

IMPROVING CANCER PAIN RELIEF IN THE WORLD

REPORT FOR 2004



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

Sponsored by:

**The Pain & Policy Studies Group
University of Wisconsin Comprehensive Cancer Center
The Medical School
Madison, Wisconsin USA**

**<http://www.medsch.wisc.edu/painpolicy>
<http://www.WHOcancerpain.wisc.edu>**

July 2005

EXECUTIVE SUMMARY

This report summarizes the work during **2004** of the World Health Organization (WHO) Collaborating Center (the Center) for Policy and Communications in Cancer Care in Asia, Europe, the Middle East and Latin America. The Center is sponsored by the Pain & Policy Studies Group, at the University of Wisconsin Comprehensive Cancer Center in the Medical School, Madison, Wisconsin, U.S.A.

In **2004**, the Center collaborated extensively with WHO Headquarters programs in Essential Drugs and Medicines, Cancer, and WHO Regional Offices in the Americas.

In February **2004**, the Center continued its work to address opioid availability in Eastern Europe. The Director and Center staff traveled to Romania to meet with the Ministry of Health (MOH), Pain & Palliative Care Commission, and our collaborator, to continue the process of drafting a new law.

In March **2004**, the Center participated in the British Pain Society meeting which took place in Manchester, United Kingdom.

In September **2004**, the Center participated in a collaborative meeting between the WHO and the International Narcotics Control Board (INCB) "Assuring Availability of Opioid Analgesics for Palliative Care," to develop a draft document outlining a global strategy to integrate the availability of opioid pain medications into palliative care for HIV/AIDS, cancer and other chronic diseases.

In October **2004**, the Center participated in the Global Day Against Pain.

The Center accomplishes its policy work in part through a program of research, development, demonstration, monitoring, evaluation, and communications. The Center develops methods, procedures and models that can be used to identify barriers to opioid availability, diagnose regulatory problems, make changes in national and state policy, and monitor outcomes.

The Center accomplishes its communications work through the publication of *Cancer Pain Release*, a quarterly WHO newsletter that provides health professionals, policy makers, and regulators throughout the world with updates on issues and developments in the field. *Cancer Pain Release* is disseminated to approximately 50,000 health-care professionals in 180 countries and is inserted in national and international pain and palliative medicine journals.

The Center participates in international and national conferences and strategy meetings for health professionals and government officials, and provides technical assistance to government and non-government organizations. The Center maintains policy and communications websites and promotes better understanding of the principle of balance that should guide national narcotics control policy to ensure availability of opioid pain medications under adequate control to prevent abuse and diversion.

THE CENTER AND ITS WHO TERMS OF REFERENCE

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Terms of Reference for the Collaborating Center:

1. Using the WHO Guidelines, assess the context of balance and barriers in national approaches to opioid analgesic regulations; cooperate with and provide related information, education and assistance to units of the WHO, national Governments, NGOs and individuals; develop methods to communicate with and train health professionals, regulators and policy makers about balanced drug control policy.
2. Develop methods including establishment of demonstration projects, to make opioids available under adequate control for the relief of cancer pain in community-based programs and hospitals, consistent with international drug control conventions and WHO Guidelines; spread the use of such methods nationally and internationally in developed and developing countries.
3. To develop methods to monitor and study national and international trends and policies related to the medical use of opioid analgesics.
4. To develop and maintain (1) a global communication network for the WHO Cancer Pain Relief and Palliative Care Program, including publication of "Cancer Pain Release", and (2) an international database of educational resources to facilitate access to professional education about pain control and palliative care worldwide.
5. To collaborate and give technical assistance to PCC initiatives or country projects regarding palliative care, especially those concerning advocacy for drug availability and policy development.
6. To support PAHO's efforts to negotiate policy changes for opioid availability through PAHO's project on non-communicable disease policy.

Madison, Wisconsin, USA
July 15, 2005



David E. Joranson
Director

CURRENT MEMBERS OF THE CENTER

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Acknowledgments:

The Center wishes to acknowledge the cooperation of the following individuals: Professor M.R. Rajagopal, Professor and Head, Department of Anaesthesiology and Palliative Medicine, Amrita Institute of Medical Sciences, Kochi, India; Dr. Cecilia Sepulveda, Coordinator, WHO Cancer Control Program, Geneva, Switzerland; the International Narcotics Control Board Secretariat, Vienna, Austria; Ms. Liliana DeLima, Executive Director, International Association of Hospice and Palliative Care, Texas, U.S.A; Dr. Daniela Mosoiu, Medical Director, Hospice Casa Sperantei, Brasov, Romania; Robert Ancuceanu, the Director General of the General Directorate for Pharmaceuticals at the Ministry of Health, Romania; Professor Florinel Badulescu, President of the National Society of Oncology, Romania; Dr. Bogdan Grigore, General Directorate for Pharmaceuticals at the Ministry of Health, Romania; and Professor Ostin Mungiu, Gr. T. Popa University of Medicine and Pharmacy and President of the Romanian Association for the Study of Pain, Romania.

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I. WORK PERFORMED IN RELATION TO THE TERMS OF REFERENCE

A. Develop Methods and Procedures

The Center has developed methods and procedures in several areas to implement its Terms of Reference. These areas include data collection, education, policy evaluation, communications, and collaboration.

Data Collection:

The Center maintains an international database to support its work with governmental and non-governmental organizations and individuals who are working to improve pain relief. The database consists of (1) statistics describing the medical consumption of morphine and other principal opioids for all countries that report to the INCB; (2) population data, by country, from the United Nations Department of Economic and Social Affairs; and (3) human development index (HDI) data, a composite score of a country's life expectancy at birth, level of education, and standard of living, from the United Nations Development Programme. These data allow the Center to monitor opioid consumption trends, to identify progress and problems in improving pain relief, to examine correlations between opioid consumption and HDI, and to inform health-care professionals and government officials about their country's trends in use of opioids. The Center's analysis of these data has been reported in numerous publications, monographs,¹⁻⁶ conference presentations and posters.

Education:

During 2004, the Center helped to organize and participated in meetings and educational programs that bring together representatives from government, drug control, cancer, AIDS, palliative care, and medical education in several countries, including India, Romania, and the Ukraine. Such efforts, and continued networking of professionals representing government and medicine, will help to develop awareness about the policy and infrastructure changes necessary to ensure opioid availability for pain management and palliative care. The Center has developed specialized presentations that explain the principles of opioid availability, their origins in international narcotics control treaties, and how to implement them. These presentations can help medical and regulatory professionals to understand and apply the treaty-based drug control policy framework that has the capability of ensuring opioid availability. The Center produced a number of monographs for distribution at national, regional and international meetings to provide participants with information about opioid analgesic consumption trends and how to access key informational resources (see Bibliography).

2004 Presentations		
<u>Title of Presentation</u>	<u>Place</u>	<u>Date</u>
Improving Access to Opioids for Cancer Pain Relief and Palliative Care	Larnaca, Cyprus	February 2004
Barriers to Pain Relief: International	New York, USA	February 2004
Regulations for Prescribing Opioids in Europe and Romania	Bucharest, Romania	February 2004
Palliative Care for HIV/AIDS: Overview of Opioid Availability	Kiev, Ukraine	February 2004
Workshop on Opioid Availability and Amendment of Narcotic Rules	Hyderabad, India	March 2004
Relief of Severe Pain in the World Remains an Elusive Goal	Manchester, UK	March 2004
International Perspective on Opioid Use: Standards for Opioid Policy	Manchester, UK	March 2004
Pain Relief for Cancer and AIDS in Low and Middle Income Countries: The Vision vs. the Reality	Geneva, Switzerland	October 2004
Relief of Pain in the World is an Elusive Goal	Dublin, Ireland	October 2004
Relief of Severe Pain in the World: A Desirable but Elusive Goal	London, UK	November 2004
Pain Relief for Patients with Cancer and AIDS in Low and Middle Income Countries: The Vision vs. the Reality	Madison, USA	December 2004

Policy Evaluation:

The Center has the capability to evaluate national opioids control policy. This work is based on a central principle of "balance," that government policies to prevent misuse and diversion of controlled substances should not interfere with their use for the relief of pain.⁷⁻¹⁰ Using this central principle, the Center helped

to prepare WHO self-assessment guidelines to encourage national governments to achieve better pain management by identifying and overcoming regulatory and other barriers to opioid availability.^{9,11} The WHO Guidelines can be used to develop balanced national drug control policies, and are intended for those who make national drug control policy, as well as those who implement it. The WHO Guidelines may also be used by health-care professionals and their organizations to establish cooperation with governments and facilitate education about the rational use of pain medications. The Center has also developed a procedure to “diagnose” and “treat” barriers to pain management and opioid availability, applying a medical model to identify and address policy problems.

