

## PAIN RELIEF AND PALLIATIVE CARE IN LEBANON PAIN MANAGEMENT AND HEALTH CARE POLICY

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**ABSTRACT :** Opioid analgesics are essential for the management of moderate to severe pain. In spite of their documented effectiveness, opioids are often underutilized, a factor which has contributed significantly to the undertreatment of pain. Many countries have developed true national policies on cancer pain and palliative care, and in others only guidelines for care have been developed. Ideally, national policies facilitate and legislate not only a patient's right to care, but also the necessary components of education and drug availability which are so critical for the appropriate achievement of public health programs.

### INTRODUCTION

For centuries, medical and surgical treatment has emphasized saving the life of the patient rather than ameliorating the patient's pain, particularly when there were few options for the latter. Today at the dawn of the 21<sup>st</sup> century, the best available evidence indicates a major gap between an increasingly understanding of the pathophysiology of pain and widespread inadequacy of its treatment. In the developed world, this gap has prompted a series of declarations and actions by national and international bodies advocating better pain control.

Insufficient pain management is a significant public health concern [1] and adequate relief depends on access to a variety of treatment options. A number of state medical boards have issued guidelines or policy statements regarding the medical use of controlled substances for treating pain.

### INADEQUATELY TREATED PAIN

Chronic pain is linked with a physical, psychologic and social consequences, and can be regarded as a disease entity *per se* [1]. Physically, these responses include reduced mobility with loss of strength, disturbed sleep, immune impairment and increased susceptibility

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**RÉSUMÉ :** Les analgésiques morphiniques constituent une base essentielle dans la prise en charge des douleurs modérées et sévères. Bien que leur efficacité dans le traitement des douleurs aiguës et chroniques soit bien documentée, la morphine et ses dérivés sont souvent sous-utilisés, ce qui contribue significativement à une défaillance dans la prise en charge de la douleur. Nombreux sont les pays qui ont établi des règlements nationaux sur la prise en charge des douleurs chez les malades cancéreux et en soins palliatifs alors que d'autres pays ont seulement défini des lignes directrices. Idéalement, les législations nationales facilitent et assurent le droit du patient au traitement de la douleur, ainsi que l'accès à l'éducation et aux analgésiques morphiniques qui sont des éléments déterminants dans l'application d'un programme national de santé publique.

to disease, dependence on medication, and codependence with caregivers [1-2]. A World Health Organization (WHO) study revealed that individuals who live with chronic pain are four times more likely to suffer from depression or anxiety than those without pain [3]. In addition, chronic pain incurs massive social and economic costs to society. Persons with chronic pain are more than twice as likely to have difficulty working [3-4]. A prevalence study in Australia revealed a strong association between chronic pain and being unemployed for health reasons and receiving disability benefits [5].

Epidemiologic evidence has proven that chronic pain is a widespread public health issue. A community-based survey found that 15%-25% of adults suffer from chronic pain at any given time, a figure that increases to 50% in those older than 65 yr [6]. Studies of cancer patients' pain control consistently reveal that up to half of patients receive inadequate analgesia and 30% do not receive appropriate drugs for their pain [7]. Equally, for patients suffering HIV/AIDS, 60%-100% will experience pain at some stage in their illness [8]. In separate large studies of cancer patients in France [9], the United States [10], and China [11], the percentages of patients receiving inadequate analgesia were 51%, 42%, and 59%, respectively. In patients with advanced cancer, pain is described as moderate to severe in approximately 40%-50% and as very severe in 25%-30% [12]. Of terminal-stage patients, 80% will have no analgesics they need.

Throughout the world, 10 million new cases of cancer are diagnosed annually. By 2020, that figure will double with approximately 70% occurring in developing countries [13].

#### PAIN RELIEF IS A HUMAN RIGHT

Pain is an international problem that requires an international solution. The Constitution of the WHO, as the supreme health agency of the UN, defines health as “*a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.*” One response to the worldwide undertreatment of pain has been to promote the concept that pain relief is a public health issue of such critical importance as to constitute an international imperative and fundamental human right [14-15]. The high watermark of this advocacy was the inaugural “Global Day Against Pain” cosponsored by the “International Association for the Study of Pain” (IASP), the “European Federation of IASP Chapters” (EFIC) and WHO. It took place in October 2004 in Geneva, Switzerland, the theme of the day was “Pain Relief Should Be a Human Right.” It states that patients have a right to pain management, and they give content to that right. Such content includes the patient’s right to be believed in the expression of pain, the right to appropriate assessment and management of pain, the right to be cared for by health professionals with training and experience in assessment and management of pain [16].

