Pain in Europe – a public health priority

A strategy to better diagnose and manage chronic pain and the responsible use of opioids





'There are many reasons for the enormity of the gap between pain treatment needs and what is delivered, but chief among them is a shocking willingness by many governments around the world to passively stand by as people suffer.'

'Please, do not make us suffer any more...'

Access to Pain Treatment as a Human Right

Human Rights Watch, March 2009

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Foreword

It has been 10 years since the European Federation of the International Association for the Study of Pain (IASP) Chapters (EFIC) launched its 'Declaration on Chronic Pain as a Disease in its Own Right' in the European Parliament, but there is little indication that the management of chronic pain has improved in most countries in Europe.

This White Paper by OPENMinds reiterates many of the key points made in the Declaration of 2001, including the devastating financial and human impact of chronic non-cancer and cancer pain. It also emphasises that in order to achieve real change, improvements in the understanding of chronic pain must extend beyond pain specialists to include non-specialist doctors and other healthcare professionals, patients and their families, and politicians. Optimal pain management requires a comprehensive multidisciplinary approach. It is also important that governments ensure that their policies on the role of opioid analgesics do not unnecessarily restrict patients' access to the appropriate use of these drugs. These initiatives should unite the community of individuals and organisations interested in this neglected disease area.

This White Paper should act as a tool to inform and educate national and European politicians and to further support all stakeholders who wish to improve the awareness, assessment and management of chronic non-cancer and cancer pain. We wish it every success and urge all politicians and healthcare practitioners to give it the consideration it deserves.

Prof. Hans G. Kress, MD, PhD

Medical University of Vienna, Vienna, Austria President, EFIC www.efic.org





1. Introduction

OPENMinds (Opioids and Pain European Network of Minds) is a group of leading European experts who specialise in the research and management of pain. OPENMinds is committed to helping patients and their families, healthcare professionals and decision-makers increase their knowledge and understanding of chronic pain to ensure that all patients receive an optimal standard of care.

Pain disrupts the lives of millions of patients and their families across Europe. Uncontrolled pain causes intense physical and emotional suffering, reduces patients' quality of life (QoL) more than any other condition, and confers an enormous cost on European economies. Chronic pain warrants serious attention by policy makers and healthcare providers and yet at present its importance remains under-recognised.

Chronic pain is classified as pain that persists or progresses over a long period of time (usually stated as more than 3 months) and may range in intensity from mild, to moderate, to severe.

In 2005, OPENMinds published a White Paper that urged governments to revise policies that contribute to the inadequate treatment of pain, in particular those that resulted in an excessive restriction of the appropriate use of opioid analgesics (e.g. morphine). This 2011 White Paper builds on the 2005 publication. It overviews recent research on the burden of chronic pain in Europe and proposes a strategy for governments to improve the care of Europeans with chronic non-cancer and cancer pain.



2. Nature and scale of the problem

2.1 Chronic non-cancer and cancer pain is common

Chronic non-cancer pain

In 2003, a large international survey found that one in five European adults suffered from chronic pain (Figure 1).² Chronic pain was of moderate intensity in two-thirds of sufferers and severe in one-third. Almost 60% had pain lasting from two to 15 years and around one-fifth (21%) had suffered with pain for 20 years or more. In 2010, the National Health and Wellness Survey in Spain found that 6.1 million (17%) of the adult population reported experiencing pain in the last month, with 7% of the population experiencing daily pain.³ The back is the most common source of chronic pain, with the most common cause being arthritis, especially osteoarthritis.²

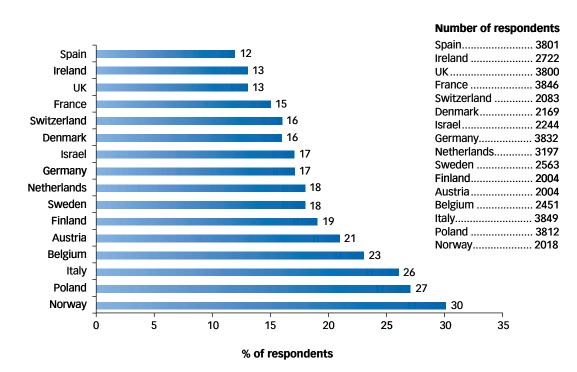


Figure 1. Prevalence of chronic pain among adults in Europe.²

Reprinted from the European Journal of Pain,² with permission from Elsevier. Survey involved 46,394 adults responding to a computer-aided telephone screening interview. Chronic pain was defined as pain lasting more than 6 months, having pain during the last month, several times during the last week, and last experienced pain having an intensity of 5 or more on a rating scale of 1 (no pain) to 10 (worst pain imaginable).

Chronic pain is generally more common in women than in men^{4,5} and it becomes more common with increasing age (Figure 2)⁶. The prevention and effective management of chronic pain in the elderly will be increasingly important as the population ages. European Union (EU) Member State Governments have been urged to focus on preventive measures, innovative and integrated care systems, and the development of innovative products and interventions specifically aimed at elderly people.^{7,8}

Women (n=7171) Men (n=1799) Prevalence of chronic pain (% of respondents) Age (years)

Figure 2. The proportion of people with chronic pain rises with age.6

Results of a survey of employees in Helsinki, Finland, in 2001–2002.

