

IMPROVING CANCER PAIN RELIEF IN THE WORLD: 1997-1999

A REPORT ON THREE YEARS OF WORK



**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
www.medsch.wisc.edu/painpolicy**

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Executive Summary

This report summarizes three years of work by the World Health Organization Collaborating Center for Policy and Communications in Cancer Care. The Pan American Health Organization designated the Center in 1996. The Center is sponsored by the Pain & Policy Studies Group of the University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin, U.S.A.

From 1997 to 1999, the Center sponsored or participated in numerous proactive efforts to improve policy and enhance communications relating to cancer pain relief and palliative care. The Center collaborated frequently with the World Health Organization, hosting three visits from WHO staff during the three year period, co-sponsoring international and regional meetings and projects with WHO and its regional offices for the Americas and the Western Pacific, and interacting with other WHO Collaborating Centers.

The Center consulted with the International Narcotics Control Board about the international and national opioid availability situation and used INCB opioid consumption data to monitor progress or lack of it. The Center collaborated on a range of projects with 9 national governments, as well as with non-governmental organizations in 21 countries in Asia, Latin America and Europe.

The Center sponsors a WHO Demonstration Project in India to show how countries can make opioids available for the relief of pain in dying patients living at home, without diversion and abuse.

The Center accomplishes its policy work through a program of research, development, demonstration, monitoring and evaluation. 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 primarily through the publication of *Cancer Pain Release*, a quarterly WHO newsletter which provides health professionals, policy makers and regulators throughout the world with updates on issues and developments in the field. *Cancer Pain Release* has a world-wide circulation of 100,000 in 128 countries and is inserted in a number of international and national journals. In addition, the Center actively disseminates information throughout the world about how to obtain WHO publications.

Every year, the Center also participates in a number of 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 two websites and promotes worldwide access to better understanding of the principles that should guide national narcotics control policy.

Each year the Pain & Policy Studies Group supports the Center's program from the unrestricted funds it raises. The PPSG does not have a consistent source of funding for its efforts to improve cancer pain relief policy and communications in the world.

THE CENTER AND ITS WHO TERMS OF REFERENCE

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Terms of reference for the Collaborating Center:

To develop methods to identify impediments to the availability of opioid analgesics; compare national approaches to opioid analgesic regulation; develop procedures to monitor the medical use and diversion of opioids before and after national cancer pain and palliative care policies are implemented.

Develop WHO Demonstration Projects to make opioids available for cancer pain relief while minimizing diversion.

To monitor development of national cancer pain relief and palliative care programs according to WHO's three measures of national policy, opioid availability and educational programs.

To maintain a communication network for the WHO Cancer Pain Relief and Palliative Care Program, including publication of a WHO/PAHO, Global Cancer Care newsletter to be distributed throughout the world, and a computer-based telecommunication system giving professionals the opportunity to access and share information.

Establish a comprehensive database of resources available to educate cancer patients about pain control and palliative care and configure the information so that it can be easily retrievable.

Madison, Wisconsin, USA
August 1, 2000



David E. Joranson
Director

*A report of Center activities prior to 1997 is available at <http://www.medsch.wisc.edu/painpolicy>.

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I. WORK PERFORMED IN RELATION TO THE TERMS OF REFERENCE

A. Develop Methods and Procedures

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

Data collection:

Barriers Survey: The Center developed a survey (called the “Barriers to opioid availability test” [BOAT]). It is a 26-item questionnaire that is used to evaluate health-care professionals’ beliefs about the use and availability of opioids such as morphine for cancer pain relief and the impediments to the use of such drugs in their country. Two publications have reported results using the BOAT.^{1,2} The Center has also developed a one-page survey that is to be completed by participants at pain and palliative care conferences as a first step in identifying unmet needs for opioid analgesics in a country.³

INCB Data: The Center has requested complete data on the medical consumption of morphine and other principal opioids for all countries that report to the International Narcotics Control Board (INCB). These data allow the Center to monitor consumption trends and progress to improve pain relief, to identify problem areas, and to educate health-care professionals and government officials from any country about their past and present use of opioids. The Center’s analysis of these data has been reported in numerous publications, monographs, and conference presentations and posters. The Center maintains an international database of opioid consumption data and makes these data available to numerous governmental and non-governmental organizations and individuals who are working to improve pain relief.

Education:

The Center has organized or participated in meetings and educational programs that bring together representatives from government, cancer control, palliative care, and education within several countries, including India, Japan, Mexico, Italy, and the United States. Such efforts, and continued networking of professionals representing government and medicine, will help create a national infrastructure that can work to ensure opioid availability and enhance the priority of a country’s pain management and palliative care in the health care system. The Center has developed presentations which explain the principles of opioid availability and how they are derived from international sources of authority such as the international narcotics control treaties, WHO and the INCB. These presentations can be helpful in understanding the policy framework for ensuring opioid availability. The Center has produced a number of monographs for distribution at national and international meetings to provide participants with information about trends and key resources (See Bibliography).

Policy Evaluation:

The Center evaluates policy at both the national and international levels. This work is based on a Central Principle of “Balance,” which states that government policies to prevent misuse of controlled substances should not interfere with their use for the relief of pain.^{4,5} From this Central Principle, the Center has developed 1) a set of evaluation criteria against which US federal and state policies have been examined to identify provisions that may enhance or impede pain management,⁵ and 2) WHO Self-Assessment Guidelines to encourage national governments to achieve better pain management by identifying and overcoming regulatory barriers to opioid availability.⁶ The WHO Self-Assessment Guidelines can be used to develop balanced national (including states, provinces or territories) drug control policies. This

document, which will be published by WHO in 2000, 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 about ensuring the availability 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 policy problems.

Collaboration:

The Center is committed to a collaborative process. The Center’s collaborative policy evaluation efforts have been conducted in India, Malaysia, Mexico and Colombia in cooperation with governmental, narcotic regulatory, cancer control and health-care professionals. The aim of this work is to establish the relationships that are necessary to evaluate and improve policies governing opioid availability. Examples of collaborative efforts appear throughout this report.

Communications:

The Center is improving its capacity to disseminate its work to a wide international audience through publications, conference participation, networking on the Internet, websites and frequent email contact with collaborators.

B. Establish WHO Demonstration Projects

The following section reports on the Center’s activities in India in collaboration with the WHO Demonstration Project in Calicut, an Indian non-governmental organization, and a number of agencies within the Central Government of India as well as several state governments.

India:

Objective:

To improve availability and access to opioid analgesics for patients with cancer and pain.

Situation:

Cancer pain relief and palliative care are relatively new developments in India. There have been major efforts to improve awareness and to educate and train health professionals according to the WHO analgesic ladder, including many sponsored by WHO and by the Oxford WHO Collaborating Center. These efforts have led to decreased reluctance to use opioids for pain relief; however, relief from cancer pain cannot be achieved unless drugs like morphine are actually available. It has been impossible for many hospitals and palliative care programs to obtain morphine, the only “third step” opioid recommended by WHO which is legally obtainable in the country (although pethidine [meperidine, in some countries] is available, it too is in short supply and in any event is not recommended for chronic pain). Ironically, regional cancer centers have received morphine donated by the WHO but many do not use it. Consumption of morphine for medical purposes decreased by more than 90% from 1986 to 1996 due in part to adoption of a new national anti-narcotics law in 1985. This decreasing availability of medical morphine in India is particularly ironic because India produces much of the opium and narcotic raw material which is exported to manufacture morphine and other opioid analgesics for the rest of the world.

Method:

The Center developed a method to identify the reasons for morphine unavailability, devised a plan for policy and systems change, developed collaboration with government and non-governmental organizations, and is helping to implement an action plan to simplify regulation of morphine.

Cooperation:

The Center developed cooperation 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 Asian Regional Office (SEARO) of WHO. The Center worked closely with the Indian Association for Palliative Care (IAPC), which appointed a Committee on Morphine Availability and Control to work with the Center.

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 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 periods 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 included development of guidelines for obtaining morphine, preparation of a plan for simplifying regulations over morphine, and sponsorship of workshops on morphine availability with state governments. The WHO Cancer and Palliative Care Unit in Geneva had also designated a Demonstration Project to make morphine available at 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 which was included in the National Cancer Control Program (NCCP). In addition, the Center designated a Demonstration Project to be a source of national expertise and leadership in opioid availability (at the Pain and Palliative Care Society [PPCS], Calicut, in the state of Kerala) on the use and control of morphine. PPCS was already a WHO Demonstration Project for providing cost-effective community-based home care for late-stage cancer patients. PPCS is directed by Dr. M.R. Rajagopal, professor of anesthesiology at the Medical College, Calicut. The WHO Demonstration Project is collecting data on the use and control of morphine as an integral part of providing sustainable low cost community-based pain relief to patients who live in their own homes. PPCS is also working with the State of Kerala to simplify the morphine rules, because the main barrier to availability of cancer pain relief is restrictive state narcotic regulations..

Outcomes:

In **1996**, in cooperation with the IAPC and the PPCS, the Center drafted “Guidelines: how to obtain morphine for cancer pain relief and palliative care in India.”⁷ These guidelines, which also explained the India narcotics law requirements for obtaining morphine, were published in the *Indian Journal of Palliative Care* in **1998**.