Communications:

The Center continues to expand dissemination of its work to a wide international audience of health-care practitioners and government officials through publications, conference participation, networking on the Internet, access to websites, and periodic email contact with collaborators. In **2004**, we communicated via email to more than 200 colleagues around the world. In February, the Center announced its development of a resource program to assist in the improvement of policies governing the medical availability of opioid pain medication in Eastern Europe. In May, the Center provided information to its international colleagues regarding the WHO’s unprecedented action to consider a draft resolution on cancer prevention and control. The Center announced in June the availability of a document providing information about rules and regulations concerning patients traveling with prescription opioid analgesics. An announcement about the Global Day Against Pain, a campaign which urges people to view pain relief as a human right, was disseminated in October. The Director of the Center participated in a press conference in Geneva for the Global Day Against Pain. Lastly, the Center publicized its recent hosting of a Study Visit held in November/December for a 5-member delegation of Romanian experts to examine and recommend changes in the Romanian regulatory system.

An index list of all PPSG news alerts disseminated since November of 2001 was uploaded to the Center’s website in **2004** and is continuously updated as new announcements are made. It can be accessed through the website’s homepage and clicking on “PPSG News Alerts.”

Collaboration:

The Center is committed to a collaborative process. For example, the Center’s collaborative efforts have been conducted with government and non-government organizations in Eastern Europe. The aim of collaboration is to develop the relationships between government and non-government organizations that are necessary to evaluate and improve policies governing opioid availability. Other examples of collaborative efforts appear throughout this report.

B. Collaboration with WHO Demonstration Project – India

Activities Prior to 2004

This section reviews the Center’s ongoing activities in India in collaboration with the WHO Demonstration Project (WHODP) in Calicut, an Indian non-governmental organization, several agencies of the Central Government of India, and several state government Ministries of Health. An historical summary of these activities is presented first, followed by an update for **2004**.

Objective:

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

Situation:

It is estimated that more than one million people a year in India suffer from pain due to cancer. Cancer is usually diagnosed when the disease is late-stage, which is when pain is severe and

sometimes excruciating. Despite India's heavy cancer burden, the country uses little morphine -- an essential drug for cancer pain management.¹² In addition, HIV/AIDS is a growing healthcare concern in India, which will require an increased commitment to pain management and palliative care.

Between 1986 and 1998, the consumption of morphine for medical purposes *decreased* by more than 90%, due in part to a plethora of state excise requirements and to a tough anti-narcotics law adopted in 1985. Ironically, this decrease occurred while there were increasing efforts to improve awareness of pain management and palliative care and to educate and train health-care professionals according to the WHO Three-Step Analgesic Ladder. Although these educational efforts have enhanced the willingness of physicians to use opioids for pain relief, the reality is that many hospitals and palliative care programs have great difficulty obtaining a continuous supply of these drugs.

Method:

The Center developed a method to:

- identify the barriers to morphine availability,
- devise a plan for policy and systems change,
- develop collaboration with governmental and non-governmental organizations, and
- implement a plan to simplify regulation of morphine in India, with leadership from the WHODP in Calicut and the Pain Relief and Palliative Care Clinic in Kochi, both in the state of Kerala.

Cooperation:

The Center has collaborated with the Narcotics Commissioner of India, and through him with the Secretary of the Department of Revenue of the Government of India, as well as with the WHO Office-India and the South-East Asia Regional Office of WHO (SEARO). The Center also worked closely with the Indian Association for Palliative Care (IAPC), which appointed a panel of healthcare professionals called the "Committee on Morphine Availability and Control" to review and comment on our work.

Problem Identification:

In 1995 and 1996, members of the Center visited India several times to participate in meetings and workshops with government officials to study the policies that govern the availability and use of opioid analgesics as well as relevant systems for delivery of health-care and distribution of drugs. We gained a thorough understanding of the requirements for obtaining morphine by conducting an evaluation of the India Narcotic Drugs and Psychotropic Substances Act, including the regulations of each state. This review showed that the licensing of morphine for medical purposes was principally a state function rather than a central government function, that the states required as many as five licenses for each medical institution wanting morphine, and that these must often be obtained from more than one branch of state government. The period of validity for some licenses was so short that they would likely expire before all necessary licenses could be obtained.

Action Plan:

The Center prepared an action plan that included (1) development of guidelines for obtaining morphine, (2) preparation of a plan for simplifying regulations over morphine, and (3) sponsorship of workshops on morphine availability with state governments and healthcare professionals. The WHO Cancer and Palliative Care Unit in Geneva had designated a Demonstration Project to make morphine available at the District Hospital level in the state of Madhya Pradesh (in cooperation with the Regional Cancer Center in Gwalior). This was the only part of the action plan that became part of the National Cancer Control Program (NCCP).

In addition, the Center designated the Pain and Palliative Care Society (PPCS), Calicut, in the state of Kerala (see map, Figure 1) to be a WHODP for a source of national expertise and leadership in opioid availability, especially on the use and control of morphine. The PPCS was already a WHODP for providing cost-effective community-based home care for late-stage cancer patients. Until February 2003, the PPCS was directed by Dr. M.R. Rajagopal, who is now Professor and Head of the Department of Anesthesiology and Palliative Care at the Amrita Institute of Medical Sciences and Research, Kochi, state of Kerala.

Outcomes:

Work has begun in 2003 to develop guidelines for procuring, stocking, documenting, and using opioid analgesics safely and effectively. Once prepared, the guidelines will be vetted by the IAPC Committee on Morphine Availability and Control.

During 2003, collaborators in India organized and participated in two workshops on morphine availability, one in Raipur in the newly formed state of Chattisgarh and the other in the state of Delhi. The workshops typically include palliative care professionals, as well as representatives from the Government of India Departments of Revenue and Health, state governments, and WHO-India when possible. The workshop participants recommended that palliative care and morphine availability should become higher priorities of the Health Ministry, the NCCP, and state governments, and that each state should be encouraged, once again, to adopt and implement the simplified morphine licensing rules and make use of a Standard Operating Procedure for approving Recognized Medical Institutions.

Use of specialized workshops reflects the value of bringing together senior officials from the concerned government departments with healthcare professionals to facilitate changes in opioid policy and system administration. Practitioners gain valuable information about the morphine licensing and control system, which will enable them to work more effectively with government in the future. The government officials learn about palliative care and the need for opioids.

Also, in September 2003, the PPCS/WHODP met with governmental officials from the New Delhi Union Territory government, chaired by the Drugs Controller of the state, to discuss formation of standard operating procedures for implementation of the newly amended rules.

Activities and Progress in 2004

During **2004** the Center continued its educational and policy research and development projects in India to improve legal access of the approximate million cancer patients to opioid pain medications, which are almost impossible to obtain in most parts of the country.

In **2004**, the Center assisted Indian colleagues to apply for two grants from the United States Cancer Pain Relief Committee to implement projects in Kochi and Calicut, India. The first grant “Improving patient access to morphine in India – Workshop program,” directed by Dr. M.R. Rajagopal, aimed to ensure adoption and implementation of simplified narcotic regulations by all states and union territories of India, so that opioids, and thereby pain relief, are available to more than a million of the needy with cancer and other incurable illnesses in India who are currently deprived of pain relief. Additionally the project aimed to develop guidelines for procuring, stocking, documenting and using opioids safely and effectively.

The second grant, “Improving patient access to morphine in India – Training program,” directed by Dr. Anilkumar Paleri aimed to train professionals (doctors and nurses) in India so that a system is in place for utilization of the amended narcotic regulations by generating a corps of professionals who no more have opiophobia, and who are trained in the proper use of opioids and other pain relief measures and in combining them with other measures to improve quality of life of patients. These professionals can then become licensed as Recognized Medical Institutions (RMIs) to obtain oral morphine.

