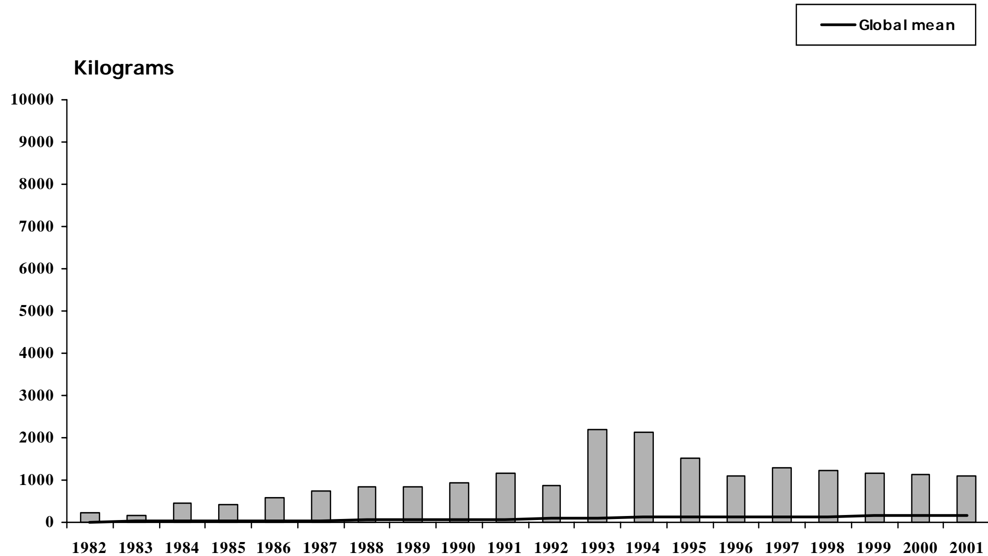

Total consumption of Pethidine in
PHILIPPINES
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

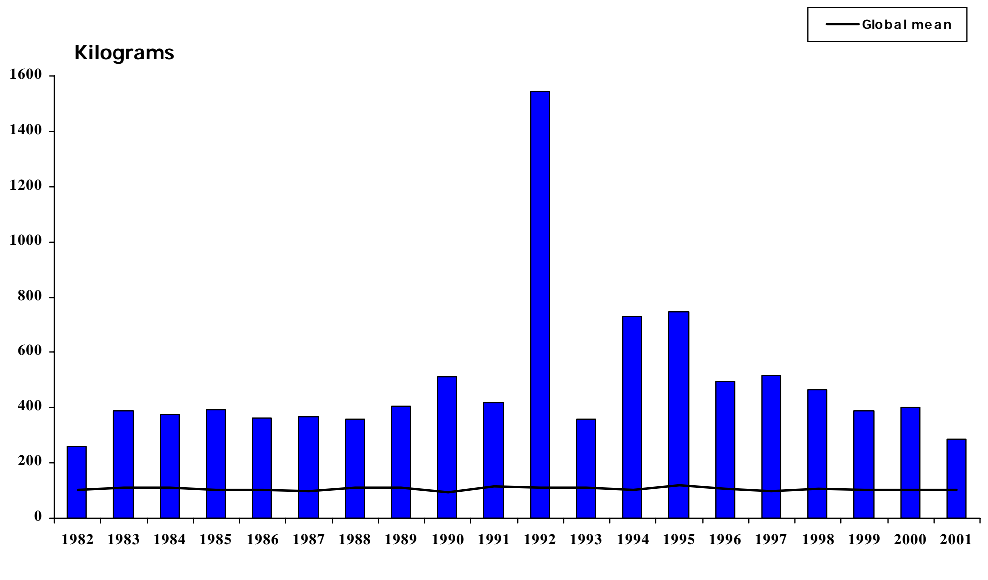

Total consumption of Morphine in
SRI LANKA
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

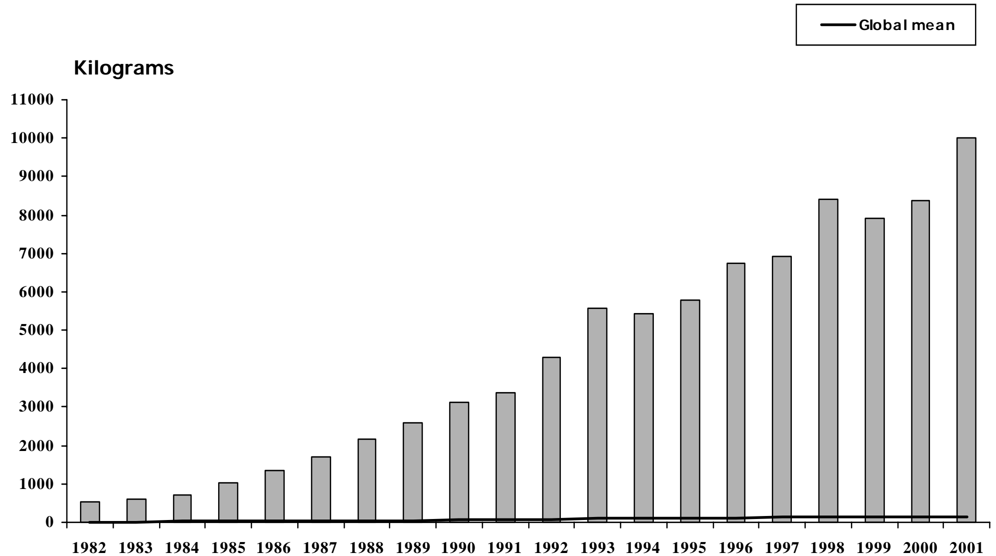

Total consumption of Pethidine in
SRI LANKA
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

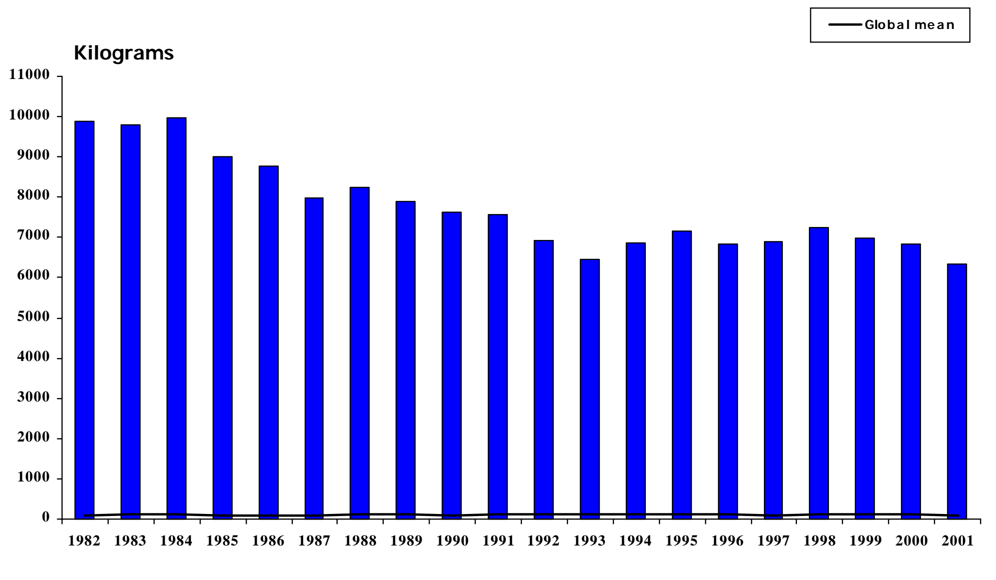

Total consumption of Morphine in
THAILAND
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