The importance of pain relief as the core of the medical ethic is clear. Pain clinicians promote the status of pain management beyond that of appropriate clinical practice or even an ethic of good medicine. They advocate a paradigm shift in the medical professions’ perspective on pain management, from simply good practice to an imperative founded on patient rights. An example from the Australian Capital Territory, where the *Medical Treatment Act* of 1994 states “*a patient under the care of a health professional has a right to receive relief from pain and suffering to the maximum extent that is reasonable in the circumstances, and the health professional shall pay due regard to the patient’s account of his or her level of pain and suffering*” [17]. Another example is a California statute that imposed three obligations. The first is a duty for doctors who refuse to prescribe opioids to a patient with severe chronic intractable pain to inform the patient that there are physicians who are specialize in the treatment of such pain. The second is a duty of all doctors to complete mandatory continuing education in pain management and the treatment of the terminally ill patients. The third is the requirement of the California Medical Board to develop a protocol for investigation of complaints concerning the undertreatment of pain. These recent statutes in Australia and California are models for any future legislative activity, offering to professional or lay groups a powerful agenda to reform local statutes. The essential components of such legislation are [16] :

1. Reasonable pain management is a right.
2. Doctors have a duty to listen to and reasonably respond to a patient’s report of pain.
3. Provision of necessary pain relief is immune from potential legal liability.
4. Doctors who are not able or willing to ensure adequate analgesia must refer to a colleague who has this expertise.
5. Pain management must be a compulsory component of continuing medical education.

#### POLICY STATEMENTS ON PAIN

In the early 1990, the practice of pain management came under increased scrutiny. To foster continued improvement in pain management, the Agency for Health Care Policy and research (AHCPR) published clinical practice guidelines for the management of acute and cancer pain. Other organizations, including the International Association for the Study of Pain (IASP) and the American Society of Anesthesiologists (ASA), have also developed pain-related guidelines [18-19].

The WHO Cancer Unit has led a global initiative in pain management. In 1986, a summary report *Cancer Pain Relief* was published, as result of a WHO Expert Panel on the Comprehensive Management of Cancer Pain. It emphasized analgesic drug therapy as the essential component of the treatment approach. The WHO “analgesic ladder” for cancer pain pharmacotherapy was a seminal contribution. This publication has had significant clinical and educational impact throughout the world for cancer pain relief [20]. By 1989, the WHO Expert Panel had reviewed and officially endorsed guidelines on teaching and training of healthcare professionals in cancer pain relief and extended the focus of the WHO program in cancer pain to include palliative care. It published a second monograph, *Cancer Pain Relief and Palliative Care*.

The WHO recommends that countries developing public health programs in cancer pain relief and palliative care establish three process measures to monitor and evaluate programs. First, develop national policies to assure patients access to cancer pain and palliative care treatment. Second, establish educational programs for healthcare professionals and the public, such as medical and nursing curricula and media coverage about pain management. Finally, ensure analgesic drug availability, including recommendations to governments on ways to facilitate opioid availability for severe cancer pain [21]. Also, the WHO has collaborated with international bodies, including the IASP and the International Narcotics Control Board (INCB) to promote both the deregulation of domestic regulatory practices that limit opioids availability for medical use, and strategies to lower the cost of opioids. An important development came in 2005, when the World Health Assembly, the highest governing body of the WHO, adopted a resolution asking WHO and the INCB to help countries to improve access to opioid analgesics. The pro-

gram recognizes obstacles to access to controlled medications. As a result, the Access to Controlled Medications Program address the broad range to appropriate use of controlled medications, including [22] :

- Improving access to effective treatment by reviewing legislation and administrative procedures
- Educating healthcare professionals, law enforcement staff and others regarding current best practices and scientific evidence
- Developing normative clinical guidelines
- Promoting a better understanding of international drug control treaties
- Assisting governments to make realistic estimates of future needs for opioid analgesics and to compile reliable statistics on past consumption
- Performing surveys on the accessibility, availability, affordability and use of the medicines and substances involved
- Helping to ensure an uninterrupted supply of controlled medications at affordable prices.

