



**International Association for Hospice and Palliative Care**  
**Project Strategy: Availability and Access to Opioid Medications in Latin American Countries**  
**Summary of Outcomes and Results**

**What is IAHPC?**

- Palliative care organization with a global approach
- Board of Directors composed of 24 individuals in 12 different countries
- Has developed and implemented programs and projects capable of making an impact both at the local as well as national levels
- Focused on palliative care and pain treatment Education, Research and changes in Policy and Legislations
- Works on advocacy campaigns with other similar organizations to increase awareness and bring about changes to improve access to appropriate care and medications
- Collaborates with organizations, governments, institutions at the local, regional and global levels.

**Mission**

The mission of IAHPC is to increase the availability and access to high quality hospice and palliative care for patients and families throughout the world. IAHPC aims to work with existing associations and agencies as well as individuals, to improve communication and access to resources as well as to foster opportunities in education and training.

**Availability and Access to Opioid Medications Strategy**

The purpose of the strategy is to identify, develop and implement the steps and changes needed to ensure access to treatment with controlled medications to patients in need.

**Objective:**

To improve the availability and access to opioid medications in selected countries of the world.

**Secondary Objectives**

- Identify the barriers which unduly interfere with legitimate medical Access to opioids and develop action plans to eliminate or minimize them
- Facilitate the development of networks of cooperation at the national level for physicians, pharmacists and the national competent authorities
- Provide the necessary tools and resources to develop and implement action plans which are safe, effective and guarantee access to opioids for patients in need.



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**Steps:**

- Identification of key persons (country coordinators) and National Competent Authorities (NCAs)
- Identification of mentors
- Preparation of material (WHO Guidelines, laws and regulations)
- Establish relation with the NCA
- Develop and implement workshop (prescribers, NCA, INCB rep, WHO rep, PPSG rep)
- Identify barriers using self assessment check list from the WHO publication Ensuring Balance in National Policies on Controlled Substances and BOAT questionnaires
- Development of an action plan: Identify solutions, responsible individuals, and timelines
- Plan is put in place and implemented
- Monitoring and follow up

**Criteria for selection of countries**

- A designated office and official responsible for the controlled medications is in place (National Competent Authority – NCA).
- There is a reporting system to the International Narcotics Control Board (INCB) in place
- There is a critical mass of prescribers in the country interested in improving the availability and access to opioid medications.
- Opioids are authorized in the country: the mechanisms for their importation, manufacture, distribution and dispensation are in place.
- There is interest on the part of the government to improve Access to treatment with controlled medications.

**Completed Workshops:**

- National workshop for Colombia: Bogotá, Colombia (2007)
- International Workshop (Peru, Mexico, Chile) Lima, Peru (2010)
- Regional workshop for Central American countries: Panama, Guatemala, Costa Rica, El Salvador, Honduras, Nicaragua (2011)
- National workshop for Chile (follow up from 2010 in Lima): Vina del Mar, Chile (2011)

**Activities and Results:**

**Colombia**

**Outcomes:** (Note: The changes in the Decree 302 below are part of the work developed by Dr. Marta Leon, as a PPSG fellow with Liliana De Lima as her mentor)

- Change in Resolution 4651 for Resolution 1478 which:



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- Increased the number of days for prescription of strong opioids from 10 days to 30 days.
- Extended the number of days for which a prescription is valid from 3 days to 10 days
- Development of agreements between the Fondo Nacional de Estupefacientes (NCA) and the secretaries of health from the different states to guarantee the availability and access to controlled medications.
- Development of a new norm which mandates the entities providing the care services (Entidades Prestadoras de Servicios – EPS) to have in each state (Departamento) at least one point of sale 24 hours, 7 days a week, of controlled medications. (Circular 011, 23 de Abril 2008, Ministerio de la Protección Social)
- Formation of a group of experts in pain management and palliative care which provides advice to the Fondo Nacional de Estupefacientes (NCA) on issues related to medical needs, therapeutic recommendations and appropriate treatment regimens, dosages and formulations for conditions requiring controlled medications.

### Panama

**Outcomes** (Note: The changes in the Decree 302 below are part of the work developed by Professor Rosa Buitrago, as a PPSG fellow with Liliana De Lima as her mentor)

- Development of a National Palliative Care Plan of the Ministry of Health, which includes a component on Access to controlled medications for the treatment of pain and relief of suffering.
- Formation of a group of experts in pain management and palliative care which provides advice to the Ministry of Health on issues related to the development and implementation of the national palliative care plan, including a person designated as responsible for access to controlled medications.
- Changes in Decree 302 which:
  - Extended the number of days for which a prescription is valid from 48 hours to 5 days
  - Increased the number of days for prescription of strong opioids in parenteral formulations from 48 hours to 5 days. Pain, palliative care, anesthesiologists and cancer specialists may prescribe for 15 days.
  - Increased the number of days for prescription of strong opioids in formulations other than parenteral from 10 days to 15 days. Pain, palliative care, anesthesiologists and cancer specialists may prescribe for 30 days.

