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#### Introduction

Pain is a physiological mechanism of paramount importance for the physical integrity of individuals. The nociceptive system comprises nervous structures whose main function is to detect harmful or potentially harmful stimuli, so as to set off reflexive and/or cognitive reactions to avoid lesions, or to prevent a lesion from becoming worse and contribute to its healing.

The importance of pain, especially acute pain, as a symptom of a lesion or an organ dysfunction is well evidenced by the fact that it represents the main reason for the general population to seek health care. Pain is also, countless times, one of the most relevant symptoms for establishing a correct medical diagnosis.

However, except for the vital sounding of the alarm, pain does not represent any other physiological advantage for the organism. In fact, in addition to causing suffering and reducing quality of life, pain is also responsible for physiopathological alterations of the immune, endocrine, and nervous systems, which contribute to physical and psychological comorbidities that may lead to the perpetuation of pain.

Moreover, pain and in particular chronic pain can be present even in the absence of an identifiable lesion, or it may persist after the lesion that originated it has been healed. In this context, pain is not a mere symptom but becomes a disease in itself, as acknowledged in a declaration at the European Parliament in 2001 by the European Federation of IASP Chapters (EFIC)<sup>2</sup>.

Therefore, and within the scope of high-quality health care services, pain management must be seen as a priority, and also as a decisive factor in the necessary humanization of health care. In fact, according to a proposal presented by the International Association for the Study of Pain (IASP) during the First Global Day Against Pain<sup>3</sup>, pain relief should be acknowledged as a fundamental human right.

In addition to the enormous impact it has on individuals, pain often constitutes a burden for the patient's family and/or caregivers and represents a loss that is difficult to quantify for society as a whole. It is worth noting that the socioeconomic repercussions of pain have been compared by EFIC to those caused by cardiovascular diseases or cancer.

Acknowledging the importance of pain management, a working group dedicated to pain was created in 1999 by the Directorate-General for Health, which worked in strict collaboration with the Portuguese Association for the Study of Pain (the Portuguese Chapter of IASP) to develop a National Program for the Fight Against Pain (NPFAP), approved by Ministry Decree on 26 March 2001. This plan, innovative at the national and international level (in Europe, France is the only other country with a governmental plan to fight pain), describes the organizational models for pain management in hospitals, including several general guidelines for pain management. The Portuguese government was also the first to establish a National Day for the Fight Against Pain in 1999.

The time frame of the NPFAP ended in 2007, and although some positive progress toward achieving its objectives is recognized, it is clear that the NPFAP will not meet all of its goals. It should be noted that after the development and publication of the NPFAP, several changes took place in the organizational structure of hospitals with implications for the achievement of its goals. Among these changes, we highlight the reformulation of the Hospital Charter, aggregating some hospitals into hospital centers, the reclassification of hospitals into four categories (multi-purpose hospitals (type A), medical-surgery hospitals (type B), local hospitals (type C), and specialized hospitals (type E), the conversion of some hospitals into public limited corporations, and later, into publicly held corporations, and the approval of the rules for the establishment of university hospitals. It was also noted that the criteria defined in the NPFAP for the classification of chronic pain clinics, based on the classification established by IASP, which follows the American model, are not the most appropriate criteria for the current reality, inasmuch as in some aspects the NPFAP criteria are more demanding than those established by IASP. The recent creation of a Competency in Pain Medicine by the Medical Association, as a way of promoting and recognizing the specialization of doctors dedicated to this field of medicine, also emphasized the need to reformulate those criteria.

The National Program for Pain Management emerged from the need to define new objectives and new operational strategies, as a follow-up to the NPFAP and using the experience gained so far. Hence, in order to obtain epidemiologic knowledge on pain and its distribution in the Portuguese population, to reinforce the organizational capacity of health care service providers, and to improve best practice models regarding pain management, this new National Program for Pain Management should be developed through the implementation, at national, regional, and local levels, of new strategies for intervention, professional development, and data collection and analysis.

<sup>2</sup> Available through www.efic.org/declarationonpain.html

<sup>3</sup> For more information see www.iasp-pain.org.