In the WHO strategy for cancer pain relief programs, availability of analgesics, including opioids, is a critical factor. The WHO examined the trends in morphine consumption, the barriers to opioid availability, and the potential approaches to improve drug availability worldwide. Since 1984, when the WHO Program in Cancer Pain Relief and Palliative Care began, the global consumption of morphine has increased by 272%. However, 57% of all morphine was consumed by the 10 countries that have ranked highest in per capita consumption for a number of years. They include Australia, Canada, Denmark, Iceland, Ireland, New Zealand, Norway, Sweden, the United Kingdom, and the United States. Almost all morphine is consumed in developed countries [21]. The WHO considers a country's morphine consumption to be an important indicator of progress toward improved cancer pain relief. Only 20 countries account for 86% of the morphine consumed in the world. The remaining 14% are consumed in approximately 100 other countries, which have the majority of the world's population [22].

It has been well recognized by the International Health and Drug Regulatory Authorities that opioid analgesics are not sufficiently available for the treatment of cancer pain in many places throughout the world. Barriers to opioid availability are numerous and vary from country to country. Some countries do not have the resources and healthcare infrastructure to produce and distribute medicines. Others have not given a high priority to the treatment of pain. In some countries, specific drug laws prohibit or restrict the availability and medical use of opioids. For each of these barriers, specific approaches need to be developed [23]. The WHO Expert Panel had advocated that each country develop an action plan that defines existing barriers within the country to opioid availability and create an action plan to deal with these barriers. The International Narcotics Control Board, which regulates global production and distribution of opioids, has requested that all countries take steps to

assure that opioids are available for pain management, particularly for cancer pain (INCB 1989).

#### REGULATORY CONTROL OF OPIOIDS

In spite of their documented effectiveness, opioids are often underutilized, a factor which has contributed significantly to the undertreatment of pain. Many factors or barriers contribute to inadequate treatment of pain ; among these are physicians' fears of being investigated for prescribing opioids. A 1990 survey of oncologists studied the reasons for inadequate cancer pain management and found that 18% rated excessive regulation of analgesics as one of the top four barriers [24]. A 1991 survey of Wisconsin physicians found that more than half would at least occasionally reduce dose, quantity or refills, or prescribe a drug in a lower schedule due to fear of regulatory scrutiny. In that same year, 40% of surveyed physician members of the American Pain Society (APS) said that concerns about regulatory scrutiny, rather than medical reasons, led them to avoid prescribing opioids for chronic non-cancer pain patients. A committee on pain management established in California (1994), that *"because of fear of investigation or action by regulatory boards or law enforcement, healthcare professionals have often been unwilling to prescribe or dispense strong pain medications appropriately"*, and at New York State (1997) *"practitioners may under prescribe pain medication due to fear of unwarranted legal consequences"* [25]. The evidence that effective pain management may be compromised by laws, regulations, and policies has led to systematic efforts to reform drug prescription laws, and state medical board policies and practices that impede effective use of opioids to relieve pain and suffering.

The Single Convention on Narcotic Drugs (1961) is the international treaty that regulates the production, manufacture, import, export, and distribution of opioids for medical use. Controlled substances laws are designed primarily to control the diversion and abuse of drugs, and federal laws recognize that opioid analgesics are necessary for the relief of pain and that their availability for medical purposes must be ensured. The INCB, the international body that monitors compliance with the treaty, has collaborated with the Department of Essential Drugs and Medicines Policy within the WHO to promote balanced regulatory approaches to avoid unnecessarily restrictive controls. Policies regulating health professional tend to encourage pain management and avoid language that restricts professional decision-making and patient treatment. Findings suggest that the positive policy change results primarily from state medical, pharmacy, and nursing boards adopting policies promoting pain management and the use of opioids, while containing few if any restrictions [26].