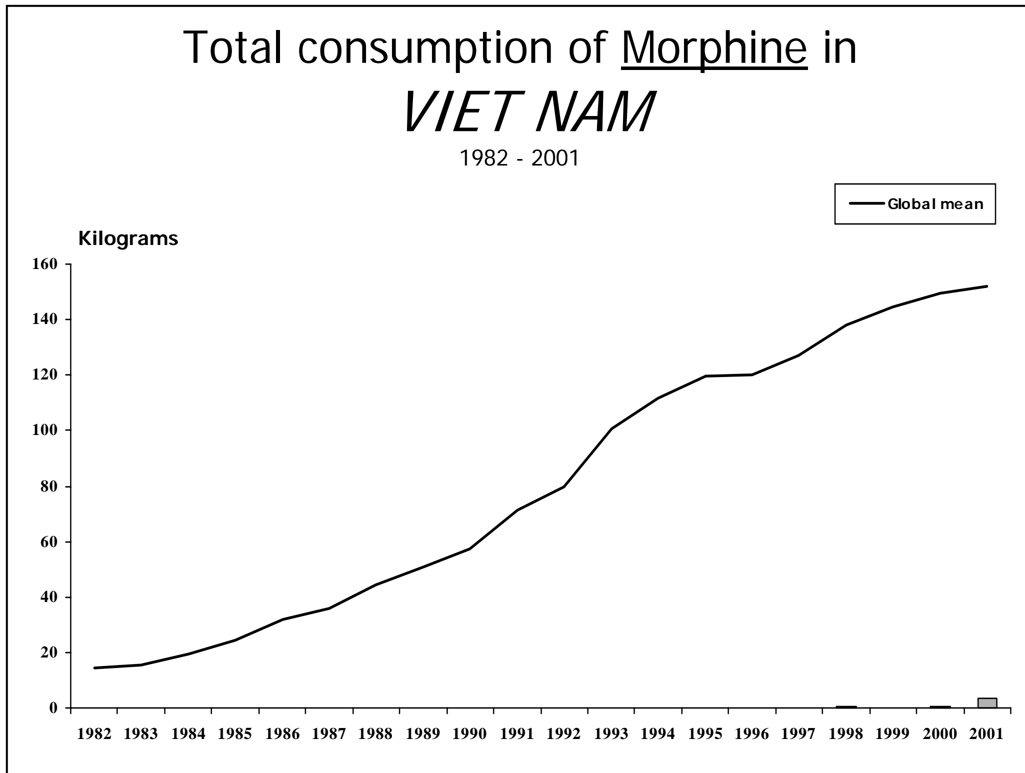

Total consumption of Pethidine in
THAILAND
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

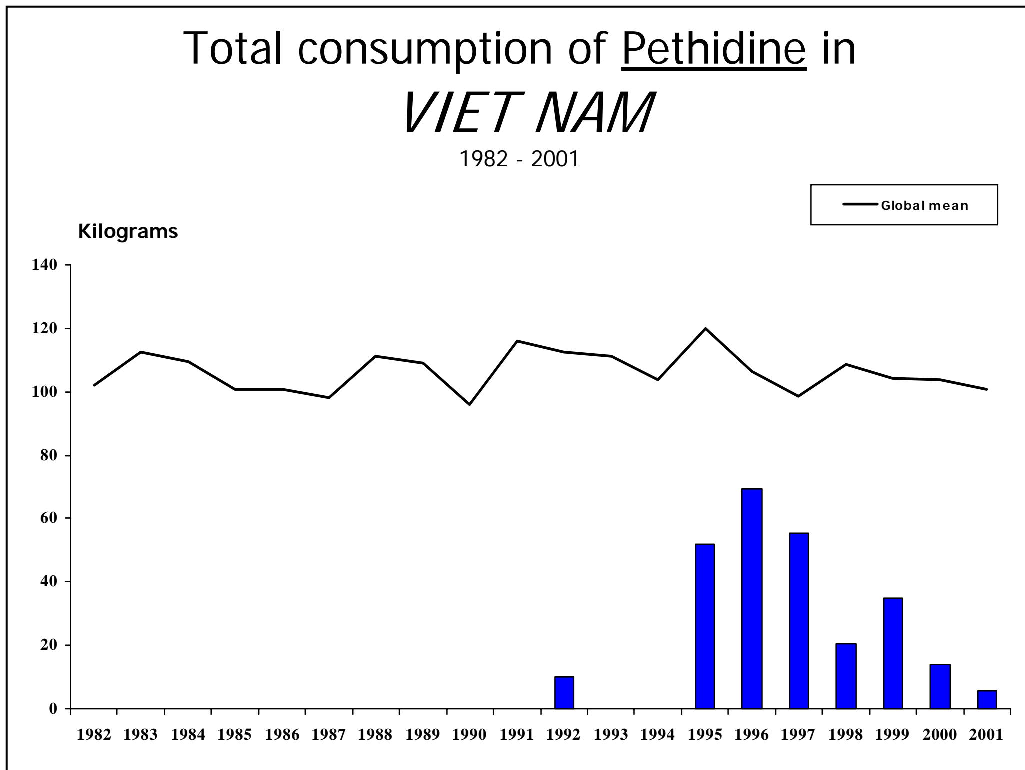

Total consumption of Morphine in
UNITED KINGDOM
1982 - 2001
Global mean
Kilograms
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001


Total consumption of Pethidine in
UNITED KINGDOM
1982 - 2001
Global mean
Kilograms
1600
1400
1200
1000
800
600
400
200
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001


Total consumption of Morphine in
UNITED STATES OF AMERICA
1982 - 2001
Global mean
Kilograms
11000
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001


Total consumption of Pethidine in
UNITED STATES OF AMERICA
1982 - 2001
Global mean
Kilograms
11000
10000
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001


Total consumption of Morphine in
VIET NAM
1982 - 2001
Global mean
Kilograms
160
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001


Total consumption of Pethidine in
VIET NAM
1982 - 2001
Global mean
Kilograms
140
120
100
80
60
40
20
0
1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001

Status of adherence to conventions, Receipt of statistics, and estimates

	ADHERENCE			
	Single Convention 1961	As amended 1961/72	Consumption statistics for 2000	Estimated requirements for 2002
CAMBODIA			●	●
CANADA	●	●	●	●
CHINA	●	●	●	●
JAPAN	●	●		
LAO PEOPLE'S DEM. REP.	●		●	●
MALAYSIA	●	●	●	●
MONGOLIA	●	●		●
MYANMAR	●		●	●
PAPUA NEW GUINEA	●	●		
PHILIPPINES	●	●	●	●
SRI LANKA	●	●	●	●
THAILAND	●	●		●
UNITED KINGDOM	●	●	●	●
U.S.A.	●	●	●	●
VIET NAM	●	●	●	●

Source: International Narcotics Control Board. *Narcotic Drugs: Estimated World Requirements for 2002 - Statistics for 2000*. New York, NY: United Nations, 2002.