The National Program for Pain Management is incorporated into the National Health Plan 2004–2010, intersecting with and complementing other national programs in the fields of cancer, rheumatic diseases, and palliative care.

The implementation of the National Program for Pain Management presupposes the participation and collaboration of various health care bodies, namely primary health care, hospitals, the Integrated Network for Continuing Care, institutions of higher education, professional associations, and scientific societies, without precluding the inclusion of other public or private institutions from cooperating as needed, during the course of implementation. The Portuguese Association for the Study of Pain constitutes the permanent scientific interlocutor of the Directorate-General for Health in all aspects of the development, implementation, and evaluation of this program.

#### 2. Context

Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant multidimensional, sensory and emotional experience associated with actual or potential tissue damage, or described in relation to such damage"<sup>4</sup>. This definition implies that pain has the capacity to affect the individual as a whole, and therefore its management must often be approached on multidimensional levels, taking into consideration not only the sensory aspects of pain, but also the psychological, social, and cultural factors associated with the painful condition.

The prevalence of pain in Portugal was studied by the National Health Observatory in 2002, by means of telephone interviews with Portuguese families that were part of the ECOS sample group<sup>5</sup>. The study concluded that approximately 74% of those interviewed had felt some kind of pain in the two weeks preceding the telephone interview. The study also revealed that low back pain, osteoarticular pain, and headaches were the types of pain most frequently referred to.

The reduced number of the sample group that participated in the study, as well as the difficulty in determining the severity of pain and its clinical relevance, precluded the establishment of the prevalence of pain in Portugal regarding acute postsurgical pain and chronic pain, the two most clinically relevant types of pain.

Several studies carried out in European countries, with greater sophistication than the ones observed in Portugal in the context of acute postsurgical pain, have demonstrated insufficiencies in the management of this type of pain. This fact is hard to understand and accept because this is a type of pain inflicted by a physician in the course of a therapeutic intervention, and therefore its causes are well known. The management of this type of pain essentially depends on the adequate application of procedural protocols in the perioperative period. The same principle applies to other types of pain inflicted by therapeutic processes or complementary diagnostic tests. On the other hand, it has also been established that as well as preventing unnecessary pain, adequate analgesia in the perioperative period contributes to the reduction of morbidity and decreases the period of hospitalization, thus representing an advantage in economic terms as well.

Chronic pain is usually defined as persistent or recurrent pain that lasts for 3 months or longer and/or persists after the lesion that caused it has been healed. In a recent European study<sup>6</sup>, which did not include Portugal, the average prevalence of chronic pain in Europe was cited at approximately 20%. Given that this study found significant differences between each country (the prevalence of chronic pain in Norway was 30%, while in Spain it was 11%), it is not possible to make a reliable estimate for Portugal. In any case, the increase in average life expectancy and the consequent aging of the population, as well as the increased longevity of patients suffering from diseases accompanied by pain, allow us to project an increase in the prevalence of chronic pain for the future.

The main causes of chronic pain in Portugal are also unknown, but several international studies corroborate in choosing low back pain as the primary cause of pain. Osteoarticular and musculoskeletal conditions, in addition to low back pain, are other causes of high prevalence of chronic pain, as well as headaches, and on a lesser scale, neuropathic pain. Pain deriving from oncological conditions, often seen as one of the main causes of chronic pain, only represents a small percentage of the chronic pain suffered by patients. However, it has a special importance because cancer is the second largest cause of death in Portugal, and moderate to severe pain is present in 90% of patients with terminal cancer.

<sup>4</sup> H. Merskey and N. Bogduk, 1994

<sup>5</sup> S. Rabiais et al., 2004

Similarly, the socioeconomic impact of pain has not been studied in Portugal. However, a study conducted in the United Kingdom<sup>7</sup> estimated that health care expenses relating to low back pain, which is, as previously stated, the most prevalent chronic pain condition, amounted to €2.5 billion in 1998 alone. However, when the consequent indirect costs are added, namely loss of productivity, absenteeism, and early retirement pensions, the total cost reaches almost €20 billion.