In 1997, the Federation of State Medical Boards in the United States (FSMB) convened a task force of pain, policy, and regulatory experts to develop "Model Guide

lines for the Use of Controlled Substances for the Treatment of Pain". The guidelines will help physicians comply with acceptable pain management standards and will help the Drug Enforcement Administration (DEA) and other regulators determine whether such treatment is appropriate under the circumstances. Perhaps most importantly, the guidelines will help ensure patient access to needed controlled substances for pain management. The Model Guidelines were unanimously adopted by the Federation's House of Delegates on May 2, 1998. Subsequently, they were endorsed by the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM) [27-28] :

- *"The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins."*
- *"The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness."*
- *"Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients."*
- *"Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agency for prescribing, dispensing, or administering controlled substance, including opioid analgesics, for a legitimate medical purpose and in the usual course of professional practice."*
- *"The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing."*
- *"All physicians should become knowledgeable about effective methods of pain treatment. The medical management of pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities."*

The laws of the United States guarantee drug availability and place no restrictions on the amount or on the length of time that a drug can be prescribed. In 1973, the DEA was created in the Department of Justice to administer the controlled substances. In the early 1990s, the DEA made three revisions in its regulations to enhance patient access to opioids. These changes permit a partial dispensing for patients with a terminal illness or for those in a long-term care (LTC) facility. Secondly, faxing of prescription orders to pharmacies for compounding of an injectable opioid for administration to a patient in a long-term care facility. Finally, extension of the time in which a pharmacy must receive a written prescription for an emergency oral prescription. Previously, regulations required that a pharmacy receive the written pre-

scription within 72 hours of the telephone call ; now the written prescription must be received within seven days [29-30].

#### MANDATED EDUCATION

One of the reasons that healthcare providers may fail to manage pain appropriately is because they receive poor education in pain management. For example, physicians receive little education about pain management and opioids in medical school and remain ignorant about appropriate treatment choices after they are in practice. This has led pain advocates to seek legislative redress for this problem. In 2000, two states passed laws that require continuing education in the subjects of pain management and the treatment of terminally ill and dying patients. West Virginia law requires physicians, nurses, and pharmacists to complete two hours of continuing education in the subject of end-of-life care including pain management during each continuing education reporting period. Californian law requires physicians and surgeons to complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. Several years ago, the State of Michigan passed a law mandating continuing education in pain management for all licensed healthcare professionals [31-32]. The Institute of Medicine, the National Institute on Drug Abuse, the American Pain Society, have long urged the nation's research establishment to focus more attention on pain and palliative care. A recent action by the federal government will spur increases in funding for basic pain research and for translation of current knowledge into clinical practice.

#### ASSESSMENT OF PATIENT OUTCOME

Chronic pain is often associated with a reduced sense of well-being. Health and quality of life are inherently interrelated, thus giving rise to the concept of health-related quality of life (HRQoL). The measurement of HRQoL is another way to assess patients' subjective perspective on their pain experience and its adverse impact on their lives. It encompasses physical, emotional, and cognitive function, as well as the ability to participate in meaningful activities within the community [37].

Individuals with chronic pain often do not experience long-term pain relief or improved quality of life from single-modality therapy. In addition, growing data support the use of an interdisciplinary approach in which the patient receives care via multiple modalities in a coordinated manner. In selected patients populations, standardizing care plans to decrease variability in patient care has been shown to improve clinical outcomes and to decrease the cost of care. This process has several key steps : 1) including the use of evidence-based medicine to guide the selection of treatment options, 2) integration of disease-specific practice guidelines into patient care, 3) monitoring of health outcomes.

Growing data support the argument that pain services provide cost-effective care [38]. An acute pain service may decrease the incidence and severity of adverse events, thus improving outcomes and decreasing health care cost. However, the increased interest in pain management is not reflected by an equal desire to pay for such services. The frequency of interventional procedures has increased substantially since 1998. The denial of payment is often attributed to limited documentation of efficacy for these procedures in the literature. Because of such resistance to pay for pain-related physician services in the United States, the Medicare payment system published payment guidelines for pain management services [39]. It is imperative for physicians to prove the effectiveness of the diagnostic and therapeutic interventional techniques and their impact and improvement in quality of life. Although, it is also imperative that pain physicians consider cost-effectiveness analysis and cost-utility analysis in their treatment algorithms for chronic pain conditions. The next logical step in the advancement of health care appears to be the melding of the well established principles of evidence-based medicine with both patient-centered outcomes and cost-utility data so as to create a value-based medicine [38].