SECTION VII.

ESTIMATED REQUIREMENTS FOR SELECTED OPIOIDS, 2002 AND 2003 (in grams)

Country & Population	Year	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
CAMBODIA	2002	50	--	2,500	--	500
	2003	50		2,500		500
CHINA	2002	1,000	20,000	6,742,304	60,000	2,226,505
	2003	2,000	20,000	5,260,000	1000	2,500,000
JAPAN	2002	14,488	500	17,240,000	160,062	113,173
	2003	25,000	10	105	50,000	100,000
LAO PEOPLE'S DEM. REP.	2002	10	--	400	--	
	2003	5		250		3,000
MALAYSIA	2002	143	--	45,000	--	115,000
	2003	430		45,000		160,000
MONGOLIA	2002	6		2,538		
	2003	4		930		
MYANMAR	2002	100	--	157	--	4,355
	2003	500		5,101		2,383
PAPUA NEW GUINEA	2002	2	--	1,000	--	15,000
	2003	2		1,000		15,000
PHILIPPINES	2002	200	1,000	20,000	10,000	50,000
	2003	200	1,000	38,000	13,000	73,000
SRI LANKA	2002	18	1,363	23,241	--	105,967
	2003	10	750	14,000		60,000
THAILAND	2002	1,035	110,000	75,463	--	263,810
	2003	500	110,000	55,000		180,000
VIET NAM	2002	250	3,000	3,000	--	50,000
	2003	250	3,000	5,000		50,000

- = No information reported

Source: International Narcotics Control Board; *Quarterly Supplement, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2002*; Advance Copy, *International Narcotics Control, Board Estimated World Requirements of Narcotic Drugs for 2003*; United Nations "Demographic Yearbook," 2000

SECTION VIII.

COMPETENT NATIONAL AUTHORITIES UNDER THE INTERNATIONAL DRUG CONTROL TREATIES

▪CAMBODIA▪

Secrétaire d´État de la santé publique
Phnom Penh
Cambodge

▪PEOPLE'S REPUBLIC OF CHINA▪

State Drug Administration	Phone:	(86) 10-68355484
No. 38A, Beilishilu	Fax:	(86) 10-68336683
Beijing		
China 100810		

▪LAO PEOPLE'S DEMOCRATIC REPUBLIC▪

Ministère de la santé	Phone:	(856) 21-214014
Direction de l´alimentation et de la pharmacie	Fax:	(856) 21-214015
Vientiane		
République démocratique populaire lao		

▪MALAYSIA▪

Director	Phone:	(60) 3-4412958
Pharmaceutical Services Division		(60) 3-4412892
Ministry of Health		(60) 3-4457389
Perkim Building, 11th Floor	Fax:	(60) 3-4457387
Jalan Ipoh		
51200 Kuala Lumpur,		
Malaysia		

▪MONGOLIA▪

Ministry of Health and Social Welfare	Phone:	(976) 1-327872
Karl Marx Street 2		(976) 1-320916
Ulaanbaatar-11, Mongolia	Fax:	(976) 1-322577

▪MYANMAR▪

Minister	Phone:	(95) 1-229299
Ministry of Health		(95) 1-210652
No. 27 Pyidaungsu Yeiktha Road		(95) 1-210618
Dagon Township	Fax:	(95) 1-210652
Yangon, Myanmar		

SECTION VIII.

COMPETENT NATIONAL AUTHORITIES UNDER THE INTERNATIONAL DRUG CONTROL TREATIES

▪PAPUA NEW GUINEA▪

National Narcotics Bureau	Phone:	(675) 3253044
P.O. Box 3880		(675) 3250190
Boroko	Fax:	(675) 3258842
Papua New Guinea		

▪PHILIPPINES▪

Executive Director	Phone:	(63) 2-5270629
Dangerous Drugs Board		(63) 2-5273223
5th floor, Champ Building		(63) 2-5276344
Bonifacio Drive, Port Area	Fax:	(63) 2-5273215
Manila, Philippines		

▪SRI LANKA▪

Medical Supplies Division	Phone:	(94) 1-694111
357, Deans Road	Fax:	(94) 1-697096
Colombo 10, Sri Lanka		

Cosmetics Drugs and Devices Authority	Phone:	(94) 1-695173
Ministry of Health	Fax:	(94) 1-689704
120, Norris Canal Road		
Colombo 10, Sri Lanka		

▪THAILAND▪

Secretary-General	Phone:	(66) 2-5907341
Food and Drug Administration	Fax:	(66) 2-5908471
Ministry of Public Health		
Tiwanond Road		
Nonthaburi Province 11000,		
Thailand		

▪VIET NAM▪

Drug Administration	Phone:	(84) 4-8461525
Ministry of Health	Fax:	(84) 4-8234758
138A Giang Vo Road		
Ha Noi, Viet Nam		

SECTION IX.

Bibliography

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Colleau SM. Highlights of the INCB report. *Cancer Pain Release*. 1996;9(Suppl):1-4.

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Joranson DE. *Status of worldwide opioid availability.* University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center for Policy and Communications in Cancer Care; Madison, WI, USA. 10th International Symposium Supportive Care in Cancer; San Antonio, TX; March 14-17, 1998 (Poster).

Joranson DE, Rajagopal MR, Gilson AM. Improving access to opioid analgesics for palliative care in India. *Journal of Pain and Symptom Management*. 2002; 24(2):152-159. (Available through http://www.medsch.wisc.edu/painpolicy/publicat/02jpsm3/index.htm.)

MacDonald DM, Finley GA. Governmental barriers to opioid availability in developing countries. *J Pharm Care Pain Symptom Control*. 2001;9(1):5-23.

Pain & Policy Studies Group. Improving Cancer Pain Relief in the World: Report for 2001. Madison, Wisconsin, USA: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center for Policy and Communications in Cancer Care; 2002. (Available through http://www.medsch.wisc.edu/painpolicy/publicat/01report/intro.html.)

Rajagopal MR, Joranson DE, Gilson AM. Medical use, misuse, and diversion of opioids in India. *Lancet*. 2001;358(9276):139-143. (Available through http://www.medsch.wisc.edu/painpolicy/publicat/01lancet/contents.htm.)

Selva C. International control of opioids for medical use. *Eur J Palliat Care*. 1997;4(6):194-198.