In **1997**, in cooperation with the IAPC and the PPCS, the Center drafted a proposal to simplify India's regulations for licensing of opioid analgesics and submitted it (February 9, **1997**) to the Revenue Secretary and to the Narcotics Commissioner of India. This proposal was published in the *Indian Journal of Palliative Care* in **1998**.⁸ In **1997**, the Government of India accepted the proposal in principle and in **1998**, assigned a government lawyer, Mr. M.C. Mehanathan, to prepare a model state regulation. The Revenue Secretary sent the model regulation, which was narrowed to pertain only to morphine, the only strong opioid analgesic recommended and available at that time, to all state and territorial governments with instructions to adopt a new state regulation to simplify licensing and access to morphine for pain relief.

In **1998**, the Center and PPCS sponsored a workshop in Trivandrum (capital of Kerala) to encourage formal consideration of the regulation. The workshop convened key individuals from the primary state government and non-government systems involved in morphine licensing and production as well as from cancer control, palliative care and medical education. Following the workshop, the Kerala Health Secretary, Mr. Vijayachandran, appointed a task force of the Drugs Controller and Excise Commissioner to undertake the necessary formalities to simplify the Kerala narcotic rules. The simplified rule was adopted in November **1999**. The new rule reduced the number of licenses needed by medical institutions from five to two, simplified the licensing procedure, linked licensing to physician training, and increased the period of validity for the required licenses.

In **1998**, at the request of the Center, the WHO Programme on Cancer Control amended⁹ the terms of reference for the WHO Demonstration Project at the PPCS, Calicut. This letter reaffirmed the previous term of reference (to demonstrate how to provide pain and palliative care coverage for cancer patients using home care and a community-based approach), and added a new term of reference: to demonstrate how to ensure that opioids are continuously available to patients in the community while preventing misuse and diversion. In **1998** and **1999**, the Center provided technical assistance to this Demonstration Project, as well as a stipend to cover costs of the additional work involved. An article reporting the results is being prepared.

In **1999**, in cooperation with state governments and the Department of Revenue (Narcotics Division), the Center and the IAPC sponsored three more workshops to stimulate state governments to consider adopting the new model regulation to simplify the morphine regulatory system. The Center obtained a grant for workshop costs from the United States Cancer Pain Relief Committee, a private non-profit educational, scientific and charitable organization. These workshops were organized by the IAPC (Dr. Rajagopal) in cooperation with the Center and palliative care physicians in the states. They were held in Cuttack on October 8, **1999** for the state of Orissa; in Mumbai on October 4, **1999** for the state of Maharashtra; and in Bangalore on February 26, **1999** for the state of Karnataka. The Center was an active participant and co-chaired the sessions with the senior government official. Each workshop also benefitted from the invaluable assistance of M.C. Mehanathan, Deputy Legal Counsel of the Division of Narcotic Drugs, whose time and expenses for all three workshops was contributed by the Department of Revenue. As a result of these workshops, steps are being taken in these states to adopt the rule to simplify morphine licensing. The states that adopted the simplified rule by the end of **1999** are: Sikkim (**1998**), Kerala (**1999**), Madhya Pradesh (**1999**), Orissa (**1999**) and Tripura (**1999**).

In **1999**, following a meeting with the national Health Secretary, the Center, PPCS, and the IAPC prepared and submitted a proposal to the Ministry of Health, Government of India, for the next steps to simplify state regulations, organize workshops, train professionals, and monitor and develop the opioid distribution system. The Center also recommended to the Health Secretary that a representative of the

PPCS be considered for membership on the committee to revise the national cancer control plan. Finally, the Center and IAPC requested the WHO Office-India and SEARO to provide support for the workshop initiative.

Each year, in **1997**, **1998** and **1999**, the Center presented a progress report to the IAPC membership on the steps being taken to improve availability of morphine. The Center participated in a panel discussion on opioid availability with the Drugs Controller from Mumbai in the state of Maharashtra during the **1998** Conference. In **1999**, the Center sponsored the participation of Professor June L. Dahl from the WHO Demonstration Project in Wisconsin, USA; she gave a presentation to the IAPC conference on the principles and actions necessary to make pain relief an institutional priority. In **1997**, **1998**, and **1999**, the Center met with the IAPC Committee on Morphine Availability and Control during the IAPC annual conference to review progress and decide on the next steps to improve availability of opioids in the country.

Evaluation:

The Demonstration Project is excelling at fulfilling its terms of reference by 1) providing cost-effective home care to more than a thousand terminally ill patients annually, and 2) showing how morphine can be used by trained health professionals with the assistance of volunteers to relieve pain in numerous patients who live at home, without misuse or diversion. The PPCS has published several articles on the program in international journals, and several more are planned in cooperation with the Center.

Progress is being made to implement the action plan to improve opioid availability and cancer pain relief. The Revenue Department has endorsed simplification of the rules and is supporting the workshops, through the contribution of the travel time and expenses, expertise and leadership of key officials; the workshops are resulting in changing the rules and improving communication.

The workshop experience made it apparent that bringing together senior officials from the concerned government departments with doctors could facilitate changes in opioid policy and system administration. Doctors gained valuable information about the morphine licensing and control system, which will enable them to work more effectively with government in the future. The workshop also made it clear that a revised regulation in itself was not enough: the state government needed to develop a procedure which heretofore had not existed, to identify the medical institutions in the state that need morphine, to establish minimum requirements for such institutions, and to train doctors about use of morphine. Indeed, a new drug distribution infrastructure for pain relief and palliative care is being created. Reports of progress are being made to IAPC meetings and in the PPCS and IAPC newsletter.

This progress, in contrast with past years of frustration, is producing enthusiasm and hope that Indian palliative care workers may finally be able to have morphine to relieve pain in the one million cancer patients with unrelieved pain.

The effort to make morphine available from the District Hospitals to patients in the community in the state of Madhya Pradesh was not successful for systemic reasons: a) cancer pain relief, while a part of the National Cancer Control Program, is not a priority for the delivery of primary health care, which is a responsibility of state government, and b) the unresolved complexity of morphine regulation in that state. It should be noted that all the physicians and administrators we worked with were very cooperative.

In the past, there were efforts to address morphine unavailability by distributing it free to regional cancer centers. While of laudable intent, this approach had a low potential for sustainable benefit to patients

because 1) it was limited only to regional cancer centers, not all of which provided pain relief, 2) it postponed the time when institutions must make their own arrangements to obtain a continuous supply, and 3) it appears that some of the morphine provided to regional centers was not used before the expiration date and had to be disposed, adding to the frustration that already existed among programs that wanted morphine and could not obtain it.

Over the last ten years, substantial resources have been devoted to many training seminars on pain relief and palliative care throughout India.

The consumption of morphine (an indicator of progress to improve cancer pain relief used by WHO) decreased through 1996. However, with the simplification of the state rules and the expansion of palliative care especially in Kerala, the Center fully expects that this trend will finally reverse and begin to increase in **1998** or **1999** (however, there will be a delay in verifying any increase due to the lag in statistical reporting and also questions about the accuracy of reporting).

It should be noted that many training sessions which have been sponsored in India by various groups are traditional lecture format and are better described as awareness sessions, and as such have little potential to change practice and therefore improve pain relief and palliative care that is so urgently needed.

Financial support for this project in India is likely to decrease because current funds from the US Cancer Pain Relief Committee will be expended in 2000. More support will be necessary to sustain the momentum. This support should come from the Government of India Health Department, SEARO, WHO-India, and other sources. Resources are needed for workshops to simplify the opioid rules in all the states, to develop infrastructure for licensing of medical institutions, determine annual estimates of need for opioids, produce and distribute opioids, and train health professionals.

C. Monitor National Policies, Opioid Availability and Educational Programs

The Center takes a proactive role in monitoring and participating in the 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.

LATIN AMERICAN REGION

Regional meeting: San Juan, Puerto Rico (December 1997):

The Center participated in a regional drug control meeting sponsored by the Interamerican Commission on Drug Abuse (CICAD) and made a presentation on "The availability of narcotic drugs for medical use." A monograph was also distributed.¹⁴

Regional meeting: Concepción, Chile (March 1998):

Since 1994, the Center has been an active participant in the Latin American conferences on palliative care which are held every other year in a different Latin American country (Florianopolis, Brazil 1994; Santo Domingo, Dominican Republic, 1996; Concepción, Chile, **1998**).

Situation:

In most Latin American countries, opioid analgesics such as morphine are not readily available for cancer pain relief. The reasons have been discussed in a number of publications (referenced on the Pain &

Policy Studies Group website), and include low prescription demand, cost, lack of palliative care infrastructure, exaggerated fears of opioids, lack of training in pain relief, and excessive drug regulation.

Method:

To study and address the situation, the Center has participated since 1994 in a number of meetings and conferences, provided presentations for health care providers and drug regulators, promoted the development of cooperation between health care professionals and drug regulators, used surveys to collect information about the barriers to opioid availability and has begun to evaluate regulatory barriers as well as national policies. The Center cooperated with Dr. Eduardo Bruera, WHO Focal Point for Latin America, and with Ms. Liliana De Lima, a Fellow and then Consultant with the Center and subsequently liaison to Collaborating Centers for the Pan American Health Organization (PAHO), to prepare for the regional meeting in Concepción. The Center assisted in the assessment of progress and future directions to improve palliative care education and opioid availability in the region according to WHO guidelines. The Center developed links with Latin American clinicians and drug regulators to identify participants for a panel discussion on opioid availability. The Center designed and administered a survey of Latin American health professionals to assess educational needs in terms of knowledge/attitudes toward cancer pain management.