#### PAIN IN LEBANON

In Lebanon, national health and political authorities should designate improving pain management as a key objective of public health policy. It is important that individuals experiencing pain receive the best possible care to relieve their suffering. It is imperative that organized efforts on the part of all pain care providers occur at the local and state level to improve our health care policy.

Several barriers to the adequate management of pain have been identified at different level : at the national policy level, in the provision of health care, and among patients themselves. Barriers at the national policy level include restrictive laws and regulations limiting the medical use of narcotics, insufficient support for pain management programs by health authorities, non recognition of pain management activities by financing authorities [33], and insufficient education of healthcare professionals. Secondly, barriers in the provision of health services include the underassessment of patients' pain by health professionals, divergent perceptions of patients' needs among health professionals, and physicians' reluctance to use potent analgesics and overestimation of the effectiveness of prescribed treatments [34]. Finally, patients themselves may be reluctant to report pain or to take analgesic medications, particularly morphine. Patients actually expect to experience pain in some medical situations or consider that pain management is not a priority with respect to other components of care. Furthermore, patients may report satisfaction with the management of their pain, even as they declare they are suffering from severe pain, and although their analgesic prescriptions seem to be inadequate [35-36].

Adoption of policies that make pain management an expectation for all physicians may make adequate relief more accessible to all people with pain. This will occur only when there are no other barriers in the health care system that will obstruct patient access to these important medications, such as the knowledge and attitudes of healthcare providers or restrictive reimbursement policies. Positive policy, with no implementation of a professional training, has little chance of affecting healthcare practice [31, 39]. So balanced state policy is insufficient by itself to enhance pain management, but it is a necessary component to achieve this important objective [32].

Achieving the appropriate social and medical change that will make pain management a fundamental component of health care is the next great challenge in our country. Education is an important component of our medical system, but there is no systematic approach to teaching pain management at any level of training. The lack of appropriate integration of pain management into medical education should lead to recent legal and regulatory mandates to bring such education to medical students and physicians [4]. Unfortunately, we should be aware that these external mandates, too often result in fragmented approaches to pain education, with each specialty offering its own approach without integrating the multidisciplinary complexity of pain and its treatment into a comprehensive curriculum. On the other hand, there is a need to update medical board members' knowledge about pain management and public policy.

Appropriate education of the public may reduce patients' reluctance to express pain and to increase their demand for adequate pain management. Information and education of the general public may help to influence policy makers and should incite health institutions and professionals to improve pain management practices. It seems likely that increased awareness of pain management choices among the public will generate increased demand on health professionals to provide precise information and adequate care to address to each patient's needs.

Healthcare professionals need to engage regulators in dialog to eliminate regulatory barriers that govern the prescribing and dispensing of opioids in our country. They have a professional obligation to understand the appropriate role of opioids in pain control and follow accepted guidelines when prescribing, administering, and dispensing these drugs. They also have a professional obligation to assist regulators and law enforcement personnel in identifying persons who may be involved in diverting opioids for non medical use.

Finally, reform will require an integrated approach to address the problem of under-treated pain at all levels [16] :

1. Education for health undergraduates and graduates, including adult health professionals
2. Adoption of universal pain management standards by professional bodies

3. Promotion of legislative reform
4. Liberalization of national policies on opioid availability
5. Provision of affordable opioids
6. Promotion of pain control programs in all nations, irrespective of resources
7. Reimbursement issues for professional and facility services for pain care
8. Continuing collaboration with the foremost international pain relief organizations and the WHO.

#### CONCLUSION

For too long, pain and its management have been prisoners of myth, irrationality, ignorance, and cultural bias. Pain management is now being addressed across the disciplines of medicine and law. Their respective contributions are coalescing into a coherent position in which unreasonable failure to treat pain is poor medicine and unethical practice. There is a need to promote policies which create conditions where human beings can bear even incurable illnesses and death in a dignified manner. Making real improvements in pain management will require the proactive efforts of many organizations, and we believe that education as well as discipline, should be the cornerstone of efforts to improve pain management.

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