ANNEX 1. CANCER PAIN RELIEF, WITH A GUIDE TO OPIOID AVAILABILITY (Verbatim)[5]

CANCER PAIN RELIEF

Second Edition

With a guide to opioid availability

World Health
Organization
Geneva

[5] World Health Organization. *Cancer Pain Relief: With a Guide to Opioid Availability*. Second ed. Geneva, Switzerland: World Health Organization; 1996. (Available through http://www.medsch.wisc.edu/painpolicy/publicat/cprguid.htm).

INTRODUCTION

Background

This part explains the system by which morphine and other opioids are made available to patients who need them. It is intended for use by both drug regulators and health care workers and to promote communication between the two groups. Opioid availability is discussed in the context of the problem of cancer pain and international efforts to address it. A number of the terms used in what follows are defined in Annex 1.

The text has been reviewed by the International Narcotics Control Board (INCB), the body responsible for administering the Single Convention on Narcotic Drugs (6), the treaty that governs opioid availability in the world. National drug regulatory authorities in ten countries have also commented on the text.

New knowledge, new hope

Research in management of cancer pain has produced new knowledge about pain and how opioids act in the body in relation to pain. Traditionally, the opioid analgesics have been used to manage acute pain. Long-term use of opioids has been discouraged because of the risk of tolerance or physical or psychological dependence. Studies have shown that, while physical dependence and tolerance do occur in patients who take opioids over a long period, psychological dependence is extremely rare. Consequently, the risk of such dependence should not be a factor in deciding whether to use opioids to treat the cancer patient with pain.

Studies have also shown that morphine and some other opioids do not have a "ceiling effect". Morphine can be safely administered in increasing amounts until the pain is relieved without producing an "overdose", as long as the side-effects are tolerated. There is no standard dose of morphine; the correct dose is the one that relieves the pain. This dose may vary from patient to patient; a few patients with severe pain may require several thousand milligrams of oral morphine daily to relieve pain.

In general, studies on the use of opioids to treat pain in cancer patients indicate that public and professional expectations about relief from cancer pain should be much higher than they are at present.

Impediments to cancer pain relief

There are many reasons why cancer pain is not adequately treated at present (*7*), including:

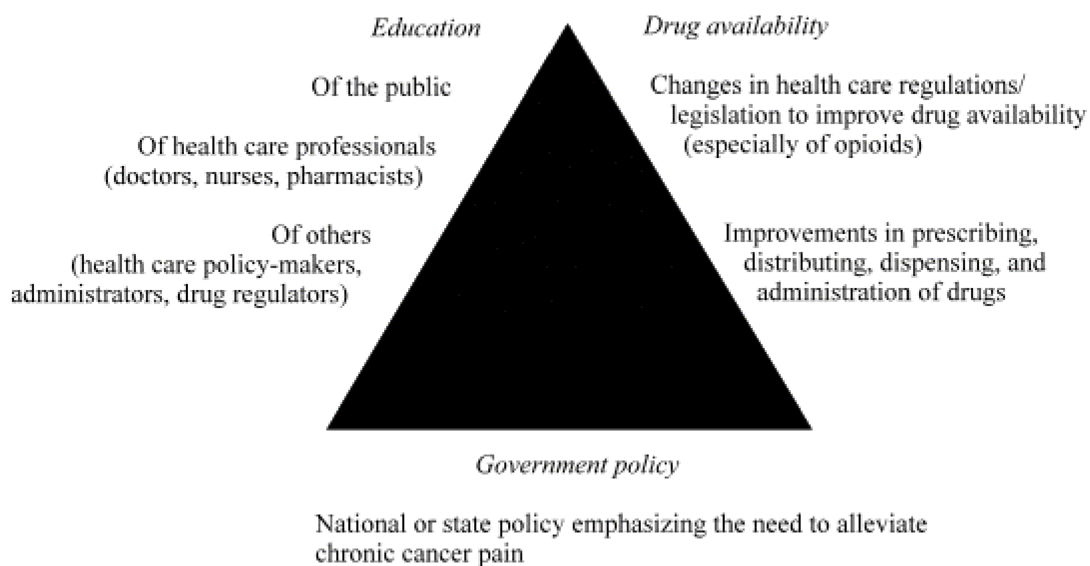
- absence of national policies on cancer pain relief and palliative care;
- lack of awareness on the part of health care workers, policymakers, administrators and the public that most cancer pain can be relieved;
- shortage of financial resources and limitations of health care delivery systems and personnel;
- concern that medical use of opioids will produce psychological dependence and drug abuse;
- legal restrictions on the use and availability of opioid analgesics.

The WHO strategy

To respond to these issues, WHO advocates a strategy with the following key components (Fig. 2):

- national or state policies that support cancer pain relief through government endorsement of education and drug availability;
- educational programmes for the public, health care personnel, regulators, etc.;
- modification of laws and regulations to improve the availability of drugs, especially the opioid analgesics.

Fig. 2. Foundation measures for implementing cancer pain relief programmes



These foundation measures are important if existing knowledge is to be implemented rationally. They cost very little but can have a significant effect (*14*).

Difficulties in obtaining opioids

Fig. 3 shows the global consumption of morphine according to population density. [note: Please refer to the original publication for Figure 3] It can be seen that morphine consumption varies greatly from country to country. Consumption figures do not completely indicate the extent to which opioids are used for treatment of moderate to severe cancer pain; however, they provide probably the best single indicator available.

WHO monitors morphine consumption in individual countries as an index of improvements in pain management. Global morphine consumption was relatively stable until 1984, when WHO began to emphasize the need to use morphine in the treatment of cancer pain. From 1984 to 1992, global consumption of morphine more than tripled.

Many countries have fundamental difficulties in obtaining and distributing drugs for any type of illness. In these countries, the unavailability of drugs is often due to a combination of factors, such as inadequate funding of health services, lack of health care delivery infrastructure and inadequate facilities for the storage and distribution of medicines.

These problems are being addressed by WHO through its Action Programme on Essential Drugs. This programme recommends that a national policy on essential drugs should exist in every country, together with an action plan to guarantee the availability at a reasonable cost of a limited number of drugs of significant therapeutic value. The goal is to satisfy the health care needs of the majority of the population. More than 100 countries have so far adopted lists of essential drugs.

The model list of essential drugs (2) includes three opioid analgesics. Codeine and morphine are on the main list; pethidine is on the complementary list. In many countries, however, morphine and other opioids are not available, or available only under very strict conditions, because of national laws aimed at preventing drug abuse. Some of these laws were established long before oral opioids became widely recognized as indispensable for the treatment of cancer pain. In such cases, it is essential for health care workers and drug regulators to cooperate in order to make opioid analgesics available while preventing their abuse. The next chapter reviews the Single Convention on Narcotic Drugs, explains the steps that must be taken to make morphine and other opioids available for the treatment of pain, and offers suggestions for doing this efficiently.

The participants in the drug distribution chain

At the outset, it should be emphasized that each participant in the chain of distribution should fulfil all the legal requirements. The chain of distribution includes:

- the national drug regulatory authority
- importers and exporters
- manufacturers
- wholesalers
- doctors, nurses and pharmacists.