Outcomes:

In March **1998**, the Center participated in the 5th Latin American Congress of Palliative Care in Concepción, Chile with approximately 200 physicians, nurses, psychologists, regulators and others from 16 Latin American countries. The Center produced two posters in Spanish: “Opioid analgesics in Latin America: trends, legal requirements, recommendations;”¹⁵ and “Panorama del cuidado paliativo en Latinoamérica: datos de 1994, 1996 y 1998.”¹⁶ The Center also produced a monograph in Spanish about opioid consumption trends in the region, and the status of regulatory requirements in selected countries.¹⁷ A report from the previous Latin American congress in the Dominican Republic was published in the *Journal of Pain and Symptom Management* in **1997**.¹⁸

Evaluation:

Regional meetings in Latin America are an opportunity to assist participants to identify and remove regulatory barriers to opioid availability, to provide information about differing regulatory requirements in the region, to promote communication between key palliative care professionals and their governments, and to gather data on the clinical practice of palliative care in the region.

There is a need for additional resources to make it possible to 1) carefully evaluate progress to improve availability of opioids in the region, on a country by country basis, 2) convene interested parties and develop action plans, 3) monitor progress and 4) provide technical assistance.

The potential for progress in pain relief and palliative care in Latin America improved when the PAHO announced in **1998** an initiative to improve palliative care in the region, including opioid availability. In the same year, the Center proposed that PAHO sponsor, in cooperation with the Center, one or more workshops to convene representatives from countries (representing drug regulation, cancer control, and palliative care) to assess opioid availability in each country, review the expectations of international treaties and government bodies to ensure not only control but also availability of opioids, identify barriers and develop action plans.

In **1999**, the Center asked the US Cancer Pain Relief Committee to arrange funding for PAHO to organize a workshop on opioid availability for the Andean countries. The new WHO Guidelines for

Assessment or National Narcotic Control Policy for Balance prepared by the Center for WHO will provide a valuable framework for the workshop discussions.

Mexico:

Objective:

To collaborate with health professionals and the national government to assist in identifying barriers to, and improving the availability of, opioid analgesics to cancer patients in Mexico.

Situation:

Opioid analgesics such as morphine are limited to a few institutions due to lack of demand and also due to regulatory impediments such as limited availability of the special government prescription form, as well as regulatory limitations on the amount and duration of opioids such as morphine that can be prescribed.

Method:

The Center approached the situation in several ways in order to develop cooperation and to systematically identify the barriers as well as the need for changes in national opioid policies.

Cooperation:

The Center was pleased to participate in several professional conferences of the National Cancer Institute (NCI) and the Mexican Association for the Study of Pain in **1997**. The Center was invited to present “Papel del gobierno: asegurar la disponibilidad de opiáceos y prevención de abuse.”¹⁹ The purpose was to present information about the principles of international opioid regulation and to become acquainted with the situation and the key people and organizations.

Exchange of information:

The Center sponsored a week-long meeting in Madison to which was invited Dra. Araceli Garcia, in charge of narcotic control for the government of Mexico; Dra. Silvia Allende, Chief of Pain and Palliative Care from the NCI in Mexico City; and her nursing colleague, Mrs. Helen Carvell. The purpose was to study the regulatory issues in providing opioids, the international requirements for doing so, to better understand the Mexico policies, and to develop a basis for future communication and collaboration.

Data Collection and Policy Analysis:

The Center, with the assistance of Ms. De Lima, had earlier prepared a monograph, “Preliminary analysis of the Mexican legislation in relation to the international principles of opioid availability.”²⁰ This policy analysis identified a number of barriers to availability of opioids in Mexico. The preliminary analysis was provided to our colleagues in Mexico. In **1997**, Ms. De Lima visited Mexico City to give a presentation on opioid availability in Latin America and Mexico and worked with health care professionals and government representatives on ways to improve opioid availability. In addition, the Center’s “Barriers to opioid availability” (BOAT) questionnaire was used by Dra. Silvia Allende to survey health professionals about their perceptions of what factors contribute to inadequate use of opioids in relieving cancer pain.

Outcomes:

The Center’s efforts to develop cooperation with the government were accepted and several meetings were held with the chief regulator as well as the director of the NCI. These meetings, the week of information exchange in Madison, and the preliminary analysis of Mexican narcotics laws subsequently

contributed to meetings of health professionals and government representatives that were organized in Mexico to formulate revisions to the regulatory requirements for opioid prescriptions. In addition, Dra. Silvia Allende published an article about barriers to pain management in Mexico, including the results of the BOAT survey.¹

Evaluation:

The Center's efforts were well received and served as one important contribution to the establishment of a more positive regulatory environment for medical use of opioids: the government adopted significant changes to the narcotic prescribing requirements, including replacement of the triplicate prescription form with a bar-coded single copy prescription form. The prescription form is to be available to physicians at the capitals of each state rather than only the federal capital, and the restrictions on amount and duration of prescribing were changed. These changes in policy are historic and should be seen as an important development for pain relief in Mexico.

The Center also became aware of strong interests to expand information and training about pain relief and palliative care in Mexico. We explored the possibility of assisting in the establishment of a cooperative newsletter venture with the Autonomous University of Mexico (UNAM), a "role model" training program adapted to Mexican needs and also providing a basic library ("biblioteca básica") of resource materials to selected libraries of medical, nursing and pharmacy schools. However, resources were not available, and these ideas will have to wait until financial support is available.

Argentina:

Objective:

To work with health professionals in Argentina to bring greater visibility to pain control and palliative care and enlist support of policy makers in government.

Method:

The Center has a 10-year history of supporting Argentinian clinicians in cancer pain control and palliative care through articles in *Cancer Pain Release*, technical assistance with publications, assistance with educational initiatives, participation in conferences, and encouragement of changes in national policy regarding cancer pain relief and palliative care.

Outcomes:

The Center provided information about the goals of Programa Argentino to the readership of *Cancer Pain Release* in May 1989, October 1990, December 1992, March 1996 and **1999**. In 1991, the Center assisted the Programa Argentino in the publication of the *Manual de San Nicolas*, a monograph describing how to select and train volunteers to assist terminally ill patients in hospital and at home, using minimal resources.

In October **1997**, the Center participated as faculty in the first Jornadas del Programa Argentino de Cuidados Paliativos in Buenos Aires, and observed the status of pain control and palliative care programs in three cities: Rosario (province of Santa Fe), Cordoba (province of Cordoba) and Buenos Aires. Dr. Colleau gave two lectures in Spanish on "WHO strategies to implement cancer pain control and palliative care," and "Can professional education change professional practice?"

In May **1999**, the Center participated as faculty in the 6th International Course on Pain Control, Fundación Dolor, Buenos Aires. Dr. Colleau gave three lectures in Spanish 1) "Strategies to overcome obstacles to cancer pain relief" ("Estrategias para superar los obstaculos al alivio del dolor en cáncer");

2) “Availability of opioids for pain relief: relevant points for Latin America” (“Disponibilidad de opioides para el alivio del dolor: puntos relevantes a Latinoamérica”); 3) “Education about the control of cancer pain and palliative care: courses for professionals, patients and families” (“La educación sobre el control del dolor de cáncer y el cuidado paliativo: recursos para profesionales, pacientes y familiares”).

The Center produced two monographs in Spanish for dissemination. One dealt with issues in opioid availability relevant to Latin America;²¹ the other presented the resources available for professional education in pain control and palliative care.²² In addition relevant Spanish editions of *Cancer Pain Release* were distributed to participants.

Evaluation:

WHO has recommended adoption of national policies to support development of cancer pain relief and palliative care. To achieve this goal, the Center recommended that Argentinian clinicians develop a consensus about and broad support for a national policy. However, the cost of analgesics prevents access to care for many cancer patients and remains a major barrier to adequate pain relief.

The Center encouraged clinicians in the Provinces of Cordoba, Santa Fe and Buenos Aires to work with drug regulators and health authorities to change the regulations to be consistent with modern medical practice and the needs of patients so that the duration of prescription of morphine as well as the amount of dosage allowed are not limited. The establishment of a national commission to harmonize and modernize opioid prescribing policy should be considered.

The Center should continue to provide coverage in *Cancer Pain Release* of Argentinian and other Latin American initiatives in national policy, drug availability and education; however, additional resources will be necessary to produce and disseminate *Cancer Pain Release* in Spanish.

In Buenos Aires, Rosario and Cordoba, the experienced program leaders who are already in place should consider developing distance learning courses in pain control and palliative care as a cost-effective method to reach health professionals in remote, rural areas of the country.

Colombia:

Previously, Ms. De Lima had assisted the Center in preparation of a “Preliminary analysis of Colombian legislation in relation to the international principles of opioid availability.”²³ In 1997, Ms. De Lima gave a presentation on opioid availability in Colombia and participated in discussions with representatives of the national chapter of the International Association for the Study of Pain and government representatives on how to improve ways to make opioids more available in the country.

On October 10, 1997, Ms. De Lima attended the 2nd International Forum on Palliative Care in Bogota, where she presented a talk on the “Status of opioid availability in Latin America” (“Disponibilidad de opioides en Latinoamérica: definiendo estrategias”).