Chronic pain in social care recipients

According to a recent survey in Norway, chronic pain affected almost twice as many patients who required long-term social care (44% of 405) compared with the general population (24% of 1455).

Cancer pain

Chronic pain is a particular problem in people with cancer. In 2006–2007, the European Pain in Cancer (EPIC) study surveyed 5084 patients with cancer across Europe and Israel. More than half of patients (56%) had moderate or severe chronic pain. Similarly, an analysis of 52 studies revealed that 53% of all patients with cancer had pain. By the time patients with cancer reach the advanced or terminal stages of the illness, 65–80% are estimated to experience pain. The advent of modern cancer treatments means that patients with cancer often live longer than previously. However, this may also mean that with inadequate care they may suffer more pain, and for longer periods of time.

2.2 Chronic non-cancer and cancer pain is undertreated

In the aforementioned study of chronic non-cancer pain in Europe, one-third of the chronic pain sufferers (n=4839) were currently not being treated and one-fifth had never used a prescription medication for their pain. Overall, 40% of pain sufferers were not satisfied with the effect of the treatment they were receiving.²

An analysis of various published studies revealed that overall half of patients with cancer pain are undertreated.¹³ In the EPIC study,¹⁰ almost two-thirds of patients prescribed analgesics experienced 'breakthrough' pain (i.e. a transitory worsening of pain in patients with otherwise stable chronic pain) or inadequate pain relief. Only 5% had their pain managed by a palliative care or pain specialist.

European Pain in Cancer study: conclusions

'Poor care of cancer pain is clearly unacceptably commonplace in Europe. Cancer pain should be included in the overall perspective of diagnosis and treatment and taken seriously at all levels of society from government to clinician.'¹⁰

2.3 Chronic non-cancer and cancer pain ruins lives

Chronic pain can have a devastating effect on the lives of sufferers and carers. People with chronic pain experience a far poorer QoL than the general population, ¹⁴ and many suffer from depression. ^{2,15} Over half of surveyed European adults with chronic non-cancer pain reported that their pain made them unable or less able to perform household chores, exercise and sleep. Strikingly, almost one-third of all respondents in the 2006 Eurobarometer survey of health in the EU reported experiencing muscle, joint, neck or back pain that affected their daily activities in the week preceding their interview. ¹⁶ One-quarter of respondents had experienced chronic restrictive pain at some point in their lives. Restrictive pain was most commonly reported by people aged >55 years, people who ended their education at age 15 years, and women.

'A major initiative to widen access to high-quality pain services would improve the lives of millions of people.'

Liam Donaldson, UK Chief Medical Officer 1998–2010¹⁷

Detailed interviews with 573 patients with cancer pain surveyed in the EPIC¹⁰ study revealed the impact of their pain:

- 69% reported pain-related difficulties with everyday activities
- 30% were in too much pain to be able to care sufficiently for themselves or for others
- 52% of employed people said that their pain affects their work performance
- 67% described their pain as 'distressing', 36% reported it as 'intolerable' and 32% reported that they felt so bad they wanted to die.

Pain worsens quality of life: example from Norway

Researchers in Norway compared the health-related QoL among 288 patients with chronic non-cancer pain being treated in a multidisciplinary pain centre with that in 434 patients with advanced cancer receiving palliative care. ¹⁴ Both groups had worse QoL, including poorer functioning and more symptoms, than the general population. Patients with non-cancer pain had even worse scores than cancer patients on overall QoL, cognitive functioning, pain, sleep disturbances and financial difficulties, while patients with cancer had greater impairment of role functioning, nausea/vomiting, loss of appetite and constipation.

The worsening of QoL among patients with chronic pain is closely linked to depression, anxiety and stress. 18-21

2.4 Uncontrolled chronic pain is costly

Uncontrolled chronic pain confers enormous costs on society in terms of the costs of healthcare and social care associated with inadequate therapy and the costs that result from sufferers and their carers being unable to work or being less productive at work. ^{22–25}

Overall costs

Studies have estimated the costs of certain types of pain in particular countries. For example, in the UK it has been estimated that back pain alone costs the economy £12,300 million per year. 17,26 However, the overall economic cost of chronic pain in Europe is not well quantified.

In Sweden, it is estimated that the direct healthcare costs and indirect costs of sick leave and early retirement for patients with diagnoses related to chronic pain amount to about 10% of the national gross domestic product. Although patients who are on analgesic drugs have twice the direct costs of those not on analgesic drugs, the costs of prescription drugs represent less than 1% of the total costs.²⁷

The OPENMinds Members recommends that further research is performed at the EU level to assess the economic costs of chronic non-cancer and cancer pain in order to better inform future healthcare policy.