THE SINGLE CONVENTION ON NARCOTIC DRUGS

Description and purpose

The 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol (*6, 8*), is the principal international treaty regulating availability of opioids. It classifies the opioids, and requires the registration of all handlers and the estimation of medical needs for opioids. It establishes rules concerning production, manufacture and distribution, and requires statistical reports. The Single Convention governs how opioids are shipped between countries, using a system of import and export approval. The treaty also defines to some extent the requirements for safe distribution within a country.

Governments that are party to the Single Convention have agreed to bring their laws and regulations into line with its requirements. A list of the parties is updated and published annually by the INCB (*9*). Countries that are not party to the Single Convention often follow its basic procedures.

The preamble of the Single Convention on Narcotic Drugs (*6*) recognizes that "the medical use of narcotic drugs continues to be indispensable for the relief of pain" [and] "addiction to narcotic drugs constitutes a serious evil".

Thus, the broad purpose of the treaty is to prevent the abuse of narcotics or opioids, while guaranteeing their availability for medical use.

The Single Convention classifies the opioids into four schedules, depending on each drug's dependence potential, abuse liability and therapeutic usefulness. These schedules do not necessarily correspond with those in national laws. The stronger opioid analgesics, such as fentanyl, morphine, hydromorphone and oxycodone are in Schedule I. Codeine and its derivatives, which are less strictly controlled, are in Schedule II. Schedule III contains specified preparations of codeine and dextropropoxyphene that are exempted from certain requirements. Schedule IV contains opioids that are considered to be particularly susceptible to abuse.

Exceptions

Codeine

Preparations containing not more than 100 mg of codeine with one or more other ingredients per dosage unit, and those with a concentration of not more than 2.5% codeine in undivided preparations, such as syrups, are exempted from certain control measures under the Single Convention.

Buprenorphine and pentazocine

These drugs are controlled by the Convention on Psychotropic Substances, 1971.

The drug distribution system

A country obtains its supply of opioids for medical purposes by importing them from another country, manufacturing them itself, or both. These opioids are then distributed by manufacturers or wholesalers to hospitals and pharmacies, and subsequently dispensed to patients by health care personnel.

The Single Convention requires that all individuals and enterprises in the distribution system should be licensed or otherwise appropriately authorized, and that transfers of opioids take place only between properly registered parties. Patients may use opioids only according to a physician's prescription. Certain records must be kept, and reports on consumption must be filed with the national regulatory authority. These, along with security arrangements and inspections, permit the detection of "leakage" or "diversion" from the legitimate system of drug distribution.

National estimates of medical need for opioids

It is vital that a country should have enough opioids to meet the demand for treatment of patients in pain. The INCB has recognized that opioids are underused in the

treatment of pain, especially cancer pain, and has called on governments to re-evaluate their needs.

Every year, national drug regulatory authorities prepare an estimate of the amount of Schedule I opioids that will be needed in the country during the following year. The estimate must be submitted to the INCB six months in advance of the period to which it applies. Under the Single Convention, the quantity of opioids manufactured in or imported into a country must not exceed the government's official estimate of the amount needed.

The treaty requires the INCB to confirm the national estimate before the national government may permit the import or manufacture of opioids. In this way, excessive manufacture or import can be monitored and the risk of diversion to non-medical use is minimized.

The treaty also requires the INCB to endeavour to ensure that opioids are available for medical purposes, and to confirm national estimates as quickly as possible. If an annual estimate proves to be inadequate, the national drug regulatory authority is permitted by treaty to submit an amendment to the INCB; the INCB will confirm amendments as soon as possible.

The responsibility for determining the amount of opioids necessary to meet the medical need in a country rests entirely with the national government, in particular with the drug regulatory authority. Countries may use different methods to calculate the estimate, but the INCB must be informed of the method used and of any changes. Typically, an estimate will reflect to some degree the amount of each opioid consumed in previous years.

Communication between health personnel and regulators

Communication between health workers and drug regulators is essential in order to ensure that each understands the other's aims. It is important for pain management experts and medical associations to understand the opioid distribution system in their country, learn about the national estimate of opioid needs, and be aware of the concerns of regulators. Opioid abuse is a reality, and health care workers must cooperate in the campaign to prevent diversion.

It is also important for regulators to learn about the importance of pain relief both for individual patients and for public health in general. Information about cancer pain, where and how cancer patients are treated, and the training of health care personnel will help regulators whose job it is to ensure the integrity of the distribution system. The knowledge that opioid use needs to increase will help regulators to make appropriate changes in the annual estimate.

Health care personnel should make sure that regulators know the salient facts related to pain relief, for example:

- Psychological dependence is rare among cancer patients who receive opioids for pain.
- Oral forms of morphine are preferred because the patient may be able to live at home, and painful injections are eliminated. However, the oral dose needs to be 3-6 times

higher than the injected dose to achieve the same degree of pain relief. Thus, the total amount of drug needed will increase significantly; this should be taken into account in preparing the national estimate.

- Pethidine, often relied upon for treatment of acute pain, is not recommended for patients with chronic pain because accumulation of a toxic metabolite may occur, causing myoclonus and seizures. Morphine and other opioids are preferred, and should be included in the national estimate.

Health care workers should tell regulators exactly which opioids are needed, including the dosages and dosage forms required, in order to ensure that the estimate is adequate to meet the needs of patients.

Obtaining a supply of opioids

After the estimate has been confirmed by the INCB, a country may either import or manufacture opioids. In both cases, the participants in the distribution chain should endeavour to ensure that the supply is reliable. Interruptions in the distribution of opioids is distressing for both patients and families and must be avoided.

Domestic manufacture

Some or all of the opioids needed may be manufactured by enterprises in the country itself, which will be regulated (or operated) by the government. Regulation of manufacture of opioid products includes licensing, requirements for record-keeping and reporting, and quality control. Resources are required for record-keeping, to provide secure facilities and maintain security procedures from the acquisition of raw materials until the distribution of the finished products, in order to prevent diversion.

The products available in a country may be limited to the opioids and dosage forms that have been approved for marketing by the national health authority.

A manufacturer may distribute the finished products directly to licensed pharmacies or hospitals, or they may be distributed by a wholesaler. Wholesalers must also be licensed by the national drug regulatory authority, and must obey rules concerning security and record-keeping.

The import/export system

Often, some or all of the opioid products a country needs are imported. The import and export requirements of the Single Convention are outlined here, so that the participants in the opioid distribution system can see what needs to be done to complete the process quickly. Specific requirements may vary from country to country.

The Single Convention lays down a step-by-step process to ensure that the movement of opioids between countries occurs only after authorization by the drug regulatory authorities, and that the amounts imported stay within the approved estimate of the importing country. The import and export certificates are the proof that the products are changing hands legally. Both certificates must be approved and must accompany each shipment. There is no standard certificate, although a model import certificate (Annex 2) has been developed by the United Nations Commission on Narcotic Drugs.