The Center also gave ongoing technical support to the chief narcotic regulator to assist the government in providing opioids for those suffering from cancer pain in Colombia.

Costa Rica:

On September 25, 1997, Ms. De Lima visited Costa Rica upon the invitation of the Ministry of Health to aid in the evaluation of the opioid distribution system and the identification of barriers within that system.

Venezuela:

The Center worked with the chief narcotics regulator for Venezuela, to assist in making opioids available and the identification of impediments.

In July 1996, Ms. De Lima visited Caracas at the invitation of the PAHO to attend a meeting on the Andean Medications Program. Ms. De Lima gave a presentation on the WHO recommendations for the use of opioids in cancer pain treatment (“Uso de medicamentos opioides en el manejo del dolor por cáncer: recomendaciones de la organización mundial de la salud”).

An article resulting from the meeting was published in the PAHO Journal, “El empleo de analgésicos opiáceos para el alivio del dolor por cáncer.”²⁴

In November **1998**, Ms. De Lima presented a talk in Caracas entitled, “Barriers to opioid utilization in Latin America” (“Barreras en la utilización de opioides en Latinoamérica”).

EUROPEAN REGION

Regional Meeting: European Association for Palliative Care (EAPC):

The Center is an active member of the EAPC, an important non-governmental organization dedicated to promoting cancer pain relief and palliative care in Europe. The Center participated in palliative care conferences of the EAPC in Cyprus (**1997**), London (**1997**), Madrid (**1998**) and Geneva (**1999**). The Center provided several presentations as well as monographs concerning barriers to cancer pain relief and methods to improve opioid availability. In Cyprus, the Center hosted a luncheon meeting of EAPC representatives to discuss ways of improving policy relating to availability of opioid analgesics in Europe, including through European Commission reform of narcotic control policy. The Center presented on “Opioid availability: diagnosis and treatment of regulatory barriers”²⁵ and provided technical assistance about methods to improve availability of opioids and has provided follow-up consultation to health professionals who are working on the problem. In London, the Center presented on “Reflections on addiction to morphine”²⁶ and met with representatives of the EAPC to explore needs and opportunities for evaluating and improving national opioid policies. In Geneva, the Center provided professional education materials in English, Spanish and French, including information about all WHO publications relevant to cancer pain, opioid availability, symptom control and palliative care.

Eastern Europe:

The Center participated in the Open Society Institute’s (OSI) conference “Palliative Care in Eastern Europe” in September **1999**. The two-day conference was held in Geneva, Switzerland, and was attended by 50 health care professionals representing 24 Eastern European countries. The Center presented a lecture titled “Drug availability and regulations” about morphine consumption in Eastern Europe, how opioid distribution systems work, and how to overcome regulatory barriers. A follow-up session occurred on the second day of the conference, during which the Center responded to questions about opioid availability and the use of opioids. All participants received several publications from the Center.²⁷⁻³⁰

The Center anticipates further involvement in Eastern Europe in conjunction with OSI. There has been preliminary discussion of a regional meeting on opioid availability in 2000.

Bulgaria:

At the invitation of Dr. Jan Stjernsward, the Center participated in a national strategy session to address cancer pain relief, palliative care and opioid availability in Sofia, Bulgaria in November of **1997**. The Center met with representatives of the government of Bulgaria to explore the opioid availability situation and to discuss a possible action plan. The government was eager to move forward with an action plan, but resources were not available for such a plan and the Center lacked resources to support follow up activities. The Center has maintained contact with several dedicated physicians in Bulgaria in an effort to encourage their work to improve opioid availability.

Germany:

The Center takes note of the successful efforts of German colleagues, in particular those of Professor Michael Zenz of Bochum, Germany, to reform restrictive German prescription requirements for opioids. The Center was invited to participate in a special seminar on morphine and pain sponsored by Professor Zenz in **1997** in Einbeck to commemorate the isolation of morphine in 1805 by the German pharmacist, Serturmer. The Center's presentation was titled "To what extent has the WHO analgesic ladder influenced morphine consumption?"³¹ This was also an excellent opportunity to consult with Professor Zenz, and also with current and past representatives of the WHO cancer and palliative care program, its Collaborating Centers and other experts. In **1998**, Professor Zenz co-authored a guide to the morphine prescribing requirements in European countries, *Morphinverschreibung in Europa*,³² in which appeared the monograph prepared by the Center for the meeting in Einbeck. In addition, the Center (Dr. Colleau) serves on the Editorial Board of the only German peer-reviewed journal dealing with pain control, *Der Schmerz*.

France:

The Center has a 10-year history of collaboration on pain research and opioid policy with French clinicians, government officials and legislators resulting in several publications. In **1997**, the first multicenter study of pain prevalence and severity in AIDS patients in France, conducted in collaboration with the Center was published in the *British Medical Journal*.³³ In April **1998**, the Center was invited to give the keynote address at the Congress of the French Society of Palliative Care. Dr. Colleau lectured in French on "The WHO Cancer Control Program: the place of pain and palliative care."

Italy:

Discussions with colleagues from EAPC based in Milan led to their interest in obtaining a better understanding of the apparent inconsistencies in the Italian morphine consumption statistics reported to the INCB, and also in changing the particularly complex prescription requirements for opioids in the class of morphine. As a result of several meetings, including with Professor Vittorio Ventafridda, the Director of the WHO Collaborating Center in Milan, in **1998** the Center began a collaborative relationship with Dr. Claudio Blengini, a general practitioner who is a member of the Special Committees of the Italian Ministry of Health on Pain and Palliative Care. The Center has provided Dr. Blengini with information and consultation to strengthen his ability to provide expert guidance to a national commission that is studying how to reform the laws of Italy with respect to the prescribing of opioids. Dr. Blengini published an article, making use of information obtained from the Center.³⁴ Dr. Blengini is monitoring the government's consideration of possible changes and provides updates to the Center.

Poland:

In May **1998**, the Center participated in the 9th Annual Palliative Medicine Advanced Course in Puszczkowo, Poland. This meeting was organized by the Palliative Care Department of the University

of Medical Sciences in Poznan, Poland and the Sir Michael Sobell House in Oxford, UK. It was sponsored by the Polish Ministry of Health and the Stefan Batory Foundation of Warsaw. Dr. Colleau gave a workshop on “Education in cancer pain control and palliative care: a guide to resources.” The workshop drew upon the recommendations of the World Health Organization and of the Institute of Medicine in the USA. to consider the key elements of professional competence in caring for patients at the end of life. A review of existing resources such as medical and nursing curricula, evidence-based clinical practice guidelines, consensus documents, and training programs was presented and discussed so that clinicians in Eastern Europe can take advantage of resources developed by others.

Two issues of *Cancer Pain Release* on the education of physicians and nurses in pain control and palliative care were made available to participants. Two monographs were developed by the Center for this meeting. “Availability of opioid analgesics for cancer pain relief”³⁵ included sections on key publications of the United Nations on opioid availability, consumption data and trends, recommendations for action, primary resources and additional references. The second monograph, “Education in cancer pain control and palliative care: a guide to resources”³⁶ contained an overview of professional education materials.

An outcome of this meeting was the Poznan Declaration of **1998** which gave the countries represented an opportunity to outline their goals in palliative care and outline steps to achieve them.³⁷

Yugoslavia:

During the **1999** International Association for the Study of Pain (IASP) conference, the Center was approached by a doctor from Belgrade who indicated that the recent war had cost them their capability to produce morphine for cancer patients. The Center agreed to make an effort to assist them and has initiated a number of contacts in **1999** to explore the options.

ASIAN REGION

Regional Meeting: Japanese International Corporation for Welfare Services (JICWELS):

Each year since 1993, including in **1997**, **1998** and **1999**, the Center has participated in the annual seminars on drug control policy and administration sponsored by the Japanese government for national drug regulators from Asian countries. The WHO (Mr. Tokuo Yoshida) sponsored Mr. Joranson as a Temporary Advisor for participation in the JICWELS seminars in Tokyo. The Center provided a presentation on the obligation of government, and the policy and methods for ensuring availability of opioids for medical and scientific purposes. Monographs prepared for these seminars are available on the Center’s website: (www.medsch.wisc.edu/painpolicy).³⁸⁻⁴⁰

Indonesia:

The Center conducted a study visit for WHO to Indonesia in July of **1997** to work with colleagues from the Ministry of Health National Cancer Control Committee, Dr. Soetomo Hospital (a WHO Demonstration Project for the development of palliative care and opioid availability), Dharmais Cancer Hospital, the Indonesian Cancer Society, the Indonesian Cancer Foundation, and the Pembinaan Kesejahteraan Keluarga (a national Indonesian women’s health and community advocacy organization). The National Committee, the Demonstration Project and the Center have been collaborating on ways to expand the use of opioids in hospitals and also for home care.

During this visit, the Center participated in several educational seminars for health professionals and site visits. The Center arranged for the visits of Dr. Judith Paice and Dr. James Cleary to assist with presentations on pain physiology, opioid pharmacology, pain assessment and pain management.

Following this visit, the Center recommended a plan of action to the Indonesia National Cancer Control Committee. The reply from Indonesia was favorable, indicating that the proposal would be submitted to the government. However, the proposed program has not been implemented due to a lack of funds and a crisis in the country.