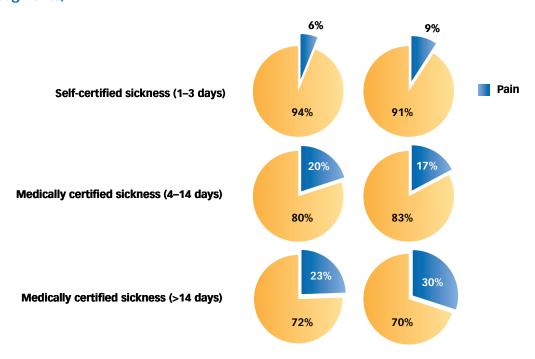
'Indirect' costs

Importantly, the bulk of the socioeconomic cost of pain arises from the 'indirect' costs of lost productivity, rather than from its treatment.²⁸

Chronic pain often prevents or hinders sufferers from working.^{2,4,6,10,29} Employed people with chronic pain are more likely to need days off, and may be less effective and productive at work. Around one-third of surveyed European workers said that their current employment status or hours that they worked were affected by their pain. Approximately 60% of those with chronic pain said that they were less able or unable to work outside of home and around one-fifth had lost their job because of pain. On average, sufferers had lost 7.8 days of work in the previous 6 months because of their pain.²

In Finland, researchers found that chronic pain accounted for 9% of self-certified short-term absence among middle-aged women and 6% among men, and up to 30% of medically certified absence lasting more than 2 weeks (Figure 3).6

Figure 3. Percentage of absence among men and women accounted for by chronic pain (blue segments).



Survey involving 8960 employees aged 40-60 years in Helskinki, Finland, in 2000-2002.6

Lost productivity: the United States perspective

In the United States, 13% of almost 29,000 workers surveyed in 2001–2002 lost productive time in a 2-week period because of a common pain condition. Lost production time cost an estimated \$61,200 million per year. Three-quarters of this loss resulted from impaired performance at work, rather than from absenteeism.²⁷

Chronic pain results in substantial claims for income and social support from governments. For example, in Ireland in 2002, people with chronic lower back pain accounted for 27% (€348 million) of the total cost of illness-related income support — more than any other patient group.³⁰

Almost one in three surveyed Europeans with chronic pain said that pain affected their ability to maintain an independent lifestyle.² This means that patients may have to purchase help to perform routine activities, or that the state will have to provide this. Caring for children who have chronic pain (e.g. due to juvenile rheumatoid arthritis) also has a substantial economic effect on the family. In the UK, the mean total cost to society for each adolescent with chronic pain was estimated at approximately £8,000 (€9,760; 2004 prices) per year. This translates to a total annual cost of adolescent chronic pain in the UK of approximately £3,800 million (€4,700 million).³¹

2.5 Treatment for pain is a human right

Governments have a moral obligation to ensure that their citizens have access to high-quality pain care and are bound by international treaty obligations in this respect. In recent years, various international organisations have also emphasised that access to pain therapy is a human right, including the International Association for the Study of Pain (IASP),³² the World Health Organization (WHO),³³ Human Rights Watch^{34,35} and the International Federation of Health and Human Rights Organisations 2010.³⁶

'Denial of pain relief for palliative care and other essential medical purposes represents a de facto form of torture that affects millions of patients with life-limiting illness worldwide'.³⁶

2.6 EU Directive: patients' rights in cross-border healthcare

A recent directive on cross-border healthcare adopted by the European Parliament provides an additional reason why European governments should assign a higher political priority to the assessment and management of chronic pain. This directive clarifies the rights of patients who seek healthcare in another member state and supplements the rights that patients already have at EU level.

It states that:

'Member States ... may not refuse to grant prior authorisation when the patient is entitled to the healthcare in question ... and when this healthcare cannot be provided on its territory within a time-limit which is medically justifiable, based on an objective medical assessment of the patient's medical condition, the history and probable course of the patient's illness, **the degree of the patient's pain** and/or the nature of the patient's disability at the time when the request for authorisation was made or renewed.' [bold highlighting added]³⁷

In other words, when a European patient goes to his or her national healthcare provider and requests advance reimbursement for treatment received elsewhere in Europe, the authority cannot refuse them without assessing their level of pain. Governments therefore need to ensure that their healthcare systems properly assess and manage chronic pain in order to avoid incurring substantial costs by having pain or underlying conditions treated overseas.

Member states will have 30 months (until 25 October 2013) to transpose the directive's provision into national legislation which will enable patients to be reimbursed at home for care received in a foreign country.



3. Barriers to optimal pain management

Pain management is currently inadequate in most of the world because of substandard access to assessment and treatment, and a failure to recognise that chronic pain is a serious chronic health problem requiring access to management akin to other chronic diseases such as diabetes or chronic heart disease.³²

Specific barriers to care highlighted by the Declaration of Montréal³² include:

- Major deficits in knowledge of healthcare professionals regarding the mechanisms and management of pain
- Chronic pain with or especially without a diagnosis is highly stigmatised
- Most countries have no national policy at all or very inadequate policies regarding the management of pain as a health problem, including an inadequate level of research and education
- Pain medicine is not recognised as a distinct speciality with a unique body of knowledge and defined scope of practice founded on research and comprehensive training programmes
- There are severe restrictions on the availability and accessibility of opioids and other essential medications critical to the management of pain.