The import certificate

The following information must appear on the import certificate:

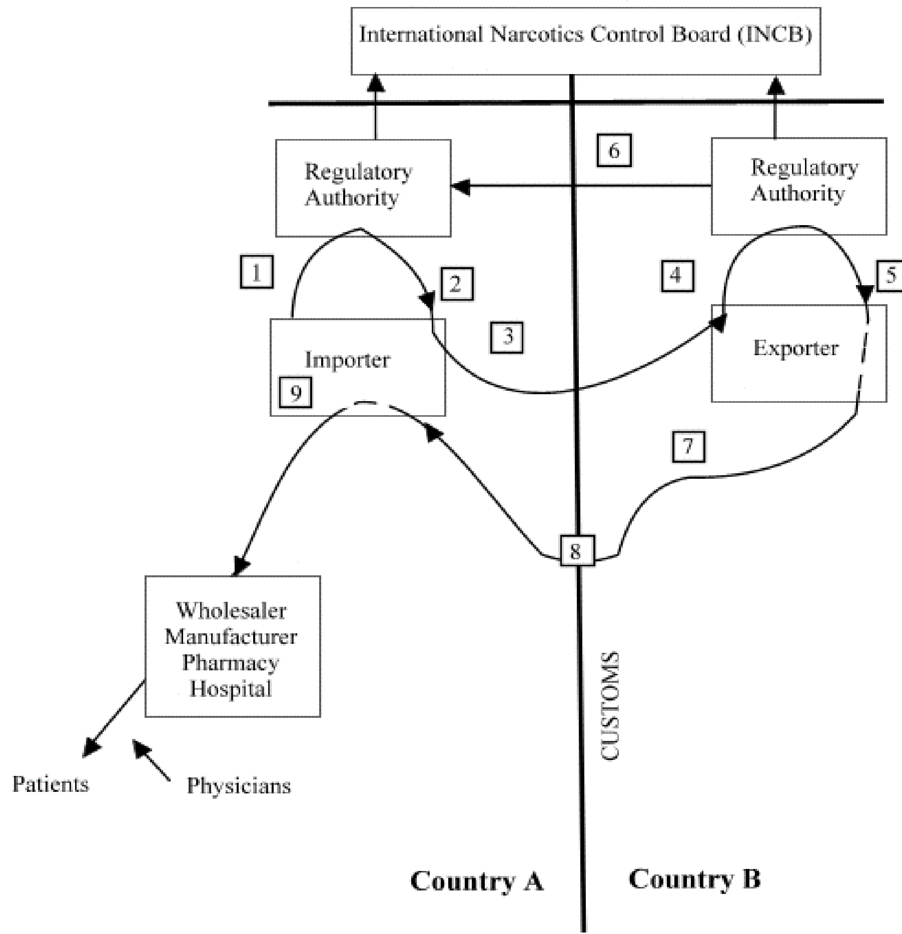
- the certificate number,
- the name of the drug,
- the international nonproprietary name (INN) of the drug (*10*),
- the exact description and quantity of the drug, including strength(s) and dosage form(s),
- the name and address of the importer,
- the name and address of the exporter,
- the period of validity of the certificate.

Steps in the import/export process

The import/export process is outlined below and in Fig. 4. It should be noted that many countries also have a certification procedure to prevent marketing of pharmaceutical products that are falsely labelled, counterfeit or substandard (*11*).

1. The entity wishing to import a substance controlled under the Single Convention applies to its regulatory authority for an import certificate.
2. The regulatory authority considers whether the company is properly licensed and whether the drug and amount are within the national estimate; if approved, an original import certificate and one copy are issued.
3. The importer sends the original of the import certificate to the entity proposing to export the substance.
4. The exporter applies to its drug regulatory authority for an export certificate.
5. The regulatory authority in the exporting country checks that an import certificate has been issued and that the exporter is properly licensed; if the application is approved, an export certificate is issued.
6. The regulatory authority in the exporting country sends a copy of the export certificate to the regulatory authority in the importing country.
7. The exporter ships the drugs to the importer, along with the originals of the export certificate and import certificate.
8. The shipment must pass a customs inspection.
9. The importer sends both certificates to its regulatory authority.

Fig. 4. Steps in opioid importations



It is important that there is complete, accurate and prompt communication between the participants to minimize the time between the various steps in the process.

The reporting system

National drug regulatory authorities must report all imports and exports of opioids to the INCB every quarter. They are also required to make an annual inventory and report the total amount of opioids manufactured, consumed and in stock. The annual inventory does not include drugs stored in pharmacies, which for official purposes are considered to have been consumed.

The INCB, in turn, uses these data to prepare reports and monitor global production and consumption of opioids. INCB statistical reports (*9*) can be useful to health care workers who need to know the quantity of opioids consumed in their country in previous years. These statistics also provide a global picture of morphine consumption. For statistical purposes, a "defined daily dose" (DDD) has been calculated to allow a rough comparison of consumption of drugs of different potencies in different countries. The DDD for morphine is 30 mg. It must be emphasized that the DDD has no significance in terms of medical use or for drawing up estimates of opioid needs, but is intended only as a tool for analysing differences in consumption around the world.

The annual reports of the INCB provide useful information about its work, as well as patterns of medical use and diversion of opioids. The INCB also produces periodic special reports that focus attention on critical issues, such as the 1989 special report *Demand for and supply of opiates for medical and scientific needs* (*12*) which called on governments to re-evaluate medical needs for opioids.

Is the international system working?

In recent years, the INCB has reported to the United Nations Economic and Social Council that the international control system continues to operate satisfactorily (*13*).

> Diversion of narcotic drugs from the licit trade into illicit channels remains relatively rare and the quantities involved are small in comparison with the large volume of transactions. That holds true for drugs in the international trade as well as in domestic wholesale circuits.

The INCB has also reported on its efforts to improve opioid availability for the treatment of pain. In the special report mentioned above (*12*), the INCB reviewed the availability of opioids for medical and scientific purposes in consultation with WHO. The INCB concluded that the medical need for opioids is not being fully met, particularly in respect of cancer pain. The INCB made recommendations to governments, WHO, professional associations and medical instructors, on the need to:

- improve methods of assessing medical needs;
- develop a monitoring system to show whether medical needs for opioids are being met and to indicate corrective actions required;
- identify obstacles to the appropriate use of opioids and facilitate their availability in cases of severe pain;

- establish national policies and guidelines on the appropriate medical use of opioids;
- ensure that health professionals are adequately trained in opioid use and informed about drug dependence;
- urge medical instructors and professional medical associations to promote the rational use of opiates for medical purposes while taking measures to ensure that they are not abused.

Regulation of health care workers

The Single Convention recognizes that individual governments must decide the level of regulation of the individuals directly involved in dispensing opioids - pharmacists, physicians and nurses. However, it expresses several principles that should be observed:

- individuals must be authorized to dispense opioids by their professional licence to practice, or be specially licensed to do so;
- movement of opioids may occur only between duly authorized parties;
- a medical prescription is required before opioids may be dispensed to a patient.