In **2004**, the Center assisted Dr. Rajagopal at Amrita institute to obtain a grant from the U.S. National Cancer Institute to conduct an assessment of the current status and needs for palliative care and opioid analgesics by convening experts from all over India. The meeting was held in Hyderabad, in March, **2004**.^{4,13} The aim of this effort was to review progress, identify barriers and develop next steps in India to improve cancer patients' access to opioid pain medications such as morphine. This involved a series of initial planning meetings of the collaborators with cancer and regulatory officials in New Delhi, including former narcotics commissioners and representatives of the departments of revenue and health. These were followed by a meeting with cancer palliative care experts for a day's agenda in Hyderabad, in conjunction with a special opioid availability workshop for state of Andra Pradesh (75 million).¹⁴ The experts discussed their perspectives on the current status of opioid availability for palliative care, regulatory and administrative barriers, and the next steps that can be taken to improve the situation. In addition, we explored how we may continue to collaborate via internet.

C. National Policies, Opioid Availability and Educational Programs

The Center is proactive in monitoring and participating in the global development of cancer pain relief and palliative care according to WHO's three measures of national policy, opioid availability, and educational programs. The following section reports on these activities in several regions and countries.

1. Eastern Europe

A. Romania

Eastern Europe, with its increasing incidence of cancer and AIDS, is particularly at risk for inadequate availability of essential medications including opioid analgesics needed by cancer, AIDS and other patients.

In February 2002, the Center and the European Regional Office of the WHO sponsored a Workshop on Opioid Availability at the Central European University in Budapest, Hungary.¹⁵ The purpose of this workshop was to address the need for opioid analgesics in Eastern Europe according to the WHO recommendations for pain relief in which opioids such as morphine are indispensable.¹² In preparation for this workshop, each of the six participating countries (Bulgaria, Croatia, Hungary, Lithuania, Poland and Romania) shared details of the current situation in their country relating to cancer pain management and opioid availability. Country participants were representatives of cancer, AIDS and narcotic regulation. Speakers included international experts in the fields of cancer pain management, palliative care, and opioid availability.

Guided by the WHO 2000 publication, "Achieving Balance in National Opioids Control Policy,"⁹ the outcome of the workshop was initial country action plans for improving availability of opioid pain medications. Following the workshop, the Center maintained contact with the six countries to offer assistance in the implementation of the action plans. Several countries made progress, including Romania, which established a new Ministry of Health Commission of Specialists in Pain Therapy and Palliative Care. Work in Eastern Europe is ongoing with support from the Open Society Institute and the US Cancer Pain Relief Committee.

In January 2003, the Center began a new initiative with Romania to assist with improving patient access to opioid analgesics. Romania was selected because of strong leadership and positive progress to develop palliative care, and its Ministry of Health had established a Commission of Specialists in Pain Therapy and Palliative Care, whose tasks included modifying national narcotics policies as needed. The Center's offer of technical cooperation was accepted by the leaders of the Romanian palliative care team and the Minister of Health.

Romania has an extremely complicated and burdensome regulatory system for prescribing opioids that makes it difficult and sometimes impossible for patients to receive pain medications like morphine. The oncologist is prevented from prescribing, and the general practitioner is limited to prescribing an unrealistically low maximum dose for limited periods of time according to the advice of a consultant who may not have examined the patient.

In the first half of 2003, the Commission members reviewed a detailed Center analysis of the Romanian laws and regulations. Our analysis was based on the WHO Guidelines for Assessing National Opioids Control Policy (2000). We held regularly scheduled conference calls with our colleagues in Romania to learn about their system, the players, and how best to approach the objective.

In July 2003, several of the Center's staff members visited Romania. The principal aim of this visit was to study the Romanian health and regulatory system for making opioid analgesics, such as morphine, available for the relief of severe pain, and to work with various units of the national government to address this issue.

On 12 July 2003, the Ministry's Commission held a meeting in Braşov at which time the Center's analysis was reviewed, and based on the WHO Guidelines, the Commission reached consensus on 18 recommendations for changing the laws, regulation and administration, and for creating a certified training program for physicians who will become licensed to prescribe opioids (http://www.medsch.wisc.edu/painpolicy/internat/E.Europe/Romania/recs_roMOH.pdf). The report of the Commission was prepared immediately and handed over to Minister of Health, Dr. Mircea Beuran, several days later when we met him in Bucharest.

During the July 2003 trip, we held several group sessions with physicians in oncology and family practice as well as nurses and social workers who provide home care in two locations in Romania; there is clear and strong consensus that the regulatory barriers to patient access to morphine are severe and the most important barrier to pain relief and palliative care in Romania. Under such a system, the growth of palliative care hoped for by the government will be very slow, and limited to the few programs that have the commitment and energy to navigate the regulatory maze for every patient, and indeed every adjustment of drug and dose. Reform of the law and regulations is imperative. We also met with various physicians and directors of regional oncology centers, including the National Oncology Institute in Bucharest.

The July 2003 trip to Romania also included a meeting with staff from the Ministry of Health Pharmaceutical Department to discuss, among other things, their perspective on the proposed changes to the law and regulations; and the Chairman of the Parliament's Senate Health Commission who likewise asked for our assistance to develop the necessary legislation in a timely way.

In a meeting with Minister Beuran on 16 July 2003, he agreed with the principles contained in the Commission's report. He announced that, in response to a request by the European Union related to Romania's possible accession, a new inter-ministerial commission will be appointed to revise the laws relating to cancer and opioids. He requested our assistance to prepare the agenda for the commission and assist it in its work.

Following a change of the Minister in summer 2003, the MOH created a new Commission with the responsibility to continue the efforts to improve patient access to opioid analgesics.

During **2004**, the Center continued work on the project to improve patient access to opioid analgesics in Romania. In February **2004**, the Director and Center staff traveled to Romania for one week to meet with the Ministry of Health (MOH) Pain & Palliative Care Commission and our collaborator, Dr. Daniela Mosoiu. The Center prepared a monograph of consumption statistics to share with the Romanian

colleagues.² The purpose of the trip was to continue the process of drafting a new law, based on the policy evaluation and recommendations that had been previously accomplished in 2003 by the Commission and the PPSG. The Chairman of the Commission, Professor Andrei Achimas, welcomed the PPSG and stated that the commission has two main objectives: (1) to change the opioids law and regulations and (2) to establish a palliative care service structure. Two representatives from the Ministry of Health Pharmaceutical Department were present. They spoke at length, making it clear that they do not want their office to be an impediment to the availability of opioids for pain relief. They claimed that Romania's consumption statistics are low because there is a low demand in the country.

The Center met with members of the MOH Pharmaceutical Department to learn more about the attitude of the regulators and to discuss how the 2003 recommendations of the Commission could be incorporated into the new draft law. We discussed the limitations of the current diagnostic restrictions on prescribing opioid analgesics and encouraged them not to specify any particular diagnostic patient groups because it would restrict the implementation of current and future medical and scientific knowledge.

The Center presented information about changes in prescribing laws in Europe as examples of what other governments have done to reduce regulatory barriers.

The Commission members stated that they envision a new system that authorizes the *doctor* to prescribe opioids, no longer requiring a separate authorization by a specialist for *each patient*. They expressed an interest in providing a 3-day training program for physicians (especially in rural areas) to enable them to receive this new authorization, provided that they can secure the necessary funding. This will be especially important if they eliminate the restrictions in allowable diagnoses for which physicians can prescribe opioids (i.e., no longer limiting outpatient opioid prescriptions to incurable cancer patients.) The Commission sees a need to begin this training before the new law and regulations are passed so that there are trained and authorized physicians who are ready to prescribe. The chair of the Commission expressed a desire to have our continued feedback and assistance in drafting both the law and regulation.

One of the key Commission members and a prominent oncologist, Professor Florinel Badulescu, President of the National Society of Oncology, had invited the director to attend and participate in a national oncology conference on February 25, **2004** in Sinaia, Romania. The Director traveled to Sinaia and gave a well-received presentation on opioid availability titled, "Relief of cancer pain: Regulatory considerations." We felt it was an excellent opportunity to speak with the majority of Romania's oncologists about our work to improve opioid control policy including in Romania.