In 2000, the WHO declared that most, if not all, pain due to cancer could be relieved through the implementation of existing medical knowledge and treatments.³⁸ Over the following decade, the WHO has repeatedly drawn attention to the barriers to effective pain care resulting from legislation and policy, knowledge and societal attitudes and economic aspects, including affordability.^{12,33}



"Please do not make us suffer any more..." Access to Pain Treatment as a Human Right

March 200934

There are many reasons for the enormity of the gap between pain treatment needs and what is delivered. Few governments have put in place effective supply and distribution systems for morphine; they have no pain management and palliative care policies or guidelines for practitioners; they have excessively strict drug control regulations that unnecessarily impede access to morphine or establish excessive penalties for mishandling it; they do not ensure healthcare workers get instruction on pain management and palliative care as part of their training; and they do not make sufficient efforts to ensure morphine is affordable.



Achieving Balance in National Opioids Control 2011³³

All countries have a dual obligation with regard to these [controlled] medicines based on legal, political, public health and moral grounds. The dual obligation is to ensure that these substances are available for medical purposes and to protect populations against abuse and dependence. Countries should aim at a policy that ultimately achieves both objectives; in other words, a "balanced policy".

Governments should comply with their international legal obligations to ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes through national legislation and drug control policies. Appropriately trained and qualified physicians, and, if applicable, nurses and other health professionals should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge and good practice without any further licence requirements.



International Narcotic Control Board (INCB) Annual Report 2006³⁹

The training of healthcare professionals should include guidance on how to promote the rational use of (narcotic) drugs in the context of the applicable regulatory requirements. Codes of conduct for associations of health-care professionals, industry and trade chambers should address the issue of the incorrect or improper handling of drugs.

4. Proposed strategy to improve chronic non-cancer and cancer pain management

Whether it is measured by its effect on clinical symptoms, human well-being, healthcare costs or socio-economic costs, the impact of chronic pain is devastating and warrants the urgent attention of governments, healthcare providers and society in general.

Based on its extensive knowledge and understanding of chronic pain treatment and its regulatory, financial, cultural and scientific influences, OPENMinds has identified five priority areas for action by governments intending to develop or improve national strategies for the assessment and management of chronic non-cancer and cancer pain.

We call on governments to:

- 1. Make chronic non-cancer and cancer pain prevention and management a priority and allocate adequate resources in terms of infrastructure, personnel, revenue, education and training to ensure an optimal level of service provision
- 2. Collaborate with national educational institutions and professional associations to improve the education of healthcare professionals and the public
- 3. Establish and/or maintain interdisciplinary pain assessment and management clinics
- 4. Ensure the availability and accessibility of appropriate pain medications, including opioids as necessary
- 5. Promote and support research to understand mechanisms behind chronic pain, and how and why acute pain becomes chronic pain, in order to improve the prevention and treatment of chronic pain. Promote research to quantify the burden of pain, to develop an internationally standardised chronic pain assessment tool, to identify gaps in pain care, and to establish the value of pain management services.

The following section explains why these components are so critical.

4.1 Prioritisation and defined budget for pain management services

Prioritisation and budgeting

Improving the assessment and management of pain should be a key priority for national annual/multi-year healthcare strategies in European countries. Governments should allocate a defined budget dedicated to the development and maintenance of pain care services capable of delivering the current standards of diagnosis, treatment and rehabilitation. This budget should be based on clinical need and should reflect the range of diagnostic techniques and treatments available. The establishment of such a budget should be weighed against the significant economic advantages that successfully managed chronic pain can bring to patients, their families and society.

Increasing the value of pain services

Assessing and increasing the *value* of healthcare services, defined as the health outcomes achieved per unit cost spent, is a compelling, patient-focused approach to improving performance.⁴⁰ Enhancing the value of services benefits all stakeholders — patients, payers and providers — and improves the efficiency and economic sustainability of healthcare systems.

Increasing the value of pain services requires governments to quantify their existing expenditure in this area, and to relate this to outcomes. Importantly, this analysis should:

- Encompass all multidisciplinary components of therapy provided throughout the cycle of care
- Have a long-term ('longitudinal') perspective in order to capture outcomes that determine the total costs of pain, including return to normal activities, recurrence and treatment-induced complications.⁴⁰

4.2 Education of healthcare professionals and the public

Healthcare professionals

Assessing and effectively managing chronic non-cancer and cancer pain presents a significant challenge to physicians and other healthcare professionals. The complexity of pain management has contributed to its neglect as a healthcare priority and its under-treatment. It is essential that healthcare professionals have a better understanding of how pain should be assessed, of the different types of pain and how each type is best treated.

Evidence-based guidelines: Various national and international guidelines for chronic non-cancer and cancer pain management have been published, including those by the WHO,⁴¹ the European Society for Medical Oncology,⁴² European Association for Palliative Care⁴³ and the British Pain Society.^{44,45} However, many of these guidelines are outdated and few, if any, fulfil the current standards of evidence-based medicine applied in other areas of medicine, whereby all relevant data are systematically identified, reviewed and graded, and recommendations are ranked according to the strength of the supporting evidence.

The OPENMinds members therefore urge governments, in collaboration with relevant national professional bodies and with due regard to the highest international standards, to take a leadership role in reviewing existing guidance on the assessment and management of chronic non-cancer and cancer pain for specialists and general practitioners and (where these do not exist) to support the development and implementation of evidence-based guidelines that reflect recent developments in pain management. Appropriate measures should be employed to ensure that the guidance is adequately distributed, understood and implemented. These guidelines must also reach beyond the medical community to include policy-makers and regulatory and reimbursement authorities.