Drug abuse versus patient need

The Single Convention recognizes that governments have the right to impose further restrictions if they consider it necessary, to prevent diversion and misuse of opioids. However, this right must be continually balanced against the responsibility to ensure opioid availability for medical purposes.

In deciding the appropriate level of regulation, governments should bear in mind the dual aims of the Single Convention. The INCB has observed that in some countries fear of drug abuse has resulted in laws and regulations, or interpretations thereof, that make it unnecessarily difficult to obtain opioids for medical use.

> Prevention of availability of opiates for medical use does not necessarily guarantee prevention of the abuse of illicitly procured opiates. Overly restrictive approaches may, in the end, merely result in depriving a majority of the population of access to opiate medications (*12*).

The WHO Expert Committee on Cancer Pain Relief and Active Supportive Care (*7*) has commented on special multiple-copy prescription programmes that are required by governments in some countries and in several states of the United States of America. Typically, these programmes reduce prescribing of covered drugs by 50% or more. Although the Expert Committee acknowledged that they may reduce careless prescribing and "multiple doctoring", it also noted:

> …the extent to which these programmes restrict or inhibit the prescribing of opioids to patients who need them should also be questioned.
>
> Health care workers may be reluctant to prescribe, stock or dispense opioids if they feel that there is a possibility of their professional licences being suspended or revoked by the governing authority in cases where

large quantities of opioids are provided to an individual, even though the medical need for such drugs can be proved.

Suggested guidelines for regulation of health professionals

It is understood that regulatory requirements for physicians, nurses and pharmacists to dispense opioids to patients will differ from country to country. However, the following are general criteria that can be used to develop a practical system.

1. *Legal authority*. Physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs.
2. *Accountability*. They must dispense opioids for medical purposes only and must be held responsible in law if they dispense them for non-medical purposes.

   Appropriate records must be kept. If physicians are required to keep records other than those associated with good medical practice, the extra work incurred should be practicable and should not impede medical activities. Hospitals and pharmacists must be legally responsible for safe storage and the recording of opioids received and dispensed.

   Reasonable record-keeping and accountability provisions should not discourage health care workers from prescribing or stocking adequate supplies of opioids.
3. *Prescriptions*. A prescription for opioids should contain at least the following information:
   - name and address of the patient,
   - date of issue,
   - drug name, dosage strength and form, quantity prescribed,
   - directions for use,
   - physician's name and business address,
   - physician's signature.
4. *Patient access*. Opioids should be available in locations that will be accessible to as many cancer patients as possible.
5. *Medical decisions*. Decisions concerning the type of drug to be used, the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, and not by regulation.
6. *Dependence*. Physical dependence, which may develop when opioids are used to treat chronic pain, should not be confused with psychological dependence.

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ANNEX 2. ACHIEVING BALANCE IN NATIONAL OPIOIDS CONTROL POLICY (Verbatim)[6]

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

[6] 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).

TABLE OF CONTENTS

		PAGES
EXECUTIVE SUMMARY		1
SECTION I	PURPOSE AND AUDIENCE	2
SECTION II	INADEQUATE PAIN RELIEF	3
SECTION III	MEDICAL NEED FOR OPIOID ANALGESICS	3
SECTION IV	THE INADEQUATE AVAILABILITY OF OPIOIDS	5
SECTION V	IMPEDIMENTS TO OPIOID AVAILABILITY	6
SECTION VI	THE IMPERATIVE TO EVALUATE NATIONAL DRUG CONTROL POLICY	9
SECTION VII	METHOD FOR PREPARING THE GUIDELINES	11
SECTION VIII	USING THE GUIDELINES	12
SECTION IX	THE GUIDELINES	12
SECTION X	SELF-ASSESSMENT CHECKLIST	25
ACKNOWLEDGMENTS		28
REFERENCES		29
ANNEX 1	USE OF TERMS IN THIS PUBLICATION	31
ANNEX 2	ORDERING INFORMATION FOR KEY RESOURCES	32
ANNEX 3	SUMMARY OF THE GUIDELINES	33
ANNEX 4	GLOBAL CONSUMPTION OF PRINCIPAL NARCOTIC DRUGS	34

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

ANNEX 3 - INCB REPORT CONCLUSIONS AND RECOMMENDATIONS (Verbatim)[7]

UNITED NATIONS INTERNATIONAL NARCOTICS CONTROL BOARD
Vienna

Report of the International
Narcotics Control Board for 1995

Availability of Opiates for Medical Needs

Special report
prepared pursuant to Economic and Social Council
resolutions 1990/31 and 1991/43

UNITED NATIONS

[7] 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

44. The Board wishes to express its appreciation to the governments that responded to its 1995 survey. The Board notes with satisfaction that a significant number of governments are making efforts to respond to its recommendations; they are increasing their estimates to meet medical demand, issuing national policies to improve medical use of narcotic drugs, supporting educational programmes and examining their health-care systems and laws and regulations for impediments, or are planning to do so.

45. Governments reported a number of problems with the availability of narcotic drugs that must be dealt with. Those problems included lack of availability of drugs recommended by WHO, such as oral morphine, in many countries and particularly in hospitals with cancer programmes; insufficient importation; periodic shortages; problems with estimating future medical needs; and national narcotic laws that did not ensure medical availability of narcotic drugs and restricted availability. Although 36 governments reported having examined their health-care systems and laws and regulations for impediments to availability, they represented only 17 per cent of the governments in the world. Those that did so identified numerous impediments, most of which were linked not only to concerns about drug addiction, drug diversion and restrictive national laws, but also to insufficient import or manufacture, as well as problems in national health-care delivery systems, including insufficient training, personnel and facilities and the cost of medication.

46. The Board notes that most governments in the world did not respond to its questionnaire; thus, the Board did not have sufficient information concerning approximately one half of the world's population. Among those governments that did not respond were most of the developing and least developed countries, as well as those governments that had frequently failed to submit annual estimates of narcotic drug requirements as required by the 1961 Convention. The Board is cognizant that less developed countries have more difficulty meeting basic health-care needs. Nevertheless, the Board encourages governments of such countries to make efforts to examine their medical needs for narcotic drugs as well as the impediments to their availability, to advise the Board of the results of those efforts and to inform the Board if it can be of assistance. The governments that did not respond included a number of developed countries that the Board believes should also concentrate their attention on identifying unmet medical needs.

47. The Board concludes that the recommendations contained in its 1989 special report are far from being implemented and that, while there have been efforts by some governments to ensure the availability of narcotic drugs for medical and scientific purposes, it appears that many others have yet to focus on that obligation.

48. The Board believes that 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. A national drug control programme should have legislative authority reflecting the provisions of the 1961 Convention, delegation of responsibility for implementation, including administrative responsibility for managing import and export licences, estimating medical requirements, reporting required statistics and supervising adequate controls over distribution. Controls over the professionals and medical facilities that distribute narcotic drugs should ensure accountability and prevent diversion while making narcotic drugs available to the patients who need them. Controls should not be such that for all practical purposes they eliminate the availability of narcotic drugs for medical purposes.