AFRICAN REGION

The Center has not conducted any activity within the African region but has provided technical assistance, information and consultation to a variety of health care providers and regulators in the African region concerning opioid availability and policy. In addition, the Center published an editorial about opioid availability in Africa.⁴¹

NORTH AMERICAN REGION

The Center is actively involved in policy and communications activities that are relevant to the Center's terms of reference in the USA. These activities are briefly summarized:

Regional Meeting: American Association for Cancer Education:

In **1998**, the Center participated in the annual meeting of the American Association for Cancer Education (Portland, Oregon). Dr. Colleau presented a lecture on "A global network for cancer pain education." The objective was to explain how the Center supports the WHO's Program on Cancer Control by providing a global communications mechanism for physicians, nurses, pharmacists, researchers, government officials and other health professionals about cancer pain relief and palliative care. Strategies to broaden the global communication network were discussed in order to keep pain control an international priority in cancer education, as recommended by WHO.

Use and Abuse of Opioid Analgesics:

In **1998**, the Center began an analysis of trends in the medical use and abuse of opioid analgesics used to treat severe pain, which was then published in the *Journal of the American Medical Association*.⁴² The study used two national databases to measure both the medical consumption and the abuse of opioid analgesics. Results demonstrated that while there was a substantial increase in the medical use of opioid analgesics between 1990 and 1996, their abuse over this same time period has remained low and stable.

The Center uses opioid consumption data to study consumption trends for the entire US and for individual states, similar to our use of such data to monitor consumption trends in the world and in individual countries. These data contribute to the Center's ability to educate health care professionals and regulators about drug availability and pain relief issues.

Analysis of State Pain Policies:

In **1999**, the Center conducted an analysis of laws and regulations in a sample of 17 states to identify provisions that may enhance or impede pain management. The analysis is based on a Central Principle of "Balance," which states that government policies to prevent misuse of controlled substances should not interfere with their use for the relief of pain. From the Central Principle, the authors derived a set of

criteria against which the policies were examined. Examples of how states may improve their policy and regulatory climate are provided. The intended audience for the document is individuals or groups working to improve end of life care, associations of professionals, cancer pain and palliative care initiatives, state professional licensing boards and state legislatures. The resulting document, *Achieving balance in state pain policy: a guide to evaluation*,⁴ was published in July 1999 and can be found on the Center's website. The publication already has been used as a tool for policy change. The Center is completing its analyses on the remaining US states and territories, as well as federal policy, and a final report will be published in 2000.

Collaboration with Regulatory Agencies: Prescription Monitoring Programs:

In 1998, the Center initiated a collaborative project with the US Drug Enforcement Administration, the Alliance of States with Prescription Monitoring Programs, and the Regulatory Affairs Committee of the American Pain Society to exchange perspectives on the relation of government prescription monitoring programs (PMPs) and the prescribing of opioid analgesics for pain management. A working group met in Madison, Wisconsin from July 20-21, and again in Charleston, South Carolina on October 29. The objective was to achieve agreement on the importance of adequate pain management and the need to achieve a balance between drug regulation and the medical use of opioids for pain management. A jointly-authored article is in preparation that outlines the need to disseminate accurate information about PMPs, how they work, what they are intended to achieve and that they are not intended to interfere in medical practice. The project is intended to increase the communication between pain management and regulatory bodies. Since 1998, there have been numerous occasions where the pain management and regulatory communities have invited each other to speak at their conferences.

Federation of State Medical Boards of the US:

The Center has collaborated on three projects with the national association of all state agencies that license and discipline physicians, the Federation of State Medical Boards of the United States (FSMB).

Survey of Medical Board Members:

We surveyed state medical board members in 1997 and compared these results to responses obtained from the same survey we conducted in 1991. There were positive and statistically significant differences over time in respondents' attitudes about the legality of prescribing opioid analgesics for various patient scenarios. Medical board members in 1997 were more accepting of the legality of extended opioid prescribing for patients with chronic cancer and non-cancer pain than they were in 1991. A manuscript has been accepted for publication in the *Journal of the American Medical Association*.⁴³

Medical Board Workshops:

We sponsored five regional workshops for state medical board members with the FSMB in 1998, bringing the total to 11. A pre-/post-test survey as well as a six-month follow-up survey was completed by each workshop participant. Statistically significant improvements in knowledge and attitudes were observed for items related to the pharmacology of opioids, their addiction potential, correct characteristics of addiction, and the legality of the prolonged use of opioids for pain management. The results of the survey suggested that these workshops were effective in promoting lasting changes in knowledge and attitudes of state medical board members regarding both clinical and policy issues. An article has been accepted for publication in the *Journal of Pain and Symptom Management*.⁴⁴

Development of Model Guidelines:

In early 1998, the Center conducted a content evaluation of pain management policies that had been adopted by state medical boards. The Center used the results of this evaluation to assist the FSMB to

draft *Model guidelines for the use of controlled substances for the treatment of pain*⁴⁵ which the FSMB adopted in May **1998** and distributed to each state medical board. The purpose of the *Model guidelines* is to promote consistency in state medical policy, to encourage better pain management, and to dispel physicians' fear of discipline by state regulatory agencies. A manuscript which describes a decade of change in state medical board policy has been submitted for publication in the *Journal of the American Medical Association*.⁴³ Representatives of the FSMB have presented the information at national pain conferences and have encouraged the adoption of the Model Guidelines by state medical boards.

D. Communications Network

PUBLISH A QUARTERLY NEWSLETTER

Objectives:

- 1) To publish a quarterly newsletter on pain control and palliative care which supports the WHO global communications program to improve cancer pain control and both palliative and supportive care.
- 2) To disseminate the newsletter throughout the world to physicians, nurses, pharmacists, researchers, government officials and other health professionals interested in cancer pain relief and palliative care.

Methods:

The Center publishes *Cancer Pain Release* in print and on the Internet three to four times a year to:

- 1) inform about new developments and guidelines on cancer control and palliative care issued by WHO, key government and non-governmental organizations;
- 2) give visibility to programs with 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 current research in cancer pain and palliative care.

Outcomes:

Cancer Pain Release, started 12 years ago, has grown from a tabloid to an eight-page newsletter with a worldwide circulation to over 100,000 professionals in 128 countries. Each issue presents abstracts and commentaries from the literature on pain, symptom control and palliative care; information on WHO guidelines on the use of analgesic medications in pain relief and palliative care; information about training opportunities and professional education in cancer pain and palliative care, as well as health policy and issues regarding the availability of opioid analgesics. The publication documents the progress of pain relief initiatives worldwide, as well as obstacles and solutions in pain relief practice and policy.

Several issues have presented a comprehensive overview of topical issues, including nursing education, physician education, home care, pain in children with cancer, fear of addiction, and breakthrough pain. These issues are particularly valuable as references for clinicians who lack access to literature searching capability. Appendix C is an index of all articles published in **1997, 1998** and **1999**.

Key Distribution:

Single copies of *Cancer Pain Release* are mailed to a growing number of clinicians and health care organizations. Multiple copies are also mailed in bulk for distribution at many professional meetings. Table 1 shows the distribution of *Cancer Pain Release* by language and by country. Tables 2, 3 and 4 show the distribution by profession of the audience for the English, Spanish and French language editions.

In **1997, 1998 and 1999**, the *Journal of Pain and Symptom Management* continued to insert *Cancer Pain Release* (English) in its issues, thereby expanding *Cancer Pain Release* distribution to about 3,000 health professionals in the US and abroad. Starting in **1999**, *Cancer Pain Release* (Spanish) was inserted in *Medicina Paliativa*, the peer-reviewed journal of the Spanish Association for Palliative Care (SECPAL).

Electronic dissemination of *Cancer Pain Release*:

The Center initiated an Internet site for *Cancer Pain Release* in 1996 to allow users access to a Table of Contents of all published issues, as well as full text version of articles and selected excerpts of others (www.medsch.wisc.edu/WHOCancerPain). This activity has not been updated since **1997** due to lack of funding. However, the website continues to receive requests for information about *Cancer Pain Release* and about WHO publications in pain, palliative care and symptom control.

INTERNET ACCESS TO KEY RESOURCE INFORMATION

The Pain & Policy Studies Group established an international section of its website (www.medsch.wisc.edu/painpolicy) to provide worldwide public access to key resource information about the WHO and its efforts to improve cancer pain, palliative care and opioid availability.