In May, **2004**, the Director traveled to Brasov, Romania on short notice to attend a meeting of the Palliative Care Commission which was going to review the most recent draft of the Romanian law. The Center staff reviewed the law in its entirety, and, prior to the trip, submitted recommendations for revisions:

- 1) Clarification that the authorization process for individual patients will be discontinued and that pharmacists can dispense (release) drugs according to a valid prescription.
- 2) Addition of language regarding the medical value of drugs and the government's obligation to ensure adequate availability for medical purposes, to be consistent with the Single Convention on Narcotics, 1961.
- 3) Changes to several definitions (related to addiction and physical dependence) in order to improve the clarity of the law and to bring into conformance with international standards.
- 4) Addition of provisions that will require notification of all affected parties of the new law and regulations, and evaluation of their implementation.

A number of the Center's suggestions had been included in the draft and several more were adopted during this commission meeting. During the meeting, the Director recommended the following points for inclusion in the law:

- 1) That the prescription be the only explicit authorization for patients to possess pain medications;
- 2) That pediatric patients should be eligible for pain relief;
- 3) That the government evaluate the revisions according to the principle of 'balance'; and
- 4) That a provision be added to specify that the Ministry of Health will report needed information to the INCB.

The Commission expressed its appreciation for the assistance of the Center in particular that the Director had been able to attend on short notice. They were eager to have the Center's endorsement of the law, feeling that recognition by a WHO Collaborating Center would help in the journey through the Romanian legislative process.

The draft of the new law reached an important stage in late September **2004**. The Center received an English translation of the latest draft, several staff performed an independent review, then, following a discussion, submitted comments to the MOH. We were happy to see the following language added to the General Provisions of the law (as we had recommended earlier):

“Medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and adequate provision must be made to ensure the availability of narcotic drugs for such purposes.”

The next step in the process was to draft the regulations that will implement the new law. The regulations are extremely important, since they will provide the detailed instructions for prescriptions for years to come. In an effort to facilitate an efficient drafting process, the Center sponsored a study visit of the Romanian team to Madison. A 5-member delegation, (comprised of two professors, two physicians, and one pharmacist) visited Madison during the week of November 28 – December 4, **2004**. The team consisted of the following members:

- (1) Dr. Daniela Mosoiu, Medical Director of Hospice Casa Sperantei (our main collaborator in this project);
- (2) Pharmacist Robert Ancuceanu, the Director General of the General Directorate for Pharmaceuticals at the Ministry of Health;
- (3) Professor Florinel Badulescu, President of the National Society of Oncology;
- (4) Dr. Bogdan Grigore, a top drug regulator in the General Directorate for Pharmaceuticals at the Ministry of Health; and
- (5) Professor Ostin Mungiu, Gr. T. Popa University of Medicine and Pharmacy, and President of the Romanian Association for the Study of Pain.

The study visit was successful, with the drafting of the new regulations according to the 2000 WHO guidelines, “Achieving Balance in National Opioids Control Policy.” The group completed those sections that are relevant to prescribing opioid analgesics for pain. According to the draft regulations, a special “authorization” is no longer required to prescribe opioids to outpatients for more than 10 days, there are no longer diagnosis-based limits on patients who are eligible to receive opioid analgesics, and more physicians will be allowed to prescribe opioid analgesics via a plan to provide certification training to any physician interested in prescribing opioid analgesics. Following finalization of the regulations in 2005, there is a plan for their dissemination and physician training.

In addition, the Center arranged a rich interaction with the cancer, hospice and palliative care units at the University of Wisconsin (UW) and in the community. There was a reception at the UW Comprehensive Cancer Center in honor of the delegation (announcement attached), and Dr. Mosoiu and Professor Badulescu delivered a Grand Rounds presentation about cancer and palliative care in Romania at the UW Comprehensive Cancer Center. Dr. James Cleary, Program Leader for Cancer Control and Population Science Program at the UW Comprehensive Cancer Center, hosted site visits for the Romanian colleagues to the UW Comprehensive Cancer Center and Hospice Care, a community-based hospice program in Madison.

B. Ukraine

The Center staff traveled to Kiev, Ukraine in February **2004** to participate in the Open Society Institute (OSI) conference “Palliative Care and HIV/AIDS,” co-sponsored with the International Renaissance Foundation and OSI-Lithuania. The Director presented on the current status of opioid availability in Eastern Europe and how to use the WHO Guidelines, and the Director and Center staff co-chaired a session on opioid availability for the 3 attending countries: Republic of Moldova, Russia and Ukraine. A monograph was prepared with opioid consumption statistics for each country in the region, highlighting the participating countries.¹ Each of the countries used the WHO Guidelines to produce an Action Plan that outlined possible next steps to improving opioid availability. There has been no follow-up due to lack of funding. However, this was a good opportunity to raise awareness in countries that may eventually be ready to make substantial policy change.

2. Middle East

A. Cyprus

In February **2004**, the Center participated in the Middle East Cancer Consortium (MECC) sponsored by the United States National Cancer Institute. The Director presented about improving access to opioid analgesics for pain relief in the Middle East. The Center prepared a monograph of opioid consumption trends for the Middle East, highlighting the participating countries.³ The countries in attendance were: Cyprus, Egypt, Israel, Jordan, Turkey and the Palestinian Authority.

3. Africa

During **2004**, the Center had no activities related to Africa due to a lack of funding.

4. Latin America

The Center was invited to provide materials to attendants of the 2nd Latin American Congress of Palliative Care in Montevideo, Uruguay in late March of **2004**. A brief monograph was prepared in Spanish and contained a table of the milligrams per capita consumption of certain opioids for 2001 of all of the countries participating in the Congress.⁵

In addition to the monograph, the Center prepared a 5-question survey, which was graciously administered to Congress attendants on the Center’s behalf by Dr. Liliana de Lima. The purpose of this survey was to collect information about the prevalence and severity of impediments from the point of view of health professionals in Latin America who care for patients with cancer.

In April of **2004**, Dr. Cheryl Cox-MacPherson, Chair of the Bioethics Department at St George's University in Grenada, visited the Center. The objectives of her visit were to learn more about pain policy in developing countries and how to persuade governments and healthcare authorities to evaluate and implement opioid prescribing policies for pain and palliative care. The Center provided her with numerous resources and also initiated contact for her with representatives from PAHO.

The Director of the Center published an article in an international journal related to end-of-life care on the development and testing of the principle of balance in Latin America. In this article, he highlights the history and progress of opioid availability in Colombia and Mexico.¹⁶

D. Communications

1. Pain Policy Website (see <http://www.medsch.wisc.edu/painpolicy> for homepage)

The Pain & Policy Studies Group established an international section of its website to provide worldwide public access to key resources and information about the WHO and its efforts to improve cancer pain, palliative care, and opioid availability.

The website describes the mission of the Pain & Policy Studies Group/WHO Collaborating Center and its work to address barriers to opioid availability in cooperation with national and international bodies.

Links are provided to many websites that contain information relevant to pain relief and palliative care.

The international section contains extensive information about the international availability and use of opioid analgesics, including: national consumption trends of opioid analgesics; monographs that review the opioid availability situation in various parts of the world; recommendations for how to identify and address regulatory barriers; annotated bibliographies; and the full-text and links to WHO and INCB publications.

Numerous updates have been made to many sections of the website in **2004**, including the sections pertaining to Eastern Europe and Latin America. Updated opioid consumption statistics and trends have been added, as well as new monographs and other resources.

In addition, a United States section contains extensive information about pain policy, including: a model policy for the use of controlled substances for the treatment of pain; a bibliography of published literature; full-text of state statutes, regulations and guidelines; a criteria-based evaluation of federal and state pain-related policies; a resource guide to regulatory issues in pain management; and information about pain management as an alternative to assisted suicide.

Several published articles written by the Pain & Policy Studies Group have been uploaded to the website throughout **2004** and made available in Portable Document Format (PDF).

The Pain & Policy Studies Group has monitored website utilization statistics since July 1997 when the website was established (Figure 2 presents monthly data on all website “hits” and users through the year **2004**). The statistics show that there is a significant and increasing use of the website as a resource for learning about pain policy. The release in August of a document created by the Pain & Policy Studies Group in collaboration with the U.S. Drug Enforcement Administration resulted in an exceptionally large amount of hits for that month. Subsequent events as a result of the release of that document have created further attention, which has resulted in a large number of hits throughout the remainder of the year.

In **2004**, the website received over 1,100,000 “hits” by US and international users, and was accessed by an average of 30 different countries per month, with the most frequent visitors coming from Canada, the United Kingdom, and Australia.