With the exception of specific cases, such as acute postsurgical pain, or pain resulting from labor, pain management should be initiated by, and in most cases restricted to, primary care services. These services must necessarily be the foundation for any strategy that aims to enhance pain management for the general population, especially considering that pain constitutes one of the main motivations for family doctor consultations. In addition to the appropriate technical know-how, the family doctor should have the necessary qualifications to evaluate the social and cultural components of the patient's environment that may be relevant to the management of pain.

However, the complexity of diagnosis, the need to perform complementary examinations or different therapeutic techniques, and the difficulty of pain management are factors that may lead to the necessity of referring the patient to specialized health facilities that have health professionals competent in pain diagnosis and management.

It is within this context that pain clinics appear within hospitals. They hold distinct levels of specialization according to the respective team and hospital structure in which they are based. The most specialized pain clinics should be at the higher level of the referral system, based on the increasing complexity of the clinical situation or therapeutic strategy.

According to a survey carried out by the Monitoring Committee of NPFAP in 2003, 53 hospitals within the National Health Service had incorporated entities dedicated specifically to chronic pain. This number represents an increase of 40% compared to a similar survey carried out in 1999, before the implementation of NPFAP. However, and similarly to the situation in 1999, the majority of the facilities did not have the recommended levels of differentiation and specialization, particularly as they were monodisciplinary units, lacking psychiatrists or clinical psychologists and doctors with other specialties, with reduced weekly activities and no clinical investigations. It should be noted that the data obtained may be overrated because no independent evaluation was performed.

The same survey stated that only 22 postsurgical acute pain clinics existed, which represents a decrease of 4 clinics in relation to 1999. The reasons for this decrease are hard to understand because such clinics are merely operational units that promote organized action plans and protocols for postsurgical analgesia, which should include all health professionals involved in the perioperative period, namely anesthesiologists, surgeons, and nurses.

Regarding analgesia during labor, it was noted that there was organized activity in 31 of the 53 hospitals that participated in the survey. The maternity centers of Júlio Diniz (Oporto), Bissaya Barreto (Coimbra), and Alfredo da Costa (Lisbon) have obstetric analgesia 24 hours a day, seven days a week. There are more than 15 hospitals offering 24-hour obstetric analgesia and 9 offering it 12 hours a day. Of these hospitals, 16 offer obstetric analgesia 7 days a week. It was also observed that pain intensity was recorded in only 24% of hospitals offering obstetric analgesia.

The Directorate-General for Health published a regulation on June 14, 2003 (no. 09/DGCG), which declares pain to be the Fifth Vital Sign. As such, it has since become considered good clinical practice and mandatory to evaluate and record the intensity of pain regularly, in all health care services, as has long been done for the four "classic" vital signs (respiratory frequency, heart rate, blood pressure, and body temperature). This regulation also indicates the scales that may be used in evaluating the intensity of pain, providing basic instructions for their use. However, it has been observed that this regulation has not yet been implemented in many health care services, perhaps due to a lack of knowledge and awareness of the duties of health care professionals and the public's right to pain management. The standardization of the evaluation and recording of the intensity of pain could have a significant impact on the treatment of pain in health care units, providing a huge qualitative leap in the humanization of the care provided.

<sup>6</sup> Breivik et al., 2006 7 N. Maniadakis e A. Gray, 2000

### 3. Guiding Principles

The National Program for Pain Management is based on the following guiding principles:

- 3.1. <u>Subjectivity of Pain</u> As it is currently understood, pain does not constitute any biologically measurable indicator, and as such, pain intensity must necessarily be considered to be the way it is described by each patient. Particular attention should be given to individuals who have difficulty in communicating, or who find it impossible to communicate verbally.
- 3.2. Pain as the Fifth Vital Sign Pain represents a vital alarm signal for the integrity of the individual and is fundamental for the diagnosis and monitoring of a number of diseases, but it should not be the cause of unnecessary suffering. As referenced in the aforementioned regulation distributed by the Directorate-General for Health, regular evaluation and recording of the intensity of pain constitutes a measure of good clinical practice and should be carried out in all health care institutions.
- 3.3. The Right to Pain Management All individuals have the right to adequate pain management, whatever the cause of the pain, so as to avoid unnecessary suffering and reduce the morbidities associated with pain.
- 3.4. <u>Duty to Manage Pain</u> All heath professionals should adopt pain prevention and pain management strategies for individuals under their care, contributing to their well-being and decreased morbidity, as well as to the humanization of health care. Particular attention should be given to the prevention and management of pain caused by diagnostic methods or therapy.
- 3.5. Special Treatment for Pain Pain management should be provided at all levels of the health care network, generally starting with primary health care, and, whenever necessary, continuing through to further levels of specialization.