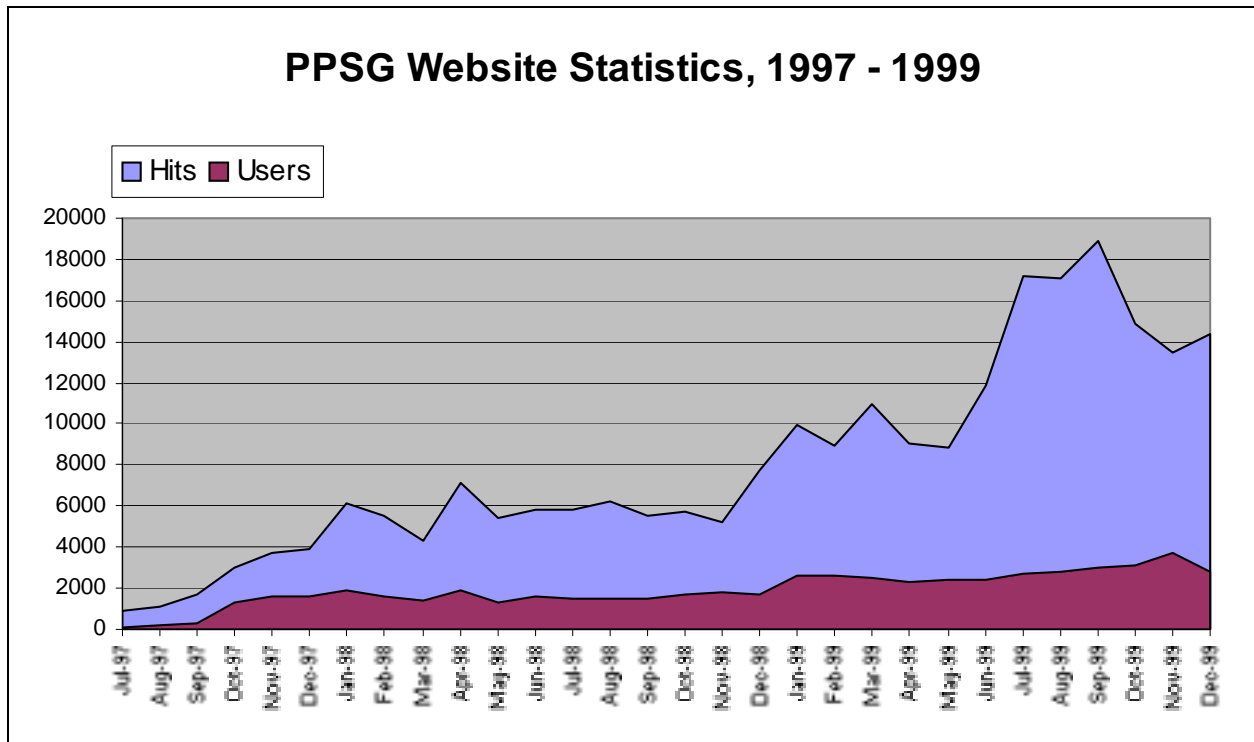
The website describes the mission of the Pain & Policy Studies Group/WHO Collaborating Center and its work to address barriers to opioid availability in cooperation with national and international bodies.

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

A United States section contains extensive information about pain policy, including: model guidelines 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.

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 of WHO and INCB publications.

The Pain & Policy Studies Group has monitored website utilization statistics since July **1997** when it was established. The statistics show that there is a significant and increasing use of the website as a resource for learning about pain policy. The website is visited by users from around the world, with the most frequent visitors coming from Latin America, Asia, Australia and Europe. The following graph presents monthly data on all website “hits” and users through **1999**.



E. Database of Professional and Patient Education Materials

Objectives: To develop an Internet-accessible annotated database of resource materials in English, French, and Spanish for patient and professional education.

Methods:

The Center periodically collects, categorizes, assesses and summarizes patient and professional education resources and research studies.

Outcomes:

Although the Center does not have funds dedicated to this objective, the following has been accomplished.

In **1998**, the Center produced and presented a monograph, “Education in cancer pain control and palliative care: a guide to resources,”³⁶ for participants in the 8th Annual Palliative Medicine Advanced Course in Poland. The monograph summarizes medical and nursing curricula, evidence-based clinical practice guidelines, consensus documents, and training programs.

In **1999**, a monograph, “Educación en el alivio del dolor y el cuidado paliativo: una guía de los recursos,”²² was produced and presented to participants in the 6th International Course on Pain Control of the Fundación Dolor in Argentina. The monograph summarizes a wide variety of Spanish-language resources that are available for professional education in pain control and palliative care.

Several issues of *Cancer Pain Release* include a “Resources” page which lists English, French or Spanish-language educational materials that are relevant to the topic discussed in that issue.

The Center designed and produced a colorful poster depicting the covers of relevant WHO and INCB publications along with information about what languages are available as well as ordering information. Many copies of the poster were distributed at the 9th World Congress on Pain.⁴⁶ Spanish and English language versions of the WHO poster will be prepared for distribution in the future.

Future goals:

When complete, the database will provide access to patient and professional education resources which will be evaluated according to criteria to be developed with the assistance of experts.

In addition, the Center would like to issue regular updates of the educational resources database, expand the section of new resources in *Cancer Pain Release*, place this information on the Center’s website, and expand capability to provide the information to conferences and workshops.

II. RELATIONSHIP BETWEEN THE CENTER AND WHO

A. Collaboration between the Center and WHO Headquarters

Visit by WHO:

On January 30, **1998**, the Center hosted Dr. Karol Sikora, Director of the WHO Cancer Unit which had been transferred from Geneva to the International Agency for Cancer Research in Lyon, France. The Center discussed with Dr. Sikora how the burden of cancer is shifting to developing countries, and how difficult it is for most cancer patients in the world to obtain opioid analgesics due to restrictive regulation of narcotic drugs. The Center described the methods it uses to improve the situation. The briefing also addressed the communications terms of reference of the Center, the publication of *Cancer Pain Release* and the need for financial support.

Visit by WHO:

On November 29, **1999**, the Center was pleased to have a visit from Ambassador Tom Loftus, WHO Special Advisor to the Director-General. As with Dr. Sikora, the Center discussed the shifting burden of cancer to developing countries, the difficulty of obtaining opioid analgesics, the methods the Center is developing to improve the situation, the communications terms of reference of the Center, the publication of *Cancer Pain Release*, and the need for support. Following the meeting, Ambassador Loftus provided the Director-General of WHO with a summary of his visit.

New WHO Guidelines on Opioid Availability:

In **1998**, the Center had proposed to WHO the development of guidelines which could be used by governments and health care professionals to evaluate national narcotics control policy for “Balance,” i.e., to determine if a government’s national narcotics control law, regulations and administration have the capability of ensuring the availability of opioid analgesics as is required of governments which are parties to the Single Convention on Narcotic Drugs, 1961. Following submission of a proposal to Mr. Tokuo Yoshida of the WHO unit for Medicines, Essential Drugs and Medicines Policy, a contract was issued to the Center to develop the guidelines. The Center staff produced a draft, and Mr. Yoshida, in cooperation with the Center, sponsored an expert working group to review the guidelines. The working

group met in Madison, Wisconsin, USA. in November, 1999; it was comprised of the co-sponsors, Mr. Yoshida, Mr. Joranson (chairperson), and representatives from countries and organizations, including Mrs. Carmen Selva (International Narcotics Control Board, Vienna), Ms. Liliana De Lima (Pan American Health Organization), Mr. Romesh Bhattacharji (Narcotics Commissioner of India), Ms. Gu Wei-ping (State Drug Administration, China), Dr. Claudio Blengini (Pain specialist, Italy), Dr. Philip Emafo (International Narcotics Control Board, Nigeria), and Dr. Alan Nixon (Palliative care specialist, Saudi Arabia). The working group provided useful comments. The draft, *Achieving balance in national drug control policy: guidelines for self-assessment*, was revised and submitted to the WHO for publication in 2000.

B. Collaboration between the Center and WHO Regional Offices

Pan American Health Organization (PAHO), Washington D.C.:

The Center was invited to participate in a PAHO planning workshop for cancer pain relief and palliative care in 1996. This initiative has resulted in plans for Latin American demonstration projects, and in 1998 the Center proposed a workshop with governments and representatives of cancer control and palliative care on opioid availability in Latin America. The Center was instrumental in locating funds to help cover the costs of the workshop which will be held in 2000 or 2001.

Western Pacific Regional Office (WPRO), Manila:

In 1998, the Center participated as faculty in a meeting in Saitama, Japan sponsored by the WHO Western Pacific Regional Office, Manila. The title of the meeting was “Workshop on Strengthening Health Professional Education in Cancer Pain Relief and Development of Palliative Care Expertise.” Mr. Joranson presented a lecture on the need to ensure availability of opioid analgesics for cancer pain relief and recommended that palliative care curricula always include material on opioid availability. A monograph was presented on “Availability of opioid analgesics for cancer pain relief”⁴⁷ in the region. Experts who participated represented Cambodia, China, Fiji, Korea, Laos, Malaysia, Mongolia, Papua New Guinea, Philippines, Singapore, and Vietnam. A report, *Workshop on strengthening health professional education in cancer pain relief and development of palliative care expertise*,⁴⁸ is available from WPRO .

In 1999, the WHO Western Pacific Regional Office requested Mr. Joranson to serve for approximately one month as a Temporary Consultant to conduct, in cooperation with the Ministry of Health in Malaysia, a review of opioid availability for cancer pain relief according to the following terms of reference:

- 1) to review relevant legislation and drug regulation on analgesics, particularly for medical use of patients with cancer and other terminal illnesses;
- 2) to evaluate supply and distribution of the pain relief drug, and use of the pain relief drug for cancer patients, particularly morphine in health delivery system (hospitals, polyclinics, and communities);
- 3) to conduct a workshop on the development of cancer pain relief for drug regulators and hospital administrators;
- 4) to advise the government on improvement of pain relief drug availability for use by cancer patients and development of cancer pain relief programme by improving drug regulations and administration.