In the future, the Center would like to continue to serve as a pain policy resource for experts and various initiatives around the world aimed at improving the regulatory environment. Dependent upon receiving

adequate resources, the Center would be interested in developing opportunities to put the WHO Guidelines for Achieving Balance into action, specifically by implementing action plans for the 17 countries in Latin America, Eastern Europe and sub-Saharan Africa that have already developed such plans. For example, the Center could offer a fellowship program for champions and regulators to learn about opioid availability and strategies for making improvements in their own countries or regions. The Center also hopes to enhance our website's ability to be used as a training tool for international professionals, which would include the development of a Spanish section of our website. Finally, the Center could conduct in-depth analyses of opioid trends and patterns in the world and participate in INCB and WHO activities related to opioid availability.

2. Publication of *Cancer Pain Release*

The Center has a mission to improve access to professional education resources in pain control and palliative care on a global scale and to actively support the WHO's Cancer Control Program to promote pain relief and palliative care.

To accomplish this mission, the Center publishes *Cancer Pain Release* in print and on the Internet in an effort to:

- 1) inform a global audience about new developments and guidelines on cancer control and palliative care issued by WHO, and by key government and non-governmental organizations;
- 2) give visibility to programs with model and teaching value in all parts of the world;
- 3) recognize achievements of countries and programs according to WHO's outcome measures;
- 4) provide access to recent research in cancer pain and palliative care.

2004 marks the 17th year of publication of *Cancer Pain Release*. Included in every issue are abstracts and commentaries from the literature on pain, symptom control and palliative care; information on the use of analgesic medications in pain relief and palliative care, as well as on training opportunities and professional education in cancer pain and palliative care. The publication discusses obstacles and solutions in pain relief practice and policy.

The first issue of *Cancer Pain Release* in **2004** (Volume 17, Nos. 1-2) reviewed the relevance of geriatrics, oncology and palliative care to the treatment of older patients in pain.

The issue featured an interview with Dr. Janet Abrahm, palliative care physician at the Harvard Medical School, and Dr. Lodovico Balducci, a pioneer in geriatric oncology at the H. Lee Moffitt Cancer Center.

A number of resources to optimize pain assessment and pain management in older patients were highlighted including:

- Selected analgesic drugs for pain relief in older adults with cancer
- Tools and techniques to assess pain and other symptoms in elderly patients
- Online resources to advance palliative care for seniors
- Recent books about aging, pain and palliative care
- New evidence about pain and aging in long-term care settings.

The next issue of *Cancer Pain Release* in **2004** (Volume 17, No. 3) focused on pain management, e-learning and the Internet.

The issue featured an interview with Dr. Alejandro Jadad, Director of the Center for Global eHealth Innovation at the University of Toronto and an expert on the use of information technologies to transform healthcare.

The issue discussed:

- How email, listservs, and web-based decision tools can enhance the practice of pain medicine;
- Benefits and barriers of e-learning and trends in online continuing education;
- Tools and links useful to pain and palliative care clinicians.

The last issue of *Cancer Pain Release* in **2004** (Volume 17, No. 4) reviewed the diagnosis and management of breakthrough/episodic pain in cancer including how to recognize episodic vs persistent pain patterns in neoplastic disease, and how to match drug therapy to the characteristics of the patient's pain.

The issue featured an interview with Dr. Sebastiano Mercadante, Chair of the Working Group on episodic/ breakthrough pain of the European Association for Palliative Care and a member of IASP Task Force on cancer pain.

The issue highlighted online tools and links to patient and professional education resources about breakthrough / episodic pain as well as recently published studies about prevalence, assessment and pharmacologic management.

Distribution:

In **2004**, the printed edition of *Cancer Pain Release* was sent to approximately 50,000 health-care providers in 180 countries. Figures 3 through 8 show the *Cancer Pain Release* distribution points in each country by WHO region. This includes mailings to individuals, libraries and professional organizations. In **2004**, special one-time mailings of *Cancer Pain Release* were made to members of the American Academy of Hospice and Palliative Care Physicians (AAHPM) as well as to members of the American Society of Pain Management Nurses (ASPMN).

In addition, *Cancer Pain Release* is disseminated at professional courses and meetings throughout the world.

A partial list includes:

- The annual meeting of the American Society of Pain Management Nurses (Myrtle Beach, South Carolina, March **2004**);
- The 2nd congress of the Latin American Association of Palliative Care (Montevideo, Uruguay, March **2004**);
- The annual meeting of the American Pain Society (Vancouver, British Columbia, Canada, May **2004**);
- The 15th Annual Meeting of the American Alliance of Cancer Pain Initiatives (New Brunswick, New Jersey, June **2004**);
- Pain physicians in Austria (August **2004**);
- The National Conference on the Care of the Terminally Ill (Montreal, Canada, September **2004**);
- The End-of-Life Nursing Education Consortium (ELNEC) (Madison, Wisconsin, September **2004**); and
- The First National Conference on Pediatric Palliative and Hospice Care, sponsored by NHPCO (Dearborn, Michigan, November **2004**)

In **2004**, the Program reached out to health-care workers globally to alert colleagues who have email about the publication of new issues of *Cancer Pain Release*. In **2004**, we sent out over 5,000 email messages to a worldwide audience of over 2,000 colleagues around the world to alert them about the availability of the electronic edition of *Cancer Pain Release*.

Cancer Pain Release website:

The English edition of *Cancer Pain Release* is available in full-text on our website (<http://www.WHOcancerpain.wisc.edu>).

WHO monographs and guidelines on cancer pain, opioid availability, symptom control and palliative care are available in multiple languages and in print and electronic format. The WHOcancerpain website contains extensive information about how to access these essential publications in all languages (http://www.whocancerpain.wisc.edu/eng/15_3/15_3.html). This section of the website will continue to be updated as new language editions become available.

The Related Links page of the *Cancer Pain Release* website contains 70 cancer, pain, and palliative care-related links in multiple countries and was updated in **2004**.

In **2004**, the website received multiple requests for information about *Cancer Pain Release*, about WHO publications in pain, palliative care and symptom control, and other educational resources. Visitors from as many as 80 countries per month accessed the WHOcancerpain website in **2004**, with a total of 610,000 hits for the year. Figure 9 presents data on website "hits" and users for **2004**.

The top 30 countries accessing the WHOcancerpain website in **2004** were: United States, United Kingdom, Japan, Canada, Australia, Italy, Spain, Argentina, Colombia, Taiwan, Mexico, Brazil, Norway, Netherlands, Denmark, Portugal, Peru, New Zealand, Belgium, Philippines, Germany, Greece, Romania, France, Poland, Sweden, Israel, Saudi Arabia, Lebanon and Singapore.

3. Database of Professional and Patient Education Materials

The Program continues to develop an Internet-accessible annotated database of resource materials for patient and professional education by collecting, categorizing, and summarizing patient and professional education resources and research results. Although the Program does not have funds earmarked specifically for this initiative, all issues of *Cancer Pain Release* include a "Resources" page that lists educational materials relevant to the topic discussed in that issue.

For example, Volume 17, Nos. 1-2, **2004** included online resources for patients and for health professionals to advance palliative care for seniors.

4. Future Goals

The Center's goals are to expand its capabilities to reach out to health-care workers electronically by issuing email alerts, to send regular updates of the educational resources database, to expand the section of new resources in *Cancer Pain Release*, place this information on the *Cancer Pain Release* website (<http://www.WHOcancerpain.wisc.edu>) and improve its capability to provide relevant information to pain and palliative care conferences and workshops worldwide.

II. COLLABORATION WITH WHO

A. Collaboration Between the Center and WHO Headquarters

In September **2004**, the Center participated in a collaborative meeting between the WHO and the INCB “Assuring Availability of Opioid Analgesics for Palliative Care”, which took place in Geneva, Switzerland. The central purpose of the meeting was to develop a draft document outlining a strategy to integrate the availability of opioid pain medications into palliative care for HIV/AIDS, Cancer and other chronic diseases. The organizations participating in the meeting included INCB, WHO representatives from non-communicable diseases, cancer, HIV/AIDS, essential medicines, ethics, and a collaborating center for policy and communications in cancer care, and a representative from the International Association for the Study of Pain. INCB and WHO propose to refine current activities and develop new and as yet un-funded projects in cooperation with partners including the Center and other NGOs such as the International Association for the Study of Pain (IASP).