## 4. General Objectives

The National Program for Pain Management encompasses three main objectives:

- 4.1. Reducing the prevalence of non-managed pain in the Portuguese population;
- 4.2. Improving the quality of life of patients living with pain;
- 4.3. Rationalizing resources and controlling the costs necessary for the management of pain.

## 5. Specific Objectives

To achieve the above-referenced general objectives, it will be necessary to achieve the following specific objectives:

- 5.1. Identify the prevalence of chronic pain among the Portuguese population;
- 5.2. Identify the prevalence of acute postsurgical pain among the Portuguese population.
- 5.3. Identify the prevalence of deliveries carried out without recourse to epidural analgesia;
- 5.4. Improve the current knowledge of health care professionals regarding the diagnosis and management of pain;
- 5.5. Establish a network of specialized hospital structures for the diagnosis and management of all types of pain;
- 5.6. Reduce the prevalence of non-managed chronic pain;
- 5.7. Reduce the prevalence of non-managed acute postsurgical pain;
- 5.8. Increase analgesia offered during labor;
- 5.9. Improve access to and rationalize the prescription and use of analgesic drugs.

## 6. Target Population

The target population of this program must include the entire Portuguese population. Particular attention should be given to patients attending health care centers.

## 7. Time Line

This program has an extended period of 10 years and will receive a strategic interim evaluation at the end of 2010. This evaluation may result in the need to introduce corrective measures.

### 8. Intervention Strategies

The following intervention strategies aim to reinforce the organizational capacity and the development of good practice models for pain management approach:

- 8.1. Reinforcement of the information referring to Regulation No. 09/DGCG of 14 June 2003, issued by the Directorate-General for Health, establishing pain as the Fifth Vital Sign;
- 8.2. Revision of the organizational regulations regarding chronic pain clinics as stated in the above-referenced National Program for the Fight Against Pain (see Appendix);
- 8.3. Revision of the organizational regulations regarding acute postsurgical pain clinics, as stated in the above-referenced National Program for the Fight against Pain;
- 8.4 Revision of the organizational regulations for obstetric analgesia, as stated in the above-referenced National Program for the Fight against Pain;

- 8.5. Establishment or development of special hospital structures for the specialized treatment of pain;
- 8.6. Evaluation of specialized hospital structures for the specific treatment of pain;
- 8.7. Establishment and distribution to health professionals of a hospital referral circuit for patients with chronic pain;
- 8.8. Establishment and distribution of technical guidelines for health care professionals regarding the referral of patients with chronic pain;
- 8.9. Establishment and distribution of technical guidelines for health care professionals on how to deal with pain in children;
- 8.10. Establishment and distribution of technical guidelines for health care professionals on how to deal with pain in the elderly;
- 8.11.Establishment and distribution of technical guidelines for health care professionals on how to deal with pain in those who suffer from substance abuse;
- 8.12. Establishment and distribution of technical guidelines for health care professionals regarding the use of opioids in the treatment of noncancer pain;
- 8.13.Preparation of a list of Homogenous Groups for Diagnosis (GDH) for activities undertaken in pain clinics;
- 8.14. Preparation of a proposal for a technical regulation regarding opioid therapy and driving;
- 8.15.Revision of the prescription rules for opioids, specifically referring to medicines subject to special medical prescriptions;
- 8.16. Preparation of a proposal for the revision of the reimbursement system for opioids.