Undergraduate education: In 2009, the British Pain Society reported that education on the identification, assessment and treatment of pain represented less than 1% of the university-based teaching for healthcare professionals in major British universities. According to this report:

'The amount of pain education in the curricula of healthcare professionals is woefully inadequate given the burden of pain in the general population in the UK.'46

This fact is of grave concern to the International Narcotics Control Board (INCB). In April 2006 the Board sent a letter to all member governments encouraging them to:

'... ensure the inclusion in university curricula of health-care professionals and other professionals, as appropriate, of the subject of rational use of narcotic drugs and psychotropic substances for medical purposes'.³⁹

Governments should co-operate with educational institutions and international/national pain societies to develop and implement a national core medical undergraduate curriculum for the assessment and management of pain. Appropriate training should also be extended to other healthcare professionals who play an important role in the delivery of pain care, including psychologists, nurses and pharmacists. In this regard, the OPENMinds members support the WHO's recommendation that governments promote the teaching of the knowledge and skills for the treatment of pain, and for substance use disorders in the context of medical use of controlled medicines, in medical, pharmaceutical and nursing schools.³³

EFIC Core Curriculum for Undergraduate Medical Education

In 2005, EFIC developed a draft proposal for a Core Curriculum for Undergraduate Medical Education. This document was designed to fit into undergraduate preclinical curricula to provide medical students in Europe with the fundamentals of pain and to provide the student with background for later instruction in mechanism-based diagnosis and therapy.

Public

Uncontrolled pain is a major public health issue and, as such, efforts to reduce its burden also require education of the public. Key areas for public education include the prevention of pain, how and when patients should self-treat pain, when patients should consult a doctor and what they can expect from therapy, and sources of additional support.

Public education about pain should ideally begin in schools, with other programmes targeting vulnerable groups (e.g. elderly and their carers).

4.3 Interdisciplinary pain assessment and management clinics

In many cases, the burden of chronic non-cancer and cancer pain can be substantially reduced by early and effective assessment and intervention.

Aims of pain management

Patients with chronic non-cancer and cancer pain should undergo a thorough assessment that takes account of the type and severity of pain, the underlying causative factors and any associated psychological and psychiatric problems. Treatment should then be provided with the aim not merely to relieve pain, but to rehabilitate the patient in terms of their physical, social and emotional functioning and where possible to help patients regain active family, social and work lives.

Defining pain conditions: ICD-10

Chronic pain is under-recognised as a specific condition and is inadequately represented within the International Classification of Diseases (ICD) system. The current ICD-10 system categorises pain under organ-specific causes (ignoring the importance of psychological factors) or under the primarily psychological 'persistent somatoform disorder'. In order to overcome this dichotomy, experts and researchers in pain and in mental and psychosocial health in Germany have proposed a new, broader classification of chronic pain conditions for the revised ICD-10 (which will become the ICD-11) that require additional psychological or psychiatric interventions.⁴⁷

Benefits of specialist care

Chronic non-cancer pain is managed most often by general practitioners,² while cancer pain is managed by both medical oncologists and general practitioners.¹⁰ Access to pain specialists varies across Europe and many governments are implementing policies that will further increase the role of primary healthcare providers in managing chronic pain. The OPENMinds members urge governments to maintain and further develop specialised pain care services to ensure that patients with chronic pain (not responding to standard measures after 3 months) should have ready access to a comprehensive, interdisciplinary pain assessment and management programme. The management of patients in specialist pain clinics has been associated with improvements in patient-reported measures of pain, even in patients with highly persistent pain.⁴⁸

Specialist pain clinics should offer access to all appropriate diagnostic methods and therapies, including imaging (e.g. bone scans, magnetic resonance imaging and computed tomography), 'interventional' pain relief techniques (e.g. certain types of local anaesthetic nerve blocks, electric stimulation of the spinal cord or parts of the brain, implantable pumps that administer pain-relieving drugs directly into the spinal canal, and others), clinical psychology (e.g. cognitive behavioural therapy), physiotherapy, occupational therapy, nursing care, pharmacy care and rehabilitation. Various additional methods are often used for the treatment of cancer pain, including surgery and radiotherapy.⁴⁵ Treatment programmes should be initiated on a trial basis with clearly defined goals (e.g. return to work) agreed in advance between the doctor and patient. Specialist pain services must work in close collaboration with primary care healthcare personnel and, in the case of cancer pain, with the disciplines of oncology and palliative medicine.