B. Collaboration Between the Center and WHO Regional and Country Offices

1. PAHO (Pan American Health Organization)

Throughout the year, the Center continued its collaboration with Ms. Liliana De Lima in her capacity as the liaison to PAHO and its Collaborating Centers.

III. COOPERATION WITH THE INTERNATIONAL NARCOTICS CONTROL BOARD

The INCB plays a critically important role in pain management and palliative care throughout the world because it administers the international system that controls the availability of opioid analgesics including the pain medications recommended by WHO as essential for cancer pain relief. Governments look to the Board for guidance in implementing the international narcotic control treaties. Many governments have reported to the INCB that they have excessively restrictive policies. The INCB can assist governments to take a more balanced approach. The Board and its Secretariat have long collaborated with WHO, recognizing that pain is inadequately managed, that opioids are insufficiently available, and that there are barriers which often involve irrational fears of opioids among governments, the public and health-care professionals. For example, in 1995, the Board asked the Center for assistance in surveying all national governments about opioid availability and their efforts, if any, to identify and remove regulatory barriers. The Board used the survey data provided by the Center to conclude that the problem was serious and that few governments had acted to improve the situation. The Board issued a report in which it made a number of recommendations to governments, the United Nations International Drug Control Program, the WHO and other groups such as the International Association for the Study of Pain; these recommendations were aimed squarely at the problems that had been identified by the survey, and urged further collaboration with WHO and governments.

The Secretariat also provides data on the consumption of opioids by each country, which is valuable for monitoring progress and identifying issues. During **2004**, the Center received consumption data on morphine and other opioids and used it to study and report on global and national trends according to its terms of reference.

In May, **2004** the Director participated in a meeting at the INCB in Vienna to review and discuss needs and opportunities in the world.

In **2004**, the INCB commented on its work to address opioid availability, paying particular attention to the need to increase demand for opioids:

“In view of the continued inadequate global consumption of opiates for the treatment of pain, the Board reiterates that it would welcome a further increase in global demand for opiates. The Board encourages Governments to take steps to increase the medical use of opiates in their countries in order to meet their real needs for the treatment of pain.” (p. 24)¹⁷

The report notes the Board’s concern about the low consumption of opioids for pain relief, especially in developing countries:

“The low consumption of opioid analgesics for the treatment of moderate to severe pain, especially in developing countries, continues to be a matter of great concern to the Board. Global consumption of morphine increased significantly throughout the 1990s; in the past 20 years, it rose almost 10-fold, from 3 tons in 1984 to about 28 tons in 2003. However, the bulk of that increase occurred in some, but not all, developed countries, which represent a small part of the world’s population. In 2003, six countries together accounted for 79 per cent of global consumption of morphine. Developing countries, which represent about 80 per cent of the world’s population, accounted for only about 6 per cent of global consumption of morphine.” (p. 25)¹⁷

In addition, the Board encourages all Governments that have not yet done so to:

“...examine the extent to which their health-care systems and laws and regulations permit the use of opioids for medical purposes, to identify possible impediments to such use and to develop plans of action for the development of long-term pain management strategies, with a view to facilitating the supply and availability of narcotic drugs for all appropriate indications.” (p. 33)¹⁷

Finally, the Board recognizes the progress that has been made in Uganda to make opioids more available to palliative care patients:

“While consumption of narcotic drugs for the treatment of pain continues to be extremely low in many countries, particularly countries in Africa and Asia, commendable progress has been achieved in some developing countries. For example, Uganda, which has been active in the field of pain management since the 1990s, has become the first African country to recognize palliative care as an essential clinical service, integrating pain treatment strategies into its health services and providing morphine free of charge to cancer and HIV/AIDS patients. The Government of Uganda has changed its national legislation to make opioid analgesics (especially morphine) more available. Health-care professionals and community workers have received training in the proper use of opioid analgesics in the management of pain. In 2004, the Government of Uganda further modified its policy on narcotics to permit nurses with a certificate in specialized palliative care to prescribe and supply certain opioid analgesic drugs, including morphine.” (p. 32-33)¹⁷

IV. FUNDING NEEDS

The Pain & Policy Studies Group supports the Center in its entirety. The Pain & Policy Studies Group receives no regular financial support from WHO, and relies on a variety of unrestricted grants and contracts to support the Center’s activities, including staff salaries, projects and travel. The Center would welcome additional support for its global policy and communications program.