Prior to the visit, Mr. Joranson was briefed at WPRO offices in Manila by Dr. Han Tieru and WPRO staff, and was debriefed upon return. Mr. Joranson made a presentation about opioid availability to a national conference on palliative care in Penang,⁴⁹ and participated in a workshop on opioid availability for palliative care specially organized by the Ministry of Health to obtain information and perspective about

opioid regulation and availability in Malaysia.⁵⁰ Copies of *Cancer Pain Release* and other resource materials were distributed to conference and workshop participants. A mission report is available.⁵¹

The WPRO has expressed interest in sponsoring a workshop on opioid availability for Asian countries, similar to the one that is being sponsored by PAHO for Latin American countries. The Center strongly endorses this activity but lacks the funds.

South East Asian Regional Office, New Delhi:

The Center informed SEARO of its activities in India with the government, IAPC and the PPCS, and the WHO Demonstration Project. The Center visited the office in **1997, 1998** and **1999**, requesting on various occasions that the regional office support the workshops that the Center and IAPC were organizing as well as the work of the PPCS including training of doctors about how to use morphine. At the request of SEARO, a proposal was submitted but it was not funded.⁵²

III. RELATIONSHIP BETWEEN THE CENTER AND OTHER WHO COLLABORATING CENTERS

Cooperation at an international pain meeting:

WHO Collaborating Centre for Palliative Care, Oxford, UK:

In **1997**, the Center was invited to participate in an international consensus meeting of experts sponsored by the WHO Collaborating Centre for Palliative Cancer Care in Oxford, UK and hosted by its Director, Robert Twycross. The meeting resulted in a publication: *Looking forward to cancer pain relief for all: international consensus on the management of cancer pain.*⁵³

First Meeting of WHO Collaborating Centers in the Americas:

On October 9-10, **1998**, the Center participated in the First Meeting of the WHO Collaborating Centers in the Americas, in Washington D.C. It was useful to learn about WHO's view of Collaborating Centers and how other Collaborating Centers function. It was apparent that the scope and amount of our Center's work compared favorably with that of other Centers.

WHO Booth at International Meeting:

In **1999**, to maintain visibility of the WHO program and to enhance communication between Collaborating Centers, the Center invited WHO Collaborating Centers in cancer pain, palliative care, supportive care and quality of life to participate in presenting and staffing a WHO booth at the 9th World Congress on Pain in Vienna, Austria. Space for the booth was graciously provided by the International Association for the Study of Pain.

Several Collaborating Centers participated, including the WHO Collaborating Center for Cancer Control and Palliative Care (Milan, Italy), the WHO Collaborating Center on Quality of Life in Cancer (Amsterdam, The Netherlands), the WHO Collaborating Center in Supportive Cancer Care (Houston, Texas), and the WHO Collaborating Center for Cancer Pain Relief and Quality of Life (Saitama, Japan). Each Center provided educational materials they had produced for distribution at the WHO booth. The booth was centrally located and very popular. Many questions were answered, many contacts made, and many publications were distributed. This led to enhanced visibility for WHO and the WHO Collaborating Centers at a meeting attended by over 6,000 clinicians from around the world. The Center was invited to organize a similar booth at the European Association of Palliative Care Congress in Geneva in September of **1999**.

WHO Collaborating Center for Cancer Pain Relief and Quality of Life:

In **1997, 1998** and **1999**, the Center met with Dr. Fumikazu Takeda, head of the WHO Collaborating Center for Cancer Pain Relief and Quality of Life, in Tokyo to discuss progress and issues in opioid availability in the region. In March of **1998**, the Center was invited by Dr. Takeda to participate in the “Saitama-Western Pacific Workshop on Cancer Pain Relief and Palliative Care” in Saitama, Japan. Mr. Joranson gave a presentation on “Drug regulation, drug dependence and morphine in cancer pain management.”⁵⁴

WHO Collaborating Center in Supportive Cancer Care:

In February of **1999**, the Center was invited by Professor Charles S. Cleeland, head of the WHO Collaborating Center in Supportive Cancer Care to participate in a meeting in Houston to explore progress, needs and strategies for pain relief and palliative care.

IV. RELATIONSHIP BETWEEN THE CENTER AND THE INTERNATIONAL NARCOTICS CONTROL BOARD

The INCB has a critically important role in pain management throughout the world because it administers the international system that controls the availability of narcotic drugs, which includes all opioids used for medical and scientific purposes. These include 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. Since many governments have excessively restrictive attitudes and policies, the INCB can and does play an important role in helping governments take a more balanced approach. The Board and its Secretariat have long collaborated with WHO and have recognized 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. 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 report²⁷ in which it made a number of recommendations to governments, the U.N. International Drug Control Program, the WHO and other groups such as the IASP; these recommendations were aimed squarely at the problems that had been identified by the survey, collaboration with WHO and experience with governments.

During the reporting period **1997-1999**, the Center has requested and received consumption data on morphine and other opioids which it uses to study and report on global and national trends according to its terms of reference. These data, coming as they do from the governments’ original reports, are detailed and complete, in contrast to the Board’s published reports in which only the statistics from countries that consume over one kilogram are published. Further, national statistics on consumption of some opioids, for example fentanyl, hydromorphone and oxycodone, are not published at all. The result is that important information about consumption trends, and therefore progress or lack of it, is unavailable for some countries with small populations and for all countries for some opioids. The Center hopes that the Secretariat will be able to continue providing these more complete data so that we may continue to implement our Terms of Reference.

In August **1999**, three members from the Center met with the INCB Secretariat. The purpose of this meeting was to inform them of our recent work to improve opioid availability and to officially request the raw consumption data for a number of opioid analgesics in addition to morphine.

We were informed that our activities and communications have assisted the INCB in its own efforts to address pain and suffering as a global concern. We were informed that the INCB would, for the first time, address the use of controlled substances for alleviating pain and suffering in their annual report:

In a large proportion of the countries and territories in the world, insignificant amounts of these medicines are available for medical purposes and it is generally agreed that the treatment of chronic or acute pain caused by cancer is still inadequate: only about 10-30 per cent of patients suffering from severe cancer-related pain may be receiving adequate treatment, even in many technologically advanced countries. The Board has requested Governments to pay more attention to this particular problem and to identify and deal with the factors that cause inadequate availability of opioids for medicinal purposes.⁵⁵

In August **1999**, the Center invited a staff member of the INCB Secretariat to participate in a workshop on opioid availability in developing countries that was organized by the Center at the IASP meeting in Vienna. It was extremely valuable to demonstrate that the principal narcotic regulatory authority in the world advocates improved availability of opioids for pain relief.

In November **1999**, the Center invited an INCB staff member to participate in the working group meeting in Madison co-sponsored by the Center. This meeting provided an additional opportunity to discuss several ideas about what actions are needed (see “Relationship between the Center and WHO” section for details).

V. FUNDING NEEDS

The PPSG, which supports the Center in its entirety including the publication of *Cancer Pain Release*, receives no regular financial support, relying instead upon many grants to support staff salaries, for various projects and travel. The Center would welcome interest in support for its efforts to improve policy and communications relating to pain management.