Importance of assessing pain

The inadequate assessment of pain is a major barrier to optimal pain relief. Currently, the methods used to assess pain vary across Europe and there is a pressing need for a standardised pain assessment method. As well as improving the care of individuals, it would also facilitate research into patterns in pain management, services and outcomes across Europe, as recently called for by EFIC.⁴⁹

Pain rating scales are one of the best ways to assess the level of pain suffered by patients, and are particularly helpful in elderly patients.⁵⁰ However, only 9% of surveyed Europeans with chronic pain reported that their doctor used a pain scale.²

The CHANGE PAIN Scale is an example of a simple, user-friendly tool designed to measure pain intensity and QoL, and to improve communication between physician and patient. It encourages the patient and doctor to agree on, and record, the level of improvement required in the patient's sleep, general activity, ability to work, relationships, mood and side effects of therapy.⁵¹

Multidisciplinary care can reduce total costs of pain

The investment in pain care and rehabilitation is expected to pay dividends to European economies as it should reduce the enormous indirect costs associated with chronic pain (e.g. those due to lost productivity and informal care). For example, in the Netherlands, a recent study assessed the cost-effectiveness of an integrated multidisciplinary care programme for sick-listed patients with lower back pain, as compared with usual care provided by general practitioners and occupational therapists alone. Total direct and indirect costs in the integrated care group were significantly lower than in the usual care group. Indeed, this study suggested that every \in 1 invested in integrated care would return an estimated \in 26.51 In Denmark, two studies of pain clinics in Copenhagen have demonstrated that the direct and indirect costs saved by treating patients with chronic non-cancer pain were twice as high as the costs of providing the clinics.53,54

Establishing multidisciplinary pain centres and clinics

The IASP recommends a multidisciplinary approach to chronic pain care, when necessary, and has recently issued guidance to health practitioners, governments and professional organisations on the desirable features of pain centres and clinics.⁵⁵ In 2008 the Portuguese government approved a National Programme for Pain Control, which also includes guidelines for the establishment of chronic pain services. The British Pain Society has also issued guidance on the establishment of multidisciplinary pain care programmes.^{45,56}

In Norway, national guidelines published in 2009 state that patients have a legal right to receive prioritised specialist healthcare in multidisciplinary pain clinics if their health-related QoL is severely affected by the pain condition and efficacious and cost-effective treatment is available. It is expected that the Norwegian national healthcare system will have to establish new pain clinics and increase capacity at existing clinics if claims for priority care are to be met.⁵⁷

4.4 Availability and accessibility of appropriate medications, including opioids

Various different types of medicines are used to treat chronic pain. These include simple analgesics (e.g. paracetamol), non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen and diclofenac), 'weak' opioids (e.g. codeine), 'strong' opioids (e.g. morphine), anticonvulsants (medicines also used to treat epilepsy), antidepressants and other drugs, such as ketamine. All of these medicines can provide benefit in some types of pain, and all have side effects that must be balanced against their benefits.

Opioid analgesics are the mainstay of treatment of cancer pain. 41,45 They are also useful in selected patients with chronic, moderate-to-severe non-cancer pain. 44,58-61 A recent review of the available evidence conducted by the Cochrane Collaboration concluded that patients who are able to continue long-term opioid therapy for chronic non-cancer pain experience clinically significant pain relief. 61 Although it is not possible to accurately predict which patients with non-cancer pain will respond to opioids, a one-month trial period can be used to determine the effectiveness and tolerability of therapy in most patients. 62 However, the evidence base for the efficacy and safety of long-term opioid therapy in this setting is limited and further research is required. 59-61,63,64 Most studies have been conducted over treatment periods lasting a few weeks or up to three months. Only one high-quality, double-blind study has evaluated the benefits and tolerability of a potent opioid compared with placebo for up to 6 months. 65 In order to assess the value of long-term opioid treatment for chronic pain, additional well-controlled, preferably double-blinded studies are needed.

Opioid facts

- Opioid analgesics are safe when prescribed in appropriate regimens, and there is no need to fear accidental death or dependence when a robust regimen is instituted with close follow-up and monitoring of effects and side-effects³³
- According to some systematic reviews, less than 0.5% of patients with no previous history of substance abuse treated with opioid analgesics to relieve pain abused their medication^{60,61}
- Opioids rarely cause fatal drug reactions66
- There is no simple relationship between legal availability of opioids and rates of mortality related to opioids
- Around 80% of the world's population have little or no access to morphine for pain relief. 67,68

Despite concerns expressed in the United States, ⁶⁹ opioid overdose is not a common cause of death related to prescription drug use in Europe. Indeed, the drugs that most commonly cause fatal drug reactions are aspirin, warfarin (and other drugs used to treat or prevent blood clots), NSAIDs and antidepressants, ⁶⁶ none of which are subject to the same restrictions as opioids. Opioids have an acknowledged potential for misuse, as have other drugs (e.g. benzodiazepines). However, opioid abuse and addiction are rare during appropriately managed pain therapy. For example, in the aforementioned Cochrane Collaboration review, signs of opioid addiction were reported in 0.27% of participants in studies that reported this outcome. ⁶¹ As this Cochrane review⁶¹ concerned mostly

short-term studies, current guidelines recommend that patients in whom opioids may be suitable should receive a closely monitored trial before long-term therapy is started.⁴⁴ Particular caution is required with regard to the use of opioids in patients with a history of current or previous substance abuse.