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FIGURE 1

KERALA



**Pain & Palliative Care
Society
*Link Centres***

FIGURE 2
PPSG Website Statistics
July 1997 – December 2004

■ Hits ■ Users

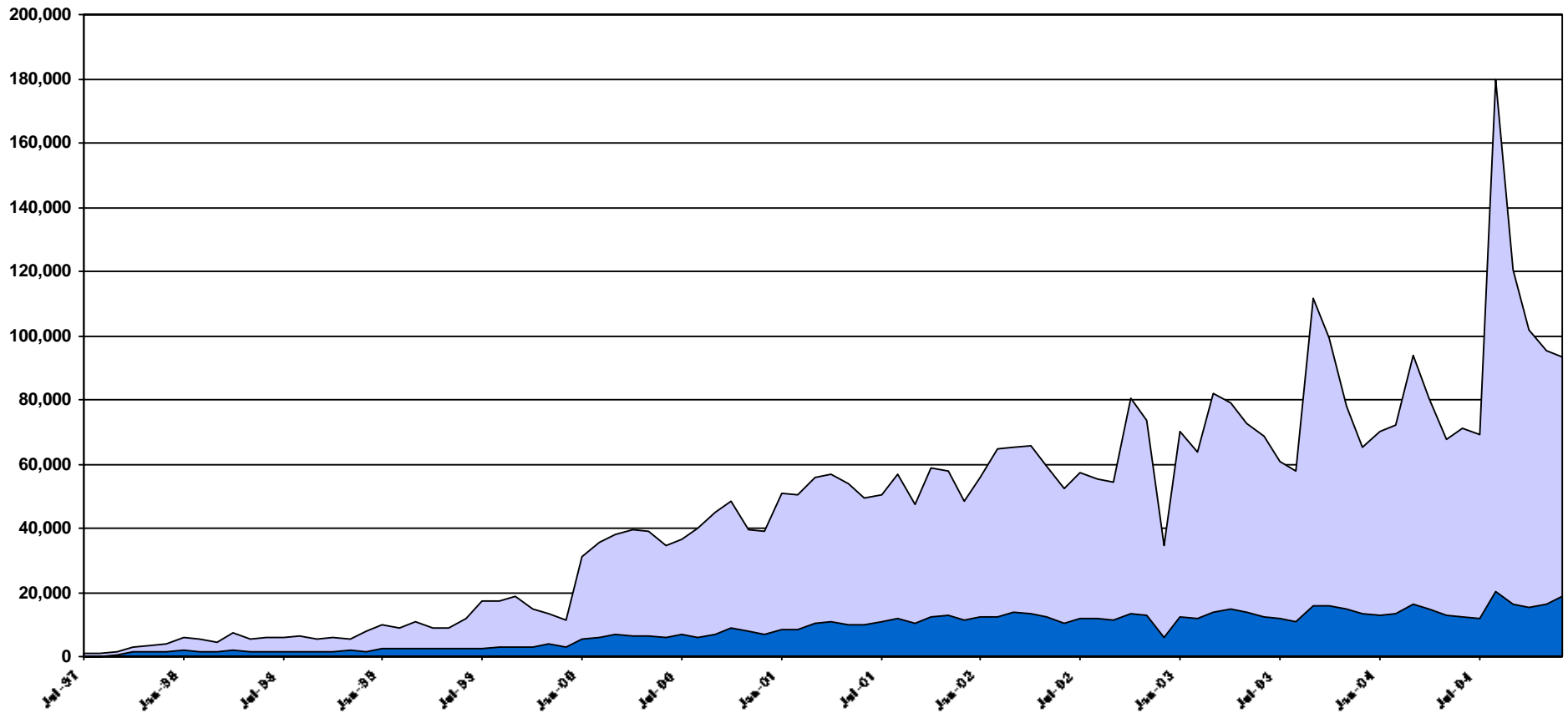
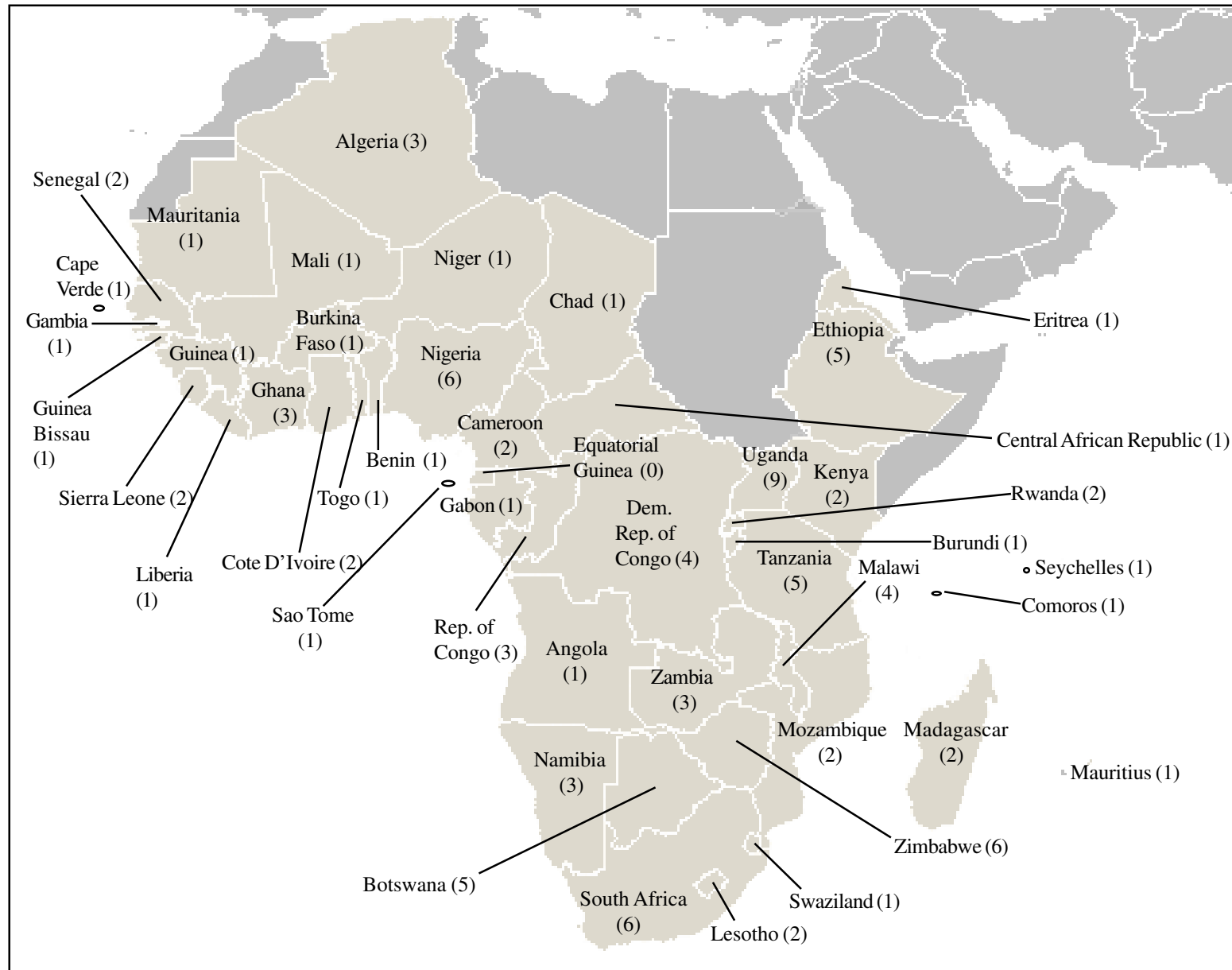


FIGURE 3

WHO Pain & Palliative Care Communication Network in AFRO Region

Cancer Pain Release Distribution Points



Cancer Pain Release is the publication of the WHO global communication program for pain control and palliative care. WHO Collaborating Center for Policy & Communication in Cancer Care, 2005

FIGURE 4

WHO Pain & Palliative Care Communication Network in EMRO Region

Cancer Pain Release Distribution Points

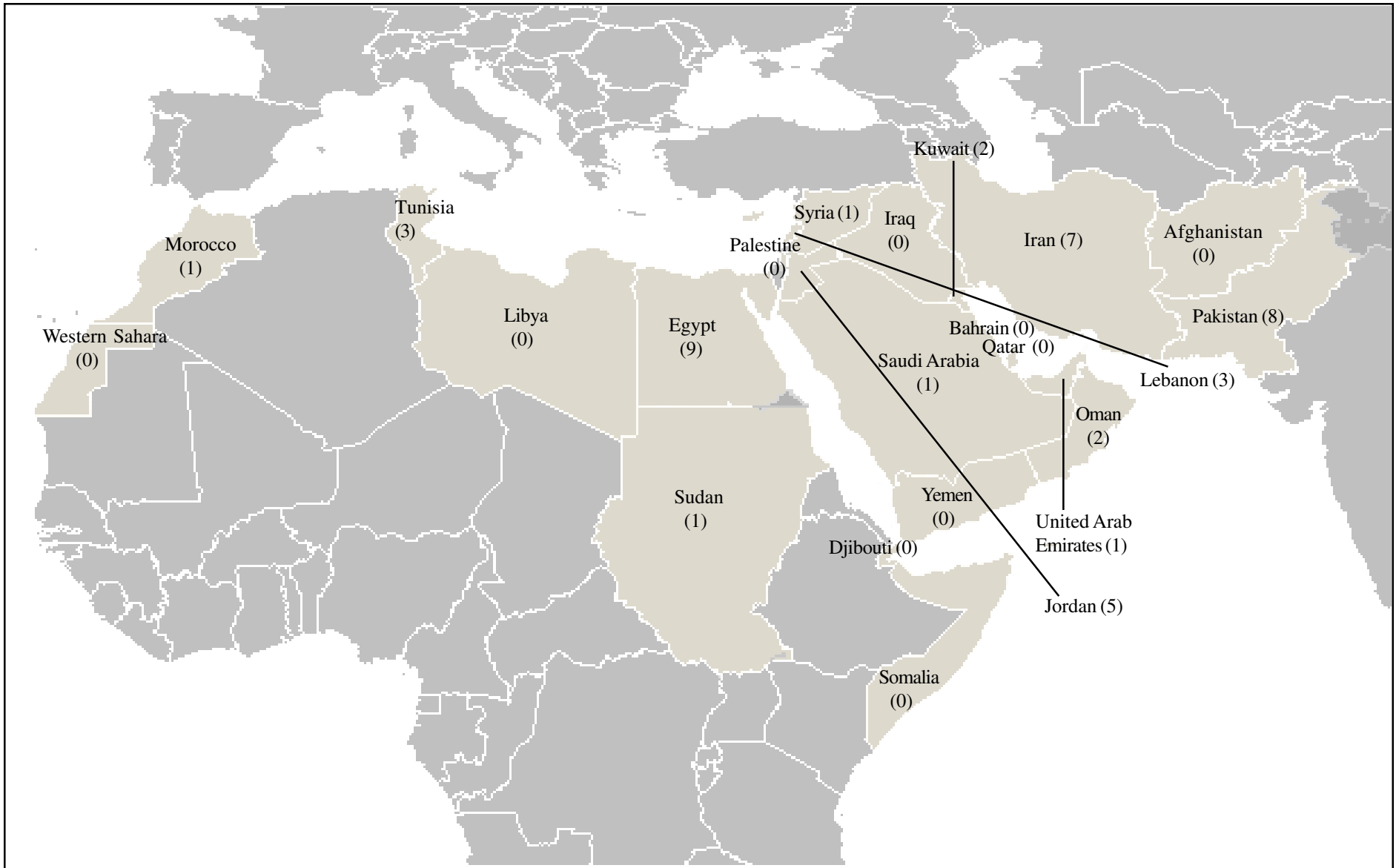


FIGURE 5

WHO Pain & Palliative Care Communication Network in EURO Region

Cancer Pain Release Distribution Points



Cancer Pain Release is the publication of the WHO global communication program for pain control and palliative care.
 WHO Collaborating Center for Policy & Communication in Cancer Care, 2005