## 9. Professional Training Strategies

The following strategies are aimed at health care professionals, and within the scope of communication, to the general population:

- To raise awareness in medical colleges of the need for improvement in dealing with pain in preand postgraduate training;
- 9.2. To raise awareness in nursing colleges of the need to improve pre- and postgraduate training in dealing with pain;
- 9.3. To raise awareness in psychology colleges of the need to improve pre- and postgraduate training in dealing with pain;
- 9.4. Preparing a proposal for mandatory professional training in dealing with pain as part of the medical residency program and general and family medicine competence;
- 9.5. Preparing a proposal for mandatory Professional training in dealing with pain as part of the complementary residency programs in surgery, vascular surgery, endocrinology, physical and rehabilitative medicine, internal medicine, neurology, obstetrics and gynecology, oncology, rheumatology, orthopedics, trauma, and psychiatry;
- 9.6. Preparing a proposal for the creation of a special cycle of studies dedicated to pain;
- 9.7. Development of multidisciplinary partnerships for the creation of teaching instruments for basic training on pain;
- 9.8. Development of multidisciplinary partnerships for clinical training sessions regarding pain, with special emphasis on family doctors;
- 9.9. Development of multidisciplinary partnerships for training sessions on pain for nurses;
- 9.10.Development of multidisciplinary partnerships for distributing information to the general population regarding pain, especially on the National Day for the Fight Against Pain.

## 10. Gathering and Analyzing Information Strategies

The following strategies for gathering and analyzing information focus on the epidemiological understanding of pain and its distribution amongst the Portuguese population, as well as measuring the health benefits arising from pain treatment:

- 10.1. Development of multidisciplinary partnerships to carry out an epidemiological study on the prevalence of chronic pain and its personal, social, and economic impact;
- 10.2. Development of multidisciplinary partnerships to carry out an epidemiological study on the prevalence of acute postsurgical pain;
- 10.3. Quantitative and qualitative assessment of implementing, at the National Health System level, Regulation no. 09/DGCG of 14 June 2003 of the Directorate-General for Health, which promotes pain as the Fifth Vital Sign;
- 10.4. Performance of an evaluation survey of existing hospital structures dedicated to the treatment of chronic pain;
- 10.5. Performance of an evaluation survey of existing hospital structures dedicated to the treatment of acute postsurgical pain;
- 10.6. Performance of an evaluation survey on the conditions for administering analgesia in labor;
- 10.7. Evaluation of the health benefits obtained by the implementation of the program.

## 11. Gantt Chart

	1 <sup>st</sup> Year Quarters				2 <sup>nd</sup> Year Quarters				3 <sup>rd</sup> Year Quarters				Γ	Qua	Year arters	3	5 <sup>th</sup> Year Quarters			
	1°	2°	3°	4°	1°	2°	3°	4°	1°	2°	3°	4°	1°	2°	3°	4°	1°	2°	3°	4°
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## 12. Follow-up and Evaluation

The Directorate-General for Health is responsible for coordinating, monitoring, and evaluating the National Program for Pain Management, carried out by a National Committee for the Management of Pain, to be officially appointed by the Minister of Health.

In order to collect data and perform a systematic analysis regarding the information on pain, to be provided to the above-mentioned Committee, there will be an effort to promote the creation of a Center for Observation of Pain, in accordance to the informative memorandum no. 46/DSPCS, of 13 October 2006, by the Directorate-General for Health.

The National Program for the Fight Against Pain is evaluated by means of the following indicators:

## 12.1 Evaluation of Impact

- 1. Prevalence of moderate or severe chronic pain;
- 2. Prevalence of moderate or severe acute postsurgical pain;
- 3. Percentage of deliveries carried out with epidural analgesia;
- 4. Number of first consultations in chronic pain clinics per million inhabitants;
- 5. Consumption of opioid drugs per capita.

#### 12.2 Implementation Monitoring

- 1. Number of chronic pain clinics, of various types, per million inhabitants;
- 2. Number of acute postsurgical pain clinics, per million inhabitants;
- 3. Number of doctors with competency in pain medicine, per million inhabitants;
- 4. "Prevalence" of regular assessment and recording of pain intensity in national health centers (pain as the Fifth Vital Sign);
- 5. Average delay for scheduling a first consultation in a chronic pain clinics.