### Panama follow up- workshop

#### **Identified Barriers**

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- Different special prescription forms used in hospitals in the health care system
- Limited availability of opioids among all the hospitals of the country
- Limited technical and human resources in the NCA office
- Limited technical and human resources in the regional hospitals and pharmacies

### **Recommendations:**

- Establish an agreement among the MOH and the Social Security system to recognize and unify a single prescription form
- Modify the current Law 23 of Decree 524 and article 323 of the Decree 178 to unify a single unique prescription form for the whole country.
- The list of essential medicines in palliative care is included in all the palliative care programs and in all levels of care.
- Increase the stock quantity of opioids in the emergency rooms so that nurses are able to supply the needs of patients during out of office hours.
- Recommend the MoH to take the necessary steps to create the positions needed within the NCA
- Computerize the information process so that monitoring and control is carried from the NCA in the dispensing sites.
- Take the steps to create the job positions of pharmacists in the hospitals in the rural areas and smaller cities.

### **Peru**

#### **Outcomes, recommendations and current progress**

- Formation of a group of experts in pain management and palliative care which provides advice to the Direccion General de Medicamentos y Drogas – DIGEMID (NCA) on issues related to medical needs, therapeutic recommendations and appropriate treatment regimens, dosages and formulations for conditions requiring controlled medications. (in progress)
- Changes to Decree D.S. 023-2001-SA which
  - Extends the number of days for which a prescription is valid from 3 days to 10 days.
  - Increased the number of days for prescription of strong opioids from 10 days to 30 days.
- Review and modification of the regulations in the national list of medications so that:
  - Special prescriptions are required only for strong opioids
  - Include definitions of the different types of prescription forms
- Adoption of treatment guidelines based on evidence
- Development and implementation of specialized programs in pain and palliative care for post graduate levels



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- Strengthen the existing programs in continuous education in palliative care
- Monitor so that there are opioids in stock in all the hospital and clinics at the third and second level and guarantee there is enough in stock for 60 days
- Establish emergency measures to ensure the availability and access to opioids 24 hours a day in hospitals and clinics, as per the current legislation.
- Implement an information registry for the unmet demands of opioids (make modifications to the current information system)
- Implementation of the norms to ensure the availability of opioids in rural areas.
- Monitoring and follow up of regions which do not report any consumption to the NCA.
- Distribution and dissemination of the Resolution No 1013-2007/MINSA which requires the provision of palliative care and pain treatment in hospitals, clinics and health institutions, so that the resolution is implemented and adopted.
- Extend the number of days for the validity of estimates of opioids for wholesaler and distributors, from 15 days to 30 days.
- Strengthening of the institutional pharmacies of DIRESA/GERESA so that they are able to dispense opioids (Public health system)
- Identify providers at the international level for DIGEMID, so that they are able to supply the medication in emergencies or stockouts due to failures in the regular providers or the procurement process.
- Request the DIGEMI (NCA) so that the reporting system of credit and debit to the stock of opioids is done electronically instead of manually.
- Develop and implement a national survey to determine the national situation on palliative care and pain treatment.
- Improve the procurement process in rural pharmacies and hospitals so that the medication is distributed more effectively.

### Chile

#### **Identified barriers:**

- Inequity in access to opioids according to the providers (different medication lists for health branches)
- Legal void in the inclusion of patients from the armed forces in the palliative care and pain relief national program
- Insufficient availability of opioids in community pharmacies
- High cost of some opioid formulations
- Difficulties obtaining the special prescription forms and its high cost
- Lack of new opioid formulations
- Codes assigned to commercial presentations and formulations which are not interchangeable in the prescription form resulting in lack of access when the specific medication is not available, but other similar are in stock and cannot be dispensed.



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- Insufficient training of the health care workers and family members on how to proceed with the remaining medications when a patient dies or stops taking the medications.
- Inadequate legislation regarding remnants of opioids
- Lack of social policies providing support to caregivers who care for terminal patients
- Insufficient palliative care training and education in undergraduate and post graduate programs in health care careers

### **Recommendations and measures to eliminate barriers:**

#### On health care policy:

- Recognize pain as a public health problem
- Develop a national survey to determine the prevalence of severe chronic non-cancer pain in Chile.
- Develop and implement palliative care and pain treatment programs for non-cancer patients

#### On Education:

- Include pain treatment in the undergraduate curricula of health care professions, as part of the training.
- Create and develop postgraduate palliative and pain treatment programs
- Strengthen internships and continuous education in palliative care and pain treatment for health care professionals.

#### On availability and Access:

- Establish emergency measures to ensure the availability and access to opioids 24 hours of the day in hospitals, clinics and community pharmacies as per the current legislation.
- Review and modify the national list of essential medicines to incorporate new opioid formulations.
- Increase the office hours for the dispensation of controlled medications with the special prescription form.

#### On Dissemination and Information:

- Disseminate to the health care services through the websites of the Ministry of Health (MOH), Chilean Association for the Study of Pain – IASP Chapter (ACHED for its letters in Spanish) - and scientific societies, the changes in the provision of the special prescription forms.
- Educate and disseminate the rational use of opioids in Alliance with the national health authorities, scientific societies, universities and related institutions.
- Disseminate the patients' right for access to pain treatment and educate patients and civil society about this right.