The import, export and distribution of opioids are regulated by international treaties and national drug control policies. It is the responsibility of governments to ensure that the potential risks associated with opioids are mitigated while adequate access to opioid treatments is provided for patients who need them. In many countries — especially in Eastern Europe and in the developing world — access to opioid therapy remains inadequate. 12,35,70,71 Indeed, the WHO estimates that 5000 million people (approximately 83% of the world's population) live in countries with little or no access to opioids for moderate to severe pain. 33,67,68 A further 250 million people (4%) have moderate access to opioids, and only 460 million people (7%) have adequate access (Figure 4).68 This is despite the fact that the most commonly used strong opioid, morphine, is included on the WHO List of Essential Medicines. The WHO has recently updated its guidelines on achieving balanced national policies on controlled substances. 33

7%

7%

Low or no access

Moderate access

Adequate access

83%

Figure 4. Percentage of the world's population who have adequate access to opioid analgesics.⁶⁸

Focus on cancer pain

The WHO estimates that 5.5 million patients with terminal cancer are suffering without adequate pain treatment in countries with low or no access to controlled pain care medicines.³³

Insufficient data

The two largest associations of cancer and palliative care clinicians in Europe, the European Society for Medical Oncology (ESMO) and the European Association for Palliative Care (EAPC) view the problem of over-regulation of opioid availability with the 'utmost gravity'. These organisations have instigated a European Pain Policy Initiative, the first step of which was to assess legal and regulatory barriers to opioid availability in Europe. The resulting study exposed formulary deficiencies and excessive regulatory barriers that interfere with appropriate patient care in many European countries, particularly in Eastern Europe. According to ESMO and EAPC, 'there is an ethical and public health imperative to address these issues'.

As Hamid Ghodse, President of the INCB, has stated:

'It is more important than ever to achieve a balance in controlled substances policies so that these work to protect societies from the misuse of controlled substances without depriving them from their immense medical and scientific benefits ... Policy makers need to go a step

further than relaxing regulatory restrictions to availability: they should devise and implement enabling policies that promote widespread understanding about the therapeutic usefulness of controlled substances and their rational use'.³³

Governmental leadership is required to help increase the understanding of the role opioids play in the management of chronic pain and to overcome the stigma arising from their misuse. A comprehensive, integrated approach is required to address the use of opioids in the context of a broader public health strategy on the assessment and management of chronic non-cancer and cancer pain.

Accordingly, in 2011 the WHO has recommended that governments should:

- Comply with their international legal obligations to ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes through national legislation and drug control policies
- Designate a National Authority for ensuring adequate availability and accessibility of controlled medicines in healthcare
- Examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines
- Ensure that in the fulfilment of their duties, they do not impede health policies and access to legitimate treatment with controlled medicines
- Health authorities should provide relevant information on treatment principles to drug law enforcement and other relevant agencies.³³

The OPENMinds members add to these calls, and call on governments to ensure that selected patients with chronic pain have access to a supervised trial of opioid therapy when this is clinically indicated and instituted in line with current recommendations, i.e. subject to careful patient selection, monitoring and supervision and in the context of a comprehensive, multidisciplinary pain management programme. ⁴⁴ Patients for whom opioids are considered necessary should be able to access their medication without difficulty or barriers of excessive bureaucracy or prohibitive cost. Governments should therefore remove or amend any policies that are inconsistent with the WHO's principle of balance in access to opioid therapy.

WHO Access to Controlled Medications Programme (ACMP)

The WHO developed the ACMP, in consultation with the INCB, following the World Health Assembly and the United Nations' Economic and Social Council of 2005. The ACMP focuses on lifting barriers that impede access to controlled medicines, including opioids, on the development of treatment guidelines, and on educational initiatives. 12,33,67

Access to Opioid Medication in Europe (ATOME)

Funded by the European Commission, the ATOME project comprises a consortium of academic institutions and public health organisations undertaking research into the reasons why opioid medicines are not used adequately for moderate-to-severe pain and for the treatment of opioid dependence in 12 European countries. The project aims to provide tailor-made recommendations to each country for improving the accessibility, availability and affordability of controlled medicines (www.atome-project.eu).

Governments should also take a responsible, proactive approach to ensuring adequate treatment availability through the creation of a clear framework for the reimbursement of pain treatments, including opioids. Such a framework should take into account the need for a portfolio of treatments required to enable doctors to deliver individualised care.

'We strongly urge that national drug control laws and public health authorities recognise the essential and indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering; and guarantee adequate availability of those medicines for legitimate medical uses while preventing abuse and diversion.'

International Association for Hospice and Palliative Care, letter to the INCB, March 2009

4.5 Research and development

There is a pressing need for governments to promote and support high-quality research to:

- Understand the mechanisms behind chronic pain, and how and why acute pain becomes chronic pain, in order to improve the prevention and treatment of chronic pain
- Quantify and document the burden of uncontrolled pain in terms of QoL and socio-economic costs
- Develop an internationally standardised chronic pain assessment tool
- Further evaluate the efficacy and safety of long-term opioid therapy
- Quantify their existing expenditure on chronic non-cancer and cancer pain care and to relate these costs to outcomes throughout the entire cycle of care in order to assess the value of pain management services
- Identify gaps in pain management services and in opioid availability.