#### 13. References

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## **Appendix**

## Organizational Rules and Classification of Chronic Pain Clinics

## 1. Chronic Pain Consultation

This refers to all organized forms of diagnosis and treatment of chronic pain that do not necessarily have the characteristics of pain clinics. In this sense, chronic pain consultations may operate with a limited number of doctors (in the extreme, only one), without other health care professionals specifically assigned to pain consultations, or having specific facilities. However, regular activities (at least once a week) should be undertaken, and patients should be registered. The doctor(s) incorporated into the chronic pain consultation clinics should have adequate training for pain management, and there should be at least one doctor with competency in pain medicine, attributed by the Medical Association. A protocol for collaboration should be established with a pain clinic, for referral of patients.

### 2. Therapeutic Pain Clinic

This is a specific clinic for diagnosis and treatment of chronic pain that carries out some treatments and, whenever necessary, refers patients to complementary services, when possible, through a protocol established with other hospital services. The clinic should have at least two doctors with competency in pain treatment and a psychiatrist or clinical psychologist. Alternatively, a protocol for regular collaboration with these doctors may be established. One of the doctors, with competency in pain medicine, should be the coordinator of this clinic. The assisting team should also comprise at least one nurse. It should operate in specific facilities, even if the facilities are shared, it should have regular activity (at least three times a week), and all patients should be registered. The clinic should be incorporated into an outpatient hospital, when there is one, but it is to be managed through a separate cost center.

## 3. Multidisciplinary Pain Clinic

This unit focuses on the diagnosis and treatment of chronic pain and comprises a multidisciplinary team. It should include at least one doctor with competency in pain management who coordinates the clinic and its doctors, who must encompass at least three different competencies, including psychiatry, or alternatively two competencies and one clinical psychologist. The team should also have a nurse, a physiotherapist, a social service technician, and an administrative technician. The clinic should be integrated into an outpatient hospital when there is one, should be managed through a separate cost center, operate in its own facilities, and have daily activities, including telephone answering services. It should be equipped to treat patients on an outpatient basis, on an inpatient basis (in collaboration with other hospital services), or in emergency situations. The activities undertaken in the clinic should be subject to therapeutic protocol, be subject to regular evaluations, and may also establish additional protocols for collaboration with complementary medical

specialties. The clinic may be involved in the treatment of acute pain by working with an acute postsurgical pain clinic. Additionally, it should take part in clinical investigation projects and postgraduate training for health care professionals.

### 4. Multidisciplinary Pain Center

This has the same characteristics as a multidisciplinary pain clinic but should have at least two doctors with competency in pain medicine and should be integrated into a university hospital or university teaching hospital, in accordance to Decree Law no. 206/2004 of August 19. In addition, a multidisciplinary pain center should conduct clinical or basic investigation through independently funded investigation programs, the results of which should be regularly published. It should also promote regular postgraduate training to health care professionals and when solicited, take part in pre-graduate teaching.

Notes on the classification of pain clinics

- I. The above-referenced requisites should be understood as minimum requirements. For example, it is stated that any pain clinic may develop or participate in clinical investigation programs, irrespective of the unit's level of specialization. Similarly, the teams comprising pain clinics may employ more specialized professionals than those mentioned here, and may comprise different specialists, such as an occupational therapist.
- II. Given that the criteria for attributing competencies in pain medicine by the Medical Association are very recent, during an interim period, pain clinics will be allowed to operate without a doctor with competency in pain medicine, but all clinic coordinators are advised to obtain this specialization.
- III. The organization and degree of specialization for the specific treatment of pain should be adjusted to the hospital into which they are integrated, and should possess at least the following characteristics:
  - (i) Pain consultation in local hospitals (type C)
  - (ii) Pain treatment clinics in surgical hospitals (type B)
  - (iii) Multidisciplinary pain clinics in multipurpose hospitals (type A)
  - (iv) Multidisciplinary pain centers in university hospitals
  - (v) Multidisciplinary pain clinics in specialized oncology hospitals (unit E)

The current document was drafted by the Directorate-General for Health, within the scope of action of the Monitoring Committee for the National Program for the Fight Against Pain.

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