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**Other**

- Form an alliance with the related associations and organizations in the country, so that this becomes a collective effort.

**Honduras**

**Identified Barriers:**

- Limited knowledge on the laws and regulations and limited communication between prescribers and the NCA.
- Lack of education in schools of medicine, nursing and pharmacy on pain treatment and appropriate prescribing.
- Lack of awareness on the procurement, distribution and importations committee on the need to ensure the availability of controlled medications for legitimate medical use.
- Incorrect application of the dispensation policies

**Recommendations:**

- Establish relationships with the medical societies
- Establish an alliance between the pain and palliative care associations
- Use the medical board and medical school congress and platform to communicate and disseminate information about lack of education and limited knowledge
- Establish an Alliance between the NCA and the faculty at the medical, nursing and pharmacy schools.
- Request the members of the pain and palliative care associations approve the delivery of pain courses, including appropriate evaluation, prescription and safety.
- Request the pharmaceutical industry its support in the distribution of tools on how to prescribe.
- Deliver the same module to interns and doctors who do their social service.
- Request the pharmaceutical industry to manufacture opioids in the country
- Develop a strategy to buy directly from different countries and keep the distribution and control within the MoH
- Harmonization of the dispensing criteria among pharmacies
- Development of a strategy to ensure the dispensation when the prescription is valid and without problems.

**Guatemala**

**Identified Barriers**

- No immediate release formulations available in the country
- There are no points of sale for 24 hours a day, 7 days a week for controlled medications



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- A stamp is required for the authorization and validation of the special prescription: patients have to travel to the MoH to register in a database and get the stamp in the prescription.
- Limited knowledge about pain management which results in very little prescription of opioid medications
- Ambulatory patients are unable to receive opioids in public hospitals

### **Recommendations**

- Meet with potential and interested manufacturers
- Identify potential pharmacies willing to dispense 24 hours
- Adopt the IAHPC List of essential medicines for palliative care
- Review the norm 17-2002 on the authorization of prescriptions and find the mechanisms to ensure the monitoring and control so that the stamp and prescription validation is eliminated.
- Develop a course on the Good Medical Prescription Practice for continuous medical education
- Develop a course on the Good Medical Prescription Practice for newly graduated professionals.
- Establish a relation with the vice-minister of hospitals to bring him up to date about the lack of access for ambulatory patients
- Create the mechanisms to facilitate the prescription and dispensation of opioids for ambulatory patients in hospitals.

### **El Salvador**

#### **Identified Barriers**

- Palliative care and Access to pain treatment are not a priority
- Lack of knowledge on pain management, palliative care.
- Lack of awareness about palliative care and the needs of patients.
- Limited availability and Access to medications

#### **Recommendations**

- Revise the laws and regulations on the use of narcotics
- Formation of a group of experts in pain management and palliative care which provides advice to the NCA on issues related to medical needs, therapeutic recommendations and appropriate treatment regimens, dosages and formulations for conditions requiring controlled medications
- Create awareness with authorities and health care professionals about the lack of Access to opioid medications
- Include in the curricula of health care professions, courses on pain management and palliative care
- Create strategic alliances with the MoH and Medical Board
- Inform and create awareness among the MoH, Social Security system

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- Train and educate doctors and pharmacists on appropriate prescription and dispensing practices.
- Disseminate through the media

### Costa Rica

#### **Identified Barriers**

- Limited availability of different formulations of strong opioids
- Lack of knowledge on the correct use of opioids and palliative care among GPs
- Lack of harmonization among the different health branches on the requirements and norms which control the procurement, storage, prescription and dispensation of opioids.

#### **Recommendations**

- Meeting with the manufacturers to register new pharmaceutical forms.
- Meeting with the pharmacotherapy committee of the Caja Costarricense de Seguro Social
- Give priority to the registration of new formulations
- Structure and adapt continuous medical education courses on pain management and palliative care for GPs
- Implement and deliver courses at least once a year
- Change the curricula to include pain management and palliative care in undergraduate levels for medical, pharmacy and nursing schools.
- Develop and implement a national survey to assess the current situation and knowledge of pain prevalence in the country among recent graduates and last year medical students
- Elaboration of public health policies on palliative care, using a situational diagnosis.

### Nicaragua

#### **Identified Barriers**

- Law and regulations which require that:
  - patients have travel to the MoH in Managua to validate the prescription
  - prescribing physician must write a summary of the medical history
  - the prescription must be signed by the director and legal representative of the hospital
- No availability of strong opioids in oral formulations
- Lack of knowledge among health professionals on pain management and palliative care

#### **Recommendations**

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- Create awareness among health authorities about the barriers that the law creates
- Create and authorize dispensing centers in other cities and areas of the country besides Managua
- Eliminate the need to write a summary of the medical history
- Create awareness and sensitize the authorities to procure oral morphine, methadone to patients in the public and private health sectors
- Work with the medical societies, industry, nurses, and other health care professionals in the field to incorporate pain treatment and palliative care courses
- Work with universities (private and public) to include pain and palliative care in the curricula.