49. Therefore, bearing in mind the conditions prevailing in individual countries and the availability of resources, the Board concludes that if the recommendations below are implemented there will be significant additional progress towards ensuring adequate availability of narcotic drugs for me scientific purposes. The Board will continue its examination of the situation and will monitor responses to its recommendations.

50. The Board will:

(a) Increase monitoring of annual estimates submitted by Governments and initiate dialogue as necessary to identify unmet needs and ensure that annual estimates of requirements for narcotic drugs are neither overestimated nor underestimated;

(b) Continue to ensure expeditious confirmation of supplementary estimates submitted by Governments to assist them in coping with unforeseeable needs;

(c) Encourage Governments to use information from a variety of sources to improve their capability to estimate foreseeable medical needs for narcotics drugs;

(d) Encourage Governments to develop drug distribution systems that are well controlled and that will ensure availability of narcotic drugs to patients in medical facilities and in the community;

(e) Convene seminars in selected regions or areas for government narcotic control authorities and health-care representatives to facilitate the exchange of information about legal requirements, unmet medical needs, methods of estimating future needs, and ways to improve the availability of narcotic drugs for medical needs;

(f) Review on a regular basis national and international developments relevant to improving the availability of narcotic drugs for medical purposes, incorporating updated information and observations into its annual report;

(g) Re-evaluate in the year 2000 the world situation and the progress of Governments and other organizations in implementing the recommendations below, issuing new findings, conclusions and recommendations.

A. Recommendations for consideration by Governments

51. Governments are invited to consider the following recommendations:

(a) Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments;

(b) Governments that have not done so should, in response to the recommendations contained in the 1989 special report of the Board, critically examine their methods for assessing medical needs for narcotic drugs and should make suitable arrangements for ensuring their availability;

(c) Governments should establish a system to collect information from medical facilities that care for surgical, cancer and other patients, from organizations that are working to improve the rational use of narcotic drugs and from manufacturers, distributors, exporters and importers and should establish groups of knowledgeable individuals to assist in obtaining information about changing medical needs;

(d) Governments should add to their annual estimates of requirements for narcotic drugs a margin of 10 per cent to allow for the possibility of increased consumption from such general causes as population growth, evolution of health services and trends in the incidence of diseases and their treatment and, if need be, should add an even greater margin in countries or territories where there is rapid economic and social development or rapid expansion of the medical use of drugs, including the introduction of new formulations or drugs;

(e) Governments that experience interruptions in supply of narcotic drugs because of delays in importation or for other reasons should examine the situation and develop a system to accomplish in a timely manner the steps involved, such as issuing licences, arranging for payment, carrying out paperwork, transporting the drugs, taking the drugs through customs and distributing the drugs to medical facilities;

(f) Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and the fact that adequate provision must be made to ensure the availability of narcotic drugs for such purposes and to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws;

(g) Governments should inform health professionals about the WHO analgesic method for cancer pain relief;

(h) Governments should communicate with health professionals about the legal requirements for prescribing and dispensing narcotic drugs and should provide an opportunity to discuss mutual concerns;

(i) Governments should inform the Board about progress and needs concerning implementation of the present recommendations;

(j) Governments that did not reply to the 1995 questionnaire of the Board should do so.

B. Recommendations for consideration by the United Nations International Drug Control Programme

52. The following recommendations are for consideration by the United Nations International Drug Control Programme (UNDCP):

(a) The UNDCP model national legislation on the control of narcotic drugs should contain provisions that recognize the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(b) The UNDCP national drug control master plan should include policies, strategies and administrative measures for accomplishing the responsibilities associated with the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(c) UNDCP should assist Governments in improving legislation and administrative capabilities to implement the obligation to ensure the availability of narcotic drugs for medical and scientific purposes;

(d) UNDCP should review situations where lack of resources prevents a Government from ensuring the availability of narcotic drugs for medical and scientific purposes and should identify sources of assistance.

C. Recommendations for consideration by the Commission on Narcotic Drugs

53. The Commission on Narcotic Drugs should call on Member States to give full consideration to the present special report and the recommendations contained in it, in the light of the following:

(a) The worldwide extent of unrelieved pain and suffering associated with diseases such as cancer and AIDS;

(b) The relatively recent medical advances that make pain relief possible;

(c) The fact that morphine and other narcotic analgesics must be available to provide such relief;

(d) The fact that there continues to be unmet medical needs for narcotic drugs particularly but not only in less developed countries;

(e) The obligation of parties to the 1961 Convention or to that Convention as amended by the 1972 Protocol to ensure the availability of narcotic drugs for medical and scientific purposes.

D. Recommendations for consideration by the World Health Organization

54. WHO is encouraged to consider the following recommendations:

(a) WHO should expand its efforts to provide Governments with information about its analgesic method for the relief of cancer pain and to educate the public, health professionals and policy makers about the rational medical use of narcotic drugs, including the analgesic method for the relief of cancer pain;

(b) WHO should continue to inform the public, health professionals, competent authorities and policy makers about the correct definition of terms regarding dependence, as well as their significance or lack of significance when narcotic analgesics are used to treat cancer pain under medical supervision;

(c) WHO should, in cooperation with the Board, assist Governments in developing adequately controlled drug distribution systems that are capable of providing narcotic drugs to patients in hospitals and in the community;

(d) WHO should encourage health-care organizations to communicate with national narcotic control authorities about the rational use of narcotic drugs, legal requirements, unmet medical needs and impediments to availability;

(e) WHO should expand its efforts to develop methods that can be used by governmental and non-governmental organizations to identify impediments to the appropriate medical availability of narcotic drugs;

(f) WHO should continue to evaluate whether national essential drug lists and formularies contain the narcotic drugs that are needed for cancer pain relief;

(g) WHO should inquire into the extent to which and the reasons why non-narcotic drugs are used in lieu of narcotic drugs for the treatment of severe pain, including the medical and regulatory factors behind that approach.

E. Recommendations for consideration by international and regional drug control, health and humanitarian organizations

55. International and regional drug control, health and humanitarian organizations are encouraged to consider the following recommendation: international and regional organizations that assist Governments with drug control, health and humanitarian aid should consider ways in which they can promote the WHO analgesic method for the relief of pain and support making narcotic analgesics available under adequate control.

F. Recommendations for consideration by educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives

56. Educational institutions and non-governmental health-care organizations are encouraged to consider the following recommendations:

(a) Educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives, should teach students in health-care professions and licensed practitioners about the rational use of narcotic drugs, their adequate control and the correct use of terms related to dependence;

(b) Educational institutions and non-governmental health-care organizations, including the International Association for the Study of Pain and other health-care representatives, should establish ongoing communication with Governments about national requirements for the medical use of narcotic drugs, unmet needs for narcotic drugs and impediments to the availability of narcotic drugs for medical purposes.

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