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TABLE 1

Distribution of “Cancer Pain Release” by language in 128 countries

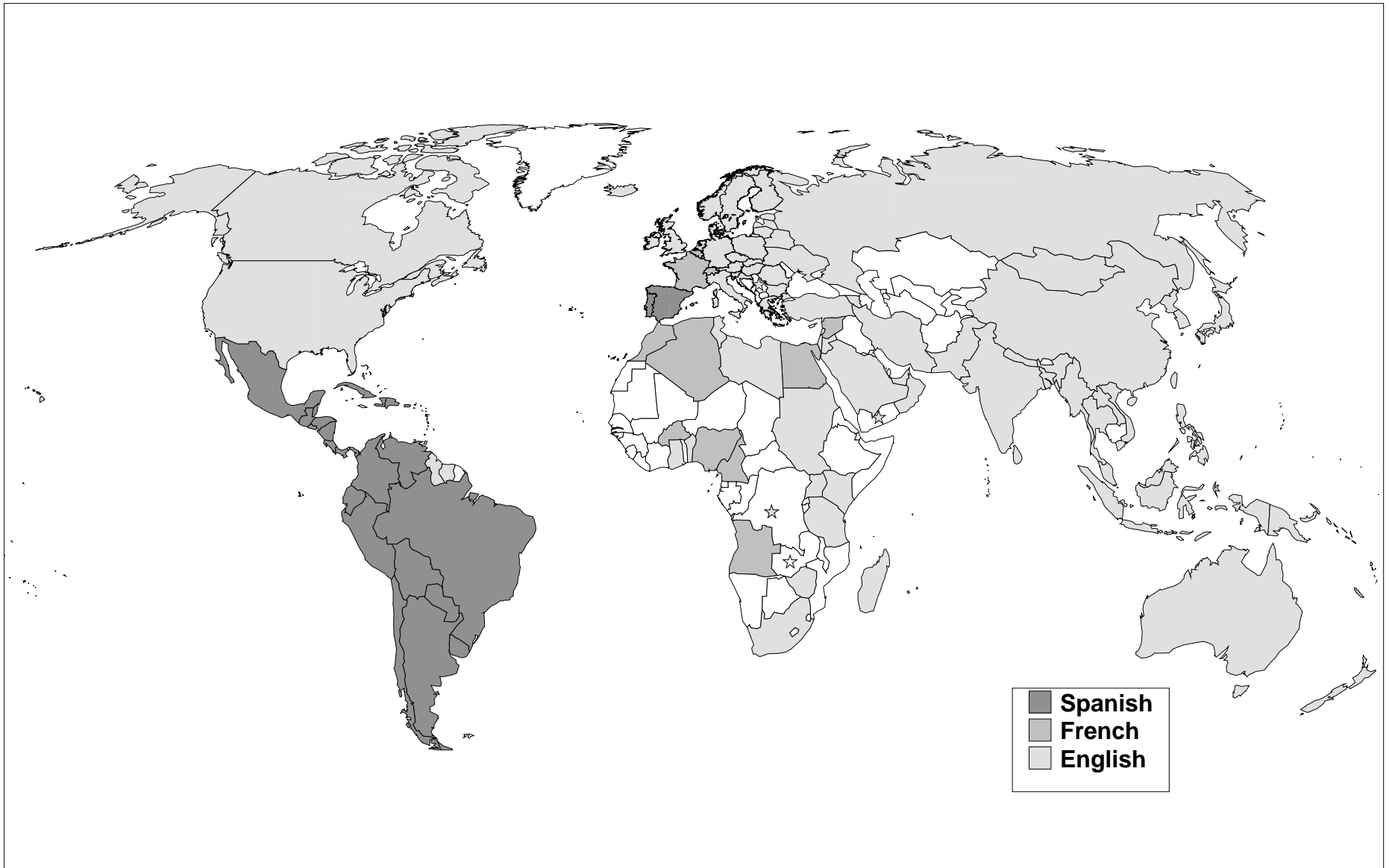


TABLE 2

“Cancer Pain Release” audience English version

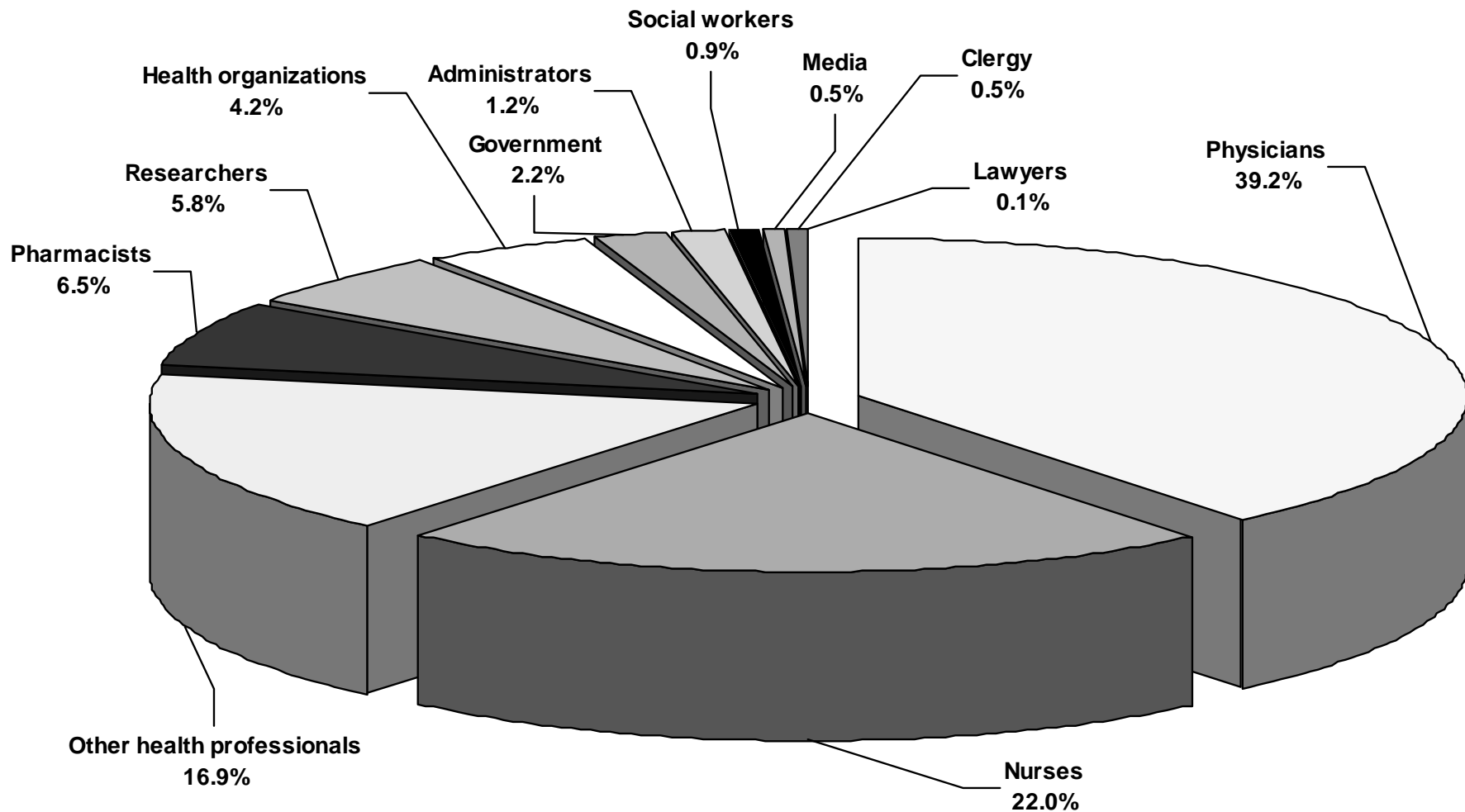


TABLE 3

El público de “Cancer Pain Release” Edición en castellano

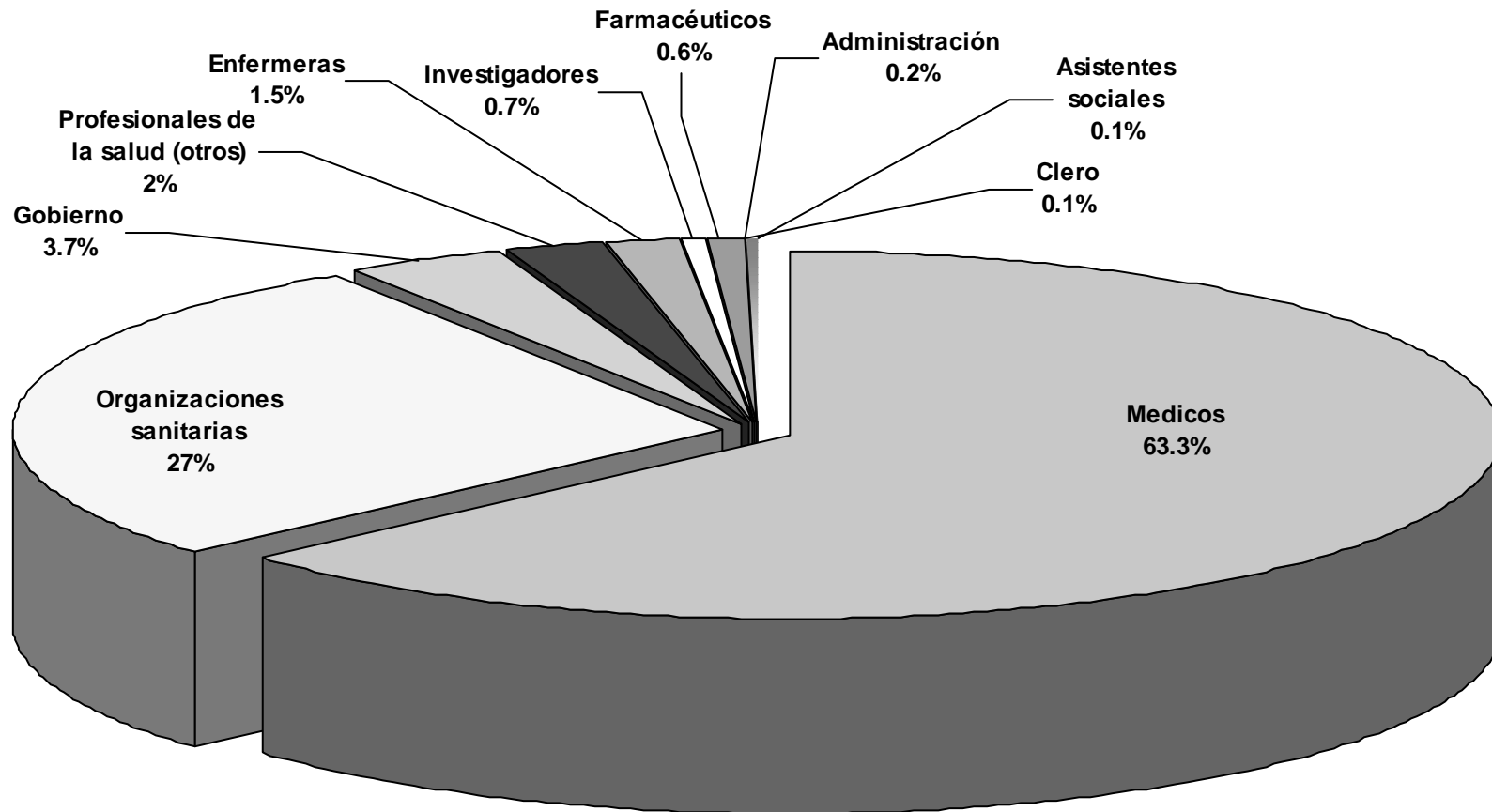


TABLE 4

Audience de “Cancer Pain Release” Edition en français