FIGURE 6

WHO Pain & Palliative Care Communication Network in PAHO Region

Cancer Pain Release Distribution Points



Cancer Pain Release is the publication of the WHO global communication program for pain control and palliative care.
WHO Collaborating Center for Policy & Communication in Cancer Care, 2005

FIGURE 7

WHO Pain & Palliative Care Communication Network in SEARO region

Cancer Pain Release Distribution Points

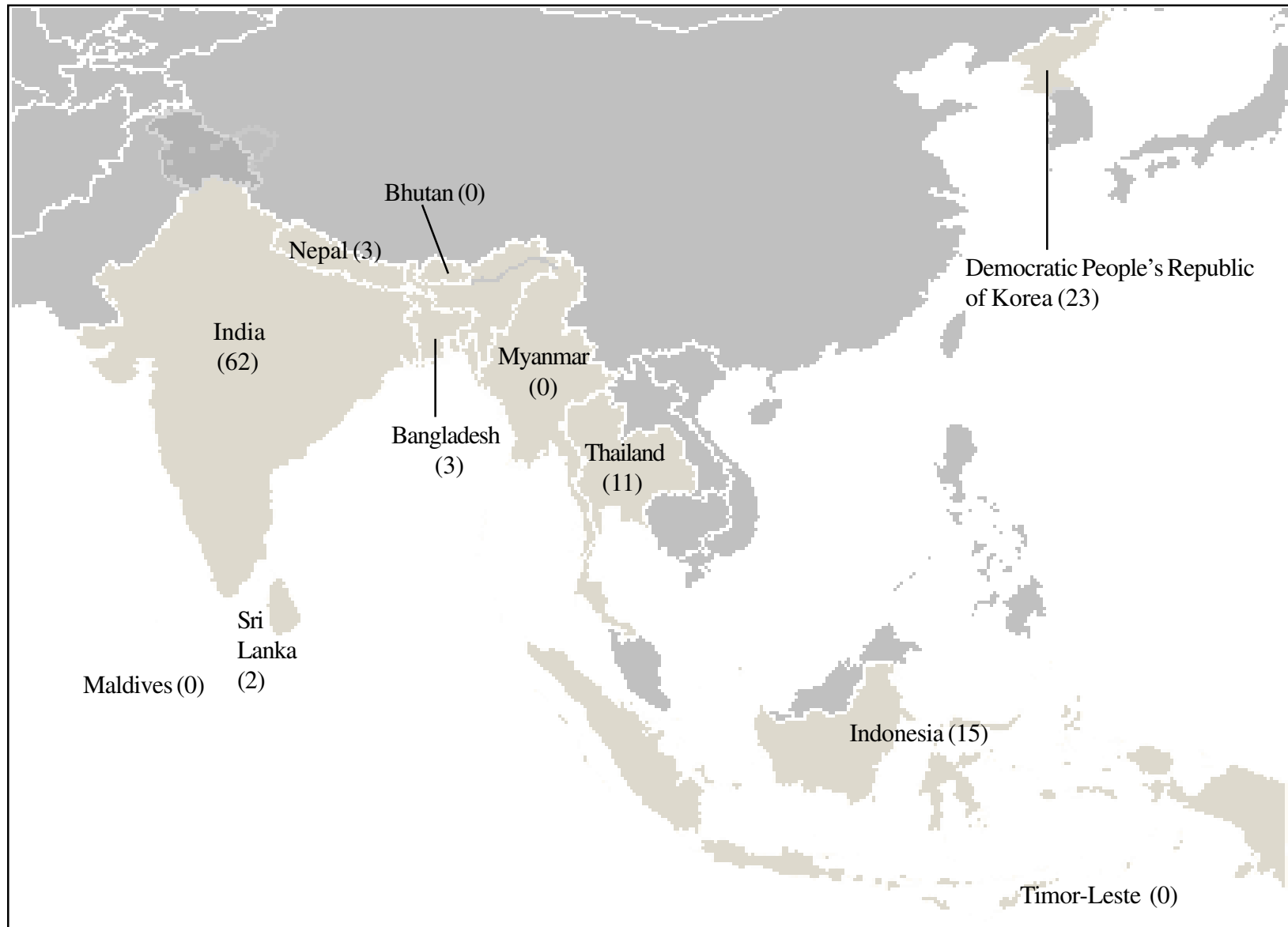


FIGURE 8

WHO Pain & Palliative Care Communication Network in WPRO Region

Cancer Pain Release Distribution Points

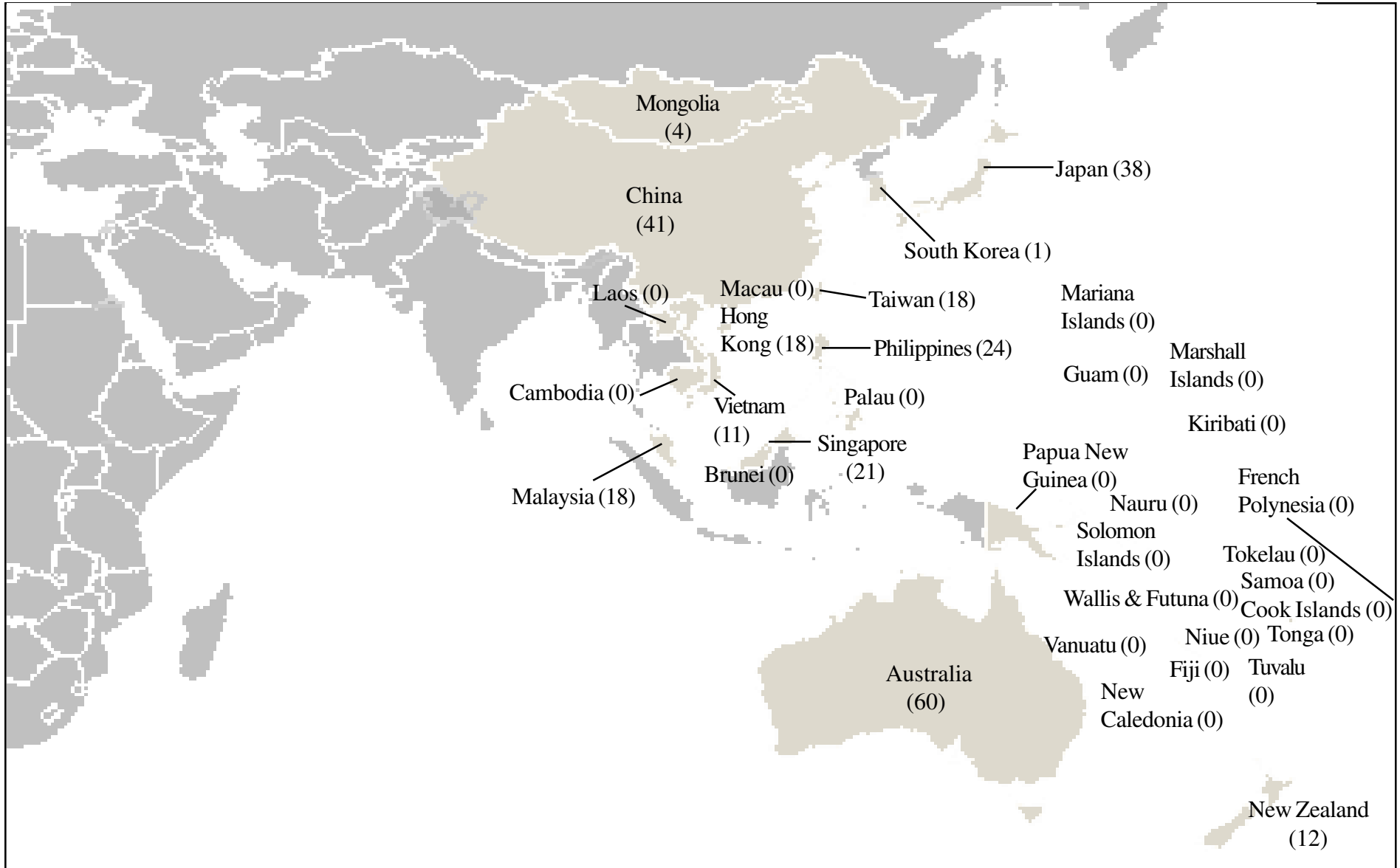


FIGURE 9. *Cancer Pain Release* Website Users, 2004