5. Conclusion and call to action to improve the prevention and management of chronic pain in Europe

The enormous burden that chronic pain confers on sufferers, carers, healthcare systems and European economies could be reduced by concerted action by governments and healthcare providers. There are compelling clinical, ethical and economic arguments for governments to give a greater prioritisation to pain assessment and management. Investment in pain management strategies that aim not merely to relieve pain, but where possible to rehabilitate patients in terms of their personal, social and work lives, is expected to pay dividends in reducing human suffering and the socio-economic costs to European societies. These strategies must be based on available evidence, recognising that the quality of evidence varies and that further research is required to help optimise the care of patients with chronic pain.

Accordingly, the OPENMinds members call on the governments of European countries to work towards implementing the strategy proposed in this document.

Strategies to improve prevention and management of chronic cancer and non-cancer pain

- 1. Make prevention and management of chronic severe pain and its consequences a healthcarepolicy priority; allocate adequate resources for organisation, education and training of qualified personnel to ensure optimal and adequate level of service to the large part of the population who suffer from chronic pain conditions
- 2. Ensure adequate education and training provided by educational institutions and professional societies
- 3. Establish and reinforce interdisciplinary pain management clinics and centres
- 4. Ensure the availability and affordability of appropriate pain modulating drugs and interventional equipment and expertise
- 5. Promote and support research to understand the mechanisms behind chronic pain, and how and why acute pain becomes chronic pain, in order to improve the prevention and treatment of chronic pain. Research is also needed to quantify and document the burden of pain, to develop an internationally standardised chronic pain assessment tool, to further evaluate the efficacy and safety of long-term opioid therapy, to assess the value of pain management services, and to identify gaps in pain management services and in opioid availability.

6. Members of OPENMinds

White Paper Working Group

Prof. Harald Breivik, DMedSci

Director, Department of Pain Management and Research, Oslo University Hospital and University of Oslo, Oslo, Norway

Dr Elon Eisenberg, MD

Director, Pain Relief Clinic, Rambam Medical Center, Technion-Israel Institute of Technology, Haifa, Israel

Dr Magdi Hanna, MD

Consultant in Pain Medicine and Director of the Analgesics & Pain Research Unit (APR Ltd), Beckenham, Kent, UK

Dr Tony O'Brien, MB

Medical Director and Consultant Physician in Palliative Medicine, Marymount Hospice & Cork University Hospital, Cork, Ireland

Members

Prof. Eckhard Beubler

Institute of Experimental and Clinical Pharmacology, Medical University of Graz, Graz, Austria

Prof. Alain Borgeat, MD

Professor of Anesthesiology, Head of the Department of Anesthesiology, Orthopedic University of Balgrist, Zurich, Switzerland

Dr Beverly J. Collett, MB BS

Consultant in Pain Management and Anaesthesia, Pain Management Service, University Hospitals of Leicester, UK

Dr Wolfgang Jaksch, MD, DEAA

Consultant in Anaesthesia and Pain Management, Department of Anaesthesiology, Intensive Care and Pain Management, Wilhelminenspital, Vienna, Austria

Dr Malgorzata Krajnik, MD

Chair and Department of Palliative Care, Nicolaus Copernicus University in Toruń, Collegium Medicum in Bydgoszcz, Poland

Prof. José Castro Lopes, MD, PhD

Full Professor, Department of Experimental Biology, Faculty of Medicine of the University of Porto, Porto, Portugal

Dr Roisin Macsullivan, MB

Consultant in Anaesthesia & Pain Medicine, Mater Misericordiae Hospital, Dublin, Ireland

Dr Sebastiano Mercadante, MD

Chief, Pain Relief and Palliative Care Unit, La Maddalena Cancer Center, Palermo, Italy

Dr Gerhard Müller-Schwefe, MD Director, Das Schmerz- und Palliativzentrum, Göppingen, Germany

Prof. Margarita M. Puig, MD, PhD

Professor of Anaesthesiology and Pain Management, Department of Anaesthesiology, Hospital del Mar, Universitat Autonoma of Barcelona, Barcelona, Spain

Dr J. Paul Schofield

Medical Director, Napp Pharmaceuticals Limited, Cambridge, UK

Dr Karen H. Simpson, MBChB

Consultant and Senior Lecturer in Pain Management, Leeds Teaching Hospitals NHS Trust, Leeds, UK

Prof. Giustino Varrassi, MD, PhD

General Manager, ASL - Teramo, Teramo, Italy

Dr Ans Vielvoye-Kerkmeer, MD, PhD

Pain Consultant, Department of Palliative Care, St Elisabeth Gasthuishof, Leiden, The Netherlands

Prof. Kris C.P. Vissers, MD, PhD, FIPP

Professor in Pain and Palliative Medicine, Department of Anesthesiology, Pain and Palliative Medicine, Radboud University Nijmegan Medical Centre, Nijmegen, The Netherlands

Prof. Michael Zenz, MD

Professor, Ruhr-University Bochum, Bochum, Germany

Dr Furio Zucco, MD

Director, Department of Anaesthesia, Intensive Care, Pain and Palliative Care, G. Salvini Hospital, Garbagnate Milanese, Italy

Dr Zbigniew Zylicz, MD, PhD

Consultant in Palliative Medicine, Hildegard Hospice, Basel, Switzerland



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